'In Only Four Weeks . . .'
The ads and labels may promise a new shape almost overnight, but the devices and treatment programs being ballyhooed often fail to deliver what they promise.
Snow White’s stepmother repeatedly importuning the mirror to proclaim her the fairest one of all may be an extreme example, but most of us are concerned about our looks and would like to look better if we could. This entirely understandable human desire sometimes prompts people who are normally cautious to rush uncharacteristically into the purchase of a product or treatment solely on the basis of ads that promise quick, easy results. All too often the results range from negligible to non-existent. And sometimes these products or treatments can be hazardous to the user’s health. When that’s the case FDA’s authority to take action is pretty clear, but if it is just a matter of inflated claims the legal situation can become a bit sticky. There’s an explanation—and some examples of recent cases—in an article this month entitled “In Only Four Weeks . . .”

Although the marvels of mass communication may have escalated the temptation, there’s nothing new about misrepresentation in the name of health to turn a fast buck. Back in 1630, Nicholas Knopp ran afoul of the Massachusetts Court of Assistants for selling “att a very deare rate” a scurvy cure that the court found to be nothing more than water of “noe worth nor value.” An account of Knopp’s aborted ripoff is among a bevy of interesting facts and anecdotes recounted by FDA historian Wallace Janssen in his article on “America’s First Food and Drug Laws.”

Those colonists who bought Knopp’s worthless water would have had no need for a scurvy cure—even one that worked—had their diets included lime juice or adequate amounts of vegetables high in vitamin C. By the same token, if more people ate a balanced diet today there would be fewer customers for promoters who promise to quickly convert our present shape into the body beautiful. Protein is an important part of a balanced diet, and seafood is an important source of protein. All of which brings us to the Pacific razor clam and an article telling how it is being brought to us. This saga of the sea—titled “Alaska Shares Its Succulent Shellfish”—is featured in this month’s color section.

Inside Front Cover Photo: A needed x ray should not be shunned, but every precaution should be taken to limit radiation to the smallest body area and dose required to do the job. That is FDA’s philosophy on diagnostic x-ray procedures. To find out what FDA is doing to give that philosophy meaning in everyday medical practice, turn to page 8.
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Caspar W. Weinberger
Secretary, U.S. Department of
Health, Education, and Welfare

Theodore Cooper, M.D.
Assistant Secretary for Health

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

John T. Walden
Assistant Commissioner
for Public Affairs

Ellis Rottman/Editor

Harold C. Hopkins/Editorial Director

Jesse R. Nichols/Art Director

Frederick L. Townshend/Production Manager

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Section 705 [375] of the Food, Drug, and Cosmetic Act:
(a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of charge and the disposition thereof.

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

Cover Design: Michael David Brown
Consumer Forum

Nitrates and Nitrites

Recently I read a very disturbing article concerning the presence of nitrates and nitrites in cured foods. If the article is correct one is virtually compelled to stop eating bacon and ham. What are the facts? Are these chemicals too hazardous to health for continued use in our food supply? Is the Food and Drug Administration fulfilling its responsibilities in guarding my health? Cyclamates and hexachlorophene have been banned. Must these nitrogen oxides be also?

If indeed a ban is in order, I expect one to be issued immediately. I can see no reason for any “footdragging” in this matter.

I sincerely hope and expect that all necessary measures are and always will be taken to protect every individual from hazards in food and drugs.

James C. Klosterman
Worthington, Minnesota

Nitrates and nitrites have been used widely in the curing and processing of meat and fish products. These additives serve as a preservative in many meat and fish products to prevent the growth of bacteria. Nitrites also prevent red meat from turning brown and give the familiar red color to such meats as ham, bacon, sausage, and hot dogs.

FDA regulations limit the amounts of nitrates and nitrites that can be used in curing and processing of fish products and the U.S. Department of Agriculture similarly regulates their use in meat products.

Nitrates and nitrites are added to foods to prevent botulism, a form of food poisoning which often is fatal. There have been no outbreaks of botulism that were known to be caused by processed foods that were treated with nitrates/nitrites. But a number of deaths have been caused by foods not treated with nitrates/nitrites. FDA believes it is necessary for manufacturers to use these additives to prevent the production of botulinal toxin in canned ham, bacon, and in some processed meat, poultry, and fish products.

As with most products, nitrates and nitrites have risks as well as benefits. Under certain conditions, nitrites and amines, which are the natural breakdown products of proteins, can combine to form chemicals called nitrosamines. Experiments have shown that nitrosamines can cause cancer in animals.

There is no evidence that nitrosamines cause cancer in humans. It is not known, at present, whether the low amount of nitrates and nitrites now permitted by regulations actually combine with amines in the stomach to form nitrosamines; nor is it known to what extent nitrosamines are formed in cured meat and fish.

Tests by the U.S. Department of Agriculture and FDA of samples of processed meats, cooked sausage, and hams showed nitrosamines in only a few of the samples. In another study, FDA found that the process of cooking bacon resulted in the formation of nitrosamines in the bacon.

The levels of nitrosamines found in these samplings were extremely low—much lower than the levels that would have to be present to cause cancer in experimental animals. However, extensive study is being conducted on the entire question of how nitrites and nitrites can be used to preserve meats and yet pose no problem for human consumption.

Research being conducted by the meat industry in cooperation with FDA and the Department of Agriculture is aimed at determining the lowest levels of nitrite and/or nitrate needed in foods to prevent the growth of organisms which cause botulism; and at the same time to determine whether nitrosamines are formed when these low levels are used in processed foods.

In the meantime, after studies revealed that in some products nitrites were being used not as a preservative but only to fix the color, FDA initiated formal action in November 1972 to ban such unnecessary use. This action, when final, will stop the use of sodium nitrate in smoked cured sablefish, salmon, and shad; sodium nitrite in smoked tunafish products; and potassium nitrate in cod roe.
Checking The Retail Shelves

Each year thousands of food and cosmetic items are purchased from stores, examined and analyzed by FDA to determine whether they comply with regulations meant to protect the consumer's health and economic welfare.

by Enoc P. Waters

One of the least publicized functions in FDA's surveillance of the Nation's food and cosmetic supply is in fact one of the most important. By extensive sampling at the retail level, FDA checks the composition, condition, and labeling of the food and cosmetic products being offered the American public to determine whether they comply with regulations meant to protect the consumer's health and economic welfare.

Every year FDA's field staff purchases thousands and thousands of food and cosmetic items from retail stores, in the same way consumers do. Although there is no difference in the way FDA acquires its samples, there is a definite difference in what is done with them. Those purchased by FDA's shoppers are sent to laboratories where they are subjected to examinations that are determined by the purpose of the sampling project. For instance, cosmetics might be purchased to check the use of color additives, or infant formula to test the microbiological quality of the milk used in it. In some cases, FDA's purpose is to examine a new product or one produced by a new process. Sometimes FDA wants to know whether the labels are untruthful or the packaging deceptive.
Some retail sampling programs involve products collected only from one geographical area; others are nationwide. To check seasonal variations in certain food products, samples might be collected periodically over an entire year. In some instances, FDA staff people are called on to buy a dozen samples of the same item from 12 different outlets. The sampling might call for a variety of brands of the same food item, or the same brand of an item in different size packages.

Retail sampling is affected by the size and complexity of this Nation's food and cosmetics industries and the various ways in which their products are marketed. Formulations on file with FDA's Division of Cosmetics indicate that some 30,000 cosmetic products are available to the American buying public. And cosmetics are outnumbered by food products.

Most housewives, and perhaps even the average farmer, might be surprised to learn that there are at least 25 varieties of what are known variously as string beans, pole beans, snap beans, or wax beans. To further complicate the matter, they are canned in at least nine different styles such as French cut, whole, sliced, and the like. Add to these the various packing mediums used in the canning process, the several combinations of the beans with other vegetables, and the variety of brands on the market and, for this one commodity alone, FDA estimates close to 100 items.

Most people assume that bananas are bananas, but authorities assert that the varieties are "innumerable." Also innumerable are the varieties of bread, and bread is just one form of baked goods.

Given this variety, it is not unreasonable to assume that there are a million types, styles, and brands of food on American retail shelves today.

FDA's overall surveillance activities, which include drugs, medical devices, and certain products regulated under the Radiation Control for Health and Safety Act, as well as food and cosmetics, are a job of great magnitude for an agency which has only about 6,300 employees. FDA estimates that 80 percent of its employees are involved in this massive undertaking, ranging from professional and skilled laboratory and office personnel, to messengers.

Factors that determine what products are surveyed include the need for information about changes in the processing or formulation of foods and cosmetics, the introduction of new ingredients, problems discovered or anticipated as the result of earlier surveys, and the need for data to reduce potential hazards for the development of new regulatory proposals.

As carefully as these programs are laid out, there is no certainty that they will be completed within set time limits, because unexpected emergencies may occur that pose imminent threats to health and require redeployment of FDA personnel from planned programs.

One of the largest and most intensive of FDA's continuing sampling programs is for pesticide residues in foods. In 1973, it included processed foods, dairy products, eggs and egg products, fish and marine animals, processed animal feeds, fluid whole milk, and baby foods. As the result of nationwide collections and extensive laboratory analyses, FDA learned what pesticide residues occur most frequently in domestic as well as imported products included in the program, the levels of various pesticides found, the products in which they were most frequently detected, the sections of the country where these products originated, and the company or plant that produced them.

A typical example of a product sampling program was conducted in 1974 for cadmium, a toxic metal, in certain foods. Each of FDA's 19 districts was instructed to collect, from retail shelves, a half-gallon of milk; four dozen eggs; two pounds each of white potatoes, cane sugar, lettuce, shredded wheat, canned baked beans without pork, all-meat frankfurters, and long grain white milled rice; and two six-ounce cans of frozen orange juice concentrate.

From this, FDA learned that the cadmium levels in the commodities tested are not at present of toxicological concern and that there are slight, but not significant, variations in the cadmium levels of products from different sections of the country.

An evaluation determined, however, that the number of commodities surveyed was inadequate to make an accurate estimate of the per person total daily dietary cadmium consumption. As a result, a follow-up survey is now underway that includes chicken, bacon, beef liver, hamburger, beef muscle, white flour, cornmeal, white bread, fresh carrots, butter, margarine, canned beets, tomato juice, and selected canned baby foods.

Evaluation of data from the analyses of food and cosmetic samples sometimes leads to regulatory revisions that in turn require manufacturers to reformulate their products, change materials used in packaging, or revise their label declarations.

In one instance, recalled by FDA veterans, a food standard was developed as a result of a product sampling and analysis program. According to the story, a U.S. senator was approached by cherry farmers in his State with a complaint that cherry pies did not contain a suitable number of cherries. It was a problem of great economic importance because the State involved is a leading cherry-growing area.

To gather evidence, the Senator purchased a number of cherry pies and counted the cherries contained. Armed with this information, he approached FDA with the complaint of the cherry farmers.
FDA, in turn, sent staff people to a number of manufacturers of frozen cherry pies, as well as to a few retail outlets, where they purchased cherry pies and found some that contained only a small number of cherries.

As a result, a standard was established requiring that the weight of the cherry content be at least 25 percent of the weight of the pie. This standard applies only to frozen cherry pies, because frozen pies often move in interstate commerce, over which FDA has jurisdiction.

In addition to producing information for regulatory revisions, analyses of food and cosmetics purchased through retail channels often lead to the discovery of violations of FDA regulations. Such findings may require a manufacturer to institute revisions to bring his product into compliance.

Much of the data required for FDA to develop good manufacturing practice (GMP) regulations for different segments of the food and cosmetic industries have been derived, in part, from sample products acquired from retail outlets. GMP regulations are the procedures a manufacturer is required to follow to assure the safety of the product he produces.

The information produced by the sampling programs has proved useful not only to FDA, but also to other Government agencies, people in the food and cosmetics industry, and consumer organizations.

Neither the food industry, nor the cosmetic industry, is static. There is hardly a product on the market today that has not undergone some change in processing, formulation, or packaging in the last several years. Some of these changes can be traced directly to FDA's retail sampling programs. Many more are an indirect result of this continuing effort to assure the safety and integrity of the products being offered the American consumer.

Enoc Waters is a public information specialist with FDA's Office of Public Affairs.
X Rays: Focusing On Patient Protection

FDA efforts to keep radiation exposure to a minimum include setting performance standards for equipment, developing training programs for medical practitioners and technologists, and educating consumers.

Protection of the patient who undergoes diagnostic x-ray procedures calls for care and clinical capability, as well as for well-designed and properly functioning x-ray equipment. The physician’s judgment as to whether to order an examination and his interpretation of its results are as critical as the technologist’s skill in obtaining needed diagnostic information with a minimum of unproductive x-ray exposure.

Although a single x-ray examination is not likely to cause damage, all exposure may involve some small risk. There is no known amount of ionizing radiation below which it can be said that no adverse health effect can occur. This does not mean that a needed x-ray should be shunned, for the potential benefits in diagnosing a serious disease or injury can far outweigh the possible damage from radiation exposure. But it does mean that all unnecessary x-ray examinations should be eliminated. And when an x-ray is required, every precaution should be taken to limit the radiation to the smallest required body area, and to keep the dose to the patient as low as possible.

One of the most important efforts in recent years to assure patient radiation protection through improved diagnostic x-ray equipment was establishment of a Federal performance standard for such equipment under authority of the Radiation Control for Health and Safety Act. The aim of the standard, which became effective August 1, 1974, is to reduce patient exposure during x-ray examinations, and provide more reliable diagnostic information by requiring additional safety features and by upgrading equipment performance.

For years, State radiation control programs had been reporting that some diagnostic x-ray equipment was being manufactured that did not meet State regulations and, as a result, patients were being exposed to unnecessary amounts of radiation. Federal and State surveys were finding various performance problems, including x-rays in which the beam was much larger than the film. FDA believes that the new Federal standard, developed by the Agency’s Bureau of Radiological Health, will resolve many of these problems.

The standard applies to major x-ray machine components, as well as to complete systems, that have been manufactured since last August. It requires manufacturers to produce x-ray components that perform in a prescribed way. As the logical sequel, it obligates those who assemble x-ray equipment, including physicians, to follow the manufacturer’s instructions in installing systems and parts and to use those components appropriate to the particular machine being installed. This stipulation recognizes that the interconnection of major components to form a diagnostic x-ray system and the adjustment and testing of the system are the final steps in the x-ray equipment manufacturing process.

The diagnostic x-ray equipment standard contains over 60 performance specifications. FDA intends to enforce the standard strictly and has developed a three-pronged approach: at the factory, in medical facilities, and in FDA laboratories. As the first step, FDA evaluates reports on quality control and testing programs submitted by x-ray equipment manufacturers, and supplements this information with factory inspections to verify that adequate testing is being conducted. FDA inspectors, as well as inspectors from States with which FDA has contracted, survey x-ray units in hospitals, clinics, and other facilities to determine if the systems have been assembled and are performing in accordance with the standard. Finally, FDA tests x-ray components and some fully assembled systems in its laboratory to check for compliance.
X-ray technologists (above) must know how to protect patients and themselves from unnecessary exposure during x-ray examinations. A series of training packages on radiation protection for technologists has been developed by FDA.

An FDA engineer (center photo) adjusts a scanner in the Bureau of Radiological Health laboratory to measure leakage from x-ray tube housing as part of a routine check for compliance with the Federal performance standard for x-ray equipment.

A state inspector (left in bottom photo) arranges a test stand for measuring exposure from a physician's x-ray unit. Such tests are part of a joint effort by FDA and State radiological health agencies to gather patient exposure data for common x-ray examinations conducted in all types of facilities.
If a particular x-ray system or product line fails to meet the standard, FDA will notify the manufacturer or assembler, as appropriate, and require that the equipment either be repaired or replaced free of charge. If these options are not possible, the cost of the equipment will be refunded.

