

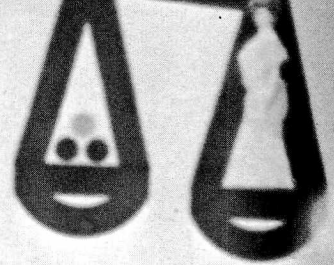
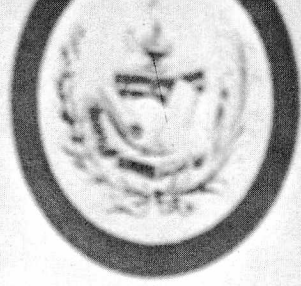
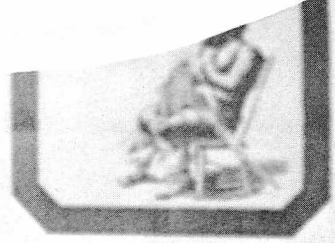
FDA PAPERS

**DRUG-PESTICIDE
INTERACTIONS**

**INDUSTRY ASSOCIATIONS
AND SELF-REGULATION**

The IND Procedure
Assuring Safe and Effective Drugs

FLAMMABLE FABRICS



Sanitation Guidelines for Food Processing

Wash hands and forearms with soap and water before and after food handling.
Wash hands and forearms with soap and water after using the toilet.
Wash hands and forearms with soap and water after touching animals or animal products.
Wash hands and forearms with soap and water after touching money or other objects.
Wash hands and forearms with soap and water after touching surfaces that may be contaminated.

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"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

In our form of Government regulation of business, industry trade associations perform functions that are almost indispensable to the industries being regulated and probably just as indispensable to the Government body responsible for their regulation in the public interest. Staffed with experts in the sciences and other fields in which members are involved, trade associations are also manned by professionals equally well informed about why and how laws came to be enacted in Washington and the regulations that ensue from them.

FDA traditionally has sought and valued collective advice and viewpoints from industry as voiced by its trade associations, and has invited participation by these associations in its regulatory and other responsibilities to the extent that law and the public interest permit. It's one of the most effective ways a Government agency can communicate with the hundreds of small and large companies that make up almost any industry.

That's why FDA continues to believe that one of the best ways to assure the public better and safer food and drugs from more companies and their employees is through the enlightened—and enlightening—efforts of trade associations among the industries they represent (see page 10).

quotes

“A separate Division of Sanitation Control has been created within the Bureau of Compliance at FDA’s Washington headquarters. The Division consists of three branches: The Milk and Food Service Sanitation Branch, The Interstate Travel Sanitation Branch, and The Shellfish Sanitation Branch. These headquarters units will provide continuing technical leadership for the existing programs in substantially the same way that they have operated in the past, and with the same personnel. They will have the support of FDA’s field organization. The field operations of these programs will be under the administrative control of the Associate Food and Drug Commissioners in the nine Regional Offices of the Department. Scientific activities associated with the programs will continue primarily at the laboratories in Cincinnati, which are a part of the FDA Bureau of Science.”

Herbert L. Ley, Jr., M.D., Commissioner of Food and Drugs, at the National Association of State Department's of Agriculture, Dairy Division, Jackson, Wyoming, July 29, 1969.

“We publish a proposal [for a food standard] in the *Federal Register* and invite comment. Our invitation is sincere. We have no problem in getting comment from those in industry who are involved in the manufacture or distribution of the product and who do not like some feature of the proposal. On the other hand, we do not get very much comment from that segment of industry which may agree with our proposal. Neither do we get very much comment from consumers.

“Now we realize that consumers generally do not read the *Federal Register*. We have explored various ways of getting this information to consumers, both individually and as groups. May I offer an invitation to all of you to give us any ideas you may have as to how we may better involve consumers in this important operation.”

J. Kenneth Kirk, Associate Commissioner for Compliance, Food and Drug Administration, at the American Medical Association Symposium on Food Standards in the United States, St. Charles, Illinois, June 27, 1969.

Robert H. Finch
Secretary, U.S. Department of
Health, Education, and Welfare

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Asst. Secretary for Health
and Scientific Affairs

Charles C. Johnson, Jr.
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Section 705 [375] of the Food, Drug, and Cosmetic Act.

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

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

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A river of wine, a flood of imports, plus a 400-mile valley of fruits, nuts, and vegetables.

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What the trade associations have done and can do to assure better food and drugs.

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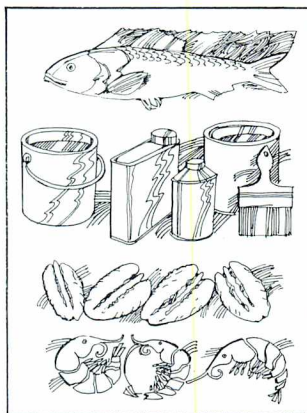
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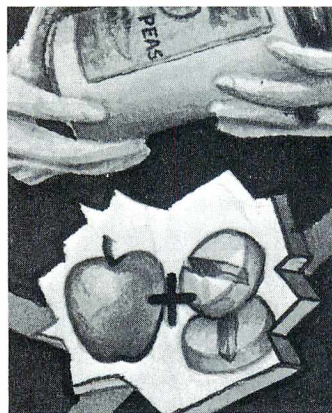
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DATE OF INJURY	YEAR OF INJURY	DAY OF WEEK INJURY OCCURRED	TIME OF INJURY	ACCIDENT LOCATION
DEC 1968	1968	MON	3:59 AM	HOME - INDOORS
DEC 1968	1968	TUE	3 AM - 8:59 AM	HOME - OUTDOORS
DEC 1968	1968	WED	3 AM - 11:59 AM	HOME - NS OR UNK
DEC 1968	1968	THUR	ON - 2:59 PM	FARM HOME - INDOORS
DEC 1968	1968	FRI	3 PM - 5:59 PM	FARM PREMISES - INCL OCCUPATIONAL
DEC 1968	1968	SAT	3 PM - 8:59 PM	FARM - NS OR UNK
DEC 1968	1968	SUN	3 PM - 11:59 PM	OCCUPATIONAL LOCATION (NON-FARM, NON-HIGHWAY)
DEC 1968	1968	UNK	1 STATED	SCHOOL FACILITY
DEC 1968	1968	KNOW		

MOTORCYCLE
PEDAL CYCLE
BUS/TRAIN
AIRCRAFT
WATERCRAFT
PEDESTRIAN
OTHER MOTOR VEHICLE
NONMOTORIZED VEHICLE
INHALATION (GAS)
INGESTION
CONTACT TOXIN
OVEREXERCISE
FALLS
FIREARMS
MISC. PROJECTILES
03 OTHER
EXPIRED (DOA)
EXPIRED IN HOSPITAL

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by McKay McKinnon, Jr.

