Partnership for Health

An Incident in Gloucester

LOS ANGELES DISTRICT

Does Something About It

PRODUCT SAFETY ACTION

The Third Dimension

POISON CONTROL DIVISION
"In the name of the great Jehovah and the Continental Congress," Revolutionary soldier-patriot Ethan Allen is said to have replied when the British defenders asked him by whose authority he demanded the surrender of Fort Ticonderoga in 1775. Providence also had a hand in the crowded series of events that followed an explosion in a New England cold storage warehouse last January 2 which left 11 million pounds of fish exposed to the elements (see page 21).

Given 6 precious days of 5° to 10° temperatures following the tragic and destructive explosion, local, State, Federal, and industry officials were able to plan and win a formidable race with time, moving 9 million pounds of salvageable fish to cold storage plants in other areas and safely disposing of 2 million pounds found unsalvageable.

This considerable feat of logistics and health protection would not have been possible without the excellent and ready cooperation that took place among industry, the Commonwealth of Massachusetts, the city of Gloucester, the military, the Department of Interior, the Environmental Control Administration, and FDA.

It is a case where the several concerned parties carried out their respective responsibilities in a coordinated effort that served all interests and protected the public health.

“We are carefully to preserve that life which the Author of nature has given us, for it was no idle gift.”

Harvey W. Wiley
From his commencement address
"Life and the Coming Time"
Hanover College, 1867

(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 the 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.

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* The Food and Drug Administration is solely responsible for the contents of FDA PAPERS. The Advisers to the Editor are consultants on matters relating to the functions of the Federal Departments and Agencies listed.
Doing Something About It at Los Angeles District

In the land of superlatives, the consumer gets superlative protection.

The Poison Control Division

Deaths, injuries, and illnesses are being reduced by a massive and coordinated attack on accidental poisonings.

The Third Dimension of Product Safety Action

A Presidential commission believes consumer safety and satisfaction are legitimate business goals.

Detecting and Confirming Mycotoxin

What FDA is doing about these naturally occurring poisons produced in some foods by molds.

Partnership for Health: An Incident in Gloucester

Industry and Government move quickly to remove a menace to health and save 9 million pounds of fish.

Field Reports

State Actions

Seizures and Post Office Cases

Notices of Judgment
An inspector at Los Angeles District (top photo) is taking a random sample of lettuce from a field near Glendale, Ariz., for pesticide analysis. The photos below show the harbor where a tuna fleet docks at Terminal Island, Los Angeles, and an FDA Inspector (right in photo) making an organoleptic (smell, sight) examination of tuna in a Terminal Island tuna processing plant. In the photo at the far right, an inspector observes the unloading of raw kelp, processed for seasonings and animal food at San Pedro, Calif.
The American Southwest is an empire of dramatic growth and development. Superimpose these changes upon a regional topography that permits skiing in the morning, lunch at a desert resort, and surfing on the Pacific in the afternoon, and the resulting diversification and variety translate into a challenge to the Food-and-Drugger. Los Angeles District, often called the Southland, includes Arizona, the nine southernmost counties of California, Clark County in Nevada, and American Samoa. We have some of almost every food and drug industry; much of most specialties, and practically all of certain ones; and more quackery than we like to admit.

The food industry that commands more of our attention than any other is agriculture, with its attendant pesticide problems. The volume and variety of agricultural production are staggering. Agricultural development in the Southwest is a chronicle of change and progress. Through ingenuity and irrigation, deserts have become orchards and fields. They produce around the calendar, with no winter respite. Unfortunately, in a climate where man and crops thrive, so do insects.

As long as there has been a Los Angeles District, the Pesticide Project has been of prime importance. We have approached it from all angles. Federal-State cooperation on pesticides between the California State Department of Agriculture's Field Crops and Agricultural Chemicals Office and Los Angeles District has existed as long as the District. We have conducted educational programs for pesticide manufacturers, applicators, growers, and shippers through meetings and seminars. We counsel with private laboratories on analytical methods. We participate in programs for the health education departments of schools and colleges. We also maintain active enforcement programs, when necessary, by conventional legal procedures. The first three FDA prosecutions for pesticide violations under the Food, Drug, and Cosmetic Act were filed at Los Angeles District in 1961.

However, we believe the man on the scene is our most effective tool to promote consumer protection through voluntary compliance on pesticide requirements. We keep inspectors in the field the year around. They meet growers, packers, and shippers at the working level where the action is. They discuss problems, regulations, and responsibilities. They collect samples and we report back to the grower, if known, and to the shipper the pesticide residue content of his products. There are more than 12,000 growers for us to try to reach. We don't know how many high residue shipments we prevent, but we do know from analyses of 1,500 domestic samples a year that the overall level of compliance in the produce industry is higher than in any other of our industries.

Then why so much continued attention?

We have sensed for years a growing concern among consumers about pesticides. Some is stimulated by irresponsible alarmists; some arises from a legitimate concern over the role of pesticides in the considerations of overall environmental health. The consumer cannot protect himself against illegal and harmful residues, but must rely on State and Federal agencies. We believe we serve our consumers and our industry best when we acquire sufficient reliable scientific data to assure that our food supply is safe, and on those occasions when we find it may not be, we do something about it.

We have other responsibilities in the field of agriculture. Southern California's San Bernardino and Riverside Counties rank one-two in egg production in the United States. Los Angeles County boasts the largest egg-producing unit in the Nation, a single ranch with 1,600,000 laying hens. This industry requires assiduous attention for Salmonella, decomposition, and standards compliance in liquid or frozen eggs. Imperial County is a major cattle-feeding area that presents us with occasional problems of pesticide residues in hay. Los Angeles County, not commonly thought of as an agricultural area, produces more milk and butterfat than any other county in the United States. Los Angeles District produces 100 percent of the commercial dates grown in this country. In the date groves of Coachella Valley ancient hand-packing practices persist alongside modern mechanical methods. Sanitation and insect infestation are presently our major interests in this industry.

There is no way to stop progress. The freeways, housing projects, factories, and shopping centers are taking their toll of the agricultural areas. Since production must go somewhere, it is moving south of the border—increasing our import load. There are 20,000 entries of fresh vegetables from Mexico each year. Most come through Nogales, Arizona, by truck and rail. We cover these importations for pesticide residues as completely as we do our own producers. To avoid the cost and delays of shipping samples from the border to Los Angeles, we station our trailer laboratory at Nogales for several weeks each winter, spread out intermittently over the peak season. We have never found a violative pesticide sample from Mexican produce, with one exception. Last August the California State Office of Agricultural Chemicals advised us of high residues on two importations of purslane, a leafy vegetable sold in local markets. These lots bore as much as 85 parts per million of DDT and 158 parts per million of toxaphene, the highest results we have ever encountered. Fortunately production was confined to a few small plots near Tijuana. The material was disposed of under State quarantine and we notified health officials in Tijuana of their problem.
The Southland has a large Mexican-American population that is supplied with traditional Mexican foodstuffs from across the border. We sometimes find that cornhusks for tamales are moldy or infested with insects. Peppers used for spicing Mexican food were once widely grown in southern California. The fields for this crop have largely given way to population encroachment, and spice grinders now rely heavily on importations from Mexico. During a recent Mexican tragedy resulting from contamination by parathion in a Tijuana bakery supply warehouse, we made extensive investigations to be certain that none of the contaminated bakery products reached our side of the border. In cooperation with Mexican officials, arranged through the San Diego County Health Department and the Office of the Mayor of Los Angeles City, we analyzed approximately 25 samples of foods and packaging for parathion residues.

In Baja California, Mexico, there are now port facilities for large freighters. More and more, cargoes once destined for California ports are now discharging at Ensenada and are carried northward by truck, requiring increased FDA vigilance at the border. We receive some 3,700 entries of frozen shellfish from Mexico annually. Detentions for decomposition detected by inspector-analyst teams at the border at one time reached as high as 40 percent of the entries. Significant improvements in production have been made and now we seldom need to detain these products.

In addition to border traffic, imports arrive from all over the world at Southland seaports. We receive 58,000 formal entries of food products a year, representing 12 percent of the United States total. These include basic food commodities produced in Europe and South America, food seeds from the Middle East, copra and spices from the South Pacific, and both basic and exotic foods from the Orient. A total of 190,000 tons of tuna, comprising half of the tonnage handled by the United States and all its possessions, was landed in 1967 to supply the southern California tuna canning industry. Much of this tuna originates in Japan, South America, and other foreign fisheries. This import workload is handled through a working agreement with the Cannery Inspection Section of the California State Bureau of Food and Drug. This agency maintains continuous inspection in tuna canneries, examining every fish that enters the cannery, and rejecting those that fail to meet standards of quality and wholesomeness. This agreement of many years standing is an excellent example of Federal-State cooperation that protects consumers without duplication of effort.

An increasing volume of imports is arriving by air, adding a third dimension to land and sea for import coverage.

The proximity of an easily accessible foreign border can pose problems on matters other than imports. Communities in Mexico can be a haven for dispensers of worthless and sometimes dangerous remedies for cancer, arthritis, and other serious diseases. These include the Hoxsey treatment and Laetrile for cancer and Liefcort for arthritis, all of which are illegal in the United States. Victims of cancer and arthritis, the hopeless, the despairing, the frightened travel from all over the United States to these so-called clinics where at best they may lose their money and, at worst, their lives.

Not all quackery is south of the border. It exists in many forms in the Southland. A mild climate that makes living easier attracts the aged and the ill. They form a group subject to exploitation whose gullibility spreads to other segments of the population. Los Angeles is a center for health food advocates. Several of the nationwide promoters of vitamin and mineral pills offered for treatment and prevention of practically every disease known had their beginnings here. Seizures, injunctions, and prosecutions have checked but haven’t stopped these door-to-door peddlers. Their labels merely become a little more sophisticated. We are now relying more on health education to help consumers protect themselves against the nutritional nonsense conjured up about alfalfa, royal jelly, chlorophyll, sea salt, and other worthless concoctions offered for diseases they do not have.

Our devices program is always active. Some device frauds come and go; old ones return to haunt us; new ones are developed. Evidence of destruction of lung tissue of mice exposed to ozone helped us eliminate ozone generators. Affidavits from cancer specialists that vacuum-type "bust developers" could stimulate growth of dormant breast cancers helped to sustain injunctions and seizures on these worthless devices. Color therapy, an ancient delusion, is revived from time to time. The wavelength therapists with their radionics and "little black boxes" are a persistent lot who need constant surveillance. Radium was used in a weird device to irradiate blood that was then reinjected to treat children for mental retardation. Since these kinds of devices are virtually worthless for any purpose, "voluntary compliance" means abandonment of the operation, a fate to which the ambitious promoters are reluctant to submit. Therefore, at Los Angeles District we rely heavily on legal action, and devices constitute a substantial part of our seizure record.

We would not be honest, however, if we did not recognize the many contributions of our cooperating agencies in controlling quackery in southern California. Under that State’s laws, direct action can be taken on charges of grand theft against licensed practitioners or other promoters who use worthless drugs for certain specifically named, serious diseases. These cases are
Top photos: In the Los Angeles District lab, a microbiologist (left) is using rubber gloves built into a sterile enclosure to operate a lyophilization apparatus, which dries live bacterial cultures for preservation after they have been frozen in an earlier process. Center, a chemist prepares a sample of carrots for pesticide residue analysis. Right, a microbiologist works with white rats used in tests for detection and assay of Clostridium botulinum micro-organisms and toxins.

Middle: A chemist in the District lab (left) uses column chromatography during a pesticide residue analysis. In a mobile FDA lab at Phoenix (right), a chemist is conducting a pesticide residue analysis on a sample of carrots.

Bottom: An Import Inspector (upper left) checks incoming parcels at Los Angeles International Airport for products that may be in violation of the Food, Drug, and Cosmetic Act. Another Import Inspector (right) at Terminal Island, Los Angeles, collects a sample of shredded coconut from the Philippines to be analyzed for Escherichia coli bacteria. Cinnamon bark from Ceylon (lower left) is being examined by an Import Inspector at Terminal Island for the presence of insects and mold.

developed by the capable and energetic Fraud Section of the California State Bureau of Food and Drug. The Section has successfully prosecuted many important cases that could not have been handled under Federal law.

Los Angeles District has moderate but growing drug and cosmetic industries. Along with other Districts, we are presently involved in the Intensified Drug Inspection Program. Manufacture of drugs is another area where we have developed a high level of cooperation and work planning with the California State Bureau of Food and Drug. An example will illustrate.

A consumer complaint that niacin had been substi-
tuted for quinidine sulfate led to a joint FDA-State factory inspection. The investigation disclosed a case of widespread conspiracy involving a factory employee, who substituted niacin capsules for the more expensive quinidine sulfate capsules and who disposed of the latter through “backdoor” sales to distributors. After study of the case, we agreed that action could best be taken under State laws. A successful prosecution resulted.