To help medical practitioners and technologists reduce unneeded or unproductive x-ray exposure and to educate consumers to the role they should have in that process, FDA is developing, or has developed, a number of educational and administrative programs. An example of FDA’s efforts to orient both the practitioner and the patient is its awareness program covering x-ray examination precautions in the case of pregnant and possibly pregnant women. The program—now in the planning stage—is intended to reduce the risk to the human embryo and fetus from radiation by informing physicians about the gravity of radiation risks to unborn children, advising them to try to find out if female patients are pregnant or may be pregnant before ordering abdominal x-rays, and encouraging them to consult with the radiologist when considering an abdominal x-ray examination on a pregnant or possibly pregnant woman to determine if the procedure can be modified to reduce exposure to the developing embryo or fetus. FDA also will urge women to inform their physicians about possible pregnancy when an x-ray examination is prescribed.

To improve physicians’ radiological health practices, FDA has devised a variety of educational tools. The Radiological Health Sciences Learning Laboratory, developed by FDA and the University of California Medical Center at San Francisco, is a comprehensive educational system in diagnostic radiology, for medical students, radiology residents, and postgraduate physicians. It covers selection of patients for x-ray examinations, x-ray examination procedures, and interpretation of results. The system consists of a file of approximately 1,200 radiographic cases in a self-teaching format, a lecture manual on selection of patients, and a lecture and laboratory series on diagnostic x-ray physics. The lecture series on selection of patients provides basic information to enable physicians to make sound judgments on the desirability of x-raying a patient.

So far, 30 of the Nation’s medical institutions have purchased the Learning Laboratory, and the number is expected to increase substantially by the end of the year. Participating schools are cooperating to update laboratory materials.

To reduce patient gonad exposure, FDA actively promotes the use of testicular shielding during x-ray procedures involving the abdominal-pelvic area. The Agency has tested several types of male gonad shields and is preparing to publish a recommended guideline on the use of shielding by radiologists and other medical practitioners.

FDA participated with the American College of Radiology in last year’s nationwide program to inform all radiologists about the importance of gonad shielding. The College sent each radiologist a sample gonad shield and manufacturers’ information about several types. Included was an FDA-prepared pamphlet pointing out that conscientious use of shielding on a national scale could significantly reduce exposure to radiation that might cause genetic mutations.

Recently, FDA has concentrated on the problems of obtaining high quality radiological services. Many patients are receiving more radiation than is necessary during diagnostic x-ray procedures, according to data collected by a program called Nationwide Evaluation of X-Ray Trends (NEXT). A joint effort of FDA and State radiological health programs, NEXT gathers patient exposure data for common x-ray examinations conducted in all types of facilities.

In response to NEXT data showing unnecessary radiation, FDA has initiated a quality assurance program for diagnostic radiology. The program seeks to find the most common causes of poor film image quality and to develop ways practitioners can produce good radiographs with minimum patient exposure.

The contribution of the x-ray technologist to health care has long been recognized. To assist technologists in their work, FDA has started several programs aimed at improving their knowledge and application of radiation protection principles.

A series of training packages on radiation protection has been developed by FDA and is now available. The series, “Radiation Protection During Medical X-Ray Examinations,” is a self-contained training program intended to teach technologists how to protect patients and themselves from unnecessary exposure during x-ray examinations. It may be used for student technologist training, refresher courses, seminars, and self-teaching laboratories.

To provide continuing education for x-ray technologists on a national basis, FDA is developing a systematized training program. It will consist of a self-evaluation test and a bibliography of available training materials. Its purpose is to enable individuals to determine their areas of weakness and find educational materials needed to correct them.

FDA believes these programs, combined with the Agency’s research activities to define radiation risks more precisely and to regulate and improve x-ray equipment performance, will do much to reduce unnecessary radiation exposure and improve the quality of diagnostic radiographs.
Statutes dating from the mid-1600's attest to the colonists' concern about adulterated food and its impact on trade and their difficulty in figuring out how to regulate drugs that ranged from the innocuous to the preposterous.
When we celebrate the 200th anniversary of Independence Day, on July 4, 1976, we will be thinking of the past, the present, and the future. We will have a unique opportunity to make an assessment of our accomplishments and institutions, viewed in a perspective of two centuries of tremendous change. This is already beginning to take place across the country, as bicentennial commissions and committees delve into local history, refurbish historic sites, prepare exhibits, and plan commemorative programs.

Taking a close look at the past, a new experience for many Americans, can have salutary effects. Every generation needs to learn anew how it got to where it is, and where it seems to be going.

When FDA Consumer was first published (as FDA Papers), each issue had in its masthead a small picture of Dr. Harvey W. Wiley, the crusading chemist and physician who led the fight for the first Federal Food and Drug Act, passed in 1906. But long before Wiley’s day there were local food and drug laws, dating from colonial times.

Today, hardly anyone knows these laws existed, much less what they contained, or why. Yet they were the forerunners of our present statutes, and dealt with some familiar problems.

In colonial days, and long afterward, consumers, to a large extent, were their own food and drug inspectors. They sniffed meat and fish to make sure it was fresh, and scrutinized flour and fruit for signs of worms. Practically all food was sold in bulk, there being few packaged, processed, or manufactured products on the market. Commercially prepared bread was a notable exception. Although much bread was made at home, every town of any size had its bakers. And because bread was the “staff of life,” especially for the poor, our first food laws were “assizes of bread.”

Originating in 13th century England, the assizes were designed to standardize the weight of loaves in relation to the prevailing price of wheat and flour. Basically, they were price-fixing laws, regulating the profit of the middleman, the baker, while leaving the price of grain free to fluctuate with the market. But they had other purposes. Such a law was enacted in

An Act againifi selling unwholefome Provisions.

WHEREAS some evilly disposed persons, from motives of avarice and filthy lucre, have been induced to sell diseased, corrupted, contagious or unwholefome provisions, to the great nuisance of public health and peace:

Be it therefore enacted by the Senate and House of Representatives, in General Court assembled, and by the authority of the same, That if any person shall sell any such diseased, corrupted, contagious or unwholefome provisions, whether for meat or drink, knowing the same without making it known to the buyer, and being thereof convicted before the Justices of the General Sessions of the Peace, in the county where such offence shall be committed, or the Justices of the Supreme Judicial Court, he shall be punished by fine, imprisonement, standing in the pillory, and binding to the good behaviour, or one or more of these punishments, to be inflicted according to the degree and aggravation of the offence.

[This act passed March 8, 1785.]
1646 by the General Court of Massachusetts Bay Colony:

It is ordered by this Court and Authority thereof; that henceforth every Baker shall have a distinct mark for his Bread, and keep the true assizes, as hereafter is expressed.

A table followed, showing what a penny loaf of three qualities of bread—"white," "w h e a t," and "household"—should weigh when wheat was selling at stated prices.

For enforcement, each town was required to have "one or two able persons" annually chosen and "sworn unto the faithful discharge of his or their office; who are hereby Authorized to enter into all houses, either with a Constable or without, where they shall suspect or be informed of any bread baked for sale, and to weigh the said bread as oft as they see cause, and seize all such as they find defective." The bread inspectors were also to check the weight of butter packed for sale and to "seize any found light after notice once given."

The penalty for short weight, or failure of the maker to identify his bread or butter, was forfeiture of the product, with one-third going to the officer "for his pains, and the rest to the poor."

In 1652, the Massachusetts bread law was amended because of "much deceit used by some bakers and others, who when the clerk of the market cometh to weigh their bread, pretend they have none but for their own use, and yet afterward put their bread to sale, which upon trial hath been found too light." The Amendment required bakers to make all their bread in the legally required sizes.

Early bread laws in England, and later in the colonies, also prohibited adulteration with foreign ingredients such as ground beans or chalk. In 1720 the Massachusetts law was completely rewritten. New provisions banned the substitution of "any other grain" than the kind specified in the law, established a quality standard by outlawing any bread "found wanting either in the goodness of the stuff whereof the same shall be made, or in the due working or baking thereof," and required "that a proper allowance (in weight) be made for the drying of biscuit."

Responding to complaints of fraud over the sale in New York City of bread made of "unmerchantable flour," the General Assembly of New York in 1773, forbade bakers to sell bread unless made from flour that had passed an inspection required for exported flour. Any consumer could sue the baker before any justice of the peace and get punitive damages of four shillings (plus costs) for each violation. The only defense for the baker was to prove that his bread was made entirely from inspected flour.

It was the merchants and traders of the colonies who first appreciated the need for additional food inspection laws. They sponsored numerous laws standardizing weights and measures, fixing the sizes of casks and barrels used to store and ship foods domestically and overseas, and providing for inspection and official certification that the products were properly packed. To a great extent these laws explain themselves, as well as giving us a picture of colonial industry and its marketing problems.

Shipping their salted fish, beef, pork, flour, ship's biscuit, and similar products overseas, American merchants risked spoilage and contamination by insects, rodents, and seawater. Making good time, it took a month to six weeks to sail from New York to Liverpool. Tight casks, barrels, and hogheads were needed, as well as proper packing and salting of perishable commodities. Even if the ships arrived safely, there was always the question of whether importers might take advantage by claiming the goods to be spoiled or of poor quality not worth the going price. The preamble to one of Pennsylvania's "Duke of York" laws hints at the situation:

Whereas, It is the interest of all governments to exercise truth and uprightness in all their Dealings & Commerce, which many persons for (base) ends do so often violate: Wherefore that the Commodities generally exported to foreign markets may be Good in respect to their Quality and, Compleat in respect to their Quantity, and to prevent differences about measures, Be it enacted . . .

The law goes on to establish standards for packing, sealing, and measures.

Massachusetts may have been the first of the colonies to routinely inspect food exports. In 1641, the Massachusetts General Court passed a law regulating the sizes of casks, and requiring each town to select a gager or packer to check containers of fish, beef, and pork. It was this official's duty to check for size and to see that beef and pork were packed so "that the best be not left out," that fish were packed "all of one kind," and that "all cask be packed full and sound, and well seasoned (salted)." He was to put his seal on casks he packed and to be paid "four shillings per tun" (a tun is a kind of cask) by the owner. He was to be paid "one shilling per tun" for inspecting and approving casks packed by others.

The laws of the colonies reflected the importance of their major industries. Massachusetts had extensive laws related to fish and fishing; in Virginia and Maryland the most detailed laws were concerned with tobacco.
THE GENERALL LAWS OF THE MASSACHUSETTS COLONY,
REVISED AND PUBLISHED, BY ORDER OF THE GENERAL COURT
in October 1658.

William Burnet (1688-1729) served in the early 1720's as Governor of New York and New Jersey and later as Governor of Massachusetts.
As early as 1668, Massachusetts appointed fish inspectors because its trade had been damaged "by bad making of Fish." In the same year a closed season was ordered against fishing for codfish, hake, haddock, pollack, and mackerel during their spawning season.

Also in 1668, Massachusetts passed a "food additive" law. It banned the use of "Turtoodas Salt, which leaves spots upon fish, by reason of shells and trash in it."

Various laws were enacted to protect and promote trade. In 1740, the New York General Assembly, concerned about damage to the reputation of local products by the practice of repacking inferior beef and pork from other places in barrels carrying the brand of the City of New York passed a law providing that repacked meat could carry the New York brand only if it were "in Fact Sound, Firm, & Really Good." Otherwise, the barrels would have to show the meat's place of origin. Some 45 years later, Massachusetts, seeing an opportunity to develop an export business
in tobacco, passed an inspection and packing law similar to Maryland's. This statute regulated butter and other products as well as tobacco, and it called on the "Provers of Butter" to take samples with "an hollow iron searcher," exactly as an FDA inspector would today.

The Treaty of Paris that formally ended this Nation's fight for independence was less than two years old when one of the most significant food laws in our history was enacted. This was the "Act against selling unwholesome Provisions," passed on March 8, 1785, by the General Court of Massachusetts, to protect consumers against adulterated food. The Act, which established criminal penalties for violations, is generally considered the first comprehensive food adulteration law passed in the United States.

In contrast to the rather numerous food laws of the colonies, there was a striking absence of statutes dealing with drugs, although such laws had existed in Europe from medieval times. This is not to say that the colonial people were unconcerned about drugs and what was done with them. In 1630, the Massachusetts Court of Assistants sentenced Nicholas Knopp to be "fyned 5 pounds for takeing upon him to cure the scurvey by a water of noe worth nor value, which hee solde att a very deare rate, to be imprisoned till hee pay his fine or give securite for it, or els be whipped & shall be lyable to any mans action of whom he hath receved money for the said water." No statute is cited in the record of this, perhaps America's first drug misbranding case. The offense was fraud, which was punishable under common law. Nor do we know the content of Knopp's "water," which may have been no less effective than some of the accepted remedies for scurvy, though lemon juice and fruits and vegetables were already known to have protective powers.

Scurvy was just one of the many diseases that ravaged the colonists. Smallpox produced more casualties than all the bullets fired in the Revolution, notwithstanding the development of workable quarantine systems as early as 1720, and compulsory inoculation of American troops in 1776.

Epidemics of yellow fever, malaria, typhoid fever, scarlet fever, diphtheria, and measles struck repeatedly. Other diseases—dysentery, pneumonia, and consumption—were endemic and killed as many people, but were less frightening, being taken for granted.

Having no lack of diseases, our colonial forebears also had no lack of drugs to treat them. But with very few exceptions these were ineffective. Why then, were there no laws to protect the drug purchaser or user?

There was no question about the desires of the people. Then, as now, they wanted safe and effective treatment—an objective clearly stated in "An Act Respecting Chirurgions, Midwives and Physicians," passed in Massachusetts in 1649, and in New York in 1684. With no provision for enforcement, it was more a code of ethics than a statute. The patient was to be protected by the practitioner's adherence to "known, approved rules of art," with no departures from accepted practice without consultation of qualified persons, and patient consent.

Yet, these restraints were not intended to "discourage any from all lawful use of their skill, but rather to encourage and direct them in the right use thereof." The parallel between this philosophy and that of modern law is striking.

The drugs of the times ranged from the innocuous to the preposterous. One of the most popular notions was that the worse a medicine tasted, the more likely it was to be effective. Dung and urine from various animals were common medical ingredients in the 17th century. If a root, seed, or leaf resembled a human organ, it was considered especially likely to be effective for conditions affecting that organ.

Patent medicines imported from England were equally ineffective. Only a bare handful of the drugs in use had medical merit—opium for pain, Peruvian bark for fevers, willow bark, which contains salicylates, being notable examples.

That some patients recovered after receiving a treatment was generally regarded as proof that it worked. Thus, coincidence created one medical fraud after another. Medical men, no less than laymen, were vulnerable to what we would consider quackery. Most of what they did, in fact, would be quackery today.

The record of the last illness of George Washington is revealing of the state of medical practice at the end of the 18th century: he was given a mixture of molasses, vinegar, and butter, which he could not swallow; he was made to eat sal volatile (a menthol salve); he was bled a pint; his throat was wrapped in flannel soaked in sal volatile; his feet were bathed in warm water; a blister (poultice) of Spanish flies (cantharides) was applied to his throat; he was bled another pint, made to gargle with sage tea and vinegar, and then bled again.

As the General worsened, he was bled a full quart, and given a laxative of calomel and an emetic of tartar. One young physician suggested a new and revolutionary surgical idea, today's tracheotomy operation, the opening of the windpipe below the point of mucous obstruction so that Washington might breathe. He was overruled by older and wiser heads, and instead, plasters of wheat bran were applied to the feet. Shortly afterward, Washington died.

Today, Washington's illness probably would be diagnosed as a streptococcal infection, and treated successfully with antibiotics.

In this maze of blunderbuss medication, superstition, ancient traditions, and uncontrolled empiricism, it is not so surprising that drug laws
were virtually non-existent. Views and theories concerning medication were so widely varied that no consensus could be achieved. Systematic study of individual drugs was exceptional. Meanwhile, the pharmacopoeias, like those published in Edinborough and London, insofar as they were known in America, seemed sufficient as a means of regulation.

Yet, there was slow progress toward rational therapeutics. The treatment of scurvy, known empirically before Nicholas Knopp peddled his “water” in 1630, became scientifically established in 1747, when John Lind, a Scottish naval surgeon, proved by experiments that citrus fruit cured and also prevented the disease. But it was not until 1794, that the British navy made lime juice a part of the daily ration. (The Dutch had required their ships to carry sauerkraut for scurvy prevention beginning in 1593).

