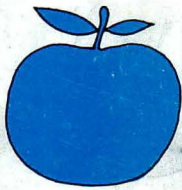


FDA **CONSUMER**

DEC. 1974—JAN. 1975



New Year's Resolutions For Health And Safety



This Month

Whether we're in our teens, twenties, thirties, or at any point beyond, the year's beginning is the traditional and symbolic time that we reassess what we have learned in the past and how we can use it to make a better future for ourselves and loved ones. While you're reflecting, FDA CONSUMER asks you, in "New Year's Resolutions for Health and Safety," to consider a few basics aimed at maintaining good health and thus making all your other aspirations worthwhile.

Those good old days—when you had to smell a fish to determine if it was spoiled—are still here. "The Smell That Tells" makes it clear that when it comes to something fishy the nose has not yet been replaced by a test tube and that FDA, to protect the consumer, has developed smelling into an art that approaches a science.

"The Cyclamate Story" is an absorbing account of how an accidental laboratory discovery in 1937 became the basis of a billion-dollar industry before cyclamate was banned by FDA in 1969 with the emergence of serious questions as to its safety as a sweetening agent, and it demonstrates how new scientific findings may influence FDA policies in its work of assuring safer food and drugs.

Should your dog eat as high on the hog as his master or mistress? Probably not, if you want him to be around a long time. Read on into "A Nutrition Guide for Pet Owners."

After the mushroom scare, FDA decided to take a look at some of the most heavily canned low-acid foods on the grocery shelves to determine if the mushroom problem was in any way representative of the canning industry as a whole. The results, described in "Canning Industry Compliance Found Good," were reassuring.

FDA **CONSUMER**

VOL. 8. NO. 10/DEC. 1974—JAN. 1975

The Smell That Tells	4
<hr/>	
A Nutrition Guide for Pet Owners	10
<hr/>	
Canning Industry Compliance Found Good	17
<hr/>	
The Cyclamate Story	19
<hr/>	
New Year's Resolutions for Health and Safety	21
<hr/>	
News Highlights	28
<hr/>	
Regional Reports	31
<hr/>	
State Actions	34
<hr/>	
Seizures and Postal Service Cases	35
<hr/>	
Notices of Judgment	37
<hr/>	

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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.

Quotes

“One of the things I’m proudest of is that we’ve turned the Agency around in an emphatic response to the Freedom of Information Act. It wasn’t too long ago that FDA routinely kept 80 to 90 percent of its information secret, and released 10 to 20 percent. The situation today is essentially reversed. FDA is among the leaders in government in spelling out positive and specific rules for operating a truly open agency. We are now putting the finishing touches on our final FOI regulations, which I predict will become a benchmark for all regulatory agencies.”

Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, at the National Press Club, Washington, D.C., October 29, 1974.

“In the 3 years of its operation, reports from alert community and hospital pharmacists have led to more than 50 drug recalls and product withdrawals, and to many more voluntary product improvements and label changes. Information made possible by this program has led to changes in compendial standards and to new directions for FDA in drug surveillance.

“Since this effective program depends entirely on the awareness, capability, and voluntary cooperation of pharmacists across the United States, its success is entirely due to pharmacists’ interest and recognition of the need for their professional contributions to better health protection.”

Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, at the National Association of Retail Druggists, Las Vegas, Nevada, October 2, 1974.

“Members of the Proprietary Association assuredly will be more concerned with the conduct and conclusions of the OTC drug review program than other members of the pharmaceutical industry. More than 100,000 different drug products are affected by this program. No such massive drug performance study has ever

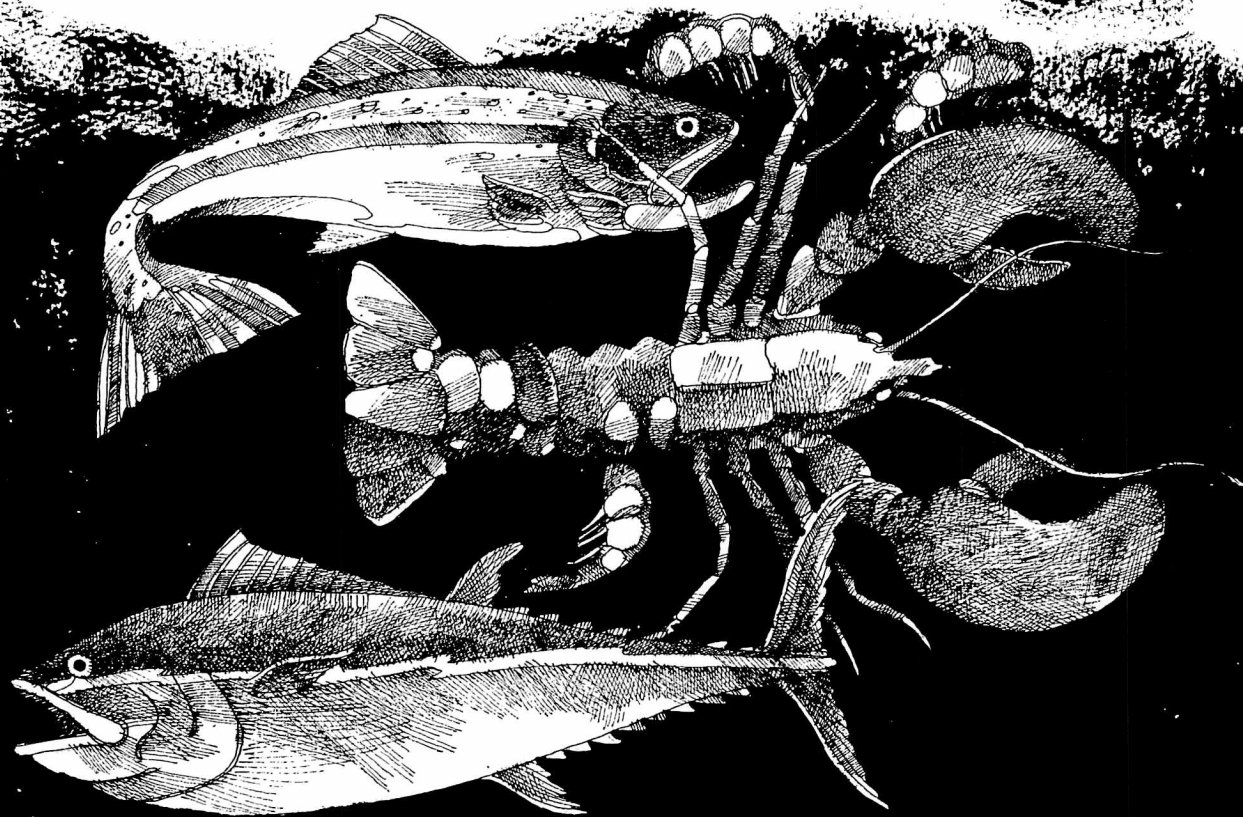
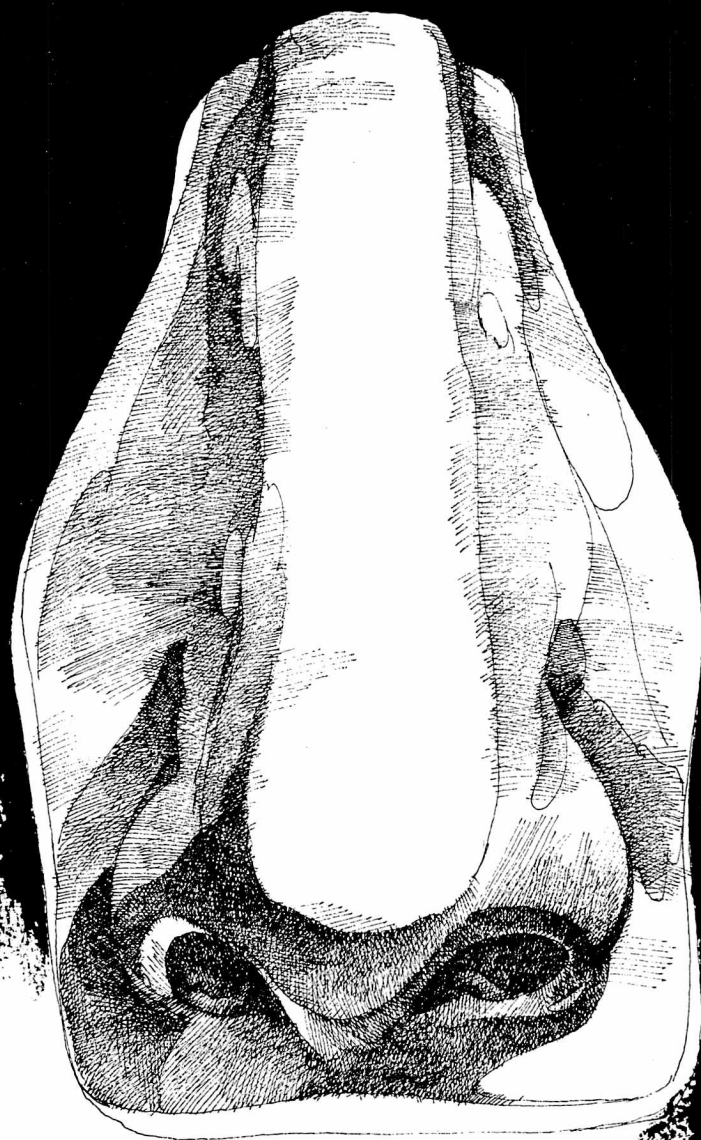
been undertaken anywhere. What makes it possible is the fact that relatively few active ingredients are used in each class of products. The job can be broken down, therefore, into manageable segments for class-by-class evaluation of ingredients by panels of non-FDA scientists and physicians. Seventeen panels each comprised of distinguished professionals from the field of medicine ultimately will be involved in this work.

“The results of these studies will produce monographs (in effect, class standards) for each of 27 basic classes of OTC drugs. Each monograph will constitute a kind of official ‘recipe book’ specifying safe and effective ingredients for each formulation, specific control requirements, and acceptable labeling.”

Sherwin Gardner, deputy commissioner, FDA, at the Manufacturing Controls Seminar of the Proprietary Association, Cherry Hill, New Jersey, October 10, 1974.

“Based on the experience of the peanut butter manufacturers and our analysis of FDA data, as well as information from USDA and Canada, I have come to the conclusion that our present legal limit of 20 parts per billion for [aflatoxin in] peanuts could be further reduced to 15 parts per billion, without significantly increasing losses of food and without seriously disrupting the industry. We plan, therefore, to propose this action within the next few weeks. The reduction should be a significant step forward in protecting the American consumer by diminishing his exposure to a chemical carcinogen while at the same time assuring that peanut butter will continue to be available as an important source of protein. In the near future, we will also be proposing tolerances for other commodities, such as corn and grains.”

Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, at the Annual Convention of the Peanut Butter Manufacturers and Nut Salters Association, Tarpon Springs, Florida, November 11, 1974.



The Smell That Tells

Smelling out trouble is the specialty of FDA's organoleptic analysts. They're a nose ahead in sniffing fish or other seafood products to determine if there has been any decomposition before sale to the consumer.

by Harold Hopkins

In these days of modern, sophisticated laboratory examinations of foods by FDA to determine whether they're fit for human consumption, there's one scientific gap that remains with us, and it involves a class of food important in the nourishment of most families.

This food is fish and other seafood products, and being able to determine with certainty if they are decomposed or spoiled is the problem, one which so far has admitted of no surefire solutions from the chemical laboratory that are both applicable and practicable in the everyday business of food regulation.

Thus in protecting the consumer from decomposed seafood products, FDA both in the past and in modern times has relied on Nature's own protective method, smelling, a gift used by the cave woman of yesterday and no less by the housewife of today. As we all know, a fish out of water soon becomes a problem not only to the fish but to anybody in the vicinity unless disposed of quickly either at the table or by suitable storage in the refrigerator or freezer.

So if her nose is still the housewife's old reliable, and the FDA's is no better, why bother with protection? Who needs it?

YOU need it, and the FDA's

nose **IS** better, at least better trained, to detect and identify decomposition odors in seafood products that can get by many people. It's also FDA's responsibility in protecting the consumer's health and pocketbook to make sure that fish and other seafood products offered in interstate commerce contain no decomposition in the first place that the housewife will encounter after she has made her purchase. She has enough to do just keeping some foods from spoiling in her kitchen without having to worry about those that may deteriorate before they get there.

FDA's nose means more specifically the smelling and interpreting capabilities of a reasonably small group of chemical analysts who have been carefully trained to sniff out and distinguish bad seafood from good, whether it's fresh, frozen, thawed, cooked and frozen, or cooked and canned; whether it's a sample collected from a retail store, cold storage plant, or a processing plant's thawing bins; whether it's salmon or sardine, shrimp or crab, clam or oyster, or sometimes a food not strictly fish, such as frog legs. This trained analyst applies his nose judiciously and expertly to any food of marine origin, whether caught in bays or estuaries or in the open sea and whether it

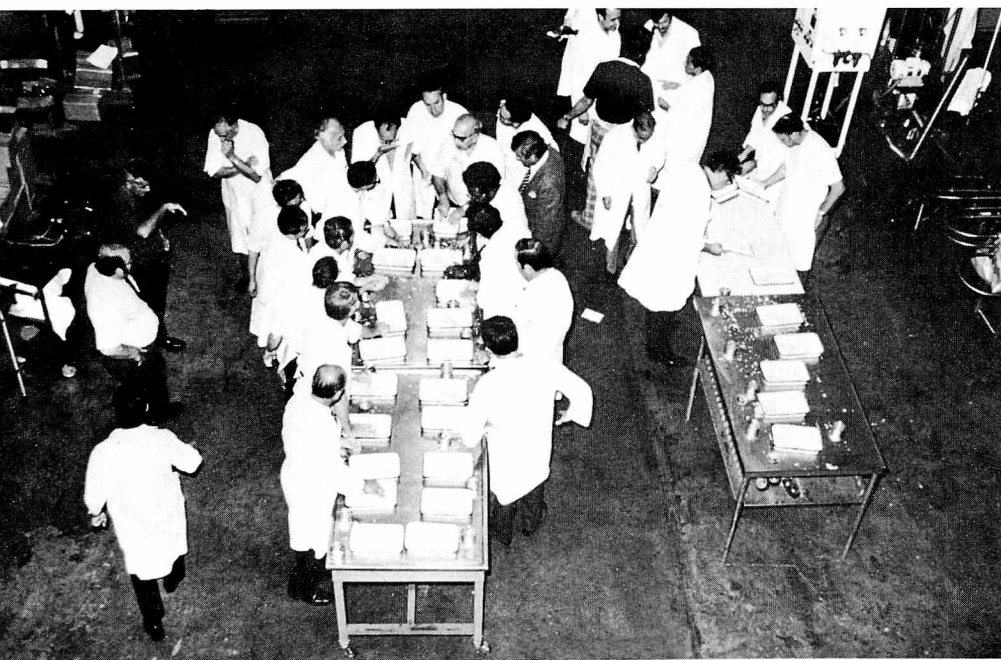
comes off an American vessel or is offered for import from abroad.

There is an official name for this kind of testing, "organoleptic analysis," which here means the use of the organs of sight, smell, and taste. Many foods are examined visually and some are tasted, but where the decomposition of fish and other seafoods is concerned, it's almost always the smell that tells.

The courts, aware of both the necessity for keeping decomposed food from being sold to the consumer and of the training FDA analysts undergo to enable them to detect and distinguish decomposition from other odors, have long accepted organoleptic evidence given by qualified FDA experts in the Agency's enforcement of the Food, Drug, and Cosmetic Act.

The key word is "qualified"—which brings us to tuna, one of FDA's major concerns in food regulation because of the large volume of this fish consumed.

Tuna is in great demand. It's a high protein food. It goes into the children's lunch boxes, the secretary's noonday sandwich, the family's casserole. It is canned in greater volume than any other fish, and in recent years a decline in the catch of salmon, another popular canned fish, has meant an even

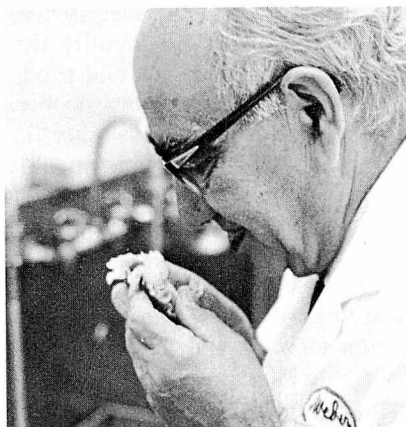


TOP

Fly's eye view of tuna samples spread out for smelling and smellers at work on them at a 5-day training course sponsored by FDA and the tuna canning industry at Berkeley, California. The course was held to give FDA organoleptic analysts special training in detecting and interpreting decomposition in canned tuna.

MIDDLE

At his home base in New York District's laboratories, Al Weber applies a knowing nose to a thawed rock lobster tail offered in a shipment for import.



BOTTOM

Two expert smellers test some tuna samples. Peter Lerke of National Canners Association sniffs a tray of canned tuna and Dick Throm of FDA's Seattle District ponders the evidence.



greater demand for tuna. Canneries up and down the West Coast, in American Samoa, Hawaii, and Puerto Rico are humming the year round to meet the country's appetite for tuna, and the catch comes in from both foreign and American vessels ranging great distances into both the Atlantic and Pacific.

Because of the large pack of this low-acid food and the mounting concern that began a few years ago about the potential for botulinum toxin in such foods and about levels of mercury, a poisonous substance, in such larger fish as tuna, FDA has a special monitoring program covering the processing of tuna to protect the consumer.

On November 16, 1971, two analysts in one of FDA's District laboratories, using the organoleptic method to examine samples from two lots of tuna canned at separate West Coast plants owned by the same company, concluded that substantial percentages of both lots were decomposed, and FDA inaugurated seizure proceedings against the products. The company contested the seizure action, and the U.S. District Court for Eastern Louisiana, sitting at New Orleans, decided on October 22, 1973, that the Government had failed to prove the tuna was decomposed and both lots were released into interstate commerce.

The court said the evidence failed to show agreement between the two District analysts on the condition of a substantial number of cans examined, and noted that one of FDA's two highest regarded organoleptic analysts subsequently examined both lots before the trial and found no decomposition in one lot and in only two cans of 24 tested in the other lot, an acceptable minimum at that time (this minimum has since been reduced to 1 can in 24).

The court also noted that organoleptic tests made by outside experts as part of the company's presentation of evidence, along with a chemical test measuring the volatile

fatty acids present in the tuna, failed to find any decomposition in the product and figured largely in its decision that the Government had no case. The opinion held that although courts do recognize organoleptic test results as valid evidence, the two FDA District analysts did not have the qualifications necessary to determine decomposition, and further pointed out that tuna examination requires special training and experience, even though the analyst may be qualified to detect and interpret decomposition odors in other seafoods.

The implication was clear. Some of FDA's noses needed to go back to the grindstone for finer honing in the art of tuna sniffing.

As it happened, such training was already in the works. In the planning stage was a special 5-day course to "standardize" the noses of FDA analysts through training by industry and Government experts and through testing with samples of tuna representing good, decomposed, and borderline conditions of the product. There had never been any argument between FDA and the tuna canning industry about the validity of smelling for decomposition, and the course held last fall, like similar courses held in 1971 and 1969, was sponsored jointly by Government and industry.

These sponsors, for the course held September 9-13 at Berkeley, California, were FDA, the National Canners Association, the National Tuna Foundation, the Food and Drug Division of the California Department of Health, and tuna industry representatives from Japan, a large exporter of tuna to this country. Two FDA analysts were sent to attend the course from each of the 10 FDA Districts where tuna canneries are located or where there are seaports handling a large volume of domestic or imported canned tuna (tuna samples taken by FDA in other Districts are sent to one of these 10 Districts for decomposition testing).

As a way of keeping these analysts on the right scent after their return to the real life of food regulation, tuna samples from the same lots used in the course have been retained for follow-up smelling by the analysts to determine whether their noses retain their accuracy.

The samples used in the course as "standards" were selected by expert organoleptic analysts of the California State division from the general run of the tuna catch encountered during State inspections of tuna canning plants and analysis of the products. They represent the three conditions (good, bad, borderline) considered in organoleptic examination, and all the parties agreed on the condition of the samples before the course began.

Making these judgments in FDA's behalf and lending their considerable capabilities to the training course were FDA's foremost experts in the organoleptic technique, Albert L. Weber of New York District and Harold R. Throm of Seattle District.

Al Weber discovered his extraordinary acuity one day 31 years ago when as a brand-new FDA food chemist he was called on to examine a suspected lot of fish because the experts were out of the laboratory at the time. The lot was decomposed, he found, as did his wife when he got home that night. She made him change his clothes, but not his newfound specialty. Dick Throm has been smelling fish for 10 years. Both have been demonstrating their art and passing on the lore to other FDA analysts for several years and both have, of course, produced evidence for the Government in countless regulatory actions. Both have at the Japanese government's request visited Japan to participate in training programs for examination of tuna.

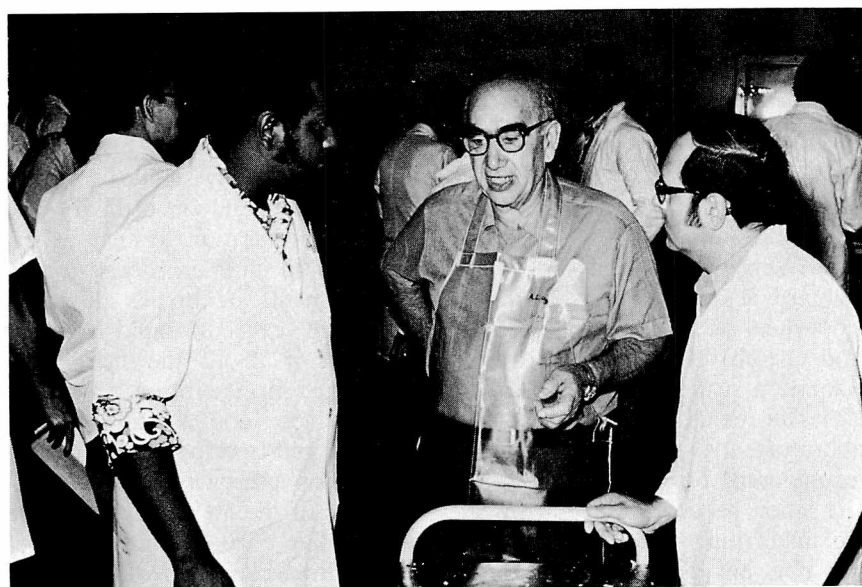
The FDA organoleptic analyst may smell samples of fish or other seafood shipped to an FDA laboratory frozen or canned or he may accompany an FDA consumer

safety officer to inspect a plant where the product is being processed. Here he'll make on-the-spot examination of the product in frozen or thawed condition or at any point in processing. If fish are examined frozen—in cold storage, transit, or in the cannery—the analyst uses an electric drill to get to the interior of the fish, the part last to freeze. The heat from the drilling friction thaws out enough of the interior for a good whiff. An FDA analyst is also trained to recognize the difference in odors between decomposition that took place before cooking and that after cooking. When an FDA analyst finds a seafood sample to be on the ripe side, his findings are verified by another analyst before the FDA initiates regulatory action.

Things can go wrong with fish when handled improperly anywhere along the way to the consumer. Modern fishing boats are equipped to freeze the fish in a brine solution, though many smaller or older boats still depend on ordinary ice. If the refrigeration system is inadequate in one or more storage compartments or breaks down, if the catch exceeds rapid freezing capacity or if all the fish aren't submerged in the brine or ice, if there is too long a wait between catching and freezing, if the fish are broken or otherwise handled improperly or die an appreciable time before they are refrigerated, decomposition can set in. If the crew is forced to spend a long period at sea before catching a full payload, there could be spoilage of the earlier part of the catch.

Tuna presents a special problem. The greater numbers of this "schooling" fish are caught in warm waters toward the equator, unlike some other fish such as salmon or halibut, which are taken in colder latitudes. The tuna is a good-sized fish, must keep moving in the water to obtain enough oxygen to live, and dies quickly when immobilized.

Catching methods are a factor. In "long line" fishing where baited



TOP

The accepted two-handed procedure for smelling tuna, the hands cupped so that the odor escapes upward toward the nose, is tried out here by the industry and FDA officials who conducted the organoleptic training course. Left to right, Walter A. Mercer, National Canners Association's Western Research Laboratory, Berkeley; Frank Allhands, FDA Bureau of Foods; and Doyle Gates, Tuna Research Foundation, Terminal Island, California.

BOTTOM

FDA's most experienced organoleptic analyst, Al Weber (center), discusses his technique with FDA Analysts Barnett F. Smith, Jr. (left), Atlanta District, and Anthony F. LaTerza, Boston District, both attending the course at Berkeley.

hooks are left on stationary long lines secured by floats, the caught fish may stay on the hook for several hours until the fisherman returns, and thus will die and begin to decompose in the warm water. To make matters more critical, the body temperature of the tuna is even higher than that of the surrounding water.

In purse seining a school of tuna is surrounded by a long purse net which may be extended to enclose an area a half-mile or more in circumference. It is then closed completely to concentrate the catch and secure and hoist the tuna aboard. If the captured fish aren't removed quickly from the warm water into the ship's refrigeration compartments, death occurs and spoilage sets in.

Hand fishing, though not as efficient as purse seining, is potentially the quickest method of disposing of fish. The crew attracts a school of tuna to the side of the fishing boat by tossing bait into the water. The hungry fish become so frenzied they will bite at naked hooks lowered by the fishing crew and are then pulled on board. Immediate icing or freezing is possible by this method, but if the fish drop on deck and the crew is too busy fishing to put them into the freezing compartments promptly, the sun and the air are their undoing.

The risk of decomposition continues in transit, in cold storage, and in the processing plant, where sometimes equipment can fail or prove inadequate or humans can err. FDA analysts examine the fish before and after thawing, butchering, and the precooking necessary to separate the tuna's loin meat, the only part used for human consumption, from red meat, skin, bones, and other parts. After this separation or "cleaning," the tuna is packed in cans in grated, flaked, chunk, and solid form to undergo a second cooking in retorts. Some of the parts not used for human consumption are processed into animal foods.

The State of California, where tuna canning is a major industry, requires its inspection teams to be present in canning plants to examine the fish at every stage of processing, look at all processing records, and finally release the product for marketing. Although FDA concentrates the bulk of its inspectional force in other States which do not oversee the processing so comprehensively, the Agency retains the right to conduct the same kind of inspections and examinations in California plants as it does in other States. FDA has in fact made several recent inspections of California tuna canning plants as part of its program to head off any problems that could result in contamination of low-acid canned foods with botulinum toxin.