The population growth in California and Arizona in the past 10 years is greater than the entire population of 41 other States. This increase affects our food manufacturers in two ways.
First, there is the expansion of production needed to provide for the millions who arrive each decade. This means new and enlarged factories, and new products requiring coverage.

Second, there is the race to keep pace in older facilities: the overcrowding, the overtime operations, the pressure for production. There is no time to clean house, no time for better storage of materials, no time to clean equipment. When contamination results, we do something about it: education where it is needed; appropriate legal action where there is neglect. We do not believe the public should have to consume contaminated food while a negligent manufacturer is learning about sanitation and potential health hazards.

Los Angeles District follows a policy of balanced enforcement through education, cooperation, and legal action. Education includes both industry and consumers. The goal of industry education is compliance. We have already referred to the field activities of pesticide inspectors and their contributions to compliance efforts. The inspector in the food, drug, or cosmetic factory serves the same purpose. Inspectors are trained to make each inspection an educational experience, directed toward voluntary compliance, for the firm under inspection. These direct communications with responsible personnel on the factory premises supplement our programs of
meetings and voluntary compliance seminars and might well be the most effective channel of industry education. We do not neglect other opportunities. Industry and trade organizations have standing invitations to discuss their problems with the District at any time. Several have taken advantage of the offer.

Consumer education is an equally important project. We have long since abandoned the shotgun approach of large numbers of speeches to all kinds of audiences. Instead, we take dead aim at organizations of persons who in turn communicate to others. Teachers’ institutes for credits were sponsored in city and county school systems. Programs include “Read the Label,” “How Safe Are Our Foods and Drugs,” “Drug Abuse,” and “Safety in the Home.” Attendance has reached more than 1,000.

With the appointment by FDA of Consumer Specialists, three primary target groups were designated, the elderly, the low-income, and youth. Los Angeles District initiated and planned with the Los Angeles County Department of Senior Citizens Affairs and the University of Southern California the first FDA seminar for specialists in the field of aging. We organized and developed the first FDA seminar sponsored by a major labor organization, the Teamsters Union. Our Drug Abuse seminar for youth held in Las Vegas, under the sponsorship of the Las Vegas Sun, the Clark County Cooperative Extension Service, and Los Angeles District, drew an attendance of more than 12,000. It was the largest live audience ever addressed by a Food and Drug representative and the largest audience ever assembled in Las Vegas.

Los Angeles District public information efforts are not confined to spectacles. Our policy is to assist every person who seeks information, whether or not it pertains to food and drug matters. If we can’t provide the desired information, we make an extra effort either to locate it or to tell the caller where he can obtain it. Apparently our efforts are getting some recognition: callers frequently tell us they were referred to FDA by some other government agency.

Other information seekers are the motion picture, radio, and television studios. They call in for information on the effects of drugs, food poisoning, toxicity of various products, and legal requirements to assist them in plots and sequences for shows.

Federal-State cooperation in the interest of consumer protection is a way of life at Los Angeles District. We have been favored with energetic State organizations under dynamic leadership and supported by strong laws. Current examples of cooperation with the California State Bureau of Food and Drug and the Office of Field Crops and Agricultural Chemicals have been mentioned previously. Prior to punch cards and data processing, communication was on a personal level, by visits and almost daily telephone interchange. Computers and printouts now make cooperative planning a different operation. But there is more to intergovernmental cooperation than computers and statistics. There must be understanding and mutual confidence. Without these intangibles, no computer system, however elaborate, will succeed.

Intergovernmental cooperation at Los Angeles District reaches beyond the States. Our good neighbors to the north some months ago advised us of a shipment of brazil nuts found to contain aflatoxin. Denied entry at Vancouver, British Columbia, the shipment was diverted to Los Angeles. We intercepted the shipment and confirmed the aflatoxin contamination. This vigilance and cooperation led directly to the FDA’s present system of compulsory aflatoxin examination for all importations of brazil nuts. On our part at Los Angeles District we advise the Food and Drug Directorate of Canada when we learn of illegal articles destined for delivery there. Last December, we alerted them about 12 shipments of carrots suspected of contamination with endrin. To the south we have cooperated with Mexican officials by making analyses of products produced and distributed in Mexico and suspected of pesticide contamination.

We are proud of our progressive Southland industries and the many whose own standards impose a higher level of compliance than the laws require. As an example, one major industry has a program on pesticide residues that is the virtual equivalent of self-certification.

There are others whose ideas of voluntary compliance consist of destroying adulterated materials when an inspector points them out, but who make no effort to correct the cause until the inspector comes back again. Inspectors have encountered delays in a plant’s front office while the mess in the firm’s production lines is hurriedly cleaned up. Defective raw materials have been granulated or otherwise comminuted so their condition is masked in the finished product. Articles known by the firm to be violative may be distributed in the hope that they will not be discovered. We are not so naive as to believe that such offenders either lack education—or are amenable to it—until they learn the hard way through the sanctions of the law. Consumers and legitimate industry are entitled to this protection.

We do not run a tight ship at Los Angeles District. Everyone is expected to understand his job and want to do it. The Food-and-Drugger is trained to hate sin, in this case, violation of the laws FDA administers. He is then on his own. Confidence begets the extra effort that produces leaders.

Superlatives are the order of the day in the Southland: the biggest and the best, the most and the greatest. Perhaps this is a legacy from the stupendous and colossal vocabulary of Hollywood and Las Vegas. Perhaps California and all the Southwest are great because those who have made it so think in superlatives.
The bewildering increase in the number and variety of products that began to enter the American household after World War II and the corresponding proliferation of such incidents as this, involving accidental poisoning or suspected poisoning of children, created mounting concern among pediatric and other medical groups, public health authorities, and other responsible persons about accidental poisonings. This concern set in motion a series of events which has resulted today in the daily 24-hour operations of some 560 autonomous Poison Control Centers in the major population areas across the country, among whom information about household products and medicines that are toxic (and nontoxic) is coordinated by a National Clearinghouse. This Clearinghouse has operated as part of the Public Health Service since it was formed and since July 1, 1968, has been the responsibility of the Poison Control Division of the FDA Bureau of Medicine’s new Office of Product Safety.

By 1952, incidents involving possible poisoning of children from various products used in the home, including medicines, were being encountered by physicians in 51 percent of reported childhood accidents. Obviously, the practicing physician cannot be familiar with the composition of all household products; yet, knowledge of the ingredients is necessary for the proper treatment of an ingestion case. Can the doctor be expected to be proficient in knowing the effects of sodium tripolyphosphate, ammonium thioglycolate, dimethyl diisooaryl, ammonium chloride, and the many other unfamiliar chemical ingredients found in common household products?

Because of this knowledge gap and because there were hundreds of thousands of such ingestions annually, the Illinois Chapter of the American Academy of Pediatrics initiated a pilot project called the “Poison Control Center,” in Chicago. From the first, the project enjoyed cooperation from the pediatric services in the local major hospitals, the State Health Department, the State Toxicological Laboratory, and other State and local authorities, and a working unit was formed representing some 20 hospitals, four full-time health departments, five medical colleges, the local medical society, the Illinois Chapter of the Academy of Pediatrics, and the American Public Health Association.

The Chicago Poison Control Center opened in November 1953. It provided information on and treatment for poisonings, and had the further objective of establishing a prevention program. The number of other poison control groups that subsequently were organized with the same goals as the Chicago Center can be considered a tribute to the latter’s success. The centers soon found, however, that they were duplicating each other’s work in compiling information and that the information gathered by one was not finding distribution to all. Moreover, information about poisoning experiences was fragmented. It became apparent that some coordination of Poison Control Center activities was necessary.

In November 1956, at a meeting of the American Public Health Association, a committee on which several groups were represented recommended that a National Clearinghouse be established to provide sources of reliable data and a meaningful case reporting system for Poison Control Centers. APHA presented this recommendation to the Public Health Service of the Department of Health, Education, and Welfare. Represented on the committee were the Poison Control Centers, the American Academy of Pediatrics, the American Pharmaceutical Association, the National Research Council, and DHEW’s Food and Drug Administration and Children’s Bureau. The committee also included PHS representatives.

As a result, the Surgeon General designated the National Clearinghouse for Poison Control Centers as an official activity of PHS and it was assigned to PHS’s Accident Prevention Program. Although the National Clearinghouse for Poison Control Centers is the name by which it became best known, it is now officially designated as the Poison Control Division of the FDA Bureau of Medicine’s Office of Product Safety.

Since 1957, approximately 560 Poison Control Centers have been established in the United States. Except for the few in Government hospitals, these centers are not under Federal control. They are largely autonomous organizations developed by local hospital or paramedical groups in cooperation with the State health departments. Most are located within hospitals, and a few in health departments. Although every hospital should be prepared to treat the emergency aspects of poisoning cases, only a comparatively small number of Poison Control Centers are needed to accumulate the specialized experience and reference material to provide information services. With few exceptions, financial support of the Poison Control Center comes from the hospital in which it resides.

The structure of a Poison Control Center varies considerably from one area to another. The majority, however, are usually located in emergency rooms of large...
community hospitals. Their documentary resources consist of a file of 5- by 8-inch cards provided by the National Clearinghouse that lists information on commercial household products and other substances, along with references that usually include textbooks on poisoning, plant toxicity, pharmacology, and occupational medicine. Most centers maintain a list of consultant experts who are called when unusual poisonings occur.

Although the Poison Control Centers were originally established as a service to physicians, they have evolved to a point where today almost 75 percent of the calls they receive are from the lay public. Centers in some communities maintain the original concept, that is, they provide information to physicians only. Most of the centers are located in hospitals and, therefore, provide treatment facilities along with their information services. Those centers located in health departments provide information and consultation to hospitals as well as to physicians and the nonmedical community. A recent survey shows that the centers were able to provide specific information in 92 percent of the cases of ingestion over the period of a year. The occupation of the professional person taking calls at the center also may vary: Often, it is a nurse or a pharmacist with several years of experience with a physician on call.

The National Clearinghouse supports Poison Control Centers by providing data to them on the ingredients, toxicity, symptoms and findings, and recommended treatment involving the more common household products and medicines children are likely to ingest. This material is periodically supplemented to cover changes in formulations and new products that enter the market. The information is gathered from a number of sources. Many manufacturers voluntarily submit formulations and toxicity data on new products. Others respond to Clearinghouse questionnaires concerning new products discovered from the case reporting system and from reviews of commercial and scientific journals. The information is researched thoroughly and evaluated by the staff. Then it is submitted to four consultants for review before distribution.

The Poison Control Centers submit case reports voluntarily to the Clearinghouse. Over 100,000 were submitted in 1967. The reports are reviewed and coded and the data placed on magnetic tape, where it can be more easily tabulated and manipulated. This information provides a variety of program materials useful in the Division's operation. The age and sex of the victim and the circumstances of the incident form a basis for prevention and education programs. The amount of a substance ingested, compared with the symptoms of the patient and days of hospitalization required, provide important clinical data on toxicity of a particular product.

... providing data to them on the ingredients, toxicity, symptoms and findings, and recommended treatment ...
Health Departments, many schools of medicine and pharmacy, and to certain designated individuals who have a need for it. The bulletin contains statistical information, interesting case reports, short reviews of new problems, and treatments. It makes no attempt to index the literature but supplements it with subjects that are of interest to the National Clearinghouse and to groups involved in poison control and management.

Prevention of poisonings and ingestion accidents is a major facet of the Clearinghouse operation. The motivation that causes a child to ingest household products and medicines has not, in the opinion of many, been appropriately defined. Although such ingestions have long been attributed to the oral curiosity of the young child, some authorities have stated the belief that they are expressions of defiant behavior vis-a-vis the adult parent. Whatever the motivation for childhood ingestions, they are preventable. If they are caused by simple curiosity, household products and medicines can be stored and locked in places where they will not excite the child's interest. If they are due to defiant behavior, then the parent should be educated to the fact that such ingestions do occur—and not only to someone else's child. Again, the same positive steps can be taken to make these items less available.

Prevention of poisonings and ingestion accidents is a major facet.

The National Clearinghouse conducts an energetic and ongoing prevention program. This work is climaxed each year by National Poison Prevention Week. In 1961 the Congress enacted Public Law 87-319, which authorizes designation by Presidential proclamation of the third week in March each year as National Poison Prevention Week. Many governmental, medical, industrial, and trade organizations have joined in the effort to promote this week by emphasizing through national and local communications media and through community programs the hazards of medicine and household products as they relate to accidental poisonings. The period is also used to initiate year-round community programs for prevention of poisonings. The Clearinghouse serves as secretariat for the Planning Council for Poison Prevention Week, which sponsors the Week. The Council, on which more than 20 interested organizations are represented, arranges for the design, production, and dissemination of such Council materials as newspaper ad mats and factsheets, television material, window banners, prepared public addresses, proclamations for public officials, and other promotional aids.

Besides this well-known program, the Poison Control Division, through controlled community demonstration studies, investigates various methods and techniques through which poisonings can be reduced. These findings can then be applied to other communities with their differing cultural, socioeconomic, and climatic conditions. Through the media of seminars and symposiums, journals and periodicals, and professional meetings, these educational and training methodologies are discussed and analyzed.