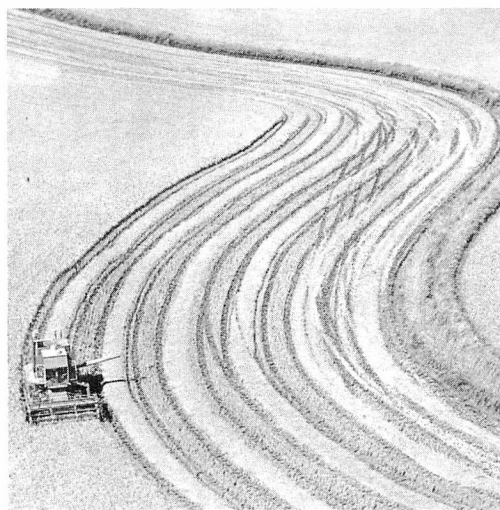
The San Francisco District of the Food and Drug Administration rose phoenix-like from the ashes of one of the six original field laboratories of the U.S. Department of Agriculture's Bureau of Chemistry. The laboratory was destroyed in the San Francisco earthquake and fire in 1906, just two months before the signing of the Pure Food and Drugs Act of 1906. Oddly enough, it was also two months before the signing of the Food, Drug, and Cosmetic Act of 1938 that the District moved into its present headquarters on Fulton Street

in San Francisco. Then known as a station, it was designated a District in 1948. Thus, the San Francisco District has operated successively in the Department of Agriculture, the Federal Security Agency, and the Department of Health, Education, and Welfare, since the turn of the century. The District territory extends from the Western Utah boundary to Nohili Point, Hawaii, and from the Oregon border to an irregular line that includes Kern County, California, but excludes Clark County, Nevada.





San Francisco District: True Wealth After the Gold Rush



In a San Joaquin Valley celery field (left), an FDA Inspector collects field samples for pesticide analysis. From top to bottom: A District Import Inspector checks food contents of containerized freight at Oakland, California. The same inspector monitors reconditioning of chocolate imported from Ireland. The aerial view of a combine harvesting rice in a field near Sacramento, shows the contour checks which are necessary to keep the water in the flooded fields at uniform depths.



The present organizational structure fits 94 employees into an Office of the Director, an Office of Administrative Management, the Inspection Branch, the Science Branch, and the Compliance Branch. The headquarters group includes investigators, scientists, and support staff. Resident posts are located in Sacramento, Stockton, Fresno, San Jose, and Honolulu. Investigators include specially trained drug inspectors, food and drug inspectors, and import food and drug inspectors. Two food and drug inspectors are designated as Workshop Coordinator and Pesticide Specialist respectively. The Science Section includes chemists, microbiologists, and microanalysts, plus scientific aides in these disciplines. One chemist is designated as a Research Coordinator. A professor of chemistry at the University of California serves as Science Advisor to this section.

The support staff, of which the Compliance Branch is a part, includes the District Director, his Deputy, and the Office of Administrative Management. The Western Medical Representative of the Bureau of Medicine and a Veterinary Medical Officer of the Bureau of Veterinary Medicine are quartered in the District and are available for consultation. They serve all three West Coast Districts. The departmental Assistant General Counsel's attorney stationed in Los Angeles provides assistance in legal matters.

Some 85 percent of the time of this work group is programmed into primary mission objectives—the protection of human health and life.

The genesis of food law is shrouded in the mists of time. Loyal Californians insist, however, that the first instance of food regulation in what is now the United States occurred within San Francisco District territory in this wise:

Long before the discovery of America, there existed in what is now the State of California, a tribe known as the Mendocino Indians. They were great lovers of shellfish, and with the arrival of spring each year would repair to the coast, there for some months to subsist largely on these delicacies of the Pacific. Every once in a while members of the tribe would become ill and occasionally some would die. What happened, we know now, was that these tribal members would feast on clams and mussels at a time when the clams and mussels in turn were feeding on a type of plankton quite prevalent in the waters of the Pacific from April to October. It still is. When present in large quantity, plankton gives the water a pink coloration. The clams and mussels which live on this plankton, if eaten raw, may transmit to humans a toxin known as gonyoulax. Gonyoulax toxin causes paralytic shellfish poisoning. State health authorities issue annual warnings against the hazard to this day.

The old Mendocino chief was no scientist, but he was a keen student of cause and effect. He associated the pink coloration in the water with the illnesses in the tribe. He, therefore, appointed a brave—the first food inspector, if you please, in what is now the United

From top to bottom, left to right: An Import Inspector records lot numbers for further action on drums of soy sauce which had been damaged in unloading. District Inspectors check the net contents of pre-packaged almonds in a Sacramento plant, and raisins in a Fresno processing plant. Label statements of imported drugs are checked by a District Inspector in the U.S. Customs airmail facility of the San Francisco International Airport.

States—and charged him to keep the tribal members away from the clam and mussel beds when the water was red. Illnesses and deaths dropped dramatically.

One Monday morning after a weekend of indiscretion, the old chief, feeling the need for a quick pick-me-up, went down to get himself a mess of raw clams. On reaching the water's edge, he was stopped by the brave, who with upraised arm said: "No! Red Water!" The old chief looked into the swirling eddies, saw no red coloration at the moment, brushed the brave aside, then ate his raw clams with fatal results. This has been humorously designated as the first instance of political interference with food law enforcement in the Nation.

Many centuries must have elapsed between this incident and 1850, when Governor Peter H. Burnett approved California's first food law: forty-nine words that established a pattern of behavior for the new State.

Although earlier reigning monarchs in Hawaii had established limited food controls, not until 1898 did Hawaii, by then a Republic, adopt a general food and drug law.

Nevada's general food law as published in the General Statutes of 1885 followed very closely the California law of 1850. It read: "If any person or persons shall knowingly sell any flesh of any diseased animal, or other unwholesome provisions, or any poisonous or adulterated drink or liquors, every person so offending shall be fined not more than \$500, or imprisoned in the county jail not more than 6 months."