In its inspections of all food establishments, including processors of tuna and other seafoods, FDA is concerned with assuring the consumer that the product is free from contaminants or adulterants of any kind that might harm his health as well as those that, while not strictly harmful, are considered by most people to be filthy or esthetically repugnant. Thus FDA in inspecting plants or examining products looks for violations of the Agency's Current Good Manufacturing Practices, which outline requirements for the condition of raw materials, employee and plant sanitation, sanitary facilities, condition of equipment and supplies, freedom from birds or rodents and insects, adequacy and safety of storage of raw materials and finished goods, environmental and building structure criteria, purity of water supplies, and so forth.

FDA also maintains standards of identity and fill of container for canned tuna which designate such things as the species of fish and the parts of it that may be labeled as tuna, the colors (white, light, dark, blended), the form (solid, chunk, flaked, grated), the packing medium (olive oil, other vegetable oils, water), and seasonings,

flavorings, and chemicals permitted, together with labeling requirements. The five species most commonly canned are known by the common names bluefin, albacore, bigeye, yellowfin, and skipjack, and only albacore has loin meat white enough to permit labeling as white.

Although the problem of tuna decomposition seems under relatively good control, FDA is scanning the horizon to the extent possible for problems that may emerge with all seafood products. Shrimp, for instance, requires constant attention. Canned shrimp is exceeded in unit sales only by tuna and, unlike tuna, shrimp is marketed in several other forms. There has been a substantial increase in 1974 in detentions of frozen decomposed shrimp offered for import, and FDA feels the problem could become a significant one because of a recent shift in international trading patterns.

Japan, which formerly imported large quantities of shrimp from Latin American, Caribbean, and Asian countries, began during the world energy crisis to concentrate more of its import purchases on oil with a corresponding decline in shrimp imports. Some of the countries that had been exporting shrimp to Japan, to continue marketing their catches, have turned to the U.S. market, where standards of quality and sanitation for shrimp are considerably different from Japan's. Another part of the current problem is that in some trawling areas of the world recently shrimp fishermen beset by fuel shortages have spent 2 to 3 days longer than normal on each fishing trip, bringing in catches larger than before but not as fresh. The larger catches have added to the problem by stretching overseas processing and freezing operations beyond their usual capacity.

To make sure that all shrimp marketed in this country continues to meet our standards, FDA is planning during this fiscal year to conduct a special course in organo-

leptic examination of shrimp. The course will be open to participation by shrimp industry and government representatives from exporting countries, and one country has already voiced interest in learning more about FDA's requirements. The potential for spoilage of shrimp is always present because a large part of the catch comes from warmer waters and because a great many shrimp fishermen are small operators not equipped with modern on-board freezing facilities.

Besides canned products, FDA analysts examine fish and other seafoods in a variety of forms: fresh, fresh frozen "in the round" (whole), partially or completely dressed, or in fillets; cooked and frozen (usually in breaded form); smoked; and mixed in recipes with other food products. Agency analysts once examined eggs for decomposition in plants which processed and froze eggs, but the U.S. Department of Agriculture now has sole jurisdiction over this activity under recent legislation covering poultry products. FDA analysts still may examine frozen eggs in food processing establishments such as bakeries which use them as ingredients in other products. They also may smell (and taste) certain dairy products such as butter and cream used in some food processing plants.

FDA continues to look for more scientific means to detect decomposition in seafoods, and one analytical chemistry method for determining decomposition in shrimp has reached the "first action" level of acceptance by the Association of Official Analytical Chemists, meaning it is now also acceptable as evidence in regulatory actions. Whatever future scientific methods are developed, they will supplement but are not likely to replace human noses, especially those to which FDA's organoleptic specialists are attached.

Harold Hopkins is editorial director of FDA CONSUMER.

A few commonsense rules, if followed by the pet owner in selection of dog and cat foods, can bring improved nourishment and often savings in the pet food budget.

Many dog owners hold erroneous beliefs about dog foods. Among the most common mistaken beliefs:

- That all dogs need high-protein products.
- That dogs need all-meat diets.
- That canned, moist, and semi-moist products are superior to dry products.
- That rich foods are good for older animals.
- That "finicky eaters" cannot or should not be trained to accept a different food (that may be better balanced).

Equally disadvantageous, many pet owners fail to consider the following principles (which apply generally to humans as well as dogs and cats) when planning pet diets:

- It's possible, through careful selection, to provide appealing and nourishing food at low cost.
- Well-balanced diets depend on a variety of ingredients.
- Certain stages of life or conditions of health require certain nutrient compositions.
- Serving too rich or too much food can lead to a variety of medical problems and can cause premature death.

About Protein

Dogs require high-protein diets only in five stress situations: puppyhood (up to about 6 months); pregnancy (protein requirements don't increase until after the sixth week) and nursing; hard work or stress; extremes of climate; and recuperation from major medical problems.

Although it's vital that these conditions be accompanied by

increased protein, it is equally important NOT to provide excessive protein otherwise for dogs. High protein consumption is suspected of contributing to an increasing rate of urinary tract problems, including cystitis, kidney disease, and calculi.

Protein, like any other ingredient, will vary in percentage of a specific ration depending on the percentage of moisture in the formulation. The National Academy of Sciences/National Research Council (NAS/NRC) has recommended the following minimum protein levels in various dog foods:

	Total Dry Basis	Dry Type Product	Semi Moist Product	Canned Product
Moisture Level Percent	0	10	25	75
Protein Percent	22	20	16.5	5.5

A Nutrition Guide For Pet Owners

Many misassumptions exist about the nutrient content of dog and cat foods and the nutrition need of these animals. This guide explains what dog and cat owners should know about such foods.

by Jane Heenan





Most commercial dog foods today supply enough protein. But pet owners should check the "guaranteed nutrient analysis" statement on the labels to see exactly what they're getting. Regular dry foods (those not formulated for one of the five stress situations mentioned above) generally do not have more than about 20 percent protein; and most canned foods usually have between 8 and 11 percent. The difference between canned and dry is that moisture accounts for about three-fourths of the weight of the canned product. If analysis were made with the moisture removed, the canned product protein percentage would be about quadrupled.

When increased protein is called for, the change still isn't dramatic. For instance, a lactating bitch requires about 24 percent of highly digestible, good quality protein in

her diet. Puppies require around 27 percent. (Both of these percentages are figured on a dry weight basis; so, again, they can be divided by four for very moist canned food.)

The source of the protein is important, because it determines the digestibility and, therefore, usability. It's possible to maintain and rear dogs on proteins solely of *plant* origin. But in practice it's wise to include some animal protein, both to make the food more acceptable to the pet and to round out the types of amino acids supplied by different protein sources. Animal-source protein does not mean the consumer must buy meat or choose canned products; the ingredient list on most dry-type foods, for instance, reveals that meat meal or meat derivatives have been used in the formula.

Other sources of good protein for dogs and cats are eggs, milk, and

cheese. However, they may not always be digested well and can pose other problems. Except for pregnant or nursing or very young animals, eggs may provide too rich an addition to an otherwise well-rounded diet. But if eggs *are* being added, they should always be cooked, because raw egg white destroys the essential nutrient biotin. Raw yolk is safe, but it doesn't provide the protein.

Many owners feel they should give their pets a dish of milk. After a pet has been weaned, he rarely needs milk, and older pets may not be able to digest it well. Particularly in dogs, milk can produce diarrhea. But for cats, there seems to be no reason to discontinue serving milk, unless the cat doesn't tolerate it well. Although cats do not need milk after they have been weaned, they can be trained to continue to accept it and

may in some cases show a preference for it all their lives.

Cheese is a good protein source and is often used for rewards or "snacks." The usual pet food cannot, because of economics, include high levels of cheese in the formulations. Cheese is used primarily as a flavoring agent in a few pet foods. Shoppers who feel a cheese flavor is desirable may simply grate a bit on top of the regular food.

About 15 years ago, researchers established that cats have a uniquely high protein requirement—so high, in fact, that a proper cat food contains markedly excess protein for dogs. Cats need about 50 percent more protein than dogs; and it must be of good quality—in other words, of high biological value. For example, in protein from animal sources, muscle meat would be far more usable than connective tissue, unless the latter is sufficiently processed and supplemented with amino acids.

Compounding the feeding problem for cat owners is that cats, even though they need a great amount of protein, are also quite susceptible to kidney and bladder problems as they get older—particularly neutered male cats. Regular veterinary check-ups, about twice a year, should help to prevent problems.

Don't Avoid By-Products

Animal by-products can be some of the most nourishing ingredients in pet foods. Regulations have specified what can and cannot be contained in by-products. Permitted are lungs, livers, spleens, kidneys, brains, stomachs, intestines, and fat and lean trimmings. Not allowed are intestinal contents, hooves, bones, hides, and horns.

Some people reportedly have been buying pet food for their families to save money; consequently, questions have been raised about the safety of this practice. The inclusion of by-products, some esthetically repugnant to many people, is one of the major objections to human use of pet food. Such consumption, however, does not pose a well-

defined health problem. In fact, all ingredients in canned pet food will have been processed according to specified temperatures and cooking times to render pathogens nonviable.

The major difference between pet food and food prepared for humans is that entirely different sources of ingredients may be used for the two products. Meat and bone meal derived from animals that have died other than by slaughter are commonly used in pet foods but not in human foods. Because of high cooking temperatures, the products should not pose a health problem. But regardless of the lack of a threat to health, FDA does not condone consumption of pet foods by humans.

Canned vs. Dry Food

Nutritionally, canned foods are generally not superior to dry types of food. Palatability is a decided plus factor for the canned ration. But many generations of animals have been raised on "complete and balanced" rations of both types of foods.

For cats, canned food is traditionally preferred—by both owner and cat. One reason that has been offered is that cats have always chosen to obtain most of their water supply from the food they eat and have, therefore, never been known as "heavy drinkers." Some scientists suspect cats may do better on moist food, although this has not been conclusively proved. At any rate, it is extremely difficult for owners to change a cat's dietary regimen against its will; although a cat may show signs of hunger—and actually be hungry—it possesses a remarkable ability to resist food it doesn't like, even for weeks. So, to a certain extent, owners do have to cater to their cats.

For dogs, dry food products are easily accepted. Commercial products are generally well formulated. The crunchy texture of dry food is appealing to most dogs and helps to clean teeth. Dry food is also easily digestible and produces firm stools.

Owners who wish to switch from

canned to dry food can usually do so easily by mixing the dry food with progressively smaller amounts of the canned food they are trying to phase out. Abrupt switches are possible, but may result in the first couple of meals being turned down. However, when really hungry, a dog will eat—and eat all it needs over about a 20-minute period. Continued refusal could be a sign of illness.

Relatively new and popular are the semimoist pet foods, packaged in individual servings. Although some animals seem to thrive on them, others find them indigestible. These products often have a high percentage of sugar and, since some dogs do not easily tolerate sucrose, diarrhea or vomiting may result. For maintaining product stability and preventing spoilage in this special packaging, a variety of nonnutritive additives are required.

Read the Label!

In choosing among moist, semi-moist, or dry food, what's listed on the label should be the consumer's main guide. To choose a food that will be acceptable to the pet, satisfy his nutritional needs, and also meet the family budget, a few minutes spent on comparison shopping is well worthwhile. Consumers should read ingredient listings and nutrient analysis statements on their favorite brands, then on the other brands, and even on the different flavors and varieties within each brand.

The first check should be the guaranteed analysis statement. Most State laws require this on the label. Here the shopper finds what percentage of protein, fat, fiber, and moisture are present; often ash and certain minerals are also part of the guaranteed analysis.

Cats and dogs require a high amount of fat in their diets. Under natural conditions, a cat obtains up to 60 percent of its calories from fat; dogs ideally should have around 10 percent or more fat in their diets.

The presence of animal fat also increases palatability for most pets. Some owners whose pets have dry skin problems have found it bene-





ficial to add one to two teaspoons of safflower or corn oil to the food. The advantage of the oil, as opposed to animal fat, is the presence of linoleic acid, which is essential for normal skin and coat development. Linoleic acid can also be purchased from pet stores in concentrated form.

Fiber provides some bulk and is usually present naturally in small amounts—around 5 percent for pet food.

Many pet foods contain cereal grains as a part of the total formulation. These, like their all-meat counterparts, may also qualify as “complete and balanced” pet food rations.

One term consumers often misunderstand is the statement of “ash,” which is really a statement of the mineral content. It came to be listed as “ash” because, when the food is tested for the percentage of minerals present, it is baked at high temperatures, and what is left—the ash—is the mineral content, which does not burn up. For most pet foods, this is around 8 percent dry weight. Not all of the ash is nutritive, since some minerals such as aluminum and silicon are naturally present in foods but not required by animals.

Calcium and phosphorus are the major nutrient minerals present in ash, and may also be listed in the guaranteed analysis. These are usually present at levels of about 1 percent of the diet for adult dogs, slightly more for puppies. Less is known about requirements for cats.

On ingredient listings, the consumer's best bet is to look for a wide variety of ingredients. Although he may not recognize the value of some of them, variety itself can be one indication that a manufacturer has tried to round out the types of protein and fat sources and the vitamin and mineral content. Whatever is listed first is the ingredient most prevalent in the product; what is listed last is present in the smallest quantity. So the order of the listing helps to size up the product.

Grains, legumes, and meat and bone meal are important sources of a variety of nutrients, and usually appear first in the ingredient list of pet foods. Fats and dairy products formulated to be acceptable to the pet are also of high value. No substance may be added that is not shown to be safe, and no indigenous substance may be present at levels ordinarily harmful to health.

Special Problems

Many pet owners today feel their cat or dog needs a vitamin or mineral supplement besides his regular food. But when regular diets supply all the vitamins and minerals in amounts known to be needed by the animal, supplements are unnecessary. They can be harmful if overused unless food intake is low due to illness.

Pregnant and lactating animals should receive supplements in the amount specified by the veterinarian. The veterinarian will normally not prescribe such supplementation until the last three weeks of pregnancy, at which time food intake is often doubled voluntarily by the animal.

Today's sciences makes possible the special formulation of diets for animals with certain medical problems. Particularly with the very old animal these may become necessary; but, again, they are prescribed—and normally sold—by veterinarians. These are special dietary foods not available on the grocery shelves. They come formulated for kidney problems, obesity, heart disease, liver disease, intestinal problems, and even for skin allergy. A main feature of the





last diet is that the meat will normally be mutton, which is a hypoallergenic meat.

What the Government Does

A small number of pet food firms are under U.S. Department of Agriculture inspection, and on their products you will see a USDA certification. This is a voluntary, continuous inspection program paid for by the manufacturer, who requests the program.

A number of products now on the market are labeled as a "complete and balanced diet" for dogs. This term is generally based on the guidelines of the Subcommittee on Canine Nutrition of the National Research Council. The NRC Committee has published a booklet titled "Nutrient Requirements of Dogs," which may be purchased from the National Academy of Sciences, National Research Council, 2101 Constitution Avenue, N.W., Washington, D.C. 20418. The publication, ISBN0-309-02042-3, Nutrient Requirements of Dogs, is now being reprinted, and the price is expected to be increased slightly over the former price of \$3.25.

Additional "complete and

balanced" claims may be based upon satisfactory feeding trials by the individual manufacturer, conducted under the feeding protocols developed by the Association of American Feed Control Officials (AAFCO).

Dog food labels bearing the term "complete and balanced diet" should be examined for limitations on use. Labels bearing this term should be carefully read for qualifications as to the class of animal for which the food is intended. These qualifications may pertain to growth, maintenance, reproduction, or lactation.

FDA's Bureau of Veterinary Medicine is working closely with the Pet Food Committee of AAFCO to assure that products labeled "complete and balanced diet" contain all the nutrients needed for proper maintenance.

Basically, FDA's responsibility for pet foods is to see that they are safe and unadulterated and have no misleading or false labeling. A major portion of inspection and enforcement comes from State and local officials. A large part of the work in checking labels, stimulating better advertising, and establishing voluntary regulations is done by the

AAFCO Pet Food Committee, made up of State regulatory officials.

AAFCO does not have regulatory enforcement authority as a body. Problems in advertising come under the authority of the Federal Trade Commission, to which consumer complaints about advertising should be directed.

Once Again

Consumers concerned about their pets should apply some of the same basic principles to their pets' diets and health that they do to their own. Overfeeding, underfeeding, or choosing food with little care can cause problems.

As with humans, overfeeding may result in fatty degeneration of the liver, a strain on the circulatory system, and heart disease.

Careful, informed shopping and twice-yearly veterinary checkups (and more if trouble is suspected) can stretch the life of the animal in whom much concern, love, and care have been invested.

Jane Heenan writes for
FDA CONSUMER.

Canning Industry Compliance Found Good

FDA decided to take a look at some of the most used low-acid canned foods to find out how well the canning industry is complying with regulatory requirements aimed at assuring a safe and wholesome product. The Agency's study found compliance very good indeed.

by Harold Hopkins

How well is the food canning industry complying with FDA requirements aimed at assuring safety, quality, and honesty in labeling—particularly that part of safety concerning low-acid foods, where the greatest possibility exists for contamination by deadly botulinum toxin?

This question is always implicit in the whole of FDA's regulatory programs concerning canned foods, but it seemed important to ask it once again in the wake of public concern over botulinum toxin found in some commercially canned mushrooms and the intensive FDA investigation which followed. Accordingly, FDA decided to survey the situation.

Other than the mushroom episode and an earlier one involving soup, there was no evidence at the time of a significant safety problem, nor of any problem at all concerning quality and economic deception. FDA nevertheless felt it ought to obtain a statistically valid picture of how well the entire low-acid canned food industry was complying with regulatory requirements through extensive sampling and analysis of several representative foods that are produced in large volume by many companies.

The answer, now available, is very well indeed, although some violations or other problems were noted in the results of the survey, published in 1974. The FDA survey as it concerns safety may be considered the forerunner of a planned program of continuous



sampling and analysis of canned low-acid foods in the retail market to determine the effectiveness of FDA programs and industry efforts to assure safe foods for the consumer.

The four canned foods chosen for the study were corn, mushroom soup, baby food carrots, and shrimp. Corn is the leading low-acid canned vegetable in sales. Mushroom soup is the leading low-acid, nonmeat canned soup, exceeded only by tomato and chicken noodle among all soups. Carrots are the leading low-acid, nonmeat baby food. Shrimp is second in canned seafood product sales to tuna, but tuna is already covered under other FDA compliance programs.

Two thousand containers of each product were collected by FDA from the various brands available in 10 major metropolitan areas. They were examined for compliance, where applicable, with the Fair Packaging and Labeling Act; for incubation in the container or by laboratory culturing (of the opened product) of bacteria and other organisms that thrive at near human body temperatures, as well as for integrity of the container against defects such as faulty seams and leaks; for decomposition of the food; net weight; filth and foreign objects; standards of identity and quality; pesticide residues; and for heavy (toxic) metals.

Examination of the shrimp samples was carried out by six State laboratories under contract. The other three products were examined by FDA laboratories.

The compliance ratings used in examining and scoring each product in the various categories were "excellent" (no defects or contaminants found), "good" (defects or contaminants either within range expected from good manufacturing practices or considered not to be of imminent concern), "poor" (defects or contaminants outside expected range or otherwise considered unacceptable), and "special" (defects or contaminants not of imminent concern but considered



worthy of further investigation).

The compliance status of all products as a whole was considered good. The only defects found requiring special consideration were the incidence of machinery mold in corn and lead levels in all products. Machinery mold is indicative of sanitation deficiencies. The lead levels, although not a cause for alarm, will be further considered by FDA within the overall context of lead intake by the consumer.

Fair Packaging and Labeling Act. All four products were classed as "good," and those failing to comply were more in the nature of technical violations than deliberate deceptions. Manufacturers concerned will be informed of deviations.

Incubation, culturing, container integrity. All products were classified "good." There was no evidence of underprocessing (inadequate heat). There were small percentages of container defects in all products. These problems will receive attention through inspections.

Decomposition. Corn, mushroom soup, and carrots were rated "excellent" and shrimp "good." A small amount of decomposition was found in 0.4 percent of canned shrimp.

Net weight. All products were rated as "good." The average for all weights was 103 percent of label declaration, though weights of the samples ranged from 80 to 136 percent of those declared on the label.

Filth and foreign objects. For freedom from filth, all were rated "good." Corn was rated "poor" for adulteration by machinery mold and FDA will emphasize plant sanitation in future inspections of corn canning plants.

Standards of identity, quality, and fill of container. Corn was rated "good" in this category and shrimp rated "good" in fill of container. This examination is not applicable to mushroom soup or carrots.

Pesticides. Corn was rated "excellent," no pesticides nor PCB's being detectable. Mushroom soup and carrots were rated "good" for freedom from pesticides and "excellent" for PCB's. Shrimp was rated "good" for both. The study's findings here will be integrated with other FDA monitoring activities.

Heavy (toxic) metals. All products were rated "good" as to freedom from mercury, cadmium, arsenic, and selenium. All were rated "special" with respect to lead, the range of lead for corn being 0-4.20 parts per million (average 0.35), mushroom soup 0-1.40 ppm (average 0.15), carrots 0-0.90 ppm (average 0.05), and shrimp 0.02-1.70 ppm (average 0.33). Further investigation will be made based on toxicological, technological, environmental, and epidemiological factors. The survey results for all products and for all metals detected will be integrated with other FDA programs and monitoring efforts.

Harold Hopkins is editorial director of FDA CONSUMER.

The Cyclamate Story

by Wayne L. Pines

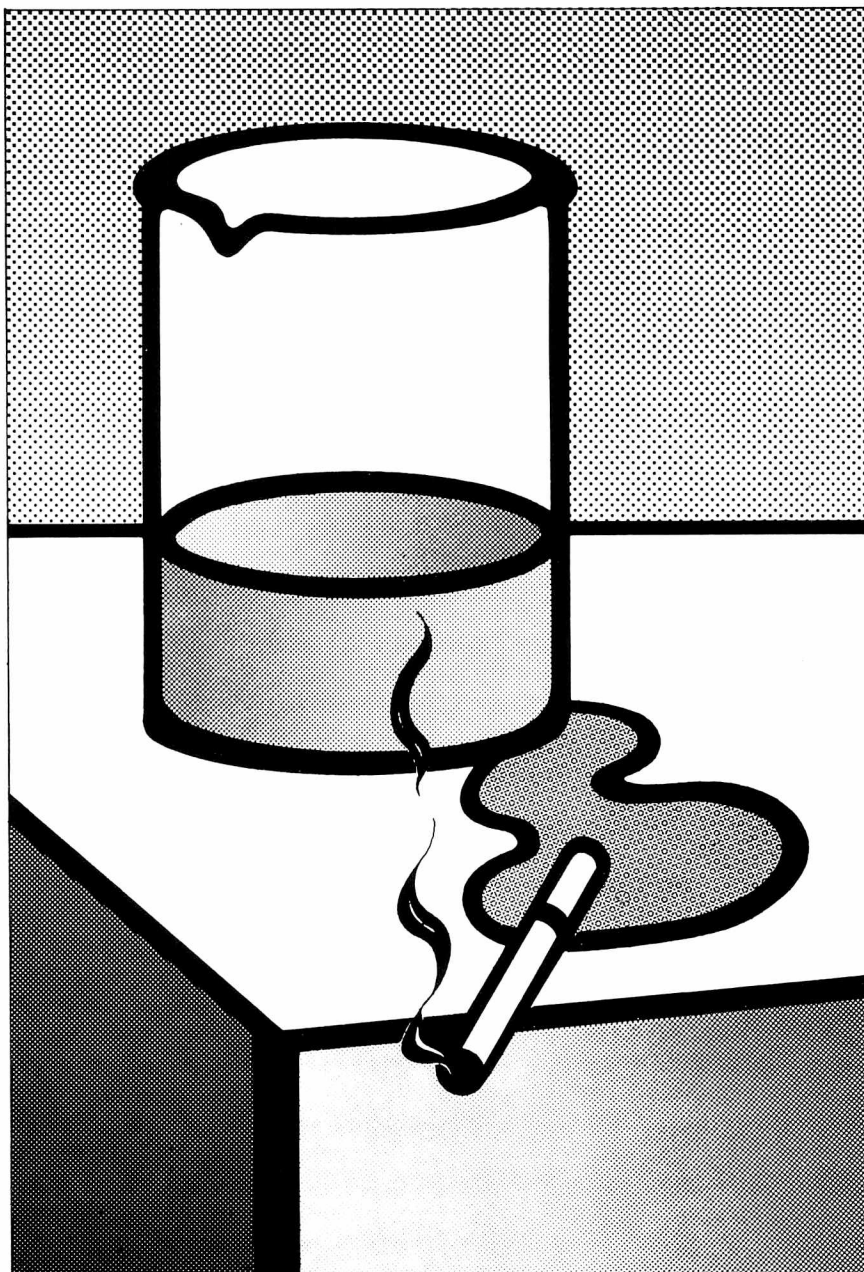
Cyclamate was once the basis for a billion dollar industry in this country, until its ban in 1969 by FDA. This past September, cyclamate again was in the news when FDA suggested that Abbott Laboratories, cyclamate's manufacturer, withdraw a petition to allow cyclamate to return to the market. This is the cyclamate story.

In 1937, Michael Sveda lit a cigarette while working at his laboratory bench at the University of Illinois. Sveda, a chemist, was working on a doctoral thesis about fever-reducing chemical substances.

Sveda put his cigarette down for a minute. When he picked it up, he was surprised to find it tasted remarkably sweet.

Sveda's scientific curiosity led him to taste the contents of all the beakers he was working with, until he found a dish of crystals which tasted extremely sweet. The compound he had just synthesized by accident turned out to be a forerunner of Sucaryl sodium, a cyclamate product that would be put on the market 13 years later by Abbott Laboratories.

Some of the history of cyclamate described in this article was based on an honors thesis written by Betty Jane Boneparth at Emory University in 1974 in partial fulfillment of her B.A. degree. The director of the thesis was Dr. James Harvey Young, professor of history at Emory.



Thus began the story of cyclamate, a story that is making news headlines even today, 5 years after the chemical accidentally discovered in that laboratory was banned by the Federal Government from the American food and drug supply.

The cyclamate saga is one of the most interesting and enlightening regulatory and scientific stories in the annals of the Food and Drug Administration. Cyclamate demonstrates how scientific standards and information may change over the years, and how a regulatory agency like FDA must act and react to these changes. It also illustrates how concern may change about the safety of items in the food and drug supply. Major amendments to the Food, Drug, and Cosmetic Act played a significant role in the development of the cyclamate story.

The introduction of cyclamate by Abbott in the early 1950's marked a new era in sweeteners. For the previous 60 years, the only sweetener available to use in place of sugar was saccharin. But saccharin leaves a bitter aftertaste with some people.

The advent of cyclamate, which had no undesirable aftertaste, led to the development of a host of artificially sweetened commercial products ranging from canned fruits and chewing gum to toothpastes and mouthwashes. These products were labeled for use only by diabetics and others who must restrict their sugar intake. But it was not long before a diet beverage craze of the early 1960's produced skyrocketing sales of cyclamate-sweetened products to a weight-conscious America.

