

MAY 1968

FDA PAPERS

ANTIBIOTICS ANALYSIS CENTER

Testing for Safety, Efficacy

DRUG SAFETY

Today's Evaluation Essentials

Shipping Pesticides

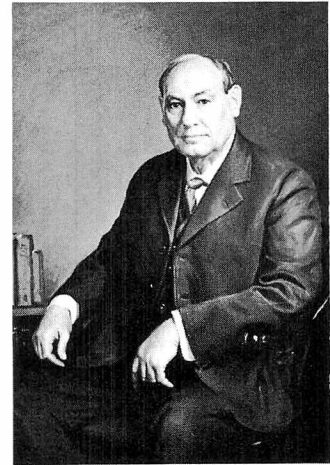
The Dangers of Contamination

PECAN SHELLING INDUSTRY

A Successful Surveillance Program



NEW YORK CENTRAL
671



"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

The danger from possible contamination of food and drugs with pesticides or other poisonous materials has disturbed responsible public officials in proportion to the increasing use of such chemicals as civilization grows more complex. Those who have been assigned the task of protecting the public health know that the potential avenues of contamination multiply as new chemicals are developed and new ways are found to use them.

The risks increase when pesticides or other potent chemicals are transported on ships, trucks, or railroad cars where they might, through carelessness or accident, contaminate nearby food and drugs—or other products that may be brought into contact with humans or animals.

Federal, State, and local officials have not been unaware of these risks and are intensifying and concerting their programs of education for industry and the public. The U.S. Department of Transportation has issued regulations intended to prevent such contamination during shipment (see page 4), and the Commissioner of Food and Drugs, James L. Goddard, M.D., has expressed full support in a letter to the transportation industry. These actions and others will do much to assure the consumer that his health remains the paramount consideration to those who are responsible for maintaining the safety of the environment.

quotes

"Incidentally, I should discuss briefly another new program, intensified drug inspections. . . . The continued marketing of prescription drugs of poor quality constitutes a situation that must be corrected. Therefore, during this type of inspection, the FDA Inspector will make an 'in-depth' review of the manufacturing and quality control practices of these manufacturers with respect to all producers. This in-depth review will identify the practices which contribute to the marketing of drugs of uncertain quality. The objective of the program is to obtain prompt correction of those inadequacies by the manufacturer, or, failing this, to initiate legal processes leading to cessation of manufacture. In simpler language, if a firm doesn't live up to the current GMP's, it has no business producing prescription drugs."

Fred J. Delmore, Director, Bureau of Voluntary Compliance, to the Pharmaceutical Manufacturers Association, Quality Control Section, Washington, D.C., April 9, 1968.

"Under the PEV (Plant Evaluation) system, the inspector will include with his regular report answers to a series of specific questions about conditions that he observed. The PEV answers will not be used to reach a conclusion on the status of compliance or noncompliance of the individual plant inspected; rather, the PEV answers will be fed into a computerized data system and will be accumulated together with answers to the same questions on the same types of plants all over the country.

"The purpose of this effort is to begin to develop data which will allow us to better understand conditions prevailing in groups of industries and changes which are or are not taking place. In the past, when FDA saw its mission primarily as one of an enforcement agency, it was necessary only to identify the defects in individual plants and to take appropriate action. But when you see your mission as one of trying to solve problems, then your first task becomes learning what the problems are."

Alfred Barnard, Director, Bureau of Regulatory Compliance, to the Dried Fruit Association of California, Monterey, Calif., March 29, 1968.

Wilbur J. Cohen
Secretary, U.S. Department of
Health, Education, and Welfare

Philip R. Lee, M.D.
Asst. Secretary for Health
and Scientific Affairs

James L. Goddard, M.D.
Commissioner of Food and Drugs

Gifford D. Hampshire/Editor

Harold C. Hopkins/Associate Editor

Sheldon Cohen/Art Director

Joan M. Galloway/Managing Editor

Frederick L. Townshend/Production Mgr.

PHOTOGRAPHY: John Crane, inside front cover, 19-22, 25; Lee Britz, inside back cover; Lee Britz/John Crane, 4-6; Vernon Merritt, 8, 10, 11; Shel Hershorn-Black Star, 26, 27, 29.

FDA PAPERS, the official magazine of the Food and Drug Administration, is published monthly, except for combined July-August and December-January issues. Subscriptions may be ordered from the Superintendent of Documents, Government Printing Office, Washington, D. C. 20402, at \$5.50 a year (\$1.25 additional for foreign mailing).

Articles published in **FDA PAPERS** are in the public domain and text may be republished without permission. Use of funds for printing this publication approved by Director of the Bureau of the Budget August 15, 1966.

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

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

Advisers to the Editor*

H. Nelson Fitton, Department of Agriculture; **Wayne Phillips**, Department of Housing and Urban Development; **Henry B. Montague**, Post Office Department; **Henry Scharer**, Department of Commerce; **Dr. John L. Buckley**, Department of the Interior; **Dr. Sam Kaim**, Veterans Administration; **Dr. Peter V. Siegel**, Federal Aviation Agency; **Dr. Spofford G. English**, United States Atomic Energy Commission; **Dr. Harve J. Carlson**, National Science Foundation; **Howard J. Lewis**, National Academy of Sciences; **Edward J. McVeigh**, Public Health Service.

*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.

Pesticide Contamination of Food and Drugs What is being done and what must be done to avoid contamination during shipment. 4

Atlanta District Its southeast coastal area includes seafoods industry, farm products, citrus fruits, imports, and elderly people. 7

Safety Evaluation of Drugs A comprehensive, thoroughgoing program is used to assure that a drug has been tested for maximum safety. 13

Testing and Certifying Antibiotics 19

Antibiotics, Insulin Analysis Exhaustive testing of every batch assures safety and efficacy of these important compounds. 23

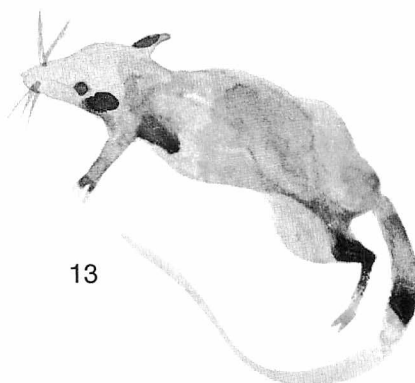
Pecan Shelling Industry of the Southwest Years of FDA work with industry has resulted in a better product for the consumer. 25

Field Reports 30

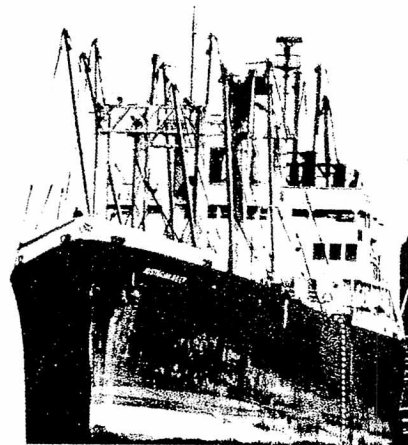
State Actions 33

Seizures and Post Office Cases 34

Notices of Judgment 37



Pesticide contamination of food and drugs during shipment



by John G. Stringer

The use of pesticides is increasing throughout the United States year by year. Although pesticides are used for many purposes during the entire year, the demand peaks sharply in spring and early summer. Great quantities are then shipped by train, truck, and boat; and in some instances these potent chemicals are shipped in the same compartment with drugs, food, toys, and clothing.

The potential danger to health and public safety caused by these mixed shipments is a problem of serious concern to the transportation industry and to Federal authorities.

Case after case from Food and Drug Administration and public health office files illustrate not only what can happen, but also what does, when basic, precautionary measures are not taken before, during, and after the transport of pesticides with other commodities.

The problem has grown to such proportions within the past few years that the U.S. Department of Transportation acted last December to restrict mixing of shipments of pesticides and other dangerous chemicals with "footstuffs, feeds, and other materials intended for consumption by humans or animals." The new regulations also restrict the re-use of transportation equipment which has been contaminated by leakage of poisonous substances.

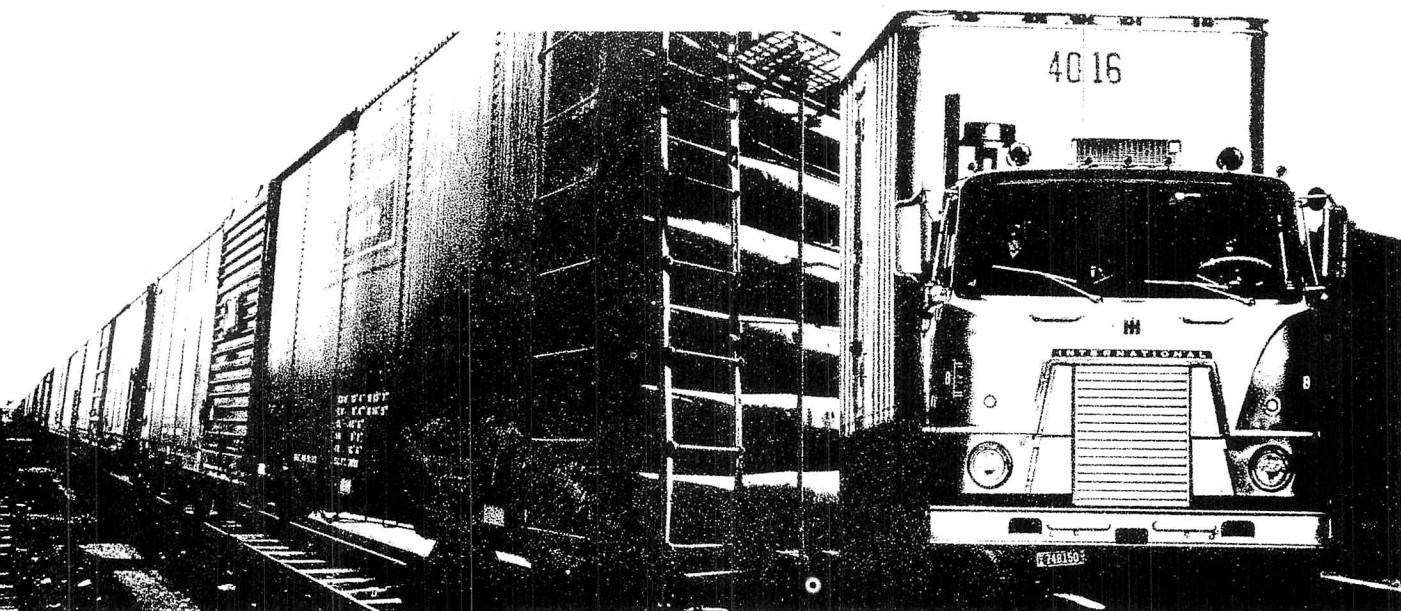
The regulations were issued December 21, 1967; they became effective on January 10, 1968.

In April, James L. Goddard, M.D., Commissioner of Food and Drugs, wrote to 19 major national and State carrier associations to urge their strict compliance with these new regulations and to ask their cooperation in applying the same precautions in handling intrastate shipments (see text of letter, page 6).

But everyone who handles pesticides, including the consumer, should be aware of the danger of mixing pesticides with other products, whether they are found in the kitchen cabinet, on the shelves at the local grocery store, or in a warehouse storage area.

The following examples of product contamination during transport point up the hazards presented by careless handling of chemicals:

- Six children in Fresno, California, were poisoned by wearing new, unwashed jeans that had been contaminated by an organic phosphate insecticide (Phosdrin) while in shipment. Prompt action by the local public health department resulted in recovery of the contaminated jeans even though the entire shipment had already been sold. One month after this "epidemic," a bill was introduced into the California Legislature to prohibit the transportation of dangerous chemicals with food or clothing.
- After receiving a complaint that a person's throat had been chemically burned from eating oatmeal, health department officials in Houston, Texas, investigated and found that an interstate shipment of the cereal had been contaminated by phenol, a highly dangerous chemical.
- Approximately 180 dairy animals died in Bellingham, Washington, from feed contamination. Inspectors found that the feed had been shipped in a railroad car which previously had been used to ship crude arsenic trioxide from a smelting firm in Tacoma, Washington. A total of 496,000 pounds of feed and grain was ordered burned, the carcasses of the dead cows were destroyed to prevent further contamination, and both the feed company and the railroad carrier involved were cited for irresponsible handling of the shipment.
- Fresh potatoes shipped in a refrigerator car from southern Oregon to Seattle, Washington, were found to be adulterated with a green paint pigment containing lead. An investigation showed that the contaminant, packaged in paper bags, had been shipped in the car earlier. One bag had broken open, and the pigment was circulated throughout the carload of potatoes by exhaust fans. Both the potato shipper and the railroad carrier officials were cited.
- A shipment of 150 cases of oatmeal cookies was



destroyed in Iowa because of contamination by the pesticide Guthion. Contamination occurred when bags of Guthion powder were loaded in a truck alongside the cookies, and pesticide dust migrated to food packages.

- FDA's New York District Import Section reported two incidents of product contamination during shipment by sea. Approximately 7,000 crates of fresh melons were detained because of contamination from DDT and sodium nitrate. The chemicals had been transported in the same hold as the melons. Cheese, beer, bulk drugs, and surgical and dental instruments were detained due to contamination with dimethylaniline. All were carried in the same hold. Several drums of the chemical broke at sea and contaminated the entire hold.

- In Cincinnati, a truck loaded with milk cartons in fiber drums and powdered paint in 50-pound bags headed for State embargo when it was found that paint dust had filtered throughout the truck. Another carrier experienced leakage of chlorine gas which was being shipped with various foodstuffs. The leakage resulted in the contamination of 25 cartons of plastic toys, four drums of vegetable cooking oil, and nine cartons of chocolate candy and bakery goods.

- FDA's Boston District reported the contamination of a shipment of 200 cases of milk filters with pentachlorophenol, a chemical that was part of the trailer's previous cargo.

Perhaps the most unusual incident reported to the FDA concerned contamination by radioactive isotopes packages on February 23, 1968, at Boston's Logan International Airport. A 1,200-pound lead shipping cask containing metal vials of irradiated nuclear material froze while stored outside on the freight dock. The freezing caused the rupture of three vials containing Cesium-134 and Rubidium-86. The water that contained these radioactive isotopes leaked, resulting in the contamination of packages of clothing, women's handbags, and automotive and electronic parts carried in

the same delivery truck. Inspectors recovered and checked all the packages. Individuals who might have been exposed were subjected to a body radiation count. An extensive decontamination effort was undertaken by an Atomic Energy Commission disaster team.

As all of these examples indicate, the problem of safely transporting hazardous materials is formidable. There have been serious incidents in other countries, some involving deaths. An awareness of the potential hazards and proper precautions is necessary to avoid similar tragedies in the United States.

Effective regulations to restrict transportation of pesticides and other dangerous chemicals are part of the answer to the problem. The transportation industry, others who handle pesticides and other chemicals, and consumers must be informed of and follow safety rules.

In Colorado, for instance, efforts are underway to alert the consumer and the small business man. It has been common practice for chain grocery warehouses as well as independent food warehouses to ship insecticides along with food products to retail stores throughout the State, according to the Colorado State Health Department. The State Department and local health agencies have teamed up to warn clerks against the practice of placing insecticides purchased in grocery stores in the same bag as food products purchased by the consumer. The consumer, too, must share the responsibility of



John G. Stringer, Public Information Specialist, joined the FDA in September 1966.



making sure when he purchases an insecticide, or some other potentially dangerous chemical, that it is properly packaged and stored.

However, the transportation industry, which handles bulk quantities of pesticides, must assume the major share of the responsibility for precautionary measures. In Memphis, Tennessee, a warehouse manager has taken the initiative against what he refers to as "questionable transportation practices" in the shipment of pesticide materials in his area. He notified the FDA Resident Inspector in Memphis of his concern. Subsequent actions included inspections at a public storage warehouse and at several truck terminals.

At one terminal, the inspector was told of an incident in which a highly toxic chemical material, packaged in 500-pound, 55-gallon drums, was being transported with children's toys and bags of sugar. A strong

chemical odor was detected when the trailer was opened at Atlanta, Georgia, for inspection.

It was determined that one drum was leaking. As a result, the foodstuffs and toys were destroyed and the trailer was decontaminated. A new floor and new side-walls were required in the trailer. It was an extremely costly leakage to the shipper and the carrier.

The surveillance in Memphis continues, but it presents a difficult situation because, as one warehouse manager observed, there is no certainty that trucks which take on partial loads of pesticides do not make stops at other warehouses to pick up additional items, including foods.

Such practices must be eliminated to protect the public health. It is a challenge that faces industry, the consumer, and local, State, and Federal agencies.

Commissioner Goddard's Letter to the
Transportation Industry

April 3, 1968

This Nation's transportation system is vital to the well-being of the people. I know the members of your organization are well aware of this fact and willingly accept the responsibilities placed upon them.

For this reason, I am asking your cooperation in dealing with a potential public health hazard involving the transport of pesticides. These are potent chemicals which can be toxic to man. There have been incidents in the past in which pesticides have contaminated foods or clothing during shipment. These have occurred during transport by road, rail, and water. There have been deaths in other countries because foodstuffs were poisoned by pesticides. Together we can prevent similar tragedies in our own Nation.

As you know, the Department of Transportation has imposed restrictions on mixed shipments* of foodstuffs with pesticides and other dangerous

chemicals and has also restricted the re-use of equipment contaminated by the leakage of poisonous substances. The new regulations became effective January 10, 1968.

The Food and Drug Administration has the responsibility to assure that foodstuffs in interstate commerce are safe and wholesome. Our personnel have at various times initiated action to destroy food products contaminated while in shipment together with pesticides.

I urge your organization to join in a common effort to seek compliance with the Department of Transportation's regulations and with the consumer protection activities of FDA personnel. I hope, too, that those organizations with affiliates who are not interstate carriers will urge full compliance with these safety rules in intrastate shipments as well.

If the Food and Drug Administration can be of any further assistance, please call upon us. We are ready to help. Sincerely yours, James L. Goddard, M.D., Commissioner of Food and Drugs.

Wine tasting is an ancient and honored art in which only the connoisseur attains the pinnacle.

A homelier talent, but one considerably more important to the public interest, is fish sniffing, which at FDA's Atlanta District has been brought to something nearing perfection. The Food and Drug Inspector uses his nose to protect the public against the dangers of decomposed or spoiled seafood.

The import of his assignment is obvious, for the fishing and seafood industries are widespread and economically vital in three of the States that lie within the District and border on the seacoast. It is in the interest of both the consuming public and the seller that trained men on the FDA District staff first seek to detect decomposition or spoilage by actually smelling fish destined for human consumption. If their noses indicate—as did that of Marcellus in “Hamlet”—that “something is rotten in the state of Denmark,” the fish is then subjected to chemical examination to confirm what the inspector's nose has already told him.

Fish, a protein food, has a high spoilage potential, and microbiological or bacteriological contamination is related directly to time and temperature. Each, or both, can cause trouble, since bacteriologically contaminated foods can cause food poisoning. Sanitation, temperature control, and proper handling, therefore, are vital to both the industry and the consumer.

Spoilage is not the only problem for the seafood industry or for the public and FDA. Fraudulent substitution of cheap for expensive fish can fool the consumer and put extra dollars in the pocket of the seller. Atlanta District Inspectors examined fish labeled “Red Snapper” in a Miami cold storage warehouse and discovered that it was actually Mexican Grouper, taken from the waters of the Campeche area of Mexico. The grouper had been imported in fillet form. Since there was no skin, the misbranding was not obvious to

the untrained eye. Alertness by FDA Inspectors resulted in the seizure of the entire lot, valued at about \$15,000.

Recently District Inspectors found another case of flagrant misbranding which resulted in the seizure of a product labeled as crabcake, but containing only 20 percent crabmeat; the rest was principally inexpensive ground fish.

New definitions and standards for breaded shrimp have largely stopped excess breading practices, once an industry problem. The preparation and handling of breaded shrimp, however, involves potential health hazards, some relating to microbiological problems in the raw product, others to processing. To protect the consumer, FDA is concerned about whether employees are sanitary in their work habits and processing routines. Inspectors are alert to assure that raw materials are maintained and defrosted at recommended temperatures; that breading, batter, or ingredients for batter are stored under sanitary conditions; and that the physical facilities of plants meet sanitary requirements.

Seafood is only one of the many businesses and industries that are of concern to the District, whose modern headquarters at 60 Eighth Street, N.E.—on the fringe of downtown Atlanta—supervises the operations of 108 employees in Florida, Georgia, South Carolina, and the western part of North Carolina. Following World War II, the economic growth of this area has far exceeded that during prewar years. The expansion in population has been accompanied by a revolution in agricultural technology and in methods of food processing and distribution.

The District's first office was in the harbor city of Savannah, because at the outset much of the Agency's laboratory work was concentrated on imports. At that time—late in 1907—the staff consisted of one chemist, two inspectors, and FDA owned one of the first touring cars in the State of Georgia. The pioneering work there is recalled by one of the orig-

Atlanta District

by

Leslie O. McMillin



Key people in daily operation of Atlanta District in this "S"-shaped grouping, reading from bottom left: Leslie Pounds, one of four Supervisory Inspectors; Leslie O. McMillin, Director; Joseph J. Milunas, Deputy Director; Nell Kenny, Clerical Operations Supervisor; Thomas W. Miller, Administrative Officer; Wilhelmina Lombardi, Consumer Specialist; Hayward E. Mayfield, Chief Inspector; and Sol Cohen, Chief Chemist.

inal employees, John McManus, who subsequently became District Chief in Atlanta after the office was moved to the capital in 1934. Mr. McManus, who is now retired and still lives in Atlanta, recollects that the first office was in the Federal Annex Building and that relocation to the capital city was indicated because State governments during the 1930's began assuming much more important roles in working with the Federal Government.

Upon enactment of the amended Federal Food, Drug, and Cosmetic Act of 1938, the FDA chose Atlanta as a training base for its young recruits, and many of today's outstanding Agency career leaders were indoctrinated here. With the District's almost explosive growth, the Federal Annex headquarters became woefully inadequate in the midcentury years, and the present headquarters building, with 28,000 square feet of space, was erected and first occupied on June 24, 1960. It was named the Charles W. Crawford Building in tribute to a former Commissioner.

The District Director today heads a staff that includes 25 inspectors and supervisors working out of headquarters, 15 inspectors in Resident Posts in other major cities in the District, and 29 chemists and bacteriologists.

Each of the States within the District has its distinct identity and its own peculiar problems.

Florida—the mecca of thousands of senior citizens who flock there annually for retirement under the warm sun—has also become the haunt of con men and sharpsters who prey upon those who have reached their mellow years. Concerned over their own health and beset by problems that often seem to mount with age, Florida's older citizens are sought out by unscrupulous operators who turn up with gadgets, devices, and concoctions they promise will cure almost anything—from cancer to gout, from aches to ennui.

Some time ago promoters readied a product called "Cramp-Eze" to be offered to the State's residents at a price of \$1.25. This astonishing "cure" consisted of a cellophane bag, which the potential user was instructed to place over his face and breathe in and out. The company claimed that the inhaled carbon dioxide would relieve body cramps, aches, pains, and many other problems. Promoters of the bags attempted to place an advertisement in a St. Petersburg newspaper. The newspaper, skeptical of the product and claims, promptly contacted FDA. Agency inspectors investigated and found the claims false. The product was seized before the first sale could be made. The company promptly went out of business.