More rapid was the introduction of digitalis to strengthen and regulate the heartbeat. Dr. William Withering’s “Account of the Foxglove,” published in England in 1785, has been characterized as the first large-scale study of any drug applying sound principles of scientific investigation. Within six months, the distinguished American physician and patriot, Dr. Hall Jackson, of New Hampshire, was writing to Withering for seeds of the digitalis plant, and in 1787 he was sending seeds to other American physicians and scientists.

The epic public health development in colonial America, however, was inoculation for smallpox.

Days of public prayer and fasting proclaimed by the legislatures had been the first official actions against the recurrent epidemics. By 1720, Boston had quarantine regulations which may have reduced the number of outbreaks, but did not prevent them. In 1721, the famous Reverend Dr. Cotton Mather read of the inoculation procedure brought to England from Turkey by Lady Mary Wortley Montagu. Failing to interest the medical community of Boston in a trial of the method (they scorned it), Mather persuaded a personal friend, the distinguished physician Dr. Zabdiel Boylston, to try it. Boylston inoculated his only son, aged 13, and two Negro servants, with complete success. In the ensuing year Boylston inoculated 247 persons, of whom only 6 died, probably because of prior infection.

Violent opposition to the practice arose almost immediately. It was contended that inoculation spread, rather than controlled the infection. The Mather and Boylston homes were bombed, and Boylston was assaulted on the street. Other inoculators were similarly attacked, but persisted in their efforts.

Benjamin Franklin, who had lost a son to smallpox, became a strong advocate of inoculation. Other prominent supporters included George Washington and Thomas Jefferson.

Opposition to inoculation continued over the next half-century (and still does among some groups) despite the demonstration of its effectiveness in one epidemic after another.

By July 1776, however, the practice was generally accepted by the public throughout the colonies. Second only to the Declaration of Independence in the news of the day at Boston, was the mass inoculation of troops and civilians which the legislature had ordered on July 3. Hannah Winthrop, writing to her friend Mercy Warren, said:

“the reigning subject is the Small Pox . . . Men, Women and Children eagerly crowding to inoculate is I think as modish as runnung away from the troops of a barbarous George was the last year.

And James Warren, writing to John Adams on July 17, 1776:

. . . this Town is now become a great Hospital for Innocation . . . this is the reigning subject of conversation and even Politics might have been suspended for a time if your Declaration of Independence . . . had not reached us. The Declaration came on Saturday & diffused a general joy. Every one of us feels more Important than ever; we now congratulate each other as Freemen. It has really raised our Spirits to a tone Beneficial to mitigate the Malignancy of the Small Pox & what is of more consequence seems to animate and inspire every one to support & defend the Independence he feels.

In the saga of smallpox immunization lies perhaps another clue to the lack of drug laws in colonial America. Various public and private interests had brought food laws into being, but the sense of urgency which finally made inoculation a war measure, was generally absent in the area of drugs.

Not until 1848 was the first Federal drug law to be enacted—the Import Drug Act, passed because anti-malarial medication for the U.S. troops in Mexico was found to be grossly adulterated and lacking in potency. But that is another story.

Wallace Janssen is the FDA historian.

ACKNOWLEDGMENTS

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FORasmuch as the Law of God allows no man to impair the Life, or Limbs of any Person, but in a judicial way;

It is therefore Ordered, That no person or persons whatsoever, employed at any time about the bodies of men, women or children, for preservation of life or health; as Chirurgions, Midwives, Physicians or others, presume to exercise, or put forth any act contrary to the known approved Rules of Art in each Mystery and occupation, nor exercise any force, violence or cruelty upon, or towards the body of any, whether young or old, (no not in the most difficult and desperate cases) without the advice and consent of such as are skillful in the same Art, (if such may be had) or at least of some of the wisest and gravest then present, and consent of the patient or patients if they be minis compotes, much less contrary to such advice and consent upon such severe punishment as the nature of the fact may deserve, which Law nevertheless, is not intended to discourage any from all lawful use of their skill, but rather to encourage and direct them in the right use thereof, and inhibit and restrain the presumptuous arrogancy of such as through preference of their own skill, or any other sinister respects, dare boldly attempt to exercise any violence upon or towards the bodies of young or old, one or other, to the prejudice or hazard of the life or limbs of man, woman or child. [1649]
Alaska Shares Its Succulent Shellfish

Since Alaska's Gold Rush and more recent Oil Gush, people no longer think of its considerable expanses as a frozen waste, but there are many, even as they dine on salmon or king crab, who fail to realize the extent of the uncounted wealth in that State's watery surroundings.

Seafood is becoming an increasingly important source of protein, and for some years now fishermen from various countries have been tangling over offshore fishing rights in the most desirable spots. Many of these areas are overfished and the catches are becoming slimmer. During all this, one juicy specimen has sat at the edge of the Alaska shoreline, oblivious to this madding crowd, buried in sand, unexploited, and, to most seafood fanciers, virtually unknown.

You might say Siliqua patula, the Pacific razor clam, wanted it that way. It inhabits the roaring, shifting, outer surf areas that are exposed only at low tides. And though Alaska has a coastline longer than all the other coastal States combined, S. patula has discriminatingly chosen from all this only 49 ecological areas it cares to call home.

To make things a little stickier, this eminently edible creature does not, like some of its more gullible cousins of the shellfish kingdom, simply clam up when it feels it's in danger. It is admirably equipped with a fleshy, pointed foot that it can thrust deeper into the watery sand, then enlarge and anchor to pull itself downward, as it were, by its bootstraps. This it does promptly when it feels the sand shift under the pressure of a clam-digger's foot, hand, or spade. Its agile foot and its elusive ways help offset the Pacific razor clam's two main weaknesses, a large, thin, elongated shell easy for predators to break to get at the tender, white, mild-flavored meat within, and an inability to travel in any direction but up or down. Until recent times its prudence and stay-at-home habits have enabled the razor clam to live alone and like it.

But no longer. Governor Jay Hammond in March announced FDA's certification of Alaska as meeting the requirements of the National Shellfish Sanitation Program, culminating several years of effort on the State's part to bring clam and consumer together. This means that Alaska's Pacific razor clams not only can now be harvested from permitted areas and eaten with safety, but can be shipped to waiting markets in other States.

Under the present plan, Alaska will permit harvesting of the razor clam in only three of the 49 areas it inhabits. The opening of three areas and closing of the others arises from the State's obligations, under the National Shellfish Sanitation Program, to assure that the clams are safe and wholesome to eat.

The major problem in Alaska is not municipal or industrial pollution, the potential threat that has been foremost in many other shellfish producing States. Alaska is still relatively sparsely settled and its people are concentrated largely around areas away from the razor

FDA certification of the State's sanitation program means the Pacific razor clam's reclusive habits and sandy habitat no longer will be enough to keep it off the menu of seafood fanciers.

by Robert F. Stott and Harold C. Hopkins

20 / June 1975 / FDA Consumer
Escape rather than resistance is the Pacific razor clam's best means of defense. Once caught, the clam's thin, long shell is not difficult for predators to break open.

Razor clams caught in Alaskan waters await analyses for paralytic shellfish poison, a substance highly toxic to humans, and bacterial and other contamination.
Helicopters often are the most practical transportation for survey teams that have to gather samples from remote, inaccessible areas to determine their suitability for commercial clam harvesting.

Alaska's problem is the potential of its waters for invasion by the toxic bloom of the dinoflagellate, *Gonyaulax catenella*, sometimes called the red tide from the way heavy concentrations of these algae cause the water to appear red. When shellfish ingest large quantities of these algae, their meat is toxic to humans. The bloom is commonly called paralytic shellfish poison, or PSP, and is rated more toxic than strychnine or cyanide.

The red tide may appear periodically and last for several weeks, most frequently in the warmer months between May and November. The bloom, of course, is not peculiar to Alaska waters and its invasions have occasionally resulted in the closing of shellfish producing waters in other states on the Pacific, Atlantic, and Gulf Coasts.

Protection of the consumer, and assurance that shellfish-producing areas are not contaminated by the bloom immediately before or during shellfish harvesting, requires constant vigilance by the appropriate regulatory authority in any shellfish-producing State. The State must devise a system to assure that shellfish are not taken from unapproved growing areas, whether closed the year-around or temporarily, as during a red tide invasion. It must take regular samples of water and shellfish in approved areas, and be able to make rapid analyses of the samples for PSP content as well as for bacterial and other types of contamination.

Alaska presents special problems. Almost any venture in this State must devise ways to cope with the remoteness and logistical problems presented by Alaska's geography, sparse population, and scattered communities. Thus, it was a formidable undertaking when the Alaska Department of Health and Social Services, in cooperation with the Department of Game and Fish, set out in 1971 to qualify the State for program endorsement by FDA under the National Shellfish Sanitation Program. The State had to:
Outer beaches exposed during low tides (center photo) may yield as much as 100 pounds of clams an hour to an expert harvester.

Dredges can harvest clams from the water during higher tides.

- Conduct initial surveys to evaluate municipal and industrial pollution potential. This included surveys of shorelines and river tributaries, collection of numerous samples of seawater and of razor clams, and bacterial analyses of both, along with analysis of the clams for heavy metals.
- Develop laboratory facilities capable of conducting rapid analysis of samples for PSP and bacteria.
- Establish a surveillance system to assure that razor clams are not harvested in unapproved areas. These efforts and a consideration of Alaska's vast stretches of shoreline made it clear that, to meet FDA's requirements for safe shellfish, the State could not possibly establish a program capable of covering all 49 of the Alaska areas inhabited by razor clams. The limitation of clam harvesting to the three areas finally chosen, was based on the money and manpower available to collect samples every two weeks and provide necessary surveillance and laboratory support. Many shore areas of Alaska are difficult to reach except from the air or sea.

The three specific areas chosen for opening to clam harvesting are all in central Alaska and were selected because of their ease of access, known resources of clams, and relative infrequency of red tide invasions.

They will be open both to commercial shellfishing and to those who want to dig this elusive clam for sport and the home table. Razor clams are found submerged in sand, on the outer beaches exposed during low tides. Low tides that make harvesting possible during daylight hours occur in spring and summer, though commercial dredges, permitted in some areas, can operate from the water at higher tides to harvest clams from the sea.
A seawater sample is taken by Ken Torgerson, Alaska State Seafood Sanitation Coordinator.

A harvest of razor clams is loaded into a plane for the first leg of a journey that will end on a shellfish fancier's plate.

bottom. A low tide may last up to 6 hours and an expert, equipped with the curved spade used by clam diggers, can harvest up to a hundred pounds an hour. A novice who has nothing but enthusiasm may dig for hours without seeing one clam.

Pacific razor clams are eviscerated and shipped fresh or frozen. When opened and eviscerated, the gills, digestive tract, the tip of the neck, and part of the foot are removed. The rest of the neck is then split to remove the sand and the rest of the foot split to make a steak, though the clam also makes excellent chowder stock. Frying should last no more than two minutes to retain the tenderness and flavor.

The Pacific razor clam is the only shellfish in Alaska covered by its shellfish program (FDA's National Shellfish Sanitation Program involves only bivalve shellfish). Alaska has 19 commercial packers and processors of these clams. Of the 46 areas remaining closed to harvesting, about half are believed to produce enough clams to have eventual commercial potential.

The three areas now open are estimated by Lloyd Morley, chief of the Department of Health and Social Services' Environmental Health Section, to be capable of yielding a harvest worth $2 million a year, a modest beginning as money goes these days, but with far greater potential if and when Alaska and its shellfishermen decide to expand into some of the 46 remaining hideaways of S. patula.

Robert Stott is a shellfish specialist for FDA's Region X. Harold Hopkins is editorial director of FDA Consumer.
The ads and labels may promise a new shape almost overnight, but the devices and treatment programs being ballyhooed often fail to deliver what they promise, or deliver results the user would rather do without.

by Margaret Morrison

“...In only 6 days I lost 4 inches off my waist and 7 pounds of weight.”
“In only 5 weeks I added 2 inches to my bust line.”
“Two full inches in the first 3 days!”

These are the kinds of testimonials used in magazine, newspaper, radio, and television ads, promising new shapes, new looks, and new happiness to those who buy the preparation, the device, or the prescribed program of action. The promoters of such products claim they can develop the bust, shape the legs, wipe out double chins, build muscles, eradicate wrinkles, or in some other way enhance beauty or desirability.

Often such devices or treatments are nothing more than money-making schemes for their promoters. The results they produce are questionable, and some are hazardous to health.

To understand how these products can be legally promoted to the public, it is necessary to understand something of the laws covering their regulation. If the product is a drug, FDA can require proof under the Food, Drug, and Cosmetic (FD&C) Act that it is safe and effective before it is put on the market. But if the product is a device, FDA has no authority to require premarketing proof of safety or effectiveness. If a product already on the market is a hazard to health, FDA can request the manufacturer or distributor to remove it from the market voluntarily, or the Agency can resort to legal actions, including seizure of the product. In such cases, FDA must prove that the device is adulterated or misbranded. A product may be considered misbranded if the directions for use on the label are inadequate, or if the product is dangerous to health when used in the dosage or manner or with the frequency or duration prescribed, recommended, or suggested in the labeling.

Obviously, most of the devices on the market have never been the subject of court proceedings, and new devices appear on the scene.
Promotions for the Iso-Tensor, a plastic tube containing a spring, claimed that exercising with the device would develop the breasts. FDA had the device banned from the market by establishing in court that it would have no effect on the size or shape of the breasts.

continually. Before buying, it is up to the consumer to judge the safety or effectiveness of such items. It may be useful to consumers to know about some of the cases in which FDA has taken legal action.

One notable case a few years ago involved an electrical device called the Relaxacisor, which had been sold for reducing the waistline. The Relaxacisor produced electrical shocks to the body through contact pads. FDA brought suit against the distributor in 1970 to halt sales of the device on the grounds that it was dangerous to health and life.

During the five-month trial, about 40 witnesses testified that they suffered varying degrees of injury while using the machine, and U.S. District Court Judge William P. Gray issued a permanent injunction prohibiting the sale of the device to the general public.

It is to be hoped that all owners of Relaxacisors have destroyed the device so there is no longer a possibility of harm to a user who might not be aware of the danger. Also, this case should serve as a reminder to consumers to be cautious of similar devices they may see on the market.

More recently, in December 1974, FDA seized and condemned three “body altering” devices: Love Legs Instant Shaper, Neckline Beauty System Chin/Neck Band, and Iso-Tensor, a breast developing device, on the grounds that they were misbranded by false and misleading labeling statements. All were distributed by Body Persuasions, Inc., of Woodland Hills, California, and were promoted internationally by a Canadian subsidiary in Toronto.

FDA instigated court proceedings to have all three products banned from the market. It charged, and the court found, that Love Legs—rubber stockings, used to induce perspiration—were not effective in trimming down heavy thighs and slimming, shaping and contouring, and firming the thighs through removal or redistribution of fat. Specifically, the court found, on the basis of medical testimony, that “perspiration has no effect on fat cells or fatty globules under the skin of the thighs” and that “the sole means of removing fat from the thighs is a loss in total body weight through decreased dietary intake.”

The court also sustained FDA charges that wearing the Love Legs devices, or performing the prescribed exercises while wearing them, could impede blood flow and worsen circulatory conditions in pregnant women and people with circulatory problems, and in some cases could cause thrombophlebitis. A label warning against use by such persons was found to be inadequate because there are many persons who are not aware that they have circulatory problems.

The chin strap device—Betty Weider’s Neck Line Beauty System—was similarly promoted as “causing fat-flushing perspiration which flushes fatty globules from
under the skin and neck, and restoring a youthful chin and neck line.” Trial evidence showed this is physiologically impossible and that “the sole means of removing fat from the chin and neck is a loss in total body weight through decreased dietary intake.”

Promotions for the Iso-Tensor, an exercise device, said it increased the size of the female breasts. This claim also is physiologically questionable because the breasts consist predominantly of fat cells. The Iso-Tensor is a plastic tube containing a spring which is compressed by twin plungers. FDA witnesses established that while using the device could exercise the muscles underlying the breasts, this would have no effect on the size or shape of the breasts.