The new development so concerned the sugar industry that, in 1964, Sugar Information, Inc., a trade group representing the sugar industry, became embroiled in an advertising and promotion race with the diet beverage industry,

each trying to persuade the public that its products were superior. By this time, cyclamate had become the staple of a billion dollar a year diet-product business.

FDA had played varying roles in assuring the safety of cyclamate from the very beginning of its marketing. In 1950, when Abbott proposed to market Sucaryl, it submitted test data to FDA purporting to demonstrate that cyclamate was safe as a drug "intended for use in foods and beverages by diabetics and by others who must restrict their intake of sugar."

FDA dismissed Abbott's petition, calling it "an illustration of how an experiment should not be conducted." But then FDA took the unusual step of conducting its own 2-year feeding study in animals to settle the question of whether cyclamate was safe for drug use. These tests indicated cyclamate was safe for its intended use, and FDA approved it. It was considered in the public interest that something besides saccharin be available for people who should avoid sugar. The only restriction was that Sucaryl had to be labeled "Should be used only by persons who must restrict their intake of ordinary sweets."

The relatively limited uses of cyclamate in the 1950's led the National Academy of Sciences-National Research Council's Food Protection Committee to conclude that cyclamate "need not be classified as an unsafe chemical on the basis of present evidence." The committee's only warning was that "at intakes of five grams or more per day cyclamate has produced a mild laxative effect." A consumer would have to use 100 Sucaryl tablets a day or drink 3 quarts of diet beverages to reach the 5-gram limit. The committee warned, however, that cyclamate should be subjected to continuing scientific observations.

Thus it was established that cyclamate could be used safely in

foods for special dietary purposes.

Then, in 1958, when Congress enacted the Food Additives Amendment to the Food, Drug, and Cosmetic Act, cyclamate was placed on a proposed list of substances that were "Generally Recognized As Safe." When FDA circulated its list to the scientific community, only one person out of 190 who commented on cyclamate suggested that there was not enough information to include it on the list. Lacking the necessary scientific support that would permit it to withhold cyclamate from the list and require further testing, FDA placed it on the "GRAS List." This marked the beginning of the uncontrolled use of cyclamate in the food supply.

Thus, by the end of the 1950's, cyclamate had become both a sweetener for use by people on special diets, and a substance that was added in generally unlimited quantities to any food. Between 1963 and 1967, the estimated consumption of cyclamate increased threefold, from 6 million pounds to 18 million pounds.

As the use of the artificial sweetener grew, the Food and Nutrition Board of the National Academy of Sciences-National Research Council revised its earlier policy statement to question the use of artificial sweeteners in weight reduction. That report, issued in 1962, questioned whether sufficient information was available to assure that such widespread and indiscriminate use of cyclamate was safe.

In 1965, however, FDA reviewed a host of scientific reports and concluded there was no evidence that use of cyclamate at levels existing at that time was a hazard to health.

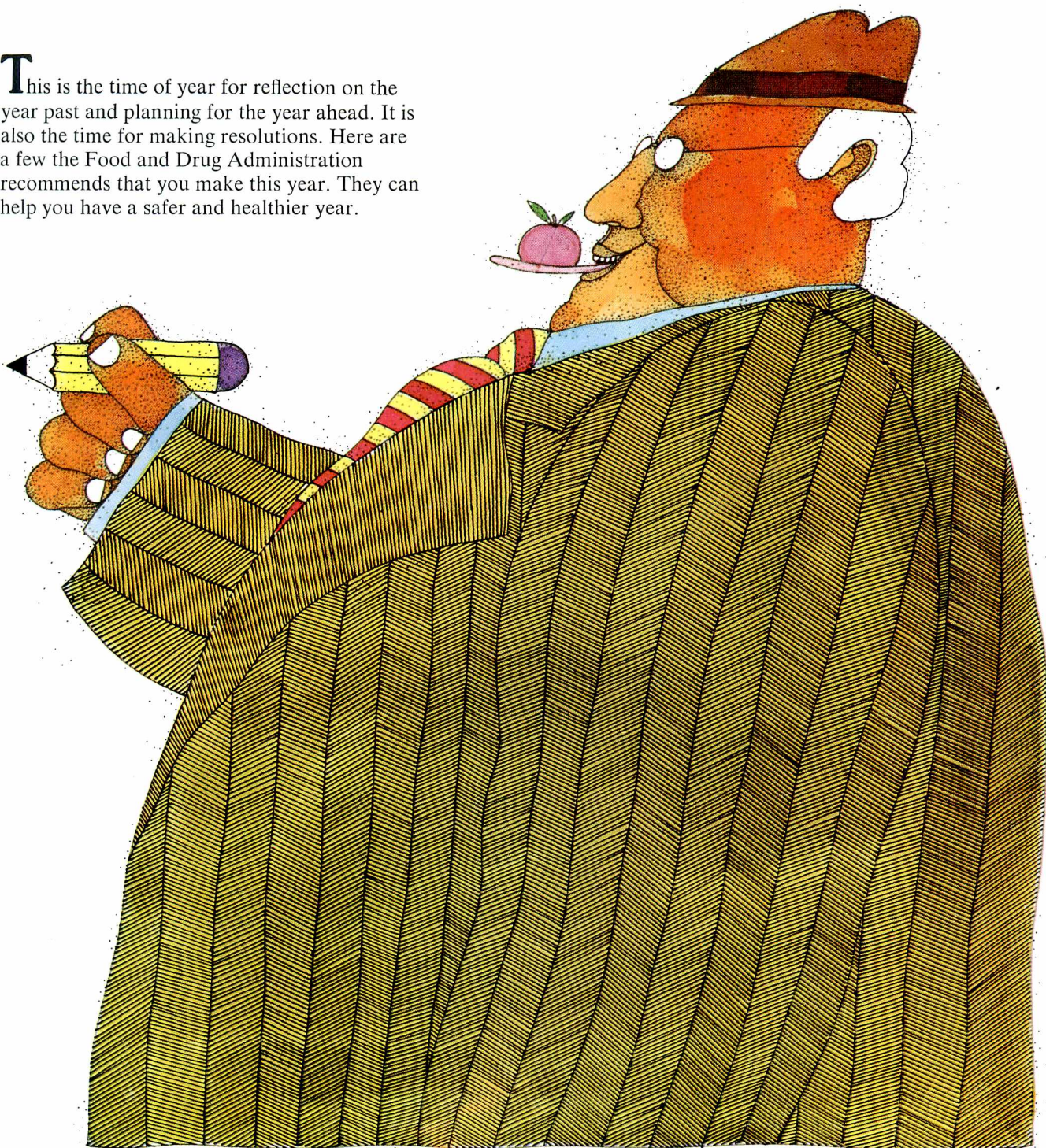
Increased use of cyclamate set off a series of claims and counter-claims between Abbott and the sugar industry, each sponsoring research purporting to demonstrate the superiority of its product over the other. One claim in particular



New Year's Resolutions For Health And Safety



This is the time of year for reflection on the year past and planning for the year ahead. It is also the time for making resolutions. Here are a few the Food and Drug Administration recommends that you make this year. They can help you have a safer and healthier year.





1. I will read the labels on all products before I use them. I will observe label directions and warnings.

The producers of consumer products spend millions of dollars to make labels informative and understandable. The Government spends millions more to monitor the accuracy of labels. FDA alone has undertaken some massive programs to improve and update the information on labels of products it regulates. Labels tell you what the product is or does, and how to use it correctly. It makes sense to read the label before you buy a product, and before you use it.

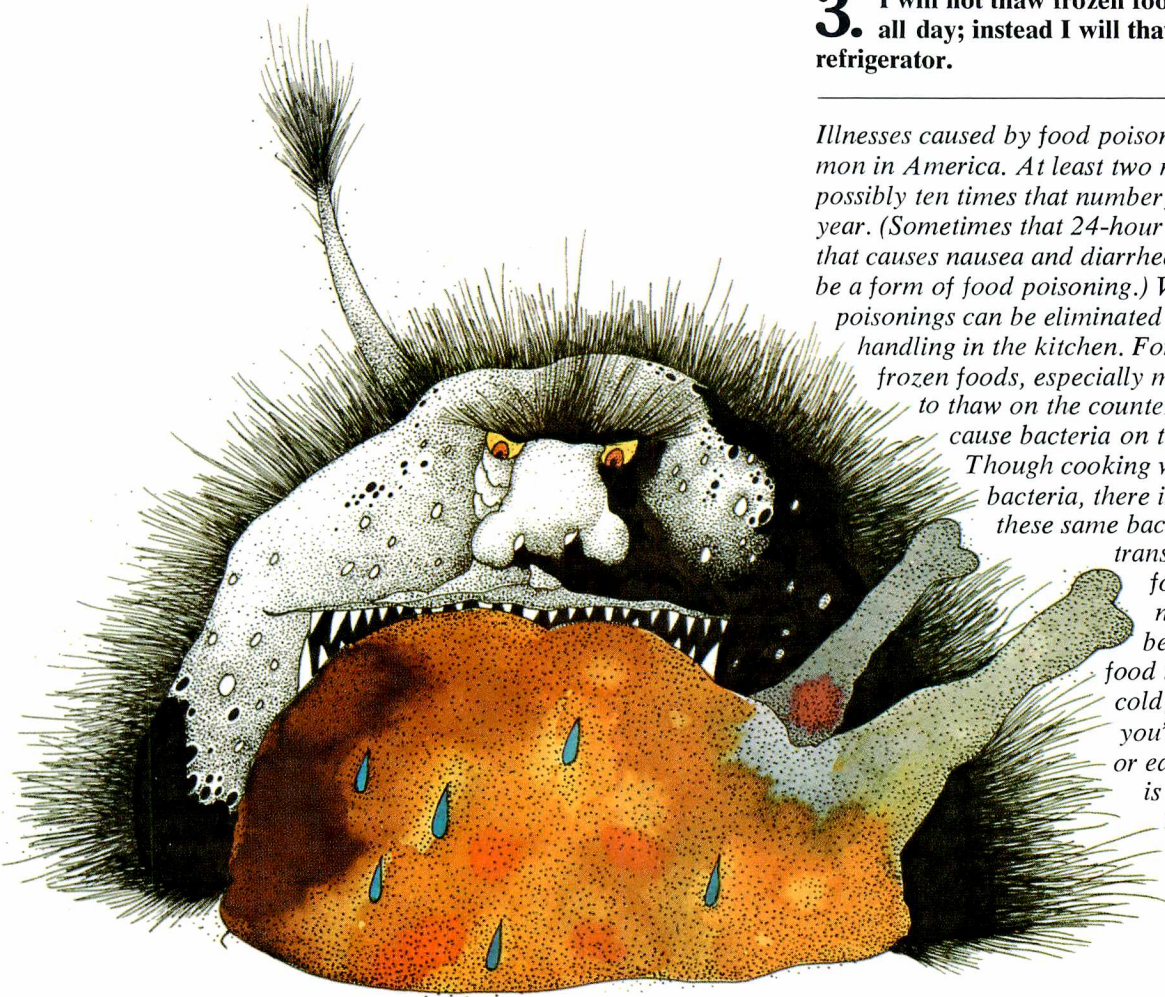
2. I will clean out my medicine chest and get rid of old medicines.

Medicines often stay in the medicine chest long after their usefulness has expired. Some medicines can keep for long periods; others deteriorate with time. Some prescription drugs such as antibiotics lose their potency within a matter of months. It is usually a good idea to go through the medicine chest once or twice a year to clean it out and destroy old medicines.



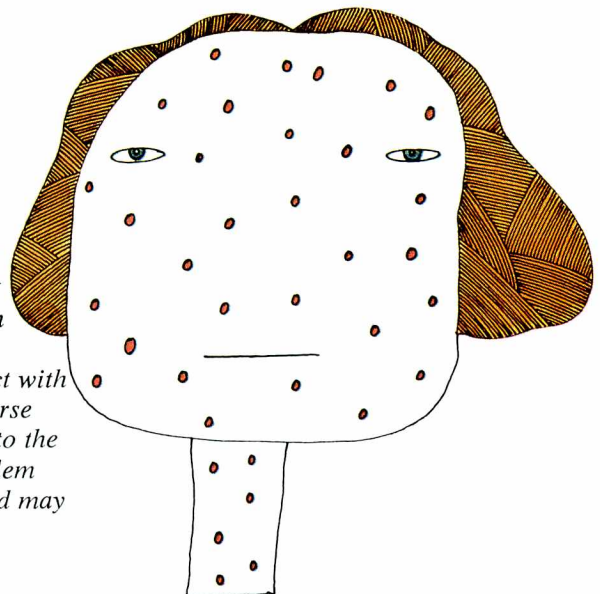
3. I will not thaw frozen foods on the counter all day; instead I will thaw them in the refrigerator.

Illnesses caused by food poisoning are common in America. At least two million cases, and possibly ten times that number, occur each year. (Sometimes that 24-hour "bug" you have that causes nausea and diarrhea may actually be a form of food poisoning.) Virtually all food poisonings can be eliminated by careful food handling in the kitchen. For example, leaving frozen foods, especially meats and poultry, to thaw on the counter all day can cause bacteria on them to multiply. Though cooking will eliminate the bacteria, there is a chance that these same bacteria can be transferred to other foods which are not cooked. The best simple rule: if a food is meant to be kept cold, keep it cold until you're ready to cook or eat it. And if a food is meant to be kept hot, keep it hot.



4. I will be careful with cosmetics and toiletries, and report any adverse reactions to the manufacturer and to FDA.

Cosmetics and toiletries can easily be taken for granted in terms of safety. But they shouldn't. It always pays to use any product with caution and with safety in mind. If an adverse reaction does occur, it should be reported to the manufacturer and to FDA. The same problem may be occurring with other consumers and may require some action by the manufacturer or FDA.



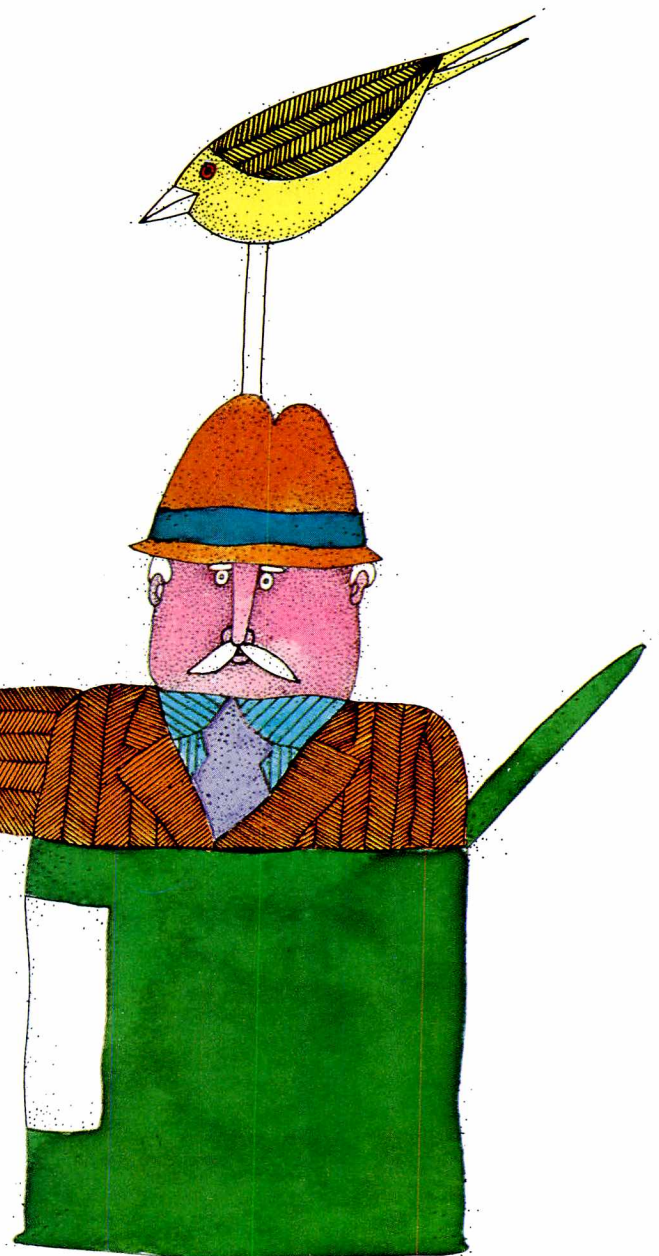
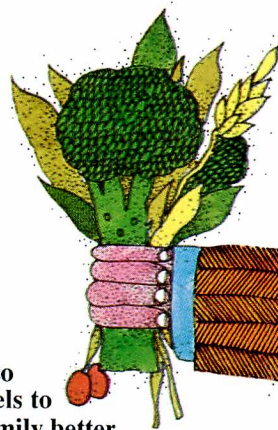
5. I will take medicines only when necessary.

There is growing evidence that Americans take too many medicines, both prescription and nonprescription. Medicines are double-edged swords. They are helpful when we become ill, but they also can cause side effects. Some can become habit-forming. Medicines should be taken only when needed to alleviate a symptom or cure an illness. Let your doctor know you do not expect a prescription every time you visit, and use only those nonprescription drugs you need.



6. I will learn how to use nutrition labels to feed myself and my family better.

Hundreds of foods now are labeled with nutrition information. Nutrition labels list how much protein, carbohydrate and fat are in one serving of the food, and what percentage of the United States Recommended Daily Allowance for protein and seven vitamins and minerals are in a serving. It takes only a few minutes to learn what types of information are on the label and how they can be used, to save money and to plan better-balanced meals.



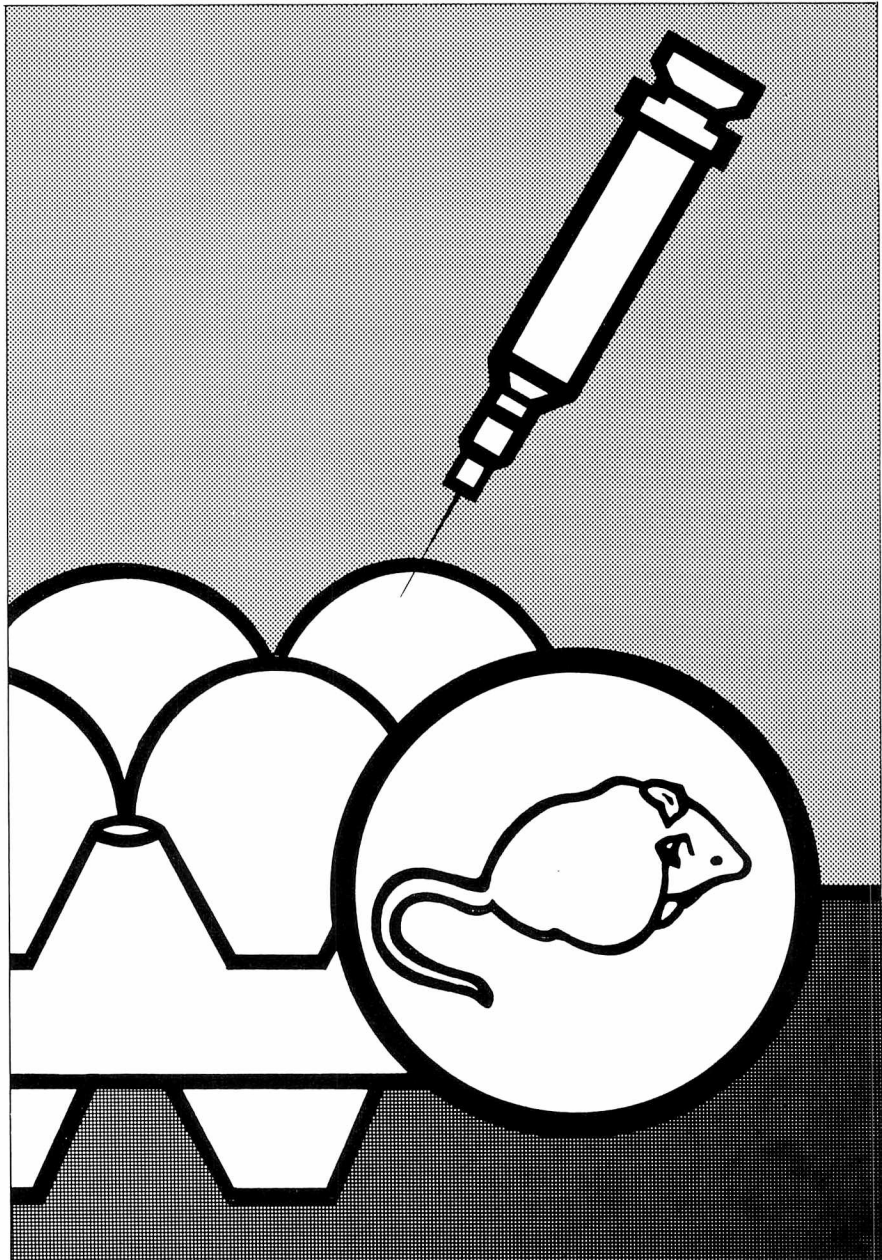
The Cyclamate Story (continued from page 20)

raised some eyebrows: Abbott's statement that cyclamate could not pose any danger to its users, since it was not metabolized in the body. Abbott's assurance that "cyclamate is simply excreted as cyclamate" was proved inaccurate in 1966 by two Japanese scientists, who discovered that a chemical called cyclohexylamine, a metabolic product, was found in humans and dogs following their ingestion of cyclamates. In later experiments, these two scientists reported that some humans who ingested cyclamate also excreted cyclohexylamine.

This finding was significant, because FDA had moved to restrict the use of cyclohexylamine in 1958 after scientific evidence showed that it could cause dermatitis and even lead to convulsions when inhaled or when applied to the skin. A host of experiments following the Japanese discovery was aimed at determining just what relationship existed between cyclamate and cyclohexylamine, and the importance of the metabolization of cyclamate to cyclohexylamine in the body.

These research projects were sponsored by Abbott and by the sugar industry. The results were conflicting, depending on who was sponsoring the study. An Abbott spokesman summed up the conflicting results by pointing out: "It's a case of experts looking at the same picture and seeing different things."

Clearly, an arbiter was needed to sort out the "facts." FDA asked the National Academy of Sciences-National Research Council in 1968 to perform the role of judge by forming a committee to evaluate the data and make a new appraisal of artificial sweeteners, including saccharin and cyclamate. That report was due in late 1968, but in the meantime, additional experiments were revealing new results, including some interesting consequences of the ingestion of cyclamate. For example, one researcher



found that small amounts of cyclamate interfere with the absorption in the body of the antibiotic lincomycin hydrochloride.

In November 1968, NAS/NRC's report to FDA reaffirmed its previous position that up to 5 grams of cyclamate per day posed no hazard to an adult. But the report cautioned against unrestricted use of

cyclamate, and called for further studies. At the same time, FDA staff members prepared a summary of existing work which urged a stronger stance by FDA restricting the use of cyclamate. In December 1968, FDA cautioned the public to limit its intake of cyclamate to 3.5 grams for 75 kilograms (165 pounds) of body weight, but said

there still was insufficient evidence to change the regulatory status of cyclamate.

On April 5, 1969, FDA proposed new label requirements for food products containing cyclamate, including a caution that an adult should not ingest more than 3.5 grams a day, and children not more than 1.2 grams. The regulation also proposed that not more than 25 parts per million of cyclohexylamine be permitted in food-grade cyclamate.

The work of two FDA scientists then going on continued to focus public attention on cyclamate. FDA biochemist Jacqueline Verrett was an expert in an extremely sensitive technique, the injection of substances into fertile chicken eggs to determine their effects. She found deformities in the embryos taken from eggs injected with cyclamate.

Meanwhile, Marvin Legator, then chief of FDA's Cell Biology Research, was finding that the chemical to which cyclamate metabolized in the body, cyclohexylamine, caused breakage in a significant proportion of chromosomes of test animals studied.

The FDA regulation restricting cyclamate proposed in April 1969 was not made final. Other evidence being gathered led later in 1969 to more drastic regulatory action. These studies concerned the possible involvement of cyclamate in causing cancer. Although initial testing for cancer in the early 1950's had revealed no cause for alarm, the newer testing procedures available in the late 1960's made earlier test methods obsolete.

By June 1969, scientists at the University of Wisconsin reported to Abbott that they had found a significant incidence of bladder tumors in two experiments with white Swiss mice. Abbott communicated these findings to FDA and the National Cancer Institute. Neither felt that the tests were relevant to the haz-

ards of cyclamate ingested by humans. But the studies encouraged scientists to give special attention to the bladder as a possible site of cancer.

In the second week of October 1969, the results of still another Abbott-sponsored study, this one at the privately owned Food and Drug Research Laboratories in New York and the Industrial Bio-Test Laboratories in Illinois, were reported. The New York research found bladder lesions in rats that had been fed a mixture of cyclamate and saccharin in a ratio of 10 to 1, the ratio found in many soft drinks. Half the tumors found were cancerous. In addition, this research showed that many of the 240 rats in the test were able to convert cyclamate to cyclohexylamine in the body.

The Illinois laboratory reported on results of an experiment in which cyclohexylamine was fed to rats at various levels over a 2-year period. One tumor was found in the bladder of one of the rats.

Further evaluation of this evidence was made by officials at Abbott, FDA, the National Cancer Institute, and the Department of Health, Education, and Welfare, FDA's parent organization. All the findings were submitted to the NAS/NRC on the morning of October 17. That afternoon, the NAS/NRC scientists recommended that cyclamate be removed from the GRAS List.

The next day, HEW Secretary Robert Finch ordered the recommendation into effect. This decision was based on the so-called Delaney Clause of the Food, Drug, and Cosmetic Act, which prohibits the use as a food additive of any chemical found to induce cancer in man or animal. Secretary Finch ordered a phase-out of existing supplies of cyclamate-containing products.

The announcement, however, did not mean a total ban on cyclamate. Secretary Finch said that cyclamate could still continue to be available

to people whose health depended on it. In other words, cyclamate could still be available as an over-the-counter drug to people who for medical reasons could benefit from it. This was permissible because the Delaney Clause applied only to foods, not drugs.

In June 1970, Congressman L. H. Fountain of North Carolina, chairman of the House Intergovernmental Operations Subcommittee, convened hearings to investigate the cyclamate case. At the hearings, FDA failed to show to Representative Fountain's satisfaction that cyclamate was either safe or effective as a drug.

Representative Fountain wrote to Mr. Finch's successor at HEW, Elliot L. Richardson, saying he believed the orders declaring cyclamate a legitimate drug were illegal. He urged that FDA rescind its decision to allow continued use of cyclamate.

In August 1970, FDA's medical advisory group on cyclamates considered all the existing evidence and decided that cyclamate could not be considered safe and effective as a drug. FDA then ordered *all* cyclamate-containing products banned as of September 11, 1970.