Other exotic but fraudulent products were offered in the area as medicinals important for the proper functioning of the body's glands. One such product was "Natural Mineral Meal Sea Salt." Another, "Sea Brine," containing 100 percent concentrated ocean water, was touted as a "chemical smorgasbord" containing 44 minerals and chemicals and recommended for individuals from ages 9 to 109. Inspectors found both products worthless for the purposes for which they were being offered and were responsible for seizures which took them off the market. Worthless and often harmful products of this kind induce ill persons to postpone or avoid visits to their doctors for possible alleviation or cure of their ailments.

The Atlanta District has been responsible for removal from the markets of many other foods, drugs, cosmetics, and devices that falsely promised renewed youth, vigor, and vitality. There are eight major drug manufacturers and more than 200 smaller drug firms in Atlanta's territory. Frequent inspections and continuous sampling and examination of drug products are made to assure the consumer of safe and effective drugs.

Lives may have been saved and injuries averted by determined and aggressive FDA action late last year. In Wingate, North Carolina, a 14-year-old boy decided to celebrate Halloween with the giant firecrackers known as M-80's, similar to those used by the Army in simulated warfare. Such fireworks are banned for sale to the general public under the Federal Hazardous Substances Act because they contain more than 2 grains of explosive material and are considered dangerous. The youth carried a bag containing 70 or more M-80 firecrackers under his coat. In his excitement, he either placed one of the firecrackers back in the bag with fuse smoldering or accidentally ignited matches in the bag. The bag's contents exploded and the boy was instantly killed.

FDA investigated promptly and found that the fatal firecrackers had been purchased in South Carolina, a few minutes' drive from where the tragedy occurred. Not only Federal but also State laws had been violated, because all States within the District prohibit sale of these larger fireworks, and only South Carolina permits the sale of any type.

The action that followed furnished both excitement and results. FDA Inspectors in unmarked radio cars set out to uncover the sources of sales of the illegal fireworks. They made purchases, which also included Cherry Bombs and Bulldogs (sometimes called Silver Salutes), at 15 establishments. About half of the roadside operators voluntarily admitted knowledge of laws prohibiting sale. The inspectors, through investigations made by the Division of Toxicological Evaluation, then established that the fireworks had been in interstate transportation. They obtained willing cooperation from the South Carolina State Law Enforcement Division in followup investigations and action. By their prompt, coordinated moves the FDA and State officials precipitated action resulting in Federal seizure of substantial quantities of illegal

Atlanta District



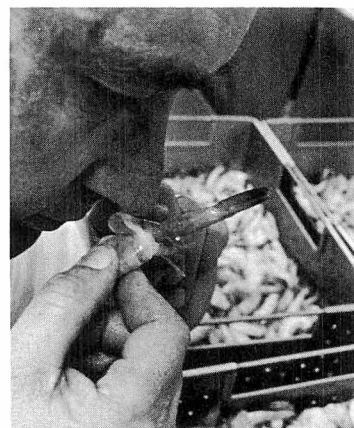
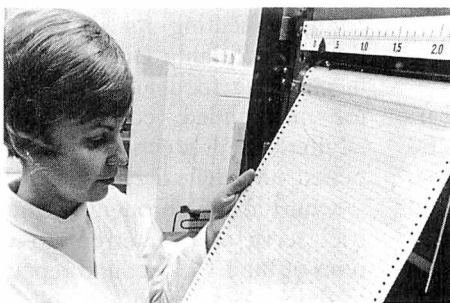
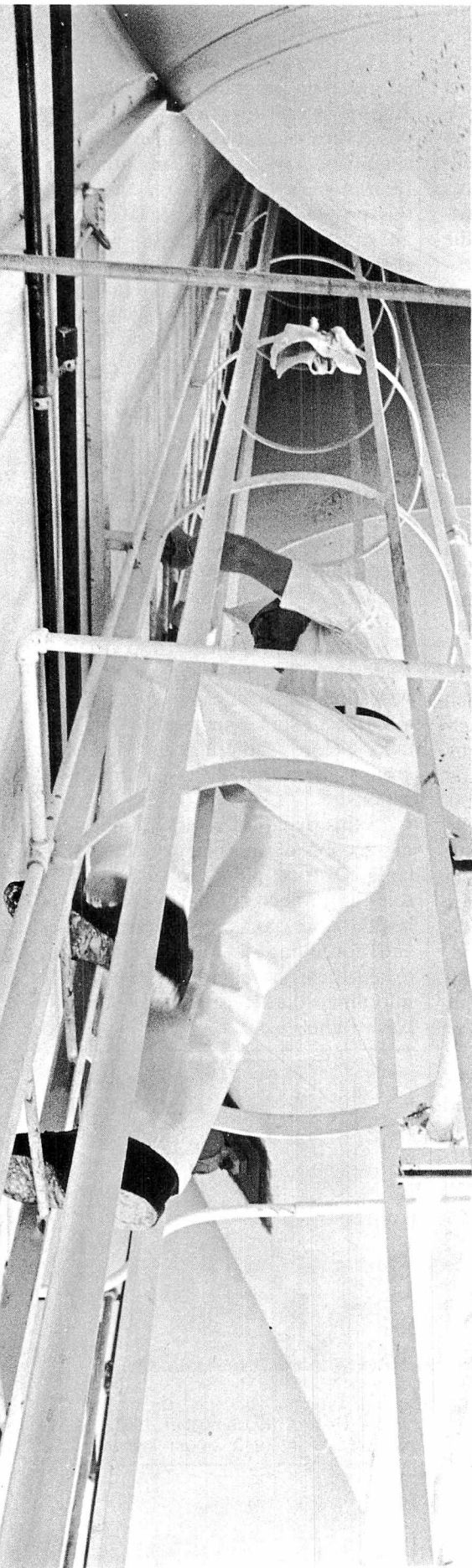
At Atlanta District lab, technician (left) grinds cabbage, and chemist (above) weighs it as part of pesticide residues analysis.



Above, farmer uses machinery to apply insecticides to cabbage crop.



At potato chips processing plant (center left), inspector checks base of conveyor belt for spillage material. At bakery, inspector (left) examines bags of flour with ultraviolet light for rodent urine stains and (opposite page) descends from checking flour storage bins.



At District lab in photos above, chemists use mortar and pestle to pulverize amphetamine tablets for drug analysis (top) and read drug analysis chart from spectro-photometer.

In above photos, chemists insert tray of coffee beans into X-ray machine for internal insect analysis (top) and smell shrimp for spoilage (bottom).



Consumer Specialist displays harmless and harmful lookalike products which may be mistaken for each other through lack of caution. The pairs are chewing gum and medicinal tablets, candy and pills, mouthwash and gasoline, rock candy and moth crystals, cereal and "cracker ball" fireworks, and peanut butter and silver polish.

fireworks and removal from public sale before the Christmas season, the traditional time of year when Southerners celebrate with fireworks.

Despite intensive industrialization, Atlanta District States remain predominantly agricultural, with a multitude of small and large vegetable and fruit packing and canning industries. FDA activity in these areas is of prime importance in protecting the public.

A sizeable section of North Carolina, extending roughly 200 miles from Boone in the northwest, south to the Scaly Mountains, and east to Hendersonville, is known as "the cabbage patch area." Farmers grow cabbage from July to October on plots ranging from a half acre to 15 acres. The cabbage patches dot the mountainous areas, and some are difficult to reach by automobile. Many of these mountain residents depend on the sale of cabbage for their livelihoods. They are known to dust the cabbage with small hand-cranked pesticide dispensers or beat a gunnysack of pesticide with a stick. If the infestation of loopers, larvae of the white moth, becomes serious, some growers will apply *any* pesticides available in efforts to destroy the larvae, then will quickly harvest the cabbage out of economic necessity. Pesticide residues, therefore, clearly present a potential hazard to consumers, and FDA keeps two to four men constantly in the area to work with the pesticide program in cooperation with the Department of Agriculture, which establishes the pesticides which may be used on crops. The District supplements this monitoring with mobile educational workshops held in schools, churches, and other meeting places in the area's small towns and hamlets to emphasize the pesticide residue problems and discuss solutions for the protection of both the farmers and their families and the general public.

The Atlanta District works closely with the U.S. Department

of Agriculture, the U.S. Public Health Service, and with State Health and Agriculture Departments and Boards of Pharmacy to protect the public. The States, too, are zealous in this area. For example, in Florida, where the economic well-being depends largely on huge citrus and vegetable crops, State authorities are vigorous guardians of the quality and purity of the crops.

Supplementing its domestic activity, the Atlanta District is vigilant in checking food and drug imports for misbranded, contaminated, or adulterated products, which are detained and denied entry.

Court actions brought by the District serve as a deterrent to violations of the FDC Act and repetitions of them. As a recent example, FDA Inspectors found a Florida firm processing macaroni products that were insect-contaminated through filthy plant operations. The firm had two prior convictions on similar charges. The jury found the company and its president guilty on each of the three counts of the indictment. The court fined the company \$2,500 and its president \$1,500 on each count, for a total of \$12,000. In addition, the court sentenced the president to a year's imprisonment, which was suspended on payment of fine, and placed him on probation for 5 years with the special condition that he comply with the Food, Drug, and Cosmetic Act and all rules and regulations during his probation.

District activities are reflected by reports indicating that in the last half of 1967, Atlanta carried out 1,620 inspections of food, drug, and cosmetic manufacturers and 140 inspections of farm growers for pesticide residues on food crops. The District collected 2,250 samples of foods, drugs, and cosmetics; 400 samples of fruits and vegetables for pesticide residues; and 150 samples of imported foods and drugs. Atlanta's laboratories analyzed 2,300 samples of foods and drugs, 400 samples of fruits and vegetables,

and more than 400 samples of imported foods, drugs, and cosmetics.

The District administers a public information program that includes industry workshops to look at industry problems and seek voluntary compliance with the law. Atlanta District feels industry's reaction to this program has been beneficial to all. In such workshops, FDA works closely with State Departments of Health and Agriculture and Boards of Pharmacy so their viewpoints may be presented fully.

The District's Consumer Education program, conducted by the Consumer Specialist, is held with leaders of three primary groups: youth, older citizens, and low-income laboring groups. District people meet annually with leaders of each. Of the two major conferences scheduled this year, one will be held with leaders of the older citizens at Atlanta. The other, "Triad for Savannah," is intended to reach leaders of all three groups and convenes in Savannah.

District spokesmen also make talks before gatherings of similar groups sponsored by other organizations.

In this dynamic, rapidly developing section of the country the Atlanta District plays an important role in protecting the consumer's health and pocketbook, advising and consulting with its industries to aid them in self-compliance and informing the consumers of their basic rights.



Leslie O. McMillin, former New Orleans District Director, became Director of Atlanta District in December 1967. He joined FDA in 1943 as an inspector.

Current Views on Safety Evaluation of Drugs

by Edwin I. Goldenthal, Ph.D.



Evaluation of safety begins early in a new drug's development and continues through clinical trials and marketing. When we speak of safety, we must recognize that this is a relative term. No absolute criteria can be applied in the evaluation of studies to support safety. Administration of a new drug to man invariably involves some risk which we must weigh against the possible benefits to the patient. For drugs which show a high potential for toxicity, we must often weigh the potential therapeutic value of the new agent against that of established drugs before deciding whether the proposed clinical testing is worth the risk.

Prior to the initial administration of a drug to man, considerable time and effort is expended in characterizing the drug from a pharmacological and toxicological standpoint. The sponsor of clinical investigations must submit to FDA the animal data from which he has concluded that they can be conducted with reasonable safety. Thus, our staff shares with the sponsor and clinical investigators the responsibility for assessing the adequacy of this data. We have prepared guidelines which describe in general the type of preclinical studies which could be used in support of the several phases of clinical investigations as well as of New Drug Application (see table facing page 17). In general, our recommendations concerning the duration of subacute or chronic toxicity studies are based on the proposed therapeutic regime in the human. We have not intended these to be used as protocols, merely guides.

A careful evaluation of these preclinical toxicity studies along with information derived from other pharmacological studies should provide some assurance of the effects to be expected when the drug is administered to man. These effects may be adverse or beneficial. It is at this point that we can begin to discuss safety with some measure of confidence.

The duration of chronic toxicity studies has become, in the past few years, a subject of considerable controversy among toxicologists. Some consider 3 to 6 months adequate for studies intended to support the use of a drug in humans for indefinite periods. They contend that the potential of any drug for organ damage, carcinogenesis excepted, can be estimated through well-designed studies of this scope. Carcinogenic potential, of course, would have to be explored in a separate study. In view of evidence to the contrary, we feel that routine reliance on studies of such short duration is inherently risky. We have encountered examples of toxicity occurring between the 6th and 12th month of treatment, e.g., ocular changes with certain psychotropic drugs and ocular and endocrine changes with some anti-

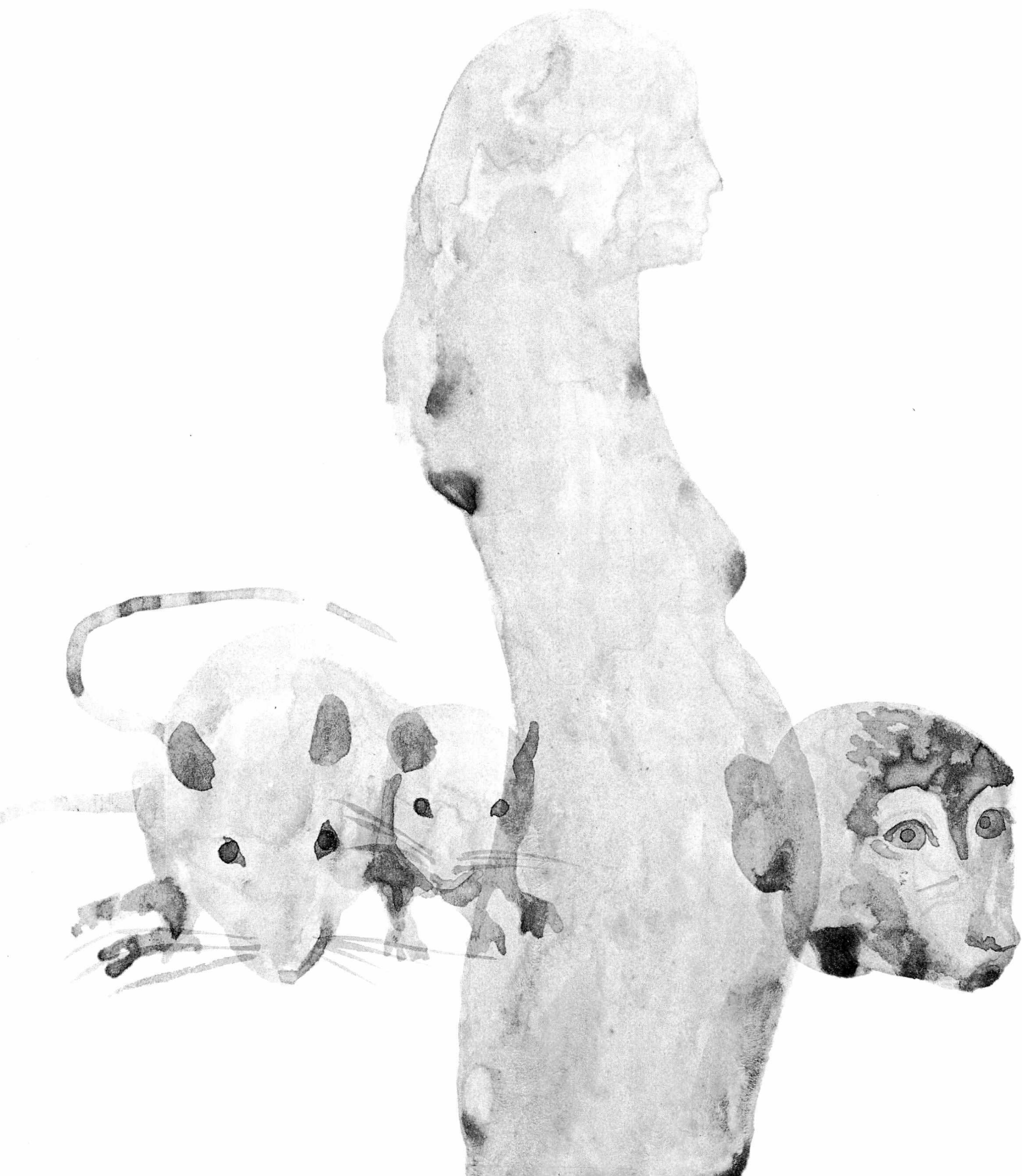




convulsant drugs. As an alternative to an 18-month study in rats, we would accept a 12-month chronic rat study, provided a 2-year mouse carcinogenesis study is also performed. Our philosophy has been that, although these shorter term toxicity studies will disclose the toxicity of a proportionately large number of drugs, more time is required to bring to light problems that might be associated with the others. In some cases, a longer test period can compensate, to some extent, for unforeseen shortcomings in experimental design. We are convinced that these longer term studies are needed for the complete assessment of the safety of drugs for which the duration of use is unlimited.

As a result of the finding of abnormal breast changes with an investigational oral contraceptive preparation, toxicological investigations of oral contraceptives involve a departure from these general recommendations. We are currently requiring, as a minimum, a 1-year toxicity study conducted in a rodent and the dog prior to initial clinical evaluation of such preparations which usually consists of a three-cycle study in the human. We have also recommended, but not insisted, that a concurrent chronic study in the monkey be initiated. We have not stipulated any further toxicity requirements for continuation of these clinical pharmacology studies (Phase 2) as long as the chronic toxicity studies are ongoing. However, prior to the beginning of the large scale clinical trial (Phase 3), we have insisted that studies of up to 7 years duration in the dog and up to 10 years in the monkey be commenced. A recommended detailed protocol for these studies can be obtained from us upon request. The results of studies of 2 years duration in the rat, dog, and monkey should be submitted in consideration for our approval of an oral contraceptive for marketing.

For the investigation of a new estrogen or progestogen, a 90-day subacute toxicity study in two species may be sufficient to support safety for a limited clinical study of a few days duration in a small number of human subjects. Administration of an estrogen or progestogen for a full menstrual cycle would require a 6-month study in two species. Experimentation in humans for intervals longer than one cycle would require 1 year in two species. We are also asking that studies of up to 7 years in the dog and up to 10 years in the monkey be conducted for new estrogens or progestogens which are to be recommended for unlimited administration in the human. These studies should be initiated prior to the large scale clinical trial (Phase 3).



Synopsis Of General Guidelines For Animal Toxicity Studies

Category	Duration Of Human Administration	Phase ⁽¹⁾	Subacute Or Chronic Toxicity ⁽²⁾
Oral Or Parenteral	Several Days	I, II, III, NDA	2 species; 2 weeks
	Up to 2 Weeks	I	2 species; 2 weeks
		II	2 species; up to 4 weeks
		III, NDA	2 species; up to 3 months
		I, II	2 species; 4 weeks
	Up to 3 Months	III	2 species; 3 months
		NDA	2 species; up to 6 months
		6 Months to Unlimited	I, II
	III		2 species; 6 months or longer
	NDA		2 species; 12 months (nonrodent) 18 months (rodent)
Inhalation (General Anesthetics)		I, II, III, NDA	4 species; 5 days (3 hours/day)
Dermal	Single Application	I	1 species; single 24-hour exposure followed by 2-week observation
	Single or Short-term Application	II	1 species; 20-day repeated exposure (intact and abraded skin)
	Short-term Application	III	As above
	Unlimited Application	NDA	As above, but intact skin study extended up to 6 months
Ophthalmic	Single Application	I	
	Multiple Application	I, II, III	1 species; 3 weeks daily applications, as in clinical use
		NDA	1 species; duration commensurate with period of drug administration
Vaginal Or Rectal	Single Application	I	
	Multiple Application	I, II, III, NDA	2 species; duration and number of applications determined by proposed use
Drug Combinations ⁽³⁾		I	
		II, III, NDA	2 species; up to 3 months

1. Phases I, II, and III are defined in § 130.0 of the New Drug Regulations.

2. Acute toxicity should be determined in 3 to 4 species; subacute or chronic studies should be by route to be used clinically.

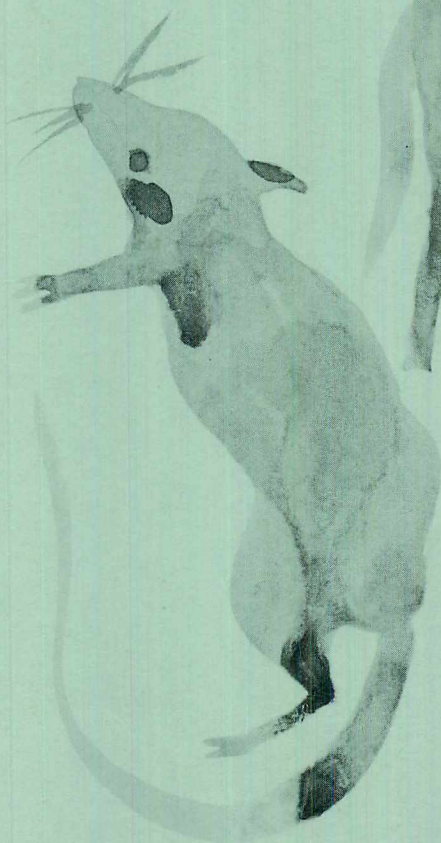
3. Where toxicity data are available on each drug individually.

Observations

Body Weights,
Food Consumption,
Behavior,
Hemogram,
Coagulation Tests,
Liver and Kidney Function Tests,
Fasting Blood Sugar,
Ophthalmologic Examination,
Metabolic Studies,
Gross and Microscopic Examination,
Others as Appropriate.

Special Studies

For parenterally
administered drugs:
irritation studies,
compatibility with
blood where applicable.



Eye irritation tests
graded doses.

Local and systematic
toxicity after vaginal
or rectal application
in 2 species.

LD₅₀ by appropriate
route, compared to
components run con-
currently in 1 species.

Studies concerning the effect of drugs on reproductive processes are an important aspect of their toxicological characterization. We are interested in estimating the potential of a drug for effects on fertility of the male and female, conception, nidation, development and survival of embryo and fetus, parturition, lactation, viability and development of offspring, and the quality of mother's milk (from the standpoint of both nutrition and toxicity). We have been requesting reproduction and teratology studies on most new drugs. A generalized protocol for such studies was developed and mailed to interested parties in March 1966. Copies of this protocol can be obtained upon request. We recommend that the animal reproduction studies be divided into three segments, each related to a specific area of the mammalian reproduction process: (I) General Study of Fertility and Reproductive Performance; (II) Teratological Study; and (III) Perinatal and Postnatal study. Our protocol allows the investigator considerable latitude in experimental design and choice of species.