Many highly promoted devices or treatments are aimed at either “spot reducing” or overall weight reduction. One method that gained considerable popularity in 1974 was use of a hormone, Human Chorionic Gonadotropin (HCG), in conjunction with a diet of 500 calories a day. The treatment, sometimes called the Simeons method after the man who introduced it, was being used on thousands of patients in “fat clinics” from coast to coast.

FDA evaluated the claims being made for HCG and concluded that the hormone has no usefulness in the treatment of obesity. FDA now requires that the labeling and advertising for all HCG preparations carry a statement that there is no substantial evidence that it increases weight loss beyond that resulting from caloric restriction or that it causes a more attractive or “normal” distribution of fat or decreases the hunger and discomfort associated with calorie-restricted diets.

The Federal Trade Commission (FTC) also has acted to protect consumers against the use of HCG in weight control. Another questionable weight control method—one that could be hazardous—is the body wrap. Promoters all over the country advertise various forms of this method for spot reducing, which usually involves use of cloths soaked in epsom salts and wrapped around the section of the body where weight loss is desired. Because they use salts, these body wraps are classified as drugs. FDA has brought suit against two such products on grounds that no New Drug Application was filed requesting FDA approval to market them, and no scientific evidence exists to show that the drug is safe and effective for the purpose claimed. In one case, the court ruled in FDA's favor and the product was seized and destroyed. The other case is still pending.

In the first body wrap case, against Dynamics Classics of New York, N.Y., promoters of Instant Trim, Dr. James Bernard Field,
The Postal Service took legal action to halt the sale of these six products through the mail. One of the products (top row, left), a water-sprinkling device accompanied by three kinds of cream, was sold as a bust developer. Another (top row, center), a battery-powered vibrating face mask, was supposed to keep wrinkles away. The other four were promoted as weight reducing aids.

A professor of medicine at the University of Pittsburgh School of Medicine, testified that use of a wrapping method such as Instant Trim could restrict peripheral circulation. He also said there is the possibility of becoming overheated and dehydrated from excessive perspiration caused by wrapping the body with soaked cloths and then putting on a plastic suit, which was part of the Instant Trim treatment. Either of these situations could be extremely hazardous to an overweight person with cardiac or circulatory problems, he testified. Because many overweight people develop conditions that affect the circulatory system, such as diabetes and high blood pressure, "adequate and well-controlled studies are necessary to establish both the safety and effectiveness of Instant Trim for its intended uses," Dr. Field said.

Although distribution of Instant Trim has been stopped, similar devices by other names continue to be manufactured and promoted. American manufacturers are not the only ones making products that are supposed to reshape the human figure. A number of foreign companies have attempted to export body-shaping devices to this country, and FDA inspections at the dock have resulted in refusal to permit import of these products into the United States. Among the recent ones were a Breast Water Circulator from Canada, and a 5 Minute Body Shaper from Taiwan, refused entry because they were misbranded or had inadequate directions for use.

FDA and FTC are not the only Federal agencies concerned about the promotion of medical devices or treatment programs that fail to deliver what they promise, or deliver results the user would rather do without. The U.S. Postal Service keeps a sharp eye out for the advertising and sale by mail of devices or plans that may be falsely advertised and misrepresented. FDA works closely with the Postal
Service on matters pertaining to identification of problem products, scientific evaluation of safety and effectiveness, and establishment of evidence of illegal practices. In the last four months of 1974, the Postal Service filed complaints against Hungrex tablets, E-Z Slim Caps, Trim Tab, Slimmers Glove System, and a grapefruit diet plan—all represented to be effective for weight loss; Dr. Frank’s Nutritional Skin Creme, represented to be effective for skin maladies; Dena of Denmark Bosom Developing Creme and Lotion, for enlargement of the bust; Youth Restoring Concentrated Wrinkle Remover, guaranteed to remove wrinkles for up to 8 hours; and a bustline developer guaranteed to increase the size of the bustline 1 to 3 inches in 8 days.

Among the many kinds of devices or programs promoted to improve the looks in some way, bust developers are always among the best sellers. While exercise devices of one kind or another may not be useful, they usually are not harmful. But one method of bust enlargement—the injection of liquid silicone into the breasts—has had tragic results.

Silicone injections became something of a craze in the 1960’s with the advent of “topless” dancers. A highly publicized San Francisco topless dancer increased her bustline from 36 to 44 inches by the injection of liquid silicone, and housewives as well as show girls began to follow suit. Many of them are now paying for it in illness, disfigurement, even death.

The biggest business in silicone injections occurred in Las Vegas, where competition for jobs is fierce, especially in the kind of work that requires pretty girls with good figures. Young women flock to Las Vegas from all over the United States, looking for work as cocktail waitresses, cashiers, dancers. It was predominantly among these women—and “show girls”—that silicone injections became popular, and among them are found some of the most unfortunate results.

Plastic surgeons in Las Vegas estimate that 12,000 women there had silicone injections during the height of the fad. Now, each year about 120 of these women seek surgical help for problems that developed within one to 14 years after injection.

Serious injury, and at least four known deaths, have been attributed to the use of silicone injections. Reported reactions include severe pain, swelling, lumpiness, discoloration, and infection. Surgical removal of the breasts has been necessary in some cases to prevent gangrene or potentially fatal migration of silicone particles from the breasts to the brain, lungs, or heart.

Even when surgical removal is not required, women suffering adverse effects from silicone injections are physically and emotionally maimed. Seeing their breasts become discolored and misshapen, these women suffer great anguish.

Medical grade injectable liquid silicone is classified as an investigational new drug and its manufacture and use is regulated by FDA. FDA has never approved its use for breast enlargement or augmentation and has joined with the American Medical Association in condemning the practice. Manufacturers are prohibited by FDA from selling silicone for unapproved medical purposes will be seized by FDA and legal action taken against the supplier.

It should be noted that injection of liquid silicone in the breast tissues is not the only method of breast augmentation with silicone. Another practice involves the use of liquid silicone in a pliable silicone bag placed between the breast tissue and the chest muscles. When used in this manner, silicone is classified as an implanted device and none of the problems connected with liquid silicone injections have been reported for this procedure.

While FDA has prohibited the injection of liquid silicone into human breasts, its use as an investigational new drug has been approved for other purposes on a limited trial basis. FDA has authorized eight highly qualified doctors to use silicone on an experimental basis for cosmetic or reconstructive purposes. Included are such uses as filling out conspicuously sunken, scarred areas of the face, and injection into the eye for detached retina. The Dow Corning Corporation, of Midland, Michigan, which manufactures the medical silicone, is required to restrict its sales to these approved physicians or to qualified researchers.

In spite of the injuries and disfigurement that have occurred, some doctors are continuing the practice of breast injections, using an industrial grade silicone, which is available to anyone. Also, breast injections of silicone are available in Mexico, and medical grade silicone from Mexico can be purchased by unethical U.S. practitioners.

Women who are seeking some kind of bust development treatment should be aware that unlawful and unethical practices do exist, and that they feed on the uninformed. Women who have had silicone injections should seek qualified medical help at the first sign of trouble.

When it comes to any treatment, device, program, or product being promoted to make the body beautiful, buyers should beware. They should learn all the facts—potential hazards as well as potential benefits. They should be especially leery of products or treatments that promise amazing results in a very short time. The human body cannot be reshaped overnight.

Margaret Morrison is a member of the FDA publications staff.
News Highlights

Manufacturer to Correct Microwave Ovens

The General Electric Company has agreed to correct possible defects in 17,800 microwave ovens that could leak microwave radiation as much as ten times the limit allowed by the Federal standard, FDA has announced.

The ovens involved are microwave thermal oven-range combination units called “Cooking Center” or “Versatronic.” General Electric’s plan for a corrective program, including letters that are being used to explain the situation to dealers and oven owners, has been approved by FDA’s Bureau of Radiological Health. The model numbers of the ovens involved are J845001, J885001, and RE747001 manufactured in Columbia, Maryland and Louisville, Kentucky, from July through November 1973, model J845001 produced through February 1974 at Louisville, and models J896002, J896003, J856003, J856004, RHV886002, and RHV886003.

FDA recommends that owners of any of the ovens involved in the corrective program discontinue using them for microwave cooking until they can be examined by the manufacturer. FDA suggests that owners of models J845001, J885001, and RE747001 check their oven’s serial number and ask a dealer for assistance in determining when their unit was manufactured. For these models, only the units made between the dates specified are affected at this time.

All of the defective ovens use a wire mesh seal around the door which, when pressed tightly against the face of the oven, prevents microwave energy from escaping.

This is the first major corrective program involving microwave ovens since the Federal standard for these products became effective in October 1971.

Microwave Diathermy Standard Planned

FDA has announced its intent to develop a radiation safety performance standard for microwave diathermy equipment through publication of an advance notice of proposed rulemaking in the June 3 Federal Register.

Microwave diathermy—often used to treat aching muscles and joints—is a procedure in which heat is induced in the tissues beneath the skin by microwaves. Because excessive microwave radiation may be harmful, precautions must be taken to assure safe equipment performance. FDA’s Bureau of Radiological Health believes that recent developments in techniques for control of unnecessary radiation associated with microwave diathermy units make a performance safety standard feasible and desirable.

Under the advance notice of proposed rulemaking, interested persons may submit written data, views, or arguments concerning the subject matter of the standard and suggest related topics for inclusion. Comments should be sent to the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20852.

Comments submitted before August 1, 1975, will be considered in development of the proposed rule. Comments received after August 1 may be considered, depending on the stage of development of the standard at the time they are received.

Report Issued on Michigan Cattle

FDA has announced the results of a survey which concluded that there are no significant health problems associated with animals who have ingested low levels of polybrominated biphenyls (PBB’s). FDA undertook this survey in March 1975 to determine whether Michigan cattle herds contaminated with the chemical were suffering greater health problems than non-contaminated herds. PBB is a flame retardant that accidentally became mixed in feed given to Michigan cattle in 1973.

In addition to FDA, the U.S. Department of Agriculture, Iowa State University Veterinary Diagnostic Laboratory, Michigan Department of Agriculture, and the Michigan State University participated in the survey. Three teams of expert veterinary toxicologists toured the state examining contaminated as well as uncontaminated cattle herds. “Based on the data collected, it was concluded that there are no herd health problems observed that could be attributed to the presence of low levels of PBB,” the survey report said.

Merrill Is New FDA Chief Counsel

Richard A. Merrill is the new chief counsel of the Food and Drug Administration. He succeeds Peter Barton Hutt, who resigned effective May 16.

Merrill comes to FDA from the University of Virginia where he was Associate Dean and Professor of Law. He has taught courses in Administrative Law, Food and Drug Law, Deceptive Practices and Consumer Protection, and Constitutional Law.

Before joining the University in 1969, he was from...
1965 to 1969 a member of the Washington, D.C. law firm of Covington and Burling.

Merrill has served as consultant to the Food and Drug Law Institute, and his published writings include a study on compensation for prescription drug injuries and an analysis of FDA food standards of identity.

**New Rules Ease Public Access to FDA**

Commissioner of Food and Drugs Alexander M. Schmidt has signed comprehensive new regulations governing FDA's administrative practices and procedures. The new regulations are designed to encourage greater public access to the Agency by making its administrative rules easier to find, read, and to understand.

The new regulations spell out in detail the procedures under which citizen petitions will be submitted to, and considered by FDA; the justification for, and conduct of, various kinds of hearings; rules concerning standards of conduct and conflict of interest for Agency employees; and rules governing documentation of meetings and public calendars of key officials.

The task of revising administrative regulations, begun in 1973, involved assembling, clarifying, and codifying hundreds of Agency practices and procedures that had been developed over the years.

Among the specific procedures now codified are several designed to facilitate consumer participation in FDA decisions. A form letter is provided to enable anyone to submit a petition to FDA requesting the Commissioner to “issue, amend, or revoke a regulation or order, or to take or refrain from taking, any other form of administrative action.” In the past there was no clear and consistent procedure for such action, resulting in confusion on the part of the petitioner as well as on the part of FDA personnel handling various types of requests.

The new regulations also make clear that every citizen has standing in the courts to contest any FDA action if he believes the Agency acted improperly, and that anyone to submit a petition to FDA requesting the Commissioner to “issue, amend, or revoke a regulation or order, or to take or refrain from taking, any other form of administrative action.” In the past there was no clear and consistent procedure for such action, resulting in confusion on the part of the petitioner as well as on the part of FDA personnel handling various types of requests.

The regulations appeared in the *Federal Register* on May 27. Interested persons may submit written comments within 60 days of publication to Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20852.

**Younger Women Cautioned on Breast X Rays**

Mammography—x-ray examination of the breast—should not be used in routine programs for detection of breast cancer in women under 35 who are “without complaint, without history, without physical findings, and without a strong family history of breast cancer.”

This is one of four recommendations presented by the American College of Radiology (ACR) expert panel on mammography and adopted, with slight modification, by FDA’s Medical Radiation Advisory Committee.

The recommendation against routine mammography examinations for women under 35 is based on the low incidence of breast cancer in this age group and the decreased effectiveness of the procedure in detecting early breast cancer in younger women. This is because the breast tissue is firmer and more fibrous which may obscure early signs of breast tumors. There have been reports that breast cancer screening centers that use mammography are being set up for young women on college campuses.

The panel said the efficacy of routine breast x-ray examinations for women in the 35-50 age group requires more study. This work is underway in a large-scale breast cancer screening program sponsored by the American Cancer Society and the National Cancer Institute. The project, begun in 1973, involves the examination of 270,000 women, none of whom have evidence of breast cancer, in 27 detection centers across the U.S. Its purpose is to learn if current detection methods, such as physical examination, x-ray film mammography, and thermography, can spot cancer before the woman becomes aware of a breast lump.

**Pet Turtle Sales Ban Linked to Salmonella**

FDA has banned commercial distribution and sales of pet baby turtles and turtle eggs.

"Despite prolonged and intensive control efforts by FDA, in cooperation with State and local health officials, turtles continue to be a significant carrier of pathogenic organisms, particularly affecting small children. We have concluded that a ban of sales is the only action which will adequately protect the public health," Dr. Alexander M. Schmidt, Commissioner of Food and Drugs, said.

Turtles carry *Salmonella* and *Arizona* organisms, which can cause acute gastrointestinal infections leading to other complications and even death. The organisms are transmitted to children when they play with pet turtles and then put their hands in their mouth without washing them. Adults can become infected through contamination of their hands or of food and kitchen utensils.

It has been estimated that as many as 280,000 cases of salmonellosis each year in the United States are turtle-associated.

For the past two years, FDA has required shippers to certify that their turtles were free of *Salmonella* or *Arizona* organisms. The certification program has failed to prevent contaminated turtles from reaching the market. Turtles certified as free of the disease-producing organisms nevertheless were highly susceptible to re-contamination from bacteria in their food and in their...
water environment. A survey showed that 54 percent of the turtles certified as Salmonella- or Arizona-free between December 1972 and December 1973 were contaminated when retested.

The ban applies to fertile turtle eggs and live turtles with a shell length of less than four inches and covers intrastate as well as interstate sales. Shipments for scientific, educational, or exhibition purposes will continue to be allowed.

In ordering the ban, FDA said it will reevaluate its position if it is shown that Salmonella- and Arizona-free turtles can be produced and kept free of contamination during shipment and marketing.

The banning action follows FDA publication on May 28, 1974, of a Consumers' Union petition for the ban, along with an alternative proposal to strengthen control procedures. Strong support for the ban came from 30 State health departments, the Humane Society of the U.S., the Center for Disease Control of the Public Health Service, and the Animal Welfare Institute.

In supporting the ban, the Animal Welfare Institute pointed out that "small turtles sold in pet shops are not miniature, but baby turtles, mostly red-eared sliders, which under proper care can attain a shell length ranging from 6 to 11 inches and can live more than 40 years in captivity; yet 90 percent of the pets survive only 4 to 6 months."