Many companies claimed they had been caught by surprise by the ban. For example, food canners felt they were complying with the latest FDA directive when they, in early 1970, began canning fruits sweetened with cyclamate with the intention of selling them for use as drugs. In April 1972, a bill was introduced in the House to reimburse the growers and canners for their losses. The bill passed the House but got nowhere in the Senate.

Since then, cyclamate has not been used in foods and drugs in the United States.

The cyclamate story resumed on November 15, 1973, when Abbott submitted to FDA a petition to permit the use of cyclamate as a sweet-

ening agent in foods for special dietary use and for specific technological purposes. The petition was made available for public examination on February 8, 1974.

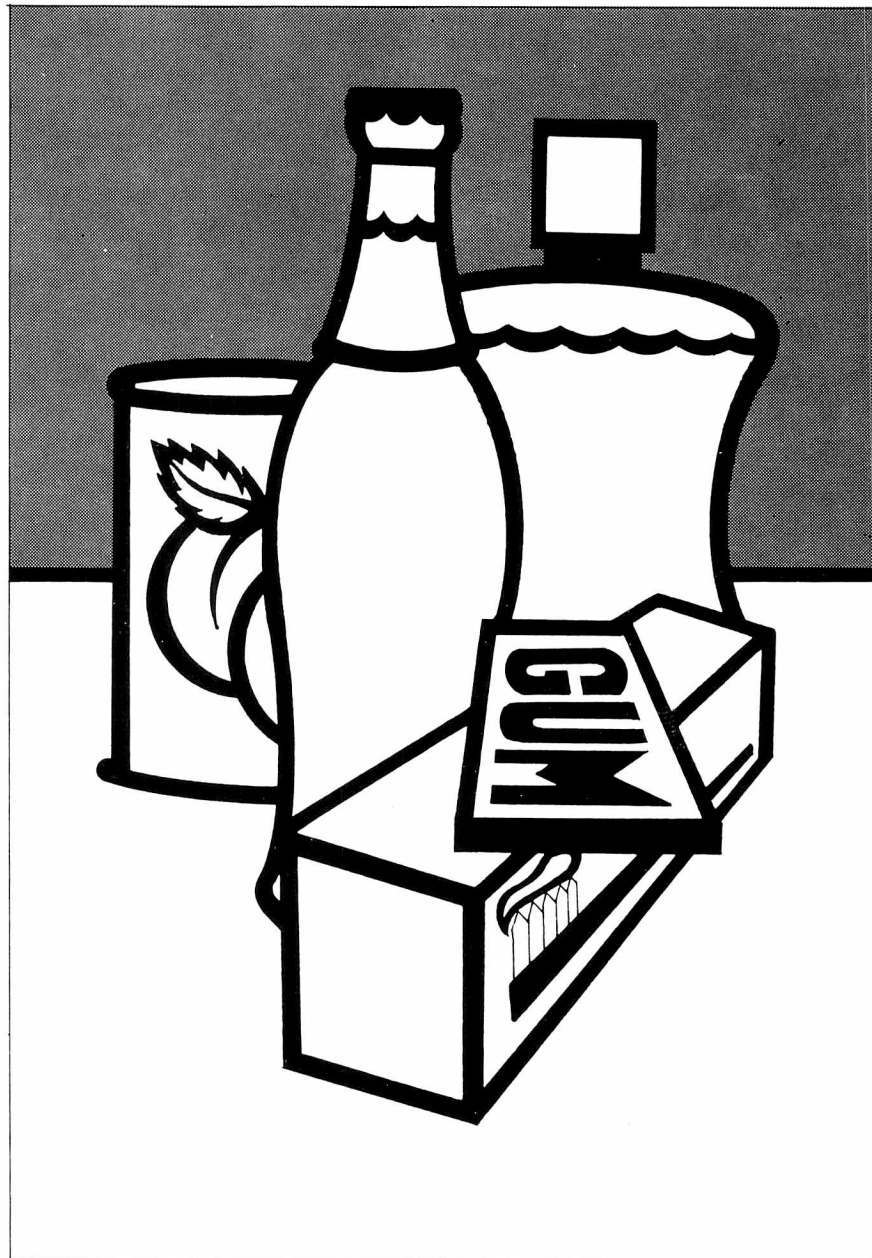
Abbott presented to FDA reports of studies conducted after 1970. Included were several long-term animal feeding studies. In all, more than 300 individual reports on toxicology were submitted in Abbott's petition.

The petition was evaluated by a team of FDA scientists including chemists, toxicologists, and pharmacologists experienced in judging the safety of ingredients added to foods. The team concluded that the petition did not contain the information necessary to support a finding that cyclamate is safe when used as an artificial sweetener. FDA asked Abbott in September 1974 to withdraw the petition until additional data could be provided.

In announcing the Agency's decision, Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, said: "We have concluded that questions about the cancer-causing potential of cyclamate are yet to be resolved. Further information is needed before a clear-cut decision on the safety of cyclamate can be made."

FDA described to Abbott the additional scientific data which would be required before the Agency could make a decision on the petition. Included is a rat-feeding study for the lifetime of the test animals to resolve the question of cancer. FDA said the specific strain of rats, Osborne-Mendel, in which cancer-causing potential was first demonstrated in an earlier study, should be used. FDA also asked Abbott for additional data on possible effects on the reproductive organs and the cardiovascular system, and for further data on levels of use, stability, and assay methods.

FDA said that while the additional data requested of Abbott



"may seem formidable . . . FDA is of the opinion that it is well worth the scientific effort to decide in a very definitive way whether cyclamate can be safely used as an artificial sweetener."

So rests the cyclamate story. It will be at least 3 years before FDA again will consider the remarketing of cyclamate. This is the minimum

time it would take to accomplish the kinds of additional testing that FDA considers essential. If and when additional evidence is available to prove its safety as a food additive, another chapter in the cyclamate story will be written.

Wayne L. Pines is editor of FDA CONSUMER.

News Highlights

Nut-Me-Ta Sandwich Filler Being Recalled Because of Spoilage From Underprocessing

FDA has advised consumers of the recall of 16-ounce cans of Nut-Me-Ta Sandwich Filler, a meat substitute manufactured by Tennessee Hills Foods, Inc., Dunlap, Tennessee.

The recall was undertaken after the company noted that spoilage had developed in some cans being stored in a warehouse. Subsequent inspection by FDA confirmed that the cans had been underprocessed. Underprocessing could result in the growth of micro-organisms in the can and create a potential health hazard.

The product was last manufactured in July and a total of 495 cases, with 24 cans in a case, were distributed, primarily to health food stores and Seventh Day Adventist churches in the following States: Alabama, Arkansas, Florida, Georgia, Kentucky, Maine, Maryland, Massachusetts, Michigan, Mississippi, New York, N. Carolina, Ohio, Pennsylvania, S. Carolina, Tennessee, Virginia, W. Virginia, and Wisconsin.

Although few cans are likely to remain on retail shelves, FDA advises consumers who may have cans of Nut-Me-Ta Sandwich Filler in their homes not to eat or throw them away, but to return them to the store where purchased.

Consumers Warned Against Two Arthritis Remedies Being Recalled Because of 'Aspirin Free' Claims

FDA has cautioned consumers not to use two newly introduced arthritis remedies labeled "Aspirin Free Arthritis Pain Formula" and "Saloxium Analgesic/Anti-Inflammatory Tablets." Both products were produced by Whitehall Laboratories of New York City, and are being voluntarily recalled from the market at FDA's request.

The products contain the pain reliever "salsalate," which converts to sodium salicylate in the body. FDA is concerned that consumers may use these drugs as an addition to aspirin or other salicylate because both are labeled "Aspirin Free." Such concurrent use with other salicylates could lead to serious salicylate toxicity. FDA also believes that the use of these products without knowledge that they contain a salicylate could lead to excessive bleeding in patients receiving anticoagulant therapy such as sodium warfarin.

Young children may also be particularly at risk if they should accidentally swallow the contents of the bottles. FDA fears that physicians or Poison Control Center staff members might not recognize that over-dosage of the little known listed ingredient, salsalate, can produce salicylate poisoning, and that treatment

should be the same as for aspirin or salicylate over-dosage.

The long, rounded tablets (both products) are nearly identical in name and appearance to another Whitehall product which does contain ordinary aspirin and is so labeled—"Arthritis Pain Formula." This product is not being recalled.

The nationally distributed "Aspirin Free" products being recalled were recently introduced and may not be available in all stores. The Saloxium product is being test marketed in Boston, Dayton, Houston, and Seattle. Both products are available in 24- and 100-tablet bottles. It is FDA's position that the products, as labeled, are new drugs which were introduced to the market by Whitehall without seeking approval from FDA prior to marketing.

FDA learned of the drug hazard through a complaint by a professor at the State University of New York at Buffalo and through a Midland, Pennsylvania, pharmacist who alerted the Agency through the FDA Community Pharmacists Drug Defect Report system.

'Lytren Oral Electrolyte Solution' Recalled In Puerto Rico Because of Defective Seals

FDA has advised consumers in Puerto Rico of the recall of all lots of "Lytren Oral Electrolyte Solution", a drug used for the treatment of infant diarrhea, vomiting, or dehydration. The product, manufactured by the Mead Johnson Company, Evansville, Indiana, is packaged in one quart cans. The recall of all lots was announced October 24 and superseded a partial recall announced October 18.

The recall was initiated after the company learned that some cans had defective seals. Further investigation by the company disclosed that this defect could cause the presence of bacteria, yeast, and mold in the cans. Infant ingestion of these contaminants may be hazardous.

"Lytren Oral Electrolyte Solution" is normally used on the advice of physicians. It is available over the counter in Puerto Rico, and a prescription is not needed for purchase.

FDA advises consumers who may have the recalled product in their homes not to use it or throw it away, but to return it to the store where purchased.

Burdock Root Tea Brand Being Recalled Because of Adulteration by Atropine

FDA has advised consumers that all six-ounce bags of "Golden Harvest Old Fashioned Burdock Root Tea" are being recalled because traces of the drug atropine

have been found in the product. It is not known how this drug, which acts upon the central nervous system, got into the tea. The recall was initiated after two people in Colorado became ill from drinking the tea. Burdock is a plant in the cocklebur family.

Samples of the tea analyzed by FDA have shown atropine contamination at levels to 310 parts per million (ppm). Such levels could present a potential health hazard to children and to the infirm or elderly.

The product, imported by the S. B. Penick Company, New York, is packaged and sold nationally by the General Nutrition Corporation, Pittsburgh. The tea is sold by mail order and in health food stores. All mail order customers and retail stores handling the product have been notified of the recall. Some 600 bags of the adulterated tea are at present unaccounted for.

FDA advises consumers who may have "Golden Harvest Old Fashioned Burdock Root Tea" in their homes not to drink it or throw it away, but to return it to the place where purchased.

FDA, Treasury Agency Sign Agreement On Labeling for Alcoholic Beverages

The Food and Drug Administration and the Department of the Treasury Bureau of Alcohol, Tobacco and Firearms (ATF) have signed an agreement defining how labeling regulations for distilled spirits, wine, and malt beverages will be handled. The major provisions of the agreement:

1. ATF will have primary responsibility for the promulgation and enforcement of labeling regulations for alcoholic beverages.
2. Such regulations will be consistent with the food labeling requirements of FDA.
3. ATF regulations will also be consistent with FDA's directives and interpretations regarding any ingredients used in distilled spirits, wine, and malt beverages.

The memorandum of understanding was published in the *Federal Register* of October 8, 1974.

FDA to Require Disclaimer of Efficacy In Obesity on Labels of HCG Hormone

FDA has announced it intends to require producers of a hormone used by "fat clinics" to say that there is no evidence the drug is useful in the treatment of obesity.

This hormone is HCG (Human Chorionic Gonadotropin). FDA is concerned about its widespread and growing use in the treatment of obesity at weight-loss clinics in major cities throughout the United States. The safety and effectiveness of HCG for obesity have not been established.

Beginning in 60 days, FDA will require the following statement in the labeling and advertising for all preparations of the hormone:

"HCG has not been demonstrated to be effective adjunctive therapy in the treatment of obesity. There is no substantial evidence that it increases weight loss beyond that resulting from caloric restriction, that it causes a more attractive or 'normal' distribution of fat, or that it decreases the hunger and discomfort associated with calorie-restricted diets."

No adverse reactions to this use of HCG have been reported, probably because the dose for obesity is low compared to the dose for other uses. However, FDA emphasizes strongly that any active drug may have unexpected adverse reactions.

FDA's position on use of a drug is that it be given only when there is good evidence of effectiveness. In the case of HCG, not only is there a lack of evidence of effectiveness, but there is not even a scientifically plausible rationale to explain how it could influence bodily fat distribution and the sense of hunger and discomfort that results from dieting, as its proponents claim.

HCG does have several effective uses, so it will remain available for physicians to prescribe. Its most important use is in stimulating ovulation, thus permitting pregnancy in certain infertile women. It is used in conjunction with another hormone in that treatment.

New labeling for HCG listing permitted claims appeared in the *Federal Register* of December 5, 1974. Makers of the drug were given 60 days from that date to request a hearing before the new obesity disclaimer requirement takes effect.

Reminder To Manufacturers On Saccharin Limitations

The Food and Drug Administration has reminded beverage and food manufacturers that the artificial sweetener saccharin cannot legally be used as a substitute for sugar unless certain prescribed conditions are met.

FDA has instructed its inspection force to take action against any illegal product encountered and has advised State and local food and drug officials to be alert to improper use of saccharin.

The only legal uses for saccharin are in foods offered for calorie control and labeled as such, or certain technological uses. Sugar can be legally combined with saccharin only in diet beverages or beverage bases. In those cases, the calorie content must be at least 50 percent less than in a similar product made exclusively with sugar and may not exceed 6 calories per fluid ounce.

Whenever it is used, the presence of saccharin must be clearly and completely labeled so consumers are aware that it is in the food.

The safe uses of saccharin were established by FDA in February 1972, based on a recommendation of the National Academy of Science/National Research Council to limit intake to 1 gram per day for a 155 pound adult. The restrictions were imposed at that time to assure that use of saccharin would not be expanded beyond the acceptable levels.

Effective Date of New Food Labeling Regulations Postponed Six Months to Ease Industry Hardships

FDA has granted the food industry six additional months to comply with its 42 related new food labeling regulations developed in a comprehensive program to provide the consumer more and better nutrition information about food products. The regulations which were to become effective as of December 31, 1974, will now become effective on June 30, 1975.

In announcing the extension, Dr. Alexander M. Schmidt, Commissioner of Food and Drugs, said there are two considerations: (1) the President's directive to weigh the impact of new legislative proposals and regulations on inflation, and (2) the plight of a small percentage of food companies faced with packaging, processing, and inventory problems because of current adverse economic factors.

"Short of compromises with safety," Dr. Schmidt said, "FDA will interpret the regulations as reasonably as possible to meet various temporary economic adversities, especially where those adversities are threatening shortages of essential products such as food."

Dr. Schmidt pointed out that an estimated 95 percent of food labels will be in conformance before the end of 1974. However, a significant number of companies, including some small businesses, would be unable to meet the December 31 deadline for all products affected by the regulations. This resulted from serious and unanticipated economic problems which have caused sales declines or slower than planned movement of some stocks.

"If these companies were forced to meet the December 31 deadline," Dr. Schmidt said, "many would be compelled to destroy valuable food, expensive containers and labels, thus incurring expenses which would be passed on to the consumer in the form of increased food costs."

Full details were announced in the *Federal Register* of November 14, 1974.

Roland Brand Canned Pimentos Recalled Because of Possible Underprocessing

FDA has announced the recall of "Roland Brand Whole Red Pimentos," packed in institutional-size cans for American Roland Food Corporation, New York City. The 4-pound cans, which would not normally be purchased by consumers, can be identified by the code letters "MT" embossed on one end of the can.

The recall was initiated after FDA analysis showed the products may not have been processed properly to prevent the growth of micro-organisms in the can. This could create a potential public health hazard.

The products being recalled were distributed to approximately 15 wholesalers in Georgia, Massachusetts, Vermont, Ohio, Alabama, Tennessee, New York, New Jersey, and Connecticut between April and August,

1974. A total of 273 cases, 6 cans per case, were shipped with the "MT" code.

FDA is unaware of any consumer injuries associated with these products. The recalled cans should not be used or thrown away, but returned to the supplier.

Green Beans Canned by New York Firm Being Recalled Because FDA Found Them Underprocessed

FDA has advised consumers of the recall of five codes of french-style green beans and wax beans processed by Lawton's Canning Company, Lawton, New York. The 8- and 15½-ounce cans being recalled are packed under five brand names with an identifying two line code embossed on the can.

The recall was undertaken after routine FDA inspection found that some of the beans canned in July, August, and September 1974 were underprocessed. Underprocessing may allow the growth of micro-organisms in the can and create a potential health hazard. FDA is unaware of any consumer injuries associated with this product.

The Agency urges all persons who have the recalled brands in their homes not to eat or throw them away, but to return them to the store where purchased.

Here is a list of the brand names and the codes involved in the recall. All known distribution was in Connecticut, Delaware, Maine, Massachusetts, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.

Brand Name	Code	Size Can
Food Club French Style Green Beans	FJL/208-4	8 oz.
Topco Associates Inc., Skokie, Ill.	FBL/208-4	15½ oz.
Suncrest French Style Green Beans	FJL/208-4	8 oz.
Gaer Bros. Inc., Hartford, Conn.		
Suncrest French Style Wax Beans	FLL/221-4	15½ oz.
Gaer Bros. Inc., Hartford, Conn.		
Finast French Style Green Beans	FJL/208-4	8 oz.
First National Stores, Somerville, Mass.		
Pathmark French Style Wax Beans	FLL/221-4	15½ oz.
Supermarket General, Woodbridge, N.J.		
Pathmark French Style Green Beans	FJL/236-4	8 oz.
Supermarket General, Woodbridge, N.J.	FBL/236-4	15½ oz.
Sweet Life French Style Green Beans	FBL/208-4	15½ oz.
Sweet Life Brands, Rochelle, N.Y.		

Regional Reports

REGION II

The New York State Board of Pharmacy has been asked by FDA's **New York District** to inquire into retail sales of crude yohimbine by Aphrodisia Products of New York City. This is an alkaloid substance from the yohimbé tree of Africa which has systemic pharmacological effects. It has been sold by Aphrodisia Products as an over-the-counter item to the general public, with no directions or precautions as to use.

Samples of surgical sutures tested by FDA's New York District were found to be nonsterile. The manufacturer, Deknata, Inc., of Queens Village, New York, voluntarily recalled two lots of sutures which may not have been properly sterilized, and changed its sterilization (Autoclave) process.

One sample of Geritone Tablets was collected by FDA inspectors at Evsco Pharmacal, Oceanside, New York, as an "unapproved dosage form of DES." It was from a lot of 313 bottles of 1,000 tablets each and had been manufactured and packaged by Leeds Dixon Laboratories, Inc., Moonachie, New Jersey. Evsco has indicated to the FDA New York District that it has discontinued the product and destroyed remaining lots.

A shipment of pistachio nuts from Iran, sampled by the U.S. Department of Agriculture on arrival in New York, was found to be contaminated with mycotoxin, the result of fungus growth. The entire 15,000 pounds was detained by the FDA **New York District's Import Section**, while a reconditioning company made two attempts to remove the mycotoxin. Sampling by FDA after each attempt showed mycotoxin still there, and also revealed that the nuts were heavily infested with insects. This placed them under an additional FDA detainer, and if both conditions are not corrected, the shipment will be refused entry or destroyed under U.S. Customs supervision. The larger problem seems to be that demand for pistachios has decreased in the U.S.; that there is a backlog building up in the producing countries; and that storage difficulties there lead to insect infestation.

The FDA Tea Examiner, Import Section, New York District, was told that tea chests in the cargo of the ship *Hellenic Challenger* may have become contaminated with asbestos and charcoal which spilled over the chests in transit. He has asked FDA in Houston and in Norfolk to inspect chests already unloaded from the *Challenger* for such contamination. Of 2,395 unloaded at

Galveston, Texas, more than half may have been contaminated with asbestos. Of 5,230 chests unloaded at Norfolk, 214 may have been contaminated with charcoal and 707 with asbestos. None can be released from the port holding area until their status has been determined.

A sampling of rutabagas from Canada was found by the Florida Department of Agriculture to have residues of the pesticide, chlordane. FDA's **Buffalo District**, which has long worked with Canadian officials, learned the rutabagas were from a grower in Ontario and were part of the 1973 crop, which is no longer on the market. Chlordane is a prohibited pesticide, and Canada will monitor that grower's production to ensure against further violations.

FDA's Buffalo District has detained mozzarella cheese offered for import from Canada because the labels did not accurately show the net contents. This has been a continuing problem with this particular Quebec manufacturer. The shipment most recently detained was 1,120 cases of part-skim mozzarella.

Six hundred cases (18,000 pounds) of raw shelled pecans were dumped and covered in a landfill near Jersey City, New Jersey, after a portion was found to be moldy. The pecans were stored by the National Cold Storage Company of Jersey City, to the account of Best Foods Division, CPC International, Wayne, New Jersey. FDA's **Newark District** noted the mold while inspecting the Best Foods Processing plant, and learned that the bulk of the lot was at the National warehouse. The State of New Jersey embargoed the stored pecans, then released them for voluntary destruction by the owner.

REGION III

Some 1200 persons attended an "Old Town Forum" on consumerism which was held in early October at the Federal Office Building in Philadelphia. The two-day event was organized by FDA's **Philadelphia District** and cosponsored by the city school system. The program included FDA films and exhibits, materials from FDA and other Government agencies, and general discussion of consumer topics. Public interest seemed to center on practical economics: fair packaging and labeling, net weights, value received for money spent. High school students constituted the largest percentage of persons attending, which reflects both school sponsorship and an interest in consumer subjects.

REGION IV

Coca Cola Bottling Company of Charlotte, North Carolina, recalled 16,392 32-ounce bottles of its product, after consumer complaints that bottle caps blew off when slightly touched. Atlanta Region officials of FDA met with company management, and a class II (potential hazard) recall was made voluntarily by Coca Cola. It began September 27 and was completed by October 3, 1974.

Two thousand frozen pompano fish dinners, intended for Eastern Airline flights out of Miami, were rejected by Eastern because of spoilage. The dinners had been shipped in two lots from the Dominican Republic. Tests by the Dade County Health Department, Miami, showed high bacterial counts in one lot that had been thawed and refrozen. It was destroyed. The second lot showed some thawing but not excessive bacterial counts. Under the Interstate Travel Sanitation Program, FDA inspects and approves sources of food, beverages, and water served on interstate carriers. FDA's **Orlando District** informed Eastern that these dinners were not from an approved source. The supplier, Oceanography Mariculture Industries, Inc., Riviera Beach, Florida, agreed to dispose of the remaining dinners.

Gross insect infestation in a food warehouse operated by Lorenzen Food Service, Tampa, Florida, led to seizure of **all** food products there which were "susceptible to insect infestation." FDA's Orlando District initiated the seizure action; supervised reconditioning of those foods that might still be sold; and required the destruction of 9,000 pounds of food, value \$30,000, which could not be reconditioned. FDA also inspected the new warehouse to which the company had agreed to move and found it acceptable for storage of food products. This was the first massive seizure for warehouse insect infestation which FDA has sought and obtained in a Federal court.

A hospital in Memphis replaced flammable ether in its operating rooms with trichloroethane, as recommended in booklet 56 of the National Fire Prevention Association. However, some patients suffered chemical-type burns when surgeons used trichloroethane as they had ether, as a defatting agent on incision sites before surgery. Burns occurred if the trichloroethane worked its way under pressure cuffs and bandages, and remained there soaking against the patient's skin. FDA's **Memphis Resident Post** investigated, to determine if using trichloroethane was in violation of the Food, Drug, and Cosmetic Act, which it apparently was not. Trichloroethane is a commercial solvent and cleaner not necessarily intended for medical use, although the FDA investigator learned that other hospitals have tried it. It is apparently a safe alternative to ether in the fire sense but requires care to keep it from getting under bandages and pneumatic cuffs.

REGION V

FDA staff from the **Chicago District** Office set up an exhibit at the mid-September PUSH Expo '74 and distributed more than 100,000 pieces of literature on FDA and consumer protection. PUSH stands for "People United to Save Humanity," and its city-wide Expo had "Save the Worker" as its theme for 1974.

Peanuts, flour, cheese, rolled oats, rolled wheat, and canned goods were seized after FDA inspectors from the **Cincinnati District** found rodent gnawings and excreta throughout five of seven floors of the Great Lakes Terminal Warehouse in Toledo. About half of the 650 lots seized had to be destroyed; a few were reconditioned; and canned goods were returned to the manu-



facturers. A truck driver loading food products had reported mice running about the rooms; FDA inspection followed. The warehouse is operated by Higginson Capital Management of New York City, and some \$36 million in food products passes through it every year.

FDA's **Detroit District** sent its mobile laboratory to eastern Indiana for that area's short, busy season of tomato processing and packing. This permitted on-the-spot analysis of mold counts, sanitation, etc.; intercepted doubtful lots that otherwise would have been shipped; and helped reduce food waste and spoilage. Eastern Indiana is one of the Nation's largest tomato processing areas, and cannery operations there are an important part of the State's economy.

FDA publications on nutrition labeling have been added to curriculum materials of the Detroit public schools in home economics and health education courses. These publications have also been placed in all school libraries in Detroit and distributed to parent-teacher organizations, FDA's Detroit District reports.

REGION VII

The Acri Wholesale Grocery Company of Des Moines, Iowa, was fined \$1,000 and two of its officers, Joseph Acri and Anthony Acri, were fined \$100 each on charges of storing food under insanitary conditions and allowing the foods to be contaminated with rodent filth. The U.S. Magistrate in the Southern District of Iowa, Des Moines, heard the case. Pleas of not guilty had been entered to the four-count charge; investigators and analysts from FDA's **Kansas City Field Office** testified as to inspectional evidence and laboratory confirmation of rodent filth.

Harry B. Kotzias of Kansas City, Missouri, was fined \$200 and placed on a year's probation by Magistrate Calvin Hamilton of the U.S. District Court for Western Missouri. The defendant, doing business as Better Foods Wholesale Grocery Company, was charged with and pleaded guilty to four counts of storing foods under insanitary conditions and causing the contamination of foods with insects and insect filth. He was told by the court that a jail sentence of up to 4 years would be considered if he violates probation.

I. D. Russell Laboratories of Kansas City has agreed to cease manufacture and distribution of its veterinary products until the company is in compliance with FDA Good Manufacturing Practices; appropriate New Animal Drug Applications have been approved; and certificates or releases are issued for certifiable antibiotic drugs. A series of investigations by FDA's Kansas City Field Office led to a consent decree of permanent injunction, issued by the U.S. District Court at Kansas City, and agreed to by Dan B. Russell, John P. Russell, and William T. Russell, principal owners of the company. FDA will monitor the company's progress in complying with terms of the decree.

