

FDA
CONSUMER

April 1977

Cosmetics

The Substances
Beneath The Form





This Month

Most people think of drugs as substances that are used to treat diseases and injuries. In animals, however, drugs are used not only for medical treatment, but also to promote growth. Animals that are raised primarily for meat and related products to be eaten by humans are given low-level doses of drugs—usually in their feed—to make them grow bigger faster. But using drugs to promote animal growth isn't as simple a process as it might seem. The food that comes from these animals must be free of harmful residues of the drugs. That's where FDA comes in. *Using Drugs in Food Animals* takes a look at this important and sometimes controversial aspect of our food supply.

Insulin is not one of the drugs that are used as a growth promotant. But cattle and swine—two of the animals often given growth-promoting drugs—are the sole source of the insulin more than a million diabetic Americans use every day. Careful control of potency and purity are important factors in the manufacture of all drugs, and particularly so in insulin. How FDA sees that every batch of insulin meets the Agency's strict standards is told in an article beginning on page 10.

Most people think of cosmetics as "beauty" aids, products such as lipstick, face cream, hair coloring, nail polish, perfume, and cologne. But toothpaste, shampoo, and mouthwash—products many people might look upon as necessities for adequate personal hygiene—also are classified as cosmetics. Soap, on the other hand, isn't regulated as a cosmetic, although many soap ads emphasize beauty and glamour rather than cleaning power. Whatever they are called, cosmetics are big business and virtually everyone uses them. What's in these products that we use every day? We examine that question in *Cosmetics: The Substances Beneath the Form*.

In a more formal way, FDA examined some 100 companies that make a variety of frozen heat-and-serve foods. The purpose was to check key manufacturing points which, if inadequately controlled, could result in contamination of the finished product. There's a report on page 16.

Food, frozen and otherwise; drugs, for people and animals; and cosmetics are just some of the products FDA regulates. All told, more than 100,000 establishments are involved in making or handling these and the other products under FDA's jurisdiction. There are more figures on FDA's regulatory universe in *Regulated Firms: A Statistical Profile*.

Inside Front Cover Photo: Juvenile diabetics learn early—often as young as five years of age—to give themselves insulin injections. Many, like this youngster, get instruction on how to care for themselves in camps sponsored by State and local diabetes associations. The insulin diabetics use is tightly regulated by FDA for reasons that are explained in *Insulin Standards: Precision With a Purpose*.

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

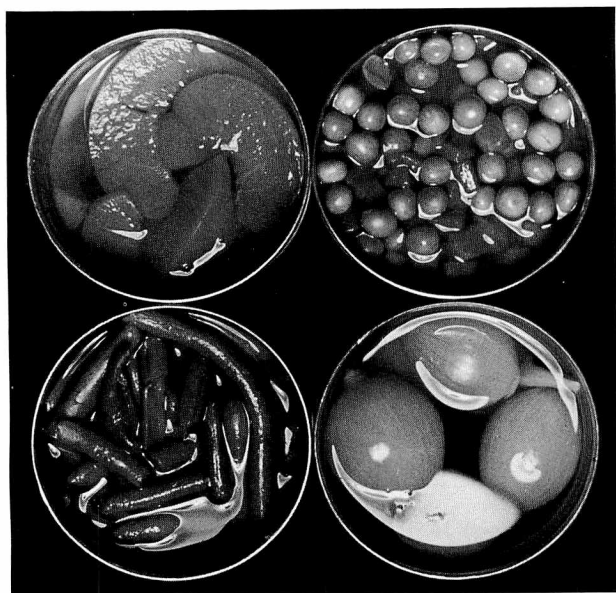
(a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of charge and the disposition thereof.

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

Cover Design: Ticia Edwards
Photography: Dan O'Toole

Update

FDA to Consider 'Solid Weight' Labeling



The net weight shown on the label of most canned fruits and vegetables includes the water, syrup, or other liquid in which the product is packed. Consumers don't really know how much solid food is in the container. In an effort to find a way to provide consumers with more information, FDA proposed that the "drained weight" of canned fruits and vegetables be shown on the label. This proposal is explained in Labels That Spill The Beans, an article in the February 1976 FDA CONSUMER. Here's an update.

The Food and Drug Administration intends to offer for public consideration a second proposal in a continuing Agency effort to decide the best way to help consumers know how much solid food is in canned fruits and vegetables.

Under this second proposal the labels on canned fruits and vegetables would show the weight of the solid food that is put into the container before water or other liquid is added and before processing. The FDA proposal, known as "solid content" weight labeling, will be based on a proposal made by the National Canners Association (NCA). If the proposal is adopted by FDA, manufacturers would be required to declare the solid weight of canned fruits and vegetables on the label.

Earlier, FDA proposed to require that the "drained weight" be declared on all cans of fruits and vegetables. Under the drained weight proposal, which will continue to be considered, the labels on all canned fruits and vegetables would be required to show the weight of the solid food after it is processed

(canned foods are heated) and the liquid is drained away. This program, if adopted, also would be mandatory. The drained weight proposal is supported by Consumers Union.

In announcing the drained weight proposal late in 1975, the FDA Commissioner said: "In any final decision . . . our primary concern will be the real dollars and cents impact on the buying public."

In announcing the decision to publish the alternative solid weight proposal, Acting FDA Commissioner Sherwin Gardner said the Agency was deferring a final decision for two reasons:

"First, the FDA must have better information than we now have on the comparative costs to the buying public of these competing plans. Second, we need to learn more about what consumers want and consider adequate, including their willingness to pay additional costs."

The NCA estimates that its proposed solid weight labeling plan would cost consumers about \$10 million per year. The drained weight proposal offered by the Consumers Union is estimated by FDA to cost about \$100 million per year.

Determining the drained weight of a product is more difficult and costly than determining the solid weight because a product may weigh more or less when it comes out of a can than it did when it went in. Some fruits and vegetables absorb water and other substances from the liquid in which they are packed and thus gain weight, while others lose water and nutrients to the liquid and thus lose weight.

The canning industry has initiated a solid weight (also called fill weight) labeling program on a voluntary basis. Canners that elect to participate in the program will be labeling their products with fill weight in addition to the net weight statement required by existing regulations.

FDA plans to allow an extended period for public comments on the solid weight proposal after it is published in the FEDERAL REGISTER. During that period the Agency will conduct inspections and sample products to obtain comparative results from "drained weight" versus "solid content" measurements to determine the degree of industry cooperation with the voluntary NCA plan, and to estimate consumer acceptance.

The period of comment and market testing will give FDA the additional facts it needs in order to make the best possible regulatory decision in the shortest possible time.

The Agency will issue a final regulation after evaluating the results from inspections and sampling, in addition to the comments received on both proposals.

The "solid content" proposal will be published as soon as it can be drafted and published in the FEDERAL REGISTER.

Discharge of PCB's Into Water Banned

Polychlorinated biphenyls (PCB's) are industrial chemicals that until a few years ago were used widely in a variety of products. Their use has declined, but once in the environment these chemicals are extremely difficult to get rid of. Coping With the Indestructible Pollutant, an article in the December 1976-January 1977 FDA CONSUMER, describes some of the actions being taken to control PCB's. Here's an update.

The Environmental Protection Agency (EPA) has ordered a ban on the direct discharge of PCB's into U.S. waters. The ban follows recent studies which showed that the levels of PCB's in certain bodies of water and in some fish are higher than permissible limits set by the Food and Drug Administration and by EPA.

The only plants covered by the ban are some 20 factories that manufacture electrical transformers and capacitors and that discharge PCB's into bodies of water. The ban does not cover PCB wastes discharged into municipal sewage systems. Such "indirect" discharges will be taken care of by additional regulations being prepared by EPA. Although the sole U.S. manufacturer of PCB's has stopped making them, there are no restrictions on the importation of the chemicals.

FDA has banned the use of PCB's in machinery used in the manufacture of food and animal feed.

Labeling of Blood From Paid Donors Asked

What FDA is doing to make blood and blood products safer is the topic of an article in the December 1975-January 1976 issue of FDA CONSUMER. Although the article, entitled Making Blood Money Safe and Respectable, deals mainly with blood plasma, which is not normally used in transfusions, it also summarizes proposed FDA regulations for the labeling of blood for transfusions. Here's an update.

The Food and Drug Administration has proposed regulations to require the labeling of blood for transfusion to specify whether it came from a paid or volunteer donor.

The regulations are designed to reduce the risk of transmitting hepatitis, a serious liver infection, through blood transfusions. Blood from paid donors and commercial blood banks has been shown to be three to ten times more likely to cause hepatitis than blood from volunteer donors.

Under the proposed regulations, all blood containers would have to say prominently either "PAID DONOR" or "VOLUNTEER DONOR."

The purpose of the proposed regulations is to provide physicians with information on whether



blood for use in transfusions is from a paid or volunteer donor. The labeling proposal also is intended to help move the Nation toward an all-volunteer donor system. Such a system is consistent with the goals of the National Blood Policy adopted by the Federal Government in 1973.

FDA first proposed blood source labeling requirements in November 1975. Comments on that proposal revealed a great deal of disagreement in the blood banking community over the meaning of the terms "paid donor" and "volunteer donor," and FDA agreed that the regulations should define them.

The new proposal defines a "paid donor" as a person who receives monetary payment for donating blood. A "volunteer donor" is a person who receives nothing for donating blood except benefits which are not convertible to cash, such as time off from work or membership in blood assurance programs.

Under the proposal, blood components, such as single donor plasma, platelet concentrate, and anti-hemophilic factor, also would be subject to the labeling requirements.

The new proposal appeared in the February 25, 1977 FEDERAL REGISTER, with 60 days allowed for comment. Comments may be sent to the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20857. After comments are evaluated, a final regulation will be issued.

Device Manufacturing Rules Proposed

Until enactment of the Medical Device Amendments of 1976, FDA did not have authority to require that medical devices be proved safe and effective

before being placed on the market. The amendments, which gave the Agency premarket clearance authority and otherwise bolstered its control over medical devices, are explained in the October 1976 FDA CONSUMER in an article entitled Medical Devices: Strengthening Consumer Protection. Here's an update.

The Food and Drug Administration has proposed the first mandatory requirements for the manufacture of medical devices.

The requirements apply to all medical devices, ranging from tongue depressors and bandages to pacemakers and heart-lung machines.

The requirements describe the quality control procedures necessary to make safe and effective medical devices.

For example, among the requirements proposed by FDA are that manufacturers establish a quality control unit independent of the manufacturing unit; that companies put in writing their manufacturing procedures; and that firms maintain complaint files.

Known as Good Manufacturing Practice Regulations, the proposed requirements are based on the 1976 Medical Device Amendments, which established new and far-reaching Federal controls to assure that medical devices are safe, effective, properly made, and accurately labeled.

Sherwin Gardner, Acting Commissioner of Food and Drugs, said: "These proposed regulations outline principles of quality assurance for the manufacture of all medical devices. We have made a concerted effort to involve consumer organizations, manufacturers, and health professionals in the development of regulations that are realistic and that will assure the safety and effectiveness of these important health care products.

"After these regulations are issued in final form, the failure of any company to abide by them will render the product subject to FDA regulatory action."

The proposed regulations set general standards for all medical devices. In addition to the general standards, special requirements are being proposed for devices intended to support life or to be implanted in the body.

FDA intends later to issue additional specific requirements for certain types of manufacturing processes, such as those used to make sterile devices or pacemakers.

The proposed regulations were published in the March 1, 1977, FEDERAL REGISTER. Comments will be accepted for 120 days from that date and may be submitted to the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20857.

Consumer Forum

Shopping for Drugs

The article entitled *On Reading Prescriptions* in the December-January issue of FDA CONSUMER provides valuable information for the consumer regarding interpretation of prescriptions. This could enhance patient understanding of medication and thus enhance patient compliance.

However, the article does the readers a disservice when it advises them to "shop around" for prescription drugs. As past articles in FDA CONSUMER have emphasized, the potential for drug-drug interactions is very real and could be serious. The one health professional who has the knowledge and opportunity to detect potentially serious drug interactions is the pharmacist. By obtaining all medications from one pharmacist, the patient provides his or her pharmacist with a central record of all therapeutic agents being used by the gynecologist, ophthalmologist, internist, etc. The pharmacist can then detect the potentially serious drug-drug interactions and prevent any harm.

A majority of the pharmacists in Delaware

maintain patient drug profiles which provide a record of all drugs being consumed by the patient. If the patient were to "shop around," obtaining an anticoagulant at one pharmacy and an aspirin-containing pain reliever at another due to a price savings, the potential adverse health consequences could be life-threatening. This short-circuits the pharmacist's patient drug profile system. "Shopping around" for prescription drugs is playing Russian roulette with your therapeutic regimen. It is not to be recommended.

Joseph L. Fink III
Executive Director
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Wilmington, Delaware

FDA has advised consumers, through several widely distributed publications, to consider the services offered as well as price in selecting a pharmacy. The keeping of patient drug profiles is an important service that should be considered along with other factors in selecting a pharmacy.

Using Drugs In Food Animals

Drugs are given to entire herds or flocks of food animals as a means of preventing disease and stimulating the growth of the animals. FDA's main concern is to make sure that harmful residues of these drugs are not passed on to people who eat the animals or consume products from them.

by Timothy Larkin

Back in the 1920's my mother used to raise chickens. It was pretty small potatoes, or chickenfeed, by today's standards. Instead of the modern chicken megalopolis of 100,000 or more, she had a village of just 500. All doing the things that chickens did best: making chicken noises; constantly sorting through the pecking order; dutifully laying eggs, sometimes in secret places where they could only be detected much later by smell. One of their most annoying habits was the alacrity with which they got very sick and their incredible devotion to dying long before the time specified in Mother's timetable.

Shakespeare certainly must have had chickens in mind when he wrote about "the thousand natural shocks that flesh is heir to," because even the toughest old cock of the walk could, and too often did, wilt overnight. Hundreds of chicks, indeed an entire flock, could expire in a matter of days from pullorum disease or from coccidiosis caused by enough varieties of protozoa to field a one-celled baseball team. And there were dozens of other potentially fatal or crippling afflictions, so many that it was almost as chancy to count your chickens after they were hatched as to do so beforehand.

The high mortality and retarded growth of chickens made them expensive. When the Republican Party in 1932 adopted the campaign slogan of "A chicken in every pot," the idea seemed to stretch beyond the possibilities of avarice, the current equivalent of "Acapulco for everyone!"

Now, of course, chickens are in every pot. We produce over three billion of them a year, making the per capita consumption of chicken roughly equal to pork and about half that of beef.

There are many reasons why chicken is so abundant, why American chickens undersell the local product, even in places like Bulgaria.

High on the list of reasons why chickens are so inexpensive, why it is

now possible to produce a three and one-half to four-pound chicken in eight weeks with a consumption of just over two pounds of feed per pound of bird produced, stands one of the most important classes of products regulated by the Food and Drug Administration: animal drugs. Such drugs play a major role in the production of cattle, pigs, chickens, and other food animals, as reflected by the fact that 80 percent of all the meat and poultry consumed in the United States comes from animals that were given drugs in their feed.

While there are a number of similarities between the drugs destined for animals and those for humans, there are important differences. Perhaps the most apparent difference is the motivation behind their use. With the exception of those for pets, animal drugs are used for economic reasons. The overriding question in the mind of the commercial producer of food from animals is, "Does it pay?" Very expensive treatments, surgery, and hospitalization are out of the question for individual animals that are being raised for a profit. Even more routine treatment of diseased animals is expensive since the margin of profit from a lot of animals is usually quite low. The loss of a few animals and low productivity for a period of time due to disease could eliminate the profit from a particular lot. It is for this reason that animal drugs are used to prevent potential disease.

Another difference is that the usual procedure is not to deal with individual animals but to assure that the entire herd or flock receives preventive medicine. In the case of potential outbreaks of coccidiosis in chickens, for example, various tailor-made drugs are used continuously in their feed.

A third difference between human and animal drugs stems from the fact that medicine is added to animal feed not only to prevent particular diseases but also to stimulate growth, or putting it another way, to suppress or eliminate (sometimes unknown) factors that might hinder growth. A few days



saved during the growing period can make an enormous difference in terms of profit and price. One large chicken-producing corporation improved its weekly profit by \$40,000 merely by saving one cent per chicken in feed costs.

Whether the livestock or poultry grower makes a penny more or less is of no official concern to the Food and Drug Administration. What *does* concern the Agency is the fourth and final difference between animal and human drugs: drugs used in food animals may affect the people who eat those animals or consume products from them.

It is vital that milk or meat or other foods contain no harmful residues from drugs given to the animals which were the source of these products. Under the Food, Drug, and Cosmetic Act, certain drugs that are used in animals are considered unsafe unless the Commissioner of Food and Drugs can find that no residue from their use will appear in edible tissues of these animals. Food containing any residues of these drugs is considered adulterated and may not be shipped in interstate commerce. For other animal drugs, limits are set on the amounts that can be present in food. If these limits are exceeded the food is considered contaminated.

Two kinds of growth-stimulating drugs are of particular interest to FDA and consumers. These are the antibacterial and the metabolic drugs.

The antibacterials are, in the main, antibiotics. Some 25 years ago scientists found that the addition of a small amount of the antibiotic chlortetracycline to animal feed markedly improved the growth rate of chickens. Since then, low doses of many other antibiotics such as penicillin, bacitracin, tetracyclines, tylosin, and flavomycin have been found to exhibit a similar growth-stimulating effect. Although there are various theories concerning how these antibacterials stimulate growth, the fact is they do work, even at very low concentrations. Hence, the antibacterials are widely used in swine and poultry feed, and as a group they constitute the largest volume of animal drugs manufactured and sold.

FDA has been concerned for some time about whether the use of antibiotics in animal feed poses a potential threat to human health. Even if no residues of the antibiotics remain in

animal products when they are ready for market, some of the bacteria in and around animals could become resistant to the antibiotics used in animal feed. If a strain of those antibiotic-resistant bacteria causes disease in people, then the antibiotics administered to people might not work in treating the disease. For example, some types of streptococcus bacteria have developed a resistance to the antibiotics erythromycin and tetracycline, drugs that sometimes are used to treat persons who are allergic to penicillin. This makes it difficult to find alternative drugs for persons with such an allergy.

As a result of these concerns, FDA asked its National Advisory Food and Drug Committee to review all information and submit recommendations on the use of penicillin and tetracycline in animal feed. Recommendations to FDA were made by this Committee in January 1977.

The Committee, concerned about bacteria resistance, urged that FDA prohibit the low levels of penicillin in animal feed that are used for growth promotion, and prohibit use of penicillin for prevention of disease to the extent that substitutes are available. It further recommended that the mixing of animal feed containing tetracycline and penicillin be limited to feed mills and livestock producers holding specific approval from the Agency, and to veterinarians.

The committee affirmed that the long-term goal of FDA should be to eliminate from animal feed the use of any antibiotic drugs used to treat disease in people.

The report of this Advisory Committee is now under review by FDA. After the evaluation is completed, FDA will announce its final policy governing any use of antibiotics in animal feed.

A different regulatory challenge was posed by another class of antibacterials, the synthetic antibacterial drugs called nitrofurans. These are used both to promote growth and to fight certain infections. FDA has proposed to withdraw approval of the use of four nitrofurans. These are furazolidone, because it has caused malignant tumors in test animals; and furaltadone, nitrofurazone, and nihydrazone because they are chemically and biologically related to furazolidone and have caused tumors in test animals.

Although a feature of FDA's basic law (the Delaney Clause) prohibits use of cancer-causing substances in food, there is an exception for use of cancer-causing drugs in food-producing animals if a number of requirements are satisfied.

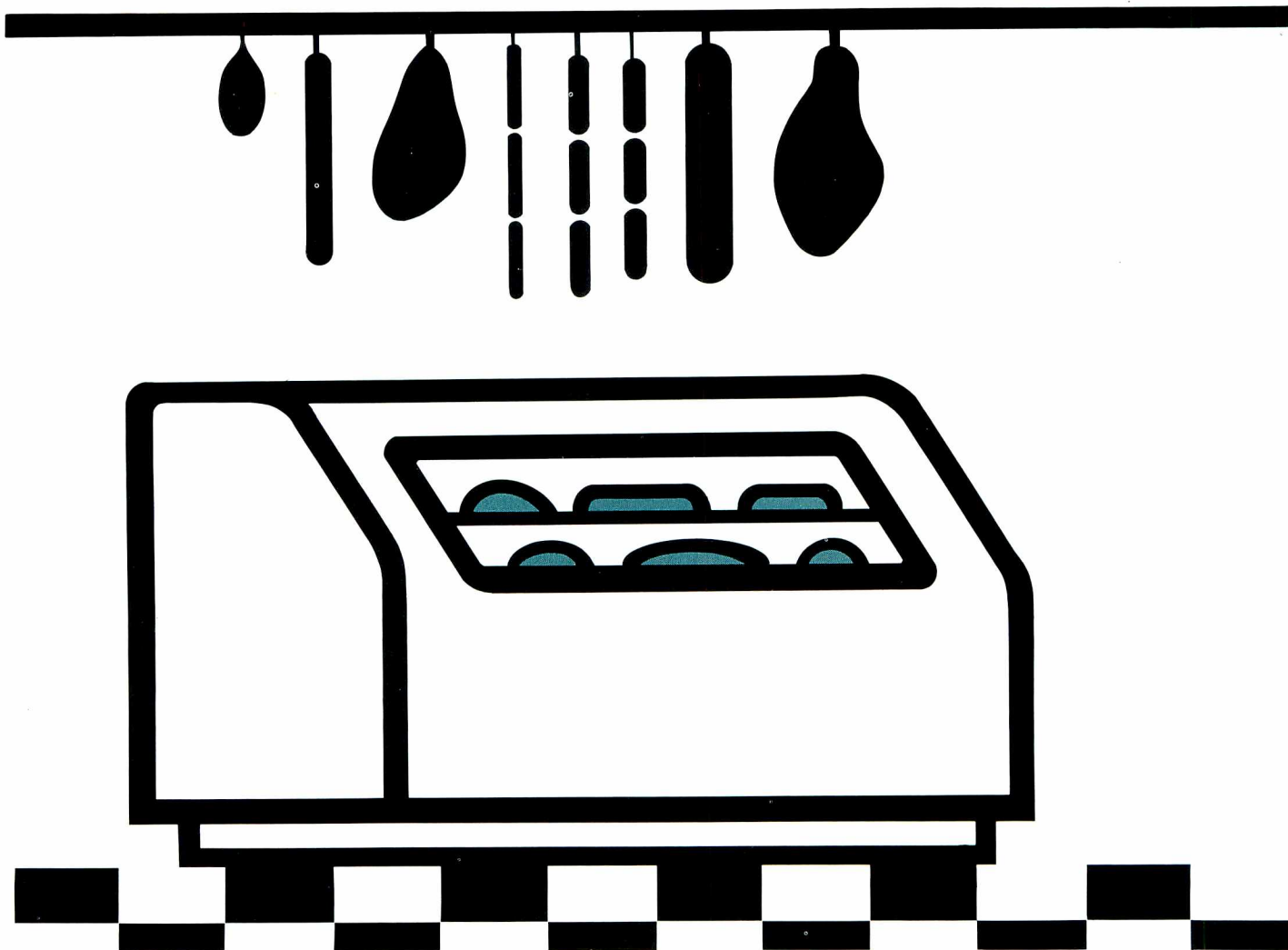
The drug can be used only if the Secretary of the Department of Health, Education, and Welfare determines that it has been shown not to affect adversely the health of the animal for which it is intended and if, in addition, the Secretary finds, to quote the complex language of the law, that "no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations . . .) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals." In short, it's illegal to use such a drug in food animals unless these findings can be made.