An important program among the Division’s preventive activities is a device actually developed during one of the community demonstration projects: Youngsters are taught poison prevention habits concurrently with programs that are aimed at their parents. Through a series of learning experiences, youngsters learn from kindergarten through third grade about the hazards of the world around them and how to cope with these situations. Their experiences include class interviews on different days with a mother, the school nurse, the school physician, a pediatrician, a pharmacist, a grocer, the health officer, or the sanitarian. The class makes excursions to the grocery store and the pharmacy. Children participate in games, songs, and plays, all on the cautionary theme of “asking first.”

Thus, the Poison Control Division is involved in the total management of this serious childhood problem. Its aim is to prevent such occurrences, and when these efforts fail, to provide appropriate diagnostic and therapeutic information to alleviate the seriousness of poisoning accidents, reduce hospital stays, and promote recovery.

Henry L. Verhulst, Director of the Poison Control Division, joined the Public Health Service in 1948, became Deputy Director of the Poison Control Division in 1957 and Director in 1960.

John J. Crotty, M.D., Deputy Director of the Poison Control Division, has been with the Division since joining the Public Health Service in 1960.
The Third Dimension of Product Safety Action

by Arnold B. Elkind

It is important not to take too in-sular a view of the efforts of those concerned with improving product safety. This caveat has special application to the work of the National Commission on Product Safety.

It is not enough to flatly conceptualize the Commission's problems in terms of ways and means of reducing 18,000 deaths per year, most of which are said to be attributable to items used in and around the home, or of cutting down on the over 20 million injuries said to result primarily from the same source. There is another dimension to the saving of lives and the reduction of accidents by group action directed to product safety.

There is in fact no certainty that everyone would agree on the nobility of the objective of saving lives and cutting down on accidents! At the December hearings of the Commission a representative of the National Safety Council expressed the view that limited trauma to an infant from his toys is, in fact, desirable as a part of the child's educational process! A representative of the Toy Manufacturers Association apocryphally observed that one way of enhancing safety is to "stay in bed all day"!

Realistically, living has always entailed elements of risk of physical harm or sudden death. Death is an inevitable consequence of living, and it is impossible to visualize the type of proliferation of legislation, regulations, and agencies that would be necessary to substantially eliminate all hazards of injury from the use of products. But I consider the work of the National Commission on Product Safety to be infinitely important because it pertains to, and is very much involved with, our emerging national character and our notions of justice. An ethic embracing the need to treat the consumer fairly and not to invade his right to safety is a sine qua non for survival of our system.

It has been observed that the United States is too recent and inexperienced an institution for its citizenry to have developed a settled national character. The Commission can make an important contribution toward increasing the consciousness of the relative values to which we must be committed as Americans.

The concept of what represents "good American character" is still very malleable and is being hammered out in our times. The heat comes from the conflict in the central cities, but the form and outline of our national character emerges through our legal and legislative institutions and through voluntary adaptation. This Commission has an intimate commitment with the evolutionary process. The language establishing the Commission and setting forth our responsibilities is clear. Pursuant to statute [Public Law 90-146], the Commission is conducting

"a comprehensive study and investigation of the scope and adequacy of measures currently employed to protect consumers against unreasonable risk of injuries which may be caused by hazardous household products. Such study and investigation includes consideration of the following:

"1. The identity of categories of household products which may present an unreasonable hazard to the health and safety of the consuming public;

"2. The extent to which self-regulation by industry affords such protection;

"3. The protection against such hazardous products afforded at common law in the States, including the relationship of product warranty to such protection; and

"4. A review of Federal, State, and local laws relating to the protection of consumers against categories of such hazardous products, including scope of coverage, effectiveness of sanctions, adequacy of investigatory powers, uniformity of application, and quality of enforcement of those laws."

These four charges, however, in the aggregate seek an expression of priorities in a specialized area. Which is more important as far as household products are concerned —profits or freedom from hazard?

There is no question but that there was a time when profits and industrial and economic growth were a prime concern of our society. Historically, this was manifested by an absence of governmental control or regulation of industry and by a lack of remedy in the courts for the victims of industrial fallout. The proliferation of governmental agencies which have assumed a role in consumer protection evidences a political search for expressing some adjustment in that order of priorities.

Industry itself, through the adoption of safety standards, certification programs, testing laboratory listings, has made a limited response to the need for adjusting priorities. Where is the balance now, and where should it be? Have we now
reached that stage of high regard for individual dignity where we can agree (except for the dissent of extremists) that we can continue to have profitable industry and a profitable economy even though substantial sums are expended to eliminate possibilities of serious accidents which are, in truth, only a remote likelihood? Ten years ago the answer would have been easy and clear. Such an expenditure would be considered wasteful. The "unnecessary" cost would be "cruelly" passed on to the consumer and "unnecessary" cost would be.

By 1969 standards, however, this kind of answer seems overly simplistic. We observe masses of people acquiring the manufactured goods that they want on an installment basis, often selecting articles that do not seem appropriate to their income level. We see increases in the sale of consumer goods and increases in the profits of the manufacturers year in and year out in spite of increases in the usual production cost criteria (man-hour of labor, ton-mile of shipping cost, etc.). We see tremendous budgetary allotments for advertising and for the styling even of household appliances. It is economically possible to give the safety of a product a much higher priority than it receives today; the gains are obvious on the economic front and on the public health front.

More important, though not nearly as obvious, is the fact of our commitment to elevate individual rights over property rights where the two are in unequal conflict. In a perfect society we would hope that industries would regulate themselves to achieve this objective. Dissatisfaction in the marketplace imperils the very system in which our industry has flourished. Long-range statesmanship unmistakably mandates advocating and working for the optimum in consumer safety. The consumer must be kept satisfied if he is to continue to lay those golden eggs.

Unfortunately, our hearings and investigations have uncovered evidence of serious gaps in the efforts of business to cater to the safety needs of our country.

The great challenge to the National Commission on Product Safety is to find the formulae to buttress, validate, and legitimize the aspirations of statesmanlike industrial leaders who recognize the long-range goal of enshrining consumer safety and satisfaction as paramount business objectives. Some refer to this as "Mission Impossible," but it is the third dimension of Product Safety Action and a source of much excitement to the Commissioners and staff.

Arnold B. Elkind, Chairman of the National Commission on Product Safety, is a trial lawyer in New York City.

In addition to the author of this article, the legal profession is also represented by Emory J. Crofoot, Senior Deputy Attorney for the city of Portland, Oreg., and Michael Pertschuk, General Counsel to the U.S. Senate Commerce Committee.

The other four commissioners are Hugh L. Ray, Director of Sears, Roebuck & Company's Merchandise Development and Testing Laboratory in Chicago; Dana Young, an engineer and former Dean of the Yale Engineering School, currently Senior Vice President of Southwest Research Institute in San Antonio; Henry Aaron Hill, chemist and President of the Riverside Research Laboratory in Haverhill, Mass.; and Sidney Margolius, New York author, columnist, and authority on consumer issues.

The Executive Director of the Commission is William V. White, whose long-term experience as a U.S. Public Health Service career official has included work on injury control and family safety. The General Counsel is Michael Lemov, formerly with the Department of Justice.

Three staff task forces are carrying out comprehensive studies and investigations for the Commission. Task Force I is putting together information on the relationship between household products and accidental injuries or deaths. The Chief of this unit is Dr. Samuel C. Southard, former chairman of the Accident Prevention Committee of the American Academy of Pediatrics.

Task Force II, headed by Biophysicist Dr. Carl C. Clark, is reviewing means employed by industry to regulate itself to attain product safety. This unit is looking into ways standards are developed in various industries, how long it takes to develop them, the quality of the standards, and how they are applied in the marketplace.

Task Force III is looking into legal means of protecting the consumer from accidents involving household products. Under the direction of New York Attorney Theodore J. Jacobs, this unit is compiling, studying, and analyzing Federal, State, and local laws, regulations, codes, and the common law to find out how conflicting legal requirements affect both manufacturers and consumers.
The problem of mycotoxins in FDA's mission of assuring the healthfulness of food consumed by Americans was, until a few years ago, of little or no concern. Mycotoxins are naturally occurring poisonous substances produced by some types of molds. Like antibiotics, mycotoxins are metabolites produced by the living processes of some molds, but the former are toxic primarily to certain types of bacteria and are nontoxic or less toxic to humans and other warmblooded animals. Mycotoxins have been shown to be toxic to laboratory test animals and some farm animals. Some mycotoxins, fed at low, nonlethal doses, have caused liver cancer in test animals. Not all molds produce mycotoxins. Many molds are harmless so far as health is concerned, and some molds are even cultivated as a part of the processing of certain foods, such as Roquefort cheese.

The Agency's concern about mycotoxins dates from 1961 when about 100,000 young turkeys died in Great Britain from an unknown cause. The deaths were found to be caused by a toxic substance produced by Aspergillus flavus, a common mold that contaminated peanut meal used to feed the turkeys and which had been imported from Brazil. This mycotoxin was named aflatoxin, and it has since been found in other crops, particularly peanuts, brazil nuts, cottonseed, copra, and to a lesser extent in cereal grains. A number of other mycotoxins have been found and isolated from foods and feeds. Although some mycotoxins are known, there are undoubtedly others yet undiscovered that are potentially harmful to the health of man and animals. FDA in recent years has been pursuing a program aimed at finding and isolating these mycotoxins so it can devise effective ways for their detection and control. FDA has developed analytical methods that detect aflatoxin in specific foods within 3 hours where once this took several days, and has devised chemical and biological confirmation methods to fully support and enforce regulatory action against contamination of foods by aflatoxin.

FDA has been carrying out a training program in mycotoxins to benefit its own scientists and others. Continued research or other work is needed in the effect on mycotoxins of various processes in production of foods; in isolation and growth of molds; in isolation of these toxins and establishment of their chemistry to make possible the development of detection and confirmation methods; in the toxicity of a given mycotoxin to biological systems and to small and large animals, including those where toxic substances may be deposited in edible tissues; and in surveys of foods for detection of known mycotoxins and for assessment of their extent and distribution.

The photographs show molds of various kinds grown on corn in the laboratory (left and right), and three adjacent mold colonies grown in the process of isolating various molds in the search for mycotoxins (center).
In FDA's procedure for detecting and confirming aflatoxin, the product sample is put into a machine that thoroughly grinds and mixes it to give a uniform mass (small photo, top left). In the chemical analysis to detect mycotoxins, a portion of the mixed sample is subjected to an extraction and cleanup process in a chromatographic column that separates the mycotoxin from the rest of the sample by the use of solvents (small photo, bottom left). This extract is then spotted in small amounts at the edge of a thin-layer chromatographic plate, a glass plate covered with an adsorbent layer of silica gel (small photo, bottom right). This edge of the plate is placed in a pool of solvent which travels up the plate in a manner similar to oil traveling up a wick. If one of the three mycotoxins detectable by the procedure is present, it will be deposited on the plate in a characteristic pattern of spots as the solvent creeps upward. The TLC plate, here under ultraviolet light (top left), shows three groups of mycotoxins: the three spots at the right are characteristic of ochratoxins, the one in the center of the estrogenic factor of gibberella zeae, and the four at the left of aflatoxins. FDA has developed this multidetection method that detects these three groups of mycotoxins simultaneously.

The preparatory TLC plate (top right) shows how the aflatoxin from a sample is obtained from the plate for chemical and biological confirmation tests. The extract from the sample is spotted in a number of places at the bottom edge of the plate and the edge dipped in the solvent. The aflatoxin thus is deposited as a strip across the plate. To obtain the aflatoxin (bottom left), this strip is marked while under UV illumination and then retrieved along with the dried silica gel coating by the use of a vacuuming device. The vacuum cleaner contains a filter that prevents the material from escaping upward. This filter receptacle is then inverted and another solvent is passed through the filter to dissolve the aflatoxin, which is caught in a small flask (bottom center).

Three chemical derivatives are made with portions of this aflatoxin. These aflatoxin derivatives are shown on the TLC plate (bottom right) and provide chemical proof because they are characteristic of aflatoxin. Another portion of the sample extract is subjected to one of two tests which confirm the biological toxicity of the aflatoxin.
In the chicken embryo test, a hole is drilled in one end of a fertile chicken egg and a portion of the extract deposited therein (bottom). Specific amounts of aflatoxin deposited in an egg at the beginning of the 21-day incubation period will destroy life in the embryo. These photos of candled eggs show regression of the blood vessels of the dead embryo in an egg in which aflatoxin has been deposited (center left), as compared to the network of healthy blood vessels in a live embryo of the same age (center right).

In the bacteriological test to confirm toxicity, quantities of the same extract are placed on a culture plate seeded with Bacillus megatarium, micro-organisms whose growth are inhibited by aflatoxin. Not only do the aflatoxin deposits create zones of inhibition to the bacteria growth as shown in the photo (top left), but around the edge of this zone, as seen under a microscope, appear abnormal forms of the injured bacteria. The microscopic photos show the normal and the abnormal B. megatarium (top right, above and below). Antibiotics and other mycotoxins tried so far by FDA have not produced similar aberrant effects in these bacteria.