Government seizure of three Diapulse devices was upheld in a recent court decision in Cedar Rapids, Iowa, as a result of investigations by FDA's Kansas City Field Office. The owner, Dr. Gordon E. Rahn, had contested the seizure and produced testimonials by five persons, including himself, as to effectiveness of the devices. The Government relied on five expert witnesses, and Judge E. J. McManus, of the U.S. District Court for Northern Iowa, hearing the case without a jury, found for the Government. Diapulse is an electromagnetic generator for which healing claims are made; it has been established that these claims are "false and misleading." In the Cedar Rapids case, the devices were destroyed after time for appeal had expired.

Cyclamate was banned by FDA in 1969 as an artificial sweetener because it caused tumors in laboratory animals. Small packets of the substance recently appeared in St. Louis, however, and FDA investigators traced them to the Dykem Company, a local food supplier.

There they found 800 pounds of bulk cyclamate and 80,000 single servings, named "Hexie" for the shape of the package. According to the owner, Dykem had held the cyclamate in hopes that it might legally be sold again some day. The entire stockpile, valued at \$64,000, was seized by the Government as an "unsafe food additive." FDA's **St. Louis Resident Post** determined that there had been only limited distribution of the item.

REGION VIII

El Molino Foods in Denver makes various Mexican food items, and uses corn husks to wrap its tamales. Three and a half tons of the husks were seized at the El Molino plant, after FDA inspectors from the **Denver District** found them to be rodent contaminated. The husks were valued at \$6,400; attempts are being made to recondition at least some of them.

Two persons in Denver became ill after drinking "Golden Harvest Old Fashioned Burdock Tea." Analysis by a hospital poison control center there showed the tea contained high levels of atropine, a toxic extract of the belladonna (deadly nightshade) plant. The root had been imported by the S. B. Penick Company of New York, and analysis by FDA's New York District showed atropine in one sample of Penick's burdock root. The tea had been sold in 6-ounce bags through health food stores and by mail order by the General Nutrition Corporation of Pittsburgh. A national recall of the product was made by the manufacturer/distributor, with FDA District offices in Denver, New York, Pittsburgh, and elsewhere helping to unravel the puzzle.

REGION IX

The **Los Angeles District** and FDA headquarters' Office of International Affairs conducted a one-day briefing for foreign trade and consulate officials at the World Trade Center in Los Angeles. The briefing, held November 12, covered import and inspection requirements; food labeling, additives, and sanitation; foreign drug registrations; and current regulatory responsibilities of the FDA.

An inspector from FDA's **San Francisco District** was denied access to some parts of the plant of Premium Products, Inc., Union City, California, a producer of cordials and liqueurs. She was also not permitted to take necessary inspection samples, and was told that she could not reenter the plant if she left to get equipment from her car. Faced with this, she returned to the District office, where an inspection warrant was obtained and the FDA inspection then proceeded under this warrant.

A shipment of preserved ginger offered for import from Hong Kong was detained by FDA's San Francisco Dis-

trict because three samples showed the presence of undeclared colors. Two of the samples contained colors not permitted in foods by FDA. One sample contained Food, Drug, and Cosmetic Red No. 40 and FD&C Yellow No. 5; these are permitted in articles of food, but no declaration was made on the label. A second sample contained Drug and Cosmetic Red No. 11, which is not permitted in food. A third sample contained Drug and Cosmetic Red No. 10, No. 11, and No. 33, which are not permitted in foods.

Some \$4 million worth of green coffee beans, most of it offered for import by General Foods, has been detained by FDA's San Francisco District in the ports of San Francisco and Oakland because insect damage exceeded the levels permitted by FDA. The District also detained 35 lots of cocoa beans from New Guinea, valued at \$1.6 million, because of insect infestation; two shipments of preserved plums from Hong Kong, for having undeclared saccharin; a shipment of frozen crab from the Philippines, for *E. coli* (fecal) contamination; and frog legs from Japan, value \$9,000, because of *Salmonella*.

REGION X

FDA's **Seattle District** inspected five fish canneries on a recent inspection trip to Alaska, and found among them 118,931 pounds of decomposed salmon, which the canneries voluntarily destroyed. Two of the canneries voluntarily closed for the remainder of the season for

cleanup and repairs. As a result of FDA findings, the Alaska Department of Health embargoed 70,000 pounds of salmon roe which had been processed with salt contaminated by rodents. The salt itself was voluntarily destroyed.

A food warehouse in Seattle was using an old hotel building for supplemental storage until FDA inspectors from Seattle District found the building infested with insects and rodents. The warehouse company discontinued use of the old building and reconditioned some of the contents for moving to another location. The remainder, 15,000 pounds of rice and 100 pounds of bran, was donated to the Washington State Game Department for wild bird feed.

A Seattle food warehouse, the Commission Company, Inc., has been reopened to interstate commerce after the FDA Seattle District determined that insanitary conditions there have been corrected. The company entered into a consent decree of permanent injunction in the U.S. Court for the Western District of Washington, Seattle, after six inspections by FDA over 15 months showed the same basic insanitary conditions and practices. The warehouse was closed to shipping and receiving of food in interstate commerce. When defective conditions were corrected, the warehouse was permitted by the court to reopen, with a program for staying in compliance with the law. Some 140,000 pounds of food contaminated by insects and rodents was voluntarily destroyed or converted to animal feed in the course of renovation.

State Actions

Sticky Business

Forty thousand pounds of soggy Christmas candy was seized by the Oregon Department of Agriculture in Portland in late October. The truck in which the candy was shipped from the East Coast had lost part of its top enroute, and the candy was left in the exposed truck to be unloaded after the weekend. That weekend it rained; the candy was water damaged; and insurance adjusters and department food specialists were to decide on final disposition.

Adulterated Macaroni

Three tons of bulk macaroni in 350 cardboard boxes, contaminated with paint and broken glass, was embargoed by the Minnesota Department

of Agriculture at a food salvage company in St. Cloud. It had been shipped from a factory in Kentucky in a freight load that also contained paint pigment powder and fluorescent light bulbs. The load arrived in Dayton, Ohio, with bits of glass and powder scattered over the boxes of macaroni, and was then forwarded to St. Cloud for salvage. The Minnesota Department of Agriculture required that 51 boxes be destroyed and allowed 299 to be converted to animal feed.

Acupuncture Embargo

Four acupuncture kits have been placed under embargo by the Pennsylvania Department of Health. They were held for sale by a company trading as Hyashiya of Phila-

delphia. The company was not registered with the Department of Health as a distributor of drugs and devices, nor were the kits themselves labeled with required warnings. A hearing is to be held on the status of the kits.

Soft Drinks Recalled

Pepsi Cola Bottling Company of Charlotte, North Carolina, recalled 36,000 32-ounce bottles of its product from 600 outlets in the Charlotte area after a defective washing device caused chipping of some bottle tops. The North Carolina Department of Agriculture ordered a seven-county check of the bottled soft drink after three bottles were found to contain small bits of glass. No injuries resulted.

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 40 actions to remove from the consumer market products charged to be violative was reported in October. These included 16 seizures of foods; 1 involved charges concerning poisonous and deleterious substances, and 15 in-

involved charges concerning contamination. Other seizures included 1 of food additive, 8 of drugs (including 2 of veterinary and medicated feed), 2 of medical devices, 1 of prophylactics, and 12 of cosmetics.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD/Poisonous and Deleterious Substances		
Soybeans/Reserve, La. 9/25/74	Shipped from Dorena, Mo.	Contain the added poisonous and deleterious substances pesticides.
Contamination, Spoilage, Insanitary Handling		
Cocoa powder/Detroit, Mich. 10/24/74	McDonald Dairy Co./Detroit, Mich. (D)	Held under insanitary conditions.
Crabmeat, canned, snow/Foster City, Calif. 10/29/74	Lein Mou Food Factory Ltd./Taiwan (M); Sung Kee Hong Ltd./Hong Kong, China (S)	Insect contaminated.
Egg noodles/Cedar Rapids, Iowa 8/21/74	Gooch Foods, Inc./Lincoln, Nebr. (M,S)	Held under insanitary conditions.
Flour/Beaumont, Tex. 9/25/74	The Phelan Co./Beaumont, Tex. (D)	"
pie and cookie/Richmond, Ind. 10/30/74	Henry Nagel & Son/Cincinnati, Ohio (M,S)	Prepared under insanitary conditions.
Buffalo, N.Y. 10/17/74	"	Prepared and packed under insanitary conditions.
Foods, various/New Orleans, La. 9/17/74	George W. Groetsch Wholesale Grocer/New Orleans, La. (D)	" ; insect and rodent contaminated.
Milk, dry/Hato Rey, P.R. 9/23/74	Industria Lechera de P.R., Inc./Hato Rey, P.R. (D)	Held under insanitary conditions; rodent contaminated.
Peanuts, runner/Hopkins, Minn. 10/9/74	Stevens Industries, Inc./Dawson, Ga. (M,S)	" ; insect contaminated.
Spanish; almonds/Boise, Idaho 6/24/74	Idaho Candy Co., Inc./Boise, Idaho (D)	Insect contaminated.
Leesburg, Ga. 10/3/74	Lee Co. Farm Center, Inc./Leesburg, Ga. (D)	"
Raisins/Omaha, Nebr. 10/15/74	Millard Warehouse/Omaha, Nebr. (D)	Held under insanitary conditions.
Rice/Denver, Colo. 10/16/74	Producer's Rice Mill, Inc./Stuttgart, Ark. (M,S)	Prepared, packed, and held under insanitary conditions.
Nashville, Tenn. 9/5/74	Central Cumberland Corp./Nashville, Tenn. (D)	Insect contaminated.
Wheat germ/Oakland, Calif. 10/23/74	Peavey Co./Oakland, Calif. (D)	Held under insanitary conditions; rodent contaminated.
FOOD ADDITIVE		
Artificial sweetener, calcium cyclamate/St. Louis, Mo. 9/19/74	Dykem Co./St. Louis, Mo. (D)	Contains calcium cyclamate, an unsafe food additive not in conformity with regulations.
DRUGS/Human Use		
Analgesic, S.A.M. Non-Narcotic/Denver, Colo. 10/16/74	Stayner Corp./Berkeley, Calif. (M,S)	New drug without an effective approved New Drug Application.
Ginseng Hui Sheng (Chinese drug)/Stockton, Calif. 9/3/74	Nan Lien Pharmaceutical Co./Tainan, Taiwan (M); P.Y. Yeh/Taipei, Taiwan (S)	" ; label fails to bear common or usual name of each ingredient; dangerous to health when used as directed.
Injections (various), I.V. sets, anesthesia trays, spinal puncture trays, catheterization trays/Memphis, Tenn. 7/23/74	T.J.M.C. DC Trucking Terminal/Memphis, Tenn. (D)	Held under insanitary conditions.
Nan Lien Herbal Pill/Berkeley, Calif. 9/6/74	Nan Lien Pharmaceutical Co./Hong Kong, China (M); Shey Lon Trading Co./Hong Kong, China (S)	New drug without an effective approved New Drug Application; label fails to bear common or usual name of each ingredient; dangerous to health when used as directed.
Sanorex tablets/Baltimore, Md. 9/13/74	Sandoz Pharmaceuticals, Div. of Sandoz-Wander, Inc./East Hanover, N.J. (M,S)	Inadequate directions for use.
Skin cleanser (pHisoHex), Minibath kit/Fort Lauderdale, Fla. 8/5/74	Delta Laboratories, Inc./Fort Lauderdale, Fla. (D)	New drugs without an effective New Drug Application; inadequate directions for use.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Veterinary/Medicated Feed		
Ana hep veterinary/Greeley, Colo. 10/17/74	Seney & Co., Inc./Denver, Colo. (M,S)	New animal drug without approved New Animal Drug Application.
Mu-Laxan/Greeley, Colo. 10/30/74	Wittney & Co./Denver, Colo. (M)	"
MEDICAL DEVICES		
Diapulse/Waynoka, Okla. 10/7/74	Diapulse Manufacturing Corp. of America/ New York, N.Y. (M)	Inadequate directions for use.
Myo flex device/Columbus, Ohio 10/3/74	Dr. Harold J. Wilson/Columbus, Ohio (D)	Inadequate directions for use; dangerous to health when used in the dosage, frequency, and duration prescribed.
Prophylactics		
Prophylactics/Topeka, Kans. 10/15/74	M & M Rubber Co./Kansas City, Mo. (M,S)	Contain holes.
COSMETICS		
Exquisite Nails/Albuquerque, N. Mex. 10/11/74	House of Barri, Inc./New York, N.Y. (Distributor)	Article contains a poisonous and deleterious substance (liquid methyl methacrylate monomer), which may render article injurious to users under such conditions of use as are customary or usual.
Long Nails/Nashville, Tenn. 9/3/74, 9/3/74, 9/3/74	C.E.B. Products, Inc./Chicago, Ill. (M,S)	"
Nashville, Tenn. 9/5/74	"	"
Cincinnati, Ohio 9/11/74	C.E.B. Products, Inc./Chicago, Ill. (M,S)	"
Garland, Tex. 9/16/74	"	"
Miami, Fla. 9/18/74	Dark Eyes Co., Inc./Chicago, Ill. (Distributor); C.E.B. Products, Inc./Chicago, Ill. (S)	"
Arlington, Tex. 9/19/74	C.E.B. Products/Chicago, Ill., Dark Eyes Co./Chicago, Ill. (Distributors)	"
Glendale, Ariz. 10/1/74	C.E.B. Products, Inc./Chicago, Ill. (S)	"
Phoenix, Ariz. 10/1/74	"	"

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 (30 U.S.C. 3005) as reported by the Chief Postal Inspector.

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

September 3, 1974: Against **Health Aids Co.**, Box 1, Rugby Station, Brooklyn, New York. Advertising and sale by mail of Kal-X Plan and Tablets to cause weight loss.

September 5, 1974: Against **Comfronics Corp.** and P.O. Box 1132, Weston Branch at Westport, Connecticut 06880. Advertising and sale by mail of the revolutionary new Youth Mask represented as equivalent to the effect produced by a miniature surgical face lift (mini lift).

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

September 4, 1974: **Associated Ski Services**, P.O. Box 3582, Chico, California 95926. Advertising and sale by mail of the U.S. Women's Ski Team Diet represented to cause a weight loss of 20 pounds in 2 weeks.

September 13, 1974: **Ginseng + E Oil and/or Marco Polo Imports**, 11526 Burbank Blvd., North Hollywood, California 91601. Advertising and sale by mail of Ginseng & E Oil represented to be effective for skin maladies.

September 4, 1974: **R & L Enterprises, Inc.**, P.O. Box 3756, Santa Monica, California 90403. Advertising and sale by mail of the Macobra bracelet represented to be effective in relieving or eliminating the pain and suffering associated with arthritis, rheumatism, or bursitis.

September 18, 1974: **Stop, Inc.**, Post Office Box 434, Fair Lawn, New Jersey 07410. Advertising and sale by mail of "Hungrex with P.P.A." represented as the most powerful reducing aid ever released for public use.

September 6, 1974: **Ionlab**, P.O. Box 5294, North Hollywood, California 91605. Advertising and sale by mail of ION-AIDS represented to be effective for the relief of aches and pains in joints, muscles, and other areas of the body.

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions FOOD/Poisonous and Deleterious Substances

- Chocolate, Santa Claus figure, at North Bergen, Dist. N.J.**
Charged 6-17-74: when shipped by R. L. Albert & Son, Inc., Bronx, N.Y., the article, labeled in part "Santa Solid Milk Chocolate . . . Made in W. Germany for R. L. Albert & Son, Inc., New York, N.Y.," and "Gerb. Heinz Duisburg West Germany," contained the added poisonous and deleterious substance *Salmonella* micro-organisms; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 59768; S. No. 56-605 H; N.J. No. 1)
- Swordfish fillets, steaks, and chunks, frozen, 7 seizure actions, at Providence, Dist. R.I.; Boston, Dist. Mass.; Watertown, Dist. Mass.; Boston, Dist. Mass.; Cranston, Dist. R.I.; Somerville, Dist. Mass.; Tampa, M. Dist. Fla.**
Charged 2-12-71, 2-16-71, 2-24-71, 3-1-71 (amended 5-3-71), 2-24-71, 3-22-71, 3-15-71: when imported into the United States, the articles contained the added poisonous and deleterious substance mercury; 402(a)(1). Part of the swordfish seized in the second action at Boston, Mass., was claimed by Samuel H. Bloom, l/a Crocker & Windsor Seafoods, Boston, Mass., who entered into a consent decree authorizing export to the original foreign supplier. The remainder of the swordfish was claimed by Pocasset Food Sales, Inc., Cranston, R.I., who denied the charges. The Government served written interrogatories on Pocasset Food Sales, Inc. Thereafter, consent decrees authorized export to the original foreign supplier. After the export of most of the swordfish, 22,505 pounds remained which the court ordered destroyed. (F.D.C. Nos. 56988/9, 57003, 57011, 57014, 57021, 57044; S. Nos. 16-767/8 D; 16-421/7 D; 16-727 D; 16-745 D, 16-880 D; 15-072/80 D, 16-701/3 D; 16-843 D; 1-211/2 D; N.J. No. 2)
- Tuna fish, canned, at San Diego, S. Dist. Calif.**
Charged 7-10-73: while held for sale, after being prepared and packed in part from tuna caught in waters outside the territorial limits of the United States off the coasts of Costa Rica and Panama, the article contained the added poisonous and deleterious substance mercury; 402(a)(1). The article was claimed by Westgate-California Foods, Inc., San Diego, Calif., who denied the charge and alleged that the Government's inspection, sampling, and testing were improper and unlawful, and that the findings procured thereby were erroneous and misleading. Postseizure samples of the article were collected by the parties, and the Government served written interrogatories on the claimant. Subsequently, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 59358; S. No. 52-472 G; N.J. No. 3)

FOOD/Contamination, Spoilage, Insanitary Handling

- Apricot kernels, at Beecher, N. Dist. Ill.**
Charged on or about 4-29-74: while held by Chicago Natural Foods Dist., Inc., Beecher, Ill., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59756; S. No. 25-914 G; N.J. No. 4)
- Black-eyed peas, at Crows Landing, E. Dist. Calif.**
Charged 11-9-73: while held for sale, the article contained insect filth; 402(a)(3). Consent decree authorized release to Dorman Brand of Texas, Inc., Tyler, Tex., for salvaging. (F.D.C. No. 59546; S. No. 93-232 G; N.J. No. 5)
- Brazil nuts, unshelled, at Los Angeles, C. Dist. Calif.**
Charged 6-18-74: while held by L. A. Nut House, Los Angeles, Calif., the article contained insects and rancid, moldy nuts; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59826; S. No. 68-064 H; N.J. No. 6)
- Breadsticks, at New York, S. Dist. N.Y.**
Charged on or about 3-13-74: while held for sale, the article contained live insects; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59696; S. No. 73-401 G; N.J. No. 7)
- Candy bars, at Kahului, Dist. Hawaii.**
Charged 6-5-74: while held for sale, the article had an oily or gasoline-like taste; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59769; S. Nos. 25-724/5 H; N.J. No. 8)
- Chilies, at Brooklyn, E. Dist. N.Y.**
Charged 7-16-71: while held by Jobart Terminal, Inc., Brooklyn, N.Y., the article contained bird filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Crescent Manufacturing Co. (George Shurman), Mamaroneck, N.Y., for salvaging. (F.D.C. No. 57310; S. No. 30-050 E; N.J. No. 9)
- Cress, canned, Betty Ann, at Greensboro, M. Dist. N.C.**
Charged on or about 3-27-74: when shipped by Monticello Canning Co., Inc., Crossville, Tenn., the article was unfit for food, since it contained cockleburrs; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59715; S. No. 6-290 G; N.J. No. 10)
- Flour, at Trenton, Dist. N.J.**
Charged 6-17-73: while held by Landolfi Food Products Co., Trenton, N.J., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59815; S. No. 56-053 H; N.J. No. 11)
- Lobster tails, at Jersey City, Dist. N.J.**
Charged 6-17-74: while held for sale, the article contained decomposed lobster tails; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59808; S. No. 55-672 H; N.J. No. 12)
- Macaroni dinner mixes, Creamette Hamburger Mate, at Sioux City, N. Dist. Iowa.**
Charged on or about 4-29-74: while held for sale, the articles contained insects—402(a)(3); and when shipped by Creamette Co., Minneapolis, Minn., the names of the articles, "Macaroni/Chili/Tomato Dinner" and "Burger 'n Cheese Dinner," and the label vignettes depicting macaroni

and ground beef with a reddish sauce (Macaroni/Chili/Tomato Dinner), and macaroni and ground beef with a yellowish sauce (Burger 'n Cheese Dinner), falsely and misleadingly suggested and implied the presence of meat in the articles, when the articles contained no meat—403(a). Default decree ordered destruction. (F.D.C. No. 59763; S. Nos. 74-906/7 H; N.J. No. 13)

- Macaroni products, Sun-Rise and Porter, at San Francisco, N. Dist. Calif.**
Charged 5-10-74: when shipped by Porter-Scarpelli Macaroni Co., Portland, Oreg., the articles had been prepared, packed, and held under insanitary conditions—402(a)(4); and the articles were in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not placed within the bottom 30 percent of the principal display panel area; the quantity of contents statement for the articles weighing less than 2 pounds was expressed as "2 Lbs." instead of "Net Wt. 32 Ozs. (2 Lbs.)," and was not qualified by the term "Net Weight"; and the quantity of contents statements appearing on the principal display panel areas of more than 25 square inches were in a type size less than 3/16 inch high—15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(3)(C)(i). Default decree ordered destruction. (F.D.C. No. 59753; S. No. 26-541 H et al.; N.J. No. 14)

- Milk, nonfat, dried, Orbit, at Montgomery, M. Dist. Ala.**
Charged 6-12-74: when shipped by St. Albans Cooperative Creamery, Inc., St. Albans, Vt., the article contained penicillin, a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to the use and intended use of such drug resulting in the presence of penicillin in the article in excess of the prescribed zero tolerance; 402(a)(2)(D). Consent decree authorized release to shipper for salvaging. (F.D.C. No. 59819; S. Nos. 118-301/5 H; N.J. No. 15)

- Nutmeg and coffee beans, at Torrance, C. Dist. Calif.**
Charged 3-28-74: while held by Farmer Bros. Co., Torrance, Calif., the articles contained insect filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Mitsui & Co., Inc., Los Angeles, Calif., for salvaging. (F.D.C. No. 59714; S. Nos. 55-751 G, 55-754 G, 55-757 G; N.J. No. 16)

- Peanuts, unshelled, at Rio Piedras, Dist. P.R.**
Charged 4-19-74: while held by Caribbean Snacks, Inc., Rio Piedras, P.R., the article contained insects and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59737; S. No. 23-421 H; N.J. No. 17)

FOOD/Economic and Labeling Violations

- Wheat flour, soya flour, and carob pod mixes, Sterling Soya-caroba, and Sterling Soya Carob, at Portland, Dist. Oreg.**
Charged 2-27-74: when shipped by Sterling Food Co., Seattle, Wash., the names of the articles were false and misleading as applied to articles consisting predominantly of wheat flour; the label statements "Guard your family nutrition," "Processed Soya for natural Protein," "Carob Pod (St. John's Bread) for Natural Sugars and Vitamins," and "Higher in Protein — Lower in Starch" (or "High in Protein — Low In Starch"), falsely and misleadingly represented and suggested that the articles were of significant nutritional value because of their high protein and low starch value, and that the articles, when used as directed, would supply a significant amount of protein, natural sugars, and vitamins; and the labeling contained false and misleading claims that the articles were hypoallergenic for those with wheat allergies, and that the articles were a substitute for wheat flour for such purposes; 403(a). Consent decree ordered destruction. (F.D.C. No. 59656; S. Nos. 99-253/4 G; N.J. No. 18)

VITAMINS/SPECIAL DIETARY FOODS

- Cereal grass extract combination tablets with hesperidin, at Kansas City, W. Dist. Mo.**
Charged 6-13-72: while held by Vitalab Co., Kansas City, Mo., who manufactured the articles using hesperidin shipped in interstate commerce, the labeling of the articles (some of which were in bulk and were unlabeled and some of which were labeled in part "Vit-Ra-Tox #21 [or "Springgreen #33" or "Sonne's No. 12"] . . . dried . . . juices of cereal grasses [or "shoots"] . . . Choline . . . Inositol . . . Pantothenic Acid . . . Folic Acid . . . Biotin . . . Cobalt . . . Manganese . . . Distributor . . . V.E. Irons, Inc., [or "Springgreen Products, Inc.," or "Sonne's Organic Food, Inc.,"] Natick, Mass., and "Vit-Ra-Tox #22 [or "Springgreen #30" or "Sonne's No. 10"] . . . dried extracted juices of cereal grasses . . . Plus Alfalfa, Hesperidin, Seaweed . . . Folic Acid . . . Pantothenic Acid . . . Choline . . . Inositol . . . Biotin . . . Manganese . . . Cobalt . . . Distributor . . . V.E. Irons, Inc. [or "Veico Products, Inc.," or "Sonne's Organic Foods, Inc.,"] . . . Natick, Mass.") contained false and misleading claims to the effect that the articles' approximate 6 mg ascorbic acid content per tablet was necessary and useful as an antioxidant; false and misleading claims to the effect that various specified ingredients, such as dried juices of cereal grasses or shoots, alfalfa, hesperidin, seaweed, and choline, were nutrients with special properties and were necessary and useful for dietary supplementation; false and misleading claims that the need in human nutrition for pantothenic acid, folic acid, biotin, and manganese had not been established; false and misleading claims to the effect that the nutritional value of various of the articles was significantly enhanced by the presence of ingredients, such as .35 milligrams vitamin E, 0.7 milligrams vitamin B₆, 40 milligrams phosphorus, and .38 micrograms vitamin B₁₂; and false and misleading claims for "Springgreen #33" tablets and "Sonne's No. 12" tablets, based on the label statement "Being a Food this product should be judged not by potencies but by nutritional Results only," to the effect that the potencies of vitamins contained in dietary supplements were not a material factor in deter-

mining the nutritional value of such products—403(a). The articles were claimed by Lee Wurst, Redding, Calif., who denied that the unlabeled bulk drums of the articles could be misbranded, and denied that the articles bearing labels were misbranded. The parties served written interrogatories on each other. Subsequently, the Government published extensive tentative regulations including those for nutritional labeling of foods and foods offered as health foods or dietary supplements; and the claimant advised the court that the labeled articles had deteriorated while in unrefrigerated storage. Thereafter, conditioned upon claimant's payment of storage, court, and other expenses, a default decree ordered destruction of the articles, except for the unlabeled drums released to the claimant pursuant to specified provisions of the decree. (F.D.C. No. 58045; S. Nos. 42-710/16 F; N.J. No. 19)

Paba Plus B-Complex tablets, at Wilmington, C. Dist. Calif.