Prior to the administration of a drug to women of childbearing potential, Segment II and the female aspect of Segment I should have been completed. We have taken the position that institutionalized women are not of childbearing potential and that no reproduction studies are needed to support studies in such a population. Studies on all aspects of reproduction should be completed prior to the initiation of Phase 3 clinical trial. The results of controls from other reproduction studies (historical controls) are of use in evaluating findings from a particular laboratory on the species and strain of animal employed.

Combinations of drugs should be tested when there is evidence of toxicological or pharmacological interaction, even though each active ingredient has been tested independently and found to be without adverse effects. If one or more of the components in a combination product has shown an adverse effect on reproduction when tested individually, additional studies should be carried out on the combination. We have not required reproduction studies for drugs used in life-threatening conditions, i.e., where a patient may die if the drug is withheld.

Traditionally, toxicologists have used at least one rodent and one nonrodent species for multidose toxicity studies. The rat and the dog have been selected in most cases, usually on an empirical basis. Recently, subhuman primates have received considerable attention as species of choice. It is highly significant that the transition from animal to man has been safely accom-

plished in the past with the vast majority of drugs. In retrospect, where adverse effects of drugs were first noted in human subjects, and the suspect drugs were subsequently retested in animals, many of these same effects were elicited. Comparative drug metabolism studies in animals and man should be the cornerstone of toxicological evaluation. Unfortunately, technical difficulties and the expense involved in developing new methods have been, in the past, somewhat of a hindrance to progress in this direction. We feel we have now reached the point where methodology is available to make implementation of this concept a reality.

It is feasible to carry out meaningful metabolic studies on every drug which is considered a candidate for trial in man. Some of the effort in the early clinical investigation should be directed toward obtaining information which would be the basis for selecting the species most suitable for further toxicological studies. The information needed might include data on absorption, excretion, tissue distribution, rate of metabolism, and the metabolic pattern.

With reference to the metabolic pattern, it is not essential to isolate and identify every metabolic product. The principal aim would be to show that the metabolic pattern in a particular species is similar to that in the human to provide a rationale for use of that species in the toxicological evaluation. Certainly, a correlation between animal and human blood levels should be established using appropriate animal models for each drug preparation. Although we have not insisted that metabolic data be submitted prior to the approval of a drug for marketing, we expect this type of data to be included in most New Drug Applications for new entities submitted after July 1969. Development of technological competence in this area in the pharmaceutical industry and toxicological laboratories is proceeding at a rate consistent with this goal.

Recent studies have demonstrated that, with continual administration, certain drugs can markedly stimulate their own metabolism as well as the metabolism of other drugs given subsequently. The increased metabolic capacity is a reflection of an increase in the amount of drug-metabolizing enzymes in liver microsomes. This phenomenon, referred to as enzyme induction, has been observed in many species, including the human. Obviously, it is of considerable importance in the planning and evaluation of chronic toxicity studies. If ignored, erroneous conclusions could be drawn regarding the safety of a drug in a given species, since enhanced metabolism usually leads to the formation of



Edwin I. Goldenthal, Ph.D., Deputy Director, Office of New Drugs, Bureau of Medicine, came to FDA in April 1956.

metabolites that are less toxic than the parent substance and which may be excreted more rapidly.

Most toxicity studies are conducted with a fixed daily dosage level; thus, an increase in the metabolism of the drug would lead to lower levels in the body as the study progressed. For evaluation of the enzyme induction potential of a drug, certain tests should be conducted early in the safety evaluation program. These could include (1) hexobarbital sleeping time, (2) zoxazolamine paralysis time, (3) antipyrine or phenylbutazone half-life, and (4) ascorbic acid or hydroxycortisone excretion. If the drug is capable of enzyme induction, this should be taken into account in the design of chronic toxicity studies and in the interpretation of the results of these studies.

Enzyme induction should also be considered in the evaluation of the possible interaction of two drugs administered concomitantly. We have been suggesting toxicological and pharmacological studies when two drugs are to be combined in a single preparation. In these studies efforts should be made to determine the effect of the first drug on the second and vice versa, both with regard to an increase or decrease in toxicity of either agent and to an alteration in pharmacological activity of either agent. In addition, if it is known that a certain drug will normally be used in concomitant therapy with other marketed drugs, their pharmacological interaction should be assessed. In certain cases, such as drugs used in the treatment of tuberculosis, where multidrug therapy is commonly employed, we have asked for subacute toxicity studies of potential drug combinations. New antiepileptic drugs should also be tested for toxicological interaction with drugs representative of those currently used in the treatment of epilepsy.

Emphasis has been, up to this point, on the preclinical assessment of data to support safety of a drug in humans. There are certain salient features of the clinical investigation also worthy of consideration. The question of drug interaction should also be evaluated in humans. Investigational agents which will ultimately be used in conjunction with established drugs should be explored. As an example, a new diuretic will normally be used with cardiac or antihypertensive drugs in the clinical situation. We would expect clinical studies to be conducted to determine the effects of these combinations.

The increasing frequency of unexpected ocular toxicity from various pharmacological agents makes it desirable that complete ophthalmological surveys be performed on patients receiving investigational drugs. The number of patients to be examined and the necessity for the studies will, of course, be dependent on the nature of the drug, stage of investigation, route and duration of administration, relationship to drugs known to cause

ocular toxicity, and demonstration of a propensity for eye involvement in experimental animals.

It has been stated repeatedly, "Children are not little adults." The determination of a safe dose of a drug for infants and children cannot be made by mere extrapolation from the adult dosage. Some preclinical information can be obtained from our recommended reproduction studies. We have also recommended that acute toxicity studies be performed comparing the newborn rat with the adult. However, with the exception of a few drugs, such as the CNS stimulants, most drugs are more toxic in neonates, and the determination of the potential toxicity in the human infant is an impossible task on the basis of this data. Efforts must be directed toward developing better methods for determination of safety in this younger age group.

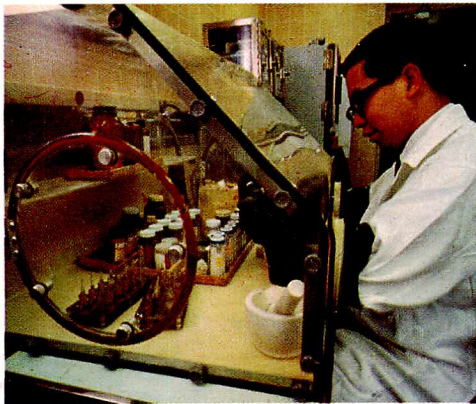
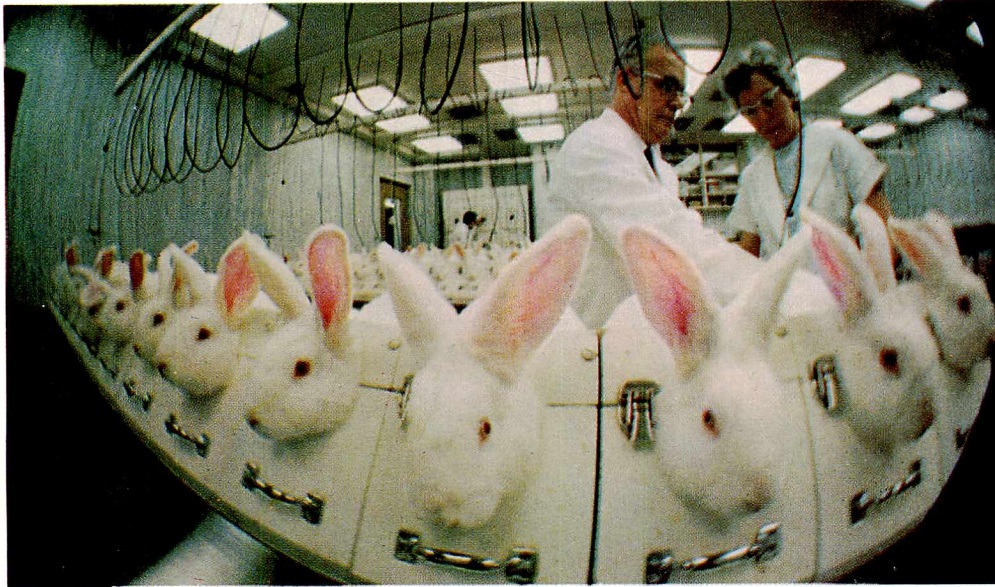
Investigations of new drugs in infants and children must be approached with extreme caution. Once the drug has been established as safe for the human adult, and no indication of toxicity has been observed in preclinical studies, the cautious use of the drug for the treatment of a diseased condition in children (i.e., Phase 2) would appear justifiable. Treatment of infants should be delayed until evidence of safety has accrued in studies involving older children. The use of experimental drugs in normal infants and children (i.e., Phase 1) does not seem defensible.

Even though preclinical studies have been performed and the results indicate no adverse effects on the reproductive process, we have required a statement in the warning section of the package insert indicating that safety of the drug in pregnancy has not been established. Specific data on the effects of the drug in pregnancy in humans will be needed to remove this warning. Only after preclinical studies have been performed and indicate safety should human studies in pregnancy be undertaken. We would recommend that a minimum of 250 patients be studied in both the first and last trimester of pregnancy with a control group of the same size. These groups should consist only of individuals who are being treated for a specific disease entity. We recognize the risk to be taken by these small groups but we must consider the safety of the total population which may receive the drug.

Development of new methods in drug safety evaluation is proceeding at a rapid rate. We are in full agreement with the critics of current procedures—the toxicological assessment of new drugs should keep pace with more sophisticated techniques, consistent with the objective of being as critical and comprehensive as possible. However, it must be borne in mind that general acceptance of these newer procedures will be predicated on their applicability and predictive value.

TESTING AND CERTIFYING ANTIBIOTICS





Testing and Certifying Antibiotics

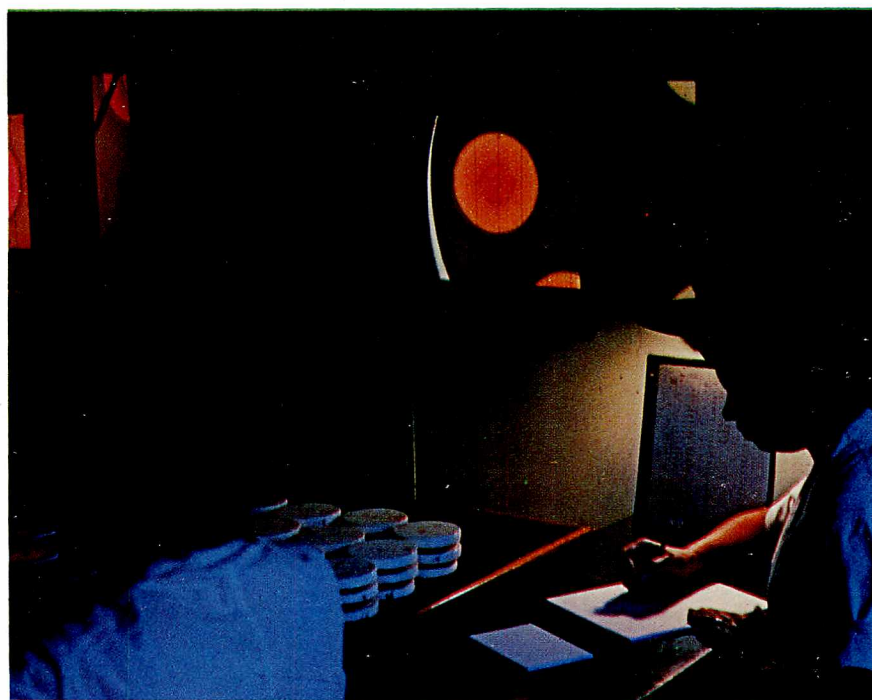
Mice shown on previous page and at top left are used by Antibiotic Biological Branch to test antibiotics for substances which might render them unsafe. Five mice are injected with sample, which is approved if none die within 48 hours. Rabbits (in stocks, center, left) are inoculated with antibiotics and temperatures checked to test for contamination with pyrogenic substances. Sample is approved if electronic rectal thermome-



ters (shown overhead) register less than 0.6-degree rise in 3 hours. Antibiotic discs (top middle) are collected for testing against FDA standards by Insulin Testing and Antibiotic Residue Branch. Each disc contains a specific antibiotic good for inhibiting growth of certain microbes, and physician uses various discs to test culture isolated from patient to help select the proper antibiotic to be used in treatment. In two photos at

left, chemists of Antibiotic Chemistry Branch use transparent "dry box" with built-in rubber gloves to remove non-liquid antibiotic samples to be tested for moisture content, and inject antibiotic sample into gas chromatograph for physicochemical identity test. Above, chemist is using iodometric titration process to measure potency of samples of orally used penicillin through measurement of iodine absorbed by sample solution.

Testing and Certifying Antibiotics



At Sterility Testing Branch (left, top), microbiologist filters antibiotic solutions through membrane under a laminar flow hood that insures sterility in the area. Membranes, which can retain any micro-organisms present, are then placed in growth medium in tubes (left, bottom) and incubated for 7 days to determine if sample is contaminated. In photos at right, analyst at Microbiological Assay Branch (bottom) prepares antibiotic sample so-



lution to be deposited on culture plate containing test micro-organisms; plate is shown (top) with six circular areas of inhibition, three where sample has inhibited micro-organisms and three containing known quantity of FDA standard antibiotic for comparison. Clouded parts of plate show uninhibited micro-organism growth. Potency of antibiotic can be determined by measuring clear areas through projector onto visual scales (center).

by
William W. Wright, Ph.D., and
Amiel Kirshbaum

National Center for Antibiotics and Insulin Analysis

The main responsibilities of the National Center for Antibiotics and Insulin Analysis are to perform the scientific laboratory work and evaluations necessary for the testing and certification of antibiotics and insulin.

These responsibilities were given to the Food and Drug Administration by Congress, starting in 1941 with the passage of Section 506 of the Federal Food, Drug, and Cosmetic Act. This section requires that samples of each batch of insulin be tested and approved by FDA before marketing.

In 1943 the War Production Board requested FDA to assay samples of each batch of penicillin before release for use by the Armed Forces. In 1945, when penicillin was about to be made available for civilian use, Congress added Section 507 to the Act to require pre-market testing of penicillin.

Section 507 has been amended three times, in 1947 and 1949 to provide for the certification of streptomycin, chlortetracycline, bacitracin, and chloramphenicol and their derivatives, and finally in 1962 to provide for the certification of all antibiotics intended for use by man. Currently there are about 40 different antibiotics subject to certification. There are, however, many salts and derivatives of these antibiotics, and hundreds of dosage forms. The regulations on certification and control, including official analytical methods, are contained in Title 21 of the *Code of Federal Regulations* under Parts 141, 144, 145, 146, 147, and 148.

Each batch of antibiotics and dosage forms must be tested by FDA and certified before marketing. This function was performed for penicillin by the Division of Microbiology until July 1945, when the Division of Penicillin Control and Immunology was formed. In 1949 the name Division of Antibiotics was adopted to reflect the general scope of the Division's work.

The insulin-testing function was performed by the Division of Pharmacology from 1941 to 1964, when it was transferred to the newly formed Division of Antibiotics and Insulin Certification.

The National Center for Antibiotics and Insulin Analysis has a complement of about 110 employees, mostly chemists, microbiologists, biologists, and technical aides. It is organized into five Branches: Antibiotics Chemistry Branch, Microbiological Assay Branch, Sterility Testing Branch, Antibiotic Biological Branch, and Insulin Testing and Antibiotic Residue Branch.

The Antibiotic Chemistry Branch performs a great variety of chemical and physical tests. Products containing penicillin in various forms are assayed by iodo-

metric titration or by an automated colorimetric procedure. Dosage forms are tested for moisture content, since excess moisture may adversely affect the stability of certain antibiotics. The oven method is used for tablets, capsules, and most powders, and the Karl Fischer titration method is used for oils, ointments, and powders containing water of hydration. Certain samples are examined microscopically to observe their crystalline structure. Colorimetric assays and ultraviolet and infrared spectroscopic methods are used for identity and quantitative measurements. Some samples are characterized by specific rotation and paper chromatography. Tests are made for pH, residue on ignition, metal particles in ophthalmic ointments, and disintegration time of tablets.

This Branch also maintains standards for antibiotics, an important responsibility since these standards are the ultimate measures against which the potency of all antibiotic preparations is gauged.

The Microbiological Assay Branch tests antibiotics for potency, that is, their ability to inhibit the growth of germs. Potency is measured in relation to one of the official reference standards. The antibiotic is dissolved or separated from the dosage form by solvent extraction, grinding, or blending. It is then assayed by either of two types of methods—plate diffusion or turbidimetric. In the plate assay, specific test organisms are "seeded" on a semisolid agar surface. Then small stainless steel cylinders are placed on the surface, and the samples and standard solutions are alternately filled into the cylinders. After overnight incubation, the plates are examined; the antibiotics inhibit the growth of the test organisms around the cylinders, forming circular zones of inhibition. These zones are measured and used to calculate potency.

A liquid medium is used in the turbidimetric assay. Each sample and standard is placed in a test tube with the test organisms. The tubes are incubated in a water bath at body temperature for 3 to 4 hours. If no antibiotic is present, the organisms grow and the liquid medium becomes quite cloudy. The tubes containing the antibiotic under test show less growth, and this inhibition is measured photometrically in terms of turbidity.

This Branch also tests all antibiotics for penicillin contamination, using especially designed methods. Since this test was introduced several years ago, the

presence of this type of cross-contamination has been virtually eliminated.

These microbiological tests utilize dozens of test organisms, each selected for its susceptibility to the particular antibiotic. They must be cultured with extreme care to keep their strains pure.

The Sterility Testing Branch examines all injectable preparations of antibiotics and insulin to insure the absence of contaminating germs. In some cases, antibiotic otic and ophthalmic preparations are also tested for sterility. There are two general methods: direct and filtration. In the direct method, samples are transferred to sterile test tubes containing culture media especially formulated to favor the growth of bacteria, molds, and yeasts. In the filtration test, the sample is passed through an extremely fine membrane that can retain any micro-organisms except viruses. Then the membrane is placed in the growth medium. All of these transfers must be done with extreme care in sterile rooms or under laminar flow hoods. In both methods, the tubes are incubated for 7 days, after which they are observed to determine if any viable germs are present.

The Antibiotic Biological Branch performs tests for toxicity, pyrogens, and vasodepressor substances. The toxicity test is actually a safety test designed to show that a predetermined test dose will not cause death in mice. The pyrogen test is performed by injection of the sample into the ear vein of each of a number of rabbits. The rabbits' temperatures are recorded electronically for 3 hours. The records are then examined to see that no fever-producing substances are present. All injectable antibiotics are subjected to this test. The Branch also performs this test on all injectable preparations of various nonantibiotic drugs and large volume parenterals collected by FDA Inspectors all over the country. The test for vasodepressor substances is done to insure that certain histaminelike impurities occasionally present in crude antibiotics have been removed by the various purification steps.

The Insulin Testing and Antibiotic Residue Branch performs most of the tests required for the certification of batches of insulin, and many other special tests. Batches of insulin are tested for potency by measurement of their ability to lower the sugar content of rabbits' blood. Tests are also done for moisture, pH, nitrogen, chloride, sulfate, zinc, protomine, and ash. The regulations governing insulin are found in Part 164 of 21 CFR.

This Branch also tests antibiotic sensitivity discs to insure that they contain the labeled amounts of antibiotics. The assay is called a "performance assay" because the discs are tested in almost the same manner as

they are used by diagnostic laboratories. The procedure is similar to the plate diffusion assay used by the Microbiological Assay Branch. This is an extremely important test, since these paper discs are used to tell if a patient's infection may be treated with a given antibiotic.

Samples of medicated animal feeds are assayed for antibiotic content by this Branch. The Branch also tests samples of fruits, vegetables, eggs, milk, dairy products, fish, and animal meats for the presence of antibiotic residues. These tests are exquisitely sensitive to small amounts of antibiotics.

Special tests are done in cooperation with the Bureaus of Medicine and Veterinary Medicine. Samples of blood and urine from human volunteers or experimental animals are assayed for antibiotic content after the administration of various dosage forms. In this way it can be determined if the particular antibiotic is properly available and is likely to be therapeutically effective.

Each year the Center receives samples of over 20,000 batches of antibiotics and insulin intended for distribution in this country or for use by our Armed Forces. The rejection rate is usually about 1 percent. About 2,000 samples are collected yearly by FDA Inspectors after certification. In all, approximately 300,000 individual tests are performed annually.

The scientific staff of the Center provides expertise in evaluating methodology and data submitted in support of Antibiotic New Drug Applications, both human and veterinary, and of Food Additive Petitions. The various Branches also carry out research and investigational projects intended to increase our knowledge of the properties of antibiotics and insulin and to develop new or improved test procedures.

The National Center for Antibiotics and Insulin Analysis was formed on January 5, 1968, as the result of a reorganization. It is an arm of the Division of Pharmaceutical Sciences in the Bureau of Science.



William W. Wright, Ph.D. (left), is Acting Director of the National Center for Antibiotics and Insulin Analysis. He joined FDA in 1944.

Amiel Kirshbaum (right) Acting Deputy Director of the Center, has been with FDA since 1946.

The Pecan Shelling Industry of the Southwest

by
James B. Hyndman

The Federal Food, Drug, and Cosmetic Act of 1938 says a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food. A food also is adulterated if prepared, packed, or held under insanitary conditions by which it may have become contaminated with filth or rendered injurious to health.

Almost as soon as the 1938 Act became effective, FDA began applying it to the extremely insanitary conditions in the pecan shelling industry at that time. Sanitation standards were not as high as now. FDA started a bacteriological survey of the pecan shelling plants in the San Antonio area after a number of magazine and newspaper articles were published describing filthy conditions. FDA began by developing basic authentic inspectional and bacteriological background data.

If micro-organisms are used as an index of insanitary food production, the specific food item must be free of specific bacteria or groups of them somewhere early in production. The coliform group, and specifically *Escherichia coli*, serve as indicators of insanitation and potential danger to health. When these bacteria are found on nut meats, it means there has been insanitary handling or improper processing, since the nut meat in the uncracked shell is free of enteric micro-organisms.

When enteric micro-organisms are found in association with an inspection clearly showing a direct route of contamination from a fecal source to the nut meats, regulatory action is warranted. Sanitization of uncracked nuts is necessary to remove fecal and other material from the orchard or the shipping environment. Thus, early in processing the product is free of the micro-organisms.

A second problem in the late 1930's was that curculio larvae infested the nut meats and there were no procedures to eliminate them. Many plants also were overrun with rodents, and nut meats were contaminated with rodent hairs or excreta or both. Often pieces of shell or septum or other types of gross nondescript filth were found because of the conditions under which pecans were shelled.

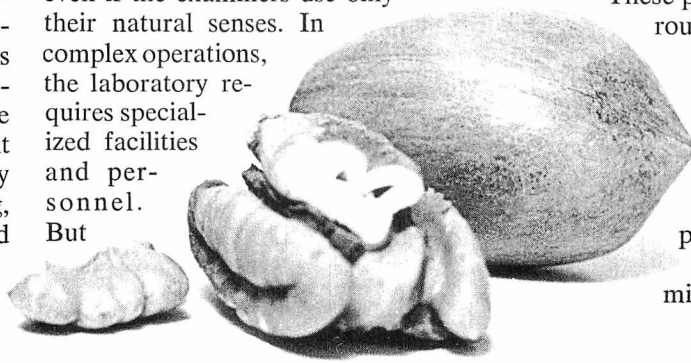
Today some form of laboratory control of plant and product is a must in most establishments. The simplest production benefits from organized inspection and control, even if the examiners use only their natural senses. In complex operations, the laboratory requires specialized facilities and personnel. But

tests of the finished product can never wholly substitute for on-the-spot control during manufacture.