All of these antedated the Pure Food and Drugs Act of 1906. With the creation of a national enforcement unit, however, a camaraderie began to develop between the Districts and the States of California, Nevada, and Hawaii, that has become increasingly valued through the years.

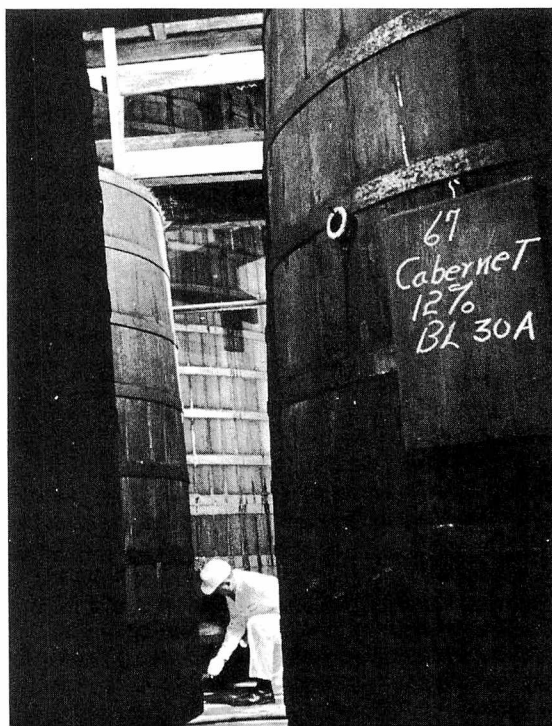
Close liaison is maintained with other Federal agencies, notably the Customs Service in the Treasury Department, regulatory and research units of the Department of Agriculture, and the offices of the U.S. attorneys, U.S. marshals, and the Bureau of Narcotics and Dangerous Drugs in the Department of Justice.

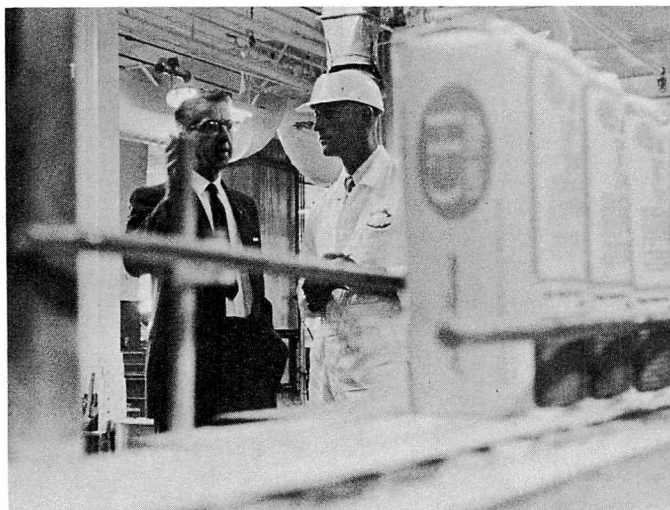
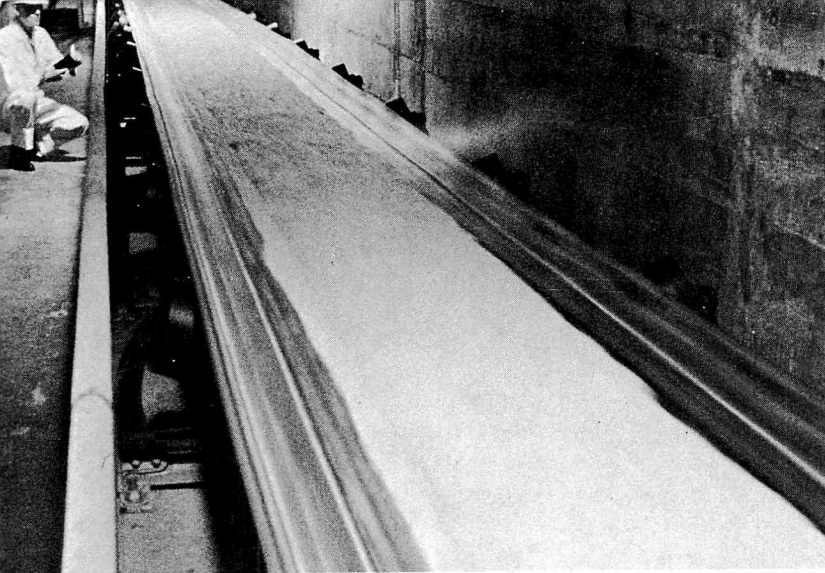
Hawaii has two major food crops and is developing others. These two are sugarcane and pineapple. Sugarcane is processed to the raw sugar stage in the Islands and is transported to a central refinery in California where the finished sugar and sirups are made. The pineapple industry, on the other hand, produces finished products consumed largely in the United States.

The most widely traded commodity in Nevada is money (and the metal from which it used to be made). Development of large agricultural production in that State awaits the arrival of water.

In California, soon after gold rush days, it became patent that the true wealth of California was to be found, not in nugget form in the streams feeding the Sacramento River, but in the magical combination of sun, water, and good earth between Mount Shasta to

From top to bottom: *District personnel: seated (front to back)—District Director, McKay McKinnon, Jr.; Deputy Director, Henry Roberts; standing (left to right)—Harold W. Geritz, Chief Chemist; Alex V. Thorson, Administrative Officer; Ronald G. Fischer, Food and Drug Officer. McKay McKinnon joined FDA in 1930 and has headed the San Francisco District since 1948. An Import Inspector collects samples of imported delicacies in a San Francisco Chinatown grocery store. In an Acampo, California, winery, an inspector examines redwood storage tanks for insect infestation.*





the north and the Tehachapi Range to the south. Extending 400 miles, this is the Central Valley, the heartland of "Agribusiness." It comprises a significant segment of the San Francisco story. A few statistics will demonstrate why:

In 1968, the national tonnage of cannery tomatoes was 7 million. Five million tons of this total was produced in the Central Valley of California; processed tomato products in 1968 approximated 90 million cases in California alone.