Charged 10-5-71: while held by Wm. T. Thompson Co., Wilmington, Calif., who had manufactured the article using para-aminobenzoic acid [PABA] shipped in interstate commerce, the labeling of the article contained the following false and misleading statements: the label statement "paba plus B-Complex Factors" which falsely and misleadingly represented that the article contained, in addition to PABA, the B-Complex Factors thiamine, riboflavin, niacin, pantothenic acid, folic acid, and vitamin B₆, which was inconsistent with the label statement of ingredients which declared that "Each tablet contains: PABA (Para-Aminobenzoic Acid) . . . 100 Mg. Vitamin B-12 (Cobalamin Conc.) . . . 60 Mcg. Choline Bitartrate . . . 20 Mg. Biotin . . . 10 Mcg.," and did not declare the presence of B-Complex Factors; the name of the article, "paba plus B-Complex Factors," and the label statements "PABA (Para-Aminobenzoic Acid) 100 mg.," "Choline Bitartrate 20 Mg.," and "Biotin 10 Mcg.," falsely and misleadingly represented and suggested that PABA was of special value in human nutrition and that 20 milligrams of choline bitartrate and 10 micrograms of biotin were of significant value in a daily diet; the label statement "Need in Human nutrition has not been established" for vitamin B₁₂, which was false and misleading, since it was contrary to fact; 403(a). The article was claimed by the manufacturer, who denied the charges. The parties to the action served written interrogatories on each other, and the claimant filed a motion for judgment on the pleadings. Subsequently, a consent decree ordered destruction. (F.D.C. No. 57535; S. No. 67-097 E; N.J. No. 20)

Vidoplex-MS, vitamin supplement tablets, at Madison, M. Dist. Tenn.

Charged 4-16-74: while held by Dee Cee Laboratories, Inc., Madison, Tenn., who repacked and labeled the article, the valuable constituent of the article vitamin B₁, had been in part omitted or abstracted from the article, and the label statement of vitamin B₁ content was false and misleading, since the article contained less than 79 percent of the declared amount of vitamin B₁; 402(b)(1), 403(a). Default decree ordered destruction. (F.D.C. No. 59741; S. No. 3-556 G; N.J. No. 21)

FOOD ADDITIVES

Bio-Strath herbal yeast food supplement drops, at Los Angeles, C. Dist. Calif. Charged 1-5-70 and amended 9-26-72: when shipped by Bio-Strath of America, Inc., Hempstead, Long Island, N.Y., the article contained the nonconforming food additive herbal processed yeast; and the label of the article lacked the common or usual name of each ingredient and lacked required statements concerning the article's represented dietary properties; 402(a)(2)(C), 403(i)(2), 403(j). The article was claimed by the shipper, who denied the charges. Pursuant to stipulation, the action was transferred to the Southern District of New York. Thereafter, the claimant served written interrogatories on the Government. Ultimately, a consent decree ordered destruction. (F.D.C. No. 56163; S. No. 166-534 G; N.J. No. 22)

Feed oil for poultry, at Morton, S. Dist. Miss.

Charged on or about 4-11-74: while held for sale, the article contained the nonconforming food additive dieldrin; 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 59746; S. No. 59-524 H; N.J. No. 23)

Fishmeal, at Mobile, S. Dist. Ala.

Charged 8-9-74: while in interstate commerce, the article contained the nonconforming food additive chlordane, a pesticide chemical; 402(a)(2)(C). Consent decree authorized release to National Broiler Marketing Association, Jackson, Miss., for fertilizer purposes only. (F.D.C. No. 59885; S. No. 115-977 H; N.J. No. 24)

Tankards, pewter, Towle Cromwell, at Amesbury, Dist. Mass.

Charged 8-27-74: when shipped by Summit House, Sheffield, England, the article contained the nonconforming food additive cadmium (approximately 1.1 parts per million in leaching solution); 402(a)(2)(C). Consent decree authorized release to Ellis-Barker Silver Co., Inc., Amesbury, Mass., for return to original foreign shipper. (F.D.C. No. 59915; S. No. 108-161 H et al.; N.J. No. 25)

DRUGS/Human Use

Acno-tabs pancreatin and vitamin combination tablets, 3 seizure actions, at Los Angeles, S. Dist. Calif.; Mt. Vernon, S. Dist. N.Y.; and Mt. Vernon, S. Dist. N.Y.

Charged 6-12-61, 4-2-62, and amended on or about 5-16-62, and 3-12-63: when the tablets seized at Los Angeles, Calif., were shipped by Pannett Products, Inc., New York, N.Y., and while the tablets seized at Mt. Vernon, N.Y., were held by Vernon Laboratories, Inc., Mt. Vernon, N.Y., who packaged the article on instructions of Pannett Products, Inc., New York, N.Y., the article's labeling contained false and misleading claims for acne (pimples), and (by amendment to the initial 2 seizure actions) false and misleading claims to rebalance the structure of skin cells, to combat the real cause of pimples and surface blemishes, to permanently get rid of acne (pimples) and surface blemishes with recurrence only in rare cases, that the article was made and sold as the result of exhaustive clinical studies, provided lacking nutritional elements, improved the skin, and was medical science's latest discovery for acne pimples—502(a); and an unlabeled 600-bottle lot at Mt. Vernon, N.Y., lacked the name and place of business of the manufacturer, packer, or distributor, lacked a quantity of contents statement, and lacked the common or usual name of the article—502(b)(1 & 2), 502(e)(1). The

articles were claimed by Pannett Products, Inc., New York, N.Y. The initial 2 actions were removed to the District of New Jersey, and consolidated for trial. After trial by the court, the court condemned the articles saying:

"An action in rem, pursuant to the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 334, was commenced by Libelant by filing of Libel of Information in the United States District Court for the Southern District of California on June 12, 1961, to accomplish seizure of 219 individually cartoned bottles of a product described as 'Acnotabs' and to obtain a decree of condemnation of the seized product on the ground that it was a drug introduced into interstate commerce and misbranded within the meaning of 21 U.S.C. 352(a). Pannett Products, Inc., a New York corporation, intervened, alleging ownership of the product seized. By stipulation of Libelant and Claimant, the action pending in the Southern District of California was removed for trial to this District.

"A second libel, directed against the same product and involving further seizure of additional quantities, was filed in the United States District Court for the Southern District of New York on April 2, 1962. Pannett Products, Inc., intervened in this case as owner and, hence, the same parties and the same product are involved in both cases.

"By Order of this Court dated May 15, 1962, on application of Claimant, Pannett Products, Inc., the action pending in the Southern District of New York was transferred to this District and consolidated with the action pending here. Trial by jury, initially demanded by Claimant, was waived by both parties, and consent to the transfer above mentioned was confirmed at pretrial with agreement of counsel that trial of the consolidated actions would proceed in this District to final adjudication on the merits.

"It was stipulated at pretrial of the consolidated cases that Acnotabs, the subject matter of this litigation, was a drug which had been introduced into interstate commerce by Claimant, and further stipulated that the only issue to be tried was whether the drug, Acnotabs, was misbranded by reason of false and misleading statements in the labeling within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 352(a). By the language of the pertinent statutory provision a drug shall be deemed to be misbranded when labeling is false or misleading in any particular. * * *

"The drug, Acnotabs, is a combination of pancreatin, bile salts, pepsin, and Vitamins A and C. According to the carton and bottle labels (Exhibit G-3 in evidence), there are 72 Acnotab tablets in a bottle. Acnotabs are advertised by the label as a drug which is 'an internal medicine for acne (pimples).' The instructions for dosage, quoted from the carton label in which the individual bottle is packaged, are:

'Take one tablet three times a day after meals or as directed by your physician. For complete directions, see enclosed folder.'

The enclosed folder to which reference is made is the leaflet identified in Exhibits G-1 and G-2. * * *

"No single prescription or standard method of treatment [of acne] which has been effective in all cases in any substantial degree has heretofore been discovered by medical science. Various methods of treatment have been tried, with overall minimum effect, consisting generally of diet restriction, external applications to dry the skin, use of vitamins (principally Vitamin A and Vitamin C in combination or Vitamin A alone), antibiotics, hormonal treatment, ultra-violet light radiation, x-ray radiation, and others, depending upon the individual case and the opinion of the individual treating physician. There has been no unanimity of opinion in the medical field as to the efficacy of any one of the known methods of treatment. In fact, Dr. McCarthy, testifying for Libelant, indicated by his testimony that, if any drug could be found which would be 25% effective, it would be a wonderful discovery.

"Claimant contends that its product, Acnotabs, has been shown to be an effective treatment for acne with results in improvement of the skin condition ranging from a low percentage in some cases up to 100% in others over relatively short periods of time. * * * Claimant relies * * * primarily upon the result of studies and clinical tests made by Dr. Shane and Dr. Kelter in the use of this drug in the treatment of patients suffering from acne. * * *

"Libelant relies for its affirmative proof primarily upon the testimony of Dr. Baer and Dr. McCarthy, each of whom is a specialist in the field of dermatology. Both expressed the opinion, based upon their medical evaluation of the ingredients in Acnotabs and on their knowledge of authoritative literature dealing with treatment of acne, together with clinical experience in treatment of patients, that the use of Acnotabs would be of no value in the treatment of acne. * * *

"The issue may be further narrowed at this point by stating that bile salts, pepsin, and pancreatin alone or in combination are not alleged to have any potential for the treatment of acne. The controversy centers about whether they, in combination with Vitamin A and Vitamin C, which make up the product Acnotabs, increase the potency of the vitamin content.

"It was conceded by Libelant's medical experts that there was reputable medical authority which held to the opinion that Vitamin A, and Vitamin A in combination with Vitamin C, were effective to a limited extent in the treatment of some cases of acne. In fact, Dr. Baer testified that he had used Vitamin A in combination with Vitamin C in the treatment of acne vulgaris, but he stated that he had discontinued such use because he found it to be of no value. He further stated that he did not recognize any Vitamin A preparation alone as an adequate treatment for acne vulgaris but that in some instances Vitamin A alone, in adequate doses over a substantial period of time, was considered by him as a useful adjunct treatment in some cases of acne vulgaris. * * * In the use of Vitamin A as an adjunct treatment in some cases of acne, Dr. Baer stated his recommended dosage to be 25,000 to 150,000 units daily. An Acnotab tablet contains 10,000 units. * * *

"There is no proof from which any inference could be drawn that the drug would have an injurious effect upon health, and it is regrettable that no clinical tests were made on either side with such controls that a more accurate assessment of the degree of effectiveness of this drug for treatment of acne could be made. As the record stands, the Court has before it the testimony of two well-qualified dermatologists on the Libelant's side who base the medical opinions expressed upon extensive experience in diagnosis and treatment of skin disease, and their knowledge of medical

literature relating to the evaluation of the ingredients in Acnotabs, particularly the efficacy of the vitamin content, for treatment of acne. On the other side, there is testimony of one general practitioner and of a well-qualified internist who treated patients suffering from acne with Acnotabs and observed beneficial results as a consequence of which each expressed the opinion that the drug was effective in substantial degree despite some variations in the extent of improvement among the patients treated.

"Before proceeding to assess the probative weight of the testimony, it would be well at this point to dispose of one argument of the Claimant raised in its Post-Trial Brief, filed in lieu of oral summation, to the effect that the New York action should be dismissed because it involved a second seizure of the same drug prior to any decree of condemnation in the California case or, in the alternative, that, if the New York action is not subject to dismissal, Libelant at least has a greater burden of proof to sustain in the New York case. * * *

"The tenor of the argument is that the action for the second seizure does not come within any one of the exceptions mentioned in the statute [21 U.S.C. 334(a)] allowing the same. Regardless of any merit that the argument might otherwise have, the answer to it at this time is that the defense to the New York action which claimant seeks to interpose now was not specifically set forth as an affirmative defense in the answering pleading in that case, nor was it raised at pretrial of the consolidated cases. * * *

"Parenthetically, it may be mentioned that, after the Claimant raised the specific defense of immunity from the second seizure in its brief filed after trial, Libelant, in a reply brief, annexed a copy of a finding of fact by the Commissioner of Food and Drugs dated May 28, 1962, the tenor of which is that the labeling of the article 'Acnotabs' by Pannett Products, Inc., 'would be and is in a material respect misleading to the injury and damage of the purchaser or consumer.' Claimant argues that this cannot be treated as part of the record. The Court agrees. But neither can Claimant come forth now with a defense not asserted as a matter of record prior to or during trial.

"The second, alternative, contention of Claimant to the effect that Libelant has a greater burden of proof in the New York case than in the California case is not supported by any authority and is without merit. * * *

"The Court was particularly impressed with the testimony of Dr. Baer and Dr. Kelter. * * * The testimony of each of these doctors is entitled to considerable weight. On the one hand, Dr. Baer's testimony was very persuasive with respect to the weaknesses in the studies conducted by Dr. Shane and Dr. Kelter, particularly so, because of the nature of the disease of acne vulgaris. On the other hand, it is difficult, in the light of the testimony by Dr. Kelter, to conclude that his observations as to improvement of patients treated with Acnotabs are to be ignored entirely. But allowance must be made for the conceivable margin of error that would be inherent in the methods used to develop the factual information upon which the report of the effectiveness of Acnotabs was based. These studies, in the opinion of the Court, had value to the extent of indicating further and more objective clinical testing. In fact, Dr. Kelter testified that his tests are still continuing.

"As a consequence, it does not seem to the Court that the results of these clinical studies can be translated into representations that Acnotabs will cure acne or would constitute an adequate effective treatment for the disease. The overall import of the leaflet literature is that the drug is the panacea for acne vulgaris and that quick and effective results, tantamount to cure, can be expected from use of one bottle, excepting in rare cases where probable recurrence of the disease would be in mild form. * * * The impression is definitely created from the printed and graphic matter of the labeling that one who takes the drug, exclusive of other treatments, may expect that the problem of acne pimples will be eliminated, or at least substantially mitigated, within a relatively short period of time.

"It may be that more objective and intensive clinical testing will demonstrate the effectiveness of the drug as a treatment for acne, or the lack of it, in a degree that cannot be determined by the evidence now before the Court. This is not to suggest that the burden of proof herein has been cast upon the Claimant. When Libelant came forth with competent expert medical testimony from which it could be inferred that the representations of Claimant as to the efficacy of its product were not well-grounded, it became incumbent upon Claimant to demonstrate otherwise by its proofs. Claimant has not done this to the satisfaction of the Court.

"When representations in the labeling of a product go beyond what has been established to be the fact, according to recognized standards in the particular field for the determination thereof, such representations must be considered as false and misleading. Whether the misrepresentation springs directly from the literal import to the average reader of the statements made in the labeling or by calculated innuendo does not matter. Statements in the labeling of a product shipped in interstate commerce which are false and misleading in any sense of common understanding are prohibited. * * *

"Having considered all of the evidence in the light of the applicable principles of law for evaluation of the probative value thereof together with the Stipulations of fact, the Court makes the following findings of fact:

1. 'Acnotabs' is a drug (hereinafter referred to as 'the drug') owned and shipped in interstate commerce by the Claimant, Pannett Products, Inc.
2. The drug is an internal medication consisting of Vitamin A, Vitamin C, pancreatin, bile salts, and pepsin prepared and recommended for use by Claimant in the treatment of acne vulgaris.
3. The drug is not injurious to health.
4. Clinical studies of the effect of the drug upon patients suffering from acne vulgaris, which were not extensive in scope or conducted with controls to assure maximum objectivity in evaluation of result, indicate that the drug does have some beneficial effects as a medication in the treatment of some cases of acne vulgaris.
5. The overall import of the labeling is that the drug has been thoroughly tested; that it is an adequate effective remedy for acne vulgaris tantamount to a cure; and that a person suffering from acne vulgaris may expect that the problem of acne pimples will be

eliminated in a short period of time with recurrence only in rare cases and then in mild form.

6. The drug will not cure acne vulgaris.
7. The drug is not an adequate effective medication for acne vulgaris in the sense that the use of it will assure a blemish-free skin within a short period of time, with recurrence of the disease only in rare cases and then in mild form.
8. The effectiveness of the drug as a treatment for acne vulgaris has not been thoroughly tested.

"Accordingly, the Court concludes that it has jurisdiction in the California case and in the New York case and finds that the drug, 'Acnotabs,' was misbranded and was shipped in interstate commerce and that Libelant is entitled to a decree of condemnation pursuant to the provisions of 21 U.S.C. 334. Destruction of the drug does not follow condemnation as a matter of course. 21 U.S.C. 334(d); *A. O. Andersen & Co. v. United States*, 284 F. 542 (9th Cir. 1922). Thus, after entry of the decree and upon payment of the costs of the proceedings and the execution of bond as provided in 21 U.S.C. 334(d), the Court may, upon application and pursuant to an appropriate Order, direct that the drug seized be delivered to the owner to be brought into compliance with the applicable provisions of Chapter 9 of Title 21."

The articles in the initial 2 actions were released under bond to the claimant for relabeling. The claimant litigated the Government's rejection of claimant's proposed labeling. Meanwhile, the third seizure action was accomplished and removed to the District of New Jersey. In seeking relabeling the claimant argued that the court's finding that there was evidence indicating that Acnotabs has some effect was grounds for FDA approval of Acnotabs for acne under labeling submitted by the claimant. The Government cited the court's qualification that there was not evidence that Acnotabs had been thoroughly tested. Following FDA's rejection of the claimant's proposed new labels, the claimant moved that such action be declared arbitrary, capricious, and unreasonable. After considerable litigation, the court denied the claimant's motion. However, the claimant represented that further substantial evidence of the efficacy of Acnotabs had been developed and could be developed which previously had not been available for consideration by FDA in its labeling review. The court authorized the claimant to submit such further evidence to FDA and directed FDA to consider such evidence to determine whether claimant's labeling was appropriate to bring Acnotabs into compliance with the law. Ultimately, after it was found in another action in which the article with revised labeling was found to be a new drug without an effective approved New Drug Application, the articles were ordered destroyed. (F.D.C. Nos. 45831, 47428, 48806; S. Nos. 72-993 R, 55-806 T, 39-779 V; N.J. No. 26)

Larry Mathews Slimmer Solution magnesium sulphate, aluminum sulphate, and sodium chloride salt mix, with Instant Trim cloth wraps and plastic pants, at Pittsburgh, W. Dist. Pa.

Charged 7-12-72: when shipped by Dynamic Classics, Ltd., Fairfield, N.J., the article was a new drug without an effective approved New Drug Application; and the name of the article "Instant Trim" and statements in the accompanying instruction folder contained false and misleading claims to reduce various parts of the body including the hips, buttocks, and waist, and for temporary inch loss, that it would guarantee the temporary loss of inches in just 90 minutes, that you could have the figure you've always dreamed about, and that you would notice a loss of inches after your very first application; 505(a), 502(a). The article was claimed by the shipper. The claimant filed a motion for an order removing the case to the U.S. District Court for the Southern Dist. of New York. The Government opposed the motion on the ground that the court was without power to remove a case where the complaint charged that the seized article was a new drug, as well as being misbranded. The court denied the claimant's motion saying:

"In response to the order to show cause, the government opposes the motion for removal. Conceding this court may in its discretion transfer a proceeding to condemn a drug when the cause of action is based on misbranding alone, the United States contends this court is without power to remove a case where the libel of information charges that the seized article is both misbranded and that it is a new drug.

"The jurisdiction of this court is limited to that conferred upon it by Congress. Express statutory authority is required to give a district court authority to remove a case to another jurisdiction. *United States v. 74 Cases, etc. Oysters*, 55 F. Supp. 745 (W.D. S. Carolina 1944); *Fettig Canning Co. v. Steckler*, 188 F.2d 715 (7th Cir. 1951); *United States v. 11 Cases, etc. Ido-Pheno-Chon*, 94 F.Supp. 925 (D. Oregon 1950)

"We do not have authority under the Food, Drug and Cosmetic Act, 21 U.S.C.A. 1404(a)(1), to remove a case when the libel of condemnation alleges a drug is both misbranded and an unapproved new drug. The act only provides for removal when a drug is alleged to be misbranded. * * * It does not provide for removal in actions to condemn unapproved new drugs. *United States v. An Article of Drug*, 308 F.Supp. 1405 (N.D. Ga. 1969).

"Nor do we have authority to remove this case under the general venue statute, 28 U.S.C.A. 1404:

(a) For the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought.

Actions seeking to condemn articles of food or drug are in rem proceedings which may only be brought in the district where the res which is the subject of the proceedings is actually found and seized, *Clinton Foods v. United States* 188 F.2d 289 (4th Cir. 1951); *United States v. An Article of Drug*, supra, regardless of where it might have been found and seized. *Fettig Canning Co. v. Steckler*, supra.

"This court is without power to remove this case."

Thereafter, the Government served written interrogatories on the claimant. Based on the claimant's answers to the written interrogatories (including the admissions that the Larry Mathews Slimmer Solution contained aluminum sulphate, magnesium sulphate, and sodium chloride), on the facts that such salts were recognized as drugs in the United States Pharmacopoeia and were intended to affect the structure of the body of man, and on the affidavits of experts stating that the article was not generally recognized as either safe or effective for its labeled uses, the Government moved for summary judgment. The claimant opposed the motion, asserting that the article was not a drug and, on the contrary, at the very most, the article would fall within the definition of a device; that the salt mix in

question was basically epsom salts; that, even if the article were a drug, the article was not a "new drug" because of the "grandfather clause" of the Drug Amendments Act of 1962; that claimant's two physicians had examined and tested the article and could testify to the article's general recognition and safety; and that, since there was a conflict of expert opinion concerning relevant factual issues, summary judgment was not appropriate. The court denied the motion for summary judgment. Subsequently, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 58091; S. No. 66-556 F; N.J. No. 27)

Neocylate analgesic tablets, Neocyten analgesic tablets, and Neocylate with Colchicine tablets, at Seymour, S. Dist. Ind.

Charged 4-6-72: while held by Central Pharmacal Co., Seymour, Ind., who manufactured the articles using ingredients shipped in interstate commerce, the articles lacked adequate directions for use and were not exempted, since the articles were new drugs without effective approved New Drug Applications and no Notices of Claimed Investigational Exemption were on file—502(f)(1); and the labeling of the articles contained a number of false and misleading claims, as follows: Neocylate analgesic tablets—false and misleading claim (by the listing of ascorbic acid in the formulation as an active ingredient of the article represented for "Temporary Relief of Minor Pain") that the ascorbic acid in the total formulation of the article was of value for such purpose; Neocyten analgesic tablets—false and misleading claims (by the listing of ascorbic acid, physostigmine salicylate, and homatropine methylbromide in the formulation as active ingredients of the article represented for "Minor pain due to or accompanying skeletal muscle spasm") that the ascorbic acid, physostigmine salicylate and homatropine methylbromide in the total formulation of the article was of value for such purposes; Neocylate with Colchicine tablets—false and misleading claims (by the listing of sodium salicylate with ascorbic acid in the formulation as an active ingredient of the article represented for use in "acute gout and gouty arthritis") that the sodium salicylate and ascorbic acid in the total formulation of the article were of value for such purposes—502(a). The articles were claimed by the manufacturer who denied the charges. The Government served written interrogatories on the claimant. Subsequently, a consent decree ordered destruction. (F.D.C. No. 57925; S. Nos. 35-036/8 F; N.J. No. 28)

Sting-Kill triethanolamine combination swabs, at Pittsburgh, W. Dist. Pa.

Charged 5-4-73: when shipped by Medical Supply Co., Rockford, Ill., the article's carton label and accompanying promotional material contained false and misleading claims for the prevention and treatment of anaphylactic shock; to give therapeutic relief from bites and stings of poisonous insects; neutralize venom, which neutralized venom, including the protein enzymes and albumens, was relatively inert and would be slowly absorbed by the lymphatic system over a period of many hours; and to furnish a decided measure of protection for individuals hypersensitive to poisonous insect stings—502(a). The article was claimed by the shipper who denied the charges and who moved for removal of the case to another district. Pursuant to stipulation, the action was removed to the Northern District of Illinois. The parties served written interrogatories on each other. Subsequently, a consent decree ordered destruction. (F.D.C. No. 54137; S. No. 184-600 B; N.J. No. 29)

White Quadrisect hyoscyamine HBr, atropine sulfate, scopolamine HBr tablets, at Peoria, S. Dist. Ill.

Charged on or about 3-18-71: when shipped by George N. Bell Manufacturing Chemists, Indianapolis, Ind., the circumstances of the article's manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; 501(a)(2)(B). The article was claimed by the shipper, who submitted to the court that the charge violated the due process clause of the U.S. Constitution, because: 1) the statutory language was vague and ambiguous; and 2) the charge's definition of adulteration given by 501(a)(2)(B) constituted an irrebuttable presumption and there was no rational connection between the facts required to be proved (lack of current good manufacturing practice) under the presumption, and the ultimate facts presumed (adulteration); such presumption being arbitrary due to lack of connection between such facts and presumption in common experience.

The parties served written interrogatories on each other, and the claimant moved to dismiss the action. The motion to dismiss was denied, and the claimant moved for an order under Section 1292(b) of Title 28 of the U.S. Code to permit an immediate appeal. In denying this motion, the court said:

"While it is recognized that such question could be a controlling one and that movant does not agree with the court, and the court in no wise degrades the right to disagree and obtain ultimate review, this court is satisfied that the law on its face and as apparently applied here is constitutional, and hence that the necessary 'substantial ground for difference of opinion' does not exist. Section 1292 is not a license to test the constitutionality of a statute through the courts of review prior to trial simply by asserting unconstitutionality and making an argument of some plausibility."

The Government moved for summary judgment. The court granted the Government's motion, and the claimant appealed. The Court of Appeals for the Seventh Circuit sustained the District Court saying:

"The lower court condemned the shipment because the defendant's production procedure violated the 'current good manufacturing practice' (GMP) provision of the Act, 21 U.S.C. § 351(a)(2)(B). Appellant contends that that provision is unconstitutional under the Due Process Clause of the Fifth Amendment because of its alleged vagueness."

"The GMP provision stems from congressional concern over the danger that dangerously impure drugs might escape detection under a system predicated only on seizure of drugs shown to be in fact adulterated. In order to insure public safety, Congress determined in 1962 that it was necessary to regulate the means of production themselves * * * By way of implementation, the FDA has promulgated detailed regulations to spell out the precise requirements of the section. 21 C.F.R. § 133 et seq."