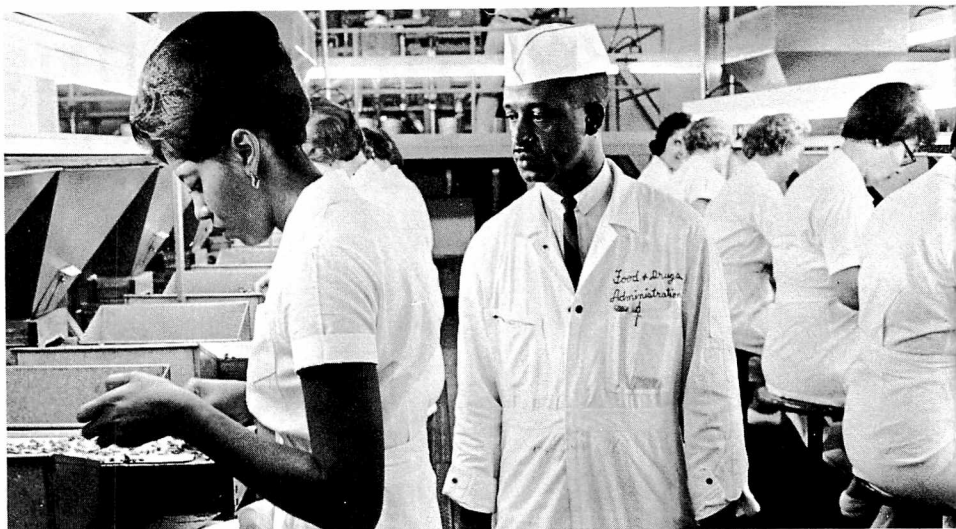
A sanitary condition, strictly speaking, insures freedom from contamination by injurious substances, particularly infectious micro-organisms. But modern concepts of food control go beyond this. Modern sanitation encompasses food plant practices and conditions that may incorporate extraneous matter that is obnoxious and repulsive and violates hygienic decency, even though it may not be an agent of disease.

Factory and product control combine some of the criteria of microbiology and entomology and other branches of science. The principal objective is to uncover routes of contamination. Microbiological principles can show potential infection by disease organisms or contamination by filth and decomposition. This potentiality can then be confirmed by microbiological procedures. Similarly, entomological principles are useful in rodent and insect problems.

These primary sources and routes of contamination should be considered in a sanitation program for pecan shelling plants: personal hygiene of employees; prevalence of rats, mice, vermin, and flies; use of



Employees separate bits of shell and other foreign matter from meat as inspector watches.



unclean equipment or polluted water; and use of unfit raw materials. Other features may be secondary, but important in filling out the picture.

The human element is hardest to control and is foremost in a sanitary appraisal. Where education lags, insanitary practices are found. Pecans are handled in many large scale operations by persons ignorant of personal hygiene principles. It is reasonable to demand that the food handler have clean hands, and that he be conscious he is preparing the nut meats for human consumption.

From the beginning of sanitary control, communities have tried to eliminate rats and mice. Nevertheless, it has been estimated that in any given community the rat population equals or exceeds that of the human. Accumulations of fresh excreta, gnawings, rat runs, and damaged merchandise provide evidence of these invaders.

Examination of excreta tells the extent of rodents and harborages and whether current or old. Structural, incidental, and temporary harborages often show the possibility of infestation. Hairs and excreta confirm evidence of depredations.

Large numbers of flies in a pecan shelling plant confirm not only the presence of these carriers of filth and possible infection but also the proximity of the putrescent or decaying matter in which they breed. Bacteriological inspections should disclose the source and establish evidence

showing the relationship of flies to contamination of the nut meats.

Dirty utensils and equipment reflect a lapse in sanitary controls. Generally, improperly cleaned equipment warns of more direct evidence of filth. The full picture of sanitation will disclose the presence or absence of suitable water supplies, detergents, and sanitizing agents. Disinfection of equipment usually requires chlorination or some similar sanitizing method. This is recommended in pecan plants, but not as a substitute for thorough cleaning. Failure to use chlorine, however, is not always in itself a cause for condemnation. Too often hypochlorite solutions are used like cheap perfume on surfaces that should be washed and cleaned of the greasy residues.

There is no excuse for using polluted water. Bacteriological tests for pollution are simple. Consulting laboratories ordinarily will make them for a reasonable fee, or local health agencies may be able to render such service. It may be generally assumed that a city water supply is free from pollution. If city water is not available, the sanitary or potable quality of the water obtained from private wells or other sources must be investigated.

The basic background bacteriological data developed by FDA in its survey of the pecan shelling industry in the San Antonio area is still the basis for much of the Agen-

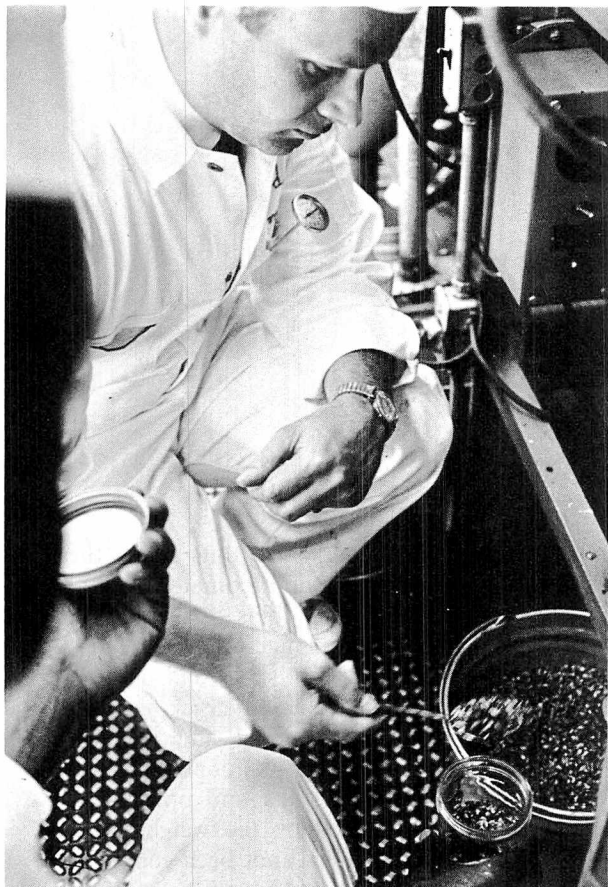
cy's current regulatory activity in this field.

The survey was one of the first major instances where the bacteriologist-inspector team was used in a large industry. The team correlated the insanitary factory conditions by recovering the coli-aerogenes group of micro-organisms, and clearly demonstrating direct routes of contamination from feces to nut meats.

Practically all cracking and shelling at that time was done by hand. It was common for workers at the plants during the day to take home 100-pound bags of in-shell nuts to be hand-shelled by their families under conditions that were repelling. Many of the workers lived in parts of San Antonio where a full city block consisted of one-room or two-room apartments, wall to wall, with a patio or courtyard in the center of the block containing possibly one or two commodes. There were no sanitary handwashing facilities.

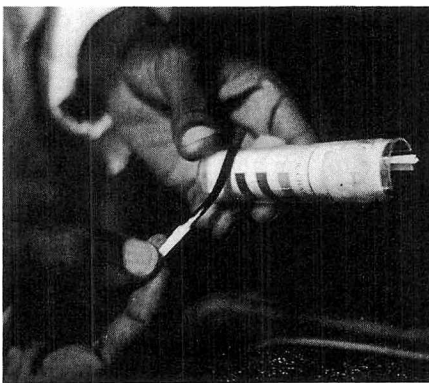
Plant conditions were primitive. Most working surfaces were wooden. Chlorine was generally unheard of, and flotation processes were primitive.

During the past 30 years, the industry has made sweeping progress in design of machinery, knowledge of sanitation, and education and supervision of personnel. Today a great many operations are almost completely mechanized, which eliminates many of the con-



Cultures from samples are placed in lab incubator in tests for micro-organisms.

Left, inspector removes sample of pecan meats during inspection on plant production line. Later in District laboratory (bottom), 50-gram portion is weighed out from sample for microbiological analysis.



Above, electronic sorting machine separates choicer, lighter-colored meats from darker "ambers," or lower grades. Left, water for in-shell sanitizing bath is tested for sufficient chlorine with chemically treated "LaMotte" paper strip, which darkens if sufficient chlorine is present.

taminated food contact surfaces that were present earlier. In 1961, upon the establishment of Dallas District, FDA found itself in a much better position to maintain surveillance over this industry. San Antonio has been called the world's largest pecan shelling center. Besides this, a number of large plants in the Dallas-Fort Worth area and in Oklahoma and smaller plants in Texas, Oklahoma, and Arkansas create much work for the Dallas District.

Today almost all plant equipment is of metal construction and is designed for easy cleaning and sanitization. Many plants have inspectional programs of their own, modeled on FDA inspectional procedures. In the microbiological examinations, most of the plants are using a modified FDA methodology.

The District continually emphasizes that *E. coli* both shows insanitary conditions where there are clear routes of contamination from feces to food and indicates the potential of food poisoning where there is gross contamination. At first, few plant managers and supervisory people really understood why FDA looked for *E. coli*—just that these organisms should not be present. In the last few years they have come to realize that *E. coli* indicates insanitary practices during processing, where the uncracked nut was properly sanitized. Since pecan nut meats are often eaten with little or no further processing, the presence of *E. coli*, a normal inhabitant of

the intestinal tract in mammals, potentially means danger to health. Whenever found, there is a possibility enteric pathogens—such as typhoid, paratyphoid, *Shigella*, dysentery—are present to cause gastrointestinal upsets or food poisoning.

Seizures have had salutary effects on the individual firms. Plant officials, learning of seizures, have set up procedures for reconditioning: washing the contaminated meats with water to remove fecal material, chlorinating them, and drying them at a pasteurizing temperature. When this is done properly, the reconditioned meats are found to be free of *E. coli*.

The use of propylene oxide sterilization during reconditioning has attracted much industry interest recently. FDA has agreed to such gas sterilization for pecan nut meats intended for further processing. The nut meats are aerated after treatment to reduce residues to food additive tolerance levels and then incorporated into foods, such as candy, breakfast rolls, and cakes. Nut meats which are going directly into consumer-size packages cannot be treated with gas.

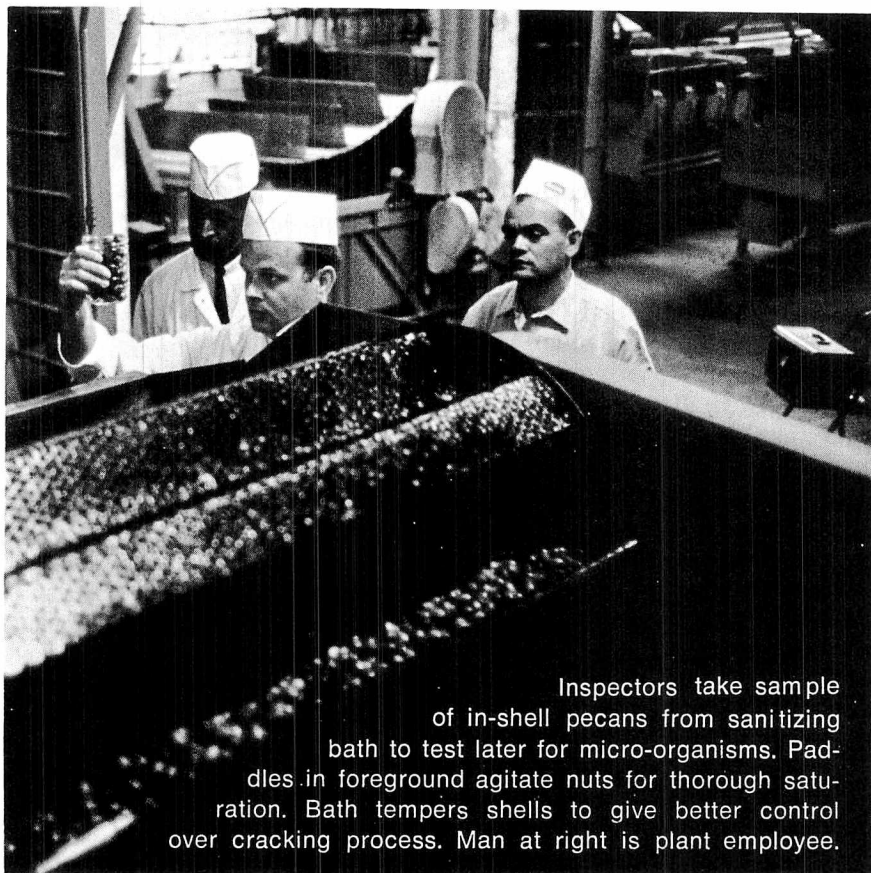
This past year one pecan sheller in the Dallas District recalled several million dollars worth of shelled pecans because of gross contamination by *E. coli* over a production period of several weeks. The firm had developed what was apparently a more modern way to wash and sanitize in-shell nuts before cracking.

The uncracked nuts were then stored in approximately 2,000 pound "tote" bins, covered, and held approximately 24 hours to moisturize the shell and make it more adaptable to cracking. After careful inspectional and analytical work, the District found that some cracks and splits and other whole nuts cracked by the weight of the nuts above had not been completely sanitized, even though the sanitizing solution contained 2,000 parts per million chlorine.

The 24-hour tempering in a closed "tote" bin acted as an incubator, allowing small numbers of *E. coli* to multiply and thus nullify the previous washing and sanitizing operation. When the nuts went to the crackers, all the equipment became contaminated, and the finished product was grossly contaminated with *E. coli*.



James B. Hyndman, Supervisory Microbiologist, has been with Dallas District since 1961. He joined FDA 26 years ago in New Orleans District.



Inspectors take sample of in-shell pecans from sanitizing bath to test later for micro-organisms. Paddles in foreground agitate nuts for thorough saturation. Bath tempers shells to give better control over cracking process. Man at right is plant employee.

Since Dallas District became operational in January 1961, there have been six prosecutions—four first offense and two second offense actions. One second offense prosecution brought a fine of \$4,000, plus jail sentences for two of the responsible individuals. This shook the entire industry.

Findings of violations during inspections, seizures, recalls, and prosecutions indicated the need for industry workshops. A series was held in 1966 at several plants to reach the worker level. A different kind of workshop was held in the fall of 1967 for supervisory employees. The result is apparent. Most employees are now conscious of the basic principles of personal hygiene and sanitation. They seem to better understand our inspectional techniques and procedures and are more qualified to interpret

the bacteriological analytical results which FDA reports after each inspection.

Industry progress over the last 3 decades has resulted in almost complete mechanization of pecan shelling operations.

Many firms conduct continuing in-plant sanitation programs. Such programs cover three areas: First, personnel education and training; as new employees are hired, supervisors train them in a prescribed program intended to eliminate as much human contamination of equipment or nut meats as possible.

Second, equipment cleaning and sanitization; most plants now have a continuing type of cleaning and sanitizing procedure. Third, storage and handling of shelled nuts; the more progressive plants handle and store shelled nuts in areas separate from the shelling to eliminate the transfer

of dust or debris from the unsanitized nuts to the area where the product is handled aseptically.

As a result of FDA educational and voluntary compliance encouragement, most of the pecan shelling plants of the Southwest today either have installed their own bacteriological control laboratories or have engaged the services of a consulting laboratory. Personnel of the Dallas District work closely with each plant to encourage responsible officials to use bacteriological control methods and to train plant personnel assigned to the microbiological examinations of nut meats. The District cooperates with consulting laboratories. This includes supplying FDA methods and interpretation of analytical findings.

Both the industry and FDA have traveled a long and arduous road over the years. The upshot has been an almost perfect example of industry cooperation and regulatory guidance that has made for a better product for the consuming public. The National Association of Pecan Shellers is currently developing a code of Good Manufacturing Practices. FDA is extending to the Association the benefit of its experiences and inspectional and analytical data. We believe that through this kind of industry-Government cooperation, FDA can direct more of its resources to more pressing problems of consumer protection.

ATLANTA DISTRICT An imported "Hubbard Mark V E. Meter" was intercepted by the Bureau of Customs at Miami, Fla., and a Notice of Detention and Hearing was issued by FDA on February 6. Shipped to a Miami address by Instrumentations, a firm in Kent, England, the device was claimed by FDA to have been misbranded because of its intended use in diagnosis, treatment, and prevention of disease. The label of the device contained a disclaimer that the "E. Meter is not intended or effective for the diagnosis, treatment, or prevention of any disease." Since no one answered the detention notice, the device was returned to the sender on February 21. As a followup to this action, the District alerted all other Districts, and Dallas subsequently detained two of these units.

In an earlier action involving the device, the Founding Church of Scientology, Washington, D.C., and some 40 individuals were defendants in a court case involving false and misleading therapeutic claims. A jury found in favor of the Government on April 18, 1967. A decree of condemnation for destruction was stayed pending appeal. The claimants filed a notice of appeal to the U.S. Court of Appeals last October 23.

Rice contaminated with rodent urine, rodent excreta, and bird excreta was seized at Great Southern Wholesale Grocery Corp., Miami, Fla., on February 8. The manufacturer and shipper of the 297 bags of rice is The Arkansas Rice Growers Coop. Association, Stuttgart, Ark.

BALTIMORE DISTRICT Part of a shipment of diet pills from Lanpar Co., Dallas, Tex., was seized at the firm's warehouse in Richmond, Va., on February 16. The District had recommended seizure of more than \$70,000 worth of the pills on February 7 because of false and misleading labeling claims. Shortly after the District collected samples of the shipment, the firm returned more than 90 percent of the stock to Dallas. The remainder was seized.

BOSTON DISTRICT Due to subpotency, 804 tubes of bacitracin ointment, valued at \$552, were seized in February. Manufactured by McKesson & Robbins, Inc., Fairfield, Conn., the drugs were seized at the firm's warehouse in Canton, Mass. As a result, some of the firm's analysts plan to visit the Division of Antibiotics and Insulin Certification to discuss FDA's method of analysis for this product.

Filberts valued at \$9,600 were voluntarily destroyed by First National Stores, Inc., East Hartford, Conn., after both FDA and the firm detected bacteriological contamination by rodent filth. The lot was shipped by Dundee Nut Growers, Dundee, Oreg.

BUFFALO DISTRICT Because of an excess of crude fiber, 141,000 pounds of ground oats imported from Canada was detained recently. Offered for feed purposes, the oats were packed in 100-pound bags labeled with a guarantee that they contained not more than 15 percent crude fiber. Examination showed 22 to 26 percent fiber. The oats were shipped by Central Grain Co., Ltd., St. Boniface, Manitoba. The New York State Department of Agriculture and Markets, Division of Food Control, had alerted the District to this type of violation. The Department reported seizure of five lots of ground oats from the same shipper because of protein deficiency and high fiber content.

As part of a developing cooperative program, FDA Inspector Sanfred Markfield spoke to 46 students at the School of Pharmacy, State University of New York at Buffalo, on "Drug Controls." A seminar followed, including a tour of the District laboratory facilities, with emphasis on drug analysis and related analytical topics. The District hopes to develop a program with the pharmacy school in which the school will present speakers to District personnel on specialized, drug-related problems.

CHICAGO DISTRICT Allied Mills, Inc., Bartonville, Ill., was fined \$2,400 on February 19 for making interstate shipments of medicated feeds deficient in antibiotics and failing to comply with certification exemptions.

The District and the Office of Legislative and Governmental Services held a training school on medicated feeds March 11-15 for 12 Illinois Department of Agriculture Inspectors. The State intends to take over the regulatory work for mills producing finished feeds.

CINCINNATI DISTRICT An Ohio drug firm has taken positive steps to correct its violative environment. In compliance with Federal court provisions (see Dec. 1967-Jan. 1968 FDA PAPERS), the C. M. Bundy Co., Cincinnati, moved to new quarters February 1. Due to a lack of updated information, the March issue of FDA PAPERS stated incorrectly that the firm was still operating in the same quarters and producing drugs which were in violation of the Food, Drug, and Cosmetic Act.

DALLAS DISTRICT A medicated feed inspection techniques course was held by the District and the Office of Legislative and Governmental Services February 13-16 at College Station, Tex. Cooperating was the Texas Feed and Fertilizer Control Service. Students included inspectors from the Texas Feed and Fertilizer Control Service; Oklahoma Seed, Feed and Fertilizer Division; and the District. The course is a prerequisite for commissioning inspectors of both of the State units to carry

out medicated feed inspections for FDA. Some Texas inspectors received the same training in May 1966 and some Oklahoma inspectors in 1965. The directors of both State units have endorsed the cooperative program.

DENVER DISTRICT More than 2 million diet pills were seized at Calvin Scott & Co., Albuquerque, N. Mex., in February. FDA had charged that the drugs were misbranded and dangerous to the user at the dosage and frequency suggested in the labeling.

Due to adulteration by insects and insect fragments, 109 cases of "Carnation Instant Breakfast" were seized in Denver, Colo., in February. The shipper was Carnation Co., St. Joseph, Mo.

Filberts contaminated by *E. coli* were seized February 8 in Denver, Colo. The nuts, valued at \$835, were shipped by Dundee Nut Growers, Dundee, Oreg.

DETROIT DISTRICT The District participated in an all-day conference for 200 physicians, nurses, and community leaders sponsored by the Michigan State Medical Society in Detroit on February 24. FDA emphasized nutritional quackery and recent seizures of products for which claims of special dietary benefits were made.

KANSAS CITY DISTRICT Due to insect contamination, 1,050 pounds of pecan pieces, valued at \$1,000, were seized at Missouri Pecan Shelling Co., St. Louis, Mo., on February 5. The nuts were shipped by Raymond & Chas. Foti Pecan Co., St. Martinsville, La.

Powdered digitalis and "Thermatalis" tablets were seized February 23 at Mills Pharmaceutical, Inc., doing business as E. W. Heun Co., Inc., St. Louis, Mo. The digitalis was valued at \$650 and the "Thermatalis" at \$1,350. Also seized were 10,000 package inserts and 5,000 labels. The products were seized because of false and misleading claims and inadequate directions for use, and because they would be hazardous to health if used as directed.

Three types of massage devices were seized recently due to false and misleading statements and failure to bear adequate warning statements. On February 21, 34 "Ped-A-Massage" devices, valued at \$1,000, were seized at Midwest Massage of Kansas, Inc., Wichita, Kans. The devices also did not bear adequate directions for use. They are manufactured by Posture Massage Manufacturing Co., Oklahoma City, Okla. Fifteen "Vita Master Belt Massagers," valued at \$1,125, and one "Vita Master Exercise Bicycle," valued at \$60, were seized on January 18 at Ardan Wholesale, Inc., Des Moines, Iowa.