FDA insists on a positive presumptive chemical test, a positive chemical derivative test, and a positive toxicity test before taking regulatory action in an aflatoxin contamination case.
Partnership for Health: An Incident in Gloucester

by Edward J. McDonnell

A tragic and destructive explosion at a New England cold storage warehouse earlier this year proved to be the catalyst in a prime example of FDA-industry cooperation in behalf of the consumer. It also provided an opportunity for Government agencies to demonstrate the importance of their supportive roles in safeguarding the health of Americans.

In the early morning of January 2, at 12:02 a.m., an explosion ripped through the plant of the Quincy Market Cold Storage and Warehouse Co. at Gloucester, Massachusetts. Two engineers were killed and a third injured as the pressurized ammonia gas in the refrigeration complex exploded because of a malfunction in the complex and completely devastated a 300-foot section of the exterior wall of the freezer. The explosion left approximately 11 million pounds of palletized frozen fish and fish foods exposed to the elements. The refrigeration system at the warehouse was completely destroyed and the industry was confronted with the enormous task of salvaging 11 million pounds of fish. The problem was compounded because of the danger of ammonia fumes further contaminating the exposed food products.

Later in the day, inspectors from FDA's Boston District Office, the U.S. Department of Interior, the Commonwealth of Massachusetts, and the city of Gloucester met with representatives from Gorton's of Gloucester, a fish processing firm which owned about 80 percent of the products in the warehouse, and the Quincy Market Cold Storage and Warehouse Co. All parties agreed that close State-Federal cooperation with industry was of paramount importance in dealing with the problem at hand. Russell Boshell, Director of Quality Control of Gorton's of Gloucester, scheduled daily meetings between industry and Government representatives to avoid problems that might arise from inadequate communications and to expedite salvage operations.

The enormity of the crisis is difficult to comprehend. Eleven million pounds of frozen fish products were exposed to the elements without any refrigeration. Obviously the frozen food had to be moved without delay to other freezers to prevent thawing. The job of moving such a huge quantity of fish on short notice is extremely difficult and complicated. Dangerous ammonia fumes impeded salvage operations and threatened to contaminate that part of the food still salvageable. An added impediment was that inventory records at the warehouse were completely destroyed in the blast and the location and identification of product lots was impossible.

The problems of the various health agencies involved were also immense. The FDA, charged with protecting the consumer from adulterated food products, faced the task of inspecting the 11 million pounds of frozen fish for ammonia contamination and mechanical damage. The Commonwealth of Massachusetts' Division of Food and Drugs was interested in inspecting all of such food that moved in the State of Massachusetts. Finally, the Bureau of Solid Waste Management of the Environmental Control Administration, Consumer Protection and Environmental Health Service, was concerned with finding a way for the damaged merchandise to be safely disposed of without further pollution of the environment.

Mr. Boshell of Gorton's of Gloucester directed salvage operations for the 35 fish processing firms involved. From the outset it was essential to remove the apparently undamaged goods to other freezers with the greatest haste to reduce the total loss and to prevent secondary contamination of the products. This consideration made inspection of the goods at the warehouse location practically impossible.

During a progress meeting on January 3, Gorton's of Gloucester estimated that 275 refrigerated trailer trucks, each carrying 40,000 pounds of the frozen products, would be necessary to move the salvageable fish. Mr. Boshell reported afterward that he had secured 200 trailer trucks to transport that part of the merchandise which was apparently undamaged to cold storage warehouses in Massachusetts, Maine, and Ohio. Vice President Michael J. Burke of the Quincy Market Cold Storage and Warehouse Co. arranged for storage in these warehouses for the products of the other 34 processing firms involved. Gorton's of Gloucester and the governmental health agencies agreed that the frozen goods should be inspected at destination rather than at the blast area to hasten removal to freezers.

FDA Inspectors estimated that if the loading crews worked 24 hours a day, it would still take 10 days to remove all of the frozen food. Obviously some cooperation from the weather was necessary to prevent thawing. The unpredictable New England weather responded by driving temperatures down around 5° to 10° F. for the next 6 days.

At the blast site, city, State, and Federal inspectors assisted Gorton's quality control inspectors in the segregation of damaged goods and salvageable products. For the next 6 days, field examinations were conducted to examine samples of the various products for mechanical damage, chemical contamination, and evidence of thawing. A field kitchen, equipped with ovens and...
Some effects of the Gloucester cold storage warehouse explosion, which blew out a 300-foot section of one 400-foot wall of the structure, are shown on the opposite page. Stored fish products had not been removed at the time the picture was taken. The car, wrecked in the blast, was about 50 feet away from the building. At top left, inspecting the damage are (left to right) Inspectors Frank Frost and Jack Giacalone, Commonwealth of Massachusetts' Division of Food and Drugs, and Inspector Charles E. Phillips of FDA's Boston District. At top right is a mobile refrigeration unit brought in to keep salvageable fish refrigerated until they could be moved. In center is a crane used to remove rubble and later to remove unsalvageable fish. At the bottom, right photo shows cartons of unsalvageable fish at dockside waiting to be loaded into barges like that shown in the photo at left and then carried out to sea and dumped. At upper left are shown some of the trailer trucks used to transfer salvageable fish to cold storage plants in other areas.

Edward J. McDonnell joined FDA's Boston District in June 1966 as a Food Inspector.
deep-fat cookers, was placed into service for organoleptic examination of suspect merchandise. The inspectors’ organoleptic examination consisted of thawing the products at room temperature, smelling them for evidence of ammonia fumes or decomposition, and cooking the products according to package directions and then smelling and tasting them. A variety of cardboard, plastic-wrap, cello-wrap, and unwrapped packages of breaded fish sticks, fried fish portions, scallops, and crabmeat were examined in this way.

Boston District Supervisory Inspector Bill R. Wobbleton coordinated FDA inspectional activities involved in the salvage operation. FDA Inspectors visited trucking firms delivering salvaged fish and determined the destination of the products. The Commonwealth of Massachusetts Inspectors agreed to inspect all frozen foods that were shipped to cold storage warehouses within the State of Massachusetts. Mr. Wobbleton coordinated the FDA resident inspectors located in Augusta, Maine, Concord, New Hampshire, and Cleveland, Ohio, to inspect frozen fish shipments at destination. Gorton’s of Gloucester quality control specialists assisted FDA Inspectors in segregating suspect lots pending positive evaluation of ammonia damage.

As a result of combined industry-Government inspectional activities, 11 large lots of frozen products were detained upon receipt at various cold storage depots. Subsequent examination following several days of storage, however, did not reveal any evidence of ammonia contamination. The lots were eventually released by industry quality control experts.

After 8 days of intensified inspectional effort, Government and industry inspectors had succeeded in segregating approximately 2 million pounds of damaged, contaminated, and decomposed frozen food products. The next problem was to determine a method by which this solid waste could be disposed of without further contaminating the environment. Because of the potential air pollution hazard and the semifrozen nature of the product, burning did not appear practicable. Gorton’s of Gloucester finally decided to dump the solid waste at sea on an outgoing tide.

The firm chose a suitable site at sea and contacted the U.S. Coast Guard, Army Corps of Engineers, and the Massachusetts Division of Waterways to obtain permission to dump the product. The Environmental Control Administration, the CPEHS Agency which has the authority to permit dumping of solid wastes at sea, reviewed the dumping operation and the safety precautions utilized by the firm. A total of 26 bargeloads was eventually deposited in the Atlantic Ocean on outgoing tides.

This incident established new lines of communication between Government agencies and the military which may be used in solving future waste disposal problems. As a result of this improvement in cooperation and communication, every individual can expect better environmental health protection.

The story of the Gloucester fish disaster is of particular interest because it represented one of the first opportunities for Government health agencies within the Consumer Protection and Environmental Health Service to share responsibility for safeguarding the environment.

Charles C. Johnson, Administrator of CPEHS, in a statement last November said:

“The new service is concerned with the whole spectrum of environmental and consumer hazards and brings together, in a relationship in which they can be mutually supportive, the principal activities of the Department of Health, Education, and Welfare which deal with these problems.”

The organization of CPEHS gave recognition to the impracticability of considering as separate and unrelated the human environmental problems of food contamination and air pollution. Both health problems combine to produce a total effect on the health of the individual. The Gloucester fish disaster is an example of how CPEHS can work effectively in providing the American consumer with better health protection.

Douglas C. Hansen, now CPEHS Regional Assistant Administrator, in a speech last December on the approach FDA would make in discharging the responsibilities of CPEHS, said:

“To accomplish this, we hope to enter into a dynamic partnership with the States and local governments. In solving the problems of inadequacy in our health care system and improving the quality of our environment, we are pledged to a program of ‘partnership for health’ with all segments of our society, which obviously includes industry.”

We believe that the so-called partnership for health was the essential ingredient in dealing with the special health problems presented by the Gloucester explosion. The cooperation between FDA and State-local health agencies, and FDA and industry, protected the welfare of the American consumer and assisted industry in minimizing the possibilities of further contamination from ammonia fumes and thawing.
ATLANTA DISTRICT  FDA’s Atlanta District Office and the Florida Department of Agriculture are establishing a collection of beans and other seeds which may be poisonous to man. This collection will aid rapid identification of the various attractively colored beans and seeds used in the manufacture of necklaces and other novelty items. The decorative beans are frequently imported from Central and South America or from the islands of the Caribbean. The possibility of jequirity beans and other toxic beans or seeds being used in these necklaces and novelty items creates an ever present hazard.

The head of the Bacteriology Lab of International Surveyors in Peru spent 10 days at the District laboratory studying methods and techniques involving analysis for Salmonella in fishmeal. Senor Juan Revolo Ampuero, an employee of Certificaciones Technicas S.A., International Surveyors, La Peria-Callo, Peru, is responsible for examination of fishmeal before it is exported to the United States. As part of his studies, he also has visited Holland and Germany, but says the aseptic sampling techniques used in the Atlanta District laboratories are superior to those used in other countries.

A consignment of approximately 480 pounds of carrots shipped by John Jacobs Farms, Phoenix, Ariz., to a distributor in Baltimore, Md., was found to contain excessive residues of endrin, a pesticide. The lot was voluntarily destroyed under Baltimore District’s supervision.

BOSTON DISTRICT  An inspection of a New England fish processor showed that breading of frozen ocean perch was taking place in the plant under insanitary conditions conducive to microbial contamination. Laboratory examination showed that the product contained E. coli, excessive coliforms, and a high bacterial count. Two shipments of the firm’s frozen breaded ocean perch were seized, one 16,980-pound shipment, valued at $6,620, at Nashville, Tenn., and one 5,940-pound shipment, valued at $2,391, at New Orleans, La. The firm, Channel Fish Co., Boston, requested and received a portion of the sample collected at Nashville from the Boston District office for its own laboratory analysis.

A seminar on Labeling of Household Hazardous Substances, held in Boston last December 5, was attended by 95 representatives of various industries. The seminar was cosponsored by Boston District, the Chemical Specialties Manufacturers’ Association, the National Paint, Varnish and Lacquer Association, and the New England Paint, Varnish and Lacquer Association.

During the morning session, FDA representatives spoke on the mutual benefits to FDA and industry of voluntary compliance, and on the requirements and exemptions of the Federal Hazardous Substances Act. In the afternoon, industry spokesmen discussed problems of labeling hazardous products, proper label control, and civil liability under the FHSA.

At the conclusion of the seminar, representatives of the National Paint, Varnish and Lacquer Association said that their organization would explore the possibilities of producing with the FDA a television documentary film on the hazards of household products.

BUFFALO DISTRICT  FDA seized two shipments of carrots consigned to distributors in Buffalo, and Pittsburgh, Pa., by John Jacobs Farms, Phoenix, Ariz. The carrots had been found to contain excessive residues of endrin.

CHICAGO DISTRICT  The Illinois Department of Public Health’s Division of Milk Control is expanding its activities to deal with manufactured dairy products as well as Grade A market milk. It is being aided in the new activities by the Chicago District.

Thirteen members of the Division attended a work-
shop at District offices December 3 and 4. The Division Chief, Enos Huffer, outlined statutory requirements for inspection under the Illinois Food, Drug, and Cosmetic Act. Chicago District Inspectors discussed inspections of cheese and butter plants, concentrating and drying operations, imitation dairy products, and general inspectional techniques and writing of reports.

A colloquium entitled “Man’s Health and his Environment” was cosponsored by the Chicago District and the Department of Health and Safety Education of the University of Illinois on December 5 and 6. It was one of the first in a series of meetings being conducted under governmental and academic auspices on man’s environment, both physical and social. A series of in-depth scientific papers was presented, followed by panel discussions among the health educators and scientists from academic, private, and governmental agencies who attended the meeting.