"The district court found violations of GMP standards by defendant which include the failure to keep basic production records, inadequate testing of active ingredients before use, and insufficient tests of the finished product prior to shipment. These findings are not contested on appeal and we therefore consider them established. * * *

"Defendant's argument is based on attacks on the statutory terms 'current' and 'good.' The term 'current' was considered by the Supreme Court in *Connally v. General Construction Co.*, 269 U.S. 385. In *Connally*, the court struck down an Oklahoma statute which prohibited the payment of 'less than the current rate of per diem wages in the locality where the work is performed.' The crucial failing of the statute related to the non-

existence of any determinable current wage rate and the ambiguity of the term 'locality.' See 269 U.S. at 393-395. Whatever strength the *Connally* decision has today, it does not compel the same result in a far different context. We have no trouble with the use of the word in § 351(a)(2)(B). The term 'current' fixes the point in time when the acceptability of the relevant production practices must be determined. Thus, the statute does not permit prosecution for failure to follow safety practices which were not recognized prior to the production of the subject drugs."

"The term 'good' likewise acquires adequate meaning when read in context even though, as defendant observes, a good dictionary lists a good many definitions of the word. Alternative definitions do not create impermissible ambiguity if the relevant definition is capable of interpretation by reference to objective criteria. We believe that § 351(a)(2)(B) affords sufficient guidance to avoid the problem encountered in *Ricks v. District of Columbia*, 414 F.2d 1097 (D.C. Cir. 1965) and *United States v. Morgeson*, 259 F.Supp. 256 (E.D. Pa. 1966), where the challenged vagrancy statutes required one to give a 'good account' of oneself. The word 'good,' as used in the GMP provision, is not unduly subjective."

"The constitution requires only a reasonable degree of certainty in statutory language. * * * Appellant also ignores the detailed regulations promulgated by the FDA which considerably illuminate the statutory language. See 21 CFR § 133 et seq."

"In view of the customary presumption of constitutionality and the established high regard for the purposes of the Act, we readily sustain the GMP provision. The language utilized by Congress in this statute is neither less certain nor more difficult to interpret than language elsewhere in the same Act which has been upheld. * * *

"Moreover, an argument identical to defendant's was made and rejected in *United States v. Bel-Mar Laboratories, Inc.*, 284 F.Supp. 875 (E.D. N.Y. 1968). Judge Mishler's treatment of the constitutional question in that case is thorough and persuasive; we adopt his views. See also *United States v. Kendall Co.*, 324 F.Supp. 628 (D.Mass. 1971). The GMP provision is as precise as necessary under the circumstances; it is not unconstitutionally vague. We hold that defendant violated reasonably stable, definite, and ascertainable standards of current good manufacturing practice designed to insure the production of unadulterated drugs."

Accordingly, a decree of condemnation ordered the article destroyed. (F.D.C. No. 56884; S. No. 26-686 D; N.J. No. 30)

DRUGS/Veterinary

Ana-Sol dimethyltoluthionine chloride combination injectable, at Denver, Dist. Colo.

Charged 7-11-74: while held by Seney & Co., Inc., Denver, Colo., who manufactured the article using dimethyltoluthionine chloride shipped in interstate commerce, the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to its use or intended use; 501(a)(5). Consent decree ordered destruction. (F.D.C. No. 59856; S. No. 81-460 H et al.; N.J. No. 31)

Mare-Plus supplement for mares, Grow Colt supplement with chlortetracycline, Vitamin A-D-E Fortified Wheat Germ Oil feed supplement, Super Coat supplement, and Vim-Con animal conditioner, at Phoenix, Dist. Ariz.

Charged 7-19-71: when shipped by Farnam Co.'s., Omaha, Neb., the articles were new animal drugs and no approval of a New Animal Drug Application was in effect with respect to their use and intended use—501(a)(5); and the articles' labeling contained false and misleading claims as follows: false and misleading claims for Mare-Plus—that the article was adequate and effective in mares to promote conception rates by 60 percent or more, to put reproduction system in top condition for breeding and to promote conception in barren and hard to breed mares; that it was the richest supplemental source of vitamin D, calcium, phosphorus, and iodine and supplied more of every vitamin and mineral necessary for the health of mares and foals; that it built strong bones, tendons, muscles, and teeth in unborn foals; that it prevented serious diseases including rickets and goiter; that it was rapidly assimilated and promoted nutritious mares milk; and that it was effective to promote service by stallions; false and misleading claims for Grow Colt—that the article might be used for horses of all ages not only colts up to 1 year of age, for which purpose it increased growth rate and feed efficiency; that it was an amazing feed additive guaranteeing 22 percent faster growth in colts regardless of size or breed without producing excess weight or fatty tissue; that it was approved by the U.S. Food and Drug Administration; that it increased resistance to disease generally; that it prevented loss of life in foals during the first year; that it enabled horses to train earlier and earn their way at a younger age; that it increased profits for breeding operations; that it contained high concentrations of "growth" vitamins and promoted strong bones and teeth and was a "growth builder"; and that it saved money on veterinary bills, and ensured bigger, stronger horses every time; false and misleading claims for Vitamin A-D-E Fortified Wheat Germ Oil feed supplement—that the article contained the most highly refined wheat germ oil available, and that it was the richest source of vitamin E; that it promoted breeding ability in mares, stallions, cows, and bulls; that it improved animal coat and built performance; was a complete conditioner; that it increased spirit, stamina, and endurance and produced healthier skin and glossy coat; that vitamin E was the "Breeding vitamin" and would increase foal production by as much as 40 percent; that it would promote stronger, healthier foals that would survive the weaning period; that it would increase production and profits; that it promoted alertness in horses, and improved their appetite; promoted growth, increased resistance to disease, and aided in development of bone structure; stimulated normal glandular function and enabled horses to maximize their potential; eliminated dry and scaly skin and promoted faster shedding of winter coats; false and misleading claims for Super Coat horse & pet supplement—that the article would quickly develop a smooth glossy coat and improve appetites in horses and other animals generally, promoted sleek coat and normal skin, faster shedding of hair, regrowth of hair and rapid repair of tissue while reducing scar formation; and prevented skin infections and external parasites generally; and false and misleading claims for Vim-Con animal conditioners—that the article was a conditioner for horses generally; that it built equine health and promoted vigor, stamina, spirit, energy, endurance, and top winning condition; that it produced healthy mares and colts; that it promoted development of strong, well-boned foals with rich, red blood, sound bone structure and strong muscles and tendons, and breeding in horses generally; 502(a). Consent decree authorized release to the shipper for bringing into compliance with the law. (F.D.C. No. 57294; S. Nos. 84-311/16 E; N.J. No. 32)

Swinacol 600 iron tonic, at Peoria, S. Dist. Ill.

Charged 4-16-74: when shipped by Anapco Products, Inc., Marionville, Mo., the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to the intended use of the drug; 501(a)(5). Consent decree authorized release to shipper for bringing into compliance with the law. (F.D.C. No. 59743; S. No. 26-148 G; N.J. No. 33)

Vi Con-12 cyanocobalamin injection, at Denver, Dist. Colo.

Charged 8-11-72: while held by Seney & Co., Denver, Colo., who manufactured the article using cyanocobalamin received in interstate commerce, the article had been prepared and packed under insanitary conditions whereby it may have been contaminated with filth and whereby it may have been rendered injurious to health; the circumstances of the article's manufacturing, processing, and packing failed to conform to current good manufacturing practice; the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to the use and intended use of the article; the purity and quality of the article fell below the U.S.P. standard since the article was not sterile and contained gram positive rod-shaped bacteria; and the article's labeling contained false and misleading claims for use in large and small animals generally for the treatment of pernicious and megaloblastic anemia; to promote the metabolism of carbohydrates, fats, and protein; to stimulate the appetite; to counteract thyrotoxic agents; to protect against liver damage caused by toxic doses of carbon tetrachloride; and to promote the formation of red blood cells in cases of anemia due to dietary deficiencies, as in cobalt deficient areas; 501(a)(2)(A), 501(a)(2)(B), 501(a)(5), 501(b), 502(a).

The article was claimed by the manufacturer who moved for a sample of the article and for the copying of certain Government documents. The Government served written interrogatories on the claimant. Subsequently, a consent decree condemned the article for violation of sections 501(a)(2)(B), 501(a)(5), and 502(a), and ordered the article destroyed. (F.D.C. No. 58165; S. No. 33-988 F; N.J. No. 34)

MEDICAL DEVICES

Diapulse electromagnetic energy generator, at Cedar Grove, Dist. N.J.

Charged 1-29-73: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the labeling of the article lacked adequate directions for use for its intended purpose, and neither adequate directions for lay use nor adequate information for use by licensed practitioners for the article's intended use could be written; 502(f)(1). The article was claimed by George S. White, Ph.D., Cedar Grove, N.J., who stated that he had been retained by Diapulse Corp. of America to do scientific work and that he had filed a claim for a research exemption on February 26, 1973. After the denial of such exemption, the claimant withdrew any claim and answer, and a default decree ordered destruction. (F.D.C. No. 58773; S. No. 91-929 F; N.J. No. 35)

Diapulse electromagnetic energy generators, 8 seizure actions, at Youngstown, N. Dist. Ohio; Selma, S. Dist. Ala.; Cleveland, N. Dist. Ohio; Newberg, Dist. Oregon; Ithaca, E. Dist. Mich.; Conway Springs, Dist. Kans.; Chambliss, N. Dist. Ga.; Garland, N. Dist. Tex.

Charged on or about 9-21-72, 10-5-72, 10-5-72, 12-27-72, 1-31-73, 1-19-73, 2-16-73, 4-17-73: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' labeling lacked adequate directions for lay use for the articles' intended purposes, and adequate information for use by licensed practitioners could not be prepared; 502(f)(1). The articles were claimed by various claimants and the Government served written interrogatories on the claimants. Thereafter, consent decrees in the Cleveland, Ohio, Ithaca, Mich., and Garland, Tex., actions ordered destruction. Default decrees after failure to answer the interrogatories in the Youngstown, Ohio, and Selma, Ala., actions and after withdrawal of claims in the other actions also ordered destruction. (F.D.C. Nos. 58264/5, 58349, 58516, 58674, 58752, 58871, 58973; S. Nos. 26-903/4 F, 816 F, 25-467 F, 79-911 F, 38-176 F, 39-898 F, 4-422 G, 36-448 G; N.J. No. 36)

Diapulse electromagnetic energy generators, 9 seizure actions, at Shawnee, Dist. Kans.; Westwood, Dist. N.J.; Logan, S. Dist. W. Va.; Chapmanville, S. Dist. W. Va.; Charlestown, S. Dist. W. Va.; Huntington, S. Dist. W. Va.; Ankeny, S. Dist. Iowa; Erwinville, M. Dist. La.; Raymondville, S. Dist. Tex.

Charged 1-15-73, 1-29-73, 7-9-73, 7-9-73, 7-24-73, 7-9-73, 8-21-73, 11-12-73, 6-6-74: when shipped after being manufactured for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' accompanying labeling, such as a treatment chart, contained false and misleading claims for normal bone and tissue healing, infections, bursitis, arthritis, and blood flow to peripheral areas; and the labeling lacked adequate directions for use for the articles' intended purposes, and neither adequate directions for lay use nor adequate information for use by licensed practitioners could be written; 502(a), 502(f)(1). In the action at Shawnee, Kans., a default decree authorized donation of the article to a government institution for nonmedical use; and, pursuant to stipulation by the parties, the claimant in the action at Ankeny, Iowa, retained the article for horticultural experiments only. Default decrees in the other actions ordered destruction. (F.D.C. Nos. 58707, 58777, 59324, 59325, 59329, 59330, 59425, 59502, 59800; S. Nos. 43-024 F, 91-926/7 F, 10-782 G, 10-782 G, 12-724 G, 12-626 G, 50-262 G, 67-036 G, 88-318 H; N.J. No. 37)

Electromagnetic energy generator, at Manchester, Dist. N.H.

Charged 12-8-72: when shipped by Mikel Electronics Co., Auburn, Mass., the article, labeled in part "P/Emf Model RS 2800 DCA Leasing Corporation as Manufacturer," was accompanied by the leaflet "P/Emf Model RS 2800 High Peak Power Electromagnetic Diathermy . . . 1972 DCA Leasing," which contained false and misleading claims for bursitis, diverticulitis, hypertrophic arthritis, otitis media, peripheral vascular disease, rheumatoid arthritis, sprains, and strains; and the labeling lacked adequate directions for use for the article's intended purposes, since adequate directions for lay use cannot be written, and the article lacked the prescription legend and lacked adequate information for use by licensed practitioners; 502(a), 502(f)(1). The article was claimed by Walter A. Golaski, D.C., Manchester, N.H., who denied the charges. The Government served written interrogatories on the claimant and the action was further litigated. The claimant argued that the article was a converted Diapulse device which the claimant had purchased and paid for two years before the device was seized; that it was used by the claimant, a duly licensed chiropractor, for a year and a half before he arranged to have it converted into a P/Emf device; that the conversion took place within the State of New Hampshire and no interstate commerce was involved; and that there was neither interstate commerce in-

involved nor any misbranding. The claimant subsequently withdrew his claim and answer; and a default decree ordered the article destroyed. (F.D.C. No. 58577; S. No. 12-016 F; N.J. No. 38)

Saf T Lab emergency oxygen kits, at Los Angeles, C. Dist. Calif.

Charged 1-20-72: when shipped by Safety Laboratories, Inc., Miami, Fla., the accompanying leaflets, entitled "Oxygen Treatment for Common Medical Emergencies & Accidents," "60 Minutes of Oxygen in the Palm of Your Hand," and "Saf T Labs Portable Oxygen," contained false and misleading claims that the article was capable of supplying sufficient oxygen for 60 minutes of emergency first aid, when the amount of available oxygen as stated on the label was not sufficient to maintain the proper supply of oxygen necessary for emergency use for 60 minutes; the article's labeling lacked adequate directions for the conditions offered in the labeling such as for heart attacks, bronchial asthma, suffocation, pneumonia, drowning, burns, hemorrhage, accidents, acute drug intoxication, acute alcoholic intoxication, unconsciousness, noxious gases, electric shock, migraine headaches, stroke, asphyxiation, hay fever, shock, sinus conditions, coma, fatigue, fainting, and driving exhaustion and adequate directions for safe use by untrained laity for these conditions cannot be written; and the article's labeling lacked adequate warnings against unsafe use; 502(a), 502(f)(1), 502(f)(2).

The article was claimed by LSM Industries, Inc., t/a Safety Laboratories West, Los Angeles, Calif. Thereafter, a consent decree authorized release to the claimant for salvaging. (F.D.C. No. 57775; S. No. 90-294 E; N.J. No. 39)

COSMETIC

Dark Eyes permanent makeup for lashes and brows, at Denver, Dist. Colo.

Charged 6-5-68: when shipped by Dark-Eyes Co., Chicago, Ill., the articles (makeup for brown, black, and light-brown colors) were cosmetics which were not hair dyes, and the articles contained the nonconforming color additives pyrogallol and silver nitrate; 601(e). The shipper claimed the articles and denied the charge except that it admitted that each of the articles was a cosmetic which was not a hair dye. Pursuant to stipulation, the court authorized postseizure sampling of the articles, the parties agreeing to furnish each other with copies of all analytical data on the samples. On motion of the claimant, the proceedings were stayed pending the determination of the seizure action in the Central District of California against Roux lash and brow tints. Subsequently, the action was ordered dismissed for lack of prosecution, but such order was vacated. Thereafter, the Government served written interrogatories on the claimant. The claimant moved that the proceedings be stayed; however, the motion was denied and the claimant was directed to file answers to the written interrogatories. The Government moved to dismiss the action without prejudice after the District Court for the Central District of California had ruled that the seizure of Roux lash and brow tint [which like the Dark Eyes lash and brow makeup contained metallic salts] had been prohibited from December 1963, to January 1973, on the basis of a December 1963 Federal Register announcement (rescinded in January 1973) that stated that hair colorings containing metallic salts would not be seized for failure to have in effect a permanent or provisional listing of the metallic salts for use as color additives. The claimant objected to the Government's motion to dismiss without prejudice, moved that the court dismiss the action with prejudice, and moved to bar the Government from seizing future shipments of Dark Eyes on the grounds that they contain unlisted color additives, or in the alternative to forbid the Government from issuing press releases and other acts which would publicize any such subsequent seizure. The District Court for the District of Colorado dismissed this Dark Eyes seizure action with prejudice, but refused to enjoin the Government from making further seizures of Dark Eyes. At the direction of the court, no seizures were to be instituted until the court decided the claimant's motion for a stay of further seizures pending claimant's appeal; and, in deference thereto, the Government voluntarily dismissed a new complaint for forfeiture which had been filed in the Central District of California against a lot of Dark Eyes makeup. The claimant appealed the district court's refusal to permanently enjoin further seizures of Dark Eyes. After consideration of the defendant's motion for a stay of further seizures pending an appeal, the court ruled against the claimant and denied the motion. Ultimately, pursuant to stipulation, the claimant's appeal was dismissed. (F.D.C. No. 55445; S. Nos. 23-629/31 C; N.J. No. 40)

NOTICES OF JUDGMENT ON Criminal Actions

FOOD

Allied Supermarkets, Inc., t/a Ideal Food Stores Division of Allied Supermarkets, Inc., Steve B. Phillips, division general manager, and **Lee Lunsford**, warehouse superintendent, Liberal, Dist. Kans.

Charged 2-17-72 by grand jury: pastry flour was held in a building accessible to rodents and insects and was contaminated with rodent and insect filth; and devil's food cake mix was held in a building accessible to insects and was contaminated with insect filth; 402(a)(3), 402(a)(4). Thereafter, an omnibus hearing was held at which the defendants moved for the Government's scientific reports and also moved for inspection of the Government's tangible evidence. The first motion was denied by the presiding magistrate and the second was granted on a reciprocal basis. Subsequently, the defendants made separate motions to suppress physical evidence based on the Government's refusal to produce samples under 21 U.S.C. 372(b) and 21 U.S.C. 374(d). A motion to dismiss the indictment on the ground of multiplicity was made by the defendants and was denied. The Government argued that the defendants were not entitled to copies of the analyses of samples on the grounds that warehousemen were excluded from that provision; that the defendants were warehousemen; that the Government had relied upon the magistrate's denial of the defendant's motion to produce samples; that the Government had, shortly before the trial date, offered to exchange evidence with the defendants (which offer had been refused as being untimely); that the defendants had not been prejudiced; and that, notwithstanding the suppression of the analytical evidence proving adulteration as defined in 21 U.S.C. 342(a)(3), the case could proceed to trial on the basis of adulteration within the meaning of 21 U.S.C. 342(a)(4) based on the testimony of the FDA inspector who observed the filthy conditions at the defendant's warehouse.

The defendants alleged that the corporation manufactured, packaged, and processed some foods in the building in question. The Government

countered that all of defendant's "factory" operations were conducted in a portion of the premises distinctly apart from the dry storage warehouse facilities, being separated from each other by a concrete wall, and that the defendants treated the operations as distinct entities, keeping separate cost accounting systems, and using different employees in each.

In denying the defendants' motion to dismiss, but ordering the Government to produce copies of the analyses of the samples taken from the defendants' warehouse, the court said:

"The sole issue presented here is whether the defendants are entitled to copies of the analyses of the samples taken by the inspector under the provisions of 21 U.S.C.A. §374(d), and whether the failure of the United States to furnish copies of the analysis warrants dismissal of the indictment. A similar motion made under 21 U.S.C.A. §372(b) for the furnishing of part of the official sample has been previously ruled upon adversely to the defendants.

"With respect to the requirement of 21 U.S.C.A. §374(d), the United States takes the position that warehousemen are excluded from the provision since they are not enumerated in subsection (d), whereas they are included in the preceding subsections. Since the words of the provision are plain and unambiguous, the Government argues there is no need to resort to general rules of statutory construction. * * *

"The Court is well aware that there is 'no more persuasive evidence of the purpose of a statute than the words by which the legislature undertook to give expression to its wishes.' However, where adherence to the plain meaning of the words would produce a result 'plainly at variance with the policy of the legislation as a whole,' the Court will instead give effect to that purpose. * * * This guideline to statutory interpretation clearly applies to this case. While the Court doubts whether defendants, as warehousemen, are clearly excluded by the plain language of the provision, that avenue need not be explored here, since the Court is convinced that to hold defendants are not entitled to copies of analyses because they are not specifically mentioned, would be plainly at variance with the legislative purpose underlying the whole of 21 U.S.C.A. §374.

"The Federal Food, Drug & Cosmetic Act, since it is remedial legislation, must be given a liberal interpretation consistent with its overriding purpose to protect the public health. * * * The dichotomy between manufacturers and processors on the one hand, and warehousemen on the other, which is evident throughout the Senate Report [S. Rep. No. 712, 83rd Cong. 1st Sess. (1953)], stems from the fact that the Food and Drug Administration has no enforcement powers over manufacturers and processors prior to the time the products enter interstate commerce, whereas the agency does have enforcement powers against a warehouseman who is holding products previously shipped in interstate commerce. Accordingly, it was emphasized that the inspection provisions would encourage compliance with the Act by bringing to light conditions which might lead to adulteration, thus enabling manufacturers and processors to correct them prior to the products entering interstate commerce. It would, however, be a derogation of the obvious Congressional intent to conclude from this distinction that Congress did not intend to include warehousemen under subsection (d).

"In amending the Act to incorporate the inspection provisions, Congress, in the Court's opinion, intended that they be employed as a prophylactic measure to encourage compliance with the Act and thereby lessen the need to resort to criminal or civil sanctions. Obviously, if a copy of the analysis of a sample will aid a manufacturer or processor in complying with the Act, it will likewise aid a warehouseman. The provisions are intended to furnish added protection to the consumer and they should be liberally construed to effectuate this purpose. An interpretation that subsection (d) incorporates these defendants is certainly more compatible with that Congressional intent than is the interpretation advanced by the Government. * * *

"A collective application of these two subsections [(c) and (d)] then would require that whenever samples are taken the Food and Drug Administration is required to furnish copies of the analyses to the owner, operator, or agent in charge of the establishment from which the samples were procured. Therefore, the Court finds that defendants are entitled to copies of the analysis of the samples and orders that such copies be furnished defendants within fourteen (14) days after this order is filed.

"Regarding the defendants' motion to dismiss the indictment, this motion was styled a motion to acquit and discharge. Under Rule 29 of the Federal Rules of Criminal Procedure, a motion for judgment of acquittal will be entertained at the earliest time after the Government has presented its evidence; the relief which defendants seek is more properly denominated a motion to dismiss the indictment under Rule 48 of the Federal Rules of Criminal Procedure. Under Rule 48, the Court may dismiss the indictment if there has been unnecessary delay in bringing a defendant to trial. Generally speaking, the Court will grant such motions only where the delay is attributable to purposeful or oppressive conduct of the Government, or where the delay is of such duration as to deny defendant his right to a speedy trial.

"Defendants rely on the case of *Triangle Candy Co. v. United States*, 144 F.2d 195 (9th Cir. 1944), as requiring dismissal of the indictment. That case involved the failure of the Food and Drug Administration to comply with the provisions of 21 U.S.C.A. §372(b) after the defendant had requested it be furnished with part of an official sample. The Court of Appeals held that furnishing a part of the official sample was a condition precedent to prosecution. In that case, however, the Food and Drug Administration's duty under the statute was uncontroverted, and its failure to furnish the sample could correctly be termed purposeful and oppressive conduct on the Government's part. The situation prevailing in this case is distinctly different. There was at least a colorable dispute as to whether 21 U.S.C.A. §374(d) required the Food and Drug Administration to furnish a copy of the analysis; the Government's failure to produce a copy thus does not amount to purposeful or oppressive conduct. Nor is the delay of such duration as to be presumptively prejudicial, thus denying defendants their right to a speedy trial. The delay complained of by defendants was from November 1, 1972, to November 15, 1972. This delay was necessitated by the Court's calendar, which prevented the trial from occurring as scheduled, and is not a ground for dismissal under Rule 48. Accordingly, defendants' motion for dismissal must be denied."

Thereafter, the corporation pleaded guilty to the count involving pastry flour and was fined; and the individuals pleaded nolo contendere

to the count involving devil's food cake mix and were fined. (F.D.C. No. 57610; S. Nos. 27-432 F, 47-929 E; N.J. No. 41)

C. Eberle Sons Co., and Walter F. Eberle, Jr., vice president, Cincinnati, S. Dist. Ohio.

Charged 4-8-74: egg noodles (count 1) and sugar (count 2) were held in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Nolo contendere plea to count 1 by individual; fine. Guilty plea by corporation to counts 1 and 2; fine. (F.D.C. No. 59480; S. Nos. 29-819/20 G; N.J. No. 42)

Endsley Grocery Co., J. D. Taylor, partner & general manager, and Lewis E. Endsley, partner & warehouse supervisor, Atlanta, E. Dist. Tex.

Charged 1-3-74: popcorn was held in a building accessible to insects and was contaminated with insect filth; 402(a)(3), 402(a)(4). Nolo contendere pleas; fines. (F.D.C. No. 59164; S. No. 85-463 F; N.J. No. 43)

John B. Fragale, t/a Fragale's Bakery, Garfield, Dist. N.J.

Charged on or about 7-18-74: when shipped, bread contained insect filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea; fine. (F.D.C. No. 58667; S. No. 55-350 F; N.J. No. 44)

Theodore J. Hiegel, t/a Hiegel Wholesale Grocer Co., Conway, E. Dist. Ark.

Charged 10-15-73: cornmeal and hushpuppy mix were held in a building accessible to rodents and insects and were contaminated with rodent and insect filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (F.D.C. No. 58899; S. Nos. 53-385 F, 53-396 F; N.J. No. 45)

Fred B. Keiser, t/a Twin Valley Mills, 2 criminal actions, Germantown, S. Dist. Ohio.

Charged 8-21-73: flour and cornmeal were held under insanitary conditions in a building accessible to rodents and were exposed to rodent contamination; 402(a)(4). Guilty pleas; fines. (F.D.C. No. 59117; S. No. 27-048 F et al.; N.J. No. 46)

Laurel Wholesale Grocery Co., partnership, and William H. Elliott, and Julian W. Fagan, Jr., partners, Laurel, S. Dist. Miss.

Charged 5-20-74: rice, salt, and flour were held in a building accessible to rodents and contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by partnership; fine, and probation. Nolo contendere pleas by individuals; fines, and probations. (F.D.C. No. 58374; S. No. 663 F et al.; N.J. No. 47)

C. Pappas Co., Inc., and Gloria Packing Corp., and John C. Pappas, Jr., corporate officer, and John Chrysakakis, general manager, Boston, Dist. Mass.

Charged 6-7-74: pignolia nuts, rice, and wheat were held under insanitary conditions in a building accessible to rodents and insects and were exposed to contamination by rodents and insects; 402(a)(4). Guilty pleas; fines. (F.D.C. No. 58893; S. No. 14-828 G et al.; N.J. No. 48)

Pioneer Market, Inc., and Dennis V. Marsh, president, Casper, Dist. Wyo.