California produces about 150 million gallons of wine annually or 75 percent of the national consumption. The commercial crush of fresh grapes for the last year on which figures are available totaled 1,455,000 tons, of which 1,280,000 originated in the Central Valley.

The San Joaquin section of the Central Valley annually produces 275,000 tons of raisins, using 1,100,000 tons of raisin grapes for this purpose. This same area accounts for all the 18,000 tons of dried figs produced in the Nation, all the 80,000 in-shell tons of almonds, and practically all the 85,000 in-shell tons of walnuts.

In an area of such concentrated production, the control of insects assumes great importance. The State of California reportedly uses 40 percent of the commercial pesticides applied to crops in the United States. Poisoning pests without poisoning people has for many years been a common problem for the Food and Drug Administration, the California Department of Agriculture, and the University of California. The Agricultural Extension Service of the Division of Agricultural Science of the University of California tailors general requirements of the USDA into specific advice for California crops. It is represented at the county level by the County Farm Advisors. The California Department of Agriculture operates in two major directions. Its statutory responsibility for the safe use of pesticides, having great potential hazard if misused, is exercised in one direction by the County Agricultural Commissioners. In addition, the State Department of Agriculture operates several laboratories equipped to handle the 16,000 to 17,000 samples of fresh fruits and vegetables collected annually from wholesale and retail points. Such laboratories are located in San Francisco, Los Angeles, Fresno, and Sacramento. Where excessive residues are found, the offending products are denied the market. Both FDA Districts located in California conduct extensive product investigations in growing areas with the cooperation of the County Agricultural Commissioners and the County Farm Advisors to determine the violative potential of growing crops in the area.

Both Districts collect samples at growing points and at packing plants for examination either in a mobile laboratory that shuttles between the two or at headquarters laboratories. They account each year for about 3,000 samples on which there is background information. Corrective action is prompt when pesticide residue tolerances are exceeded. Results are exchanged between the

From top to bottom: In a sugar refinery in Crockett, California, the FDA Inspector collects sanitary inspection samples from the conveyor belt which carries partially refined sugar from the storage tanks to the refinery. After collecting samples, the inspector talks with the plant manager concerning the packing of the refined sugar. Masked and suited to conform to germ-free environment conditions, a District Inspector takes aseptic samples of imported fishmeal from a mound more than two stories high. The meal will be examined by the District's microbiology labs.

State laboratories and the District laboratories. Work is planned jointly and a common data base is in prospect.

Both Honolulu and San Francisco are primary ports of entry for many of the exotics from the Far East which not only have captured the interest of the American market, but which still comprise substantial elements in the diets of those who follow the eating customs of their countries of origin. A typical day on the piers at either port may turn up products ranging from New Zealand deer meat for jerky, to canned duck eggs in oil from Taiwan, to cure-alls from Hong Kong, to fresh ginger root and disguised betel nuts, to such staples as coffee, tea, copra, nutmegs, and cassia.

The District staff can deal with labeling problems in 12 languages, ranging from Slavic to Oriental.

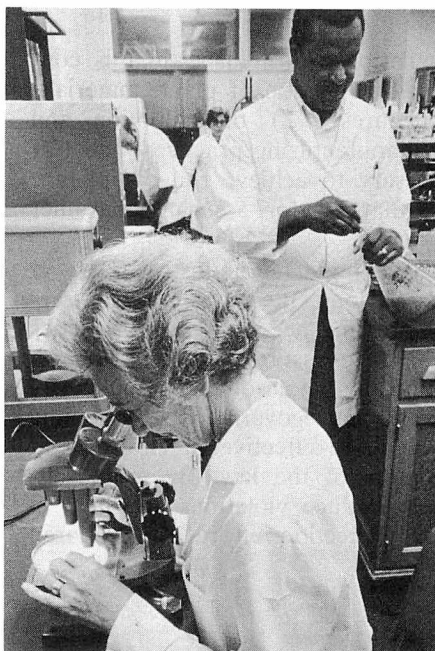
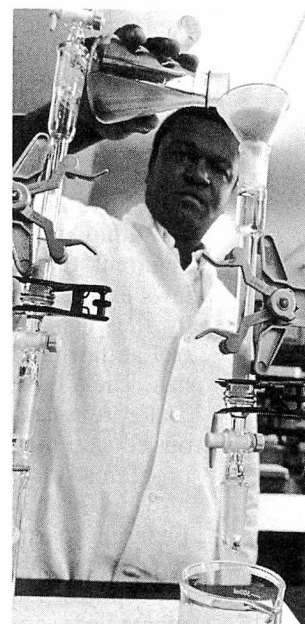
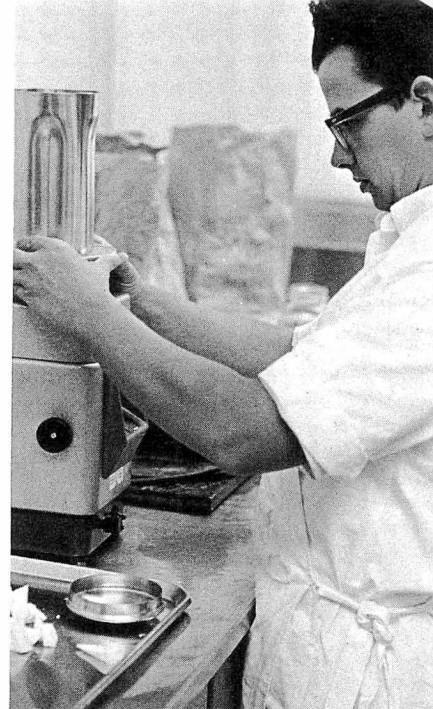
Within a given year, in addition to wharf examinations, 2,250 samples will be collected and examined by the San Francisco District and 1,300 detentions will be made. These figures are exclusive of tea, which under a special law in force since the last part of the 19th century requires examination of every lot offered for entry. This adds 2,750 additional samples to the import total.

Stockton, although well up the San Joaquin River, has become a substantial port of entry. It may soon be the primary West Coast port for fishmeal, a source of protein highly regarded by poultry raisers. South American interests have joined in a venture they hope will provide *Salmonella*-free fishmeal to Central Valley feeders. The meal is now moving in bulk, and as inbound steamers discharge cargoes, it is run through a continuous controlled-heat, controlled-moisture setup to eliminate *Salmonella* and similar pathogenic organisms. If the project is successful, delivery delays will be a thing of the past.