For the nitrofurans listed above (drugs that were developed especially for use in animals) no adequate test exists for detecting residues that may remain in edible animal tissue after slaughter or in milk and egg products. Therefore, it was necessary for FDA to take action leading to withdrawal of approval.

The prohibition against using cancer-causing drugs that leave residues in the edible portion of the animal has complicated FDA's efforts to regulate the other major class of growth-promoting chemicals: the metabolic drugs. These drugs include the estrogens, progesterones, and a combination of progesterone and testosterone, all of which are hormones. Also included is the drug diethylstilbestrol, or DES, which is used as a growth promotant in cattle and sheep both in feed and as a pellet implanted in the ear of the animal.

Regulation of DES, which causes cancer in test animals, has involved controversy because the law says such drugs can't be used in food animals unless the Secretary of Health, Education, and Welfare makes the findings described above. When the Delaney Clause was added to the law there was no "prescribed method" of analysis. Later, a method was developed that was capable of detecting as little as two parts of DES per billion parts of meat, but which could not distinguish DES from other estrogenic substances.

Drug companies were able to show



that if the use of DES was halted by a certain time before an animal was slaughtered, residues of the drug would not be apparent in meat or other edible tissues at levels of 2 ppb or above. On this basis, use of DES in food animals was approved as long as residues of the drug were not present in meat or other edible tissue at levels of 2 ppb or above.

But analytical methods have improved since the Delaney Clause was amended in 1962, and today amounts above one-half of a part per billion, or 0.5 ppb, can be detected. By means of radioactive tracers, it is possible to find just 0.04 (or 4/100's of a part) per billion, the latter fraction being equivalent to one second in about 793 years. There is no evidence that two parts per billion is a safe amount, or that one-half or 4/100's of a part per billion are any more, or less, safe than the original tolerance.

Regardless of any controversy over the amount of residues, the law is

specific and unequivocal: if any residue of a cancer-causing drug is detected in edible animal tissue approval for use of that drug must be withdrawn. And so, in 1973 FDA withdrew all DES animal drug approvals. That action was challenged in court, however, and the court ruled that FDA could not withdraw approval for use of DES without first having provided a proper opportunity for a hearing on the issue. Such a hearing has begun, but in the meantime FDA was required to continue to permit use of DES in food animals.

Meanwhile, to come to grips with the question of exactly what constitutes the proper method of measuring residues of potentially cancer-causing substances, FDA has issued what are called "sensitivity of the method regulations." These regulations, which were published in the *FEDERAL REGISTER* February 22, 1977, establish test procedures to determine whether a substance intended for use in food-producing animals does cause cancer.

If a substance is found to be carcinogenic, the regulations require that a reliable method acceptable to FDA be found to detect residues at levels below the point considered to be harmful to humans.

If such a detection method cannot be developed for a particular drug, FDA will refuse to approve that drug for use in food animals. If the drug has previously been approved, as with the four nitrofurans, it must be withdrawn from the market until the manufacturer develops a satisfactory method.

From the point of view of FDA this approach seems the only reasonable way to assure the continued safety of the animal products we eat. From the point of view of the consumer, it may be the only reasonable way to assure the continued availability of these products at reasonable prices as well.

Timothy Larkin is a special assistant to the Commissioner of Food and Drugs.

Insulin Standards: Precision With A Purpose

FDA goes to considerable lengths to assure that every batch of insulin is pure and is made to a very precise potency level. Strict standards are essential because more than a million diabetics depend on insulin, and a dose that is too strong or too weak can cause a serious reaction, even death.

by Annabel Hecht

In a laboratory in a Federal building near the National Capitol more than 200 white rabbits sit patiently in their cages. These docile animals will never lead anyone down a rabbit hole to Wonderland, but they do play an important part in one of the Food and Drug Administration's programs to assure the quality of drugs. They are used to test the potency of insulin—the drug that means life itself to more than a million diabetics in the United States. Every batch of insulin made in this country must be certified as meeting standards of purity and potency established by the U.S. Pharmacopeia (U.S.P.). FDA was given this responsibility by an act of Congress on December 22, 1941.

Insulin was not a new drug in 1941. Discovered 20 years earlier by two researchers at the University of Toronto in Canada—Frederick Grant Banting and Charles Herbert Best—insulin had been produced in the intervening years under the close supervision of the University, which held the patents on it. But in 1941 these patents were about to expire—a situation that could have led to serious consequences for diabetics who depended on insulin.

Continued surveillance was essential to assure that each dose of insulin was of uniform strength. A product that was too weak or too strong could mean death. As a committee of the U.S. House of Representatives noted: "With no other drug are the consequences of failure of accurate standardization so dramatic and so immediate."

Even before President Roosevelt signed the insulin certification legislation, FDA's Division of Pharmacology

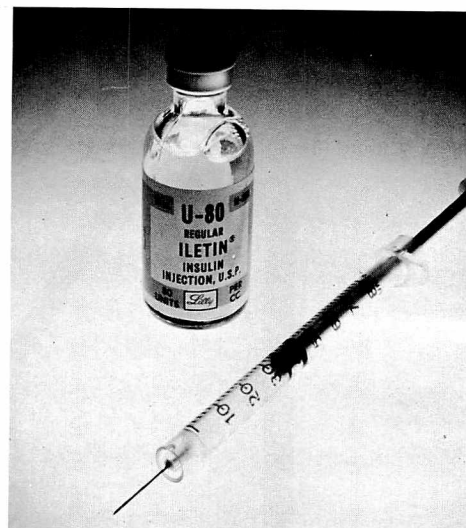
was making preparations to take over the vital work of assuring the quality of insulin. Conferences were held with representatives from the University of Toronto, American drug manufacturers, and the revisions committee of the United States Pharmacopeia Convention. (The Convention, composed of representatives from pharmacy and medical schools, State pharmaceutical associations, and appropriate Federal agencies, publishes the U.S. Pharmacopeia [U.S.P.], a book containing authoritative standards of identity, strength, and purity of substances used in drug products.) The first certificates for insulin-containing products were issued in February 1942. Today the certification testing program is carried on by a five-member staff that is part of the Drug Bioanalysis Branch of FDA's Bureau of Drugs.

Diabetes is an inherited disease that is probably as old as man. For thousands of years physicians have recognized the characteristic symptoms: fatigue, excessive thirst, frequent passage of excessive amounts of urine, and sugar in the urine.

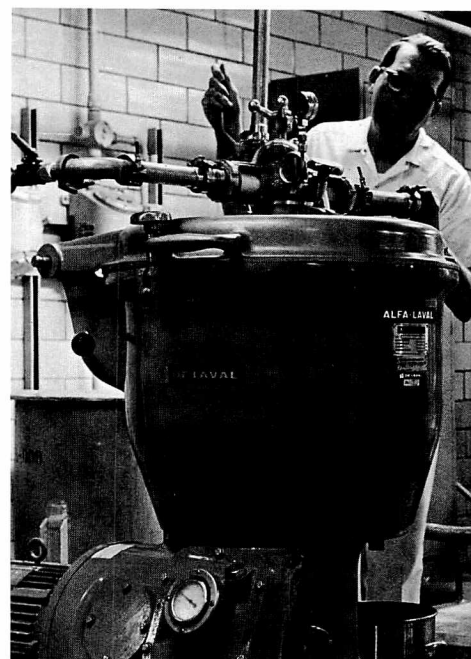
It was once thought that diabetes is caused solely by a lack of insulin, a chemical secreted by the pancreas—a gland involved in the digestive process. It is now known that some diabetics have plenty of insulin but it is somehow prevented from performing its natural function of regulating the way the body uses starches and sugars. Without this "regulator" the body cannot store sugar properly or use it in the form of energy; thus the excess of sugar spills over into the blood and urine and is not available to the body.

Earlier scientists had explored the relationship between the pancreas and diabetes, but Banting and Best were the first to demonstrate in the laboratory that the blood sugar of a dog made diabetic by removal of the pancreas could be lowered by injections of insulin taken from the glands of other animals.

Recognizing the importance of standardized potency if insulin were to



For over a million diabetics who cannot control their disease by diet and exercise, injections of insulin are a vital part of their daily routine.



A production operator at Eli Lilly and Company keeps an eye on a continuous flow centrifuge in which crude insulin is collected from a solution extracted from ground-up pancreas glands.



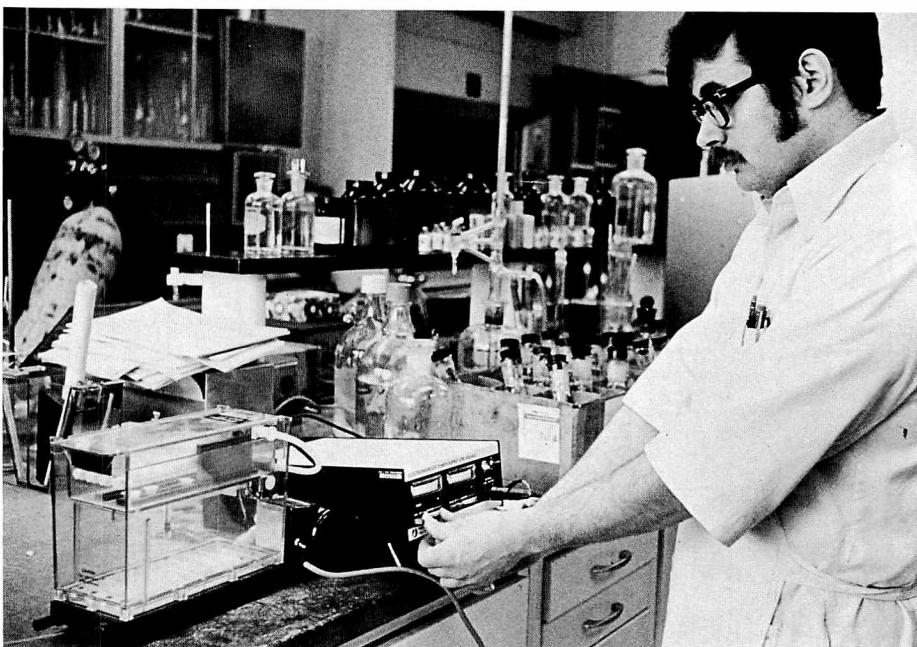
As one of the final steps in the purification process, aluminum hydroxide is added to a solution to stimulate the formation of insulin crystals.

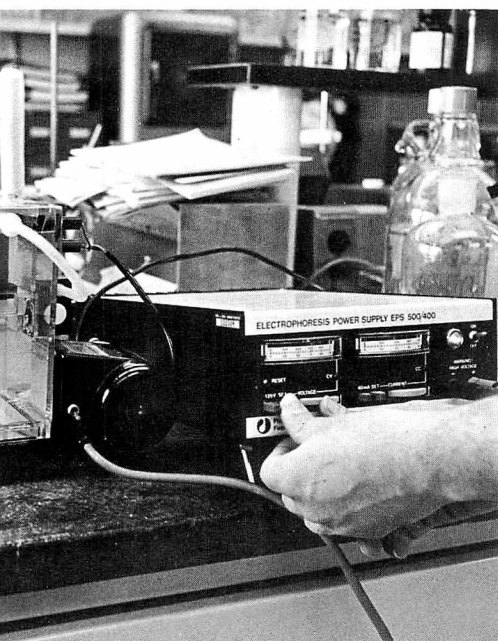
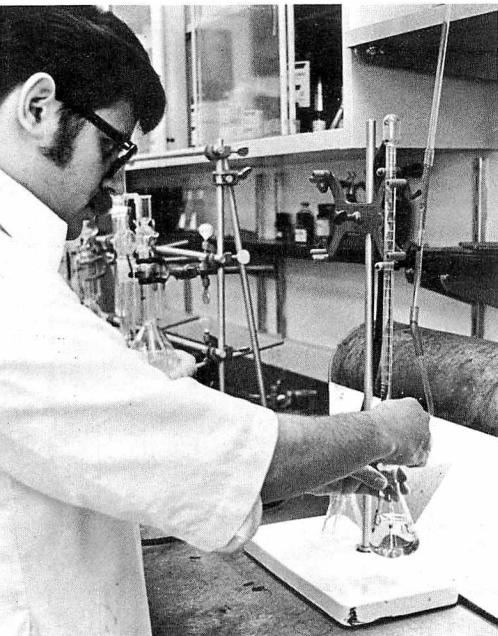
In FDA's insulin laboratory, Chemist Robert Rosenthal measures the zinc concentration in an insulin sample using an atomic absorption spectrophotometer. The process starts in the chamber in the center of the apparatus, where a solution containing the insulin sample is sucked into a flame which vaporizes it. Light from a cathode ray tube, enclosed at left, distinguishes zinc atoms from others in the solution and transmits the count to the small screen at the right. Zinc is an essential ingredient in insulin but the amount present must be carefully controlled.

On the other side of the laboratory, Biologist Charles Dieter adds sulphuric acid to an insulin sample to determine its nitrogen content.



"Gel electrophoresis" is one technique for checking the purity of insulin. FDA's scientists are developing their own methodology for using this procedure which calls for insulin to be injected into small test tubes filled with a jelly-like material. When an electrical current is passed through the gel, as Charles Dieter demonstrates, protein in the insulin separates into distinct bands of varying widths indicating the purity of the drug.





be made commercially, the University of Toronto asked the two men to patent their discovery and turn the patents over to the University. An Insulin Committee was established to administer a licensing program and a laboratory set up to test the finished product. Eli Lilly and Company, an American drug manufacturer, offered its assistance in developing the new drug and was granted a one-year exclusive license to develop a standardized product that would be acceptable for use in people.

At one time, four American companies produced insulin. Today, Eli Lilly and Company and E.R. Squibb and Sons are the only American firms still in this business. Insulin crystals are also imported from several foreign countries and the final product made by these firms.

Insulin has been produced artificially in the laboratory for experimental use, but as far as commercial production is concerned the only source of raw material is pancreas glands taken from cattle and swine at the time they are slaughtered. The glands are immediately frozen to 0° F to prevent other secretions in the pancreas from destroying the insulin, then are shipped to the drug manufacturer or processed in part by a pharmaceutical affiliate of the meat packing plant.

Wherever the initial processing takes place, the steps required to produce pure insulin crystals are the same. The frozen glands are ground up in a high-speed grinder and acidic alcohol is added to extract the insulin from the gland tissue. The mixture is then purified, concentrated, and converted into a solid. In the final step, the insulin is placed in a solution containing zinc ion which produces zinc-insulin crystals. These crystals are pooled with others accumulated over many months to form a "master lot" from which the final insulin products will be made. Master lots vary in size, ranging from 100 to 200,000 or more grams. It takes 10,000 pounds of pancreas to make one pound of insulin crystals. Thirty-two head of cattle and pigs are needed to

supply enough insulin for one diabetic for one year.

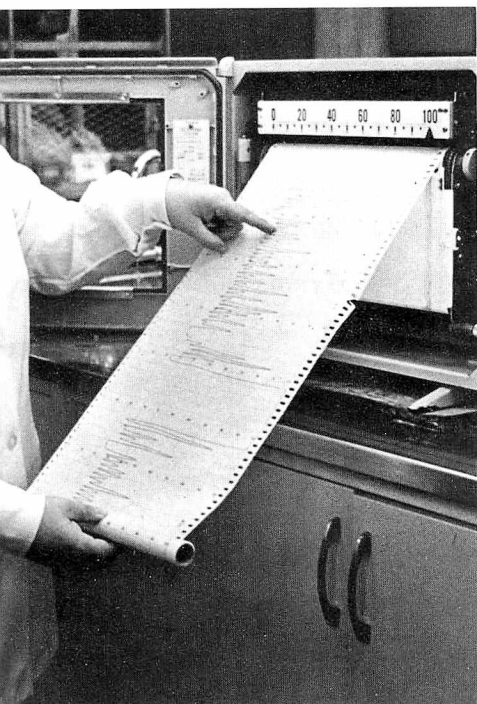
FDA's certification process has several phases. The first step is to determine the potency of the master lot of insulin crystals, that is, to find out how many U.S.P. units of insulin there will be in a milliliter of a solution made from that lot. The International or U.S.P. Unit of Insulin was established by the League of Nations in 1925. It is a fixed quantity of insulin which has a predictable effect when taken by a diabetic. Potency testing is done independently by both FDA and the manufacturer.

For the potency test, FDA technicians use six groups of 28 rabbits which are injected with one of four solutions: either a high or low dose of the insulin made from samples provided by the manufacturer; or a high or low dose of a standard reference solution of insulin prepared to a precise potency level in the FDA insulin laboratory. One hour after the injection and again 1½ hours later the rabbits are bled and the level of sugar in their blood is measured. A second run is made the following day using the same rabbits but giving each one a different solution than it received the first time. The potency of the master lot can then be determined by comparing its ability to lower blood sugar with the results using the standard reference solution. FDA determines the official potency by combining its test results with those obtained by the manufacturer. This method of potency testing has been used for 40 years.

Chemical tests are also run on samples from the master lot to determine the amount of moisture, ash, nitrogen, and zinc present in the insulin. Data from FDA's and the manufacturer's tests are then sent on to the Certification Services Branch of the Bureau of Drugs where they are reviewed before a certificate is issued, giving the manufacturer the green light to go ahead with production of specific insulin products.

There are seven types of insulin, each characterized by the length of





An hour after the insulin injection, the first of two blood samples is taken from each rabbit being used in the test. Chemist Kathleen Griego prepares the sample for analysis in an autoanalyzer, which measures each animal's response to the insulin and records it as a peak on the chart which Miss Griego unrolls at the end of the machine.

time it is effective in the body. The unmodified form is fast acting. The addition of substances such as protamine, a basic protein from fish, or globin from the red cells of ox blood, produces long-acting types of insulin. Diabetics may use just one type of insulin or several types depending on their individual needs. Because insulin must be taken daily, most diabetics who use it learn early how to give themselves the drug by injection.

Insulin is bottled in vials containing 40, 80, or 100 units of the drug. The bottle cap, outside packaging, and label are color-coded to identify the potency and type of insulin. Before these vials reach the patient, each batch of each type of insulin must go through more tests by FDA.

The final certification procedure requires that a trial mixture be tested for each kind of insulin product to be made from the master lot. Various tests are done on the trial mixture; for some products two groups of 24 rabbits are used to determine whether the product is effective over the proper time. When a final batch is made at least 30 vials are submitted for sterility and other tests, along with the firm's test results.

After all tests are done and the labels on the vials are examined to make certain that they contain all the information FDA requires, the test results are sent to the Certification Services Branch of the Bureau of Drugs which notifies the manufacturer that the insulin in that batch can be released.

Total production time for a batch of insulin, from the slaughter of the animals whose pancreases are used to final certification by FDA, is about 8 months. For its certification services FDA charges the manufacturer set fees that are specified in Federal regulations.

FDA's responsibility does not end here, however. Representative samples collected at intervals by FDA inspectors in the field are checked to make sure nothing happened to the product

after certification and that outdated stocks are removed from pharmacy shelves. Insulin carries a two-year expiration date.