Charged 9-25-73: flour was held in a building that was accessible to rodents and was contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine, and probation. Nolo contendere by individual; fine suspended, and probation. (F.D.C. No. 59305; S. No. 34-184 F et al.; N.J. No. 49)

Ranney-Davis Mercantile Co., and John M. Ranney, president, Arkansas City, Dist. Kans.

Charged 8-23-73 against corporation and individual by grand jury and 2-6-74 against individual: pancake mix (count 1) was held in a building accessible to insects and was contaminated with insects; 402(a)(3), 402(a)(4).

The corporation and the individual moved to inspect the Government's samples, the Government's alleged filth obtained from the samples, and other Government records and evidence. The Government agreed to allow inspection and copying of its various records, reports, and drawings except for the internal Government documents made in connection with the investigation and prosecution of the case. Upon arraignment, the defendants stood mute, and pleas of not guilty were entered for them. The defendants moved to strike various phrases of the indictment including the words "to be exposed to contamination by insects," and moved under the Freedom of Information Act for the production and copying of various FDA rules and procedures, statements of policy or interpretations, permitted tolerances, final orders, and other documents relating to the food products involved in this case. The defendants also moved to dismiss the indictment on the grounds that count 1 was pleaded in the conjunctive [i.e., 402(a)(3) and 402(a)(4)] rather than the disjunctive, was duplicative and charged two offenses in one count, and that the indictment (which included counts 2 and 3 charging only a 402(a)(4) violation) was defective because of multiplicity. Prior to trial, the defendants made additional motions. Except for one motion related to a court order pertaining to counts 2 and 3 which was taken under advisement, the defendants were either generally supplied the requested information or the defendants' motions were denied. Upon the conclusion of the presentation of the Government's evidence, the corporation pleaded guilty to count 1 of the original indictment, and the individual pleaded guilty to a new one-count superseding information. The individual was sentenced to 2 years' probation and fined \$750, and the corporation was fined \$2,500. (F.D.C. No. 58890; S. No. 40-248 F; N.J. No. 50)

Sackett W. Siegenthaler, t/a Town House Bakery, Canton, Dist. S. Dak.

Charged 1-10-74: macaroon base, cake base, pumpernickel mix, donut mix, and rye bread flavoring were held in a building accessible to insects and were contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty plea; suspended sentence and probation. (F.D.C. No. 59405; S. Nos. 44-161/5 G; N.J. No. 51)

Simon Bros., Inc., Kirt Simon, president, and Harold T. Walsh, vice president, South Bend, N. Dist. Ind.

Charged 8-31-73: flour was held in a building accessible to rodents and was contaminated with rodent filth; 402(a)(3), 402(a)(4). Nolo contendere plea by corporation; fine plus costs. Nolo contendere pleas by individuals; sentencing suspended. (F.D.C. No. 59115; S. No. 34-710 F; N.J. No. 52)

Specialty Bakers, Inc., and Arthur L. Roberts, president, Shreveport, W. Dist. La.

Charged 3-2-73: flour (counts 1 and 2) and cornmeal (count 3) were held in a building (all counts) accessible to insects and rodents and in insect-contaminated flour conveying equipment (count 1), and the articles were contaminated with rodent and/or insect filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Guilty plea by individual; fine, imple-

sonment suspended, and probation. (F.D.C. No. 58376; S. Nos. 53-438/9 F, 53-641 F; N.J. No. 53)

Super Valu Stores, Inc., Green Bay, E. Dist. Wis.

Charged 9-14-73: rice, Great Northern beans, corn flakes cereal, flour, and salt were held in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Nolo contendere plea; fine. (F.D.C. No. 57904; S. Nos. 34-868/70 E et al.; N.J. No. 54)

NOTICES OF JUDGMENT on Criminal Actions

DRUGS

Agri-Lines Corp., t/a Prescription Premix of Billings, Billings, Dist. Mont.

Charged 9-25-73: liquid animal feed was manufactured from bulk urea and molasses (which had been shipped in interstate commerce) and was held in a bulk storage tank; which manufacturing and holding resulted in the feed being contaminated with the new animal drug diethylstilbestrol, and with respect to the use and intended use of such contaminated feed, there was no approval in effect of a New Animal Drug Application; and which manufacturing and holding resulted in the feed being prepared and held under insanitary conditions whereby it may have been rendered injurious to health; 402(a)(2)(D), 402(a)(4). Nolo contendere plea; fine. (F.D.C. No. 58082; S. Nos. 33-213 F, 33-968 F; N.J. No. 55)

Barrows Chemical Co., Inc., Inwood, E. Dist. N.Y.

Charged 6-20-67 by grand jury: when shipped, the strength of dextro-amphetamine sulfate capsules differed from its purported strength, and its labeling was false and misleading, since the capsules contained more than the declared 15 mg dextro-amphetamine sulfate, and the circumstances of the article's manufacture, processing, packing, and holding failed to conform to current good manufacturing practice; 501(c), 501(a)(2)(B), 502(a). Guilty plea; fine. (F.D.C. No. 53042; S. No. 1-022 B et al.; N.J. No. 56)

NOTICES OF JUDGMENT on Injunction Actions

Marshall Pharmacal Corp., and Gustave A. Godinez, president and general manager, South Hackensack, Dist. N.J.

Charged 4-21-72 in complaint for injunction: that the defendants were engaged at their plant at South Hackensack, N.J., in manufacturing, processing, packing, labeling, and holding articles of drugs for human use (such as digoxin tablets, digitoxin tablets, prednisolone tablets, prednisone tablets, reserpine tablets, ethinyl estradiol tablets, isoniazid tablets, and phenobarbital and belladonna alkaloid combination tablets), in distributing such articles in interstate commerce, and in holding for sale a number of such articles after shipment of one or more of their components in interstate commerce; that FDA analyses had indicated that the content uniformity of a number of the defendants' digoxin tablets and prednisolone tablets failed to comply with U.S.P. standards, and, pursuant to a survey of the defendants' digoxin tablets, FDA analyses of approximately 43 lots showed that approximately 24 lots failed the U.S.P. tests including 5 lots that the defendants had reworked; that such failures to meet U.S.P. standards were routinely not revealed by any of the defendants' analyses; that FDA inspections showed a number of inadequacies in the methods, facilities, and controls used by said defendants; that a number of defendants' drugs had been found to be in violation of the Federal Food, Drug, and Cosmetic Act; that the defendants had recalled a number of violative drugs; that the circumstances used for the manufacture, processing, packing, and holding of drugs failed to conform to current good manufacturing practice; that the strength of a number of the defendants' drugs differed from and their quality and purity fell below the compendium standards, and their labeling was false and misleading with respect to the strength of the articles; that the defendants' isoniazid tablets was a new drug without an effective approved New Drug Application; and that the defendants were well aware that their activities were in violation of the law; 501(a)(2)(B), 501(b), 502(a), 505(a).

The defendants entered into a consent decree of permanent injunction that enjoined the violations complained of and enjoined the shipment of drugs or the production of drugs at the defendants' plant using ingredients shipped in interstate commerce, unless and until a number of specified current good manufacturing practices were put into practice at the plant, all drugs on hand at the plant were examined by FDA, necessary assays were made, necessary recalls were made of drugs distributed from the assayed lots as determined by FDA, and such assayed and recalled drugs were destroyed or otherwise brought into compliance. (Inj. No. 624; S. Nos. 202-643 C, 52-250 D, 96-766 E et al.; N.J. No. 57)

Sunshine Biscuits, Inc., Charles Holland, manufacturing services director, and Herbert F. Berlin, plant manager, Dayton, S. Dist. Ohio.

Charged 3-31-72 in complaint for injunction: that the defendants were engaged at their plant at Dayton, Ohio, in manufacturing, processing, packing, holding, and distributing in interstate commerce crackers, cracker meal, cookies, cereals, and specialty foods; that in February 1972, FDA analysis showed the presence of the pesticide chemical Ronnel in saltine crackers from such plant; that a February-March 1972 FDA inspection disclosed that the firm's insect control program involved spraying the pesticide chemical Ronnel and that the cracker meal room had been fogged with piperonyl butoxide; that subsequent inspections in March 1972 revealed Ronnel on various surfaces of the plant, in piperonyl butoxide, in finished cracker meal (0.04 parts per million of Ronnel), and in other finished food (0.02 parts per million of Ronnel); that the defendants' foods contained the nonconforming food additive Ronnel, that such foods were prepared, packed, and held under insanitary conditions, and that the defendants were well aware that their activities were in violation of the law; 402(a)(2)(C), 402(a)(4).

A consent decree of permanent injunction enjoined the violations complained of, and enjoined the interstate shipment of any food from the Dayton, Ohio, plant (except temporarily warehoused, finished, and packaged foods which had been manufactured, processed, and packaged at other plants), unless and until a number of specified provisions to assure against food being contaminated with pesticides were established, and all stocks of food on hand which had been processed at the plant were destroyed or disposed of under FDA supervision. (Inj. No. 625; S. No. 26-294 F et al.; N.J. No. 58)

NOTICES OF JUDGMENT on Miscellaneous Actions

Birth control pill warnings, suit for declaratory judgment and injunction,

Washington, Dist. Columbia.

Charged 7-2-70 and amended 8-14-70: in complaint for declaratory and injunctive relief by James S. Turner (Center for Study of Responsive Law consultant), Carolyn D. Smith, Judy Holmberg, and Judith Edes (as representatives of the class of women who have taken, are taking, or are considering taking birth control pills—a class so numerous that joinder of all members was impracticable), and American Patients Association, against FDA Commissioner Charles C. Edwards and the Food and Drug Administration: that oral contraceptives were prescription drugs which, in some users, caused harmful side effects and which might cause cancer and damaging metabolic change; that oral contraceptives should not be used at all by women with certain medical conditions, and should be used only under special medical supervision by women with certain other medical conditions; that many users of oral contraceptives did not obtain such drugs by a physician's prescription; that many users of oral contraceptives had not been fully and accurately informed of the potential harmful side effects of using oral contraceptives; that the FDA Commissioner proposed, but never published in the Federal Register, a 600-word labeling on the hazards of oral contraceptives; that the defendants proposed and published in the Federal Register a shorter proposed labeling on such hazards; that plaintiffs Turner and Smith commented against such shorter labeling, submitted alternative labeling, and requested a public hearing, as did others; that defendants published a regulation ordering specified brief labeling to be in packages of oral contraceptives commencing September 9, 1970, and requiring preparation of a fuller informational statement (pamphlet) for dissemination by prescribing physicians to their patients, upon request and at the physicians' discretion; that the defendants' regulation did not ensure that the information statement for patients would provide adequate directions for use or adequate warnings against unsafe use, or would not be misleading; that, because the defendants' labeling was misleading, lacked adequate directions for use and warnings against unsafe use, and because the labeling regulation was not supported by the facts of the record, was inconsistent and contradictory, and was based on an irrelevant factor, the order was null and void; that the defendants should be ordered to issue a new regulation requiring a labeling fully disclosing the potential harmful side effects, contraindications, and symptoms of serious disorders related to the use of oral contraceptives, or alternatively the defendants should be ordered to hold a public hearing.

The district court denied the plaintiffs' motion for a preliminary injunction on the grounds that the plaintiffs had not shown a substantial likelihood of ultimately prevailing on the merits, that the court was not persuaded that placing copies of the longer pamphlet in the packages was required to protect the consumer, and that a preliminary injunction would, indeed, delay the regulated distribution of copies of the warning pamphlet (which at the time of the hearing on the preliminary injunction were in the hands of physicians for distribution under the regulations effective the next day).

FDA moved to dismiss the action for summary judgment. After initially deferring ruling on such motion, the court ruled in favor of FDA, saying:

"Plaintiffs brought this action to review certain regulations of the Food and Drug Administration governing the labeling of birth control pills. Those regulations require that a short warning of potential side effects of the pill be inserted in each package, along with a statement that the user should consult her doctor for further information; a longer, more comprehensive discussion [pamphlet] of the health hazards of the pill, prepared in cooperation with the AMA, is distributed by physicians who prescribe the pill.

"At a hearing in September, 1970, the Court denied plaintiffs' motion for a preliminary injunction, on the grounds that plaintiffs had not demonstrated a likelihood of success on the merits and had not shown any threat of irreparable harm. The Court found at that time that the FDA's regulations were developed after adequate study and appropriate administrative proceedings, and that the challenged regulations met the legal standards for labeling of prescription drugs. The complaint asserted, however, that birth control pills were being extensively distributed outside prescription channels. If that were true, different standards of labeling might be applicable under the rule in such cases as *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 133 (9th Cir. 1968), and *United States v. Articles of Drug, Thyrolog Tablets*, 306 F. Supp. 247, 251 (D. Colo. 1969).

"Without deciding whether the existing warnings are adequate even for nonprescription drugs, the Court deferred ruling on the FDA's motion to dismiss or for summary judgment, in order to give the agency an opportunity to conduct a limited market survey to determine the extent to which birth control pills are being distributed outside prescription channels. This was done. The survey disclosed that by and large the pills are being dispensed only on prescription, and that the new warning pamphlets are being effectively distributed by physicians.

"Plaintiffs have requested extensive further discovery on the manner of distribution of the pills and the pamphlets, but the agency's survey taken in good faith adequately demonstrates the absence of special circumstances suggested by the cases cited. The motion for further discovery is denied. Defendants' motion for summary judgment is granted, and the complaint is dismissed."

The plaintiffs filed a notice of appeal, but subsequently obtained the dismissal of their appeal. (Misc. No. 147; N.J. No. 59)

Cothyrobal thyroxine and vitamin B₁₂ combination injectable, suit for damages and injunction, Washington, Dist. Columbia.

Charged 12-24-69 in complaint for damages and injunction by Murray Israel, M.D., Roslyn Heights, N.Y., Vascular Pharmaceutical Co., Willis-ton Park, N.Y., and Edison Pharmaceutical Co., New York, N.Y., [proponents of Cothyrobal], against Baxter Laboratories, Inc., and Travenol Laboratories, Inc., [distributors of Choloxin], Morton Grove, Ill., Marion Finkel, M.D., [FDA Medical Officer], Washington, D.C., and David Kritchevsky, M.D., [FDA consultant], Philadelphia, Pa.: that Cothyrobal was a patented drug containing the natural thyroid hormone L-thyroxine, vitamin B₁₂, and other ingredients; that Cothyrobal was used and recommended for the prevention and treatment of certain diseases of the heart and blood vessels; that Cothyrobal was in competition with Choloxin, which contained D-thyroxine; that the defendants conspired to illegally restrain trade; that Dr. Finkel conspired by denying approval, acceptance, and/or clearance from HEW and other Federal agencies, or by arbitrarily making such approval, acceptance, and/or clearance extremely difficult or impossible; that Dr. Kritchevsky, while a consultant, employee, and/or

agent of Baxter Laboratories, Inc., and a stockholder in Baxter Laboratories, Inc., also served FDA; that Dr. Kritchevsky conspired to prevent Cothyrobal from gaining approval, acceptance, and/or clearance, for interstate shipment and sale from the FDA; and that by reason of the conspiracy, Dr. Israel was damaged in his practice, reputation, and standing in the medical and scientific community, that Vascular Pharmaceutical Co., had lost and been deprived of large gains and profits from interstate sale of Cothyrobal, that Edison Pharmaceutical Co., successor in interest to Vascular Pharmaceutical Co., had similarly been deprived; that the purpose of the action was to recover damages resulting from the defendants' violation of the antitrust laws and to enjoin the defendants from interfering with plaintiffs' marketing, sale, distribution, research, development, or promotion of Cothyrobal.

Baxter Laboratories, Inc., and Travenol Laboratories, Inc., moved to dismiss the complaint, or for summary judgment, on the grounds that the conduct complained of did not violate the Federal antitrust laws; that the complaint did not allege any injury to the plaintiffs by reason of any conduct of the defendants; that the complaint failed to allege any conduct that violated any State laws, and that there was no valid service of process upon Baxter Laboratories, Inc. The Government, on behalf of Dr. Finkel, moved for dismissal on the grounds that she was acting in line of her official duties as an FDA employee, and that any injury suffered by the plaintiffs was caused by their own failure to submit required information to FDA. The court dismissed the action; and the plaintiffs appealed. Upon appeal, the court of appeals said in part:

"On motion of defendants to dismiss or, in the alternative, for summary judgment, the District Court dismissed the complaint, holding, first, that this case fell within the exemption from the antitrust laws enunciated in *Eastern Railroad Presidents' Conference v. Noerr Motor Freight, Inc.*, and second, that plaintiffs had not exhausted their administrative remedies. From this ruling plaintiffs appeal.

"Perhaps the case involving an issue most similar to the one at bar is *Woods Exploration and Producing Co., Inc. v. Aluminum Company of America*, in which plaintiffs alleged that two large-tract natural gas producers violated the antitrust laws by filing false nomination forecasts with the Texas Railroad Commission, which regulates the available amount of gas to be produced from each well or unitized tract, in order to reduce the production allowed others, especially small-tract producers.

"This case is relied on by the defendants here for the result reached by the District Court on the merits, a grant of summary judgment for the defendants on the grounds that even wilful and fraudulent joint efforts to induce a governmental agency to arrive at an erroneous result cannot provide the basis for an antitrust action. The District Court's judgment on the merits, however, was preceded by then District Judge Ingraham's denial in the same action of defendants' motion, raising the *Noerr-Pennington* defense, to dismiss for failure to state a claim and in the alternative for summary judgment.

"Furthermore, the Fifth Circuit, in reviewing the decision of the District Court on the merits, reversed and carefully circumscribed the *Noerr-Pennington* doctrine: * * *

"For the political process itself to be effective there must be freedom of access, regardless of motive, to ensure the 'right of the people to inform their representatives in government of their desires with respect to the passage or enforcement of laws.' . . . Where these political considerations are absent the *Noerr* doctrine is inapplicable . . . The policies of the Sherman Act should not be sacrificed simply because defendants employ governmental processes to accomplish anti-competitive purposes . . . The Fifth Circuit went on to find '*Noerr-Pennington* inapplicable to the alleged filing of false nominations (since) this conduct was not action designed to influence policy, which is all the *Noerr-Pennington* rule seeks to protect.' It found that the 'abuse' of the administrative process alleged by plaintiffs did not justify antitrust immunity. * * *

"Plaintiffs in the case at bar allege that the real purpose of defendants' joint efforts is to preclude, not induce, fair FDA consideration of the safety and efficacy of plaintiffs' drug Cothyrobal for interstate sale, and as such should be viewed as falling within the 'sham' exception to *Noerr-Pennington*. As the Court noted in *California Transport*, . . . '[w]hat the proof will show is not known, for the District Court granted the motion to dismiss the complaint. We must, of course, take the allegations of the complaint at face value for the purposes of that motion.'

"Therefore, in a manner similar to the Fifth Circuit in *Woods Exploration*, *supra*, we remand all issues to the District Court, with directions that it retain jurisdictions over the subject matter, but in turn, subject to plaintiffs reactivating their last-filed application for FDA approval of Cothyrobal, remand the original question of the safety and efficacy of Cothyrobal for interstate sale to the Secretary of Health, Education and Welfare for initial determination on the merits. This will provide the FDA with the opportunity of passing on plaintiffs' application first, which is appropriate in view of its primary jurisdiction over the approval of drugs for interstate sale. * * *

"On remand, and subject to plaintiffs reactivating their last-filed application for FDA approval of Cothyrobal for interstate sale, the District Court will be confronted with two issues: (1) whether plaintiffs' drug Cothyrobal is safe and effective for interstate sale, and (2) whether plaintiffs' allegations as to the existence of a conspiracy on the part of defendants to prevent full and fair FDA consideration of plaintiffs' application for approval of Cothyrobal and thereby to favor defendants' drug Choloxin are true. These two questions appear to be inextricably linked insofar as portions of the evidence which may be offered; however, the decision on the first issue is most properly for the FDA, while decision on the second (antitrust) issue is reserved for the District Court.

"The reason for affording the FDA the first opportunity to decide whether Cothyrobal is safe and effective for interstate sale is essentially practical: In view of the comprehensive scheme enacted by Congress for the testing of new drugs with respect to their safety and efficacy before they may be approved for interstate sale, and of the expertise required to conduct such tests, the question of the efficacy and safety of Cothyrobal is clearly inappropriate for original consideration by the courts. Plaintiffs themselves recognize this and do not dispute the primary jurisdiction of the FDA over such questions. * * *

"Accordingly, the decision of the District Court is vacated and remanded, with directions that the District Court retain jurisdiction over the plaintiffs' cause of action, subject to plaintiffs reactivating their

last-filed application for FDA approval of Cothyrobal, and subject also to any amendment of this application permitted by the FDA. If, however, plaintiffs do not then obtain full and fair consideration by the FDA drug Cothyrobal for interstate sale, they may obtain a full hearing in the District as to the safety and efficacy of their Court on all their allegations.

"The District Court should not be inhibited from considering the conclusions reached by the FDA with respect to the safety and efficacy of Cothyrobal for interstate sale in light of whatever showing plaintiffs make of the existence of a conspiracy, unfairness, or a conflict of interest on the part of defendants.

"The knowledge that the ultimate FDA determination on the safety and efficacy of Cothyrobal for interstate sale may be subject to careful District Court scrutiny should not deter the FDA from making its customary thorough investigation of drugs submitted for approval for interstate sale. Rather, the FDA should be encouraged to make such a determination by personnel and standards which are unimpeachable."

In June 1972, pursuant to the suggestion in the court of appeal's opinion, the New Drug Application for Cothyrobal at the request of Edison Pharmaceutical Co., was reactivated and again reviewed. No additional data was submitted by the applicant. After review by personnel unconnected with any previous review of any New Drug Application for Cothyrobal, the latest New Drug Application for the drug was found not approvable. The subsequent filing over-protest, the reevaluation, the notice of opportunity for hearing on the refusal to approve, and the denial of a hearing, were acts done concerning which the defendant Finkel took no part. The administrative proceedings being completed, the defendants renewed their motions for summary judgment. The court dismissed the action as to defendant Kritchevsky because no valid service of process had been made upon him. The court found that the defendant Finkel was entitled to judgment as a matter of law because, at all times pertinent, she was acting in line of her official duties as an employee of FDA and was immune to a suit of this nature pursuant to the doctrine of "official immunity." Summary judgment was granted the other defendants on other grounds. (Misc. No. 140; N.J. No. 60)

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

Alexander M. Schmidt, M.D., *Commissioner of Food and Drugs*

Washington, D.C., December 1, 1974

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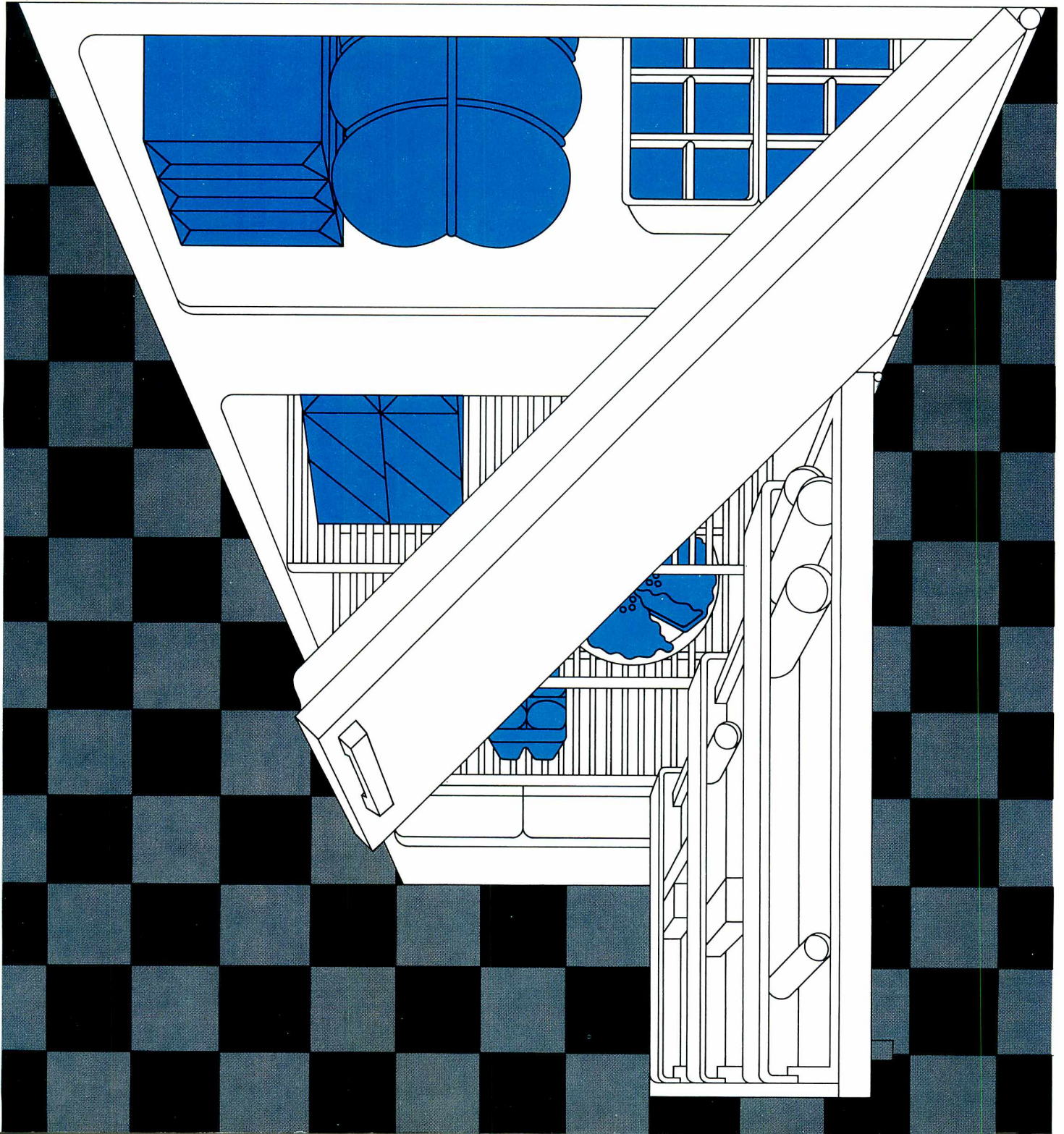
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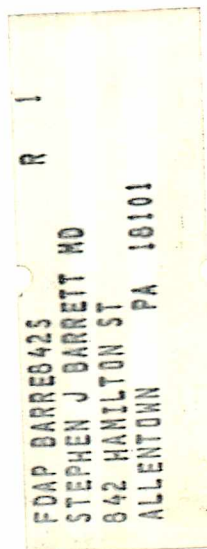
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