LOS ANGELES DISTRICT Oxygen respirators became contaminated with the pesticide thiodan when containers of the pesticide broke while being carried on a truck with the devices. The pesticide dust entered the uncovered ends of tubes on the devices. The firms involved voluntarily corrected the problem.

Danger to health, inadequate directions for use, and false claims caused seizure of 1,275,000 thyroid-digitalis tablets and high potency thyroid tablets in three actions in February. Twelve different drugs, totaling 1,086,000 tablets, were seized at Panthera Pharmaceutical, Phoenix, Ariz. At Associated Researchers, Las Vegas, Nev., 109,000 tablets manufactured by Leo Linden Laboratories, Los Angeles, Calif., were seized. Two lots of drugs totaling 80,000 tablets were seized at Myers-Carter Laboratories, Phoenix.

MINNEAPOLIS DISTRICT The District sent more than 20 warning letters in February to firms which have violated the Federal Food, Drug, and Cosmetic Act. The cooperative responses of the recipients demonstrate that compliance can often be accomplished through such letters in preference to lengthy litigation.

Mill-Brook Macaroni Co., Minneapolis, Minn., was fined \$1,000 in February for causing macaroni products to be adulterated with lindane, malathion, and insects and insect fragments, and for preparing these products under insanitary conditions.

NEW YORK DISTRICT FDA, in another action against misbranded obesity preparations, caused seizure of more than \$700 worth of "rainbow" pills at a New York distributor on February 27. The tablets, which contained a combination of thyroid, digitoxin, and ascorbic acid, were manufactured by Seaway Pharmaceutical Corp., Muskegon Heights, Mich. FDA alleged, among other things, that the drugs were not safe and effective to treat hypothyroidism, cretinism, low metabolic rates, and obesity.

The District detained 30,000 crates of Chilean melons on board the *SS Imperial* in March because of contamination with DDT and sodium nitrate which was being carried on the ship. After the melons were washed to remove the chemicals and reexported, FDA released the shipment for entry into the United States.

NEW ORLEANS DISTRICT Reinspection in February of a firm which had been violative showed much physical improvement of the facilities to eliminate insanitary conditions. Following a reported food poisoning incident in Chicago, the District inspected Morgan City Freezer & Cold Storage Co., Morgan City, La., in July 1967. The firm was breeding shrimp under insanitary conditions, and 13 seizures were made, based on bacteriological findings. The firm has since made improvements costing approximately \$50,000.

PHILADELPHIA DISTRICT A workshop for drug repackagers who specialize in packaging physicians' samples was held February 28 in Philadelphia, Pa. Topics included compliance with good manufacturing practices and the responsibility of repackagers to maintain proper identity and purity. The District conducted the workshop with assistance from FDA's Bureau of Voluntary Compliance and Regulatory Compliance.

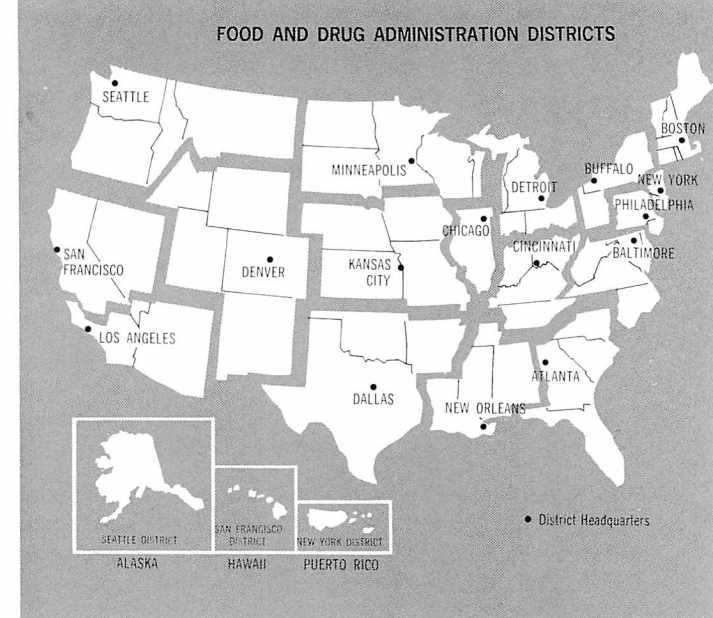
Those attending the workshop represented 90 percent of the Nation's packagers of drugs in blister form.

SAN FRANCISCO DISTRICT "Ionic Calcium," valued at \$2,677, was seized on February 5 due to misbranding. Labeling statements falsely suggested that the drug is adequate and effective to cause weight gain; to increase stamina; and to treat colds, destructive diseases of the joints, minor infections, allergic conditions, and asthma, among other ills. The IC No. 39 Ionic Calcium was manufactured by Ionic Calcium Products Co., Eugene, Oreg.

Mung beans imported from Peru were detained in February due to contamination with endrin. This same type of contamination had been found on some earlier shipments. A commercial laboratory has also analyzed the beans and found endrin. When the lab grew bean sprouts from some of the detained beans, the sprouts also carried traces of endrin. The beans are used commercially to grow bean sprouts for use in Chinese dishes.

SEATTLE DISTRICT "Current Concepts in Nutrition" was the topic of a lecture series assisted by FDA and sponsored by Continuing Medical Education, University of Washington, and the Washington State Dietetic Association. Eugene Stevenson, Division of Nutrition, gave the first lecture to 135 Seattle area dieticians on February 21.

To help improve the quality of mushrooms imported from Taiwan, the District trained a quality control technician from Green Giant Co. on the problem in November. Recently the firm informed the District that it had



passed on the methodology in three training schools held in Taiwan. Approximately 220 quality control technologists attended the sessions in an effort to upgrade the quality of the company's canned mushrooms. The District had detained the mushrooms a number of times because of insect infestation.

Deputy Commissioner Winton B. Rankin has congratulated the District on its excellent safety record for the calendar years 1966-67. A review of accident experience records of each Bureau and District shows Seattle District reduced motor vehicle accidents from four in 1966 to one in 1967. No member of the District staff incurred a disabling injury in either year. Mr. Rankin also extended thanks to all members of the staff for their personal interest in safety and the attainment of FDA's Mission Safety-70 goals.

FDA DISTRICT OFFICES

ATLANTA 60 Eighth Street, N.E.
Atlanta, Georgia 30309

BALTIMORE 900 Madison Avenue
Baltimore, Maryland 21201

BOSTON 585 Commercial Street
Boston, Massachusetts 02109

BUFFALO 599 Delaware Avenue
Buffalo, New York 14202

CHICAGO Main Post Office Bldg.
Rm. 1222/433 W. Van Buren Street
Chicago, Illinois 60607

CINCINNATI 1141 Central Parkway
Cincinnati, Ohio 45202

DALLAS 3032 Bryan Street
Dallas, Texas 75204

DENVER New Customhouse Bldg.
Rm. 5604/20th & California Streets
Denver, Colorado 80202

DETROIT 1560 E. Jefferson Avenue
Detroit, Michigan 48207

KANSAS CITY 1009 Cherry Street
Kansas City, Missouri 64106

LOS ANGELES 1521 W. Pico Boulevard
Los Angeles, California 90015

MINNEAPOLIS 240 Hennepin Avenue
Minneapolis, Minnesota 55401

NEW ORLEANS U.S. Customhouse
Rm. 222/423 Canal Street
New Orleans, Louisiana 70130

NEW YORK 850 3rd Avenue (at 30th Street)
Rm. 700/Brooklyn, New York 11232

PHILADELPHIA U.S. Customhouse
Rm. 1204/2nd & Chestnut Streets
Philadelphia, Pennsylvania 19106

SAN FRANCISCO Federal Office Bldg.
Rm. 518/50 Fulton Street
San Francisco, California 94102

SEATTLE Federal Office Bldg.
Rm. 501/909 First Avenue
Seattle, Washington 98104

FDA REGIONAL ASSISTANT COMMISSIONERS' OFFICES

REGIONS I-IX

BOSTON J. F. Kennedy Federal Bldg.
Government Center
Boston, Massachusetts 02203

NEW YORK 42 Broadway
New York, New York 10004

CHARLOTTESVILLE 220 7th Street, N.E.
Charlottesville, Virginia 22901

ATLANTA 50 7th Street, N.E.
Rm. 404/Atlanta, Georgia 30323

CHICAGO New Post Office Bldg.
433 W. Van Buren Street
Chicago, Illinois 60607

KANSAS CITY 601 East 12th Street
Kansas City, Missouri 64106

DALLAS 1114 Commerce Street
Rm. 911/Dallas, Texas 75202

DENVER Federal Office Bldg.
19th & Stout Streets
Denver, Colorado 80202

SAN FRANCISCO Federal Office Bldg.
Rm. 416/50 Fulton Street
San Francisco, California 94102

state actions

Connecticut Commission Reorganized Connecticut State Consumer Protection Commissioner James J. Casey reorganized the Commission's food and drug divisions in February. Both divisions were placed under one director. Former food division chief Eaton E. Smith became director of food and drugs and former senior food inspector Kenneth W. Crane became provisional chief of the food division. Mr. Casey indicated the changes will make for better administrative efficiency and that the new structure parallels the Federal food and drug organizational structure and the structures of 30 other States.

Milk Producers Restrained The Montana Livestock Sanitary Board has issued restraining orders against three Grade A dairy farmers in the Bozeman area. The Board found heptachlor epoxide and chlordane residues by routine sampling. Seattle District has confirmed heptachlor epoxide residues in the milk and chlordane residue on alfalfa hay. The State intends to take samples from all producers in the Bozeman area and issue restraining orders against any producer where excessive residues are found. Seattle District is assisting the State by analyzing check and overload samples and by field investigation.

Firm Ordered to Cease Repackaging Working together, the New Jersey State Department of Health and FDA's New York District have stopped a New Jersey firm from shipping drugs adulterated with toxic pesticide chemicals. During a joint inspection of Octagon Process, Inc., Edgewater, N.J., FDA Inspectors confirmed that the company was repacking glycerin, petrolatum, and mineral oil with the same equipment used to manufacture agricultural poisons. Samples of the drugs collected as part of the investigation

were found to be adulterated with malathion, lindane, and DDT. All the suspect drug products were being shipped to the Veterans Administration for use in Government facilities. FDA notified the VA, which froze all stocks in its supply depots and notified all of its hospitals to which the product had been consigned.

Dr. Roscoe P. Kandle, Commissioner of Health, State of New Jersey, ordered on February 29 that the firm cease processing drugs effective March 1 until it could adequately comply with current good manufacturing practices. His action was the first order under the new "Single System Concept" (see accompanying story).

New 'Single System' Compliance Program Started A new "Single System Concept" compliance program involving Federal and State agencies is being started in New York and New Jersey.

FDA's Region II Assistant Commissioner, Ralph Bernstein, is supervising the State-Federal consumer protection program. Broadly speaking, the Single System Concept employs both State and Federal resources as a single shield for the consumer instead of duplicated effort. Emphasis is on the major problem areas.

A joint team from FDA's New York and Philadelphia Districts is holding discussions on the program with New Jersey officials, and a joint team from New York and Buffalo Districts similarly is talking to New York State officials.

In outlining the Single System, FDA refers to the "Six C's": common program objectives, cooperative attitudes, communications, comparability (i.e., equivalency of personnel and compatibility in data presentation), continuity, and compliance.

The teams are discussing such ef-

forts as tying the States into the FDA teletype network for instantaneous transmittal of vital data (already done); matching problem and commodity codes for compatible data retrieval; exchanging total information on establishments; establishing joint inspection teams; setting up an intensive joint training program; exchanging key staff members between States and FDA; and combining establishment inventories.

The first action against a firm under the Single System Concept took place February 29, when the New Jersey State Commissioner of Health ordered a drug and pesticide manufacturing firm to cease repacking drugs until this operation could be separated from that involving pesticides (see accompanying story).

FDA Commissioner James L. Goddard congratulated the New Jersey official on his decision and added in his telegram: "This was a very fine example of Federal-State partnership in action. This first order under 'Single System Concept' will most assuredly mean greater public protection through your Department's efforts."

Drug Company Closing A New York drug company is closing its business. Isaac Zonana, doing business as Bronx Drug Co., Bronx, N.Y., was called to a New York State Board of Pharmacy hearing in February. He did not appear, but his attorney entered a plea of no contest to charges of unprofessional conduct in illegal drug sales (see story in April 1968 FDA PAPERS). The attorney indicated that Mr. Zonana and the firm would surrender their licenses as manufacturer and wholesaler in New York State. The firm is now liquidating its stock. Representatives of FDA's New York District and the Board of Pharmacy will examine the entire stock and cause all misbranded or adulterated drugs to be destroyed prior to the auction.

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 60 seizure actions to remove adulterated, misbranded, and unsafe products from the consumer market were reported in February. These included 23 seizures of foods: 1 because of poisonous and deleterious substances, 18 because of contamination, and 4 because of economic

violations. Other seizures included 3 of vitamins and dietary foods, 20 of drugs (including 1 of medicated feed), 5 of medical devices (including 1 prophylactic), and 9 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD / Poisonous and Deleterious Substances		
Butter-Sugar Mix/Salt Lake City, Utah 2/6/68	Amtraco Commodity Corp./New York, N.Y. (S)	Contains BHC, an unsafe pesticide chemical.
Contamination, Spoilage, Insanitary Handling		
Beans, Cookquik, Great Northern/East St. Louis, Ill. 2/16/68	Gaylor-Fox Wholesale Grocer Co./East St. Louis, Ill. (D)	Held under insanitary conditions.
Candy Ingredients/Laredo, Tex. 12/18/67	Imported from Mexico (M, S)	Prepared and packed under insanitary conditions.
Carnation Instant Breakfast/Denver, Colo. 2/20/68	Carnation Co./St. Joseph, Mo. (S)	Insect contaminated.
Coffee beans, green/Port Allen, La. 2/20/68	Greater Baton Rouge Port Commission/Port Allen, La. (D)	Held under insanitary conditions; bird contaminated.
Dutch Village Home Style Cookies/Paramount, Calif. 1/24/68	Bakkers Royal Dutch Cookies, Inc./Draper, Utah (M, S)	Prepared and packed under insanitary conditions.
Filberts/Denver, Colo. 2/8/68	Dundee Nut Growers/Dundee, Oreg. (M, S)	Prepared and packed under insanitary conditions; E. coli.
Pecan(s)/Indianapolis, Ind. 2/6/68	Roper Pecan Co./Hickman, Ky. (M, S)	"
pieces/St. Louis, Mo. 2/5/68	Raymond & Chas. Foti Pecan Co./St. Martinsville, La. (S)	Insect contaminated.
Perch fillets/Detroit, Mich. 2/21/68	East Erie Packing Co./Port Dover, Ontario, Canada (P)	Contain decomposed fish.
Popcorn and cornmeal/Vicksburg, Miss. 2/8/68	P. P. Williams Co./Vicksburg, Miss. (D)	Held under insanitary conditions; rodent contaminated.
Pretzels, citric acid, sodium bisulfite/Kaysville, Utah 2/7/68	Clover Club Foods Co., Inc./Kaysville, Utah (D)	"
Rice/Philadelphia, Pa. 2/5/68	Comet Rice Mills, Inc./Stuttgart, Ark. (S)	Prepared and packed under insanitary conditions.
Kan-Tung/Miami, Fla. 2/8/68	Great Southern Wholesale Grocery Corp./Miami, Fla. (D)	Held under insanitary conditions.
Patna/Santa Barbara, Calif. 12/27/67	Chef's Vendors, Inc./Santa Barbara, Calif. (D)	"
brown, long grain/Los Angeles, Calif. 1/18/68	Kahan & Lessin Co., Inc./Los Angeles, Calif. (D)	"
Shrimp meat, frozen/Newport Beach, Calif. 12/12/67	Astoria Sea Food/Charleston, Oreg. (S)	High total bacteria count.
Wheat flour/Santa Barbara, Calif. 12/27/67	Chef's Vendors, Inc./Santa Barbara, Calif. (D)	Held under insanitary conditions.
germ/Los Angeles, Calif. 1/18/68	Kahan & Lessin Co., Inc./Los Angeles, Calif. (D)	"
Economic Violations		
Cheddar cheese, unsalted/Los Angeles, Calif. 1/16/68	L. D. Schrieber Cheese Co., Inc./Green Bay, Wis. (M, S)	Not in conformity with definition and standard for cheddar cheese because it has not been salted as required by regulation.
Diet cookies/Boston, Mass. 1/2/68	Prince Butter Cookie Co., Inc./Brooklyn, N.Y. (M, S)	Label falsely represents article as valuable for weight reduction and control.
Ocean Delight Herring Snacks, in soybean oil/Chicago, Ill. 2/7/68	Port Clyde Packing Co., Inc./Port Clyde, Maine (M), shipped from Hicksville, N.Y.	False and misleading claims to be of unique nutritional benefit.
Tomato juice/Williamsburg, Ky. 1/19/68	Kenneth N. Rider Co., Inc./Trafalgar, Ind. (S)	Inaccurate statement of quantity of contents.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Vitamins—Dietary Food		
Albetal vitamin-mineral capsules, Estro-X tablets, High Potency B-Complex tablets, Therinall vitamin-mineral tablets/Saugus, Calif. 12/14/67	Rider's Ltd./Saugus, Calif. (D)	Not in conformity with regulations. Therinall tablets contain an unsafe food additive—potassium iodide; inadequate labeling information and full disclosure.
Multivitamins, vitamin B and vitamin C/Wausau, Wis. 2/19/68	B & B Distributors/Wausau, Wis. (D)	Moldy and water-damaged containers and labels.
Nu-Youth Gland Food/Marion, Ohio 2/12/68	Nu-Youth Products Co./Marion, Ohio (D)	False and misleading claims to have special effect on glands, to regenerate sterile sexual organs.
DRUGS / Human Use		
Aspirin/New Castle, Ind. 2/6/68	Plymouth Laboratories, Inc./Plymouth, Mich. (M, S)	Below USP standards of strength and quality.
Bacitracin ointment/Canton, Mass. 1/30/68	McKesson & Robbins, Inc./Fairfield, Conn. (M, S)	Below labeled potency.
Bon Coif Hair Conditioner, Color Booster, Shampoo, Hair Creme, and Magique Creme/Mesa, Ariz. 1/25/68	L. T. Products, Ltd./Los Angeles, Calif. (S)	False and misleading claims to promote hair growth, eliminate dandruff, to treat blackheads, acne, and externally caused skin problems.
C. T. White Sulfisoxazole tablets/Maryland Heights, Mo. 1/24/68	Shaw Pharmacal Co./Maryland Heights, Mo. (D)	Below USP standard of strength.
Elastoplast Coverlets and Bandages/Los Angeles, Calif. 11/30/67	Duke Laboratories, Inc./South Norwalk, Conn. (S)	Below USP quality standard; nonsterile; no indication on label that the shipper is not the manufacturer.
Fem Glan dextro-amphetamine—estrogenic substance/Glendale, Ariz. 12/19/67	Nacrison Vial Co./Chicago, Ill. (M, S)	New drug not approved for safety and efficacy.
Lithium Carbonate tablets/Omaha, Nebr. 2/15/68	Bernard Co./Omaha, Nebr. (D)	New drug not approved for safety and efficacy.
Liver injection/Whittier, Calif. 1/22/68	Hillco Drug Distributors, Inc./Whittier, Calif. (D)	Below NF standard of potency.
Mammary substance/St. Louis, Mo. 2/16/68	Knight Drug Co./St. Louis, Mo. (D)	Inadequate directions for use; adequate directions cannot be written, since this is a glandular substance.
Methyltestosterone/Monrovia, Calif. 1/24/68	Town Paulsen & Co./Monrovia, Calif. (D)	Below NF standard of potency; inadequate full disclosure.
Mycaloid tablets, Unitrim capsules/Glendale, Ariz. 2/6/68	Myers-Carter Laboratories, Inc./Glendale, Ariz. (D)	Mycaloid tablets falsely represented as effective in the treatment of hypothyroidism and as a metabolic stimulant; Unitrim capsules—for the treatment of obesity; Mycaloid tablets are dangerous to health when used as recommended in the labeling.
Oti-Fungal/Jacksonville, Fla. 2/26/68	Table Rock Laboratories, Inc./Greenville, S.C. (M, S)	New drug not approved for safety and efficacy.
Parkquad No. 3/Morgantown, W.Va. 3/5/68	Milan Pharmaceuticals, Inc./Morgantown, W.Va. (M, S)	False and misleading claims for treatment of simple obesity; inadequate directions for use.
Sodium butabarbital tablets/Maryland Heights, Mo. 2/7/68	Shaw Pharmacal Co./Maryland Heights, Mo. (D)	Below NF standard of potency.
Thermatalis tablets and capsules, powdered digitalis/St. Louis, Mo. 2/23/68	Mills Pharmaceutical, Inc./St. Louis, Mo. (D)	Inadequate directions for use; dangerous to health when used as recommended in the labeling; insufficient labeling information.
Thyalis, C.T., S.C., E.C./Richmond, Va. 2/16/68	Lanpar Co./Dallas, Tex. (M, S)	False and misleading claims for treatment of hypothyroidism; dangerous to health when used as recommended in the labeling; inadequate labeling information; no prescription legend.
Thyroid tablets, thyroid-digitalis tablets/Las Vegas, Nev. 1/29/68	Associated Researchers, Inc./Las Vegas, Nev. (D)	Inadequate directions for use; dangerous to health; false and misleading claims.
Thyroid capsules and tablets, phenobarbital, dextro-amphetamine sulfate, butabarbital, thyroid & digitoxin/Albuquerque, N. Mex. 2/8/68	Calvin Scott & Co., Inc./Albuquerque, N. Mex. (D)	Repack drugs and labels fail to bear required information and warnings; drugs are dangerous when used in the dosage and with the frequency or duration recommended.
Thyroid-digitalis/Phoenix, Ariz. 2/23/68	Panthera Pharmacal/Phoenix, Ariz. (D)	False and misleading claims for treatment of amenorrhea and a variety of diseases unrelated to thyroid function; inadequate labeling information.
Veterinary / Medicated Feed		
Guido (vet drug)/Omaha, Nebr. 2/13/68	Anthony Products Co./El Monte, Calif. (M, S)	Inadequate directions for use; no prescription legend.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
MEDICAL DEVICES		
Good Sleep/San Diego, Calif. 10/17/67	Imported from Japan (M, S)	False and misleading claims to induce sleep.
Hydro Massage/Los Angeles, Calif. 2/1/68	Splendour Products/St. Petersburg, Fla. (M, S)	False and misleading claims to treat nervous tension, pains of rheumatism, arthritis, bursitis, eliminate discomfort of fractures, hemorrhoids.
Ped-A-Massage/Wichita, Kans. 2/21/68	Posture Massage Manufacturing Co./ Oklahoma City, Okla. (M, S)	Inadequate directions and warnings.
Vita Master Belt Massager, Exercise Bicycle/ Des Moines, Iowa 1/18/68	T. J. Thomas Co., Brooklyn, N.Y. (M, S)	False and misleading claims; inadequate warning statements.
Prophylactics		
Rubber/Jackson, Miss. 2/16/68	Akwell Corp./Dothan, Ala. (M)	Defective; holes.
HAZARDOUS SUBSTANCES		
Color Spray All-Enamel/Jacksonville, Fla. 2/26/68	Chase Products Co./Broadview, Ill. (M, S)	Lacks consumer protection information required by the Fed. Hazardous Substances Act.
Firecrackers/Bamberg, S.C. 2/7/68	B. Lloyd's/Bamberg, S.C. (D)	"
Fireworks, Bomb Aerial, Super Salutes, Skyrockets, Shot Bomb/Charleston, S.C. 1/12/68	Naval Weapons Station, Ammunition Magazine, Charleston, S.C. (D)	"
Cherry Flash Salutes, Super Bull Dog Salutes, M-80 Firecrackers/Gaffney, S.C. 2/7/68	Campbells Wholesale Fireworks/Gaffney, S.C. (D)	"
Globe Torpedoes, Silver Salutes, Cherry Flash Salutes, M-80's/Olanta, S.C. 2/7/68	Mac's Gulf Service Station/Olanta, S.C. (D)	"
Summerton, S.C. 2/7/68	Stuckey's/Summerton, S.C. (D)	"
Super 2" Flashlight Crackers, American Buffalo/Santee, S.C. 2/7/68	B. Lloyd's/Santee, S.C. (D)	"
Inknix/Culver City, Calif. 2/7/68	Max J. Swarner & Co./Dallas, Tex. (M, S)	"
Sneezing Powder/Greensboro, N.C. 2/13/68	Fred Alan Novelty Co., Inc./Greensboro, N.C. (D)	"

POST OFFICE DEPARTMENT actions taken in medical cases under provisions of the Postal Fraud Statutes as reported by the Chief Postal Inspector.