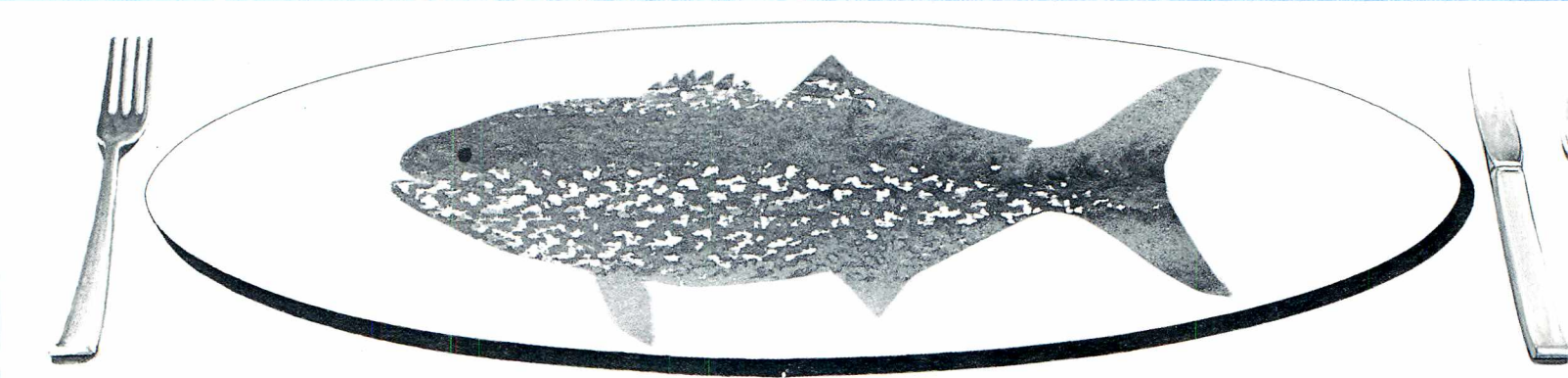
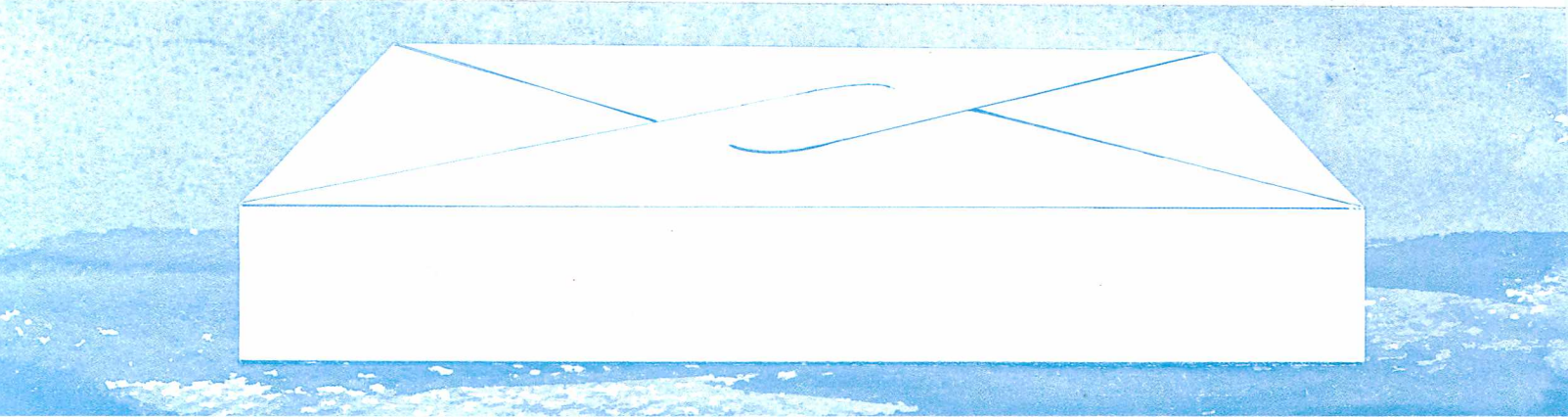
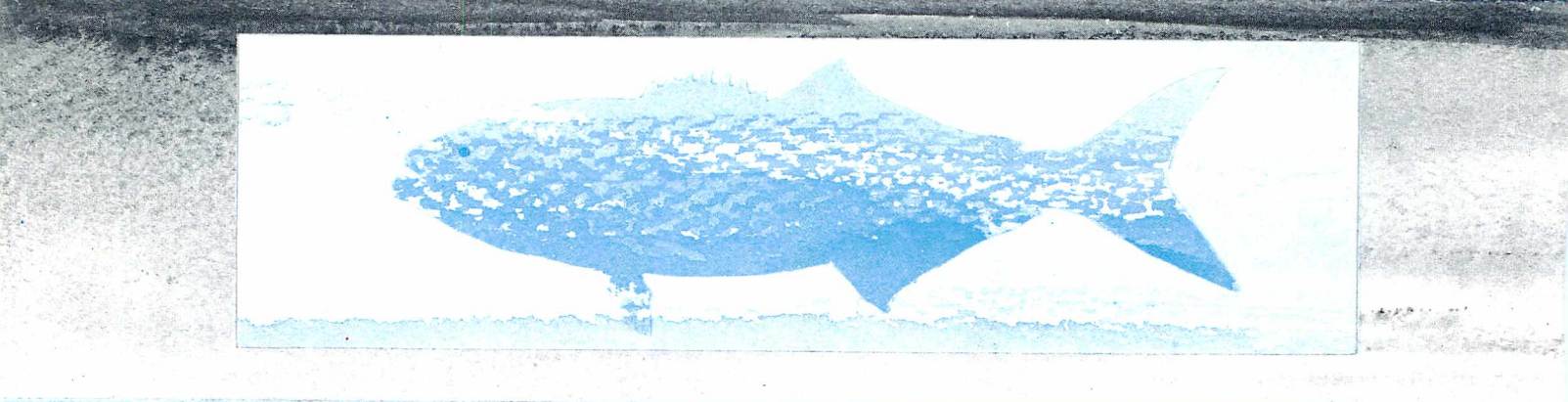
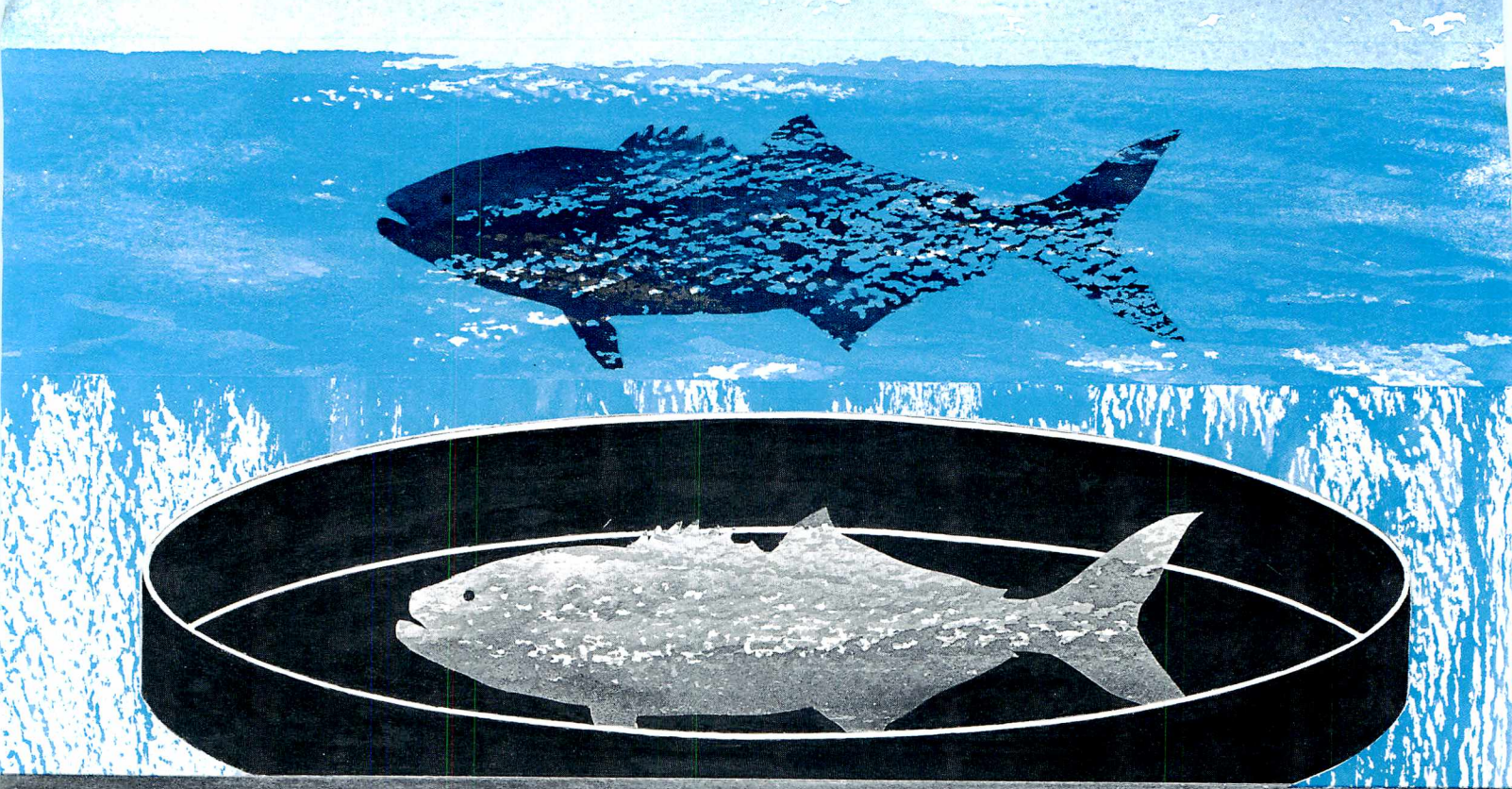
Occasionally a consumer will send a sample to the FDA insulin laboratory, through an FDA field office, with a complaint such as that the insulin didn't look right or that it caused an unusual reaction. Because of concern that an entire batch might be involved the laboratory examines such samples with the same care as those going through the regular testing schedules. Samples from each batch that has been certified are kept in the laboratory. This makes it possible for FDA to check insulin about which a complaint has been made against a sample of known potency and purity from the same batch. More often than not the problem turns out to have been caused by the consumer himself—not keeping injection equipment sterile or perhaps not mixing the medication correctly.

FDA's insulin laboratory does potency tests on an average of 18 master lots each year. How this translates into individual vials of insulin is difficult to estimate since the master lots vary in size. However, 35 million vials were produced from the insulin certified by FDA in 1975.

As for the white rabbits—except for having to go without food for a day before they become “guinea pigs”—they seem not to suffer from having their blood sugar lowered time after time. As long as they remain healthy these animals can stay on the job for about two years. Some have stayed in FDA's animal colony for as long as four or five years.

Not all diabetics need insulin. Many are able to control their disease with carefully designed diets and exercise. But for the million and a quarter who have to rely on this drug, FDA's certification program provides assurance that the product they use meets the highest standards of quality.

Annabel Hecht is a staff writer with FDA's Office of Public Affairs.



Safety Of Frozen Heat-And-Serve Foods

After analyzing the results of inspections of 100 companies that make a variety of frozen heat-and-serve products, FDA has concluded that better control of key points in the manufacturing process is needed to guard against contamination.

by Harold Hopkins

There's not only room for but necessity for improvement in the commercial processing of frozen "heat-and-serve" foods to assure they are safe to eat.

So FDA has concluded after taking a critical and comprehensive look at the operations of a substantial number of processors of several frozen heat-and-serve food products. The Agency is now considering the adoption of the proposed Good Manufacturing Practice (GMP's) Regulations it has developed for this industry. These GMP's, the Agency said, could be beneficial to the industry by identifying "the particular processing operations that need to be controlled."

The draft GMP regulations are based on a 1974 survey of the frozen heat-and-serve food industry. Analyses of the results of the survey were recently completed and released by FDA. FDA investigators looked at 100 companies representing a substantial number of manufacturers of five frozen heat-and-serve product categories: bakery items; seafood products; non-meat casserole and nationality dishes; cheese pizzas; and agricultural products, including vegetables in sauce, onion rings, and potato products. The only preparation of these products required of the consumer is heating or warming, except for custard-filled pastries, which must be thawed.

FDA investigators identified 78 important control points in the manufacturing processes of the 100 companies as a whole and the studies determined

that this group of firms is in need of better control of these points. Unsatisfactory control at such points in the manufacturing process is a potential cause for the production of hazardous products, the report points out.

Some of the hazards that could result from these failures are pesticide residues in agricultural products, introduction of harmful bacteria into a seafood product, or conditions under which bacteria could multiply to dangerous levels in a bakery product. Some control points, such as freezing and storage, are applicable to all products, and others are applicable to specific products, such as "field management" of agricultural products. A failure at one of these control points may not be harmful, but the potential for harm is there, the report notes.

The shortcoming found most often by FDA investigators was inadequate quality assurance, both during production and in the finished product. Handling of raw materials also caused trouble for a large number of companies, especially in sampling and analyzing materials for contamination. Other major problem areas concerned use of water by the plants, the freezing process for finished products, and some steps in the processing of materials and components.

This sampling of companies may not be statistically representative of the frozen heat-and-serve industry, FDA said, but it can be viewed as indicating an industry trend toward failure to control the stages in processing that are critical to safety of the products.

If the Good Manufacturing Practice (GMP's) Regulations developed by FDA to deal with the problems revealed by the inspections are proposed by publication in the FEDERAL REGISTER, they are likely to include:

- Requirements for construction and design of plants and measures to prevent contamination of products,

raw materials, and packaging material.

- Standards for equipment and utensils to prevent microbiological contamination.

- Regulations on sanitation of facilities, equipment, utensils, and personnel.

- Quality control methods to ensure that foods are wholesome and packaging materials are safe and suitable.

- Requirements for coding of product containers or packages and for recordkeeping.

The survey of heat-and-serve food manufacturers is the first published study of an entire food industry product class under FDA's Hazard Analysis and Critical Control Point (HACCP) inspection procedure. This inspection procedure was devised for food plants where improper processing of the food can constitute a danger to health. Under the HACCP system FDA investigators examine the critical control procedures in a plant's operation.

The HACCP inspection determines how well the company operates not only on the day of inspection but also in the past, the latter determined by reviewing the records and the plant's quality control practices.

The HACCP inspection procedure was first used extensively in FDA inspection of low-acid food canning plants. A separate report will be issued for the canned food industry.

Copies of the frozen heat-and-serve foods survey (*FY '74 Hazard Analysis and Critical Control Point Inspections—Frozen "Heat and Serve" Type Foods*) are available without charge from the Assistant Commissioner for Professional and Consumer Programs (HFG-1), Food and Drug Administration, Room 15B-41, 5600 Fishers Lane, Rockville, Maryland 20857.

Harold Hopkins is editorial director of FDA CONSUMER.

Cosmetics

The Substances Beneath The Form

There's nothing new about cosmetics. They've been used for thousands of years—in virtually every country and culture—but never in greater amounts than today. Although ads for cosmetics sometimes hint of magical ingredients, chemical analyses show that the products in any category—lipsticks, face creams, deodorants—are basically similar in composition.

by Margaret Morrison

Whether you buy an expensive hair color because you think you're "worth it," or use a certain toothpaste because someone has told you to "put your money where your mouth is," chances are you're doing the same thing millions of other Americans are doing—using cosmetics in record amounts in an effort to look young or alluring or just plain clean.

Probably from the day Adam and Eve started wearing leaves, they also started using the oils from plants to soften their skins or smooth their hair or make their skin color more attractive. Throughout the ages, people have used cosmetics to enhance their personal appeal. The tombs of Egyptian kings dating back as far as 3500 B.C. contain evidence of perfumed hair oils. "Cold creams" reputedly were invented by Claudias Galen (A.D. 130–200). And the foppish gentlemen of 17th and 18th century Europe used cosmetics lavishly, as did their fashionable ladies.

But the United States today tops anything ever seen in the number and amounts of cosmetics "consumed." Each year we spend billions of dollars on everything from lipstick to mascara, from shave cream to musk oil.

A recent survey conducted for FDA showed that the cosmetic product used by more Americans than any other is soap. This is not surprising, since soap is used by practically everyone and is considered more of a bodily necessity than a "cosmetic." In fact, although the definition of cosmetics in the Food, Drug, and Cosmetic Act includes articles "applied to the human body for cleansing," soap is specifically excluded from coverage of the law. Soap ads, of course, often claim that the product does considerably more than just clean the skin.

Toothpaste is the next most-used cosmetic, according to the FDA survey, with shampoo, mouthwash, talcum, and hand lotion following in volume. These "basic" products account for about 22 percent of cosmetics sales each year, but that still leaves a substantial amount for such glamorizing products as lipsticks, eye cosmetics, face creams, hair conditioners, perfumes, and colognes.

Cosmetics manufacturers often claim their products contain some secret ingredient that is superior to the ingredients used by other lines, or some magic formula that will accomplish extraordinary results. But chemical analyses

show that products in any category—lipsticks, face creams, etc.—basically are similar in composition. An inexpensive substance such as vegetable oil can be just as effective in keeping the skin soft as the most expensive face cream. In the expensive cream you may be paying for a pretty jar, an appealing fragrance, extensive advertising and promotion, or a feeling about the product which is esthetically pleasing to you—but not a magic formula that will do for you what no other product can.

You should remember, too, that many terms used in the promotion and labeling of cosmetics are not well defined. For example, you may see a claim that a product is a "rich emollient." Rich in what? The manufacturer may not say. One word which is used frequently and which probably is more confusing than any other is "moisturizer." The word would seem to imply the product would make something moist or wet. But moisturizers do not add moisture to the skin. They merely put a protective cover on the skin, so the skin can retain its own moisture. Another confusing term is "penetrating." Actually, the manufacturer may use this term merely to indicate that the product will rub in well and form a dry film which gives the skin a feeling that the product has disappeared. Many such terms used in cosmetics promotion must be taken "with a grain of salt" by consumers.

This raises some questions as to how cosmetics are manufactured, promoted, and regulated. Cosmetics are regulated by the Food and Drug Administration under the authority of the Food, Drug, and Cosmetic Act. Congress passed this law in 1938 to prohibit the movement in interstate commerce of adulterated and misbranded foods, drugs, cosmetics, and medical devices.

Another law which affects cosmetics is the Fair Packaging and Labeling Act. Its purpose is to ensure that packages and labels provide consumers accurate information about the identity of the product, the net contents, and the name and address of the distributor. The FDA is responsible for establishing packaging and labeling regulations for food, drugs, and cosmetics.

The Food, Drug, and Cosmetic Act defines cosmetics as articles which may be "rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the



human body for cleansing, beautifying, promoting attractiveness or altering the appearance

without affecting the body's structure or functions." Products such as antiperspirants and antidandruff shampoos that affect the structure or functions of the body are legally classified as drugs although they are also promoted as cosmetics and most people consider them cosmetics. To consumers, probably the most significant difference between a product classified as a cosmetic and one classified as a drug is that drugs must be proved safe and effective before they are put on the market, while cosmetics generally do not require premarket testing.

As might be expected, regulation of cosmetics is not as stringent as regulation of food and drugs. Firms that manufacture cosmetics are not required to register with FDA, nor do they have to tell FDA the formulas they use in making their products. In recent years, some manufacturers have voluntarily registered their firms' addresses and product formulations with FDA and have made available to the Agency consumers' reports of adverse reactions to their products.

Most cosmetic manufacturers test their products for safety before putting them on the market. The law does not specifically require such tests, however, and few manufacturers make available to FDA any data on the safety testing of their products. Although FDA has no authority to require premarket testing of cosmetics for safety, the Agency can take legal steps to have a product removed from the market if it proves to be a health hazard.

Most cosmetics are safe for use by most people, but a survey conducted for FDA in 1974 showed that adverse reactions to cosmetics occur far more often than had been assumed in the past. The ten categories of products showing the highest rate of adverse reactions were: deodorant/antiperspirants; depilatories (chemical hair removers); moisturizer/lotion; hair spray/lacquer; mascara; bubble bath; eye cream; hair color/dye lighteners; facial skin cream/cleaner; and nail polish.

To provide greater consumer protection, FDA has taken

a number of important actions concerning cosmetics in the past two years, dealing mostly with la-

beling (see accompanying summary). Specific warnings now are required on cosmetic aerosol products, such as hair sprays, deodorants, and feminine deodorant sprays. Another recent regulation deals with use of the term "hypoallergenic" and similar claims. But perhaps the most far-reaching regulation is one requiring that the ingredients in cosmetics be listed on the product label.

The listing of ingredients on cosmetics is important for two reasons. First, consumers have a right to know what is in any product they are buying. And second, the requirement will promote truth in advertising. Many consumers may understand only a little about the ingredients that are in cosmetics. But if you have a problem with a product and the ingredients are shown on the label, you and your doctor can determine the ingredients you should avoid in the future.

Listing of ingredients also can help you compare the value of competing brands of cosmetics. And when ingredients are known to consumers and competitors alike, the manufacturer is less likely to make exaggerated claims about what the product will do.

Although the listing of ingredients will mean more complete information on cosmetic labels, many consumers no doubt will be surprised—or even puzzled—when they see what is in the cosmetics they use.

For example, take cleansing cream, today's version of what used to be called "cold cream." Although washing with soap and water will do the same job—removing dirt and oil and makeup from the face—a cleansing cream sometimes may have certain advantages. Some studies have showed that cleansing creams are more effective in removing makeup, and creams leave an emollient (softening) film on the skin, which gives greater protection for dry skin or keeps "normal" skin from becoming dry.

In some cleansing creams consumers will see listed such ingredients as mineral oil, beeswax, borax, and water. The beeswax-borax mixture is the emulsifier which keeps the oil and water together. In others, glyceryl stearate and wool-



wax alcohol, cholesterol, and mineral oil are used. These ingredients—the oils and the emulsifiers—

when used in appropriate proportions or concentrations, form a cream or lotion and serve to cleanse the skin without leaving the skin dry or taut.

Some ingredients, on the other hand, have little to do with the cleansing action itself. Sorbitan sesquioleate, for example, serves no purpose for the skin but is used to keep the cream from separating into oil and water.

Just as some ingredients are used in creams to keep them soft, some ingredients are used in lipsticks to keep them firm. Lipstick is composed essentially of an oil-wax base stiff enough to form a stick, with red-staining dye and pigments in the oil, and perfume. Castor oil is the principal ingredient in lipsticks. Beeswax, carnauba, and candelilla are the waxes used most often in lipstick.

At one time, staining dyes were used extensively in lipsticks, to give a color that would adhere to the lips and last longer. In recent years, “high stain” lipsticks—the vivid blueish reds—went out of style. Most women, going along with the “natural look” trend, preferred the more delicate shades and a lipstick they would apply often, instead of one that gave a “hard” lasting color. Now, fashion magazines are showing a return to the more vivid shades of lipstick, but it is too soon to tell whether a preference for deeper color actually will prevail among consumers.