The main speakers and their topics: Dr. John J. Hanlon, Deputy Administrator, Consumer Protection and Environmental Health Service, Department of Health, Education, and Welfare, “Environmental Health Concerns and Issues”; C. Jellef Carr, Director, Life Science Research Office, Federation of American Societies for Experimental Biology, “Man and Drugs”; Hilda S. White, Associate Professor of Home Economics, Northwestern University, “Man and his Diet”; Daniel Horn, Director, National Clearinghouse for Smoking and Health, “Man, Cigarettes, and the Abuse of Gratification.”

CINCINNATI DISTRICT “Non-medicated” dairy feed, contaminated at the manufacturer’s plant in La Vergne, Tenn., by the addition of returned feeds containing penicillin, was seized by the Tennessee Division of Feeds, Fertilizer, and Seeds. The seizures, based on Cincinnati District’s inspectional findings and laboratory confirmation of the presence of penicillin, took place within the State at various branch facilities of the manufacturer, Tennessee Farmers Cooperative.

Frozen breaded ocean perch, valued at $6,620, was seized at Nashville, Tenn., last December 15 because the 16,980-pound lot contained E. coli, excessive coliforms, coagulase positive staphylococci, and a high total bacterial count. The lot, shipped by Channel Fish Co., Boston, Mass., had been prepared in an insanitary plant (see Boston District).

DALLAS DISTRICT Publicity about the recall of jewelry items containing poisonous jequirity beans, sold through Sears, Roebuck & Co., attracted the attention of a husband and wife, who then turned in a jequirity bean necklace to the Dallas District office last December 17. The necklace had been purchased at a Dallas museum. The District investigated and found the museum had sold 26 of the necklaces, imported from South Africa. On December 18, the story was carried by the news media and as a result over 100 telephone calls were received by the District office. Within a short time, 16 necklaces were recovered—six sold by the museum and 10 from other sources.

The State of Texas has successfully terminated its court case against Carl Emil Sweeny, trading as the Durlis Fish Camp, Oyster Creek, Tex., in which he was charged with selling oysters from an uncertified source. Dallas District worked with the Texas Department of Health’s Food and Drug Division in prosecuting the case, which was concluded last December 16. Mr. Sweeny was fined $200, plus costs, and was placed on probation for a year.

An explosion at Comet Rice Mill, Houston, Tex., last December 13, injured several employees and caused water damage to 300 to 400 barrels of rice. FDA’s Dallas District worked in conjunction with the city of Houston sanitarians in seeing that the water-damaged rice was destroyed by the firm.

DENVER DISTRICT Frozen french-fried potatoes contaminated by excessive ammonia residues from faulty cooling mechanisms in a storage warehouse were seized by deputy U.S. marshals in Greeley, Colo. Approximately 13,500 cases, valued at $40,000, were seized from the warehouse because of FDA charges of contamination.

Failure to print proper label warnings and an affirmative statement of hazards resulted in the seizure of 371 “Bellini Oil Painting Kits” in Denver. Required warnings such as “Keep out of the reach of children,” “Danger,” and “Harmful or Fatal if Swallowed” were omitted from the labels. Each kit contained three tubes of permanent oil colors, a half-ounce bottle of turpentine, and other, nontoxic materials.

DETROIT DISTRICT Representatives of the disadvantaged living in the Model Cities attended a series of 10 2-hour seminars on the scope of contemporary health products. The seminars were sponsored by FDA and Wayne State University and were held November 26 and December 3, 5, 10, and 12 in Detroit on the university campus. Topics included the safety, efficacy, purchase, storage, use, misuse, and quackery involved in drugs, therapeutic devices, and cosmetics.

The audience was selected by the Consumer Research Advisory Council for its members’ ability to communicate the information within the inner city. They represented 60 inner city organizations.

KANSAS CITY DISTRICT A quantity of a veterinary drug, valued at $600, was seized by a U.S. marshal last December 20 after various charges had been made by the Government against it. The drug, “Ru-Vi-Otic Powder,” is manufactured by the I. D. Russell Co. Labs, Kansas City, Mo. The Government charged that the drug differed in strength from that it purported to
National Park Service has contracted with the salvagers taking place in the DeSoto Bend Recreation Area. The Missouri changed course, so salvaging is possible at Nebr., where the Bertrand sank on a sandbar about 1865. The boat was covered with 30-40 feet of silt, then the Missouri changed course, so salvaging is taking place in the DeSoto Bend Recreation Area. The National Park Service has contracted with the salvagers to retain certain items classified as antiques. Omaha Senior Resident Inspector Carl A. Larrick is FDA's liaison with the National Park Service.

Salvaging operations are taking place near Omaha, Nebr., where the Bertrand sank on a sandbar about 1865. The boat was covered with 30-40 feet of silt, then the Missouri changed course, so salvaging is taking place in the DeSoto Bend Recreation Area. The National Park Service has contracted with the salvagers to retain certain items classified as antiques. Omaha Senior Resident Inspector Carl A. Larrick is FDA's liaison with the National Park Service.

**LOS ANGELES DISTRICT** Samples of shipments of carrots grown in the fields of John Jacobs Farms, Phoenix, Ariz., were found by Los Angeles District to contain the pesticide chemical, endrin. Five seizures were made at destination—totaling 948 bags and cartons. Other dealers destroyed their stocks voluntarily.

Although the firm claimed it had not used endrin on any crop grown on the plots of land since 1963, endrin still persisted in the soil from prior applications, and was picked up by the carrots in later years. The absence of warning statements on hazardous substances was the basis for seizure of 92,000 tear gas gun shells in possession of the distributor, G-G 31, Inc., North Hollywood, Calif. The shells had been shipped from a Pennsylvania firm and were being distributed in States whose laws are not restrictive for this type of product.

**MINNEAPOLIS DISTRICT** A product its promoters claimed would restore natural color to gray hair and destroy dandruff was seized in possession of National Products Co., Eau Claire, Wis. FDA charged that the product, “K. O. Gray,” was misbranded by false and misleading statements in the accompanying labeling which represent and suggest that the article is adequate and effective for restoring natural color to gray hair. FDA further charged that the article, manufactured and shipped by Laser Laboratories, Inc., Minneapolis, is a new drug that may not be introduced or delivered into interstate commerce since it lacks an approved New Drug Application.

**NEW ORLEANS DISTRICT** An industry workshop for the rice growing industry, held last December 3 at the Rice Festival Building, Crowley, La., drew an attendance of approximately 200. The meeting was co-sponsored by the Rice Millers Association, the Louisiana Rice Dryers and Warehousing Association, Louisiana Rice Growers Association, Louisiana Farm Bureau Federation, and FDA.

Principal speakers at the workshop included: Dr. John Bagent of Louisiana State University Extension Service; Dr. John B. Halleck of Uncle Ben’s Rice Mill; George Abraham, Division of Wildlife Service, U.S. Department of Interior, Baton Rouge; Bob Russell, National Pest Control Association; J. P. Gaines, Executive Vice President, Rice Millers Association; David H. Bryant, FDA Inspector, and Helen C. Barry, Chief Chemist, New Orleans District.

Foods contaminated by Salmonella organisms accounted for a significant number of import detentions in December by the New Orleans District. Salmonella detentions involved one lot of 410 cases of chocolate candy eggs manufactured in Holland by Konink Lijke Fabrieken Boon, N. V., and a shipload of 25,021 bags of fishmeal worth $125,511. In the latter case, Salmonella was found in each of the 11 lots in the shipment, which had originated with Pasquero Indo S.A., Arica, Chile.

**NEW YORK DISTRICT** Misbranded mozzarella cheese valued at $2,560 was seized in Brooklyn on December 9 by the U.S. marshal for the Eastern District of New York. The seizure involved 128 cases each containing 8 5-pound loaves of cheese. When introduced into interstate commerce, the cheese was misbranded in that it was represented as low moisture and contained less than 45 percent of milk fat. The cheese was manufactured and shipped by Richmond Co-op Association, Inc., Richmond, Vt.

The District seized approximately 798 pounds of smoked salmon in Brooklyn on December 11 because excessive nitrates were found in the product. The salmon, manufactured by Roodman’s, Inc., St. Louis, Mo., was valued at $1,750.

FDA’s concern with setting standards and providing practical assistance to industry in meeting those standards was pointed out recently at a Good Manufacturing Practice seminar. The day’s seminar, sponsored by the New Jersey Pharmaceutical Control Association, heard a progress report by Kenneth Silver, New York District’s Executive Officer, on the District’s operations under the Intensified Drug Inspection Program, one of the key elements in the FDA’s new approach. Mr. Silver reported that of the 10 drug firms undergoing intensified drug inspections, five have been rated satisfactorily.
factory, four inspections are still underway, and a consent decree of permanent injunction was obtained against the 10th firm.

PHILADELPHIA DISTRICT Feed grade bulk riboflavin, contaminated with 2,4-D, a pesticide chemical, was destroyed December 6 at Nutley, N.J. FDA Inspector Samuel Jones of the Newark office, was present at the destruction of the lot of 815 kilograms.

Contamination occurred when the riboflavin was spray-dried by Custom Processing Corp., Trenton, N.J., which used the same equipment for drying as had been used for 2,4-D a week previously. A report on the operations of the dryer has been filed with the New Jersey Bureau of Foods and Drugs.

An extensive series of court proceedings, started in 1964, culminated December 20 in the signing of a consent decree of permanent injunction against York Barbell Corp., Hoffman Laboratories, Inc., and Robert C. Hoffman. The injunction enjoined the firm from shipping dietary foods which utilize as part of their labeling certain specific literature which may misbrand the product or any presentation for a long list of maladies and deficiencies due to improper diet.

SAN FRANCISCO DISTRICT On December 17, 43 100-pound bags of converted long grain rice were seized in the possession of the California Sun Dry Bulgar Co., Fresno, Calif. The lot was valued at $694. FDA’s complaint charged that the rice had been held under conditions whereby it may have become contaminated with insects and that it was in fact so infested.

SEATTLE DISTRICT District Director Franklin Clark and Supervisory Inspector Richard Dawson met with the Alaska Commissioner of Health and Welfare and some members of his staff at Juneau, Alaska, to discuss findings for salmon cannery inspections during the past season and areas of priority attention for the next season. Walt Yonker, Manager, Northwest Branch of the National Canners Association, also attended.

The Seattle District’s annual conference, held December 4-6, was attended by three men who have become new FDA members through the Consumer Protection and Environmental Health Service reorganization. They are: William Beck, Director of the Pacific Northwest Marine Health Science Laboratory, Purdy, Wash.; Homer Wolfe, Acting Director, Pesticide Research Laboratory, Wenatchee, Wash.; and Dr. William Stevenson, Public Health Service Project Coordinator, State Pesticide Control, Portland, Ore.

The three new FDA’ers presented talks on their organizations, staffs, and programs.
Poison Honey  Bees gathering nectar from mountain laurel (*Kal- mia Latifolia*) instead of the usual fireweed produced a toxic honey believed to have caused the illness of five persons reported by a local Washington health district. Washington State Inspectors tested the honey and found it contained andromedotoxin, a substance toxic to man and found in mountain and sheep laurel. The honey was disposed of under the inspector's supervision.

The afflicted persons exhibited the typical symptoms of breathing difficulty, blurred vision, slight paralysis of extremities, and nausea. All recovered, though one person required hospitalization.

Similar events occurred in 1942, 1953, and 1959. During seasons when fireweed does not blossom, the bees gather nectar from the laurel, which abounds in the area, extracting the poisonous andromedotoxin from these plants along with the nectar. The substance is apparently harmless to bees.

False Alarm  Local publicity in the Portland, Oreg., area concerning the recall of products containing jequirity beans was too effective. Portland officials relayed information to FDA's Seattle District that decorative table centerpieces containing these beans were produced in the Portland area. Considerable investigative efforts by city officials and the District's Portland resident inspectors turned up nothing. It now appears that overzealous citizens were responsible for a false alarm.

Toxic Dishware  Baltimore, Md., residents were warned by the city health department last December 27 that a glazed dishware with a holly green and red pattern, sold during the holiday season, was potentially toxic. In view of possible national distribution, the department notified the Baltimore District office of FDA so that action could be taken at the Federal level, if necessary.

Baltimore City Health Department laboratory tests revealed a high percentage of lead in the dishware glaze which could be leached into liquids or other foods with which it came into contact, and could cause lead poisoning.

Merchants known to have sold these items were asked to discontinue their sale.

**Maine-FDA Cooperation**  The Maine State Division of Consumer Protection met with FDA's Boston District in December to discuss a mutual agreement whereby the State of Maine inspects sardine manufacturers, warehouses, and bakeries. Since this agreement was initiated, the State of Maine reports discovery of warehouses which had never previously been inspected by any agency. State inspection of these warehouses has brought about voluntary corrective measures in construction of additional storage space and placement of pallets under warehoused merchandise.

As part of the agreement, Maine sends written reports of its inspections to the Boston District to improve the exchange of inspection information between the agencies. Initial findings indicate that this cooperation is improving consumer protection.