As part of its continuing program of promoting voluntary compliance by industries whose products or activities fall within the laws administered by the Food and Drug Administration, San Francisco District conducted eight industry workshops in 1968. Strong support was provided by trade associations and by State officials with related responsibilities. The areas explored included smoked fish, drug GMP's, convenience foods, medicated feeds, hazardous substances, tree nuts, warehouses, and crab and shrimp handling. Five workshops emphasized microbiological problems and correction.

San Francisco District's mission is substantially furthered by effective trade associations and in-house efforts to meet its regulatory objectives. In time, it is to be hoped, additional funds will be appropriated to increase the degree of protection to the complying manufacturers—particularly those in the Central Valley—and thereby maintain positive pressure against the heedless, the careless, and the greedy. The U.S. consumer, whose welfare and interest is in the continued enforcement of standards promulgated by the Federal food and drug statutes, looks to FDA to do this.

From top to bottom, left to right: Fluorometric determination of sterols as cholesterol in egg noodles. Examining imported cheese for pesticide residue. Microbiologist testing nuts for aflatoxin by *B megaterium* inhibition. Chemist analyzing drug samples using ion exchange chromatography cleanup procedure. In the chemical lab's food section, the chemist in the background treats fig paste by the flotation procedure, while in the foreground, another chemist examines insect fragments separated from the paste. Research on *Cl. perfringens* in dehydrated soup bases.



Industry Associations and Self-Regulation

by Fred J. Delmore and Kermit V. Sloan

There has been much discussion in recent times concerning self-regulation by the food, drug, and other industries subject to the laws administered by the Food and Drug Administration.

This is not a new concept. For many years there has been a considerable degree of self-regulation among the more enlightened and progressive elements of these regulated industries. If there had not been, FDA's job of administering the consumer protection laws would have been well nigh impossible.

However, the enormous increase in production and processing of foods in this era of technological revolution, the manufacture of more and more sophisticated drugs, and the proliferation of cosmetics and household chemical products have made it highly important that the producers, distributors, and marketers of these consumer essentials largely regulate themselves. Government enforcement of laws and regulations cannot alone provide the protection consumers demand and must have in our modern society.

Within the last few years it has become increasingly apparent that assurance that the consumer protection laws are complied with must be a responsibility shared by the regulated industries, State food and drug control authorities, FDA and other Federal agencies. FDA has officially recognized this important fact, first, by a major reorganization in 1964 to place more emphasis on education, information, and voluntary compliance programs in cooperation with industry; second, by moving formally within the last year to set up a State-Federal "partnership" to share inspection and other regulatory responsibilities; and, third, by promoting the concept of self-certification through voluntary agreements between FDA and qualified firms. (Details of the self-certification concept will appear in a future issue of FDA PAPERS.)

The term "self-regulation" by industry in this connotation means (1) self-inspection of plant, materials, and production procedures; (2) the adoption and maintenance of good manufacturing practices; and (3) all other actions necessary to achieve full compliance with the law and regulations for assuring consumer protection.

Large segments of the regulated industries have in past years adopted various measures of self-regulation. But there is a pressing need for more activities on an industrywide basis to assure the safety and effectiveness of drugs and the wholesomeness and purity of food. The Federal and State governments by pooling their resources can be more effective in enforcement activities against violators of the law. By more self-regulation, industry can reduce violations and help in the overall consumer protection effort. In a shared

"partnership," Government and industry can make consumer protection a reality.

Historically, the industry trade associations have played a prominent role in fostering and promoting self-regulation and voluntary compliance by their member firms. A number of effective programs for improving sanitation standards, manufacturing practices, and product quality, for example, have been initiated by trade associations, both alone and in cooperation with FDA. Among the various functions of associations and services provided for their constituent companies, none are more important or valuable to consumers than those which aid in the protection of the public health and safety.

Throughout the years, FDA has recognized the importance of this role of associations and has been greatly assisted in the performance of its mission of consumer protection by their activities. There are a number of outstanding examples of association cooperation with FDA in programs to improve sanitation standards and product quality in the food industries.

Among such self-regulation pacts is the Better Salmon Control Program. This program was originated in 1937 as a cooperative effort on the part of FDA, the salmon cannery, and the National Cannery Association to improve the quality of salmon and to keep from the market any portion of the pack considered unmerchantable for any reason. For many years this program in its original form served its purposes very well. However, in 1967 it was revised and strengthened. It is now known as the Canned Salmon Control Plan of 1967 and has the same objectives as the original pact—self-regulation to improve the quality of salmon and to keep from the market any of the product that is contaminated or unmerchantable for any reason.

The National Cannery Association also is active in research to improve food quality and has a number of other programs for promoting voluntary compliance and improving consumer protection.

Another example is The Dried Fruit Association of California Program. This association has been designated by the U.S. Department of Agriculture as the official inspection agency for the marketing of California figs, almonds, walnuts, and prunes. Upon request of individual packers, the association also inspects dried-cut fruits—peaches, pears, and apricots.

Still other outstanding examples of self-regulation are the baking industry self-inspection programs. The American Baking Institute in 1946 initiated an effective program covering plant inspection, training of personnel, and standardization of equipment designed in the interest of improved sanitation. This program and a voluntary inspection program carried on by the Quality

Bakers of America cover some 80 percent of the Nation's baked goods production. These programs have helped raise the average standards of the baking industry to a point where it is only infrequently that FDA finds it necessary to take legal action.

Although there are no industrywide self-regulatory programs as such in the drug area, many individual drug manufacturers have self-inspection programs and a number of companies have adopted "zero defects" or error-free production programs.

In addition to information and research programs for its member companies, the Pharmaceutical Manufacturers Association has cooperated extensively with FDA and leading universities in sponsoring seminars on quality controls in drug production. PMA recently entered into a major contract to set up a programmed


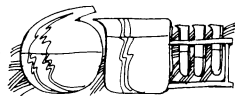




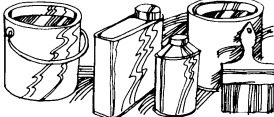





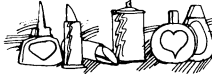
learning course for packaging mechanics in drug plants. This course, it is understood, will be available to the entire industry.