Unlike other ingredients, the color additives used in cosmetics must be approved by FDA for purity and safety. Bromo acid and related dyes are responsible for most of the color quality of practically every modern lipstick. Each dye has its own peculiarities, and this explains why two lipsticks may look very much alike in the tube but produce very different tones on the lips.

Glossy and pearly colors have become increasingly popular in recent years for producing lustrous lipsticks. Some ingredients used to obtain the lustrous look include guanine crystals, bismuth oxychloride, and mica coated with titanium dioxide.

Perfumes in lipsticks are used mainly to obscure any fatty

odor that might be present in the basic ingredients, rather than to give a perfumed fragrance.

Antioxidants are frequently used to prevent the development of unpleasant odors which some oils and waxes produce when they become stale.

In recent years eye makeup has joined lipstick as one of the most popular types of cosmetics, especially among younger women. Eyeshadow is one of the biggest selling cosmetics in the country today. It is available in blue, green, violet, beige, white, and combinations of these. Mascaras and eyeliners come mostly in black or dark brown.

Many color additives that have been approved by FDA for general cosmetic use are not approved for use in eye products. With a few exceptions, only inorganic pigments may be used in eye cosmetics. The main coloring agents are ultramarines, iron and chromium oxide pigments, and carmine N.F. (derived from cochineal, which is made from the dried bodies of the females of certain scale insects).

Typical ingredients used in paste or cream-type eye makeup include petrolatum, lanolin, ceresin, carnauba wax, beeswax, stearic acid, isopropyl myristate, propylene glycol, gum tragacanth, water, and methyl cellulose. In addition, there may be preservatives, ingredients to give a “pearly” look, and perfume based on natural oils and aromatic chemicals.

Because of the sensitivity of the eye area, and the serious damage that could result from irritants, manufacturers’ safety testing for eye cosmetics usually is more strict than for other types of cosmetics. Even so, consumers should remember to be very careful when using eye cosmetics.

Along with creams, lotions, lipsticks, and eye makeup, antiperspirants and deodorants are among the top selling cosmetic products. Judged by the definition in the Food, Drug, and Cosmetic Act, antiperspirants are considered drugs because they alter a bodily function. But most consumers consider antiperspirants as well as deodorants to be cosmetics. It has been estimated that nine out of ten women and eight out of ten men regularly use either an antiperspirant or a deodorant. Both products are formulated to control

the odor of perspiration, but antiperspirants also are intended to check the flow of perspiration.

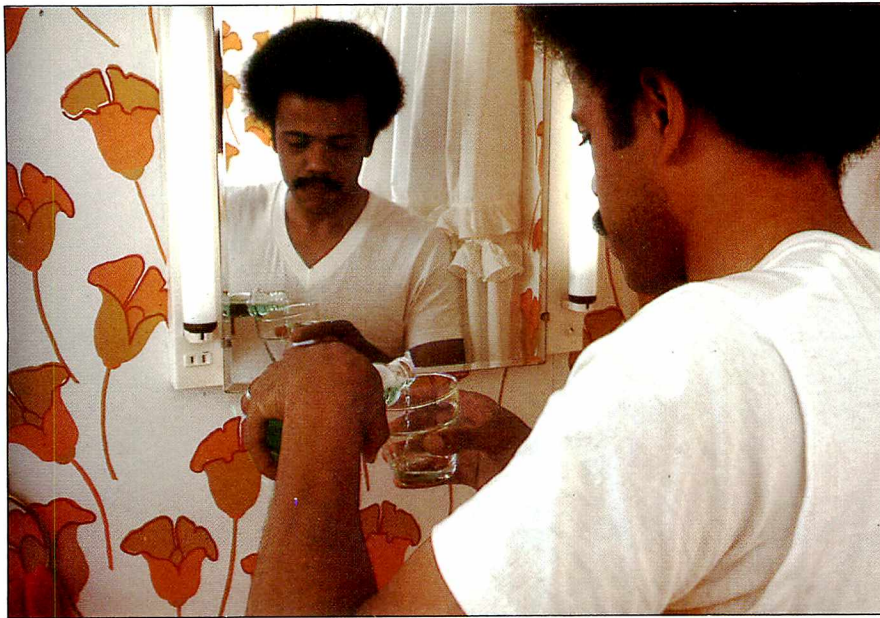
To reduce the flow of perspiration, certain substances (called astringents) which affect the body's sweating mechanism are required. Antiperspirant properties are found in the salts of a number of metals, but the most commonly used antiperspirants are the salts of aluminum.

Unlike antiperspirants, deodorants are designed merely to prevent body odor, not to stop perspiration. Since most body odor is the result of bacterial action on perspiration, most deodorants contain an effective antibacterial agent—a substance that can kill bacteria or prevent their growth. The aluminum salts which have astringent properties (and are thus used in antiperspirants) also have antibacterial properties. Ingredients such as aluminum chloride, aluminum sulfate, aluminum chlorhydroxide, and other aluminum compounds often are used in antiperspirants. Deodorant powders consist mostly of talc and perfumes. Sometimes they contain an antibacterial agent, such as kaolin, zinc oxide, zinc stearate, or other ingredients.

Whatever antibacterial agent is used, it generally comprises a very small percentage of the deodorant. The other ingredients either provide a cosmetic benefit, such as fragrance, or make application easier, as does the propellant in an aerosol or water in a roll-on product. Many deodorants and antiperspirants contain alcohol, which has a potential for stinging or burning, and these products may carry a warning statement on the label that they should not be used immediately after shaving (underarms).

The labeling and advertising for an antiperspirant are permitted to say that the product "checks" or "reduces" perspiration, but claims that a product "stops" perspiration are not permitted. Deodorant products may claim that they "decrease" or "stop temporarily" the odor of perspiration.

Although most people probably consider toothpaste or powder a practical necessity, advertisers often promote the products with an eye to glamour and sex appeal. In recent years there also has been a considerable push to develop products that are capable of reducing tooth decay or dis-



eases of the gums as well as cleaning the teeth. One ingredient that has been used for such thera-

peutic purposes is stannous fluoride. Fluoride toothpaste, when used regularly and at an early age, is effective in reducing the incidence of tooth decay, according to the Council on Dental Therapeutics of the American Dental Association.

Some dentifrices make the claim that they are "lower in abrasion." How desirable is this? Most experts agree that to do a satisfactory job of removing film from the teeth a dentifrice must have some degree of abrasiveness, but the ideal dentifrice should combine a minimum of tooth abrasion with maximum cleaning efficiency.

The most widely used abrasives are calcium carbonate, dibasic calcium phosphate dihydrate, anhydrous dibasic calcium phosphate, tricalcium phosphate, calcium pyrophosphate, insoluble sodium metaphosphate, and hydrated alumina.

In examining some of the ingredients in five categories of cosmetic products, this article has touched only the tip of the iceberg. Cosmetics on the market today include hair-grooming preparations, permanent waves and hair straighteners, shaving preparations, nail polishes and nail polish removers, suntan lotions, beauty masks, face powders and body powders, hair colors, mouthwashes, skin creams, and many other products.

FDA is seeking to assure that consumers be as well informed as possible about this maze of products—by requiring that ingredients and appropriate warnings be shown on labels, and that the reliability of hypoallergenic claims be substantiated by testing.

As for most other claims made on behalf of cosmetics, your own satisfaction is the best guide. If a cosmetic causes you no problem and is pleasing to you, it probably serves a useful purpose. How useful, in terms of dollars spent, only you can decide.

Margaret Morrison is a staff writer with FDA's Office of Public Affairs.

Recent Regulations Affecting Cosmetics



Over the past few years FDA has taken a number of actions to assure that the labels on cosmetics provide consumers with adequate, meaningful information about the product. Here's a summary of recent FDA regulations on cosmetic labeling.

Ingredient Labeling

The labels on all cosmetics now are required to carry a list of the ingredients that are in the cosmetic. Consumers can use cosmetic ingredient labeling to compare products and to avoid substances to which they may be allergic. Ingredients must be listed in order of amount contained, with the major ingredient first. Ingredients that constitute less than 1 percent of the product need not be listed by amount, and color ingredients can be listed in any order regardless of the amount used in the product.

Ingredients must be listed by uniform names established especially for ingredient labeling. This rule is intended to prevent consumers from being confused or misled by the use of different names for the same ingredient.

The ingredient list is not required to include the names of specific fragrances or flavors used in a product. These may be listed simply as "fragrance" or "flavor." A fragrance or flavor may contain a dozen or more ingredients of its own and FDA felt that requiring the listing of all these substances would confuse consumers. FDA is aware, however, that fragrances and flavors may contain substances that could cause adverse reactions in certain individuals and the Agency welcomes comments on this subject from the public as the basis for future change in the regulation. The Agency is trying to determine whether certain fragrance or flavor ingredients that may cause harm should be carried on the list by their individual names to alert consumers who are susceptible to them.

Some ingredients used in cosmetics are said by the manufacturer to be trade secrets. If FDA agrees that a specific ingredient is a bona fide trade secret it need not be carried on the list.

No label listing is required for incidental ingredients if they are used in insignificant amounts and have no technical or functional effect in the cosmetic.

Warnings Required on Labels

Many products have a potential for harm if they are not used with reasonable care by the consumer. To help consumers protect themselves, FDA has issued regulations requiring appropriate warnings on the labels of three kinds of cosmetic products: feminine deodorant sprays, cosmetics packaged in aerosol (self-pressurized) containers, and cosmetics which have not been substantiated for safety by their manufacturers.

The requirement for warnings on the labels of aerosol containers provides for two types of statements. The first is a general warning that must be carried on all aerosol cosmetics. It says:

"WARNING—Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120° F. Keep out of reach of children."

This statement is intended to help consumers protect themselves against injury from explosion of the container and from accidental discharge into the eyes, which could cause serious injury. The statement may be modified to be appropriate for the product. For example, on foams or creams, which are not expelled as a spray, the words "Avoid spraying in eyes" may be deleted.

A second warning is required on aerosol products in which the propellant is a halocarbon or hydrocarbon. Some of these propellants have been responsible for a number of deaths, especially among juveniles who deliberately concentrated and inhaled the vapors to induce a euphoric effect or "high." Cosmetics using halocarbon or hydrocarbon propellants must carry this statement:

"WARNING—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal."

This warning is not required when the product is expelled as a foam or cream and the halocarbon or hydrocar-

bon constitutes less than 10 percent of the product.

A cautionary statement on feminine deodorant sprays is required by FDA because of complaints from consumers and physicians about adverse reactions such as itching, burning, and blistering. These products must state:

"CAUTION—For external use only. Spray at least 8 inches from skin. Do not apply to broken, irritated, or itching skin. Persistent, unusual odor or discharge may indicate conditions for which a physician should be consulted. Discontinue use immediately if rash, irritation or discomfort develops."

To be sure the consumer does not miss this warning statement, FDA requires that it be on the spray container itself, and it must be prominent and conspicuous.

The Food, Drug, and Cosmetic Act does not authorize FDA to require cosmetic manufacturers to test their products for safety. However, FDA does require that if a cosmetic manufacturer has not substantiated the safety of a product, the label must carry a message to that effect. The statement on such a cosmetic must read:

"WARNING—The safety of this product has not been determined."

Use of the Term "Hypoallergenic"

For years, some cosmetics have been advertised or promoted as being "hypoallergenic." Most consumers believed that the use of this or similar claims meant that the product was less likely to cause adverse reactions than products not making such claims. But there was no requirement that manufacturers have proof that this was so.

FDA now requires that a cosmetic may be labeled "hypoallergenic" only if scientific studies show that it causes significantly fewer adverse reactions than competitive products used for similar purposes. Manufacturers must submit test results to FDA to back up their claims before using on their products the word "hypoallergenic" or such terms as "allergy tested," "safer for sensitive skin," or "lower rate of reactions."

Regulated Firms: A Statistical Profile

More than 110,000 establishments fall under FDA's regulatory jurisdiction in one way or another. The bulk of these—more than 77,000—are involved in the processing, storage, or repackaging of food.

by Annabel Hecht

For Americans who have been taught to "think big" it should come as no surprise that the Food and Drug Administration keeps an eye on about 110,000 establishments that make, process, store, or distribute the wide variety of products that are covered by the Federal food and drug laws.

FDA does not know, for certain, how many such establishments there are, but can come up with some pretty good estimates since some must register with the Agency in order to be in business, others must undergo inspections routinely, and many must file reports with FDA.

The largest category of FDA-regulated establishments are those involved in the processing, storage, or repacking of food—77,220 all told. This includes 6,970 whose "primary" industries are nonfood products such as drugs or colorings.

An "establishment" is a place of business. A parent company or firm may own and operate one or more establishments. If an establishment makes more than one type of product, FDA considers its "primary industry" to be the one with the potential for the most serious problems in consumer protection. For instance, if a company

makes both candy and medicated syrup, the syrup will be the primary industry in FDA's book even though the company's candy sales are higher.

FDA includes in its inventory 11,810 establishments involved with human drug products. This breaks down to 2,900 manufacturers; 1,100 repacking and relabeling establishments; 200 quality control testing laboratories; approximately 6,870 warehouses, distributors, importers, and research laboratories; and 730 methadone treatment centers.

It's a simple matter to count the 33 producers of biological products, such as vaccines, and the 758 establishments that ship blood and blood products in interstate commerce since these must be licensed by FDA. In addition, there are 6,495 establishments not licensed by FDA that collect and process blood for use within their home States.

To meet the needs of the animal world there are 990 establishments that produce or repack animal drugs; 13,570 that make medicated feeds; 3,970 that make non-medicated feeds; and 1,320 that deal in by-products for animal feeds. The actual count of establishments in the animal food and drug business is only 17,740, since some of them make two or more of these products.

Some 2,850 establishments are in the cosmetics business: 1,200 in the manufacturing end, and 1,650 concerned with distribution or storage.

When it comes to medical devices, which range from tongue depressors to heart-lung machines, FDA's authority to require registration of the makers of these products is so new that not all

firms have registered yet. It is estimated, however, that there are in the neighborhood of 1,900 companies which make products in several of the following categories: x-ray and electromedical equipment, surgical appliances and supplies, dental equipment and supplies, and surgical and medical instruments.

Keeping tabs on establishments that deal with ray-emitting products presents yet another problem. FDA requires an initial report from every company that produces lasers, ultrasonic products, microwave heating equipment, high voltage vacuum switches, rectifier tubes, shunt regulators, cathode-ray tubes, television receivers, and products to produce x radiation. Approximately 1,660 domestic and foreign manufacturing companies, importers, and assemblers of diagnostic equipment have filed such reports. But some companies don't have to file such reports as yet even though their products are regulated by FDA. These include manufacturers of mercury vapor lamps and microwave products not intended as heating equipment.

Anyone who takes the time to count all the foregoing figures will discover that they total more than the 110,000 establishments cited at the outset of this statistical countdown. That's because many establishments are counted in more than one category. And, of course, the numbers change from time to time, as new companies enter the field and others drop out.

Annabel Hecht is a staff writer with FDA's Office of Public Affairs.

News Highlights

FDA to Ban Saccharin

The Food and Drug Administration has announced it intends to prohibit use of saccharin in foods and beverages because the artificial sweetener has caused malignant bladder tumors in test animals.

The ban is expected to take effect some time this summer.

Saccharin is the only artificial sweetener currently approved for use in the United States. At least five million pounds a year are used in food, about three-quarters in diet sodas and the remainder in dietetic foods and as a tabletop sweetener in place of sugar.

The decision to prohibit use of saccharin was taken after careful consultation with the Health Protection Branch of the Canadian government. The action is based on two factors:

- A study sponsored by the Canadian government showed that saccharin, when fed in high doses to rats, caused malignant bladder tumors. FDA obtained preliminary results of the study at a meeting March 7 in Ottawa with Canadian scientists. Canada is taking action similar to that being announced by FDA.

- The so-called "Delaney Clause" of the Food, Drug, and Cosmetic Act prohibits the use in food of any ingredient shown to cause cancer in animals or man.

Sherwin Gardner, Acting Commissioner of Food and Drugs, said: "Previous animal tests have not demonstrated with any degree of certainty whether saccharin could cause cancer. But these Canadian tests show unequivocally that this substance can produce malignant bladder tumors in rats.

"The law is equally clear. It says that no ingredient that causes cancer in man or animals may be added to our food supply.

"Science and law dictate that saccharin be removed from our food supply."

Gardner continued: "Saccharin has been in use for more than 80 years and has never been known to harm people, and since the Canadian data do not indicate an immediate hazard to public health, we do not consider the recall of existing products to be necessary. We, nevertheless, encourage manufacturers to discontinue use of saccharin as soon as possible, even while we are drafting the documents needed to accomplish this action.

"Consumers who want to avoid saccharin in the interim may do so, since FDA requires that all products containing saccharin must list it on the label."

In the Canadian study, 50 male rats and 50 female rats were fed 5 percent saccharin in their diets. Three males and no females developed malignant bladder tumors.

In addition, 50 female and 50 male offspring of these rats were fed saccharin. Two female and 12 male rats developed bladder tumors.

Thus, of a total of 200 rats, 17 developed malignant bladder tumors.

In contrast, of 100 "control animals"—those not fed saccharin—only two developed tumors.

The dosages of saccharin fed the rats in the Canadian study were in excess of the amount that a consumer would receive from drinking eight hundred (800) 12-oz. diet sodas daily over a lifetime.

As part of the test, scientists tried to learn whether an impurity in saccharin called ortho-toluenesulfonamide (OTS) might have been responsible for earlier suspicions that saccharin could cause cancer. No tumors were found in rats fed OTS. The studies, therefore, indicate that saccharin, not OTS, was responsible for adverse effects in the rats.

The Canadian study was undertaken in February 1974 in an effort to provide a definite answer on whether saccharin could cause cancer. Studies conducted earlier by FDA and others raised questions about the cancer-causing potential of the artificial sweetener, but a National Academy of Sciences/National Research Council evaluation of all earlier studies concluded in 1974 that further research was needed.

Since 1972, FDA has imposed limits on saccharin use. The intent of those limitations was to discourage general use by consumers of saccharin and to prevent an increase in its use.

FDA does not permit the sale of any artificial sweetener other than saccharin. Cyclamate was banned in 1970. Its manufacturer, Abbott Laboratories, subsequently petitioned for reconsideration of that ban. FDA denied the petition, concluding that there was insufficient evidence to demonstrate that cyclamate was safe. FDA recently granted Abbott and the Calorie Control Council a hearing on that denial.

Another artificial sweetener, Aspartame, was approved by FDA in 1974 but has never been marketed. FDA stayed its approval for Aspartame in December 1975, after an audit of the safety data submitted by the manufacturer, G. D. Searle & Company, revealed discrepancies. FDA is now reviewing Aspartame to see whether its approval should be reinstated or permanently revoked. In the meantime it may not be sold.

Drug Industry Adopts Testing Guidelines

Guidelines for monitoring the testing of drugs in humans have been adopted by the Board of Directors of the Pharmaceutical Manufacturers Association.

Pharmaceutical Manufacturers Association (PMA) President Joseph C. Stetler said that although FDA has the major responsibility for monitoring the testing of new drugs in humans, there is a need to more clearly define the role of drug firms which sponsor such tests. PMA's guidelines will clarify the responsibilities of the company sponsoring the tests and the investigator who is carrying it out, Stetler said.

The guidelines stress personal visits by drug company sponsors on at least a quarterly basis to ensure that

investigators understand and adhere to their obligations in testing drugs in humans (usually called clinical testing). Among the points covered by the guidelines:

- Summaries of existing preclinical testing information, including requirements for informed patient consent, should be provided by the sponsor to the investigator.
- Investigators must be qualified medical doctors and personally involved in any tests conducted.
- Study facilities where patients are seen and tested should be adequately monitored by the drug sponsor to assure reasonable study performance and patient safety.
- Drug sponsors should make certain that informed patient consent procedures required by law are followed and that an Institutional Review Committee (required to oversee all studies of investigational new drugs) does exist, where applicable.
- The sponsor should advise the investigator of legal and regulatory requirements for reporting adverse drug reactions, and must report such reactions to the FDA, as specified by regulations.
- Case reports must reflect the condition of the patient before, during, and after the study, including results of clinical and laboratory observations made and any concurrent therapy administered during the course of the study.
- Evaluation reports of each case study should include any conclusions drawn as to the safety and efficacy of the investigational drug.
- Although not required by regulation, the drug sponsor should urge the investigator to retain records for at least five years (two years is now required) after the new drug is approved or the request for its approval is withdrawn. Such records would be useful in the event that followup is necessary to help determine any potential hazards to patients who took part in the tests.

FDA Suspends Plastic Bottle Approval

A Federal court has temporarily set aside an FDA order suspending marketing approval for beverage containers made from the plastic acrylonitrile.

The FDA ban on acrylonitrile bottles was supposed to go into effect March 11, but the action was challenged in court by the Monsanto Corporation, a manufacturer of the bottles. The U.S. Court of Appeals in Washington, D.C., temporarily stayed the order and directed FDA to hold a hearing.

One company, Coca-Cola, has test marketed soft drinks in acrylonitrile plastic bottles made by Monsanto Corporation, St. Louis. Another company, Musselman Fruit Products, Biglerville, Pennsylvania, has sold fruit juices in containers of acrylonitrile made by Borg-Warner, Chicago. FDA knows of no other beverages marketed in containers made from this plastic.

In a related action, FDA is proposing to lower the maximum amount of acrylonitrile permitted in the product as a result of migration or leaching from margarine tubs, vegetable oil bottles, food wraps, and other nonbeverage packing made from acrylonitrile.

The present maximum migration level is 300 parts per billion (300 parts of acrylonitrile per billion parts of the product). FDA is proposing that this be lowered to 50 parts per billion, the lowest amount that can be reliably detected with present analytical methods.

The actions by FDA are the result of findings from recent studies of acrylonitrile in test animals.