**FDA Seeks Proof of Safety of Zirconium**

FDA has proposed that the sale of all aerosol drug and cosmetic products containing zirconium be halted until their safety and effectiveness can be established by their manufacturers.

A proposal signed by Commissioner of Food and Drugs Alexander M. Schmidt and published in the Federal Register of June 5 would declare aerosol drugs and cosmetics containing zirconium "new drugs" under provision of the Food, Drug, and Cosmetic Act. If FDA issues the proposal as a final regulation—after considering public and industry comments on it—all such products would be ordered off the market until their manufacturers could prove that they are safe and effective.

FDA's action is based on the report of an expert advisory panel which asserts that aerosol antiperspirants with zirconium subject "millions of Americans" to unnecessary risk when exposed to these products over prolonged periods. Zirconium in various forms is used as a perspiration inhibitor. When inhaled, some forms of the substance have been shown to cause lung disease in test animals.

The expert panel said in its recommendations to FDA that the benefit from using aerosol antiperspirants with zirconium is insignificant when compared to the risk. Such antiperspirants are not more effective than nonaerosolized antiperspirants containing zirconium or aluminum, the panel said, and it agreed unanimously that zirconium use in an aerosol product is unjustified.

Commissioner Schmidt said he was particularly influenced in his decision to require proof of zirconium's safety by two points made by the expert panel. First, that "where little benefit is obtainable (to the consumer)... little or no risk is acceptable," and, second, that during a two-day open hearing none of the experts who testified would state "that in their opinion, zirconium-containing aerosol antiperspirants were generally recognized as safe."

Because the major safety issue is attributable to repeated human exposure to zirconium over a prolonged period, FDA at this time does not anticipate recall of affected products on the market before the "new drug" determination.

The Commissioner has provided 90 days for public comment on the proposed order. The proposed effective date for halting interstate shipment of affected products is 30 days after publication of a final order.

Comments may be submitted to the Office of the Hearing Clerk, Food and Drug Administration, Room 4-67, 5600 Fishers Lane, Rockville, Maryland 20852.

**FDA Defines ‘Hypoallergenic’ for Cosmetics**

FDA has issued final regulations defining the term “hypoallergenic” for cosmetic products. Under the new definition, a cosmetic may be labeled “hypoallergenic” if scientific studies show that it causes significantly fewer adverse reactions in human test volunteers than competing products.

FDA developed an official definition to end consumer confusion and to establish a uniform meaning for the term “hypoallergenic.”

For cosmetics which meet requirements established by the regulation, the statement "less likely to cause adverse reactions than some competing products" must appear on their labels close to the word "hypoallergenic" in a conspicuous and prominent manner.

To claim hypoallergenicity, a product must be dermatologically tested against reference products having at least 10 percent of the market share of all similar products.

Manufacturers of products now being marketed who wish to continue using the term "hypoallergenic" will have two years to conduct the required tests. Products not now being marketed will have to justify claims of hypoallergenicity before they may make those claims. Test data will be submitted to the FDA and will be made available to the public. A substantiated claim for hypoallergenicity will be valid for five years.

The final regulation was published in the Federal Register on June 6, 1975. All cosmetics introduced into interstate commerce two years from that date must be in compliance with the regulation.
REGION II

A laboratory procedure developed in FDA's New York District was used to supply evidence in a mail fraud case which a U.S. attorney was trying in nearby Newark. FDA was asked to analyze the contents of two bottles of liquid being sold as a weight reducer. The liquid was to be rubbed into the skin. The laboratory found that the bottles contained meta- or para-methyl hydroxybenzoate, a chemical preservative which has no weight-reducing properties. The laboratory procedure used was developed by FDA chemist James Nelson and involves high-speed chromatography, a method of separating mixtures into their constituents by absorption by a solid.

It all started with an article in the December 1974—January 1975 issue of FDA Consumer about how FDA analysts smell fish to determine its acceptability as food for the American dinner table. In FDA's New York District, where a great percentage of imported fish enters the country, such smelling is done by Al Weber, FDA senior expert on the organoleptic examination of fish.

After reading about Weber's knowledgeable nose in FDA Consumer, CBS-TV reporter John Stossel interviewed him on the evening news program in New York City, the first in a chain of stories in the press, TV, and radio.

Lewis Grossburger followed with a story on Weber in the New York Post, and then Bert Haney of TV station WPIX in New York came to Brooklyn to tape a short feature on Weber for the "people" slot on the 10 p.m. news.

Wind of Weber's nose reached the ABC-TV morning "America" program and he showed a national audience how he sniffs fish to determine its acceptability. On the same day a TV crew from a national education TV station in New York went to Brooklyn to film Weber at work for Bess Myerson's "In the Public Interest" program.

But that wasn't the end. The story of Weber's nose, and what it accomplishes for the consumer, will be heard in Canada from an interview taped by a reporter from the Canadian Broadcasting System.

FDA's Buffalo District detained a shipment from Canada of 62.5 tons of bulk fishmeal at Champlain, New York, which was destined for use in animal feed by a New York City processor, after FDA laboratories determined it was contaminated by Salmonella. The New York City processor said the shipment would be returned to the producer in Nova Scotia. The District notified Canadian authorities for follow-up.

A total of 30 lots of food stored at Maritime Food Corp., Hoboken, was seized by the Federal Government because of rodent contamination. Over 50 percent of the lots examined by FDA's Newark District were found adulterated. Total value of the foods is $10,000.

Minerva C. Sanchez, FDA's consumer affairs officer for the San Juan District, was an honored guest at a ceremony given by the City of San Juan for major contributors to the Head Start Program. During the past year, Ms. Sanchez had provided FDA support in the Inner City Educational Program for Head Start Parents.

Six million pounds of flour, cornmeal, rice, and similar foods, stored in warehouses operated by the Social Services Department of Puerto Rico was found by FDA San Juan District inspectors to be infested with insects, and was embargoed by Puerto Rican health authorities. The foods had been given to the social service agency last summer, when the U.S. Department of Agriculture discontinued the distribution of surplus foods. The embargoed items are being converted to animal feed, or destroyed if the insect problem is too great.

FDA learned of the situation when a bakery operator, during a regular inspection, mentioned that the bakery's equipment was soon to be used for a large project using Government surplus foods. FDA inspection of the warehouses followed.

REGION III

Six lots of drugs, including Ossonate Plus Capsules, Normotensin Injectable, Lipo-K Injectable, Ossonate Plus Injectable, Virozyme Injectable, and Ossonate-75 Injectable, were seized in Philadelphia by the Federal Government. Marcen Laboratories of New Rochelle, New York, shipped the drugs, which are charged by the Philadelphia District with being in violation of the Food, Drug, and Cosmetic Act in that they are new drugs shipped in interstate commerce without an approved New Drug Application.

With the installation of several thousand dollars worth of processing equipment, Cross Brothers Meat Packers of Philadelphia is now back in the business of processing animal by-products for animal feed in
its home plant. The firm had been enjoined on May 8, 1973, from shipping animal by-products in interstate commerce after FDA’s Philadelphia District found some of these products contaminated with *Salmonella* organisms. FDA and the firm later entered into a consent decree under which the firm was allowed to send its production to a feed manufacturer for heat processing to destroy the *Salmonella*. Recently Judge William Ditter, Jr. of the U.S. District Court, Eastern District of Pennsylvania, signed an order to dissolve the consent decree, thus permitting Cross Brothers to return to normal processing procedures.

The Consumer Affairs Office of FDA’s *Baltimore District* took part in the celebration of Baltimore Urban League Week, marking the 50th year of the Urban League’s service to the community. The traditional trappings of an oldtime county fair—midway, side shows, and a big top—were used to teach consumers, particularly those from the inner city, how to get the most for their money through wise selection of consumer goods. The Consumer Affairs staff provided speakers, films, slides, and an exhibit on nutrition labeling.

**REGION IV**

The *Atlanta District* monitored recall by Avon, Inc., New York, from Atlanta area salespeople of 92 packages of Avon Clearly Gentle Liquid Cleaner in 10-ounce squeeze bottles after FDA was notified by the company that the products had been found to be contaminated by *Enterobacter hafniae* bacteria. No bottles reached consumers, and no injuries were reported. The 92 units, formulated in Morton Grove, Illinois, had been sent to the Atlanta company representatives as demonstrators. The recall was restricted to the Atlanta area.

Over a two-month period, 14 lots of stuffed and salad olives from Spain, valued at $37,168, were detained by FDA’s *Orlando District* after investigators Stephen Tunks in Miami, and Herb Smith and Frank Gregorio in Tampa, collected samples which were found upon analysis to contain excessive amounts of pit fragments.

Rodent activity, noted during a routine inspection of the warehouse section of Shepard’s Mill, Greensboro, Florida, a cornmeal manufacturer and repacker of rice and beans, led to Federal Government seizure of 36 hundred-pound bags of rice and 4 hundred-pound bags of lima beans contaminated by rodents. The inspection was made by John Sears and Rick Spicher of the Orlando District.

Gressinger and Sons, Inc., Belle Glade, Florida, a large vegetable grower, pleaded guilty and was fined a total of $15,000 on three counts of interstate shipment of parsley contaminated by four pesticides: nitrofan, in excess of tolerance; and toxaphene, methyl parathion, and parathion, for which there are no established tolerances. U.S. District Court Judge Charles B. Fulton of the Southern District of Florida, West Palm Beach, also placed the company president, William D. Gressinger, on probation for one year. The legal action was based on the Orlando District’s investigation in 1973 after receiving information from the Florida Departments of Agriculture and Consumer Services.

FDA’s activities in assuring the quality, safety, and effectiveness of drugs manufactured and distributed in this country, were outlined by Maurice D. Kinslow, food and drug director, FDA Region IV, in an appearance before the Tennessee Legislature’s Committee on Labor and Consumer Affairs. The Legislature has been considering a bill to permit substitution of generic drugs for brand name drugs written on a prescription.

The Federal Government has seized over 340,000 pounds of shelled black walnuts valued at about $1 per pound at Block Brothers, Inc., Nashville, because inspection by FDA’s *Nashville District* investigators Jerry M. Baker, Clifford S. Purdy, and William M. Todd indicated the product had been adulterated while held for sale.

A total of 13,585 pounds of flour, valued at $2,109, was seized by the Federal Government at Beattyville Wholesale Grocery Co., Beattyville, Kentucky, because of defilement by rodents, following investigations by Michael A. Chattell of FDA’s Nashville District and William J. Thompson of the District’s resident post at Lexington, Kentucky.

**REGION V**

The Federal Government seized approximately $16,000 worth of diethylpropion hydrochloride tablets and raw materials at Camall Co., Detroit. Used as appetite depressants, these tablets are marketed under the trade name of Camuate. In a routine inspection and analysis, investigators from FDA’s *Detrot District* found the raw material and the finished product to be subpotent.

Edward F. Devitt, president and principal managing agent of Action Warehouse, Inc., Chicago, has been found guilty of criminal contempt of court by the U.S. District Court in Chicago for refusing to permit completion of an inspection of the warehouse pursuant to a properly issued warrant. The U.S. Attorney’s office for the Northern District of Illinois prosecuted the complaint on behalf of FDA. District Court Judge Bernard M. Decker sentenced Devitt to incarceration.
for a period of time equal to that he spent in custody
of the U.S. marshal on March 7 and 8, and gave him
credit for the time served.

As a result of inspection by investigators from
FDA’s Chicago District, certain lots of dates in the
warehouse were found to be adulterated by maggots
and insects and basil was found to be rodent and in-
ssect contaminated. The lots were subsequently seized
and condemned. FDA’s Chicago District Compliance
Officer Jerome Bressler coordinated Agency activities.

FDA’s Detroit District reports that seizure was
made at Dearborn, Michigan, of 1,178 cases of imita-
tion-flavored syrups, valued at over $10,000. FDA
laboratory analysis found the syrups contained the
artificial sweetener saccharin instead of sugar, as was
declared on the label. The syrups were manufactured
by Midwest Carbonic, Rock Island, Illinois.

REGION VI

The Texas State Division of Food and Drugs and
the Dallas District collaborated in monitoring the sal-
vage of medical equipment and supplies, damaged in
a $500,000 fire, at the Texas Hospital Supply Co.,
in Dallas. Stock which could not be reconditioned or
salvaged was destroyed.

Regulation of dairy products shipped interstate
was described to the Agriculture Committee of the Okla-
ahoma House of Representatives in mid-March, by Wil-
liam A. Graham, Dallas District compliance officer.
The Committee was considering a proposal for State
inspection of dairy products entering Oklahoma, and
seemed most concerned about Salmonella contamina-
tion of dried milk. The Committee was assured that
FDA samples such milk products shipped interstate,
and that State regulation would be largely a duplica-
tion. Action on the proposal was deferred.

Three truckloads of wheat, valued at $48,000 and
weighing 600,000 pounds, were seized by the Govern-
ment at Topeka, Kansas, because of contamination
with ammonium phosphate pellets. The trucks, oper-
at by Stratton Equity Corp., of Stratton, Colo-
rado, had been used earlier to transport the pellet
fertilizer and had not been properly cleaned before
being loaded with wheat. FDA’s Denver District and
Kansas City Field Office cooperated in the investi-
gation and seizure.

REGION VII

The Government seized mixed nuts valued at over
$2,000 at the Greater Kansas City Council of Handi-
capped Citizens, Kansas City, after that organization
complained to the Kansas City Field Office. The Field
Office investigation showed that the nuts, shipped by
A. L. Schultzman Co., Brookville, Wisconsin, were
adulterated by insects and that inferiority of the prod-
uct was concealed. The nuts were condemned and de-
stroyed.

REGION VIII

The Federal Government has seized and will destroy
under condemnation proceedings, a supply of candy
paciﬁers, held by a dealer in Fargo, North Dakota.
The paciﬁers, imported from Belgium, have been clas-
siﬁed as unsafe by FDA because of the possibility that
infants might choke on the candy tip. Originally, seven
U.S. shippers were importing the products from vari-
ous European sources and six of them later voluntarily
recalled their products from the market. One, Paul
Spitz, Bronx, New York, refused to recall and the
FDA instituted the seizure proceedings against the
shipment he had made to Fargo.

It was blue, true, but hardly a piece of sky. So con-
cluded the Federal Aviation Administration after in-
specting a large chunk of blue ice that fell through the
roof and into the kitchen of a house near the Denver
Airport. FAA concluded the block of ice was frozen
toilet waste that fell from an unidentified commercial
airliner. A faulty toilet discharge valve allowed the
waste to leak and freeze on the outside of the plane,
the FAA believes, and then it fell off as a result of
rising temperatures or fuselage stress during the plane’s
landing approach. Investigation by William Biggs, FDA
interstate travel sanitation consultant in Denver, and
the FAA, failed to pinpoint the particular airline or
plane involved, but the prohibitions by the Interstate
Quarantine Regulations against indiscriminate dis-
charge of waste from public carriers have been brought
to the attention of the airlines by FDA. The airlines
contacted were advised to make new efforts to service
and maintain aircraft waste systems.

A carload of barley, seized under a consent decree
by the Federal Government as a result of ﬁndings by
FDA, has been diverted from food use and will be used
as seed. After receiving a report from Bowden Grain
and Elevator Co., Bowden, North Dakota, that the bar-
ley had a musty smell that made it objectionable for
commercial use, Don Fernholz, consumer safety ofﬁcer
at FDA’s Denver District Resident Inspection Post in
Fargo, North Dakota, went to examine it. But before
Fernholz arrived, the local elevator owner poured
malathion on the barley, later stating that he had heard
that this chemical pesticide would remove the objec-
tionable odor. It did, but resulted in contamination of
the barley by the pesticide, which had been used in
such concentration that it soaked through the bottom
of the paper bag Fernholz used to obtain a sample of the
grain.

After the sampling, the carload was removed to St.
Cloud, Minnesota, where FDA's Minneapolis District instigated seizure proceedings. The consent decree that resulted from the seizure action, specified that the barley be disposed of in such a way that it would not become human or animal food. The carload was then returned to Fargo, where it was converted to seed use under monitoring by FDA's Denver District.