**Can-opener Problem**  A consumer's complaint brought an investigation of a bakery's operations by the Lincoln-Lancaster County Health Department, Lincoln, Nebr. It was found that metal filings were being produced by the cutting blade of a machine used to open cans of filling for rolls and pastries. R. E. Devol, Chief Food Sanitarian, reported that corrective measures to eliminate this problem have been taken by the bakery.

**Drug Safety Talks**  Representatives of professional, youth, educational and service organizations met under the auspices of the Twin City (St. Paul/Minneapolis) Federal Executive Board and FDA's Minneapolis District, to discuss safe use of drugs in Minnesota. After several meetings, the group recommended that coordination of drug education and information be established under the direction of the Governor's office. Governor Harold L. Vander has now recommended establishment of a drug education center in his state-of-the-State message to the legislature.

**Single System Plans**  Facets of the State-Federal Single System Concept are being worked out in cooperative efforts between New York State and FDA District officials. George Gerstenberg, Chief, Brooklyn Section, and Supervisory Inspector Joseph Faline conferred with State officials at Albany last October 16-17 to work out preliminary details for implementation of the system. The New York State Department of Agriculture and Markets is reviewing a suggested new format which will enable its inspection reports to mesh with the FDA's.

In addition, the State Board of Pharmacy will implement the Single System Concept for drugs. The board has agreed to its line personnel to be trained by the FDA and to make joint inspections with a view toward being commissioned. The board has also agreed to take responsibility for over-the-counter drug work (non-DACA drugs) not being covered by the FDA due to shortage of manpower.
seizures and post office cases

SEIZURE ACTIONS

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

A total of 24 seizure actions to remove adulterated, misbranded, and unsafe products from the consumer market, were reported in December. These included 11 seizures of foods: 1 because of poisonous and deleterious substances, 8 because of contamination, and 2 because of economic violations. Other seizures included 2 of vitamins, and 11 of drugs (including 1 for veterinary use).

<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>Lettuce/Landover, Md. 11/27/68</td>
<td>Mel Finerman Co., Inc./Toltec, Ariz. (S)</td>
<td>Contains excessive parathion and toxaphene residues.</td>
</tr>
<tr>
<td>Cocoa powder/Collinsville, Ill. 12/12/68</td>
<td>L. Bruno &amp; Sons, Inc./Collinsville, Ill. (D)</td>
<td>Contamination, Spoilage, Insanitary Handling</td>
</tr>
<tr>
<td>Flour/Selma, Ala. 11/12/68</td>
<td>Selma Wholesale Grocery Co., Inc./Selma, Ala. (D)</td>
<td>Held under insanitary conditions; insect contaminated.</td>
</tr>
<tr>
<td>Ginger ale/Hampton, Va. 12/10/68</td>
<td>Suburban Club Carbonated Beverage Co., Inc./Baltimore, Md. (M,S)</td>
<td>Held in a rodent-contaminated warehouse.</td>
</tr>
<tr>
<td>Rice/Fresno, Calif. 12/17/68</td>
<td>California Sun Dry Bulgur Co./Fresno, Calif. (D)</td>
<td>Held under insanitary conditions; insect contaminated.</td>
</tr>
<tr>
<td>Tomatoes, canned/New Albany, Miss. 10/3/68</td>
<td>Emerson Canning Co./Reeds Spring, Mo. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Starkville, Miss. 10/21/68</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixed fruit/Columbus, Ohio 12/4/68</td>
<td>Tri-Valley Growers/Modesto, Calif. (P,S)</td>
<td>Prepared, packed, and held under insanitary conditions.</td>
</tr>
<tr>
<td>Mozzarella cheese, whole milk, low moisture/Brooklyn, N.Y. 12/9/68</td>
<td>Richmond Co-op Association, Inc./Richmond, Va. (M,S)</td>
<td>Contains less than 45 percent of milk fat.</td>
</tr>
<tr>
<td>Liver Iron B-Plex tablets/Milwaukee, Wis. 12/11/68</td>
<td>Formulations, Inc./Milwaukee, Wis. (M,S)</td>
<td></td>
</tr>
<tr>
<td>RMP Vitamin B-12, 30-cc. and 10-cc. vials/Phoenix, Ariz. 10/18/68</td>
<td>Rocky Mountain Pharmacal Co./Phoenix, Ariz. (D)</td>
<td>Below USP standard of strength.</td>
</tr>
</tbody>
</table>
### DRUGS / Human Use

<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>Apacol tablets/Philadelphia, Pa. 12/4/68</td>
<td>S. F. Durst &amp; Co./Philadelphia, Pa. (D), C. M. Bundy Co./Cincinnati, Ohio (bulk S)</td>
<td>Below labeled strength; inadequate directions for use, but no adequate directions can be written for children under 6 years of age, since preparation contains atropine sulfate.</td>
</tr>
<tr>
<td>Bismuth subgallate tablets/Largo, Fla. 11/13/68</td>
<td>United Surgical Corp./Largo, Fla. (D)</td>
<td>New drug not approved for safety and efficacy.</td>
</tr>
<tr>
<td>Consin-Diu tablets, Consin cold capsules/ Milwaukee, Wis. 12/10/68</td>
<td>Formulations, Inc./Milwaukee, Wis. (M,S)</td>
<td>Prepared, packed, and held under insanitary conditions; methods used, facilities, and controls not in conformity with good manufacturing practice.</td>
</tr>
<tr>
<td>Digoxin tablets, Conjutrone tablets, Methenamine Mandelate tablets, Phenobarbital USP tablets, The-Ephetal tablets/Milwaukee, Wis. 12/10/68</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fingernail conditioner cream/Indianapolis, Ind. 11/20/68</td>
<td>Amazing Corp./Groves, Tex. (M,S)</td>
<td>New drug not approved for safety and efficacy.</td>
</tr>
<tr>
<td>Jensenex tablets/Auburn, N.Y. 11/25/68</td>
<td>C. M. Bundy Co./Cincinnati, Ohio (M,S)</td>
<td>Contaminated by zinc and copper; not produced under good manufacturing practice.</td>
</tr>
<tr>
<td>Pituitary gland tablets, 1 gr./Milwaukee, Wis. 12/13/68</td>
<td>C. M. Bundy Co./Cincinnati, Ohio (M,S)</td>
<td>Inadequate directions for use; no full disclosure labeling.</td>
</tr>
<tr>
<td>Salipap tablets, Fedacap capsules/Freeport, Ill. 11/26/68</td>
<td>Formulations, Inc./Milwaukee, Wis. (M,S)</td>
<td>Prepared, packed, and held under insanitary conditions; methods used, facilities, and controls not in conformity with good manufacturing practice.</td>
</tr>
</tbody>
</table>

### Veterinary / Medicated Feed

<table>
<thead>
<tr>
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<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ru-Vi-Otic Powder/Kansas City, Mo. 12/20/68</td>
<td>I. D. Russell Co. Labs./Kansas City, Mo. (D)</td>
<td>Below labeled strength in potassium penicillin and streptomycin sulfate; methods used and facilities not in conformity with good manufacturing practice.</td>
</tr>
</tbody>
</table>

### POST OFFICE DEPARTMENT

Actions taken in medical cases under provisions of the Postal Fraud Statutes as reported by the Chief Postal Inspector.

**Fraud Orders Issued by Judicial Officer Under 39 U.S.C. 4005 (Fraud)**

January 14, 1969: Fraud Order issued against Hydromassagic Research Center, Los Angeles, Calif. Solicitations of orders and sales through the mails of “Jaqualator,” for $24.95, a device claimed to develop and increase size of male erectile tissue.
NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

Eggs, frozen, at Buffalo, W. Dist. N.Y.  Charged 12-31-67: when shipped by Brasher Bros., Inc., Burbank, Calif., the article contained the added poisonous and deleterious substance di-nitrosoguanidine; 402(a)(1). Consent decree authorized release to Edward C. Fallon, Inc., Buffalo, N.Y., for reconditioning. (1)

Squash, honeydew, fresh, Puff, at El Paso, W. Dist. Tex.  Charged 3-2-68: when shipped by Del Monte. Fruit Exchange, Inc., Pompano Beach, Fla., the article contained the pesticide chemical endrin for which there was no tolerance or exemption; 402(a)(9). Consent decree ordered destruction. (2)

FOOD / Contamination, Spoilage, Insanitary Handling

Beans, Great Northern, at Cairo, E. Dist. Ill.  Charged by Grayney Brokerage Co., Cairo, Ill., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (3)

Beans, turtle-soup, black, at Detroit, E. Dist. Mich.  Charged 12-5-68: when shipped by Hollandia Trading Corp., New York, N.Y., the article contained rodent and insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (4)

Candy, at Laredo, S. Dist. Tex.  Charged 12-6-67: when shipped by M. M. Import Co., Laredo, Tex., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (5)

Caraway seed, sesame seed, poppy seed, and shelled peanuts, at Detroit, E. Dist. Mich.  Charged 12-11-67: while held by Philip Olander & Co., Detroit, Mich., the article was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for reconditioning. (6)

Cashew nuts, shelled, at Denver, Dist. Colo.  Charged 1-2-68: when shipped by Hollander Trading Corp., New York, N.Y., the article was held in part "Shelled Cashew Nut" from Lekshmi Vihar Cashew Industries Quilon—I.S. India, contained insect filth; 402(a)(4). Default decree ordered destruction. (7)

Chili pods, dried, at Los Angeles, S. Dist. Calif.  Charged 2-26-68: while shipped by Weber Truck & Warehouse, Los Angeles, Calif., the article contained rodent and insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the shipper for destruction of the chocolate drink and salvaging of the bottles. (8)

Chocolate drink, bottled, at Cincinnati, S. Dist. Ohio.  Charged 1-8-68: when shipped by Chocolat Royal, Ltd. (The Glacier Co.), Cincinnati, Ohio, to Louisville, Ky., and returned to the shipper, the article contained insect filth and mold; 402(a)(3). Consent decree authorized release to the shipper for the destruction of the chocolate drink and salvaging of the bottles. (9)

Coffee beans, green, at Port Allen, E. Dist. La.  Charged 12-18-67: while held by Greater Baton Rouge Port Commission, Port Allen, La., the article contained bird and rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the shipper to be salvaged, New Orleans, La., for salvaging. (10)

Coffee beans, green, at Port Allen, E. Dist. La.  Charged 11-28-67: when shipped by M.G. Inc. Feed Division Weimar, Texas, the article, labeled in part "M.G. Inc. Feed Division Weimar, Texas," contained insect filth and moldy cornhusks; 402(a)(3). Default decree ordered destruction. (11)

Danish mix, donut flour, and donut sugar, at Franklin Park, N. Dist. Ill.  Charged 12-7-67: when shipped by Chesapeake & Ohio Railway Co., Franklin Park, Ill., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the railway company for salvaging. (12)

Filberts, shelled, at Denver, Dist. Colo.  Charged 2-6-68: when shipped by Dundee Nut Growers, Dundee, Oreg., the article, labeled "Nut Secret Brand Almond Meat," was packed by Norpac Growers, Inc. Newberg-Dundee, Oregon, contained E. coli and was spoiled and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (13)

Flour, at New Orleans, E. Dist. La.  Charged 12-6-68: when shipped by George W. Grotches, New Orleans, La., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (14)

Flour, at West Point, N. Dist. Ga.  Charged 12-8-67: when shipped by West Point Wholesale Grocery, West Point, Ga., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for reconditioning. (15)

Garlic, at San Juan, P. R.  Charged 12-18-67: when held for sale, the article contained insect filth; 402(a)(3), 402(a)(4). Default decree ordered destruction. (16)

Ham, chopped, canned, at Los Angeles, C. Dist. Calif.  Charged 5-8-68: while held for sale, the article contained decomposed ham and was unfit for food by reason of presence of swollen cans; 402(a)(3). Default decree ordered destruction. (17)


Milk, nonfat, dried, at Mendota, N. Dist. Ill.  Charged 12-8-67: while held by Mendota Creamery Co., Mendota, Ill., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to National Cheesecake Co., for salvaging. (21)

Onions, pickled, and olives, unpitted, pitted, and pimento stuffed, at Denver, Dist. Colo.  Charged on or about 11-27-67: while held by Superior Honey & Olive Co., of Colorado, Inc., the articles contained insect filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree condemned the articles. The onions were subsequently destroyed and the olives were released to the dealer for reconditioning. (22)

Paprika, powdered, at New Orleans, E. Dist. La.  Charged 1-23-68: when shipped by Lykes Brothers Steamship Co., Inc., New Orleans, La., the article was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for reconditioning. (23)

Peanut pieces, Kentucky Kernel, at Indianapolis, S. Dist. Ind.  Charged 2-1-68: when shipped by Proctor & Gamble Co., Kidman, Ky., the article contained E. coli and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for reconditioning. (24)

Pork bellies, frozen, at Detroit, E. Dist. Mich.  Charged 1-30-68: while held for sale, the article contained decomposed fish; 402(a)(3). Default decree ordered destruction. (25)

Popcorn, at Dallas, N. Dist. Tex.  Charged 11-29-67: when held by Matthews Candy Co., Dallas, Tex., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for reconditioning. (26)

Peanut pieces, at Vicksburg, S. Dist. Miss.  Charged 1-10-68: when held by P. P. Williams Co., Vicksburg, Miss., the article contained insect filth; 402(a)(3), 402(a)(4). Default decree ordered destruction. (27)

Potatoes, french fried, frozen, at Laramie, Dist. Wyo.  Charged 1-11-68: when shipped by Idaho Potato Growers, Inc., Aberdeen, Idaho, the article had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to public institution for use as animal feed. (28)

Pretzels, at Kansas City, C. Dist. Mo.  Charged 12-9-68: when shipped by Great Southern Wholesale Grocery Corp., Miami, Fla., the article contained rodent filth and bird filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to public institution for use as animal feed. (29)

Rice, at Atlanta, N. Dist. Ga.  Charged 12-6-67: when held by Paley Bros., Inc., Atlanta, Ga., the article was held under insanitary conditions; 402(a)(4). Consent decree ordered destruction. (30)

Rice, at Knoxville, N. Dist. Calif.  Charged 12-7-67: while held by Saroni Sugar & Rice, Inc., Emeryville, Calif., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for reconditioning. (31)

Rice, at Miami, S. Dist. Fla.  Charged 2-6-68: when shipped by Great Southern Wholesale Grocery Corp., Miami, Fla., the article contained rodent and bird filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (32)

Alaska, as frozen salmon and canned at Seattle, Wash., the article contained decomposed tomatoes—402(a)(3). Consent decree authorized release to shipper for reconditioning. (52)

Shrimp, breaded, frozen, Treasure, 3 seizure actions at Chicago, N. Dist. Ill., and Urbana, E. Dist. Ill.