The Proprietary Association and the National Association of Pharmaceutical Manufacturers similarly have participated with FDA in conferences on manufacturing controls and various drug production problems.

These are by no means all of the self-regulatory activities of associations and individual firms in the regulated industries. But they do exemplify what can and should be done to a greater extent by organized industry groups.

For its part in promoting and assisting voluntary compliance, FDA, in the 1964 reorganization, grouped and expanded its activities in these areas and mounted a major program to provide information and advisory

OUTSTANDING EXAMPLES OF ASSOCIATION PROGRAMS

Association	Product	Objective
American Baking Institute	Baked goods 	To establish an effective program of plant inspection, personnel training, and to standardize plant sanitation equipment.
Chemical Specialties Manufacturers Association	Chemicals 	To promote self-regulation and voluntary compliance with requirements for labeling hazardous household chemical products.
Dried Fruit Association of California Program	Figs, almonds, walnuts, prunes 	Designated as the official inspection agency and, on request of packers, will inspect dried-cut fruits—peaches, pears, and apricots.
National Association of Frozen Food Packers	Frozen foods 	To prepare and issue specific guidelines, including in-plant test procedures and steps for controlling bacterial buildup.
National Association of Pharmaceutical Manufacturers	Drugs 	To participate with FDA in conferences on manufacturing controls and drug production problems.
National Canners Association	Salmon 	Industry wide program to improve the quality of salmon and to keep from the market any portion of the pack considered contaminated.
National Paint, Varnish and Lacquer Association	Paint 	To sponsor national conferences and regional seminars on self-regulation and voluntary compliance with requirements for labeling hazardous chemical and paint products.
National Pecan Shellers and Processors Association	Pecans 	To distribute a set of specific good manufacturing guidelines for the pecan shelling industry.
National Shrimp Breaders Association	Shrimp 	To develop a GMP appendix containing regulations for the shrimp industry.
Pharmaceutical Manufacturers Association	Drugs 	To sponsor university seminars on quality control in drug production.
Proprietary Association	Non-Rx drugs 	To participate with FDA in conferences on manufacturing controls and drug production problems.
Quality Bakers of America	Baked goods 	To establish a voluntary inspection program.
Toilet Goods Association	Cosmetics 	To solve microbiological contamination problems in the cosmetic industry.

assistance for industry. Initially, the new program was developed in two principal areas: (1) advisory assistance to individual firms on such compliance problems as labeling of products, suitability of ingredients, application of the law to particular situations; and (2) dissemination of information for industry generally on requirements of the law and regulations.

The latter program includes the preparation and distribution of a variety of information materials, such as booklets, speeches, articles, fact sheets, posters, motion pictures, and exhibits. In addition, a large number of copies of *Federal Register* reprints of regulations and orders are distributed.

A special information and educational service initiated within the last two years is a series of drug recall case studies. These studies, without disclosing the identities of the firms involved, show the production and other errors which led to the recall of various drugs. These case studies, based on FDA's and the firms' own investigations of what went wrong, have proved to be very valuable to the industry generally in assessing its operations to prevent similar errors (see FDA PAPERS, June 1968).

The overall purpose of the FDA information and educational program is to make available to industry (a) an explanation of how laws and regulations affect it; (b) results of FDA's scientific research and improved analytical methodology; (c) recommendations for controlling bacterial contamination and adopting good manufacturing practices, and (d) advice and support in adopting self-regulation, self-inspection, and error-free production programs.

A collateral activity that quickly became, and still is, a leading part of FDA's voluntary compliance effort is a program of conferences, seminars, and workshops. These are intended not only to brief members of industry on the requirements of the law and regulations but also to provide a two-way communication on industry problems and their solutions.

This program was begun in fiscal year 1966 with a modest schedule of six workshops. With increasing industry interest and support, a heavy schedule of national and regional conferences and District workshops was developed thereafter. From its inception up to the present, the program has included an aggregate of 325 workshops and 40 national and regional conferences and seminars. More than 34,000 industry officials and supervisory and production personnel representing nearly 16,000 individual firms have attended these meetings.

The various conferences and workshops have covered subject matter in the entire range of FDA regulatory jurisdiction. They have dealt not only with specific legal requirements but with a variety of problems, such as bacterial and chemical contamination of foods. Some of the major national conferences have explored technical and scientific problems, such as small particles of foreign matter in large volume parenteral (injectable) drug solutions, indirect additives entering food through

processing equipment or packaging, sterile packaging of devices, and stability of drugs.

Various associations in each of the regulated industries have been active in sponsoring and participating in the many conferences and workshops. Drug associations, as previously mentioned, have sponsored seminars on good manufacturing practices and quality controls. Food associations have participated with FDA in national conferences and in workshops on various contamination problems. Feed industry associations have sponsored a long series of workshops on manufacturing practice regulations for medicated feeds, reaching many thousands of individuals and firms in this industry.

The Toilet Goods Association has sponsored a national joint conference on cosmetic sciences and has taken other steps to help solve microbiological contamination problems in the cosmetic industry.

The Chemical Specialties Manufacturers Association and the National Paint, Varnish and Lacquer Association have been quite active in promoting self-regulation and voluntary compliance with requirements for labeling hazardous household chemical products and paints under the Federal Hazardous Substances Act. Over the last year they have initiated and cooperated with FDA in sponsoring one national conference and six regional seminars in major cities across the Nation.

All these workshops, conferences, and seminars have had a common objective—to help give the industries a better understanding of the law and regulations, to make available the benefits of FDA research and methodology to help solve contamination and other problems, and to encourage maximum self-regulation.

Associations that have initiated voluntary compliance programs and have participated with FDA in a co-operative effort to promote industry self-regulation can rightfully take pride in their contributions to consumer protection. FDA continues to welcome their cooperation, and earnestly solicits a greater effort by all trade groups in the regulated industries to achieve full compliance with the consumer protection laws.

Right now, associations in the food and drug industries have an excellent opportunity to provide an essential service for their members and at the same time perform an important public service in the interest of consumer protection. They can do so by developing educational and information programs to instruct and train food and drug plant employees at all levels in good manufacturing practices and sanitation standards. Industrywide programs of in-plant training together with aids such as booklets, posters, slides, exhibits, and perhaps motion pictures would greatly aid the cause of voluntary compliance with legal requirements as well as help assure safe and effective drugs and pure and wholesome food. Many of the human errors that lead to recall of defective and unsafe drugs and to contamination of foods can be eliminated by such programs.