Sherwin Gardner, Acting Commissioner of Food and Drugs, said: "The amount of acrylonitrile fed to experimental animals in recent tests exceeded by far the amount to which any consumer would be exposed from present uses of acrylonitrile food containers or wrappings. But the adverse findings in these studies show that stricter controls must be placed on the use of these materials.

"It is, therefore, prudent at this time to prohibit further use of beverage containers made from this plastic. Since there is no danger to the public from the limited number of beverage bottles now available, there is no need for a recall.

"The amount of acrylonitrile to which a consumer might be exposed from normal consumption of margarine or vegetable oil would be extremely small when compared to soft drinks or fruit juice," Gardner said. "Therefore, we do not believe that the nonbeverage container uses of acrylonitrile need be prohibited."

Acrylonitrile plastics have been used for 30 years as food containers or wraps. Until 1973, test results led scientists to conclude there was no significant migration of acrylonitrile to food.

In that year, however, one manufacturer reported to FDA that migration occurred when acrylonitrile bottles containing beverages were held at a high temperature for an extended time.

FDA then required manufacturers to conduct additional safety tests if they wanted to continue using acrylonitrile to make food containers or wraps. The Agency further ordered that the level of maximum migration be limited to 300 parts per billion.

Some of the required tests were conducted by the Manufacturing Chemists Association and funded by nine interested companies.

In late 1976, the Association reported that one study showed acrylonitrile could cause birth defects in animals fed very high doses.

In mid-January 1977, the Association provided FDA with an interim report on a second study. After 13 months of this two-year study, test animals fed large amounts of acrylonitrile in their drinking water had significantly lowered body weight and other adverse effects, including growths in the ear ducts and lesions in the central nervous system.

In accordance with regulations, FDA is allowing 90 days for public comments on the proposal to lower the migration limit. After the comments are evaluated, FDA will take final action.

Comments on the proposed regulation on acrylonitrile migration may be sent to the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20857.

FDA announced its intention to take these two actions on February 11, 1977. The implementing documents appeared in the *FEDERAL REGISTER* March 11, 1977. The 90-day comment period began March 11.

'Action Level' for Kepone Raised

FDA has adopted a recommendation by the Environmental Protection Agency (EPA) to raise the "action level" for Kepone in finfish from 0.1 part per million (ppm) to 0.3 ppm. The action level for crabs (0.4 ppm) and shellfish (0.3

ppm) will remain the same.

EPA re-evaluated the Kepone action levels in light of monitoring studies recently conducted by FDA and the States of Maryland and Virginia. Part of the EPA review was public hearings in January, in which FDA participated.

Under the new action levels, FDA will consider fish containing more than three-tenths of a part of Kepone per one million parts of fish to be subject to regulatory action if it is shipped in interstate commerce.

In making the recommendation to raise the action level for finfish, Edwin L. Johnson, EPA deputy assistant administrator for pesticide programs, said, "Protection of the public health has been our primary concern in reviewing these action levels. We have now received and carefully reviewed data on the actual amounts of Kepone found in fish during the last year.

"These data indicate that actual residues were far less than we had originally anticipated. The actual residues were well below the maximum permissible intake, or acceptable dietary exposure originally calculated, based on toxicological data.

"As a result of this new information, we believe that public concern associated with Kepone-contaminated seafood from the Chesapeake Bay should be lessened. In fact, given assurances from the Commonwealth of Virginia that current restriction on the James River will remain in effect, our recommended action level for finfish will continue to provide protection even for the high seafood consumer."

FDA, in cooperation with Maryland and Virginia, will continue to spot-check seafood from the Chesapeake Bay and its tributaries for Kepone.

Budget of \$279 Million Asked for FDA

A budget of \$279 million for fiscal year 1978—which begins this October—has been proposed for FDA. This budget request was submitted to Congress by the outgoing Ford Administration and no changes were made in it by the incoming Carter Administration.

The proposed budget of \$279 million is an increase of \$26 million over the current FDA budget. Most of the increase will go for mandatory payroll expenses and to offset the effects of inflation on FDA operating costs.

About \$4.4 million of the increase is targeted for new enforcement and regulatory activities to carry out the 1976 Medical Device Amendments. With this money, FDA will fill 200 new positions in the medical device area. These new positions will permit FDA to register medical device manufacturers, inspect some 5,000 establishments, conduct premarket reviews of the safety and effectiveness of products, and make good manufacturing practices in the medical device industry a part of the FDA inspection program.

Except for medical devices, there are no increases in other FDA programs. The small increases in funding requested for other programs are needed to continue operations at existing levels.

FDA's Help Sought on Nuclear Medicine

FDA's Bureau of Radiological Health has been designated as a World Health Organization (WHO) Collaborating Center for Nuclear Medicine and for Radiation Medicine.

The designations, which are for a three-year period, were proposed by the Director General of WHO.

As a Collaborating Center for Nuclear Medicine, the Bureau will help improve and promote nuclear medicine worldwide by collecting and providing information on the best use of equipment and techniques and on various aspects of the use of radioactive drugs, including selection and quality control, radiation dose, and adverse effects.

In addition, the Bureau will issue recommendations on the organization of nuclear medicine facilities and on radiation protection measures and will set up training activities for personnel in this field.

As a Collaborating Center for Radiation Medicine, the Bureau will gather and distribute material for training medical and engineering radiological technicians, medical physicists, and physicians in all branches of radiation medicine. This material will be used in different WHO projects. The Bureau also will work with WHO in developing recommendations and guidelines for training and for the medical applications of radiation.

For the past three years the Bureau has been a Collaborating Center for Standardization of Protection Against Nonionizing Radiation. Microwaves, light, and sound are examples of nonionizing radiation.

Film on X-ray Safety Wins Award

"The Double-Edged Sword," an FDA movie on analytical x-ray safety, has been awarded a diploma for quality as an educational film by the International Film Exposition, in Rio de Janeiro, Brazil.

Produced by FDA's Bureau of Radiological Health under a contract with the National Bureau of Standards, the 23-minute color documentary stresses the need for safe use of analytical x-ray equipment through interviews with laboratory personnel who have been injured on the job. The film also features discussions of all phases of the safety problem by equipment manufacturers, university instructors, State and Federal officials, and laboratory managers.

Copies of the 16 mm. film may be borrowed from Association-Sterling Films, 600 Grand Avenue, Ridgefield, New Jersey 07567, or purchased from the National Audiovisual Center, Washington, D.C. 20409. Videotapes are available for loan from the Bureau of Radiological Health, Training Resources Center (HFX-70), 5600 Fishers Lane, Rockville, Maryland 20857.

FDA Counsel to Return to Teaching Post

Richard A. Merrill, chief counsel for the Food and Drug Administration, will return this fall to the University of Virginia Law School, from which he is on leave, as Professor of Law. Merrill will leave FDA in August. He will resume teaching at the University in September.

Merrill joined the Government on May 18, 1975, as head of the Food and Drug Division of the General Counsel's Office of the U.S. Department of Health, Education, and Welfare (HEW). In this post he serves as Chief Counsel to the Food and Drug Administration, a constituent agency of HEW.

The resignation is in line with Merrill's long-range teaching plans and with his commitment to HEW at the time he joined the Department.

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

Maroun Bros., Inc., Lawrence, Massachusetts, and Alfred G. Maroun, treasurer, were fined \$4,000 and \$2,000 respectively by U.S. District Judge Walter Skinner of the District of Massachusetts for storing food under insanitary conditions. The five-count indictment charged that five lots of packaged foods which included potatoes au gratin, hashed brown potatoes with onions, chicken noodle soup, and baby cereals were stored where they may have become contaminated with filth, and that one lot was adulterated with insect filth. In addition, Maroun was given a three-month suspended jail sentence and placed on two years' probation. The legal action was the result of an inspection by FDA's **Boston District**. The firm was convicted of similar violations in 1974.

Sun Ray Bakery, Inc., Methuen, Massachusetts, and Francis S. Faro, its treasurer, pleaded guilty before U.S. District Judge Walter Skinner of the District of Massachusetts for allowing bakery goods to become contaminated with insects while being held under insanitary conditions in the bakery. Judge Skinner fined the firm \$4,000 and the treasurer \$2,000. In addition, Faro was sentenced to a three-month

suspended jail sentence and placed on two years' probation. The court action resulted from an inspection by the **Boston District** which revealed extensive insect infestation in and around the bakery's processing equipment.

REGION II

New Jersey, New York, Puerto Rico, Virgin Islands

Fara San Martino Corp., Brooklyn, voluntarily destroyed four lots of rodent- and insect-infested macaroni after an inspector from FDA's **New York District** discovered the damaged pasta stored in a section of the warehouse designated for salvaged goods. The macaroni was valued at \$5,000.

A shipment of bulk green coffee, offered for import from Doula, Cameroon, was detained by the New York District at the Port of New York because of chemical contamination. An inspector discovered that several bags of the shipment were stained with a white powder. Further investigation revealed that the coffee inside many of the 2,256 bags were contaminated with a white powder, which FDA laboratory analysis identified as sodium metaphosphate, a substance used primarily as a water softener. The entire shipment, valued at more than \$226,000, was detained until the damaged bags could be segregated and reconditioned. Some 2,500 bags of another shipment of coffee beans, offered for import from Santos, Brazil, were also detained after inspectors found them to be contaminated with antimony trisulfide, a toxic substance used in fireworks. The value of these beans was about \$660,000. Both actions were the result of routine import dock inspections by the New York District.

The U.S. Board of Tea Appeals, after hearing testimony from expert tea trade tasters, upheld a decision by Robert Dick, FDA's supervisory tea

examiner, to reject a shipment of 500 chests of black tea because of poor quality. The tea, valued at \$25,000, had been shipped from Kenya and offered for entry at New Orleans, from where samples were sent by the import broker to New York, one of three FDA offices in the country used for tea testing. Because Kenya tea is normally of good quality and seldom rejected, another sample was furnished to Dick at his request for a second tasting. FDA's New Orleans District furnished this second sample as well as a sample for the expert tea trade tasters.

Lester Altman Produce Co., Buffalo, voluntarily destroyed \$3,000 worth of Florida tangelos and oranges after an inspection by FDA's **Buffalo District** revealed the produce was contaminated with fuel oil. The investigator found that the driver of a truck carrying the fruit had been cautioned to keep the temperature in his trailer between 38° and 40° F. during the trip. When fuel for the trailer heater ran out and the driver noticed frost damage on the fruit, he obtained two salamander-type kerosene heaters, normally used on construction sites and other outdoor activities. Fumes from the burning fuel, however, tainted the fruit and part of the shipment was saturated when the portable heaters overturned. The 950-crate shipment was destroyed under the supervision of the New York State Department of Agriculture and Markets, which had embargoed the produce following FDA inspection.

A shipment of 40,000 pounds of whole coriander, an aromatic herb of the carrot family was denied entry by FDA's Buffalo District at the Port of Buffalo after an FDA laboratory examination found the product was adulterated with mites. The action was the result of a routine import inspection. The shipment, valued at about \$12,000, was made by a firm in Winnipeg, Canada, and was destined for a spice com-

pany in Baltimore, Maryland.

Investigators from FDA's **Albany Resident Post**, in cooperation with Car-gill, Inc., one of the Nation's largest wholesale grain dealers, supervised the destruction of more than 3,600 bushels of corn which was damaged by a fire of unknown origin in a grain elevator at the Port of Albany. The corn was valued at about \$8,000.

Anheuser-Busch, Inc., recalled one lot of Michelob beer brewed in its Newark plant because of defects in the linings of the 12-ounce steel cans. The problem came to light after FDA's **Newark District** received a consumer complaint about a lacquer-like taste and odor in the product. Investigation by FDA inspectors revealed that the firm also had received a consumer complaint and had found that the linings of 27 cans were blistered. Company officials believe the defective linings permitted the beer to react with the steel and produced the offensive taste. The manufacturer began a voluntary telephone recall to all direct wholesale accounts which had received beer from the suspect lot.

Investigators from the Newark District witnessed the voluntary destruction of about \$1,000 worth of carp fillets at the Mother's division of Vita Food Products, Inc., Newark. The fish were destroyed after samples collected during an FDA inspection were analyzed and found to be decomposed. The firm uses carp fillets as one of the ingredients in its gefilte fish.

A U.S. magistrate in San Juan, Puerto Rico, fined Juan Batista Rivera, a warehouse operator in San Sebastian, \$1,500 and sentenced him to a year's probation for operating a food warehouse infested with rats and insects. Garcia had been fined on two other occasions during the last four years. Last year a U.S. marshal seized about \$20,000 worth of foods at Garcia's warehouse following an inspection by FDA's **San Juan District**.

REGION III

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

A U.S. marshal seized a product labeled as a neuro structural device in

the possession of a doctor of chiropractic, in Point Marion, Pennsylvania, because of mislabeling violations. The product, which sold for \$2,500, failed to bear adequate directions for its intended therapeutic purposes. The product was supposedly useful in treating psychosomatic illnesses and was manufactured and shipped by Sea Communication, Inc., Seattle, Washington. The seizure resulted from an investigation of the product by FDA's Bureau of Medical Devices and Diagnostic Products following a consumer complaint.

REGION IV

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

Cooperation between FDA's Denver and Orlando Districts resulted in the destruction in Miami of 52 cases of human blood plasma which were shipped from Denver to Miami in an unrefrigerated truck by Morris Randolph, president of A-1 Biologicals, Denver. FDA had revoked the license of A-1 Biologicals in 1975 because of poor quality control. The firm was not allowed to ship or sell any of the plasma on hand. During a followup inspection at the Denver facility, FDA investigators found the plasma missing and learned that Randolph had moved to Miami. The **Orlando District** was notified of the situation and traced the plasma, valued at \$30,000, to a Miami cold storage warehouse where Randolph had stored it.

A consumer complaint about finding worms in a can of cashew nuts was investigated by FDA's **Miami Resident Post** and led to the recall and voluntary destruction of 640 12-ounce cans of cashews that had been distributed to 110 supermarkets in Miami, Fort Lauderdale, and West Palm Beach. FDA's Miami mobile laboratory analyzed samples collected by FDA inspectors and confirmed the contamination. The cashews, valued at nearly \$1,300, were packed by Fisher Nut Co., Division of Beatrice Foods Co., St. Paul, Minnesota.

REGION V

Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin

M. M. Mast & Co., Cleveland, has

agreed in court not to pack or sell any drugs in interstate commerce until it can comply fully with FDA's Current Good Manufacturing Practice Regulations (GMP's). The injunction, issued by the Federal District Court of the Northern District of Ohio, was the result of a year-long investigation by FDA's **Cincinnati District**. The District said the company repeatedly short cut GMP's intended to assure quality products. Some of the company's violative practices included packaging nitroglycerine in unapproved containers, packaging hypnotics without adequate warnings on the label, and marketing a variety of antibiotic substances without FDA certification for safety.

Robert Linblad, president of Linblad, Inc., Dearborn, Michigan, pleaded guilty to two counts of distributing Laetrile, an unproven drug sold to treat cancer, and was fined \$1,000 on each count by Judge James P. Churchill of the U.S. District Court for Eastern Michigan in Detroit. Elmer Linblad, resident agent and director of the firm, pleaded no contest to three counts and was fined \$3,000. In addition, the firm pleaded no contest to three counts and was similarly fined. Charges against the individuals and firm included selling the drug without a prescription and promoting an unapproved drug as a cancer cure. The judge also placed the corporation and Robert Linblad on unsupervised probation for one year. The legal action was the result of an investigation by FDA's **Detroit District**.

Investigators from the Detroit District witnessed the voluntary destruction of approximately 4,300 cases of tomato catsup bottled by Naas Foods, Inc., Portland, Indiana. The product was transported to a landfill, crushed, and buried by a bulldozer. The catsup was found to have a high mold count during a survey of tomato canning manufacturers in Indiana conducted by an FDA mobile laboratory.

A six-month investigation by FDA's **Minneapolis District** resulted in the mass seizure of 16 types of misbranded vitamin and health food preparations and accompanying literature with a total retail value of approximately \$90,000 at Nutrition World, Inc., in Edina, Minnesota, and 12 of its retail outlets in the Minneapolis-St. Paul

area. The seizures were carried out by 12 deputy U.S. marshals, assisted by 12 investigators from FDA's Minneapolis District. The investigation began when FDA's Minneapolis District received a consumer complaint about a product being sold at a Nutrition World retail outlet in the Minneapolis area. When an FDA investigator visited the firm's warehouse in Edina to determine the source of the product he found literature which misbranded numerous vitamin and health food products sold by the firm. Visits to several of the firm's retail stores established that this literature was being used to promote the products for treatment of various serious diseases. For example, the labels on a number of products which supposedly contained vitamin C claimed that the products could be used to treat illnesses ranging from arthritis and glaucoma to hay fever and infectious hepatitis. Another item, labeled Kelp-lecithin-vinegar-B6, claimed to be basic and essential to life. In all, approximately 16,000 mislabeled bottles were seized.

REGION VI

Arizona, Louisiana, New Mexico, Oklahoma, Texas

The Federal Government seized 400,000 pounds of adulterated sugar at a bulk loading and unloading plant owned by Atlantic and Gulf Stevedores, Inc., New Orleans. The seizure resulted from information supplied to FDA's **New Orleans District** by U.S. Customs agents in New Orleans, who found that some 300,000 pounds of imported sugar had been contaminated with industrial grade urea, an ingredient common in fertilizers. Further investigation by the New Orleans District revealed that a gate in the firm's conveying system had been set by accident so that it routed raw sugar into a bin which contained approximately 100,000 pounds of urea. The 400,000-pound lot had been transferred to railroad cars, where U.S. marshals seized it.

A joint inspection by FDA's **Little Rock Resident Post** and the U.S. Department of Agriculture (USDA) at the Standard Ice Co., Little Rock, resulted in detention by the USDA of over 360,000 pounds of meat because of possible rodent contamination. In addition, rodent activity was noticed in

three of four lots of butter stored in a freezer, which prompted sanitarians from the Pulaski County Department of Health to embargo approximately 500 cases of the butter. The sanitarians supervised the reconditioning of all the butter. The joint inspection was prompted by a USDA compliance officer who contacted FDA's Little Rock Resident Post when he discovered that the rodent activity in the plant freezer involved products regulated by USDA and by FDA.

REGION VII

Iowa, Kansas, Missouri, Nebraska

The Federal Government seized 70,000 bottle caps at the Goodrich Dairy Co., Omaha, which were being used on the firm's diluted orange drink beverage. Investigators from FDA's **Kansas City District** had notified the firm during an inspection that the labeling on the caps was in violation of FDA regulations since it failed to declare the percentage of orange juice in the product. Seizure was made after a followup inspection revealed the firm was still using the caps.

The Federal Government seized approximately 10,000 pounds of contaminated sugar, valued at \$1,500, at Buttercup Foods, Omaha, because of rodent contamination. The seizure resulted from an inspection of the plant, by the Kansas City District which revealed that a lot of granulated sugar was contaminated by rodents and was stored under insanitary conditions. The firm manufactures ice cream cones and candy.

REGION VIII

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

The Federal Government seized 23 50-pound cartons of imported fennel at a meat company in Arvada, Colorado, after tests by FDA's **Denver District** confirmed that the herb seeds were contaminated with insect, bird, and rodent excreta. The seeds had been shipped to the firm for use in its meat curing processes. A meat inspector from the U.S. Department of Agriculture and meat company personnel noticed the contaminated seeds, and contacted the Denver District which collected samples for laboratory examination.

REGION IX

Arizona, California, Guam, Hawaii, Nevada

A U.S. marshal seized a lot of 1,015 bags of coffee under California State embargo at Alexander-Balant Co., a coffee roaster in Daly City, California, after an inspection by FDA's **San Francisco District** revealed widespread rodent activity in the firm's storage area. The coffee, valued at nearly \$280,000, was found to be rodent contaminated. The State of California had been asked by FDA to embargo the lot pending its seizure by the Government.

Ramar International Corp., San Francisco, doing business as Orientex, was put on two years' probation by Chief Magistrate Richard S. Goldsmith of the U.S. District Court in San Francisco after being found guilty on three counts of operating a food warehouse infested by insects and rodents. The court action resulted from an inspection by FDA's San Francisco District which found the rodent and insect contamination. In addition, the firm was sentenced to pay a fine of \$1,500, and another \$1,500 was suspended by the judge for the two-year probationary period. If during this period the firm violates FDA regulations it will be prosecuted on the previous counts, and any additional counts arising from subsequent violations.

A Deputy U.S. marshal, accompanied by an investigator from FDA's Los Angeles District, seized 73 bottles of three products labeled Aangamik, Gluconic 15, or Vitamin B-15 at Food For Health, a food distributor in Phoenix, Arizona. In addition, 3,700 pieces of literature which made unproved therapeutic claims for the products were also seized. The products, of a wholesale value of about \$500, have not been approved for use as drugs by the FDA. The seizure was the result of an inspection at the distributor by FDA's **Los Angeles District**.

Florence Macaroni Co., Los Angeles, has resumed production after closing down for a week to correct insanitary conditions found during an inspection by FDA's Los Angeles District. The inspection revealed insects in various parts of the plant. The firm had signed a consent decree for permanent injunction in the U.S. District Court

for the Central District of California in Los Angeles which directed the firm to cease production until FDA inspectors were satisfied that the insanitary conditions had been remedied. The firm is now shipping products again under close scrutiny from FDA's Los Angeles District.