Charges 1-19-68: when shipped by Beveridge Developers, Anahiem, Calif., the label statement of being suitable for use in meat and of being a claimant's ingredient shipped in interstate commerce. Following the claimant's withdrawal and consent to the court, the court granted Leddy's motion saying:

"After careful consideration of the issue involved and applying the test stated in Libbey's brief in support of its position, that whether the answers 'would expose the witness to the danger of prosecution or result in disclosure of facts which form a necessary and essential link in a chain of evidence that would be sufficient to convict him of any crime,' the Court does now find that the business was not incorporated, and that the information sought would, if divulged, subject the corporation to prosecution, and that the answers were protected as a claimant. Following the claimant's withdrawal and consent to the destruction of the article, the article was ordered condemned and destroyed. (39)

Kelp tablets, at Cincinnati, S. Dist. Ohio.

Charged on or about 1-4-68: when shipped by Spatz Health Foods, Cincinnati, Ohio, after repacking, the article contained the nonconforming food additive iodine, and its labeling lacked required information concerning its purported special dietary uses; 402(a)(2)(C), 403(j). Default decree authorized donation to charitable institution. (60)

Young's Food vitamin capsules, at Marion, N. Dist. Ohio.

Charged 2-26-68: when shipped by Nu-Youth Products Co., Marion, Ohio, after the articles' manufacture from active ingredients shipped in interstate commerce, the dealer's label statement: "Young's Food Vitamin Formula #10 with choline, inositol, iron, liver, minerals, and rubber, was marketed as having no special or unusual effect on glands, and the dealer's accompanying printed literature was designed to lead the consumer to believe that the folders contained false and misleading claims, including claims for longer life, regaining sexual powers, and revived energy; 403(a). Default decree authorized donation to charitable institution. (80)

FDA / Economic and Labeling Violations

Food / Drugs / Human Use


Charged 2-21-68: when shipped by Absopure Water Co., Detroit, Mich., the article contained behavioral film and it was not packaged as prescribed in the U.S.P., in that it is not preserved in tight containers; 402(a)(3), 501(a), 502(g). Default decree authorized destruction. (67)


Charged 6-14-67: when shipped by Kelly Products, Inc., Royal Oak, Mich., the article was a new drug without an effective approved New Drug Application, the label lacked the established name of each active ingredient, and the article had no special or unusual effect on glands; 505(a), 502(e)(1)(A)(ii), 502(o). Default decree authorized destruction. (62)

Alergiest intranasal solutions A and B, at Charlotte, W. Dist. N.C.

Charged 9-3-65: when shipped by Bronson Corp., Miami Springs, Fla., the articles were new drugs without an effective approved New Drug Application, 505(a). The shipper requested transfer of the action to the Middle District of North Carolina. Since it appeared to the court that condemnation was sought on new drug charges and that this sort of proceeding had not been among those designated by Congress as reviewable, the court denied the request, and it is the court's conclusion that the shipper answer the charges or the court would condemn the drug. The shipper failed to answer the suit, and the court condemned the drugs and ordered them destroyed. (63)

Amphetamine and barbiturate drugs, at Denver, Dist. Colo.

Charged 11-28-67: while held by Leverichs, Inc., Denver, Colo., complete and accurate inventory records and receipt and disposition records of all such drugs were not prepared and kept; 301(q)(a). Default decree authorized destruction. (65)

Amphetamine, barbiturate, and other depressant or stimulant drugs, at Baltimores Dist. Md.

Charged 11-30-67: when held by Louis J. Glass, M.D., Baltimore, Md., the article, labeled in part "Lee Tomatoes . . . Isis Foods, Inc., Distributors, Kansas City, Missouri," fell below standard of quality because of excess peel; 403(1). Default decree authorized donation to charitable institution. (56)
Amphetamine, barbiturate, and other depressant or stimulant drugs, at Brooklyn, Dist. N.Y. Charged 1-4-68: while held by Melitor's Drug Store, Brooklyn, N.Y., complete and accurate receipt and disposition records were not prepared and kept; 301(q)(4). Default decree ordered destruction. (66)
Amphetamine, barbiturate, and other depressant or stimulant drugs, at Brooklyn, Dist. N.Y. Charged 1-4-68: while held by North Drug Co., t/a Hatch's Drug, Brooklyn, N.Y., complete and accurate inventory records and receipt and disposition records of all such drugs were not prepared, obtained, and kept; 301(q)(4). Consent decree authorized release to dealer for preparation of records. (69)
Amphetamine, barbiturate, and other depressant or stimulant drugs, at Brooklyn, Dist. N.Y. Charged 1-4-68: charged with Hahn Pharmacy, Brooklyn, Colo., complete and accurate inventory records and receipt and disposition records of all such drugs were not prepared and kept; 301(q)(4). Default decree ordered destruction. (68)
Amphetamine, barbiturate, and other depressant or stimulant drugs, at Denver, Dist. Colo. Charged 12-6-67: while held by T. K. Pharmacy, Inc., Denver, Colo., complete and accurate inventory records and receipt and disposition records of all such drugs were not prepared, obtained, and kept; 301(q)(4). Consent decree authorized release to dealer for preparation of records. (70)
Amphetamine, barbiturate, and other depressant or stimulant drugs, at Denver, Dist. Colo. Charged 12-6-67: while held by North Drug Co., t/a Hatch's Drug, Denver, Colo., complete and accurate inventory records and receipt and disposition records of all such drugs were not prepared, obtained, and kept; 301(q)(4). Default decree ordered destruction. (70)
Phenylbutazone tablets, at San Antonio, Dist. Tex. Charged 1-4-68: while held by John C. Wahl, t/a Lazelle Labs., Los Angeles, Calif., complete and accurate inventory records and receipt and disposition records of all such drugs were not prepared and kept; 301(q)(4). Consent decree authorized release to dealer for preparation of records. (70)
Phenylbutazone tablets, at San Antonio, Dist. Tex. Charged 12-5-67: while held by Fred O. Caller, M.D., Glendale, Calif., after having received and released such drugs, the article failed to bear the prescription legend; the article failed to be the property of the United States; the article was not packaged as prescribed by the U.S.P.; 301(b), 301(c), 502(a), 502(g). Default decree ordered destruction. (70)
Phenylbutazone tablets, at San Antonio, Dist. Tex. Charged 1-29-68: when the article was shipped by Richlyn Laboratories, Inc., Philadelphia, Pa., and while it was held by Direct Laboratories, Inc., Buffalo, N.Y., after such firm had labeled a portion of the article, the labeling lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information; 502(f)(1). Consent decree authorized release to shipper for relabeling. (90)
Phenylbutazone tablets, at San Antonio, Dist. Tex. Charged 11-16-67: when shipped by Duke Laboratories, Inc., South Norwalk, Conn., the article's strength fell below the U.S.P. standards, and the label statement "Sterilized" was false and misleading as applied to a product in wrappers not conforming to the prescription; the article failed the U.S.P. disintegration test; the quality of the article fell below U.S.P. standards, since the article failed to be the property of the United States; the article was not packaged as described on the label; 301(f)(1). Consent decree authorized release to dealer for preparation of records. (70)
Phenylbutazone tablets, at San Antonio, Dist. Tex. Charged 2-14-68: while held by Chemico of Gardena, Inc., Gardena, Calif., after having received and released such drugs, the article's strength fell below the U.S.P. standards, and the label statement "Sterilized" was false and misleading as applied to a product in wrappers not conforming to the prescription; the article failed the U.S.P. disintegration test; the quality of the article fell below U.S.P. standards, since the article failed to be the property of the United States; the article was not packaged as described on the label; 301(f)(1). Consent decree authorized release to dealer for preparation of records. (70)
Phenylbutazone tablets, at San Antonio, Dist. Tex. Charged 1-29-68: when the article was shipped by Richlyn Laboratories, Inc., Philadelphia, Pa., and while it was held by Direct Laboratories, Inc., Buffalo, N.Y., after such firm had labeled a portion of the article, the labeling lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information; 502(f)(1). Consent decree authorized release to shipper for relabeling. (90)
Phenylbutazone tablets, at San Antonio, Dist. Tex. Charged 1-29-68: when the article was shipped by Richlyn Laboratories, Inc., Philadelphia, Pa., and while it was held by Direct Laboratories, Inc., Buffalo, N.Y., after such firm had labeled a portion of the article, the labeling lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information; 502(f)(1). Consent decree authorized release to shipper for relabeling. (90)
Phenylbutazone tablets, at San Antonio, Dist. Tex. Charged 11-16-67: when shipped by Duke Laboratories, Inc., South Norwalk, Conn., the article's strength fell below the U.S.P. standards, and the label statement "Sterilized" was false and misleading as applied to a product in wrappers not conforming to the prescription; the article failed the U.S.P. disintegration test; the quality of the article fell below U.S.P. standards, since the article failed to be the property of the United States; the article was not packaged as described on the label; 301(f)(1). Consent decree authorized release to dealer for preparation of records. (70)
Phenylbutazone tablets, at San Antonio, Dist. Tex. Charged 2-14-68: while held by Chemico of Gardena, Inc., Gardena, Calif., after having received and released such drugs, the article's strength fell below the U.S.P. standards, and the label statement "Sterilized" was false and misleading as applied to a product in wrappers not conforming to the prescription; the article failed the U.S.P. disintegration test; the quality of the article fell below U.S.P. standards, since the article failed to be the property of the United States; the article was not packaged as described on the label; 301(f)(1). Consent decree authorized release to dealer for preparation of records. (70)
Phenylbutazone tablets, at San Antonio, Dist. Tex. Charged 1-29-68: when the article was shipped by Richlyn Laboratories, Inc., Philadelphia, Pa., and while it was held by Direct Laboratories, Inc., Buffalo, N.Y., after such firm had labeled a portion of the article, the labeling lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information; 502(f)(1). Consent decree authorized release to shipper for relabeling. (90)
Phenylbutazone tablets, at San Antonio, Dist. Tex. Charged 12-5-67: while held by Fred O. Caller, M.D., Glendale, Calif., after having received and released such drugs, the article's strength fell below the U.S.P. standards, and the label statement "Sterilized" was false and misleading as applied to a product in wrappers not conforming to the prescription; the article failed the U.S.P. disintegration test; the quality of the article fell below U.S.P. standards, since the article failed to be the property of the United States; the article was not packaged as described on the label; 301(f)(1). Consent decree authorized release to dealer for preparation of records. (70)
Phenylbutazone tablets, at San Antonio, Dist. Tex. Charged 1-29-68: when the article was shipped by Richlyn Laboratories, Inc., Philadelphia, Pa., and while it was held by Direct Laboratories, Inc., Buffalo, N.Y., after such firm had labeled a portion of the article, the labeling lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information; 502(f)(1). Consent decree authorized release to shipper for relabeling. (90)
Phenylbutazone tablets, at San Antonio, Dist. Tex. Charged 12-5-67: while held by Fred O. Caller, M.D., Glendale, Calif., after having received and released such drugs, the article's strength fell below the U.S.P. standards, and the label statement "Sterilized" was false and misleading as applied to a product in wrappers not conforming to the prescription; the article failed the U.S.P. disintegration test; the quality of the article fell below U.S.P. standards, since the article failed to be the property of the United States; the article was not packaged as described on the label; 301(f)(1). Consent decree authorized release to dealer for preparation of records. (70)
Phenylbutazone tablets, at San Antonio, Dist. Tex. Charged 1-29-68: when the article was shipped by Richlyn Laboratories, Inc., Philadelphia, Pa., and while it was held by Direct Laboratories, Inc., Buffalo, N.Y., after such firm had labeled a portion of the article, the labeling lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information; 502(f)(1). Consent decree authorized release to shipper for relabeling. (90)
Charged 2-13-68: when shipped by Paul B. Elder Co., Chicago, III., the article's labeling contained false and misleading claims for treatment of obesity and lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information; 502(a); 502(f)(1). Default decree ordered destruction. (99)