Arrests, Indictments, or Convictions Occurring Under 18 U.S.C. 1341 (Fraud)

February 12, 1968: On this date at Sioux City, Iowa, one of the 22 defendants indicted (chiropractors and chiropractic students) in July 1967 on charges of mail fraud, fraud by wire, and conspiracy, changed his plea of not guilty to guilty on two counts of the indictment. The scheme alleged involves the obtaining of Basic Science Certificates from Basic Science Boards in certain States by false and fraudulent pretenses and representations.

March 4, 1968: After a 30-day trial in Federal court, New York, N.Y., ending March 4, 1968, **Doctors Bernarr Zovluck and Alvin Eisenstein**, chiropractors, and **Mrs. Ann Friedman**, Zovluck's sister, were found

guilty of charges, including mail fraud and conspiracy. On March 13, 1968, after a further trial, Dr. Eisenstein was found guilty of assault upon a U.S. Marshal. The assault was incident to arrest of Dr. Zovluck in June 1967 and the subsequent search of his offices. The three are scheduled for sentencing on April 15, 1968. The scheme involved the exploitation of poorly educated and low-income persons by means of unneeded treatments; expensive and unnecessary X-rays; worthless vitamin tablets at a cost of up to \$27.50 a bottle; suggestions that failure to have treatments might result in total disability; harrassing telephone calls regarding payment of account, etc.

notices of judgment

NOTICES OF JUDGMENT On Seizure Actions

FOOD / Poisonous and Deleterious Substances

- Beans, garbanzo, dried**, at New Orleans, E. Dist. La.
Charged on or about 1-27-67: while held by L. H. Hayward & Co., New Orleans, La., the article contained the pesticide chemical DDT in excess of the tolerance, and the article was held under insanitary conditions; 402(a)(2)(B), 402(a)(4). Consent decree authorized release to dealer for salvaging. (1)
- Brazil nuts, unshelled**, at Los Angeles, C. Dist. Calif.
Charged 2-1-67: while held for sale, the article contained an added poisonous and deleterious substance, aflatoxin; 402(a)(1). Consent decree authorized release to Los Angeles Nut House, Los Angeles, Calif., for salvaging. (2)
- Eggs, frozen, and egg whites, frozen**, 2 seizure actions at Newport and Providence, Dist. R. I.
Charged 2-15-67 and 2-20-67: when shipped by J. Fleishman & Co., Inc., Roxbury, Mass., the articles contained an added poisonous and deleterious substance, *Salmonella* micro-organisms; 402(a)(1). Default decrees ordered destruction. (3)
- Lettuce**, at New York, S. Dist. N.Y.
Charged on about 11-22-66: when shipped by Western Growers Distributing Co., Glendale, Ariz., the article contained a quantity of the pesticide chemical toxaphene in excess of the tolerance; 402(a)(2)(B). Default decree ordered destruction. (4)

FOOD / Contamination, Spoilage, Insanitary Handling

- Beans, pink**, at San Juan, Dist. P. R.
Charged 3-31-67: while held for sale, the article contained insect filth; 402(a)(3). Consent decree authorized release to José Malgor & Co., Inc., for salvaging. (5)
- Beans, pinto**, at Charleston, S. Dist. W. Va.
Charged on or about 9-18-64: while held by Dan Williams Brokerage Co., Charleston, W. Va., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (6)
- Beans, pinto**, at Topeka, Dist. Kans.
Charged 5-6-65: when shipped by Z & W Milling & Refining Co., Inc., Torrington, Wyo., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for salvaging. (7)
- Butter**, 2 seizure actions, at Hagerstown, Dist. Md.
Charged 4-20-66 and 4-28-66: while held by Potomac Creamery Co., Inc., Hagerstown, Md., after being prepared and packed from products shipped in interstate commerce, the article contained decomposed butter or cream, and one lot consisted of a product containing less than 80 percent by weight of milk fat which had been substituted for butter; 402(a)(3), 402(b)(2). Consent decrees authorized release to dealer for salvaging. (8)
- Candy**, at Portland, Dist. Maine.
Charged 3-1-67: when shipped by Matthews Candy Co., Dallas, Tex., the article, labeled "Peanut Candy Crunch," Humpty Dumpty Potato Chip Co. Distributors Portland, Maine, contained rodent filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (9)
- Cheese food, grated**, at Dallas, N. Dist. Tex.
Charged 2-24-67: while held by Norris Dairy Products, Inc., Dallas, Tex., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (10)
- Cocoa powder**, at Los Angeles, C. Dist. Calif.
Charged 3-13-67: while held by Overland Terminal Warehouse, Los Angeles, Calif., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (11)
- Cornhusks**, 3 seizure actions, at San Jose and Stockton, N. Dist. Calif., and Los Angeles, S. Dist. Calif.
Charged 5-17-63, 6-10-63, and 8-8-63: when shipped by Merced Torres, Jalisco, Mexico, the article, labeled "Corn Husks Product of Mexico . . . A. E. Sanchez, Importer," contained insect filth; 402(a)(3). Consent decrees authorized release to Merced Torres and A. E. Sanchez for reconditioning. (12)
- Crackers, cookies, and rolled oats**, at Los Angeles, C. Dist. Calif.
Charged 9-21-66: while held by Dart Warehouse Corp., Los Angeles, Calif., the articles contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (13)
- Donut mix**, at Waynetown, S. Dist. Ind.
Charged 2-15-67: while held by Boldt Milling Co., Inc., Waynetown, Ind., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (14)
- Eggs, frozen**, at Brooklyn, E. Dist. N.Y.
Charged 12-13-66: when shipped by Nulaid Farmers Association, Pacific Growers, San Leandro, Calif., the article contained decomposed eggs; 402(a)(3). Consent decree authorized release to Pacific Growers for salvaging. (15)
- Eggs, frozen**, at Chicago, N. Dist. Ill.
Charged 12-22-66: when shipped by Pacific Growers, San Leandro, Calif., the article contained decomposed eggs; 402(a)(3). Consent decree authorized release to I. Schneider Co., Div. of On/Cor Frozen Foods, Inc., for salvaging. (16)
- Flour, donut mix, and nonfat dry milk**, at Indianapolis, S. Dist. Ind.
Charged 5-5-65: while held by Koehler's Wholesale Restaurant Supply, Indianapolis, Ind., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (17)
- Macaroni, rice, and raisins**, at Lenoir, W. Dist. N.C.
Charged on or about 11-29-66: while held by City Flour & Feed Co., Inc., Lenoir, N.C., the articles contained insect filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered release to charitable institution for use as animal feed. (18)
- Margarine**, at Augusta, S. Dist. Ga.
Charged 6-21-66: when shipped by Shedd-Bartush Foods, Inc., Greenville, S. C., the article had been prepared, packed, and held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (19)
- Peanuts, shelled**, at Oakland, N. Dist. Calif.
Charged 3-22-67: while held by Granny Goose Foods, Inc., Oakland, Calif., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to California Packing Corp., San Francisco, Calif., for salvaging. (20)
- Peanuts, shelled**, at Riverdale, N. Dist. Ill.
Charged 6-14-66: when shipped by Dixie Peanut Co., Fitzgerald, Ga., the article contained insect filth and was prepared, packed, and held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for reconditioning. (21)
- Pecan pieces**, at Fort Worth, N. Dist. Tex.
Charged 3-13-67: when shipped by Wynnewood Pecan Co., Wynnewood, Okla., the article contained *E. coli* and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (22)

- Pecan pieces**, at Mansfield, W. Dist. La.
Charged 3-13-67: when shipped by, and thereafter returned to, Louisiana Pecan Shelling Co., Mansfield, La., 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 salvaging. (23)
- Pecan pieces**, at Phoenix, Dist. Ariz.
Charged 3-14-67: when shipped by Azar Bros., El Paso, Tex., the article contained *E. coli* and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (24)
- Pecans, unshelled**, 4 seizure actions at Fort Worth, N. Dist. Tex.
Charged 5-17-65: while held by United States Cold Storage Corp., Fort Worth, Tex., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decrees authorized release to H. C. Minton, Fort Worth, Tex., R. B. Bagley & Sons, San Saba, Tex., Sunshine Pecan Co., San Antonio, Tex., and Sam H. Rahl & Co., Goldthwaite, Tex., for salvaging. (25)
- Pepper strips, red, canned**, at Everett, Dist. Mass.
Charged 2-27-67: while held for sale, the article contained decomposed red pepper strips; 402(a)(3). Default decree ordered destruction. (26)
- Popcorn**, at Springfield, W. Dist. Mo.
Charged 12-14-65: while held for sale, the article contained insect filth; 402(a)(3). Default decree authorized donation to public/charitable institution for conversion into animal feed. (27)
- Pork luncheon meat, canned**, at Buffalo, W. Dist. N.Y.
Charged 4-3-67: while held for sale, the article contained decomposed meat; 402(a)(3). Default decree ordered destruction. (28)
- Potatoes, dehydrated**, at Trenton, W. Dist. Mo.
Charged 3-23-67: when shipped by Idaho Potato Foods, Inc., Idaho Falls, Idaho, the article contained *E. coli* and bacterial filth; 402(a)(3). Default decree ordered destruction. (29)
- Tomatoes, canned, Powhatan**, at Statesville, W. Dist. N. C.
Charged 4-20-67: when shipped by Dade Farms, Inc., Princeton, Fla., the article contained insect filth; 402(a)(3). Default decree ordered release to charitable institution for use as animal feed. (30)
- Tomatoes, canned, Red-Glo and Pride of the Farm**, 2 seizure actions at Florence and Bennettsville, Dist. S. C.
Charged 5-29-67: when shipped by Homestead Canning Co., Homestead, Fla., the article contained insect filth; 402(a)(3). Default decrees ordered destruction. (31)
- Wheat**, at Spokane, E. Dist. Wash.
Charged 4-22-66: when shipped by Leeds Elevator Co., Leeds, N. Dak., the article contained rodent filth; 402(a)(3). Consent decree authorized release to shipper and J. & O. Grain Co., Minneapolis, Minn., for conversion into animal feed. (32)
- Whitefish, frozen**, at Chicago, N. Dist. Ill.
Charged on or about 2-13-67: when shipped by Canadian Fish Producers, Winnipeg, Canada, the article contained parasitic cysts; 402(a)(3). Consent decree authorized release for exportation to the shipper. (33)

FOOD / Economic and Labeling Violations

- Applejuice**, at Los Angeles, C. Dist. Calif.
Charged 5-27-66: when shipped by Skyland Food Corp., Delta, Colo., the article was short in volume (approx. 1.5 to 3 percent); 403(e)(2). Consent decree authorized release to shipper for salvaging. (34)
- Apricots, canned**, at Louisville, W. Dist. Ky.
Charged 9-21-66: when shipped by USP Corp., San Jose, Calif., the article labeled "Iona for 'A & I' Apricots . . . The Great Atlantic & Pacific Tea Co., Inc., N.Y., N.Y. Distributor" fell below standard of fill, since the quantity of apricot ingredient was less than that prescribed, and the label of the Iona brand lacked the name of the optional packing medium "slightly sweetened water" specified in the identity standard, since the label read "In Light Syrup"; 403(h)(2), 403(g)(2). Default decree authorized release to charitable institution. (35)
- Beverage concentrate mixes, orange and grape flavors**, at Catonsville, Dist. Md.
Charged 12-23-66: when shipped by DCA Food Industries, Ellicott City, Md., after having manufactured the article and subsequently reshipped it to Catonsville, Md., the article contained saccharin, sodium and calcium cyclamate which had been substituted for a nutritive sweetener and the name "Beverage Concentrate Orange [or 'Grape']" was false and misleading; 402(b)(2), 403(a). Consent decree authorized release to DCA Food Industries, Inc., New York, N.Y., for relabeling. (36)
- Butter**, at Chicago, N. Dist. Ill.
Charged on or about 4-27-66: when shipped by Meinerz Creamery, Fredericksburg, Iowa, the article contained less than 80 percent by weight of milk fat; 402(b)(2). Consent decree authorized release to Berkshire Foods, Inc., Chicago, Ill., for salvaging. (37)
- Butter, whipped, Challenge**, at Los Angeles, S. Dist. Calif.
Charged 1-25-66: when shipped by Peters Pak, Grand Rapids, Mich., the article's labeling contained false and misleading nutritional and weight control claims; 403(a). Consent decree authorized release to Challenge Cream & Butter Association, Commerce, Calif., for salvaging. (38)
- Candy, lollipops**, at Philadelphia, E. Dist. Pa.
Charged 1-16-67: when shipped by the Mumsey Candy Co., Camden, N.J., the article was short weight (approx. 7 percent); 403(e)(2). Default decree authorized donation to charitable institutions. (39)
- Coffee, instant, Rich-Taste**, at San Francisco, N. Dist. Calif.
Charged 1-10-66: while held by Caswell Coffee Co., San Francisco, Calif., after repackaging, the article was short weight (approx. 4 percent); 403(e)(2). Consent decree authorized release to Western Coffee Instants, Inc., San Francisco, Calif., for salvaging. (40)
- Oysters, canned, Negro Head**, at Houston, S. Dist. Tex.
Charged 2-27-67: when shipped by Aughtabaugh Canning Co., Biloxi, Miss., the article fell below the standard of fill, since the drained weight was less than that prescribed; 403(h)(2). Default decree authorized donation to charitable institution. (41)
- Peanut butter**, at Beaver Heights, Dist. Md.
Charged 10-28-66: when shipped by Old Dutch Foods, Inc., Blasdel, N.Y., the article, labeled in part "Elna Creamy Peanut Butter . . . Elna Brands, Inc. Distributors Skokie, Ill.," was short weight (approx. 2.5 percent); 403(e)(2). Consent decree authorized release to Old Dutch Foods, Inc., for reconditioning. (42)

FOOD ADDITIVES

- Ice elephants, plastic**, at Chicago, N. Dist. Ill.
Charged on or about 6-24-66: when shipped by South Sea Trading Co., Ltd., Hong Kong, China, and an unknown shipper from outside the State of Illinois, the article, labeled in part "Frosty Drink Coolers . . . Water is inside . . . Unique Products, Chicago, Ill.," was a nonconforming food additive (the plastic was thin, leaking in part, and easily punctured and cracked; and the fluid within contained miscellaneous debris and viable micro-organisms); 402(a)(2)(C). Default decree ordered destruction. (43)
- Industrial deodorant**, at Miami, S. Dist. Fla.
Charged 4-27-67: when shipped by Odor-No International, Houston, Tex., the article, labeled in part "O-Dor-No Your Space-age Industrial Deodorant . . . Distributed by Biscayne Chemical Labs, Inc. . . Miami, Florida" and represented for washing down

or sluicing down food equipment and food holding areas, contained the nonconforming food additives, potassium permanganate and chlorotetracycline; and the article's labeling contained false and misleading claims of nonotoxicity and FDA approval; 402(a)(2)(C), 403(a). Default decree ordered destruction. (44)

Oleoresin capsicum and oleoresin ginger, at Detroit, E. Dist. Mich.

Charged 6-1-65: when shipped by Joseph A. Adams, Cleveland, Ohio, the article contained the nonconforming food additive hexane; 402(a)(2)(C). Consent decree authorized release to shipper for reconditioning. (45)

VITAMINS / DIETARY FOODS

Across liquid diet drink, at Los Angeles, C. Dist. Calif.

Charged 9-21-66: while held for sale, the article contained a decomposed substance; 402(a)(3). Default decree ordered destruction. (46)

Crinoad dietary supplement capsules, at Salt Lake City, Dist. Utah.

Charged 12-6-66: while held by W. H. Grew Manufacturing Co., Salt Lake City, Utah, after manufacture from an ingredient shipped in interstate commerce, the article contained the added poisonous and deleterious substance *Salmonella* micro-organisms; 402(a)(1). Default decree ordered destruction. (47)

Vit-Ra-Tox No. 21 GreenLife diet supplement tablets, No. 16 bentonite suspension, No. 53 wheat germ oil combination capsules, and No. 19A laxative herb tablets, at Omaha, Dist. Nebr.

Charged 5-16-62: when shipped by Vita Laboratory Co., Inc., Kansas City, Mo., and/or V. E. Irons, Inc., Boston, Mass., the accompanying brochure "Your Life" and accompanying pamphlet "Hydrated Bentonite" contained false and misleading claims about nearly everyone in this country being in danger of or suffering from malnutrition because of soil depletion and food processing, about tracing human ills to improper nutrition, and about the nutritive treatment and curative properties of Vit-Ra-Tox No. 16 and 21; 502(a). While held for sale, the brochure "Your Life" contained additional false and misleading claims; and the labeling of the articles lacked adequate directions for use for cancer, heart trouble, arthritis, polio conditions, diabetes, mental problems, and other conditions for which the articles were recommended by Paul Zdan and Robert D. Christensen, Omaha, Nebr.; 502(a), 502(f)(1). The articles were claimed by Paul Zdan and Robert Christensen, who subsequently withdrew in favor of W. E. Whitehead, Omaha, Nebr.; W. E. Whitehead withdrew, and Edward F. Fille claimed the articles. After 2 years, Fille moved to have source of the articles destroyed because of deterioration. The Government contested this, and the court denied Fille's motion saying:

"Once an article is seized, the issue of adulteration or misbranding must be determined by the Court. It is only after a decree has been entered that destruction or sale of the seized article may be ordered by the Court. U.S. v. 893 One-Gallon Cans More or Less, etc., labeled Brown's Inhalant [D.C. Del., 1942] 45 F. Supp. 467."

After trial by the court, the Vit-Ra-Tox products Nos. 16, 21, and 53 were found to be misbranded by the brochure "Your Life"; and, by agreement of the claimant, Vit-Ra-Tox product 19A, which the Government failed to prove was misbranded, was acknowledged to be deteriorated and was to be destroyed.

In an opinion of 1-4-67, the court said:

"We find that 'Your Life' is labeling for all of the seized products with the exception of '19A'."

"Claimant's position, that 'Your Life' is labeling for '21' only, would appear to be grounded on the fact that the greater portion of the text is concerned with that product than the others. The brochure is divided into two major sections: . . . Chapter one describes the need for improved nutrition. Chapter two first explains how Vit-Ra-Tox 21 is processed, then why natural vitamins are superior to their synthetic counterpart, and concludes with a section called 'Vit-Ra-Tox Accessory Products.' The final transition is accomplished in this manner:

"Vit-Ra-Tox Accessory Products. Your Automobile has many valuable accessories that add to your pleasure and convenience but are not absolutely essential to your transportation.

"Green Life" [Vit-Ra-Tox No. 21] is the building product of the Vit-Ra-Tox Line but accessories are needed."

"The booklet then describes the entire 'Vit-Ra-Tox Line' [except No. 19A] including those articles seized and subject to this condemnation proceeding. . . .

"The products involved here were orally represented to be an effective cure for everything from a backache to cancer. In a sales pitch, . . . the 'Vit-Ra-Tox' products were represented to be a remedy for several diseases. The sales pitch . . . transcription shows conclusively that the products are drugs. Our finding that the products are drugs, however, need not rest on the sales pitch. The pamphlet, 'Your Life,' implies that 'the products are for use in prevention of disease and they are therefore drugs within the Act's definition. This conclusion remains unaltered by the statement contained in 'Your Life' that '*** Green Life Products are Foods not drugs.' When healing powers are attributed to 'foods,' they become drugs within the meaning of the Act. . . .

"Your Life' is an illustrated pamphlet which describes the need for 'natural' vitamins, a variety which appears to be inaccessible, but for 'Vit-Ra-Tox 21.' The need described is couched in terms of emergency and is obviously intended to place the reader in fear of his well-being. . . .

"The message conveyed by the first chapter of 'Your Life' is that a great majority of our population are sick; that poor nutrition is the primary source of the illnesses; that processed food is the cause of our nutritional problems; and that synthetic vitamins are not up to the job. Chapter II then explains why the Vit-Ra-Tox program is the only available solution to the dilemma described in Chapter I.

"We have concluded that the booklet 'Your Life' is misleading. We have not decided that any particular statement or portion of its text makes it objectionable, rather that the brochure as a whole distorts the truth, and if accepted at face value, would mislead the reader." (48)

ANIMAL FEEDS

Antibiotic feed concentrate, at Cairo, M. Dist. Ga.

Charged 1-24-67: while held for sale, the circumstances of the article's holding so that it became water damaged lacked conformity with current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (49)

Co-op Chick Pre-starter, at Eagle Grove, N. Dist. Iowa.

Charged on or about 1-27-67: while held by Boone Valley Cooperative Processing Association, Eagle Grove, Iowa, after manufacture in part from an ingredient shipped in interstate commerce, the article was deficient in strength, and the labeling was false and misleading, since the article was deficient in amprolium (approx. 40 percent); and the article lacked exemption from antibiotic certification; 501(c), 502(a), 502(l). Default decree ordered destruction. (50)

Co-op Chick Starter, at Cheraw, Dist. Colo.

Charged 2-3-67: while held by Farmland Industries, Inc., Cheraw, Colo., after having manufactured the article from an ingredient shipped in interstate commerce, the article was deficient in strength, and the labeling was false and misleading, since the article was deficient in amprolium (approx. 29 percent); and the article lacked exemption from antibiotic certification; 501(c), 502(a), 502(l). Default decree ordered destruction. (51)

Hubbard Sunshine Medicated Feed, at De Smet, Dist. S. Dak.