REGION X

Alaska, Idaho, Oregon, Washington

Phillips Industries, Inc., Malad City, Idaho, has agreed in court to shut down its food processing operation until it corrects gross insanitary conditions found at the plant by inspectors from FDA's **Seattle District**. The firm is a flour mill which produces and distributes flour for human, animal, and industrial uses. The inspection revealed numerous infestations by insects of milling equipment and storage areas. Under the consent decree of permanent injunction which was entered into by the company and its responsible officials in the U.S. District Court for the District of Idaho, the firm's food operation is shut down until it establishes effective sanitation control to bring it into compliance with

FDA regulations. The firm must eliminate insects and vermin and renovate its facilities and equipment and select a qualified individual to be responsible for maintaining the facilities, equipment, and operations in a sanitary condition. The decree also requires that all foods stored within the facility be examined for filth, and any food found contaminated be destroyed or brought into compliance with the Federal Food, Drug, and Cosmetic Act. The firm is permanently enjoined from distributing foods which are adulterated, which means, in effect, that if there are any further violations, the firm could be held in contempt of court.

In a two-month period, the Seattle District refused entry into the United States of 36 sets of soft contact lenses which have not been approved for use in this country. The lenses, produced by the Canadian firm of N&N Opticals, were found by Seattle District investigators during routine visits, at the U.S. Customs Mail Division in Seattle. The lenses were mailed, usually in single shipments, and addressed to various consignees, mainly in the Pacific Northwest.

A lot of canned salmon, totaling 18,830 eight-ounce cans, was seized by a U.S. marshal at Bellingham, Washington, because of decomposition. The salmon, caught in Alaskan waters, was shipped to the Port of Bellingham where an investigator from the Seattle District collected a sample. Laboratory analysis of the sample revealed the product contained decomposed fish. The lot, valued at approximately \$20,000, was canned by Ebb Tide Processing, Inc., Anacortes, Washington.

Nine lots of frozen halibut, totaling 67,000 pounds, were seized by a U.S. marshal at Bellingham, Washington, because of mercury contamination. A sample collected by Seattle District investigators at Bellingham Cold Storage Co., was sent to FDA's Seattle Laboratory where tests revealed mercury in excess of the maximum 0.5 parts per million allowed by FDA regulation. The fish, valued at approximately \$120,000, was shipped from Alaska by Sitka Sound Seafoods, Excursion Inlet Packing Co., Seward Fisheries, Inc., and Petersburg Fisheries, Inc.

State Actions

Feed Materials Contaminated

A joint inspection by FDA and the State of Oklahoma of the O. A. Cooper Co., an Oklahoma City mill that makes medicated animal feed, resulted in voluntary destruction by the firm of over 26,000 pounds of raw materials, which had been contaminated by insects, birds, rodents, and skunks. Investigators from FDA and the State witnessed the destruction, which included outdated drugs, fishmeal, and other nonmedicated feed additives.

Chili Sauce Destroyed

Nearly 30,000 cans of green chili and chili sauce were destroyed by the Colorado Department of Health after the District Court of Adams County, Colorado, issued a consent decree of con-

demnation. The action was based on an inspection of the U.&H. Chili Co., Commerce City, Colorado, in 1975 by FDA's Denver District which revealed serious deficiencies in the firm's processing of low-acid canned foods. Since the firm did almost no interstate business, FDA requested the State's help in halting distribution of the firm's products, particularly because of the potential threat of botulinal contamination of improperly processed low-acid canned foods. The company refused to voluntarily destroy the products which led the State to place an embargo on the entire lot, pending court action.

Unapproved Drugs Destroyed

Cooperation between FDA and the Pennsylvania Department of Health resulted in the voluntary destruction of two lots of trichlormethiazide and hy-

drochlorothiazide tablets by Harvey Laboratories, Inc., Philadelphia. The drugs, manufactured and shipped by Rovers Pharmacal, Inc., North Bayshore, New York, do not have FDA-approved New Drug Applications. Investigators from FDA's New York District discovered during an inspection of Rovers Pharmacal that it was manufacturing the unapproved drugs. After learning of the shipment of the drugs to Philadelphia, the investigators contacted the Pennsylvania Department of Health, which embargoed the lots pending seizure by the Federal Government. Harvey Laboratories then notified the State that it would voluntarily destroy the lots. Inspectors from the Pennsylvania Department of Health's Division of Drugs, Devices, and Cosmetics witnessed the destruction.

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 31 actions to remove from the consumer market products charged to be violative was reported in February. These included 17 seizures of foods: 3 involved charges concerning poisonous and deleterious substances, 13 involved charges concerning contamination, and 1 involved charges concerning economic and labeling violations. Other seizures included 1 of vitamins and dietary food; 1 of food additive; 1 of color additive; 7 of drugs (including 1 of veterinary and medicated feed); and 4 of medical devices.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD/Poisonous and Deleterious Substances		
Halibut fletches, frozen/Bellingham, Wash. 1/25/77	Excursion Inlet Packing Co./Excursion Inlet, Alaska (P,S)	Contains the added poisonous and deleterious substance mercury.
Cincinnati, Ohio 1/27/77	Petersburg Fisheries, Inc./Bellingham, Wash. (S)	"
Halibut, trimmed, frozen/Los Angeles, Calif. 1/13/77	Excursion Inlet Packing Co./Excursion Inlet, Alaska (P); Haines Packing Co./Bellingham, Wash. (S)	"
Contamination, Spoilage, Insanitary Handling		
Cherries, brined/Cleveland, Ohio 11/9/76	Ramsey Laboratories, Inc./Cleveland, Ohio (D)	Prepared and held under insanitary conditions; contains cockroaches.
Cleveland, Ohio 1/21/77	Briggs-Aitchison Co., Inc./Wenatchee, Wash. (P); Northland Products, Inc./Wenatchee, Wash. (S)	Prepared and packed under insanitary conditions; contains drosophila insects and insect eggs.
Coffee beans/San Jose, Calif. 1/18/77	Hank & Frank Drayage Co./San Jose, Calif. (D)	Held under insanitary conditions; rodent contaminated.
Flour/Newport News, Va. 11/17/76	Milton D. Brenner (Brenner's Warwick Bakery)/Newport News, Va. (D)	"
Flour, high gluten/Detroit, Mich. 1/13/77	Brothers Deluxe Bakery/Detroit, Mich. (D)	"
Macaroni products, popcorn, cereals, rice, cake mixes, and similar products/Tucson, Ariz. 11/26/76	Southwestern Grocery, Inc./Tucson, Ariz. (D)	Held under insanitary conditions; some products are insect contaminated.
Popcorn, and oats cereal/Centralia, Ill. 1/20/77	Kohl & Meyer Co./Centralia, Ill. (D)	Held under insanitary conditions; contain insect filth.
Salmon, canned/Bellingham, Wash. 1/6/77	Ebb Tide Processing, Inc./Anacortes, Wash. (P); Denton Sherry (Bellingham Packing Co.)/Seattle, Wash. (S)	Contains decomposed salmon.
Sesame seeds/Elk Grove Village, Ill. 12/9/76	Flavor Tree Foods, Inc./Elk Grove Village, Ill. (D)	Held under insanitary conditions; contains insect filth.
Spaghetti, egg noodles, macaroni/Tampa, Fla. 1/13/77	A & H Warehouse, Inc./Tampa, Fla. (D)	Held under insanitary conditions; contains insects.
Squash, canned, and canned pumpkin/Andover, Mass. 1/20/77	Medomak Canning Co./Winslow's Mills, Maine (M,S)	Contain decomposed squash/pumpkin.
Various grocery stocks, including oats cereal, cake mixes, and barley/Kenosha, Wis. 11/9/76	Kenosha Wholesale Grocery Co./Kenosha, Wis. (D)	Held under insanitary conditions; some stocks are insect contaminated.
Vinegar/Cincinnati, Ohio 1/27/77	Wiard's Orchards, Inc./Ypsilanti, Mich. (M,S)	Prepared and packed under insanitary conditions; contains vinegar eels (nematodes).

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Economic and Labeling Violations		
Fruit cocktail in heavy syrup, canned, Hunt's/East Hartford, Conn. 12/28/76	Hunt-Wesson Foods, Inc./Hayward, Calif. (M,S)	Fails standard of identity for canned fruit cocktail, since lacked some pear, pineapple, and cherry and contained excessive peach.
VITAMINS-DIETARY FOOD		
Drink mix, Hoffman's Hi-Proteen; Energol germ oil concentrate; Hoff- man's Hi-Proteen Quick Gain Weight powder/Kent, Wash. 1/12/77	York Barbell Co., Inc./York, Pa. (M,S)	False and misleading vignettes and statements about body building and other false and misleading nutri- tional claims; certain required information is not on a single panel of the label, without other interven- ing material; some information is in too small type size; and the Energol lacked required nutritional labeling.
FOOD ADDITIVE		
Calcium gluconate & dimethyl glycine tablets, and calcium pangamate tab- lets/Spokane, Wash. 1/26/77	Food Science Laboratories/Burlington, Vt. (M,S)	Contain the nonconforming food additives calcium pangamate, or calcium gluconate & dimethyl gly- cine; false and misleading claims concerning na- ture, identity, and usefulness; and lack common or usual names of ingredients described as binder and lubricant.
COLOR ADDITIVE		
Syrups, sala-flavored, and strawberry- flavored, Hale's Blue Boy/San Fran- cisco, Calif. 1/24/77	Siam Ltd./Bangkok, Thailand (S); Hale's Trading/Bangkok, Thailand (M)	Contains the nonconforming color additive external D & C Red No. 10.
DRUGS/Human Use		
Aspirin, epsom salts, isopropyl alcohol, mineral oil, hydrogen peroxide, Mer- curochrome, and similar drugs/York, Pa. 1/3/77	Davis Manufacturing Co., Inc./Knox- ville, Tenn. (M,S)	Circumstances of products' manufacture, processing, packing, and holding not in conformity with current good manufacturing practice.
Benylin cough syrup/Dallas, Tex. 12/1/ 76	Parke, Davis & Co./Detroit, Mich. (M,S)	New drug without effective approved New Drug Application; labeling lacks adequate warnings against unsafe use and lacks prescription legend.
Benzthiazide tablets/Farmington, Mich. 11/8/76	Drummer Labs/Sellersville, Pa. (S)	New drug without an approved New Drug Applica- tion.
Mercurochrome, mineral oil, aspirin, boric acid powder, and tincture of merthiolate/West Haven, Conn. 12/ 29/76 & 1/12/77	Davis Manufacturing Co., Inc./Knox- ville, Tenn. (M,S)	Circumstances of products' manufacture, processing, packing, and holding not in conformity with current good manufacturing practice.
Potassium sulfate tablets/Fort Worth, Tex. 1/27/77	Private Formula, Inc./St. Louis, Mo. (M)	Quality falls below that which it purports to possess; new drug without an effective approved New Drug Application.
Triple sulfa tablets/Detroit, Mich. 11/5/ 76	Cord Labs/Broomfield, Colo. (M,S)	New drug without an effective approved New Drug Application.
Veterinary/Medicated Feed		
Rx Stop-the-Itch liquid for dogs/Dallas, Tex. 1/4/77	Thuron Industries, Inc./Dallas, Tex. (P)	New animal drug and no approval of a New Animal Drug Application was in effect with respect to use or intended use of such drug.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
MEDICAL DEVICES		
Acu-Aid Ion spheres/Van Nuys, Calif. 4/13/76	Tama Enterprises, Inc./Tokyo, Japan (S); Ionlab, Inc./Van Nuys, Calif (D)	False and misleading claims for "pain ailments", coughing, stiff chest, slight cold, headache, dizziness, insomnia, and other diseases; fails to bear adequate directions for use.
Mini-Mask/Belleville, Ill. 1/24/77	William J. Schlosser/Belleville, Ill. (D)	False and misleading claims including prevention of pulmonary inflammation and sinus congestion, protection from various particles and pollens, and failure to bear adequate warnings against unsafe use.
Neuroceptor devices, Clinical Neuroceptor device/Wichita, Kans. 11/11/76 & 1/6/77	Med General, Inc./Minneapolis, Minn. (M,S)	False and misleading claims including pains associated with ileus; bursitis; and contusions.
Thermolastic Assortment Packs, Thermolastic Knee, Hand, Elbow, and Ankle Comforters/St. Louis, Mo. 12/16/76	Jung Products, Inc. (Futuro Thermolastics Div.)/Cincinnati, Ohio (M,S)	False and misleading claims, including reducing edema, relieving stiff and aching joints, and (hand comforter) assisting return of blood flow; inadequate directions for intended lay use, and not exempted therefrom.

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)

- January 14, 1977: **Hanover House**, Hanover, Pennsylvania. Advertising and sale through the mail of the product, "Bathe 'N Shape," representing the ability to tighten and firm skin, help rid stretch marks, and firm, uplift, and beautify the bustline.
- January 18, 1977: **Gustave Leckney**, 2488 Smith Street, Kissimmee, Florida. Advertising and sale through the mail of a report containing information representing the ability to relieve arthritis.
- January 19, 1977: **Bio Folic H, Inc.**, P.O. Box 156 and 4326 Calle Real 148 N.W., Santa Barbara, California. Advertising and sale through the mail of the product "Bio Folic H" tablets representing the ability to help cure and relieve baldness, thinning hair, and soft and brittle nails.
- January 19, 1977: **Personna-Genic Research Institute**, 2600 Virginia Avenue, N.W., Suite 301, Washington, D.C. Advertising and sale through the mail of a cassette tape containing information representing the ability to increase the size of the breasts.
- January 19, 1977: **Studio Productions**, P.O. Box 4261, North Hollywood, California. Advertising and sale through the mail of the product "Stay Erect Sheath," representing the ability to cause "staying power," to maintain an erection after ejaculation.
- January 21, 1977: **Manuel Garcia Imports**, Box 1426, Studio City, California. Advertising and sale through the mail of the products "Mexican Spanish Fly" and "Imported Type Spanish Fly," tablets representing the ability to be aphrodisiac in nature.
- January 25, 1977: **Heavenly Products**, 2329 Waterby Street, Westlake Village, California. Advertising and sale through the mail of a cream representing the ability to cause younger looking facial skin.

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

- January 19, 1977: Against **Progressive Sales Group**, P.O. Box 310, New Rochelle, New York. Advertising and sale through the mail of the product "PSG Pumpometer," representing the ability to increase the length and width of the penis and create erections.
- February 1, 1977: Against **Nutrient Labs, Inc.**, P.O. Box 80308, Chamblee, Georgia; and P.O. Box 81105 and 95543, Atlanta, Georgia; and P.O. Box 4283, New Windsor, New York; and P.O. Box 2511, Newburgh, New York. Advertising and sale through the mail of the product "The Skin Vitamin," pills representing the ability to improve the appearance of the skin.
- February 1, 1977: Against **Shore Products**, Box 174, Edison, New Jersey, and Box 214, New Hampton, New York. Advertising and sale through the mail of the products, "Gege Lotion," "New Skin," and "Pure Skin," representing the ability to eliminate stretch marks, smooth, soften, and restore the tone of skin.

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Swordfish chunks, frozen, at Los Angeles, C. Dist. Calif.

Charged on or about 10-22-76: when shipped by Fresh Water Fish Co., Boston, Mass., the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 60942; S. No. 77-78-336; N.J. No. 1)

Swordfish chunks and filets, frozen, at San Pedro, C. Dist. Calif.

Charged 10-15-76: when shipped by Garcia Bros. Seafood, Miami, Fla., the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 60958; S. No. 77-78-340; N.J. No. 2)

FOOD/Contamination, Spoilage, Insanitary Handling

Cake mixes, cornmeal, cereal, and lasagne noodles, at Altus, W. Dist. Okla.

Charged 11-17-76: while held by Moore Wholesale Co., Altus, Okla., the articles contained insect filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60988; S. No. 77-15-166 et al.; N.J. No. 3)

Cereals for babies, at Caguas, Dist. P.R.

Charged 9-16-76: while held for sale, the articles contained insect filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60898; S. Nos. 77-83-821, 77-50-980; N.J. No. 4)

Coffee beans, at San Francisco, N. Dist. Calif.

Charged 10-7-76: while held by Pacific Oriental Terminal Co., San Francisco, Calif., the article contained bird filth; and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Folger Coffee Co., Cincinnati, Ohio, for salvaging. (F.D.C. No. 60927; S. No. 77-73-916; N.J. No. 5)

Confectionary products, cashew nuts, pretzels, cookies, brazil nuts, and other warehouse stocks, at Brooklyn, E. Dist. N.Y.

Charged 1-9-76: while held by Sherwood Warehouse Corp., Brooklyn, N.Y., a number of lots of the articles named above contained rodent and/or insect filth, and all the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decrees authorized release for salvaging of the following: the nuts to Hollander Trading Corp., New York, N.Y.; cake decoration confections and curry powder to Lou Scharf, Inc., New York, N.Y.; halvah and other confections to Israel Lieber, t/a Lieber Chocolate Co., Brooklyn, N.Y.; chocolate-covered coconut cream eggs to Plymouth Enterprises, Inc., New York, N.Y.; marshmallow bunnies and matzos to the dealer; and pretzels, cookies, and the remaining articles to Roslyn Bros., Brooklyn, N.Y. (F.D.C. No. 60607; S. No. 76-40-032 et al.; N.J. No. 6)

Cuttlefish in sauce, canned, Vencedor, at Pawtucket, Dist. R.I.

Charged 11-9-76: when shipped by Conservas Independencia, Lda., Matosinhos, Portugal, the article contained animal hair, and rodent and insect filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60970; S. No. 77-06-269; N.J. No. 7)

Flours (such as rye, pastry, gluten, bread, and cake flours), sweet rice, rice, and corn starch, at Edgewater, Dist. N.J.

Charged 8-23-76: while held by Merse Bros. Trucking, Inc., Edgewater, N.J., a number of lots of flour contained insects, and all the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to various claimants for salvaging. (F.D.C. No. 60868; S. Nos. 77-88-042/7; N.J. No. 8)

Green beans, canned, at Pasco, E. Dist. Wash.

Charged 12-21-76: while held for sale, the article was unfit for food, due to a metallic odor and being contained in internally detinned cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61029; S. No. 77-70-708; N.J. No. 9)

Peanuts, Spanish, at Minneapolis, Dist. Minn.

Charged 11-2-76: while held by Martin Brokerage Co., Minneapolis, Minn., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60973; S. No. 77-31-091; N.J. No. 10)

Peanuts, unshelled, salted, at Indianapolis, S. Dist. Ind.

Charged 11-8-76: while held by Central Indiana Supply Co., Indianapolis, Ind., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging.

(F.D.C. No. 60977; S. No. 77-69-334; N.J. No. 11)

Peas, flaked rice, puffed rice, uridal, lentils, and cuminseed, at Newark, Dist. N.J.

Charged 6-16-76: while held by Greenpoint Terminal Warehouse, Inc., Newark, N.J., some lots of peas and rice contained rodent filth, and the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Famous Overseas Corp., Hoboken, N.J., for salvaging. (F.D.C. No. 60760; S. No. 76-36-200 et al.; N.J. No. 12)

Salmon, canned, at Wilmington, C. Dist. Calif.

Charged 5-11-76: when the salmon was shipped by Astoria Fish Factors, Astoria, Oreg., and while it was canned and held by Frosty Fish, Wilmington, Calif., who labeled some lots "Frosty King Salmon . . . Packed By Frosty Fish Co., Wilmington, Calif.," the article contained decomposed salmon; 402(a)(3). The article was claimed by Frances O. Drummond as receiver for Frank Mateljan, t/a Frosty Fish, Wilmington, Calif. Subsequently, the claim was withdrawn and a default decree ordered the article destroyed. (F.D.C. No. 60727; S. Nos. 76-27-632/3 et al.; N.J. No. 13)

Salmon, canned, unlabeled, at Anacortes, W. Dist. Wash.

Charged 4-12-76: when shipped by Whitney-Fidalgo Seafoods, Inc., Anchorage, Alaska, the article contained decomposed salmon; 402(a)(3). Consent decree authorized release to shipper for salvaging. (F.D.C. No. 60700; S. No. 76-71-001; N.J. No. 14)

Sugar, cornstarch, crackers, breakfast cereals, and other grocery stocks, at St. Louis, E. Dist. Mo.

Charged 11-16-76: while held by N.C.D., Inc., t/a Acme Foods, Inc., St. Louis, Mo., the crackers contained insects, and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 60922; S. No. 77-24-052 et al.; N.J. No. 15)

FOOD/Economic and Labeling Violations

Oil blend, at Los Angeles, C. Dist. Calif.

Charged 10-18-76: when shipped by Roberts Food Corp., Brooklyn, N.Y., the article, labeled in part "Mamma Mia Brand Imported Product . . . Pure Olive Oil . . . Packed by Sunshine Vegetable Oil Corp. Edison, N.J.," had had another oil substituted in part for olive oil; 402(b)(2). Default decree ordered destruction. (F.D.C. No. 60955; S. No. 77-28-730; N.J. No. 16)

Shrimp, breaded, at Indianapolis, S. Dist. Ind.

Charged 1-13-76: when shipped by Singleton Packing Corp., Tampa, Fla., the article, labeled in part "Las Vegas Style Breeding with Shrimp . . . Ingredients . . . sodium tripolyphosphate . . . High Tide . . . Distributed By High Tide Co., Tampa, Florida," failed to conform to the definition and standard of identity for breaded shrimp, since the article tested as being less than 50 percent shrimp material and since the article contained the unpermitted ingredient sodium tripolyphosphate; 403(g)(1). Consent decree authorized release to shipper for bringing into compliance. (F.D.C. No. 60602; S. No. 76-19-278; N.J. No. 17)

VITAMINS/SPECIAL DIETARY FOODS

Lecithin with vitamin D capsules, at Bronx, S. Dist. N.Y.

Charged 2-2-76: when shipped by Vegetates Co., Los Angeles, Calif., the labeling of the article lacked adequate directions for safe (nontoxic) lay use, since the recommended frequency of administration of three or six capsules per day permitted daily ingestion of vitamin D in excess of the allowable daily intake level of vitamin D established for nonprescription use; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 60635; S. Nos. 76-39-410/4; N.J. No. 18)

FOOD ADDITIVES

Calcium pangamate tablets, at Scottsdale, Dist. Ariz.