FDA's Good Manufacturing Practice regulations (GMP's) for drugs and its "umbrella" GMP regulations

for the food industry provide the basis for association-sponsored programs of this kind.

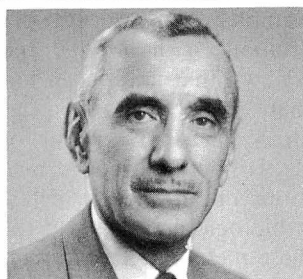
The PMA-FDA-university regional seminars on quality controls in drug production and the FDA-industry workshop conferences on good manufacturing practices have done much to explain the drug GMP's to top and middle management of individual drug firms. But education in GMP's should be carried to employees all down the line. It is here that associations can perform their most valuable service—by developing industrywide programs for training employees in GMP's and providing incentives for error-free production. FDA can be counted on to provide whatever assistance it can in the development and conduct of such programs. As Food and Drug Commissioner Herbert L. Ley, Jr., said a few months ago: "It is industry's responsibility to comply with the law and regulations voluntarily. FDA has a responsibility to provide the kind of information and education that will help industry to comply."

FDA's new umbrella food GMP's and the necessity of developing specific GMP appendices for particular foods similarly provides food associations with the opportunity to perform one of their most important and responsible functions as representatives of their industries.

The umbrella regulations are so designated because they cover the food industries generally and the practices which should be followed by all the food industries to maintain good sanitation.

To supplement the umbrella regulations, FDA now is undertaking to develop a series of appendices spelling out current good manufacturing practices for specific food industries. In this task it hopes to draw on the expertise and cooperation of the industries involved.

FDA invites and urges food associations to draft proposed GMP appendices for their particular industries. With their superior knowledge of the food technology of the particular products involved and of current good manufacturing practices in their fields, they are in a far better position than FDA to prepare GMP appendices. And they, too, can develop programs and aids to instruct and train plant employees in following these regulations.



Fred J. Delmore, Acting Associate Director, Bureau of Compliance, joined FDA in 1965 after retiring from military service. Kermit V. Sloan, Project Leader, Hazardous Substances and Cosmetics, Division of Industry Services, joined FDA in 1963.

FDA experts in food science and technology are available to counsel with industry groups in the development of such guidelines, whether or not these are formally promulgated as appendices to the umbrella GMP's.

Some associations already have drafted current good manufacturing practice appendices to supplement the umbrella regulations, and others are in process of doing so. The National Pecan Shellers and Processors Association, in cooperation with FDA, has prepared and distributed a set of specific good manufacturing guidelines for the pecan shelling industry. The National Shrimp Breaders Association has worked closely with FDA in developing a GMP appendix containing regulations for the industry. The National Association of Frozen Food Packers has prepared and issued to its member companies specific guidelines, including in-plant test procedures and steps for controlling bacterial buildup.

The primary and most important reason for developing GMP regulations and guidelines, of course, is to improve consumer protection against adulterated foods. Another important reason is to provide standards by which compliance or noncompliance with the law can be better judged by enforcement officials and industry itself.

GMP's provide an internal standard by which FDA itself can judge conditions in various manufacturing plants and avoid possible inconsistencies in evaluating and acting on borderline findings by different inspectors and administrative reviewers of inspection reports.

GMP's for specific foods also will provide the industries with knowledge of the yardstick by which they are being judged, as well as a basis for appraising their own performances. Top management will have a standard against which it can measure the performance of individual staff members responsible for plant sanitation. Industry, furthermore, will be provided the means by which specific sanitation programs can be developed, planned, and budgeted with a clearer understanding of what the current regulatory demands are with respect to its particular operations.

Food GMP's also will provide State and local enforcement authorities with a clear picture of the standards being applied by FDA in the sanitation area. This will permit more effective joint planning and uniform enforcement under the cooperative State-Federal program mentioned earlier. And GMP's will provide a basis for understanding what does and does not constitute violative conduct by food plants.

FDA applauds the initiative and cooperative activities of trade groups in the GMP area as well as in the fields of education and information to promote voluntary compliance and self-regulation. And it urges an even greater effort in these respects by all associations in each of the regulated industries. Through their leadership, associations can assure that their industries increasingly share responsibility with regulatory authorities for providing protection in today's society.

Drug-Pesticide Interactions

by Clara H. Williams, Ph.D.

The drug sulfanilamide, marketed in 1938, was the first of a series of so-called wonder drugs. In the ensuing years, many drugs, including tranquilizers, antibiotics, and antihistamines, have been added to the series and are being used extensively for the treatment of man's illnesses, both mental and physical. DDT, the first man-made organic chemical used as a pesticide, was marketed in 1944. Since that time, many synthetic chemicals have been used as insecticides, fungicides, herbicides, and other pesticides. In 1962, for example, almost 500 compounds incorporated into more than 54,000 formulations were registered for use in the United States.

The Food and Drug Administration is required by law to assure the public that drugs are safe and effective before release for use in man, and in animals whose meat or milk may be consumed by humans. FDA is also responsible for regulation of pesticide residues in food at levels considered safe for the general population. FDA's Bureau of Medicine evaluates the safety and efficacy of drugs; the Bureau of Science evaluates the safety of pesticides and recommends tolerances for their use.

Increasingly sensitive biochemical and pharmacological experimental techniques used for research by the laboratories of both Bureaus and by many scientific laboratories throughout the world have shown that drugs and pesticides can interact with each other; that is, each may influence the way in which the body normally reacts to these chemicals. There is now a growing feeling that the phenomenon of drug-pesticide interaction needs further investigation so that the safe use of drugs and of pesticides can be properly evaluated. Even though the chemical structure of both the drug and the pesticide may be known,

their metabolic interaction cannot be predicted solely upon this basis because of the complex metabolic capabilities which man and animals possess and because of the wide variations in body mechanisms within a particular species and between different species.

Drug-pesticide interactions are of two types, antagonistic and synergistic (also referred to as potentiating).

In antagonism, the concurrent presence of a drug and a pesticide in the body may result in a decreased efficiency of the drug's action or, as often occurs in treatment of cases of pesticide poisoning, administration of a drug may decrease the toxic action of a pesticide by increasing the metabolism of the chemical into a less toxic compound.