**REGION X**

The Federal Government seized three “Blanketrol” Hyper-Hypothermia devices at a weight reducing salon in Eugene, Oregon, after charges were brought by the Seattle District that the product was misbranded. The District acted after being notified by FDA's Cincinnati District that the devices had been shipped to the Oregon salon by a company in Cincinnati. The labeling failed to bear adequate directions for use and against misuse. FDA’s position is that adequate labeling cannot be written for safe use of this device by lay persons for weight control.

As a result of findings during a joint FDA and Washington State Department of Agriculture (WSDA) inspection conducted by FDA investigator Jonetta I. Collins and WSDA inspectors David Knadle and Pat Sietsmam, the owners of The Fish House, a Seattle seafood processor and retail store, chose to close until a new location can be established. The inspectors found numerous rodent entry points into the building, rodent excreta pellets throughout the storage and processing areas, a dead rodent in the storage area, and rodent burrows in the insulation of the ice-making machine. The establishment was in a structure built on pilings over the water on Seattle’s waterfront. According to the management, it had been in business at that location since 1904.

Two devices in the possession of doctors of chiropractic in Cornelius and Salem, Oregon, were seized by the U.S. marshal from Portland after FDA’s Seattle District office charged that the devices, labeled in part “Toftness Radiation Detector,” were misbranded because the labeling fails to bear adequate directions for the use for which they are intended. The devices, manufactured by the Toftness Chiropractic Clinic, in Cumberland, Wisconsin, are allegedly used to detect disease by measuring electrical emanations from the body.

### Commission Presented

T. C. Maraviglia, Food and Drug Director for FDA’s Region III, presented an FDA Commission to Pennsylvania Secretary of Health, Leonard Bachman, M.D., in ceremonies in Harrisburg, thereby giving him authority to act under the Federal Food, Drug, and Cosmetic laws. At the same time, a new work-sharing memorandum of understanding was signed to develop a cooperative drug inspection program between the State and FDA to eliminate duplication of effort and enhance consumer protection.

### Salt Labeling Upheld

There is no significant difference between “sea salt” and common salt, the Oregon Department of Agriculture has said in rejecting a request for repeal or amendment of a section of its food regulations relating to terms that may be used in labeling or advertising salt. The regulation permits the use of only four descriptive terms for salt when sold or used for seasoning or preserving food or as an ingredient of food: “salt,” “table salt,” “iodized salt,” or “iodized table salt.” A Eugene, Oregon firm objected and asked for repeal or amendment, claiming there were substantial differences in the amount of three trace elements in two brands of unrefined sea salt it distributes compared to common table salt.

A hearing was held and the hearing officer concluded that the differences, if any, between “sea salt” and common salt are insignificant, as shown by laboratory tests.

### ‘Sugar Volcano’ Erupts

A sugar processing plant in Tuscola County, Michigan, recently experienced a volcanic style eruption of some 19 million pounds of sugar. An unknown source caused the sugar to heat up to 320°F., breaking it down into carbon which erupted as a black syrupy substance.

The liquid carbon was pumped into trucks which hauled it away around the clock for several days. The cleanup and reprocessing took a number of weeks to complete. Michigan Department of Agriculture Food Inspection personnel consulted with the firm in its salvage of part of the sugar for reprocessing.

### X-ray Machine Destroyed

When Delaware health officials learned that an upright fluoroscope x-ray machine was to be sold by the owner at public auction to pay for storage charges, they called in a radiology expert from FDA’s Region III headquarters in Philadelphia to help inspect the machine. Inspection showed the machine to be obsolete and unsafe, and the owner agreed to destroy it.
### 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 34 actions to remove from the consumer market products charged to be violative was reported in April. These included 27 seizures of foods; 27 involved charges concerning contamination. Other seizures included 2 of food additives, 3 of drugs, 1 of medical device, and 1 of prophylactics.

<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anchovy fillets/Granite City, III. 2/14/75</td>
<td>Action Warehouse, Inc./Chicago, Ill. (D)</td>
<td>Decomposed. Held under insanitary conditions; rodent and insect contaminated.</td>
</tr>
<tr>
<td>Basil/Chicago, Ill. 3/26/75</td>
<td>D &amp; S Warehousing, Inc./Newark, Del. (D)</td>
<td>Rodent contaminated.</td>
</tr>
<tr>
<td>Beans, fava; horsebeans/Newark, Del. 2/19/75</td>
<td>Ashley's, Inc./El Paso, Tex. (M.S)</td>
<td>Contain stones.</td>
</tr>
<tr>
<td>Chili peppers/Tumacacori, Ariz. 1/9/75</td>
<td>Santa Cruz Chili &amp; Spice Co./Tumacacori, Ariz. (D)</td>
<td>Insect contaminated.</td>
</tr>
<tr>
<td>Chocolate powder/Hato Rey, P.R. 3/13/75</td>
<td>Industria Lechera de Puerto Rico/Hato Rey, P.R. (D)</td>
<td>Held under insanitary conditions; insect contaminated.</td>
</tr>
<tr>
<td>Coffee beans, green/New Orleans, La. 3/13/75</td>
<td>Jan C. Uiterwyk Co., Inc./New Orleans, La. (D)</td>
<td>Held under insanitary conditions.</td>
</tr>
<tr>
<td>New Orleans, La. 4/1/75</td>
<td>Hellenic Lines, Ltd./New Orleans, La. (D)</td>
<td>&quot;; contain mold.</td>
</tr>
<tr>
<td>Com/Pittsfield, III. 3/25/75</td>
<td>Tabor &amp; Co./Decatur, Ill. (S)</td>
<td>&quot;; rodent contaminated.</td>
</tr>
<tr>
<td>Cormeal/Shreveport, La. 4/4/75</td>
<td>Shreveport Grain &amp; Elevator Co./Shreveport, La. (D)</td>
<td>&quot;; insect contaminated.</td>
</tr>
<tr>
<td>Dandelion root; whole orange peel; seedless hops; sassafras; peppermint leaves; chicory root; dandelion herbs; fenugreek seeds; Irish moss, bleached; quince seeds; blackberry root bark/ Harbor City, Calif. 11/20/74</td>
<td>Hathaway Allied Products/Harbor City, Calif. (D)</td>
<td></td>
</tr>
<tr>
<td>Dates/Chicago, Ill. 4/10/75</td>
<td>Action Warehouse/Chicago, Ill. (D)</td>
<td></td>
</tr>
<tr>
<td>Flour, corn starch/New Bedford, Mass. 4/17/75</td>
<td>National Wholesale Co./New Bedford, Mass. (D)</td>
<td>Held under insanitary conditions; rodent contaminated.</td>
</tr>
<tr>
<td>Foods, various/Yonkers, N.Y. 3/3/75</td>
<td>Dresser Sales Co., Inc./Yonkers, N.Y. (D)</td>
<td>Held under insanitary conditions.</td>
</tr>
<tr>
<td>Lobster tails/Jersey City, N.J. 6/17/74</td>
<td>Imported from India. Imported from Belgium and France.</td>
<td>Decomposed.</td>
</tr>
<tr>
<td>Milk, whole/Caguas, P.P. 4/1/75</td>
<td>Florida's Own Foods, Inc./Fort Lauderdale, Fla. (D)</td>
<td>Held under insanitary conditions; insect contaminated.</td>
</tr>
<tr>
<td>Pinto bean dry; dextrose/Fort Lauderdale, Fla. 1/22/75</td>
<td>Maloney Trucking &amp; Storage Co./New Orleans, La. (D)</td>
<td>&quot;; insect contaminated.</td>
</tr>
<tr>
<td>Patty mix of processed soya and spices/New Orleans, La 2/28/75</td>
<td>Port Terminals, Inc./Boston, Mass. (D)</td>
<td>&quot;; rodent contaminated.</td>
</tr>
<tr>
<td>Peanuts, shelled; rice/Boston, Mass. 4/2/75</td>
<td>A.L. Schutzman Co., Inc./Brookfield, Wis. (D)</td>
<td>&quot;; insect contaminated.</td>
</tr>
<tr>
<td>split Spanish/Brookfield, Wis. 3/14/75</td>
<td>Manuel Rogers Produce Co./Conroe, Tex. (D)</td>
<td>&quot;; rodent contaminated.</td>
</tr>
<tr>
<td>Potatoes/Conroe, Tex. 2/26/75</td>
<td>Texas Gulf Warehouse, Inc./Houston, Tex.</td>
<td>Held under insanitary conditions.</td>
</tr>
<tr>
<td>Rice/Houston, Tex. 4/1/75</td>
<td>Camp Chemicals Corp./South Boston, Va. (D)</td>
<td>&quot;; rodent contaminated.</td>
</tr>
<tr>
<td>Salt/South Boston, Va. 3/17/75</td>
<td>Puryear Grocer Co./Jonesboro, Ark. (D)</td>
<td>Insect contaminated.</td>
</tr>
<tr>
<td>Sugar/Jonesboro, Ark. 2/19/75</td>
<td>W.T. Wilson Transfer &amp; Storage Co./Abilene, Tex. (D)</td>
<td>Held under insanitary conditions; rodent contaminated.</td>
</tr>
<tr>
<td>Abi gene, Tex. 4/7/75</td>
<td>Cargill, Inc./Minot, N. Dak. (S)</td>
<td></td>
</tr>
<tr>
<td>Wheat, bulk/Minneapolis, Minn. 3/10/75</td>
<td>Joseph Fragola, Inc./Brooklyn, N.Y. (D)</td>
<td></td>
</tr>
<tr>
<td>Wheat; chick peas/Brooklyn, N.Y. 2/24/75</td>
<td>W. T. Wilson Transfer &amp; Storage Co./Abilene, Tex. (D)</td>
<td></td>
</tr>
</tbody>
</table>

#### FOOD ADDITIVES

Article contains the nonconforming food additive saccharin; saccharin had been substituted for sugar; and false and misleading claims about fruit juice and sweetener content, and use as cocktail mix, when article contains no fruit juice, was sweetened with saccharin, whose use in alcoholic beverages was not provided for in regulations because the natural high caloric value of alcoholic beverages would preclude valid special dietary use.
FOOD ADDITIVES (cont’d)

Mixtone Dietetic Base for ice cream and ice milk/Omaha, Nebr. 2/27/75
Mixtone Products Co., Inc./Los Angeles, Calif. (M,S)
Contains the nonconforming food additive saccharin; and the name of the article was false and misleading since a frozen dessert made from the article would not comply with the standards of identity, due to the presence of saccharin and sorbitol.

DRUGS/Human Use

Amygdalin solution/Portland, Oreg. 2/11/75
John A. Richardson, M.D./Albany, Calif. (S)
New drug without an effective approved New Drug Application.

Myotonachol tablets/Brainerd, Minn. 2/20/75
Glenwood Laboratories, Inc./Tenafly, N.J. (S)
Contains insect excreta and wood splinters.

Provitamin B-15 capsules, Amygdalin solution/Spokane, Wash. 2/6/75
John A. Richardson, M.D./Albany, Calif. (S)
False and misleading statement "Pro-Vitamin B-15 (Pan-gametin or Pangamic Acid) a non-toxic water soluble food factor" (Provitamin B-15 capsules); new drug without an effective approved New Drug Application (Amygdalin solution).

MEDICAL DEVICE

Hyper-Hypothermia/Eugene, Oreg. 2/14/75
Cincinnati Sub Zero Products, Inc./Cincinnati, Ohio (M,S)
Inadequate directions for safe use by laymen.

Prophylactics

Prophylactics/Columbus, Ga. 4/1/75
M & M Rubber Co./Kansas City, Mo. (M,S)
Contain holes; and label claim for prevention of disease was false and misleading due to the holes.

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

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

February 26, 1975: 4-Way Diet, Caroline Road, Philadelphia, Pennsylvania. Advertising and sale by mail of tablets, Kelpathin, to cause weight loss of 12 pounds in 2 weeks.

February 27, 1975: American Consumer, Inc., Caroline Road, Philadelphia, Pennsylvania. Advertising and sale by mail of Electro-Vibrator to attack cellulite, equivalent to thousands of leg bends.

February 28, 1975: Hollywood Beautiful Breast, 520 and 521 Fifth Avenue, New York, New York 10017. Advertising and sale by mail of “FAMOUS METHOD” represented as effective for enlargement of the bosom.

March 4, 1975: H&M Pharmaceuticals, P.O. Box 370-352, Buena Vista Station, Miami, Florida 33137. Advertising and sale by mail of a bust developer.

March 4, 1975: Richard, P.O. Box 4307, Englewood, California 90309. Advertising and sale through the mail of a weight loss method represented to be effective for weight loss of 3 to 6 pounds per week.

March 4, 1975: Vital Energy, P.O. Box 256, Claremont, California. Advertising and sale by mail of Bio-Folic H represented to be an effective remedy for baldness.

March 5, 1975: Almante, Box 11608, Santa Rosa, California 95406. Advertising and sale by mail of a bracelet represented to be effective for arthritis pain.

March 5, 1975: Regai Star Body Creme, P.O. Box 599, New York, New York 10017. Advertising and sale by mail of Regai Star Body Creme represented to contain “tremendous units of estrogenic hormones” for bustline development.

March 5, 1975: Royale Star Method, 520 Fifth Avenue, New York, New York 10036. Advertising and sale by mail of the “Royale Star Method” represented as effective for increasing the bustline up to 6 inches.

March 11, 1975: American Beauty Products Co., Inc., P.O. Box 3183, Tulsa, Oklahoma 74101. Advertising and sale by mail of a hormone hair treatment.

March 11, 1975: Mr. America Waist Trimmer, P.O. Box 21303, Chattanooga, Tennessee 37421. Advertising and sale by mail of a waist trimmer belt.

March 19, 1975: Treatment, P.O. Box 221, Lovelock, Nevada. Advertising and sale through the mail of a system for growing hair.

March 19, 1975: Kalaco, 5632 11th Street, NE, Seattle, Washington 98108. Advertising and sale by mail of the Kalaco Grapefruit Diet represented to be effective for weight loss.

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

February 24, 1975: Against Arway Co., Box 173, Malone, Florida 32445. Advertising and sale through the mail of a product called “new love potion.”