Charged 9-3-76: while held by Naturally Vitamin Supplements, who had repacked and partially relabeled bulk tablets into the retail bottles, the article, labeled in part (bottles) "Calcium Pangamate 50 mg., a salt of Pangamic Acid B-15 . . . Tablets especially processed for Naturally Vitamin Supplements Phoenix, Ariz. . . 1 or two tablets daily as a dietary supplement," the article in unlabeled bottles contained the nonconforming food additive "Calcium Pangamate, a salt of Pangamic Acid"; the labeled article's label statements and vignette of a cornucopia showing various fruits and

vegetables was false and misleading, since calcium pangamate was not an identifiable substance and was not a vitamin nor a provitamin, since there was no accepted scientific evidence which established any nutritional properties of the substance nor which had identified a deficiency of calcium pangamate in man or other animals, since no medical, nutritional, or other usefulness for calcium pangamate had been established, and since the article would supply an insignificant amount of calcium when taken as recommended on the label; required information (the name and address of the packer and distributor) was not prominently placed in the label with the appropriate conspicuousness, since the letters were, in part, thin, in a type size less than $\frac{1}{32}$ inch high, and were not in the required minimum type size of at least $\frac{1}{16}$ inch high; and the label lacked the common or usual name of each ingredient, since the major portion of the ingredients of each tablet were not disclosed; 402(a)(2)(C), 403(a), 403(f), 403(i)(2). Default decree ordered destruction. (F.D.C. No. 60865; S. Nos. 77-78-063/4; N.J. No. 19)

Sodium pangamate tablets, at Bronx, S. Dist. N.Y.

Charged 9-24-76: while held for sale after manufacture by Contract Pharmacal Corp. (Gourmet Health Products, Inc.), Hauppauge, N.Y., from sodium pangamate shipped in interstate commerce, the article bore and contained the nonconforming food additive sodium pangamate—402(a)(2)(C); the label statements "The Health Gourmet," "Vitamin B-15 (Sodium Pangamate) 50 mg," "Suggested Dose: As a dietary supplement . . . daily or as prescribed by a physician," and other references to "Vitamin B-15" were false and misleading, since, in truth and in fact, (1) sodium pangamate and "Vitamin B-15" neither were identifiable substances nor were they vitamins nor provitamins; (2) there was no accepted scientific evidence which established any medical, nutritional, or other properties of the substance, nor which had identified a deficiency of sodium pangamate in man or other animals; and (3) physicians generally did not prescribe sodium pangamate—403(a); and the article's label lacked the common or usual name of the major portion of ingredients in the tablets—403(i)(2). Default decree ordered destruction. (F.D.C. No. 60884; S. Nos. 77-42-143/4; N.J. No. 20)

DRUGS/Human Use

Benzthiazide tablets, at Farmington, E. Dist. Mich.

Charged 11-4-76: when shipped by Drummer Laboratories, Sellersville, Pa., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 60960; S. No. 77-69-165; N.J. No. 21)

Calcium disodium ethylenediaminetetraacetate powder, at Wauconda, N. Dist. Ill.

Charged 1-19-76: while held by N. B. Purdy Products Co., Wauconda, Ill., and while accompanied by labeling, such as leaflets entitled "Medical Uses & Toxicity," "Cholesterol," and "I Wish To Take The E.D.T.A. for . . .," newspaper reprints captioned "Soapmaker's cure-all EDTA," tape recordings labeled "Alsleben Shute Symposium . . . Womach Enterprises," and several promotional and testimonial letters, the article's labeling lacked adequate directions for use, since none could be written for lay use and the article was not exempted therefrom, since it was a new drug without an effective approved New Drug Application; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 60613; S. No. 76-08-933; N.J. No. 22)

Plasma and other human blood derivatives, at Chicago, N. Dist. Ill.

Charged 10-10-75: when shipped by Bishop Laboratories, Inc., Cincinnati, Ohio, and while held for sale, the circumstances used for the articles' manufacture, processing, packing, and holding failed to conform with current good manufacturing practice—501(a)(2)(B); the label statements "Plasma For Fractionation Normal (Human)" and "U.S. License No. 394" on one lot of the articles was false and misleading, since it represented that the article was a blood component which was applicable to the prevention, treatment, or cure of diseases or injuries of man and which had been prepared at a licensed establishment, when the establishment did not have a license for the article—502(a); the label statements "Anti-A" and "Anti-D" of other lots represented that such articles were blood-typing sera which had been prepared in a licensed establishment, when the establishment was not licensed—502(a); a number of the articles lacked a label containing the name and place of business of the manufacturer, packer, or distributor—502(b)(1); a number of the articles lacked a quantity of contents statement; a number of the articles lacked the established name of the article—502(e)(1)(i); a number of the articles lacked the name and/or quantity of their anticoagulant ingredient—502(e)(i)(ii); and the labeling of all of the articles lacked adequate directions for use, since the labeling failed to indicate that the articles were suitable for use as *in vitro* reagent, but were not suitable for use as or in licensed biologicals—502(f)(1). The articles were claimed by the shipper who denied the charges. Subsequently, a consent decree

ordered destruction. (F.D.C. No. 60521; S. No. 76-09-605; N.J. No. 23)

Sulfisoxazole tablets, U.S.P., at Gardner, Dist. Kans.

Charged 9-13-76: when shipped by Cord Laboratories, Inc., Broomfield, Colo., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 60891; S. No. 77-55-082; N.J. No. 24)

Triple sulfa (sulfadiazine, sulfamethazine, and sulfamerazine) suspension, at St. Louis, E. Dist. Mo.

Charged 9-22-76: when shipped by Cord Laboratories, Inc., Broomfield, Colo., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 60889; S. No. 77-24-172; N.J. No. 25)

DRUGS/Veterinary

Naquasone boluses, and Dexamycin, Dexamethasone, Stilbestrol and Oxytocin injectables, at Binghamton, N. Dist. N.Y.

Charged 5-20-76: while held by Wesley R. Smith, t/a Independent Buyers Association, Millbury, Mass., the articles lacked adequate direction for use and were not exempted therefrom, since the articles were prescription veterinary drugs but were not held to be sold only to, or on the prescription of, a licensed veterinarian; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 60731; S. No. 76-58-372; N.J. No. 26)

MEDICAL DEVICES

Neuro-Structural Scanner electrical device, at Decatur, N. Dist. Ala.

Charged 4-26-76: when shipped by L. L. Hardy, D.C., Decatur, Ala., from Lexington, Ky., the labeling of the article lacked adequate directions for use for the article's intended purposes and adequate directions could neither be written for lay use, nor could adequate information for use by licensed practitioners be furnished; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 60716; S. No. 76-00-230; N.J. No. 27)

Solarama 17" x 19" bedboards, at Lebanon, Dist. Oreg.

Charged 8-19-76: when shipped by The World of Solarama, Ltd., Greenville, S.C., and while held for sale, the accompanying labeling (including, leaflets entitled "The Electron and You and Solarama," "Some Results From the Solarama Board," "My Solarama Surprise," a brochure entitled "The Story of Solarama," and various testimonials) contained false and misleading claims for relaxation of tension; sinus infections; asthma; migraine headaches; high blood pressure; peptic ulcers; neurosis; hay fever; head tremors; muscle spasms; allergy conditions; chronic bronchitis; emphysema; spastic colon; acute colitis; chronic constipation; cataracts; kidney trouble; helping to correct degenerative diseases such as arthritis, aging, emotional disturbances, sexual imbalance; promoting better health; inducing a sense of well being; and helping one sleep better; and the labeling lacked adequate directions for use for the article's intended purposes, since neither adequate directions for lay use nor adequate information for use by licensed practitioners could be furnished; 502(a), 502(f)(1). Default decree ordered destruction. (F.D.C. No. 60800; S. No. 76-53-303; N.J. No. 28)

NOTICE OF JUDGMENT on Criminal Actions

DRUGS

Linblad's, Inc., Robert F. Linblad, president, and Elmer A. Linblad, resident agent and director, Detroit, E. Dist. Mich.

Charged 7-13-76: when shipped, the labeling of yellow tablets intended for use for cancer (labeled in part "AMIG/LAN Amygdalin from Apricot Kernels . . . Natrel Supply Inc. Palos Hills, Ill.") and accompanied by letters reading in part "it is safe and effective. Do you want it for prevention?" lacked adequate directions for use in the treatment or prevention of cancer, was dispensed without a prescription, and was a new drug without an effective approved New Drug Application—502(f)(1), 503(b)(1), 505(a); when shipped, the labeling of yellow tablets intended for use for cancer (labeled in part "MANDL (Amygdalin) Each Tablet 500 mg. Salutrition Ltd. N. Bergen, N.J.") and accompanied by printed sheet reading in part "Non-Toxic Therapies for Cancer—from the standpoint of treating cancer") lacked adequate directions for use in the treatment or prevention of cancer, was dispensed without a prescription, and was a new drug without an effective approved New Drug Application—502(f)(1), 503(b)(1), 505(a); and while held for sale, amygdalin tablets were repackaged and accompanied by labeling (e.g., books entitled "Magic Vitamins and Organic Foods," "Cancer How To Prevent and Gain Remission from Cancer," and "World Without Cancer"); leaflets reading in part "Non-Toxic Therapies for Cancer," "Alternative Cancer Therapies," and "Vitamin B-17—Lae-trile—Amygdalin—Nitriloside"; letters; and a card entitled "So you know someone who has cancer.") which resulted in the labeling of the drug lacking adequate directions for use in the treatment or prevention of cancer, and in lacking the prescription legend—502(f)(1), 503(b)(4). Guilty plea by Robert F. Linblad to

two counts involving Mandl tablets; fine. Nolo contendere plea by Elmer A. Linblad to two counts involving Amig/Lan tablets; fine. Nolo contendere plea by corporation to two counts involving Mandl tablets and one count involving the repackaging of amygdalin tablets. (F.D.C. No. 60513; S. No. 42-890 H et al.; N.J. No. 29)

NOTICES OF JUDGMENT on Injunction Actions

Cetylite Industries, Inc., and Harry Chanin, president & treasurer, and **Stanley L. Wachman**, presidential assistant, Long Island City, E. Dist. N.Y.

Charged 6-14-76 in complaint for injunction: that the defendants, at their Long Island City plant, manufactured, processed, packed, labeled, and distributed in interstate commerce a number of drugs, and held for sale various drugs after interstate shipment of such drugs' components; that FDA inspection showed that circumstances used for the manufacture, processing, packing, labeling, and holding of the defendants' drugs were inadequate in a number of specified respects; samples of a number of such drugs were found to be adulterated, such as the following: Cetacaine topical anesthetic liquid—subpotent in butyl aminobenzoate, Cetacaine topical anesthetic spray—subpotent in benzocaine and butyl aminobenzoate, Cetacaine topical anesthetic gel—superpotent in butyl aminobenzoate, and Zarosen desensitizer—subpotent in strontium chloride; that Zarosen desensitizer had been recalled twice; and that the defendants were well aware that their activities were in violation of the law; 501(a)(2)(B), 501(c). A consent decree of permanent injunction enjoined the complained of violations, and enjoined the interstate shipment of any drug manufactured, processed, packed, or labeled at the defendants' plant and the manufacturing, the processing, the packing, or the labeling at the defendants' plant of any drug held for sale after interstate shipment of a component unless and until: the circumstances for the production of drugs at the plant conformed with current good manufacturing practice (including a number of specified circumstances), and the drugs on hand at the plant were examined and all such drugs were brought into compliance or destroyed. (Inj. No. 725; S. No. 45-094 H et al.; N.J. No. 30)

Medwick Laboratories, Inc. (subsidiary of S. J. Tutag & Co.), and **Robert S. Tutag**, president, **George A. Albrecht**, quality control director, **James J. Boyce**, vice president, and **Jack Antus**, corporate quality control director of Cord Laboratories, Inc. (subsidiary of S. J. Tutag & Co.), Melrose Park, N. Dist. Ill.

Charged 4-14-76: that the defendants held for sale, after interstate shipment of the components, various sterile injectable products and a sterile ophthalmic solution, and manufactured, processed, packed, labeled, and distributed in interstate commerce such drugs; that FDA inspections of the defendants' plant at Melrose Park, Ill., revealed that the circumstances used for the manufacture, processing, packing, and holding of such drugs failed to conform with current good manufacturing practice; that a number of the defendants' drugs had been recalled from channels of distribution, such as: progesterone aqueous suspension which had a separation of pectin from the drug and clumping in the vial, subpotent cortisone acetate aqueous suspension, subpotent lidocaine hydrochloride injection, and promethazine hydrochloride injection which had a chemical breakdown of the active ingredient and which was subpotent; that a number of the defendants' drugs were ones recognized in the U.S.P. and their strengths differed from and their quality and purity fell below the U.S.P. standards; that the defendants had, on a number of specified occasions, been advised that their activities were in violation of the law; 501(a)(2)(B), 501(b).

The court issued a temporary restraining order enjoining the defendants from the complained of violations, and enjoining the interstate shipment of sterile injectable and ophthalmic drugs and the manufacture, processing, packing, and labeling of such drugs held for sale after interstate shipment of one or more of their components unless and until: all the plant's "on-hand" sterile injectable or ophthalmic drugs were examined, found to be in compliance, or brought into compliance or destroyed, and any portion of a batch already distributed and found after examination to be adulterated was recalled; and the circumstances for the manufacture, processing, packing, and labeling of such drugs at such plant were established, operated, and administered in conformity with current good manufacturing practice. Subsequently, upon stipulation, a consent decree of permanent injunction was entered which permanently enjoined violative actions by the defendants. (Inj. No. 729; S. No. 76-17-593 et al.; N.J. No. 31)

Peter Cooper Corporations (Camden Gelatin Division), and **Charles L. Pearson**, production vice president, and **Thomas D. Downey**, plant manager, Camden, Dist. N.J.

Charged 1-16-76 in complaint for injunction: that the defendants were engaged at their Camden N.J., plant in preparing, packing, and holding the food Dicalcium Phosphate, and in distributing such food, and in holding such food for sale after shipment in interstate commerce of its component raw material; that such food contained

the poisonous or deleterious substance *Bacillus anthracis*; that such food had been prepared, packed, and held under insanitary conditions whereby it may have been rendered injurious to health; that the defendants' plant had been inspected following the hospitalization of an employee due to a *Bacillus anthracis* infection; that such inspection revealed a number of specified inadequacies in the defendants' methods, facilities, and controls; that such food (prepared, packed, and held under the above conditions) was customarily used for animal feed without any further treatment which would destroy *Bacillus anthracis*; that the Government believed the circumstances for the production of the Dicalcium Phosphate were not adequate to preclude contamination with *Bacillus anthracis*, and believed the defendants would continue such violative shipment and production unless enjoined by the court; 402(a)(1), 402(a)(4). The parties entered into a consent decree of permanent injunction which enjoined the complained of violations, and enjoined the interstate shipment of the defendants' Dicalcium Phosphate, and the preparing, packing, and holding at the defendants' Camden plant of Dicalcium Phosphate held for sale after the interstate shipment of its raw material component, unless and until: such plant was thoroughly cleaned, renovated, and rendered suitable for production of such food; appropriate procedures and controls were established and operated to assure the manufacturing, processing, packing, and holding of Dicalcium Phosphate so as to preclude contamination by *Bacillus anthracis*; the defendants selected a person qualified to inspect bone processing and gelatin plants who inspected the defendants' plant and certified that the plant had been renovated and procedures and controls had been established as specified above; and all Dicalcium Phosphate on hand or subsequently returned, was destroyed, denatured, or otherwise brought into compliance with the law. (Inj. No. 718; S. No. 76-35-309 et al.; N.J. No. 32)

NOTICES OF JUDGMENT on Miscellaneous Actions

Diethylstilbestrol for mixture into feed for cattle and sheep, and revocation of New Animal Drug Applications for such use, and amendment and revocation of the Food Additive, New Animal Drug, and Antibiotic Drug regulations concerning such use; two petitions for judicial review, U.S. Court of Appeals, Washington, Dist. Columbia.

Petitioned 9-15-72 and 12-22-72 by Chemetron Corp., Chicago, Ill., Dawe's Laboratories, Inc., Chicago, Ill., and Hess & Clark, Div. of Rhodia, Inc., Ashland, Ohio, against the U.S. Department of Health, Education, and Welfare, H.E.W. Secretary Elliot L. Richardson, the U.S. Food and Drug Administration, and FDA Commissioner Charles C. Edwards, M.D.: *Petition of 9-15-72*—that the court review the FDA order (37 F.R. 15747) which denied the petitioners a hearing with respect to the FDA Commissioner's proposal to revoke the petitioners' New Animal Drug Applications (NADA's) for diethylstilbestrol (DES) for premixes for animal feed. The petitioners moved for a stay of the FDA regulation pending judicial review. The Government opposed such motion and the court denied the petitioners' motion for a stay. Thereafter, the petitioners moved that certain confidential materials and trade secrets be treated *in camera* by the court; and *Petition of 12-22-72*—that the court review the FDA order (37 F.R. 26307) which amended and revoked Food Additive regulations, New Animal Drug regulations, and Antibiotic Drug regulations concerning the use of diethylstilbestrol in animal feed.

The petitioners moved to consolidate the two proceedings, which motion was granted. The Court of Appeals ruled in favor of the petitioners and vacated the FDA orders. The court said:

"DES is a synthetic estrogen used to promote animal growth. The petitioners in the instant case manufacture DES in both liquid and dry form for mixture into feed for cattle and sheep. Typically, cattle are given the feed containing DES in a feed-lot for several weeks immediately prior to slaughter. It enables them to grow faster while using less feed, and while generating less solid waste. When used in this fashion, DES yields significant economic benefits for beef consumers.

"Counter-balancing these benefits is a known risk: DES is a carcinogen. As such it ordinarily would be kept from the market by the Delaney Clause, . . . which flatly prohibits sale of drugs that are proven carcinogens—subject however, to the exception contained in a clause sometimes labeled the 'DES clause.' The 'DES clause' allows the sale of carcinogenic animal drugs [under the certain conditions of use] This exception to the Delaney Clause recognizes the fact that DES passes out of an animal's system within a relatively short period. For that reason, if administration of DES ceases a sufficient time prior to slaughter, the slaughtered carcass will contain no DES residues.

"Adhering to the provisions of the clause, the FDA allowed DES to be sold until 1973 because it never detected any disqualifying residues while using the 'approved test method,' the mouse-uterine test. In 1971, however, the U.S. Department of Agriculture began to test carcasses using a different method, a method that was not

then and is not now an 'approved test method.' This testing revealed residues which USDA attributed to DES usage. Apparently, however, the USDA and FDA felt that these detected residues resulted from improper administration of DES, for the FDA's response was to extend the required time period between cessation of DES administration to animals and slaughter of those animals.

"Nonetheless, the USDA continued to detect residues after this change in the regulations. Accordingly, on June 21, 1972, the Commissioner issued a notice of intent to withdraw his approval of all NADA's for DES, and offered all interested NADA holders an opportunity for a hearing (37 Fed. Reg. 12,251). In the Notice, the Commissioner indicated his particular concern with the possibility of misuse of DES feed premixes, which are anonymous when added to feed. As noted in the *Hess* [and *Clark v. FDA*] opinion [405 F.2d 975], this Notice explicitly contemplated that it was a precursor to hearings to be held to investigate the nature of the DES problem.

"Petitioners timely responded to the June, 1972, Notice, and requested hearings. The FDA, however, on August 4, 1972, refused the requests for hearing, and simultaneously withdrew its approval of the NADA's for feed premixes. (37 Fed. Reg. 15,747) In taking this action, the FDA relied upon test results received just prior to promulgation of the Order. . . .

"In turn, the Commissioner stated that these test results [from tests using radioactive-tagged DES], uncontroverted by any submitted alternative data, did not admit 'the existence of a genuine and substantial issue of fact' so that no hearing need be held. Moreover, the Commissioner found that the test results compelled him to withdraw his approval of petitioners' NADA's. . . .

"Although ordering an end to manufacture of premixes, the FDA allowed continued marketing of existing inventories until January 1, 1973. . . . Thereafter, on December 9, 1972, the FDA withdrew the regulations governing use of DES feed premixes, as required by statute. (37 Fed. Reg. 26,307) Petitioners appealed these Orders and their appeals are the subject of the instant case. . . .

"As in *Hess*, the petitioners argue that the challenged FDA order is legally defective because the FDA promulgated it without giving them a hearing. There are two means by which the approval of an existing NADA can be withdrawn without holding a hearing. . . . First, the Secretary can suspend the approval on the basis of a finding that continued approval would present an imminent hazard to public health. Second, the summary judgment procedure may be invoked. In the instant case, the Commissioner expressly denied the presence of any public health hazard in the order of withdrawal. Instead, he relied on the summary judgment power. The issue is whether he properly invoked and executed the summary judgment procedure.

"The first question is whether the FDA provided petitioners 'due notice and opportunity for hearing'. . . . The Commissioner argues that the only notice given to petitioners, in June 1972, meets the statutory requirement. . . .

"... [T]he June, 1972, Notice falls far short of the standard announced in *Hess* for notice adequate to permit summary withdrawal of petitioners' products. It failed to present a *prima facie* case against petitioners' products. Indeed, it had to fail, for the Commissioner had no data on which to base his ultimate actions until a month after issuance of the June Notice. Thus, petitioners never had a genuine opportunity to respond to the actual basis of the FDA action. . . . Accordingly, the FDA's summary action withdrawing approval of petitioners' NADA's without hearing was illegal and cannot stand. . . . In the Order of August 4, 1972, the Commissioner announced that his withdrawal of approval of petitioners' NADA's was required by the Delaney Clause. . . .

"At oral argument, government counsel referred numerous times to DES as a known carcinogen, but he admitted, on being pressed, that the FDA could not invoke the Delaney Clause. That is also our view. The 'DES' exception to the Delaney Clause, discussed above, continues effective unless the agency detects residues in a slaughtered animal while using an approved test method. And the residues detected by the Department of Agriculture were not found by an 'approved method.'