Charged on or about 1-19-67: when shipped by Hubbard Milling Co., Mankato, Minn., the article's strength was deficient and its label was false and misleading, since it was deficient in diethylstilbestrol; 501(c), 502(a). Consent decree authorized release to shipper for remilling. (52)

Medicated feed concentrate, at Cheraw, Dist. Colo.

Charged 2-2-67: when shipped by Farmland Industries, Inc., Muncie, Kans., the article labeled in part "Co-op Chick Feed Fortifier . . . Manufactured by Consumers Cooperative Association . . . Kansas City, Mo." had a strength which differed from that which it purported to have and the label was false and misleading, since the article was deficient in amprolium; and the article (which contained bacitracin) lacked exemption from antibiotic certification; 501(c), 502(a), 502(l). Default decree ordered destruction. (53)

Nutrena egg ration, at Hankinson, Dist. N. Dak.

Charged 2-16-67: when shipped by Cargill, Inc., Gluek, Minn., the strength of the article was deficient and the labeling was false and misleading, since the article con-

tained about 3.8 percent arsenic acid, and the labeling contained false and misleading egg production and feed efficiency claims; 501(c), 502(a). Consent decree authorized release to Cargill, Inc., for reworking. (54)

Nutrena Poultry and Swine Medicated Rx feed, at Lennox, Dist. S. Dak.

Charged 2-14-66: when shipped by Nutrena Mills, Sioux City, Iowa, the article contained the nonconforming food additive arsenic acid, and the label was false and misleading, since the article had an excess amount of arsenic acid (approx. 38 percent); 402(a)(2)(C), 501(c), 502(a). Consent decree authorized release to Nutrena Mills Div., Cargill, Inc., for reconditioning. (55)

Sweet Pig Formula medicated pellets and Pig Formula 'One Three' medicated feed, at Downsville, W. Dist. Wis.

Charged 1-18-67: when shipped by Land O'Lakes Creameries, Inc., Minneapolis, Minn., the strength was deficient and the labeling was false and misleading, since both articles were deficient in penicillin (approx. 62 percent); and the Formula 'One Three' was deficient in chlorotetracycline (approx. 42 percent); and the articles lacked exemption from antibiotic certification; 501(c), 502(a), 502(l). Default decree ordered donation to public/charitable institution on condition that the institution be warned of the articles' deficiencies. (56)

Wayne Tail Curler feed, at Covington, S. Dist. Ind.

Charged 2-17-67: when shipped by Allied Mills, Inc., Peoria, Ill., the article was deficient in strength and the labeling was false and misleading, since the article was deficient in penicillin (approx. 38 percent); and the article lacked exemption from antibiotic certification; 501(c), 502(a), 502(l). Default decree ordered destruction. (57)

DRUGS / Human Use

Alergimist intranasal solution A, at Wichita Falls, N. Dist. Tex.

Charged on or about 7-13-66: when shipped by the Brunson Corp., Miami, Fla., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (58)

Alpha Dex 1A, Chemidex Forte, Alpha Dex Forte #3, and Chemidrine Forte #1, at Gardena, S. Dist. Calif.

Charged 5-12-66: while held by Chemico of Gardena, Gardena, Calif., after having been manufactured in California on order of the dealer from ingredients shipped in interstate commerce, all the articles were deficient in dextro-amphetamine sulfate (approx. 12, 32, 40, and 28 percent, respectively), and the Chemidex Forte was deficient in phenobarbital (approx. 24 percent); 501(c). Default decree ordered destruction. (59)

Amphetamines, at Santa Paula and Camarillo, S. Dist. Calif.

Charged 6-20-66: while held by George E. Miller, D.S.C., Santa Paula and Camarillo, Calif., the article was possessed for sale outside the ordinary and authorized course of the individual's professional practice; 301(q)(3). Default decree ordered destruction. (60)

Amphetamine, barbiturate, and other depressant or stimulant drugs, at Plainfield, Dist. N.J.

Charged 12-29-66: while held by Plainfield Surgical Supply Co., Plainfield, N.J., complete and accurate record and disposition records of all such drugs were not prepared and kept; 301(q)(4). Default decree ordered destruction. (61)

Amphetamine, barbiturate, and other depressant or stimulant drugs, at Marshall, E. Dist. N.C.

Charged 8-2-66: while held by Moore's Pharmacy, Marshall, N.C., the articles were possessed for sale outside the ordinary and authorized course of the dealer's business; 301(q)(3). Consent decree ordered destruction. (62)

Amphetamine, barbiturate, and other depressant or stimulant drugs, at Norwalk, Dist. Calif.

Charged 4-12-67: while held by William B. Hogue, D.O., Norwalk, Calif., 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. (63)

Cellustop capsules, at Yauco, Dist. P.R.

Charged 12-27-66: while held by Dr. Juan G. Vasquez, t/a J.G.V. Pharmacal, Yauco, P.R., after being manufactured on order of the dealer from ingredients shipped in interstate commerce, the article's quality was deficient because of tablet weight variation, the labeling contained false and misleading traumatic surgery and cellulitis claims, and the labeling lacked adequate directions for use and did not comply with the exemption requirement for the disclosure of information with respect to an Rx drug which was a new drug; 501(c), 502(a), 502(f)(1). Default decree ordered destruction. (64)

Dibno tablets, at Weaubleau, W. Dist. Mo.

Charged on or about 3-14-63: when shipped by Nysco Labs., Long Island City, N.Y., the article was a new drug without an effective approved New Drug Application—505(a), and while held by Dibno Labs., Weaubleau, Mo., after being in part repacked and relabeled, the dealer's labeling contained false and misleading diabetic claims—502(a). Default decree ordered destruction. (65)

Droga skin care milk, soap, tonic, gel, and cream, at Glendale, C. Dist. Calif.

Charged 7-5-67: when shipped by Les Grands Parfums De France, Lynn, Mass., the labeling of the article labeled in part "Droga Skin Care Cleansing Milk (or 'Creamy Soap', 'Tonic', 'Nourishing Gel', or 'Azuken Cream') Manufactured by Cosma-Droga GMBH, Baden-Baden, Made In W. Germany" contained false and misleading claims for skin health, skin regeneration, and other skin therapy; and the label lacked the established name of each active ingredient; 502(a), 502(e)(1)(A)(ii). Consent decree authorized release to Vincent W. Burke, Lynn, Mass., for relabeling. (66)

GH-4 digestant capsules, Diazym capsules, Four Sixty Five capsules, at Los Angeles, C. Dist. Calif.

Charged 11-3-66: when shipped by W. H. Grew Manufacturing Co., Salt Lake City, Utah, the articles labeled "Besco GH-4 . . . digestant . . . [and 'Besco Diazym']" . . . Distributed by Basic Endocrines Sales Co. Inc. Los Angeles, Calif., were deficient in purity and quality since they contained *Salmonella* micro-organisms—501(c); and the article labeled "Besco Four Sixty Five . . . Distributed by Basic Endocrines Sales Co. Inc." contained the poisonous and deleterious substance *Salmonella* micro-organisms—402(a)(1). Default decree ordered destruction. (67)

Jojoba oil, at Glendale, S. Dist. Calif.

Charged 5-5-66: while held by Ho-Ho-Ba, Inc., Glendale, Calif., the labeling contained false and misleading claims for baldness, cancer, and kidney disease; 502(a). Consent decree authorized release to dealer for salvaging. (68)

Meprobamate tablets, N.F., at South Kearny, Dist. N.J.

Charged on or about 6-1-66: when returned to New Jersey from Chicago, Ill., the article, labeled "From: Riverton Laboratories, Inc., . . . Newark, New Jersey," was a new drug without an effective approved New Drug Application, and the circumstances of the article's manufacture, packing, and holding lacked conformity with current good manufacturing practice; 505(a), 501(a)(2)(B). Default decree ordered destruction. (69)

Mersalyl and theophylline injection, at Los Angeles, C. Dist. Calif.

Charged 4-29-66: when shipped by Philadelphia Labs, Inc., Philadelphia, Pa., the article's quality was deficient, since the article showed evidence of leakage consisting of dried crystalline material around and under cap of vial; and the labeling was false and misleading, since the article was not recognized in the National Formulary; 501(c), 502(a). Consent decree authorized release to shipper for salvaging. (70)

Methioplex, at Athens, E. Dist. Tex.

Charged 3-14-67: when shipped by Lincoln Laboratories, Inc., Decatur, Ill., the article's labeling contained false and misleading therapeutic claims of leakag damage and alcoholism; 502(a). Default decree ordered destruction. (71)

Nasprin acetaminophen tablets, N.F., at East Point, N. Dist. Ga.

Charged 1-5-67: when shipped by Rexall Drug Co., St. Louis, Mo., the article's quality fell below N.F. standards, since the article failed the N.F. disintegration test; 501(b). Default decree ordered destruction. (72)

Nicon oil, at Brooklyn, E. Dist. N.Y.

Charged 6-17-66: when shipped by Harich Chemical Co., Stowe, Pa., the article was a

new drug without an effective approved New Drug Application and was not exempt for investigational use; 505(a). Default decree ordered destruction. (73)

Panbiline solution, at Coral Gables, S. Dist. Fla.

Charged 12-12-66: when shipped by Pharmaceutical Enterprises, Atlanta, Ga., the labeling contained false and misleading hepatic and biliary insufficiency claims, and the labeling lacked adequate directions for the article's intended uses; 502(a), 502(f)(1). Default decree ordered destruction. (74)

Pentaerythritol tetranitrate capsules, at St. Louis, E. Dist. Mo.

Charged 5-15-63: when shipped by Shaw Pharmacal Co., St. Louis, Mo., to Cincinnati, Ohio, and thereafter returned, the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (75)

Potassium chloride tablets, U.S.P., at Dallas, N. Dist. Tex.

Charged 2-8-67: while held by Lanpar Co., Dallas, Tex., after having manufactured the article from potassium chloride crystals shipped in interstate commerce, the circumstances of the article's manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice, and the article's quality fell below U.S.P. standard, since the article failed the U.S.P. disintegration test; 501(a)(2)(B), 501(b). Consent decree ordered destruction. (76)

Prescription drugs, at East Point, N. Dist. Ga.

Charged 1-23-67: while held by City Pharmacy, East Point, Ga., the labeling lacked adequate directions for use and was not exempt therefrom, since the dealer was not a person authorized to possess the article; 502(f)(1). Default decree ordered destruction. (77)

Quindul quinidine sulfate capsules, N.F., at Portland, Dist. Maine.

Charged 12-27-66: when shipped by Brewer & Co., Worcester, Mass., the article's strength differed from N.F. standards, since the article was deficient in quinidine sulfate (approx. 13 percent); 501(b). Default decree ordered destruction. (78)

Rand coupled fortified antigen (RCFA), at Miami, S. Dist. Fla.

Charged on or about 1-20-67: when shipped by Rand Development Corp., Cleveland Ohio, and personally transported by Ernest Ayre, M.D., from Long Island, N.Y., the article was a new drug without an effective approved New Drug Application; the circumstances of the article's manufacture, packing, and processing lacked conformity with current good manufacturing practice; the label lacked the name and place of business of the manufacturer, packer, or distributor; and the label lacked the established name of the article; 505(a), 501(a)(2)(B), 502(b)(1), 502(e)(1)(A)(i). Default decree authorized release to FDA. (79)

Rand coupled fortified antigen (RCFA), at Old Westbury, Long Island, E. Dist. N.Y.

Charged 1-23-67: when shipped by Rand Development Corp., Cleveland, Ohio, the article was a new drug without an effective approved New Drug Application; the circumstances of the article's manufacture, packing, and processing lacked conformity with current good manufacturing practice; the label lacked the name and place of business of the manufacturer, packer, or distributor; and the label lacked the established name of the article; 505(a), 501(a)(2)(B), 502(b)(1), 502(e)(1)(A)(i). Default decree authorized release to FDA. (80)

SafTCell heparin sodium syringes, estradiol valerate syringes, liver injection syringes, prednisolone acetate syringes, and proteolytic enzyme syringes, at Massillon, N. Dist. Ohio.

Charged 10-28-66: when shipped by Safety Syringe Corp., Massillon, Ohio, and thereafter returned to shipper, the articles were new drugs without effective approved New Drug Applications; 505(a). Default decree ordered destruction. (81)

SafTCell testosterone enanthate syringes, at St. Louis, E. Dist. Mo.

Charged 1-6-67: when shipped by Safety Syringe Corp., Massillon, Ohio, the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (82)

Surgidine antiseptic, at Seattle, W. Dist. Wash.

Charged 6-15-66: when shipped by Continental Labs., Inc., Palo Alto, Calif., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (83)

Tincture of iodine, U.S.P., at Seattle, W. Dist. Wash.

Charged on or about 3-15-66: while held by Howe Products, Inc., Seattle, Wash., which manufactured the article from ingredients shipped in interstate commerce, the article's strength differed from U.S.P. standards; 501(b). Default decree ordered destruction. (84)

Trim N' Slim tablets, at Miami, S. Dist. Fla.

Charged on or about 11-12-65: while held by Barry Martin Pharmaceuticals, Inc., Miami, Fla., after repacking, the dealer's labeling contained false and misleading claims for keeping one trim and slim; 502(a). Default decree ordered destruction. (85)

Tyroderm ointment and potassium chloride tablets, U.S.P., at Boston, Dist. Mass.

Charged 9-12-66: while held by A. E. Halperin Co., Inc., Boston, Mass., after being repacked by the dealer, the Tyroderm ointment contained tyrothricin and was not from a certified batch, and the potassium chloride tablets' labeling lacked adequate directions for use and did not comply with the exemption requirement for an Rx new drug for disclosure of information, and the tablets lacked the required prescription legend; 502(l), 502(f)(1), and 503(b)(4). Default decree ordered destruction. (86)

Vaginal jelly, at Dayton, S. Dist. Ohio.

Charged 4-14-67: when shipped by Table Rock Laboratories, Inc., Greenville, S.C., the article, labeled in part "Vaginal jelly . . . Distributed by Moffet Laboratories, Inc., Dayton 4, Ohio," was short weight (approx. 3 percent); 502(b)(2). Consent decree authorized release to Fidelity Medical Supply Co., Dayton, Ohio, for relabeling. (87)

DRUGS / Veterinary

At Last canine filariasis treatment, at Biloxi, S. Dist. Miss.

Charged 10-3-66: when shipped by At Last Laboratories, Theodore, Ala., the article was a new drug without an effective approved New Drug Application; 505(a). Consent decree ordered destruction. (88)

Dog-Tone sulfur combination tablets, at Addison, E. Dist. Mich.

Charged 12-20-63: while held by Hickory Labs., Inc., Addison, Mich., which had packed and labeled the article, its labeling contained false and misleading claims for toning, conditioning, cures, distemper, worms, diarrhea, stomach cramps, fits, and fever in dogs; 502(a). Consent decree ordered destruction. (89)

Piperazine dihydrochloride powder, at Siler City, M. Dist. N.C.

Charged 9-15-66: when shipped by Progress Chemical Co., Canton, Ga., the article contained the nonconforming food additive sevin, and the circumstances of the article's manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice; 402(a)(2)(C), 501(a)(2)(B). Default decree ordered destruction. (90)

Super Speed Anemia Ban injectable, at Omaha, Dist. Nebr.

Charged 10-4-66: when shipped by Anthony Products Co., El Monte, Calif., the article was a new drug without an effective approved New Drug Application, the labeling contained false and misleading claims for treatment of anemia in horses and other animals, and the labeling lacked adequate directions for use; 505(a), 502(a), 502(f)(1). Default decree ordered destruction. (91)

MEDICAL DEVICES

Body energizer device, at Redmond, W. Dist. Wash.

Charged on or about 10-7-66: when shipped by Aquarian Enterprises, Burbank, Calif., the labeling contained false and misleading therapeutic claims; 502(a). Default decree ordered destruction. (92)

Cameron Splitter Ambly-Syntonzonizer device, at North Platte, Dist. Nebr.

Charged 7-27-64: while held by J. O. Jenkins, D. O., North Platte, Nebr., the labeling lacked adequate directions to correct nerve and muscle eye malfunctions; 502(f)(1). Answers to interrogatories were filed by J. O. Jenkins. The Government's motion for summary judgment was granted pursuant to an opinion of the court, 261 F. Supp. 243, and a decree of destruction was entered. (93)

Catheterization sets, at Evanston, N. Dist. Ill.

Charged 10-11-66: when shipped by Pharmasal Labs., Johnson City, Tenn., and Irwindale, Calif., the article's quality was deficient, and the label claim of sterility was false and misleading, because of holes and tears in the packages of the article; 501(c), 502(a). Default decree ordered destruction. (94)

Cervical traction set, at Greeley, Dist. Colo.

Charged 3-16-67: when shipped by Larkotex, Texarkana, Tex., the article's labeling failed to bear adequate directions for use and did not comply with the Rx device exemption requirement; 502(f)(1). Default decree authorized release to FDA. (95)

Eye Sweep device, at Philadelphia, E. Dist. Pa.

Charged 3-8-67: when shipped by Fulton Drug Co., New York, N.Y., the labeling lacked adequate directions and did not comply with the Rx device exemption requirement that the label bear the prescribed prescription legend; 502(f)(1). Default decree ordered that 20 devices be delivered to FDA and that the remainder be destroyed. (96)

Isometric yogi nova device, at Tulsa, N. Dist. Okla.

Charged 6-2-66: when shipped by Akin Distributors of Calif., Inc., Sun Valley, Calif., the labeling of the article labeled "The Isometric Yogi Nova Conditions . . . Lou Nova Enterprises . . . Hollywood 27, California" contained false and misleading therapeutic claims; 502(a). Default decree ordered destruction. (97)

Nusauna bath cabinet, at Beverly Hills, S. Dist. Calif.

Charged 4-27-66: when shipped by Battle Creek Equipment Co., Battle Creek, Mich., the labeling contained false and misleading therapeutic claims, and the labeling lacked adequate warnings against use by elderly persons and those with heart disease and high blood pressure; 502(a), 502(f)(2). Default decree ordered destruction. (98)

Super pulse electronic device, at Cincinnati, S. Dist. Ohio.

Charged 2-28-66: when shipped by Kenneth Webber Industries, Burbank, Calif., the labeling contained false and misleading arthritis, hepatitis, and other therapeutic claims, and the labeling lacked adequate directions and did not comply with the Rx device exemption requirements; 502(a), 502(f)(1). Default decree authorized delivery to FDA. (99)

PROPHYLACTICS

Rubber prophylactics, Royal Knight, at Middletown, S. Dist. Ohio.

Charged 12-9-66: when shipped by Allied Latex Sales Co., Dothan, Ala., the article's quality was deficient, and the labeling was false and misleading, since the article contained holes; 501(c), 502(a). Default decree ordered destruction. (100)

Rubber prophylactics, Trojan-Enz, at Oak Lawn, N. Dist. Ill.

Charged on or about 4-19-67: when shipped by Youngs Drug Products Corp., Newark, N. J., the article's quality was deficient since it contained holes; 501(c). Decree of dismissal without prejudice ordered release to shipper's counsel for testing and destruction. (101)

HAZARDOUS SUBSTANCES

Craftsman silver solder kits and Marquette silver solder, at Minneapolis, Dist. Minn.

Charged 6-20-66: while held by Marquette Corp., Minneapolis, Minn., the articles repacked from bulk lots by the dealer were toxic, and their immediate and outside containers and their accompanying literature lacked the required conspicuous label statements; 2(n)(1)(B, D, E, F, G & J), 2(n)(2), 2(p)(1)(B, D, E, F, G, I & J). Consent decree authorized release to dealer for relabeling. (102)

Marquette stainless steel solder flux, at Minneapolis, Dist. Minn.

Charged 7-5-66: while held by Marquette Corp., Minneapolis, Minn., the article repacked from bulk by the dealer was corrosive, and its containers lacked required conspicuous label statements; 2(p)(1)(B, C, E & G). Default decree ordered destruction. (103)

Old Masters stain, at Corpus Christi, S. Dist. Tex.

Charged 10-15-64: when shipped by Master Products, Nevada, Iowa, the article presented a special hazard by reason of its petroleum distillate content (approx. 55 percent), and its containers lacked required conspicuous label statements; 2(p)(1)(A, B, E, F, G, I & J), 3(b). Consent decree authorized release to Painter's Supply Co., Corpus Christi, Tex., for relabeling. (104)

Qwite laundry detergent booster, at Roanoke, W. Dist. Va.

Charged 10-13-64: when shipped by Calusa Chemical Co., Cincinnati, Ohio, the article had an alkalinity of about 37 percent calculated as sodium hydroxide and was corrosive, and its containers lacked the required conspicuous label statements; 2(p)(1)(B, C, E, F, G & J). Default decree ordered destruction. (105)

COSMETIC

Cinnamon hot toothpicks, 5 seizure actions, at Los Angeles, Vernon, North Hollywood, Long Beach, and Northridge, S. Dist. Calif.

Charged 5-6-66, 5-17-66, and 6-2-66: when shipped by Baden's, Independence, Kans., the article contained an added poisonous and deleterious substance, oil of cinnamon; 601(a). Default decrees ordered destruction. (106)

NOTICES OF JUDGMENT On Criminal Cases

FOOD

Casso, Guerra & Co., Alfonso Casso, partner, and Alfonso I. Casso, partner, Laredo, S. Dist. Tex.

Charged 5-23-67: popcorn and egg noodles were held and stored under insanitary conditions in a building accessible to insects; 402(a)(4). Guilty plea by partnership; fine. Guilty pleas by partners; fines suspended. (107)

Cushing Grocery Co., Inc., Cushing, W. Dist. Okla.

Charged 3-24-67: flour, beans, and popcorn were held in a building accessible to insects and were contaminated by insect filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (108)

Elsa Canning Co., and Carl A. Roettele, president, Elsa, S. Dist. Tex.

Charged 2-9-65 by grand jury: when shipped, Ro Tel brand tomatoes contained decomposed tomatoes; 402(a)(3). Guilty pleas; fines. (109)

F & E Wholesale Grocery, Inc., and Sam F. Farha, vice president, Wichita, Dist. Kans.

Charged 3-29-67: cake, pancake, and donut mixes, and bulghur were held in a building infested with insects and rodents and were contaminated with insect and rodent filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (110)

John Mantia & Sons Co., Inc., and John A. Mantia, corporation clerk, Boston, Dist. Mass.

Charged 5-15-67: when shipped, Georges Bank ocean perch fillets contained copepods (parasites); 402(a)(3). Nolo contendere pleas; fines. (111)

Mountain Pass Canning Co., Inc., Anthony, W. Dist. Tex.

Charged 8-2-67: when shipped, Mountain Pass and Tastewell tomato sauces contained decomposed tomato material; 402(a)(3). Guilty plea; fine. (112)

Weston Biscuit Co. of Texas, Bruce T. Smith, production manager, and L. V. Rhodes, assistant production manager, Waco, W. Dist. Tex.

Charged 7-20-67: when shipped, cookies, labeled in part "Select Assortment . . . Distributed by Value Foods Company, Waco," contained rodent and insect filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty pleas; fines. (113)

DRUGS

Ted A. Adams, student, Lawrence, Dist. Kans.