ERRATA: On page 35 of the Seizure Actions for the April 1975 issue of FDA Consumer, the charge for the Cosmetic entry contained a typographical error. It should have read: Containers mislabeled as “Pure Lard” and “Soft Margarine.”
**NOICES OF JUDGMENT on Seizure Actions**

**FOOD/Poisonous and Deleterious Substances**

Charged 7-18-74: when shipped by Monticello Canning Co., Inc., Crossville, Tenn., the article contained the added deleterious substance cockleburs—402(a)(1); and the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was expressed as "Net Weight 1 Pound" instead of "Net Wt. 16 Oz. (1 Lb.)". The quantity of contents statement, appearing upon the principal display panel area of more than 5 square inches, was in a type size less than 1/8 inch high. The label bore a statement as to the number of servings per can without stating the quantity of each such serving—15 U.S.C. 1453(a)(3)(B). 18 U.S.C. 1453(a)(3)(C). 1453(a)(4). Default decree ordered destruction. (F.D.C. No. 59870; S. No. 111 942 H; N.J. No. 1)


Pecans, unshelled, at Laredo, S. Dist. Tex.
Charged 11-19-74: when shipped by Morrow Produce Co., Boardman, Oreg., the article contained the added pesticide chemical chlordane in excess of the tolerance; 402(a)(2)(B). Default decree authorized release to Cook Industries, Inc., Memphis, Tenn., for reconditioning. (F.D.C. No. 59979; S. No. 54-581 H; N.J. No. 4)

**FOOD/Contamination, Spoilage, Insanitary Handling**

Anchovy fillets, canned, Roland, at Atlanta, N. Dist. Ga.
Charged 2-22-74: when shipped by American Roland Food Corp., New York, N.Y., the article was contained in swollen, rusty, and leaking cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59673; S. No. 6-192 G; N.J. No. 5)

Bean thread and rice, at Laredo, S. Dist. Calif.
Charged 2-13-74: when held by Wing Sing Chong Co., Inc., San Francisco, Calif., one lot of rice contained rodent filth, and all the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Food Industries, Inc., Memphis, Tenn., for reconditioning. (F.D.C. No. 59655; S. Nos. 94-222/5 G; N.J. No. 6)

Brie cheese, cold pack cheese food, and Swiss cheese, at New York, Dist. N.Y.
Charged on or about 5-14-74: while held for sale, the cold pack cheese food and Swiss cheese contained mold, and the brie cheese contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59775; S. No. 42-337 H et al.; N.J. No. 7)

Cherries, chopped, frozen, at Hudson, S. Dist. N.Y.
Charged 6-27-74: while held by Clermont Fruit Packers, Hudson, N.Y., who had prepared and packed the article using sugar shipped in interstate commerce, the article contained decomposed cherries; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59884; S. No. 106-322 H; N.J. No. 8)

Flour, cinnamon, and approximately 900 other lots of foodstuffs in containers of burlap, cloth paper, & Pliofilm, at Laredo, S. Dist. Tex.
Charged 6-27-74: while held by Casso, Guerra & Co., Laredo, Tex., the articles were held under insanitary conditions; 402(a)(3). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 59833; S. No. 89-242 H et al.; N.J. No. 9)

Flour mix, at Totowa, Dist. N.J.
Charged 6-17-74: while held by S.B. Thomas, Inc., Totowa, N.J., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59798; S. No. 56-511 H; N.J. No. 10)

**NOTICES OF JUDGMENT on Seizure Actions**

Charged 7-18-74: when shipped by Monticello Canning Co., Inc., Crossville, Tenn., the article contained the added deleterious substance cockleburs—402(a)(1); and the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was expressed as "Net Weight 1 Pound" instead of "Net Wt. 16 Oz. (1 Lb.)". The quantity of contents statement, appearing upon the principal display panel area of more than 5 square inches, was in a type size less than 1/8 inch high. The label bore a statement as to the number of servings per can without stating the quantity of each such serving—15 U.S.C. 1453(a)(3)(A). 1453(a)(3)(C). 1453(a)(4). Default decree ordered destruction. (F.D.C. No. 59870; S. No. 111 942 H; N.J. No. 1)

Soybeans, at Reserve, E. Dist. La.
Charged 8-23-74: when shipped by Liberty Rice Mill, Inc., Kaplan, La., a bag of the articles contained insect and/or rodent filth, and the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to deal for salvaging. (F.D.C. No. 59928; S. No. 40-093 H et al.; N.J. No. 13)

Potatoes, Dregon Bounty, at Los Angeles, C. Dist. Calif.
Charged 6-20-74: when shipped by Western Produce Co., Los Angeles, Calif., the article contained the added pesticide chemical chlordane in excess of the tolerance; 402(a)(2)(B). Consent decree authorized release to Van Brute Milling Co., Inc., Clinton, Mass., for salvaging. (F.D.C. No. 59752; S. Nos. 108 065/6 H; N.J. No. 15)

Garlic buds, at Laredo, S. Dist. Tex.
Charged on or about 11-5-73: while held by David M. Slaughter & Son, Inc., Laredo, Tex., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59545; S. No. 37-152 G; N.J. No. 11)

Milk, bottled, at San Juan, Dist. P.R.
Charged 8-27-74: while held for sale, the article contained decomposed milk; 402(a)(3). Consent decree authorized release to Bravo Co., Div. Amtrak Corp., New York, N.Y., for salvaging. (F.D.C. No. 59940; S. No. 23-123 H; N.J. No. 12)

Muffin mix, dessert mixes, cookies, oatmeal, and other grocery warehouse stocks in containers of burlap, cloth, paper, Pliofilm, cardboard, and similar materials, at Tampa, M. Dist. Fla.
Charged on or about 6-13-74: while held by Lorenzen Food Service, Tampa, Fla., a number of the articles contained insect and/or rodent filth, and the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59926; S. No. 40-093 H et al.; N.J. No. 13)

Rice, at Clinton, Dist. Mass.
Charged on or about 5-14-74: while held for sale, the article contained insect—402(a)(3); and when shipped by Liberty Rice Mill, Inc., Kaplan, La., some bags of the articles were unlabeled, and therefore lacked both the common or usual name of the food, and the name and place of business of the manufacturer, packer, or distributor—403(e)(1); and the unbalelled bags and some of the labeled bags lacked an accurate statement of the quantity of contents—403(e)(2). Consent decree authorized release to Van Brute Milling Co., Inc., Clinton, Mass., for salvaging. (F.D.C. No. 59752; S. Nos. 108 065/6 H; N.J. No. 15)

Rice and soybeans, at Columbus, Dist. Md.
Charged on or about 9-9-74: while held for sale, the articles contained rodent filth and had been held under insanitary conditions; 402(a)(3). Consent decree authorized release to Japan Food Corp., Columbus, Md., for salvaging. (F.D.C. No. 59685; S. Nos. 113 004/7 H; N.J. No. 16)

Cheese, Cheddar, Brie cheese, Port Lava, Dist. Tex.
Charged 12-7-72: while held by H. Morgan Daniel Seafoods, Inc., Port Lavaca, Tex., the article had been prepared, packed, and held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58615; S. Nos. 83 112 F & 83 114 F; N.J. No. 17)

Walnuts, black, shelled, Tennessee Belle, at Nashville, M. Dist. Tenn.
Charged 7-1-75: when returned from Springfield, Ohio, to Block Brothers, Inc., Nashville, Tenn., the articles contained rodent filth and had been prepared, packed, and held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59853; S. No. 95-002 H; N.J. No. 18)

Gingersnap cookies, at Demopolis, S. Dist. Ala.
Charged on or about 8-17-70: while held by The Tasty Cookie Co., Louisville, Ky., the article, labeled in part "GA Cookies . . . Ginger Snaps . . . Distributed by independent Grocers Alliance Distributing Co. Chicago, U.S.A. Toronto, Canada," was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not placed in the bottom 30 percent of the principal display panel area, and the quantity of contents statement was expressed as "1 3/4 Lb." instead of "Net Weight 28 Oz." (GA)
Bismuth ammonium citrate combination fluid, at Houston, Dist. Tex.

Charged on or about 10-25-72: when shipped by E.W. Heun Co., St. Louis, Mo., the article, labeled in part “Bentex... Bentex Ammonium Citrate... Manufactured for Bentex Pharmaceutical Co., Houston, Tex.,” was a new drug without an effective approved New Drug Application; 505(a). The article was claimed by Bentex Pharmaceutical Co., Houston, Tex., who denied the charge. The Government moved for summary judgment based upon the prior adjudication in favor of the Government in the U.S. v. Bentex Ulcerine, 469 F.2d 875. The court granted the Government’s motion and ordered the destruction of the article. (F.D.C. No. 58372; S. Nos. 29-396 F; N.J. No. 23)

Bismuth ammonium citrate combination fluid and concentrated bismuth solution component, 2 seizure actions at Houston, Dist. Tex.

Charged 8-17-70 and 11-2-71: initial action—while the concentrated bismuth solution component was held by Dow B. Hickam, Inc., Houston, Tex., for manufacturing the finished fluid, and while the finished fluid, labeled in part “Bentex Ulcerine... Bismuth Ammonium Citrate... Pepsin... Potassium Chloride... Manufactured for Bentex Pharmaceutical Co., Houston, Tex.,” was held by Bentex Pharmaceutical Co., Houston, Tex., the articles’ labeling lacked adequate directions for use, and the articles were not exempted therefrom, since the articles were new drugs without effective approved New Drug Applications; 502(f)(1). Subsequent action—when shipped by E.W. Heun Co., St. Louis, Mo., the article, labeled in part “Bentex Ulcerine... Bismuth Ammonium Citrate... Pepsin... Potassium Chloride... Manufactured for Bentex Pharmaceutical Co., Houston, Tex.,” was a new drug without an effective approved New Drug Application; 505(a).

The articles were claimed by Bentex Pharmaceutical Co., Houston, Tex., who denied the charges, contending that the “grandfather” clause of the Act (21 U.S.C. 201(i)) excluded the articles from the new drug procedures and provisions. In the claimant’s answer to the charges filed on 11-13-71, the claimant also asserted that the subsequent action was contrary to the statutory provisions of bringing more than one seizure action against an article of drug and constituted a multiplicity of suits; and the claimant prayed that the subsequent action be dismissed and/or joined with the initial action. Subsequently, upon motion of the parties, the two actions were consolidated as involving the same six doctors, both physicians and surgeons. The physicians testified essentially that each of them had used the drug when the more accepted and recognized remedies had failed; and that the results had been very satisfactory; in even dramatic cases. Each was an enthusiastic advocate of its virtues. The surgeons testified that they had resorted to surgery with much less frequency than formerly, and attributed many non-surgical cures to the Ulcerine treatment. Some of these witnesses were quite impressive.

On October 10, 1962, the Kefauver-Harris Amendments (Public Law 87-781), known as the Drug Amendments Act of 1962, became effective. This legislation changed the pre-existing definition of a new drug by adding the words “and effectiveness” and the word “approved” to the present definition. Therefore, from 1938 to 1962 an “old drug” pre-existing definition of a new drug by adding the words “and effectiveness” and the word “approved” to the present definition. Therefore, from 1938 to 1962 an “old drug” was a drug and not a new drug, if the drug was generally recognized as safe and effective by those qualified in the field. It, therefore, was subject to for a multiplicity of suits; and the claimant prayed that the subsequent action be dismissed and/or joined with the initial action. Subsequently, upon motion of the parties, the two actions were consolidated as involving the same six doctors, both physicians and surgeons. The physicians testified essentially that each of them had used the drug when the more accepted and recognized remedies had failed; and that the results had been very satisfactory; in even dramatic cases. Each was an enthusiastic advocate of its virtues. The surgeons testified that they had resorted to surgery with much less frequency than formerly, and attributed many non-surgical cures to the Ulcerine treatment. Some of these witnesses were quite impressive.

The government urged strongly that the admitted fact that laboratory testing and experimentation had been very limited and articles appearing in medical journals and periodicals almost non-existent is itself enough to show that the test has not been met. I am not prepared to accept this at face value... I, however, persuasive. Certainly it is not unreasonable that if a drug is generally recognized as safe and effective, one would find in the medical literature over a period of years support for this premise from wide experimentation and study...

I drew the impression from the claimant’s medical witnesses that each considered himself something of a pioneer in his use and advocacy of this medication. Each had talked to his fellow physicians and associates about it, but I drew the impression that until such discussions these associations were unfamiliar with the drug.

Thus, I think it may be said that the claimant’s evidence shows at best that while some popularity of the drug has increased rather drastically—while it is advocated as safe and physicians who strongly espouse its use in preference to other more accepted measures, I am of the view that it still falls short of being generally recognized as safe and effective by those qualified in the field.

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claimant served written interrogatories on the Government. The Government answered some of the interrogatories but objected to the claimant’s seventh interrogatory on the ground that it was irrelevant and that some of the information sought was exempt from disclosure. The claimant moved to compel the Government to answer. In ordering the Government to answer except with respect to certain confidential formulas and sales information, the court said:

“A ‘new drug’ is one whose composition is not generally recognized by qualified experts as safe and effective for the use recommended on its label. In answers to other interrogatories, the Government has listed six experts who have advised it concerning the drug in question and each of these experts states that the claimant’s mixture is a new drug. In the absence of specific expert testimony to the contrary, it is clear that the mixture is a new drug.”

In all other respects, however, the Government should answer the contested interrogatory.

The Government moved for summary judgment. Supplemental interrogatories were then served. The Government answered the interrogatories as follows:

“In answers to interrogatories, the Government concedes that each of the four ingredients of Excedrin P.M. is generally recognized as safe and effective, and that these four ingredients are generally recognized as safe and effective when combined in the proportions found in Excedrin P.M. In answers to other interrogatories, the Government concedes that the claimant’s mixture is a new drug.”

Still another government answer to an interrogatory lists sixteen drug products containing three of the four ingredients of Excedrin P.M. It is sufficiently established so that the court cannot say that the specific combination of ingredients in the claimant’s mixture is not a new drug. In the answer to another interrogatory, the Government reported that another expert who had consulted, the author of a textbook on pharmacology, had recognized Excedrin P.M. as safe and effective for its labeled uses.

The Government answered the interrogatories and argued that the claimant has failed to show that the specific combination of ingredients in its mixture is not generally recognized as safe and effective.

The claimant moved to compel the Government to answer the interrogatories. In granting the Government’s motion, the court said:

“Given the volume of medical literature and the variety of combinations of analgesics and antihistamines which have been used, the absence of published studies on adverse interactions may justify exactly the opposite inference from that which the government experts draw.

Considering that the four government experts largely parrot each other’s words, that the specific cases of adverse interaction which they quote do not support their general statements of risk, for this particular combination, and that not only is each component of Excedrin P.M. individually recognized as safe and effective, but various combinations are also recognized as safe and effective, the court cannot say that the absence of general recognition has been sufficiently established so that the claimant should be deprived of its right to cross-examine the Government experts and establish its case.

There is a disputed issue whether the specific combination of ingredients in Excedrin P.M. is generally recognized by qualified experts as safe and effective for the use indicated in the label.

Subsequently, upon motion of the Government, the court’s order denying summary judgment was amended to state that such order involved a controlling question of law as to which there was substantial ground for difference of opinion and that an immediate appeal might materially advance the ultimate termination of the litigation. Accordingly, the Government petitioned the Second Circuit Court of Appeals for permission to appeal. Despite the lack of cooperation of the claimant to the appeal, the petition was denied. Meanwhile, FDA promulgated regulations (21 CFR 330) for administratively classifying over-the-counter human drugs as drugs which are generally recognized as safe and effective and not misbranded and commenced rulemaking proceedings with respect to thus classifying such drugs. Accordingly, the action was dismissed. (F.D.C. No. 56131; S. No. 195-396 C. N. J. No. 27)

Nan phenylbutazone and amimidine combination tablets, at Berkeley, N. Dist. Cal.

Charged 8-28-74: when shipped by Shy Ron Trading Co., Hong Kong, the article was a new drug without an effective approved New Drug Application; the article's label lacked the established name of each active ingredient; and the article was dangerous to health when used as directed; 505(a), 502(e)(4)(A)(ii), 502(i). Default decree ordered destruction. (F.D.C. No. 59883, S. No. 27-143 H. N. J. No. 28)

Phenylbutazone amidimidine combination tablets, at Stockton, E. Dist. Cal.

Charged 8-27-74: when shipped by P. Y. Yeh, Taipie, China, the article, labeled in part "Gingpu Hue Sheng Tsai Taoe Wan Nan Lien Pharmaceutical Co. Ltd., Tainan, Taiwan," was a new drug without an effective approved New Drug Application; the article's label lacked the established name of each active ingredient; and the article was dangerous to health when used as directed; 505(a), 502(e)(4)(A)(ii), 502(i). Default decree ordered destruction. (F.D.C. No. 59893, S. No. 27-143 H. N. J. No. 28)

Phenylbutazone amidimidine combination tablets, at Berkeley, N. Dist. Cal.

Charged 8-28-74: when shipped by Shy Ron Trading Co., Hong Kong, the article was a new drug without an effective approved New Drug Application; the article's label lacked the established name of each active ingredient; and the article was dangerous to health when used as directed; 505(a), 502(e)(4)(A)(ii), 502(i). Default decree ordered destruction. (F.D.C. No. 59883, S. No. 27-143 H. N. J. No. 28)


Charged 5-10-74: while held by U.S. First Aid Co., Warren, Mich., who was repackaging drugs using components shipped in interstate commerce, the circumstances of the repackaging, packing, and labeling failed to conform to current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 59761; S. Nos. 42-759/60 C. N. J. No. 30)

MEDICAL DEVICES

Angel ion B-I electric nerve and heat lamp, at Los Angeles, C. Dist. Cal.

Charged 11-6-74: when shipped by Angel Ion Co., Japan, the requisite directions for use nor adequate information for use by licensed practitioners could be written; 502(a). Default decree ordered destruction. (F.D.C. No. 60027; S. No. 68-098 H. N. J. No. 31)

Bedboards, at Nampa, Dist. Idaho.