"Government counsel are of course restricted to the basis for the order articulated by FDA. . . . They now rely on 21 U.S.C. § 360b(e)(1)(B). While that section is mentioned in the August, 1972, Order, the context satisfies us that the Commissioner was relying on the Delaney Clause. But in any event, for reasons stated in both *Hess* and this opinion, any effort at this time by the Commissioner or counsel to rely on the 'new evidence' provision in Section 360b(e)(1)(B) is unavailing, because the FDA chose to act summarily, without a hearing, without making known to petitioners the nature of the 'new evidence,' or of the underlying tests, and without giving petitioners an opportunity to controvert the new evidence.

"For the reasons stated, we vacate the Order of August 4, 1972, and remand the case to the FDA. By this action we also vacate the ancillary order of December 9, 1972." (Misc. Nos. 200, 211; N.J. No. 33)

Polychlorinated biphenyl (PCB) tolerance level for paper food-packaging material, suit for judicial review and injunction, Boston, Dist. Mass.

Charged 9-4-73 by Natick Paperboard Corp., Natick, Mass., and Crown Paperboard Co., Inc., Philadelphia, Pa., against H.E.W. Secretary Caspar Weinberger, and FDA Commissioner Alexander Schmidt, in suit for injunction and declaratory relief: that polychlorinated biphenyls (PCB's) were a class of highly stable, heat-resistant chemicals that had been used widely for over 40 years in numerous industrial applications; that FDA found that PCB's had become a persistent and ubiquitous contaminant in the environment but had consistently taken the position that PCB's in the food supply presented no immediate hazard; that FDA had taken steps to reduce the overall intake of PCB's by establishing tolerances; that plaintiffs did not dispute the legal right and duty of FDA to establish PCB tolerance levels for foods; that FDA had promulgated final regulations (although stayed at that time) which established a PCB tolerance level of 10 parts per million for paper food-packaging material and had announced that, after September 4, 1973, paper food-packaging material exceeding the stayed tolerance level would be seized as an adulterated food; that evidence and objections, which had been received by FDA, demonstrated: the lack of sound evidence for the proposed regulation, the lack of FDA jurisdiction over paper food-packaging material, the problems of recycling waste paper, the impossibility of eliminating PCB's from paper food-packaging material, the heavy reliance of the waste paper recycling industry on sales for food packaging material, and the irreparable damage to the plaintiffs and the industry; that FDA promulgated regulations to take effect on September 4, 1973, which established temporary PCB tolerance levels for eight categories of food and for paper food-packaging material; that because of objections the regulations were stayed; that, despite the stay of the regulations, FDA gave notice that it would enforce the temporary tolerance level for paper food-packaging material by seizing any paper food-packaging material shipped in interstate commerce after September 4, 1973, which contained PCB's; that such seizures would irreparably damage the waste paper recycling industry; that preventing such seizures would, in no significant way, present any danger to the American Public, since the present level of PCB's was presently decreasing, since such level was extraordinarily small compared to the quantity required for toxicity, and since, to the extent, if any, that PCB's did migrate to food from paper food-packaging material, such migration had a potential of constituting only a minute percentage of the overall human consumption of this pervasive chemical; and that the defendants would be acting arbitrarily and capriciously and in excess of their statutory authority, by seizing paper food-packaging material containing PCB's, since such action was not authorized by law and was outside the clear intent of Congress; and that plaintiffs prayed that the defendants be enjoined from seizing paper food-packaging products, and their (the defendants') extension of jurisdiction over paper food-packaging material be declared arbitrary, capricious, and in excess of statutory authority.

The defendants filed a motion to dismiss for failure to state a claim upon which relief could be granted. The motion was denied. After a hearing on the plaintiffs' request for a temporary restraining order, the court denied that request, saying that the plaintiffs had failed to show that there was a reasonable possibility that they would prevail on the merits and had failed to establish that irreparable injury or loss would result if such temporary restraining order was not granted. Meanwhile, the defendants moved to dismiss the complaint for declaratory relief and, in the alternative, for summary judgment. The court dismissed the complaint, saying:

"Both plaintiffs are engaged in the business, *inter alia*, of manufacturing paper products from recycled waste paper. Included among the products manufactured by plaintiffs is a paper food-packaging material sold by plaintiffs in interstate commerce for use in the packaging of foods. It appears that the packaging materials contain a certain amount of polychlorinated biphenyls (hereinafter PCB's). It is the position of defendants that PCB's are toxic substances which above a certain level should not be found in foods for human consumption. The Commissioner of Food and Drugs has issued a regulation . . . and has issued a notice of proposed rules limiting the amount of PCB's that may be found in paper food-packaging material to 10 parts per million (hereinafter 10 PPM). It is defendants' theory that PCB's are toxic substances which may be and are found in food products so wrapped because of migration of the PCB's from what the defendants contend is contaminated paper packaging material into foods so packaged.

"After the promulgation of its regulation limiting the PCB level to 10 PPM, . . . objections to the regulation were filed by representatives of the paperboard industry whereupon the FDA . . . stayed the effective date of the regulation pending a public hearing on the industry objections.

"At about the same time, however, the FDA notified the industry that it would seize all paper food-packaging materials shipped in

interstate commerce if those materials had a quantity of PCB's contained therein in excess of the permitted tolerance of 10 PPM. The instant complaint was filed in this Court on September 4, 1973 in quest of both injunctive relief against the FDA's threatened seizures and also in quest of declaratory relief to the effect that the FDA lacked legal authority to direct the seizure of paper food-packaging materials because plaintiffs contend that the food-packaging materials did not constitute 'food' within the meaning of 21 U.S.C.A. § 334 which contains the statutory basis for seizure of contaminated 'foods.' * * *

"It is now well settled law in this Circuit that in order to obtain a preliminary injunction the plaintiff moving therefor must show a substantial likelihood of success on the merits and a probability of immediate and irreparable harm if the injunction is not granted. In passing on these two issues a court is to consider also whether the failure to issue an injunction will cause more harm to plaintiff than the granting of an injunction would cause to defendants. . . .

"Plaintiffs' application for a preliminary injunction founders on the second of these two grounds because it is clear that these two manufacturing corporations allege as the irreparable harm, said to be consequent to the denial of an injunction, the fact that the sale of paper food-packaging material amount to 7½% of Natick's gross sales and 12% of Crown's gross sales. It is further alleged that seizure of packaging materials exceeding the 10 PPM tolerance will at least temporarily eliminate these portions of plaintiffs' gross sales. Plaintiffs further allege that failure to supply their customers because of the threatened seizure will to an unspecified extent damage the good will of their businesses and that adverse publicity from the seizure will scare away customers who otherwise would purchase food-packaging materials from plaintiffs. Assuming all of the foregoing to be true, I find and rule that economic injury to this limited extent does not constitute irreparable harm since it is well settled law that something other than monetary damages recoverable in a court of law must be shown in order to establish irreparable harm. Accordingly, without re-examining the issue of probability of success which has already been ruled on adversely to plaintiffs by another member of this Court, I rule that plaintiffs have failed to demonstrate that the denial of injunctive relief herein will visit irreparable harm upon them. Accordingly, assuming this Court to have jurisdiction only for purposes of the ruling on this part of the case, the application for preliminary injunction is denied.

"A more fundamental issue exists as to whether or not this Court has subject matter jurisdiction to entertain a suit seeking an injunction against the threatened seizures.

"The basis for the proposed seizure of these materials lies in 21 U.S.C.A. § 334(a)(1) Defendants argue herein that the intent of Congress in enacting the quoted language from Section 334 was to make the libel for condemnation the only legal proceeding in which the validity of a seizure could be tested in a United States District Court. Defendants argue that a United States District Court does not have jurisdiction to review actions of the Food and Drug Administrator other than in the course of determining a libel of forfeiture. This say defendants is the thrust of the opinion of the Supreme Court in *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 600-601 (1950). Plaintiffs respond with the contention that the later decision of the Supreme Court in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967) undercuts the vitality of *Ewing* and operates to make the regulations in issue here reviewable in the instant litigation.

"An examination of the statutory basis of the Commissioner's action in the two cases persuades this Court that plaintiffs have misread *Abbott*. . . . In *Abbott* the Commissioner did not purport to make the finding of probable cause required by 21 U.S.C.A. § 334(a), whereas in the instant case the Commissioner has undertaken to make a finding of probable cause as to materials containing PCB's in excess of 10 PPM. . . . I rule that the instant case involves the finding of probable cause required by Section 334(a) by the Commissioner as a statutory prerequisite to the bringing of libels of forfeiture at which the legal issues may be aired. Accordingly, I rule that this Court lacks jurisdiction to entertain the instant complaint for injunctive relief which must be dismissed for lack of subject matter jurisdiction.

"With reference to that portion of the complaint which seeks declaratory relief on the issue of whether or not the paper packaging material may be found to be 'food' within 21 U.S.C.A. § 321(f) on the basis of the Government's theory that packaging paper containing PCB's is a 'food additive' because the PCB's migrate from the paper into the food, within 21 U.S.C.A. § 321(s), I rule that this Court also lacks subject matter jurisdiction because of the provisions of Title 21 U.S.C.A. § 348(g)(1) which provides in pertinent part that jurisdiction of a law suit to determine the correctness of a decision by the agency as to what constitutes food lies in the Court of Appeals. . . ."

The plaintiffs appealed and won a reversal of the district court's dismissal with respect to the declaratory relief jurisdiction. The Court of Appeals stated:

"Appellants brought the instant action seeking injunctive and declaratory relief against the announced seizures. They contended that their paper food-packaging materials were not 'food' within the meaning of the Federal Food, Drug, and Cosmetic Act, and therefore the Commissioner had no authority to seize the materials, whatever his reasons. The district court did not reach this issue. Instead, it held that it lacked jurisdiction to grant either the injunctive or declaratory relief sought, and on that basis dismissed the complaint. 367 F. Supp. 885 (D. Mass. 1973). For the reasons that follow, we affirm as to injunctive relief but reverse as to declaratory relief.

"In holding that it lacked jurisdiction to enjoin the recommended seizures, the district court correctly relied upon the Supreme Court's decision in *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), *rev'g* 87 F. Supp. 650 (D. D.C. 1949). . . .

"Appellants contend that *Ewing* is distinguishable from the instant case and that in any event its authority has been undercut by the Supreme Court's more recent decision in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967). We disagree as to both contentions.

"First, although there are some differences between *Ewing* and the instant case, these do not warrant a different outcome. Appellants stress that in *Ewing* the plaintiffs challenged only the scientific findings of the FDA whereas here they challenge the FDA's statutory authority even to consider the dangerousness of their product. Although this is so, we think that the fundamental purpose of § 334 recognized in *Ewing*—speedy protection of the public from dangerous articles in interstate commerce—similarly requires that no seizure be halted pending judicial resolution of the definitional issue. Indeed, the policy consideration is even more compelling in the instant case than in *Ewing* because here the product has been alleged to be toxic, . . . while in *Ewing* no one contended the product was harmful to health. . . .

"Second, the *Abbott Laboratories* decision, far from undercutting *Ewing*, expressly reaffirmed this earlier decision as 'quite clearly correct.' 387 U.S. at 147. The several distinctions noted by the Court between the promulgation of industry-wide regulations at issue in *Abbott Laboratories* and the recommendation of seizure proceedings under § 334 need no further elaboration here. . . . Therefore, we conclude that the district court lacked jurisdiction to grant injunctive relief. . . .

"We now turn to the district court's holding that it lacked jurisdiction to grant declaratory relief. The court did not rely on *Ewing* for this part of its decision. Instead, it relied on 21 U.S.C. § 348(g)(1) (1970), which it construed as vesting exclusive jurisdiction in the courts of appeals on this aspect of the case. . . . This was error. Section 348(g)(1) applies only to regulations on food additives and thus was an improper basis for the court's decision that it lacked jurisdiction with respect to seizures under § 334.

"This does not necessarily end the matter. The question remains whether § 334 itself, as construed in *Ewing*, precludes jurisdiction in the district court to grant the declaratory relief sought by appellants in the same way that it bars pre-seizure injunctive relief. This is a difficult issue, in which we must accommodate the conflicting policies of two relevant Supreme Court decisions, *Ewing* and *Frozen Food Express v. United States*, 351 U.S. 40 (1956).

"We hardly need to elaborate again the fundamental *Ewing* policy of promptly protecting the public from dangerous articles in interstate commerce. It is for that reason we hold *supra* that the statute deprives district courts of jurisdiction to grant pre-seizure injunctive relief even when the question raised is whether the particular product is covered at all by the regulatory statute. On the other hand, it must also be recognized that appellants may be affected in many ways other than by the proposed seizures by the implicit conclusion in the FDA's seizure announcement that their product is now considered 'food' within the meaning of the Act. On this aspect of the case, the *Frozen Food* decision is relevant. . . . In general, *Frozen Food* stands for the proposition that where an agency has determined that a particular product or entity falls within its statutory province, the affected private interests are then entitled to judicial review of that decision. . . .

"In the instant case, it seems clear that if the FDA had simply announced its conclusion that henceforth paper food-packaging materials would be considered 'food' within the meaning of the Act, the policies expressed in *Frozen Food* would entitle appellants to immediate district court review of that decision. But FDA did more than make a simple announcement. Instead, it linked its definitional conclusion with the further announcement that it will hereafter seize under § 334 certain food-packaging materials containing more than 10 ppm of PCB's. Hence, the policies of *Ewing* come into play as well.

"We think the best accommodation of these conflicting policies is to construe § 334 as not precluding district court jurisdiction to decide the definitional question within the context of an action solely for declaratory relief. At the same time, we want to make clear that the existence of this limited jurisdiction does not permit the district court to halt in any way the seizure of appellants' food-

packaging materials while the definitional issue is being resolved. . . . The interest of protecting the public health is plainly paramount to the business interests of the appellants.

"Finally, it has been proposed that we decide the definitional issue on the merits at this time. Although we understand the parties' desire for speedy resolution of this question, we nevertheless prefer to wait until we have the considered decision of the district court before us. . . . Therefore, we reverse the district court's judgment only with respect to declaratory relief jurisdiction and remand the case to that court for further proceedings not inconsistent with this opinion. Nothing in this opinion shall be deemed to bar the institution of seizures in the interim under § 334."

The case having been remanded to the district court, both the plaintiffs and defendants sought summary judgment on their own behalf. The district court denied the plaintiffs' motion for summary judgment as to declaratory relief, but granted it to the defendants. In ruling in favor of FDA, that FDA, as a matter of law, had the authority to recommend seizure of paper food-packaging material containing PCB's in excess of 10 parts per million as adulterated food, the court said:

"Basically, the controversy between the parties is as to whether or not food-packaging materials can properly be construed as food within the meaning of § 321(f). . . .

"Section 321 was enacted in 1938 and some twenty years later the food additive amendment of 1958 was enacted. Significantly, this amendment contained a new provision that a food is adulterated 'if it is, or it bears or contains, any food additive which is unsafe within the meaning of § 348 of this Title.' 21 U.S.C.A. 342(a)(2)(C). The same amendment added the definition of food additive now contained in 21 U.S.C.A. 321(s). . . . I rule that the clear, unambiguous language of Section 321(s) establishes that food-packaging materials may be found to be food additives. . . .

"The broadly protective intent of this legislation appears from the legislative history thereof. The Senate Committee report contains the statement, 'We want the record to show that in our opinion the bill is aimed at preventing the addition to the food our people eat of any substance the ingestion of which reasonable people would expect to produce not just cancer but any disease or disability.' . . . The legislative history further establishes that the House subcommittee analyzing the bill considered, and explicitly rejected on the ground of surplusage, a proposed amendment that would have brought 'food additive' within the definition of 'food.' . . .

"From the foregoing, it may be fairly adduced that the committee intended that the same controls and regulations which apply to food also apply to food additives. This is consistent with Congress' concern that the Secretary be empowered to monitor and regulate anything traveling in interstate commerce which ultimately would be ingested by human beings, regardless of the label appended thereto.

" . . . In 1968 [the Supreme] Court reaffirmed the principle [expressed in *United States v. Dotterweich*, 320 U.S. 277 (1943)] that remedial legislation, such as the Food, Drug, and Cosmetic Act, is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health, and the Court also told us that this is a 'well-accepted principle.' *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1968).

"The only case discovered specifically applying the philosophy of the *Bacto-Unidisk* case to the precise type of problem now before this Court resulted in a ruling favorable to the Secretary. In *United States v. Articles of Food . . . Pottery . . . Contemporary Ironstone (Cathy Rose)*, 370 F. Supp. 371 (E. D. Mich. 1974), the Secretary sought forfeiture of pottery dinnerware, alleging that it contained a food additive, lead, which the Secretary asserted was unsafe within the meaning of 21 U.S.C.A. 342(a)(2)(C). The Government's theory in that case was that the lead could migrate from the pottery to the food being served in it. . . .

"Having in mind the statutory provisions . . . , the legislative history which I rule is supportive of the Secretary's position, and the attitudinal directives from the Supreme Court . . . , I rule that plaintiffs have not shown a right to the declaratory relief sought herein, and that defendants are entitled to summary judgment that they have the authority . . . to recommend seizure of paper food-packaging material containing polychlorinated biphenyls (PCB's) in excess of 10 parts per million as adulterated food."

Again, the plaintiffs appealed. In this instance, the Court of Appeals affirmed the judgment of the district court and upheld FDA's jurisdiction over paper food-packaging material. The Court of Appeals said:

"The food additive provisions of the Act were added by the Food Additive Amendment of 1958. . . . Its basic purpose is to permit FDA to regulate the use of substances affecting food without first determining that they are in fact dangerous; the method is to require that such substances be established as safe before being used. . . .

"The protection of the public from unsafe food additives was accomplished by amending sec. 342(a), defining 'adulterated food'. . . . No other means of prohibiting the unauthorized use of unsafe food additives was provided for in the Amendment; none was needed. We conclude that 'unsafe food additives,' whether intentional or incidental, are 'adulterated food' under sec. 342(a)(2)(C), and, therefore, may be seized, subject to the provisions of sec. 334(a)(1) and (b).

"It would defeat the policy of the Act to require, as plaintiffs contend, that FDA must wait until the unsafe food additive has actually entered or come in contact with food before it can be seized; it is enough that FDA has reasonable cause to expect that the additive will be used in such a way as to enter or otherwise come in contact with food. To wait until actual contamination occurs, in the warehouse of the food processor, on the shelf of a grocery store, or in a family kitchen would effectively deny FDA the means to protect the public from adulterated food. . . .

"We do not hold, however, that FDA can properly take steps to seize any and all paperboard containing PCB's in excess of 10 ppm wherever it is located and whatever its intended use may be. The district court properly limited its judgment to paper food packaging material. We interpret this to mean that the FDA must be able to prove that any paperboard intended to be seized before it has actually been used as a container for food is either in the hands of a packager of food or in transit to, ordered by, or being produced with the intention that it be sold to a packager of food, or that its intended use otherwise meets the test of sec. 321(s). If the packager or other claimant can show that the food placed in or to be placed in the paper container is or will be insulated from PCB migration by a barrier impermeable to such migration, so that contamination cannot reasonably be expected to occur, the paperboard would not be a food additive and would not be subject to seizure under the Act. So interpreted, the notice of intended seizure is not overbroad." (Misc. No. 250; N.J. No. 34)

Vitamin and mineral supplement regulations and suit to enjoin enforcement of such regulations, Clearlake Highlands, N. Dist. Calif.

Charged 9-7-73 by Leah Connors, R. N., Clearlake Highlands, Calif., against U.S. Attorney General Elliot Richardson, FDA Commissioner A. M. Schmidt, and numerous John Does, in suit for injunction: that FDA's vitamin and mineral supplement regulations violated the first and fourteenth amendments of the Federal Constitution; that the promulgation of such regulations (set forth under the administration of FDA Commissioner Schmidt, with his agents) was an action, in restraint of trade, by the drug industry in collusion with American Medical Association officials, to destroy the health food manufacturers and store outlets; that plaintiff spoke for thousands of citizens who pleaded with her, as a registered nurse, to do something; that FDA was not regulating the sale of aspirin and other toxic products known to be detrimental to the health of persons, but food supplements and vitamins, which had been proven to be helpful to persons, had been an improvement to the health of users, and had saved the Government hundreds of thousands of dollars in Medicare and other medical services, were being regulated; and that a dozen attached exhibits (consisting mostly of copies of newspaper articles) were proofs of FDA's negligence and failure to research.

The defendants moved to strike the complaint and to dismiss the action for lack of jurisdiction and for failure to state a claim upon which relief could be granted; it was asserted that other actions for review of the FDA regulations had been filed in various courts of appeal, including *Archon Pure Products, Inc. v. Weinberger*, in the Ninth Circuit Court of Appeals; that three other such cases had been removed to the Ninth Circuit Court of Appeals for consolidation with the action there, and that the plaintiff had incorrectly filed her complaint in the District Court. After a hearing, the District Court found that it lacked jurisdiction. The District Court accordingly granted the defendants' motion, and without prejudice dismissed the action in its entirety. (Misc. No. 252; N.J. No. 35)

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

Notices of Judgment are prepared by Food and Drug Division, Office of the General Counsel, DHEW.

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Sherwin Gardner, Acting Commissioner of Food and Drugs
Washington, D.C., April 1, 1977

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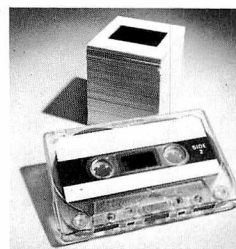
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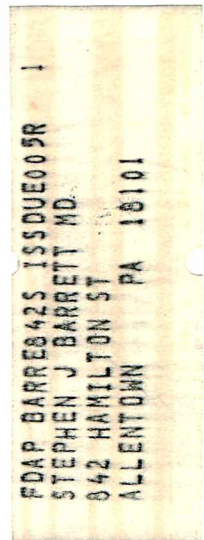
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