Charged 6-13-67: LSD was unlawfully possessed and was unlawfully sold, delivered, and disposed of; 301(q)(2), 301(q)(3). Guilty plea; probation. (114)

Armour Pharmaceutical Co., Kankakee, E. Dist. Ill.

Charged 8-19-67: when shipped, chymoral enzyme tablets had advertisements in medical journals that did not fairly present information concerning the drug's efficacy, since such advertisements contained claims of healing speed that were not in the

labeling of the approved New Drug Application and were not supported by the clinical studies submitted as part of such application, and since such advertisements also contained representations contrary to fact that such claims were supported by a specified study; 502(n). Nolo contendere plea; fine. (115)

Edward O. Baldwin, truck-stop employee, Seneca, W. Dist. Mo.
 Charged 12-22-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; probation. (116)

Edwin Brands, plumber, Queens, E. Dist. N.Y.
 Charged 8-25-66: LSD was unlawfully sold and delivered; 301(q)(2). Guilty plea; imprisonment. (117)

Benjamin F. Callihan, truck-stop employee, Joplin, W. Dist. Mo.
 Charged 12-22-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment suspended and probation. (118)

Jerry Callihan, truck-stop employee, Seneca, W. Dist. Mo.
 Charged 12-22-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment and probation. (119)

Arthur D. Corpolongo, D.O., Harrisonville, W. Dist. Mo.
 Charged 9-19-66: phenobarbital tablets and dextro-amphetamine hydrochloride tablets were unlawfully sold and delivered; and failure to prepare, obtain, and keep complete and accurate records concerning depressant and stimulant drugs; 301(q)(2), 301(q)(4). Guilty plea; fine and probation. (120)

George F. Dixon, employee of drug manufacturer, Baltimore, Dist. Md.
 Charged 11-28-66: secobarbital sodium capsules were unlawfully delivered and were unlawfully sold and delivered; 301(q)(2). Guilty plea; imprisonment suspended and probation. (121)

Raymond E. Dymkoski, t/a Ray Banks, Kansas City, W. Dist. Mo.
 Charged 5-31-67 and amended 5-12-67: chlordiazepoxide hydrochloride capsules were dispensed without a prescription; 503(b)(1). Guilty plea; probation. (122)

Ralph E. Eisenach, t/a Eisenach's Pharmacy, Duluth, Dist. Minn.
 Charged 12-19-66: amphetamine hydrochloride tablets were unlawfully sold and delivered; 301(q)(2). Guilty plea; probation. (123)

David E. Elkus, New York, S. Dist. N.Y.
 Charged 4-18-67: Barbitol sodium powder was unlawfully sold and delivered; 301(q)(2). Guilty plea; probation. (124)

Don Frizzell, musician, Dallas, N. Dist. Tex.
 Charged 10-25-66 by grand jury: secobarbital sodium capsules, LSD, and dexanobarb capsules were unlawfully sold and delivered and were unlawfully possessed; 301(q)(2), 301(q)(3). Guilty plea; imprisonment. (125)

Robert M. Greene and Richard McWilliams, drug firm salesmen, Burlington, S. Dist. Iowa.
 Charged 12-20-66 by grand jury: dextro-amphetamine sulfate tablets, and amphetamine-amobarbital combination tablets and capsules were unlawfully sold and delivered; 301(q)(2). Guilty pleas; imprisonment suspended, fines, and probation. (126)

Johnny W. Jewell and William L. Landers, truck-stop employees, Texarkana, W. Dist. Ark.
 Charged 9-27-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty pleas; fines and probations. (127)

Robert L. Kimble and Bill Lineberry, Neelyville, E. Dist. Mo.
 Charged 4-20-67 by grand jury: with intent to defraud and mislead, caffeine tablets were held, offered for sale, and delivered in bottles labeled "Methamphetamine [and "Amphetamine SO"]... Caution: Federal law prohibits dispensing without a prescription," which article was offered for sale under the name of another drug, and which label was false and misleading because the article was not methamphetamine or amphetamine sulfate, lacked the true name and place of business of the manufacturer, packer, or distributor, lacked the established name of the drug, and unlawfully bore the prescription legend; 502(a), 502(b)(1), 503(e)(1)(A)(i), 502(i)(3), and 503(b)(4). Guilty pleas; imprisonments. (128)

Horace N. Mathis, taxi driver, Gainesville, N. Dist. Ga.
 Charged 4-5-65 by grand jury: desoxyephedrine hydrochloride tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment. (129)

Danne McGinty, Columbia, W. Dist. Mo.
 Charged 6-2-67: LSD capsules were unlawfully sold and delivered; 301(q)(2). Guilty plea; fine. (130)

Ignacio D. Medrano and Terry Robert Schultz, Los Angeles, S. Dist. Calif.
 Charged 7-17-64: secobarbital sodium capsules were dispensed without a prescription; 503(b)(1). Guilty plea by Schultz; probation. Guilty plea by Medrano; imprisonment. Upon appeal by Medrano, the Court of Appeals for the Ninth Circuit affirmed Medrano's conviction. (131)

Justin Mutrux, Columbia, W. Dist. Mo.
 Charged 6-2-67: LSD tablets were unlawfully sold and delivered; 301(q)(2). Guilty plea; fine and probation. (132)

Edward Plymack and Nathan Skop, officers of pharmaceutical firm, Guttenberg, Dist. N.J.
 Charged 6-9-67: when shipped and while held for sale, amphetamine sulfate tablets were dispensed in unlabeled bottles without a prescription; 502(b)(1) & (2), 502(e)(1)(A)(i), 502(f)(1), 503(b)(4), 503(b)(1). Guilty pleas; fines and probations. (133)

Bernard Roseman and Bernard Copley, Menlo Park and San Francisco, N. Dist. Calif.
 Charged 10-9-63 by grand jury: facilitation of the transportation, concealment, and sale of LSD which was known to have been imported into the United States contrary to the Federal Food, Drug, and Cosmetic Act—18 U.S.C. 545; while held for sale, unlabeled bottles of LSD were offered for sale and sold and were dispensed without a prescription—502(f)(1), 502(f)(2), 505(a), 502(b)(1), 502(b)(2), 502(e)(1), 502(e)(2), 503(b)(1); and conspiracy to transport LSD, a new drug, into California to offer for sale and sell it in unlabeled bottles; to sell LSD without a prescription, to sell LSD at \$500 per 60 ml. for cash only, and to do business under the name of Hypnosophic Institute—18 U.S.C. 371. Not guilty pleas. After trial by the court, judgment of guilty; imprisonment. (134)

The Court of Appeals, in affirming the convictions, said that the trial court could properly find that there was interstate commerce of LSD when evidence showed that the defendants possessed LSD in California, Canada, and then again in California when they returned from Canada, even though the defendants claimed that they buried the LSD in California when they were traveling to Canada and picked it up upon their return to California; that shipment from Canada to Washington constitutes interstate commerce; that importation into the United States contrary to the provisions of the Federal Food, Drug, and Cosmetic Act is an importation "contrary to law" within the meaning of the law against smuggling goods into the United States (18 U.S.C. 545), even though the Federal Food, Drug, and Cosmetic Act is a complete body of law carrying its own penalties and was enacted subsequent to 18 U.S.C. 545; that 18 U.S.C. 545 evinces a congressional intent to have such smuggling statute apply concurrently with other criminal statutes, since the smuggling statute prohibits importation "contrary to law"; and that the overlap between the two statutes is necessary to avoid a loophole in the law, since, if the Federal Food, Drug, and Cosmetic Act did not cover importation, it would be possible to transport merchandise into the United States, or from one border State to another via a foreign country without violation of that Act or the contrary-to-law provisions of 18 U.S.C. 545. 364 F.2d 18 (C.A. 9, 1966), cert. denied 386 U.S. 918 (1967). (134)

Henry Schein, Flushing, E. Dist. N.Y.
 Charged 8-26-64: when shipped, pentobarbital sodium capsules and procaine penicillin in aqueous suspension lacked adequate directions for use, and were dispensed without a prescription; 502(f)(1), 503(b)(1). Guilty plea; imprisonment and fine. The defendant thereafter filed a motion for reduction of sentence on the grounds of new evidence pertaining to the background and character of the defendant. Such motion was denied. Subsequent motions were filed by defendant (1) for dismissal of the counts of the information involving the above charges on the ground that such counts failed to charge a crime, and (2) for leave to withdraw his plea of guilty for the reason that he was misadvised to plead guilty on the mistaken assumption that there were no defenses thereto.

Such motions were denied by the court on 5-31-66. The Court of Appeals for the Second Circuit affirmed the conviction of the defendant and the orders of the District Court. Cert. denied 385 U.S. 1009 (1967). (135)

Michael Segreti, Chicago, N. Dist. Ill.
 Charged by grand jury 3-28-67: amphetamine tablets were unlawfully sold and delivered; 301(q)(2). Guilty plea; imprisonment. (136)

Charles E. Smith, truck-stop employee, Steele, E. Dist. Mo.
 Charged 10-27-66: amphetamine sulfate tablets were unlawfully sold and delivered; 301(q)(2). Guilty plea; imprisonment suspended, fine, and probation. (137)

Alpha D. Taylor, restaurant operator, Springdale, W. Dist. Ark.
 Charged 6-15-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Not guilty plea. After trial, verdict of guilty; imprisonment, fine, and probation. (138)

Frederick G. White, Kansas City, W. Dist. Mo.
 Charged 5-3-67: chlordiazepoxide hydrochloride capsules were dispensed without a prescription—503(b)(1); and phenobarbital tablets were unlawfully sold and delivered—301(q)(2). Guilty pleas; imprisonment and probation. (139)

Elizabeth R. Wilkens, M.D., Westminster, Dist. Md.
 Charged 4-17-67: amphetamine tablets were unlawfully disposed of, sold, and delivered; 301(q)(2). Nolo contendere plea; fine. (140)

INJUNCTION ACTIONS

Aldrich Milk Products, Inc., John Friedli, Sr., president, John Friedli, Jr., secretary-treasurer, and Robert Burke, cheesemaker, Aldrich, Dist. Minn.
 Charged 11-19-65 in complaint for injunction: that the defendants operated a cheese manufacturing plant at Aldrich, Minn., and were distributing in interstate commerce cheddar cheese which contained manure fragments and plant fragments, and insect and rodent filth, primarily because of the use of contaminated milk in the manufacturing of the cheddar cheese; and that the defendants were well aware that their activities were violative; 402(a)(3).
 A temporary restraining order and decree of permanent injunction were entered which enjoined the interstate shipment of any cheddar cheese, and any similar article of food, which contained filth or was made from filthy milk; and which similarly enjoined shipments unless and until measures were taken to ensure that only clean milk would be used in the manufacture of cheddar cheese. (141)

William M. Dobbs, t/a Cash & Haul Grocery Co., and Walter W. Robbins, service man engaged in furnishing pest-control services, Blue Ridge, N. Dist. Ga.
 Charged 4-2-65 in a complaint for injunction: that the defendants were causing a water solution of the poisonous rodenticide, sodium fluoroacetate, commonly known as compound 1080, to be placed in a grocery warehouse, in close proximity to the food therein, that such act was done while the food was being held for sale after shipment in interstate commerce, and that such act resulted in the food being held under insanitary conditions whereby the food may have been rendered injurious to health; 402(a)(4).
 A temporary restraining order was entered, and after a hearing, a decree of permanent injunction was entered which enjoined the defendants against doing the act complained of so as to result in food becoming adulterated as alleged, and against placing any compound 1080 in the warehouse unless it was colored with nigrosine black dye and dispensed in protected bait boxes. All personnel in the warehouse were made aware of the use of such compound, and such other precautions were taken as would keep the food safe from contamination by such compound. (142)

Newman Rice Mill, Alvin, S. Dist. Tex.
 Charged 1-9-64 in complaint for injunction: that the defendant operated a rice milling facility for the milling, bagging, and storage of rice, that such food was being shipped in interstate commerce; and that such food was prepared, packed, and held under insanitary conditions resulting from rodent and insect infestation in the rice milling facility; 402(a)(4). Consent decree of permanent injunction enjoined the introduction into interstate commerce of rice which had been prepared, packed, and held under insanitary conditions and required the defendant before making any further interstate shipment of rice to clean and make its mill suitable for milling and storing rice and to destroy or recondition the rice on hand. (143)

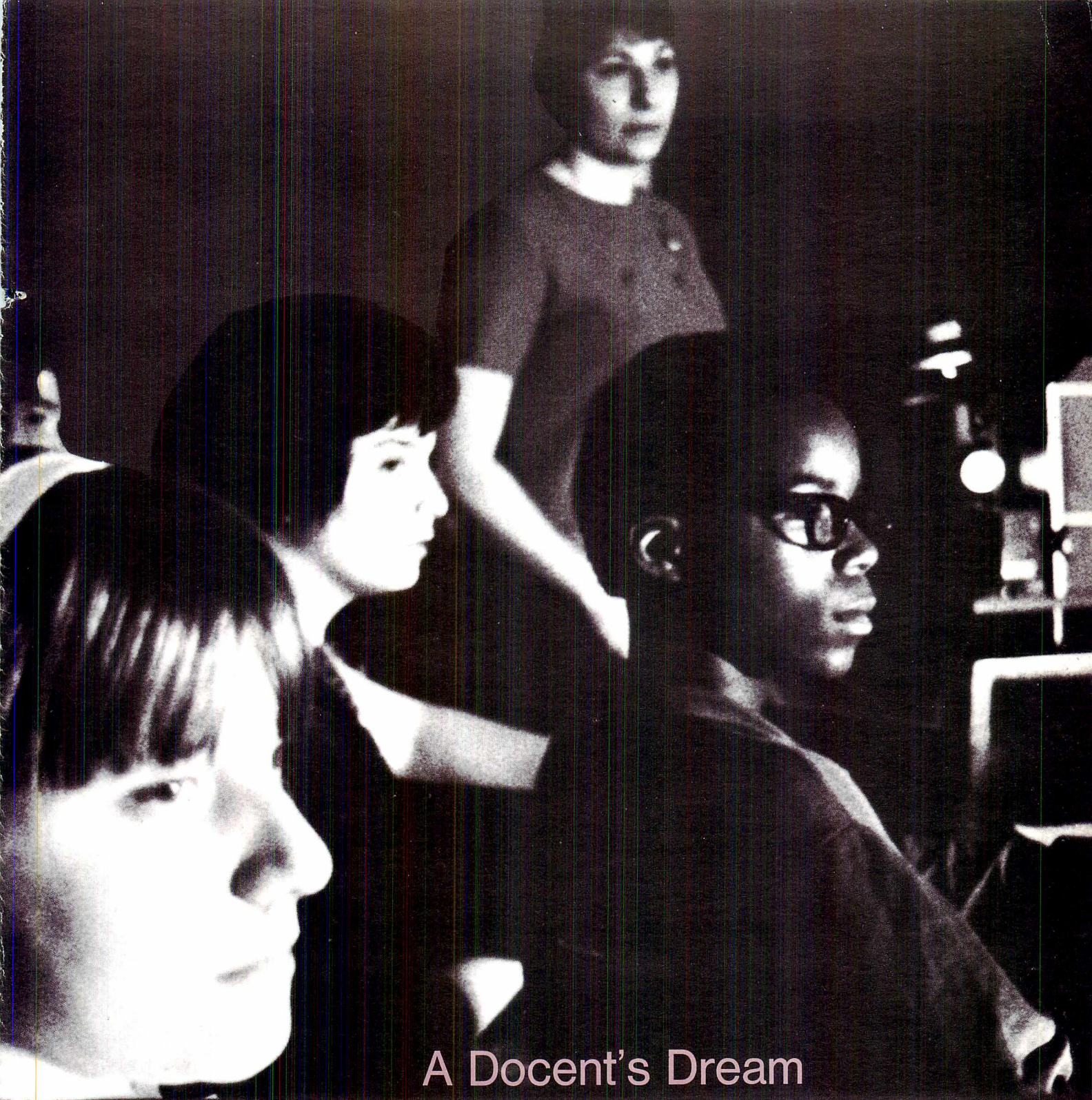
Nysco Laboratories, Inc., and Eugene J. Yoss, president, Long Island City, E. Dist. N.Y.
 Charged 6-1-60 in complaint for injunction: that the defendants operated a drug manufacturing plant at Long Island City, New York, and were preparing and distributing in interstate commerce, capsules of phenylpropanolamine hydrochloride in various strengths; that the labeling of such drug contained false and misleading claims for weight reduction and suppressing the appetite; and that the defendants were well aware that their activities were violative; 502(a).
 After the Government answered the defendants' interrogatories, it served its own interrogatories upon the defendants. Defendants objected to answering the Government's interrogatories, but the court ordered defendants to answer after certain changes were made in the interrogatories (26 F.R.D. 159). The Government thereafter moved for summary judgment, which the court granted (215 F. Supp. 87). A permanent injunction was then entered which enjoined the interstate shipment by the defendants of any drug consisting of timed disintegration capsules containing 75 or 50 milligrams of phenylpropanolamine hydrochloride, capsules containing 75 or 50 milligrams of phenylpropanolamine hydrochloride with vitamins and minerals, and any similar drug, whose labeling contained the false and misleading claims mentioned above. Upon appeal by the defendants, the lower court's order granting the injunction was affirmed (318 F.2d 817). (144)

Clarence Patrick Sundance, Lava Hot Springs, Dist. Idaho.
 Charged on or about 2-7-64 in a complaint for injunction: that the defendant was engaged in manufacturing herbal preparations from raw materials received from outside the State of Idaho and in selling and distributing such preparations under representations that the articles were for use in the cure and treatment of cancer, diabetes, and other serious diseases and without labeling bearing the name and place of business of the manufacturer, packer, or distributor, an accurate statement of the quantity of contents, the established names of the preparations or their active ingredients, and adequate directions for use for the purpose for which the articles were intended; 502(b), 502(e), 502(f)(1).
 Following the entry of a temporary restraining order, a consent decree of permanent injunction was entered which enjoined the defendant against introducing into interstate commerce herbal preparations prepared by him and represented for use in the diseases alleged in the complaint, against causing any such herbal preparations while held for sale to be represented for use in such diseases, and against introducing into interstate commerce herbal preparations which fail to bear, and causing such preparations while held for sale to fail to bear, labeling containing adequate directions and the other information as alleged in the complaint. (145)

Notices of Judgment are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act and section 13 of the Federal Hazardous Substances Act. Notices of Judgment report cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizure proceedings are civil actions taken against goods alleged to be in violation, and criminal and injunction proceedings are against firms or individuals charged to be responsible for violations. The cases generally involve foods, drugs, devices, cosmetics, or hazardous substances which were alleged to be adulterated or misbranded or otherwise violative of the law when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce.

Case summaries are prepared by Food and Drug Division, Office of the General Counsel, DHEW.
 Published by direction of the Secretary of Health, Education, and Welfare.

James L. Goddard, *Commissioner of Food and Drugs*
 Washington, D.C., May 1, 1968.



A Docent's Dream

FDA's LIFE PROTECTION SERIES
and
FDA's SCIENCE PROJECT SERIES

Curriculum resource guides on the safety, labeling, and use of foods and drugs, with related laboratory activities and visual aids, for middle and secondary schools.

Special attention given to problems with misuse of stimulants, depressants, and hallucinogens.

For a complete listing of titles and prices and how to order, write to:

Director, Educational Services Staff
FOOD AND DRUG ADMINISTRATION
Washington, D. C. 20204

OFFICIAL BUSINESS

Announcements

DRUG RECALL STUDIES FDA's "Case Studies of Drug Recalls" are proving to be one of the most popular and valuable educational services now furnished industry by the Agency.

Each "study" is a case history of the recall of a drug from the market because of defects or mislabeling. The study gives the reasons for an actual recall, based upon the findings of the firm and the FDA during the postrecall inspection and investigation.

Issuance of the case studies was begun in January of this year with the objective of alerting drug manufacturers to the reasons for recalls and helping them improve their quality control procedures. Up to press time for this issue of FDA PAPERS, three issues of "Case Studies" covering nine recalls were available.

The studies are issued periodically by FDA's Bureau of Voluntary Compliance, and are sent to the drug industry and other interested parties on request to the Division of Drug and Device Industry Relations.

GOVERNMENT-INDUSTRY SEMINAR

The FDA Seminar on Labeling of Household Chemicals and Paints, scheduled for May 28 in Washington, is a major co-operative effort by Government and industry to promote voluntary compliance with Federal requirements for labeling these products.

The Seminar, which will feature both Government and industry speakers, is being sponsored by FDA in cooperation with the Chemical Specialties Manufacturers Association and the National Paint, Varnish, and Lacquer Association. The Federal Trade Commission and the Department of Commerce also will take part in the program.

The Seminar will deal principally with requirements of the Federal Hazardous Substances Act, which regulates the labeling of such household products as cleaners, detergents, and paint. The labeling of cosmetics under the Fair Packaging and Labeling Act also will be discussed.

FDA INDUSTRY WORKSHOPS During June and July, 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)) and foods (microbiological contamination, chemical residues, and sanitation). Anyone desiring to attend should contact the nearest District.

SCHEDULE OF FDA WORKSHOPS AND REGIONAL CONFERENCES JUNE & JULY 1968

FDA District	Date	Location	Subject Area
Minneapolis	June 12	Minneapolis, Minn.	Bacteriological Problems—Eggs
San Francisco	July	San Francisco, Calif.	Pesticides—Dairy Industry & Hay Growers

HAZARDOUS SUBSTANCES ACT REQUIREMENTS

Requirements of the Federal Hazardous Substances Act, which regulates the labeling of hazardous household products such as solvents, cleaners, waxes, detergents, and the like, are explained in detail in a new booklet being printed by the Food and Drug Administration. The booklet, consisting of 28 pages of text and color illustrations of required labels, also explains FDA's regulations regarding type size, placement, and contrast of the required labeling statements for hazardous products. The Child Protection Amendments of 1967 also are covered.

The booklet is a valuable guide for manufacturers and repackers of household chemicals who are required by the law to place specified cautionary information and warning statements on the labels of these products.

The Federal Hazardous Substances (Labeling) Act, which became effective February 1, 1962, was enacted to protect consumers from accidental injury from misuse or improper storage of hazardous substances used around the home.

The new booklet, titled "Requirements of the Federal Hazardous Substances Act," will be for sale. Order from: Superintendent of Documents, U. S. Government Printing Office, Washington, D. C. 20402.

COSMETIC CONFERENCE PAPERS

Papers presented by FDA scientists at the Joint Conference on Cosmetic Sciences in Washington, D. C., April 21-23 are available upon request to Bureau of Voluntary Compliance (VC-1), Food and Drug Administration, Washington, D. C. 20204.

REVISED INDUSTRY INFORMATION CATALOG

A revised edition of FDA Publication No. 39, "A Catalog of Industry Information Materials," is now available free upon request to the Bureau of Voluntary Compliance, Food and Drug Administration, Washington, D. C. 20204. The catalog contains an up-to-date listing of all FDA industry publications, fact sheets, movies, slides, exhibits and other information materials available to help industry to understand and comply voluntarily with the laws administered by FDA.