Charged 7-3-74: when shipped by World of Solarama, Ltd., Greenville, S. C., and/or Robert L. Scribner (Solarama of Carolina), Burbank, Calif., the articles, labeled in part "Thermo Plant Board By Jimmy Scribner . . . The World of Solarama Ltd., . . . Greenville, S. Carolina," or "Thermo Electronic Plant Board . . . Mfg. by Jimmy Scribner’s Thermo Plant . . . Greenville, S.C.," were accompanied by instruction leaflets, testimonials, and advertisements contained in letters, booklets, and leaflets that contained false and misleading claims for arthritis, tension, sleeplessness, nerves, poor circulation, ruptured disk, common ailments, pain, cropping, symptoms and debility of various ailments, malignant brain tumor, terminal cancer, cancer, for the sake of every single cell, "electronic parasites," deterioration of the human cell, pneumonia, heart condition and related problems, degenerative diseases, aging, paralysis, and emotional disturbances; 502(a). Default decree ordered destruction. (F.D.C. No. 59836; S. No. 19-543 C. N. J. No. 32)

Diapulse electromagnetic energy generator, at Stockwell, N. Dist. Ind.

Charged 3-28-74: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N. Y., and while held for sale, the article's labeling lacked adequate directions for use for the article's intended purposes, and neither adequate directions for lay use nor adequate information for use by licensed practitioners could be written; 502(k)(1). The device was claimed by the possessor who denied the charge, the seizure violated his constitutional rights, and claimed that the device was exempt. The claimant moved for a stay of the action pending final determinations of a motion for modification of a judgment in an injunction action against Diapulse Corp. of America in the District Court for the Eastern District of New York and in an appeal in the Second Circuit Court of Appeals. The motion for a stay had been granted by the court prior to the actual seizure of the device and prior to the filing of a verified claim. Upon motion of the Government, such stay had been vacated on the grounds that the possessor was not a proper party until the article was seized. However, the article was seized and, upon the filing of the possessor's verified claim, the stay was reinstated. The Government subsequently served written interrogatories on the claimant, moved to vacate the stay, and moved that the U.S. marshal remove the seized device from the claimant's office. In granting the Government's motions, the court said:

"This cause is before the court on plaintiff's motion to vacate the ex parte order to stay the proceedings entered by this court on April 5, 1973 and on plaintiff's request for an ex parte order directing the United States Marshal to remove the "Diapulse Device" from claimant's office. Both the motion to vacate and the request for an order directing removal of the device will be granted.

The first question presented was whether it is necessary to continue to stay the proceedings in support of his motion to stay, claimant Forrest J. Babb, M. D., cited United States v. Diapulse Corp. of America, No. 68 C 391 in the United States District Court for the Eastern District of New York where a motion for modification of judgment was pend
ing at that time. However, that motion was denied on February 16, 1973. Claimant had also argued that he was entitled to an injunction pendente lite in the United States Court of Appeals for the Second Circuit, entitled United States v. Diapulse, in support of his motion to stay. On October 24, 1973, that court affirmed the district court. Both of these rulings were adverse to the position argued for by the claimant. Although the attorney for the Diapulse Corporation of America has indicated that he intends further action in both cases, a continued stay of the instant action is not warranted. Plaintiff's contentions have been heard and accepted in several district courts and have been argued before the United States Court of Appeals for the Second Circuit on several occasions and have not found meritious on each occasion. Any further stay of these proceedings to await some planned action by the attorney for "Diapulse" will only result in a needless proloning of the instant litigation.

"The second question presented is whether the Government has a right to remove the 'Diapulse Device' from claimant's office since it has reason to believe that such device is being used during the pendency of this litigation. It cannot be disputed that the device is currently in the custody or constructive possession of United States Marshall. * * * Rule E(4)(b) provides that where tangible property is to be arrested, the marshal shall take it into his possession for safe custody. If actual possession is immediate from the requirements of the act regarding adequate directions for use, an instant action that the United States Marshal was authorized to seize the 'Diapulse Device' when the Warrant of Seizure and Monition was issued. At that time the marshal was not in the custody or constructive possession of the device. The United States therefore has the power to take the actual possession of the device without proof of any justification for seizure. When the marshal seized the 'Diapulse Device' in this action, he took custody of it constructively. Nothing has been done to prepare the device for use. The constructive possession of the device exists. There is no necessity to prevent him from removing the device from the office of Forrest J. Babo to another place of storage. * * *

"Whether the device is being used or not is not controlling since the device is in the custody of the Government who can convert the constructive possession to actual possession if it becomes convenient for him to do so. In any case, it was held in United States v. Diapulse, No. 73 C 157, United States District Court for the Northern District of Illinois, that the United States has the right to seize the device for use pendente lite. For all of the above reasons, claimant has no basis to contend that the Government has no right to remove the device from his office. The device is in the custody of the United States Marshal and may be removed and stored elsewhere.

"The claimant also served written interrogatories on the Government. After answers to the interrogatories had been filed, the Government moved for summary judgment and the court disposed of the motion.

"The mere fact that a claimant is a licensed physician does not entitle him to an exception from the labeling requirements of the act regarding adequate directions for use. United States v. Ellis Research Laboratories, supra at 552-53. Commercial use of an alleged misbranded device even by a licensed physician must yield to the right of the Government to take such devices, if, in its opinion, they present an undue risk to public health. United States v. Olsen, 161 F.2d 669 (9th Cir. 1947), cert. denied, 330 U.S. 768 (1947). The United States therefore has the power to take the actual possession of the device for use pendente lite. For all of the above reasons, claimant has no basis to contend that the Government has no right to remove the device from his office. The device is in the custody of the United States Marshal and may be removed and stored elsewhere.

"There is no necessity that claimant show that diathermy or ultra-sound treatment is based on a concept which is physically dissimilar to diathermy and ultra sound treatments. * * * Claimant's burden is to show that the directions, hazards, warnings and other information on operating the device are common knowledge among practitioners. There is no necessity that the directions, warnings and other information contained in the labeling for the device apply commonly to the Diapulse but only that literature on these other methods supply some information relevant to the operation of the Diapulse. Claimant must show that the information is common knowledge among practitioners. The claimant's contentions with respect to directions, hazards, warnings and other information can only be shown indirectly. The court concludes that a genuine issue of fact exists as to whether there is common knowledge regarding the required information on the operation of the Diapulse among practitioners. * * * Most of the studies [made of the Diapulse device] candidly admitted that more research on the device was needed. Nevertheless, for purposes of this action several facts disclosed by the studies are relevant. First, it is clear that evidence exists that the device may be beneficial in treating some medical problems. Secondly, many of the studies set forth the method which was used to achieve the results. This presents some evidence, albeit minimal, that directions for the use of the device were commonly known since most practitioners have access to these reports. Thirdly, the reports indicate that the device was safe, that no contraindications were noted and no hazards incurred. Arguably, no warnings need be given as to hazards since the device is safe to use. Finally, the studies indicate that more research is needed. These studies do create a factual dispute as to whether common knowledge exists among practitioners as to operation of the device and other relevant information. * * *

"Claimant has argued that the court should order that the device be relabeled if it finds that common knowledge does not exist among practitioners and that the device was misbranded. However, the court is not an expert on medical and scientific issues which must be explored to produce accurate labeling. The FDA is best qualified to work with interested parties to formulate adequate labeling.

"Painite is as argued that the device is incapable of being properly labeled. Claimant has presented an affidavit which states that the device can be relabeled and adequate directions prepared for its use. Therefore, the issue remains as to whether the court in the exercise of its discretion should provide the claimant with an opportunity to have the device relabeled to comply with the law, if it should be determined that the device is misbranded, i.e., that directions for use and other information concerning the Diapulse are not common knowledge among practitioners. The parties should be prepared to address this issue. The event that claimant is unable to prevail on its argument that the exception provided in the regulation applies to it.

"The court finds that all other arguments presented in the motions now before it are without merit. Consequently, the only issues which remain to be decided are the following: (1) is the device entitled to the exception from labeling provided in the regulation, 21 C.F.R. §1.106(d), more particularly, whether the provision of §1.106(d)(3) is applicable; (2) if the device is not entitled to the exception from labeling and is therefore misbranded, was it misbranded when offered for sale after a shipment in interstate commerce. (3) is the device, if misbranded, capable of being relabeled to conform with the law or must the device be destroyed.

"Ultimately, a consent decree ordered the article destroyed. (F.D.C. No. 58521; S. No. 40 268 G. N.J. No. 33)

"Elcar ozone generator, at Minneapolis, Dist. Minn.

"Charged on or about 12-27-74, when brought from Bow, N.H., to Service Ideas, Inc., Minneapolis, Minn., the article's instruction sheet contained false and misleading claims, for purifying the air and treating respiratory problems, and the article was dangerous to health when used as directed: 502(a), 502(j). Default decree ordered destruction. (F.D.C. No. 60137; S. No. 64-706 G; N.J. No. 34)


"Charged 11-20-73 and amended 7-1-74: when shipped by James W. Young, Menlo Park, Calif., and while held for sale, the accompanying pamphlet entitled "Research and Development of the Specific Adjusting Machine (SAM)," contained false and misleading claims for removal of pressure from the spinal cord, back pain, arthritis, ruptured disc, headaches, asthma, stomach ulcers, bursitis, eczema, inflammation, frontal and sinus headaches, general debility, backache, persistent cough, rapid heartbeat, tuberculosis, pain in the face and head, and to clear skin conditions, the article lacked adequate directions for lay use for its intended purposes, and was not exempt therefrom due to failure to comply with exempting regulation; and the labeling lacked adequate warnings against unsafe use: 502(a), 502(j), 501(k)(2). The article was claimed by Edwin C. Dickens, D.C., Albuquerque, N. Mex., as having borne the charges. The Government denied the density and validity of any written interrogatories on the claimant. The claimant filed requests for admission of the Government. Consequently, a consent decree of condemnation authorized release to claimant for bringing the article to market. The article was destroyed. (F.D.C. No. 59553; S. No. 37-198 G. N.J. No. 35)

"COSMETICS/BEAUTY PRODUCTS


"Charged 7-21-71: when shipped by Hatzlach Supply, Inc., New York, N.Y., the article, labeled in part "Brylcreen . . . hairdressing . . . beeham Products (UK)," Bradford, England 75 Cp. was in violation of the Fair Packaging and Labeling Act, since the article's principal display panel and alternate principal display panels lacked quantity of contents declarations—15 U.S.C. 1453(a)(2); and the quantity of contents statement (i.e., "75 CC") was not in terms likely to be read, understood and known by the ordinary individual under customary conditions of purchase and use: 602(b)(2). Default decree ordered destruction. (F.D.C. No. 57326, S. No. 89-995 E. N.J. No. 36)
Long nails methyl methacrylate monomer fingernail lengthener kits, 10 seizure actions, at Kay-Gee Sales Inc., and Meyer Gilgus, president, Kansas City, W. Dist. Mo.

Gila Feed Yards, Inc., and Donald M. Martin, vice president, Gila Bend, Ariz.

rice were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty pleas; fines.

Charged 2-28-75: pie crust mix, brownies, and two lots of rice were held under in sanitary conditions; and while held for sale, flour (counts 3 & 4) was held under insanitary conditions—402(a)(4); and Cheddar cheese was held under insanitary conditions in a building accessible to rodents and exposed to contamination—402(a)(4). The court issued a

The defendants subsequently moved to suppress evidence from samples taken as a result of FDA inspection. The court denied this motion saying:

"The position adopted by the defendants is that the consent was not 'voluntary.' The only factual support for this contention put forth by the defendants is that the employee who actually gave the consent for the inspection lacked any knowledge of a right to refuse consent. Granting this fact to be true, it still does not adequately support the defendant's position. The Supreme Court in Schneckloth v. Bustamante, 412 U.S. 218 (1973) clearly stated that such lack of knowledge, in and of itself, would not warrant a finding of involuntariness. Rather, the Court would have this issue of voluntariness of consent resolved by an examination of the 'totality of all the circumstances.' The concern of the Court in Schneckloth was with the general search 'the product of duress or coercion, expressed or implied.' There is nothing in the facts of the present case to indicate that the consent involved here was the product of any such prohibited conduct. In fact, according to the uncontested affidavit of the F.D.A. inspector, the individuals granting the consent indicated they wished to get to the bottom of the problem which generated the inspection in the first place. As evidence of this desire, they provided an inspecting truck driver to go out and collect the samples which they now seek to suppress. An examination of the facts of this case, therefore, indicate that no coercion was present at the time defendant's employees granted the F.D.A. inspector consent to examine defendant's facilities and take samples.

"The only facts set forth by defendant which could affect the voluntariness of the consent was the lack of knowledge of a right to refuse consent. As discussed above, however, this fact alone is insufficient to support defendant's motion. See United States v. Biswell, 446 U.S. 604 (1980). The motion for a bill of particulars is denied.


drug

F D A C o n s u m e r / J u n e 1 9 7 5 / 4 3
Diethylstilbestrol use in cattle and sheep, suit to ban such use, Washington, Dist. Columbia.


Charged 6-7-72 in petition for judicial review by Label [law students Association for Buyers' Education and Labeling], Inc., and National Health Federation [subsequently added as additional petitioners] against FDA Commissioner Charles C. Edwards, and the Food and Drug Administration: that petitioners sought review of the action of the Food and Drug Administration in rejecting a proposed regulation concerning disclosure on the label of all ingredients contained in standardized and nonstandardized foods.

The Food and Drug Administration had denied the petitioners' proposal on the grounds that statutory authority did not exist to require the declaration of mandatory ingredients on the label of standardized foods. In affirming the defendants' action, the court said:

"The Food and Drug Administration is empowered to express its impression on the label as to all optional ingredients of food products for which the Administrator has promulgated definitions and standards of identity. The Administrator has announced its intention to exercise this authority to the utmost, and to seek at the same time legislation that would specify its authority to promulgate substantive rules requiring effective information to the consumer of composition of standardized foods, even as to mandatory ingredients. The agency does not dispute the objectives of the type of labeling sought by petitioners. Given the language of Section 403(e) of the Food, Drug, and Cosmetic Act, 21 U.S.C. 343(g), and the references in Federal Security Administration v. Quaker Oats, 318 U.S. 216 (1943), we cannot say that the Commissioner erred in determining to delay the petitioners' proposal, and to seek enactment of legislative provisions expressly setting forth pertinent authority."

A subsequent appeal by the petitioners to the court of appeals resulted in the district court being affirmed without an opinion. Subsequently, petitioners' petition for certiorari was denied (Misc. No. 192; N.J. No. 52).

Sodium nitrite food additive data, suit for access thereto, N. Dist. Calif.

Charged 3-3-72 in complaint for injunctive and mandatory relief by Environmental Defense Fund, Inc., Berkeley, Calif., and Dale B. Halts, graduate student, Palo Alto, Calif., against H.E.W. Secretary Elliot L. Richardson, FDA Commissioner Charles C. Edwards: that FDA had, by regulation, established a tolerance level for sodium nitrite governing its use as a food additive; that sodium nitrite was widely used as a color fixative and preservative in salami, frankfurters, and cold cuts; that, subsequent to the enforcement of the regulation, scientific evidence tended to indicate that sodium nitrite, when combined with certain other substances commonly found in the human diet, yielded nitrates which were carcinogenic and mutagenic under laboratory conditions; that, mindful of such scientific experimentation results, FDA requested that petitioners file a supplemental safety petition for the new drug application for sodium nitrite; that, in response to the request, petitioners filed a supplemental safety petition; that, FDA had submitted to petitioners, on the authority of Section 403(e) of the Food, Drug, and Cosmetic Act, 21 U.S.C. 343(g), and the references in Federal Security Administration v. Quaker Oats, 318 U.S. 216 (1943), a request for data submitted by parties registering sodium nitrite as a food additive and were refused such access by FDA on the ground, inter alia that the information was "confidential"; and that, unless and until such information was made available to petitioners, petitioners' petition for access to such data was denied.

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

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

Alexandra M. Mennel, Commissioner of Food and Drugs, Washington, D.C., June 1, 1975.
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