Lactose powder: At Phoenix, Dist. Ariz., the strength of the article was deficient and the label was false and misleading since the labeling was false and misleading, and the article's labeling contained false and misleading claims for use and did not comply with the Rx drug exemption requirement for disclosure of information; 502(a); 502(f)(1). Default decree ordered destruction. (102)

Charged 1-2-68: when shipped by Shaw Pharmacal Co., Maryland Heights, Mo., the labeling contained false and misleading claims for certain uses the article was offered; 502(f)(1). Consent decree authorized release to C. A. Schmitz & Co., Inc., and while held by J. H. Furber Co., Columbus, Ohio, the labeling was false and misleading, since the article was deficient in estrofum; 501(b). Default decree ordered destruction. (104)

Narcotic tablets: At Phoenix, Dist. Ariz.
Charged 1-11-68: when shipped by Globe Veterinary Supply, Artesia, Calif., the article was a new drug without an effective approved New Drug Application and was not found to meet such requirement; 505(a). Default decree ordered destruction. (111)

BARBITURATES & SODIUM channel blockers
Charged 3-28-68: when shipped by E. D. Jamesonic, International, Inc., Grand Rapids, Mich., after manufacture from reserpine alkaloid shipped in interstate commerce by the manufacturer, the article contained false and misleading claims for certain uses the article was offered; 502(f)(1), 502(j). Default decree ordered destruction of all devices, except two, which were turned over to FDA. (119)

Electrotherapeutic devices
Charged 1-3-68: when shipped by Spectrowave Corp., Chicago, Ill., the labeling was false and misleading, since the article was deficient in estrofum; 501(b). Default decree ordered destruction. (101)

Selenium tablets, at Albuquerque, Dist. N. Mex.
Charged 12-4-67: when shipped by Arizona Laboratories, Inc., Phoenix, Ariz., the strength of the article was deficient and the label was false and misleading, since the labeling was false and misleading; 501(b). Default decree ordered destruction. (100)

Sodium butabital tablets, N.F., at Dayton, Dist. Ohio.
Charged 1-12-68: when shipped by Halsem Drug Co., Dayton, Ohio, the labeling contained false and misleading claims for certain uses the article was offered; 502(f)(1). Consent decree authorized release to C. A. Schmitz & Co., Inc., and while held by J. H. Furber Co., Columbus, Ohio, the labeling was false and misleading, since the article was deficient in estrofum; 501(b). Default decree ordered destruction. (104)

Thyroididiotin combination tablets, at Farmingdale, E. Dist. N.Y.
Charged 7-16-65: when shipped by Health-Mor, Inc., Chicago, Ill., and while held by The Pill Mill, Inc., Grand Rapids, Mich., the labeling contained false and misleading claims for certain uses the article was offered; 502(f)(1). Consent decree authorized release to C. A. Schmitz & Co., Inc., and while held by J. H. Furber Co., Columbus, Ohio, the labeling was false and misleading, since the article was deficient in estrofum; 501(b). Default decree ordered destruction. (104)

Vitamin A: At South Bend, W. Dist. Ind., and while held by the National Health Co., Chicago, Ill., the article contained false and misleading claims for certain uses the article was offered; 502(f)(1). Consent decree authorized release to C. A. Schmitz & Co., Inc., and while held by J. H. Furber Co., Columbus, Ohio, the labeling was false and misleading, since the article was deficient in estrofum; 501(b). Default decree ordered destruction. (104)

Charged 10-15-64 and 8-5-66: when shipped by Cameron-Miller Surgical Instruments Co., Chicago, Ill., the labeling of the G5 model device at New Baltimore contained false and misleading claims for certain uses the article was offered; 502(f)(1). Consent decree authorized release to C. A. Schmitz & Co., Inc., and while held by J. H. Furber Co., Columbus, Ohio, the labeling was false and misleading, since the article was deficient in estrofum; 501(b). Default decree ordered destruction. (104)
NOTICES OF JUDGMENT on Criminal Cases

FOOD


Charged 3-8-68: when shipped, the government alleged the article was false and misleading, it contained several undeclared ingredients, and it failed to bear adequate directions for use. Guilty plea by corporation; fine and probation. (126)


Charged 1-17-64: when shipped, the alleged article was false and misleading; in its labeling, it failed to contain adequate directions and constitutes a misbranding of the article. Guilty plea by corporation; fine and probation. (131)

Abbot Laboratories, Chicago, N. Dist. Ill.

Charged 9-19-66: when shipped, the labeling of Euphony pargyline hydrochloride tablets as an effective, active ingredient, failed to bear adequate directions for use. Guilty plea; imprisonment suspended, fine, and probation. (130)

DRUGS

Abbott Laboratories, Chicago, N. Dist. Ill.

Charged 9-19-66: when shipped, the labeling of Euphony pargyline hydrochloride tablets was false and misleading because the labeling constituted a misbranding of the article. Guilty plea by corporation; fine and probation. (132)

Notices of Judgment are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act. Notices of Judgment report cases involving seizure or injunction proceedings, criminal proceedings, and injunction proceedings. Seizure proceedings are civil actions taken against goods alleged to be in violation of the Act, and the cases are titled as such. Injunction proceedings, criminal proceedings, and injunction proceedings combine the purpose of obtaining a permanent injunction with the purpose of seizing goods involved in a violation of the Act. Seizure cases are those in which the Government has obtained a judgment of condemnation and has been awarded possession of the article seized. The defendant in a seizure case will be found either guilty or not guilty of a violation of the Act. A guilty plea in a seizure case constitutes a finding of fact that the goods seized were in violation of the Act.

The obvious dangers inherent in the lay use of prescription drugs are even more serious because prescription drugs are marginally effective for their intended uses and they are usually habituating or depressant drugs. It is impossible for prescription drugs to comply with the provisions of 502(f) and (1) and was therefore contrary to the intent of Congress. In rejecting this contention, the court said:

"The Court does not adopt the Government's position. . . . The intent of Congress must be presumed to be to protect the public from harmful consequences of the illegal introduction into commerce of the use of drugs. The obvious dangers inherent in the lay use of prescription drugs are even more serious because prescription drugs are marginally effective for their intended uses and they are usually habituating or depressant drugs. It is impossible for prescription drugs to comply with the provisions of 502(f) and (1) and was therefore contrary to the intent of Congress. The Court agrees that in the case of prescription drugs they will almost always need to bear adequate directions for use. The defendant need not show inadequate directions in order to secure the exemption from the requirement of adequate directions for use in so doing, Congress intended that the public health be protected through regulations promulgated by the Food and Drug Administration."

The defendant pleaded not guilty, and the case was tried by the court. The court found the defendant not guilty. (129)


Charged 3-28-68: when shipped by Cameron-Miller Surgical Instruments Co., Chicago, Ill., the labeling of the device contained false and misleading weight reduction claims. Guilty plea by corporation; fine and probation. (124)

The defendant moved to dismiss the case on the grounds that the regulation, 21 CFR 1.106(b)(4)(i), pursuant to which FDA had initiated an administrative action against the defendant for failure to bear adequate directions where not necessary for the purposes for which the devices were intended, the court denied the motion to dismiss. (126)
Maximum Benefits to Animal Owners Consistent With Maximum Public Health Protection

Bureau of Veterinary Medicine

NAS/NRC-FDA Veterinary Drug Efficacy Review of Over 700 Drugs Marketed Before 1962

The 1962 Drug Amendments to the Food, Drug, and Cosmetic Act require that all drugs—for human and for veterinary use—must not only be safe, but effective as well.

The National Academy of Sciences/National Research Council and the FDA are now reviewing all veterinary drugs marketed between 1938 and 1962 for efficacy.

Final evaluations are published in the Federal Register as they are completed.

Any manufacturer, packer, distributor, or other interested person may obtain a copy of a NAS/NRC report by writing to the Food and Drug Administration, Press Relations Office, CE-300, 200 “C” Street, S.W., Washington, D.C. 20204.
DRUG INDUSTRY TRAINING FILM

The Food and Drug Administration's color motion picture, "Good Drug Manufacturing Practices: No Margin for Error," has proved to be a highly popular employee training and motivational tool since it was introduced in January 1968. To increase the value of this movie as a training aid, FDA has issued a discussion guide containing some suggestions for management and employee discussion sessions in your training program using the FDA film. Statistics compiled from industry and FDA Districts' reports on the film's use show that a total of 21,671 persons viewed the film at 607 showings last year. The Government's contractor sold 99 prints to industry purchasers for continuing use. Even these figures do not reflect the film's total audience, since they do not include complete data on loans from FDA Districts or viewings at FDA workshops during the entire year.

The film is available for free short-term loan (up to 2 weeks) from: Bureau of Compliance, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204, or the nearest FDA District office. Information concerning purchase of the film also may be obtained from the Bureau of Compliance.

CONFERENCE-WORKSHOP PROGRAM

Industry acceptance and participation in FDA's conference and workshop program continued to accelerate in 1968. As a result, FDA expanded its efforts to assist particular industries in identifying and solving specific compliance problems of major health significance to consumers. A total of 138 District workshops and 14 national or regional conferences were held and were focused on these critical problem areas, as shown in the table at the right.

These FDA-industry meetings concentrated on major problems in each of the project areas, such as Salmonella and Botulism in smoked fish; bacterial contamination in convenience foods, shelled pecans, and shellfish; and pesticide residues in dairy products.

The increasing importance of a free exchange of ideas, suggestions, and solutions to these problems attracted skilled specialists from industry, universities, FDA, and other State and Federal agencies to participate in the programs. More than 13,500 professional and management personnel, representing over 6,700 firms, participated in the various seminars, conferences, and workshops during 1968.

FDA INDUSTRY WORKSHOPS

During April and May, FDA Districts will conduct a series of workshops and regional conferences on specific compliance problems of major health significance. These problems deal with drugs (good manufacturing practices (GMP)), foods (microbiological contamination, chemical residues, and sanitation), and labeling of hazardous household substances. Anyone desiring to attend should contact the nearest District.

SCHEDULE OF FDA WORKSHOPS AND REGIONAL CONFERENCES

April & May 1969

<table>
<thead>
<tr>
<th>FDA District</th>
<th>Date</th>
<th>Location</th>
<th>Subject Area</th>
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<tbody>
<tr>
<td>Baltimore</td>
<td>April 8</td>
<td>Virginia</td>
<td>Bacteriological—Crab</td>
</tr>
<tr>
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<td>April 29</td>
<td>Virginia</td>
<td>Bacteriological—Convenience Foods</td>
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<tr>
<td>Buffalo</td>
<td>May 1</td>
<td>Syracuse, N.Y.</td>
<td>GMP—Drugs</td>
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<td></td>
<td>May 2</td>
<td>Buffalo, N.Y.</td>
<td>GMP—Drugs</td>
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STATISTICAL SUMMARY OF INDUSTRY PARTICIPATION IN FDA WORKSHOPS, SEMINARS, AND CONFERENCES / JANUARY THRU DECEMBER 1968

<table>
<thead>
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<th></th>
<th>ATTENDANCE</th>
<th>ATTENDANCE</th>
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<tr>
<td></td>
<td>District Workshops</td>
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<tr>
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<td>Firms</td>
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<td>GMP—Drugs—Human</td>
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<td>Drugs—In Plant—for Employees</td>
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<td>GMP—Drugs—Veterinary</td>
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<td>Foods—Bacterial Contamination</td>
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<td>Foods—Chemical Contamination</td>
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<td>Foods—Sanitation</td>
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<td>1773</td>
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<td>Hazardous Substances</td>
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<td>86</td>
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<tr>
<td>Total</td>
<td>138</td>
<td>5217</td>
</tr>
</tbody>
</table>

|                | Seminars and Conferences |             |
|                | No. | Firms | People |
| Hazardous Substances Seminar | 4  | 359   | 668    |
| Drugs—GMP | 3  | 345   | 690    |
| Drugs—DACA | 1  | 20    | 50     |
| General—FDLI National Conference | 1 | 200   | 753    |
| Therapeutic Devices | 3  | 193*  | 193    |
| Cosmetics | 1  | 225   | 700    |
| Foods—Chemical | 1  | 150   | 300    |
| Total | 14 | 1492 | 3354   |

*Hospital Representatives.