In synergism, a drug and a pesticide may interact in the body to produce a potentiating effect that is much greater than the sum of the separate effects of the two compounds. This action can be detrimental to the organism: a clinical case has been reported in which the administration of the tranquilizing drug chlorpromazine increased the toxicity to a crop-spraying worker of the organophosphate pesticide parathion. Synergism between a drug and pesticide can also be beneficial, for example, if the drug has an effective action at a lower dose because of the pesticide. The synergistic or antagonistic action of pesticides on drugs, and vice versa, may vary at different dose levels, for large doses of drugs often produce synergistic reactions.

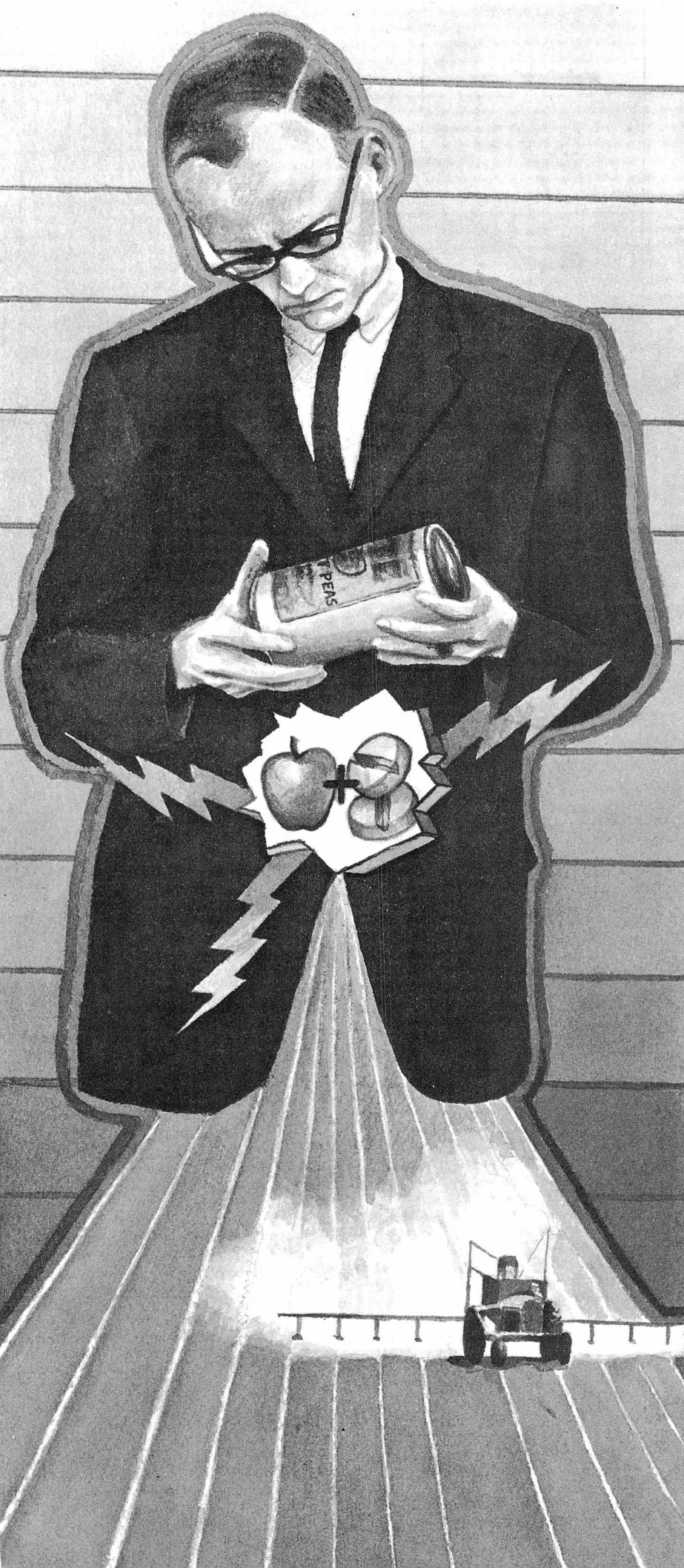
The problem confronting FDA is not so much the effects of the interaction of drugs and pesticides at high levels of pesticide exposure (although work in this area is important and is being done), but more importantly the effects of the interactions that may occur when man

is chronically exposed to pesticides at low levels at the same time he is receiving therapeutic doses of drugs.

Many of the chemicals commonly used as pesticides fall into three groups of similar compounds: the organophosphates, the carbamates, and the organochlorine compounds. These compounds are not administered directly to man, as are drugs; man is normally exposed to them only through indirect contact. A vast number and variety of drugs exist, and their prescribed use depends on the nature of the disease in man. An individual being treated for more than one pathological condition or even for only one may be taking a number of different drugs simultaneously.

Adding to the complexity of the problem is that the effects of a drug-pesticide interaction may be quite different in man than in one or more of the animal species used to test the interaction. FDA assumes that man is at least as sensitive as the most sensitive animal species tested, and when the Agency grants a no-effect level for a pesticide, this is based on a safety factor derived from a particular species of animal and extrapolated to man. Factors such as age, sex, nutritional status, and the nature of the disease in man, and other forms of stress also are included in the evaluations.

For example, many drugs are poorly metabolized in infants, and it is well known that adults can tolerate higher doses of most drugs than children can. How a drug or a pesticide is metabolized is also of paramount importance in determining its biologic activity, and the effect of these metabolic transformations on the drug-pesticide interaction is pertinent. To test for antagonistic or synergistic action between all new drugs and all new pesticides and to reinvestigate the many ap-



proved by FDA in the past would require an astronomical number of experiments. Investigations describing the reactions of pesticides of known chemical structures with those of certain types of drugs have appeared in the scientific literature, and these have formed the basis for continuing research in both FDA and other laboratories.

The President's Science Advisory Committee, in its "Report on the Use of Pesticides" (released by President Kennedy, May 16, 1963), recommended that toxicity studies of pesticides include determination of "possible synergism and potentiation of effects of commonly used pesticides with such commonly used drugs as sedatives, tranquilizers, analgesics, antihypertensive agents, and steroid hormones, which are administered over prolonged periods."

Some of the documented reports of drug-pesticide interactions indicate the nature of experimentation in this area.

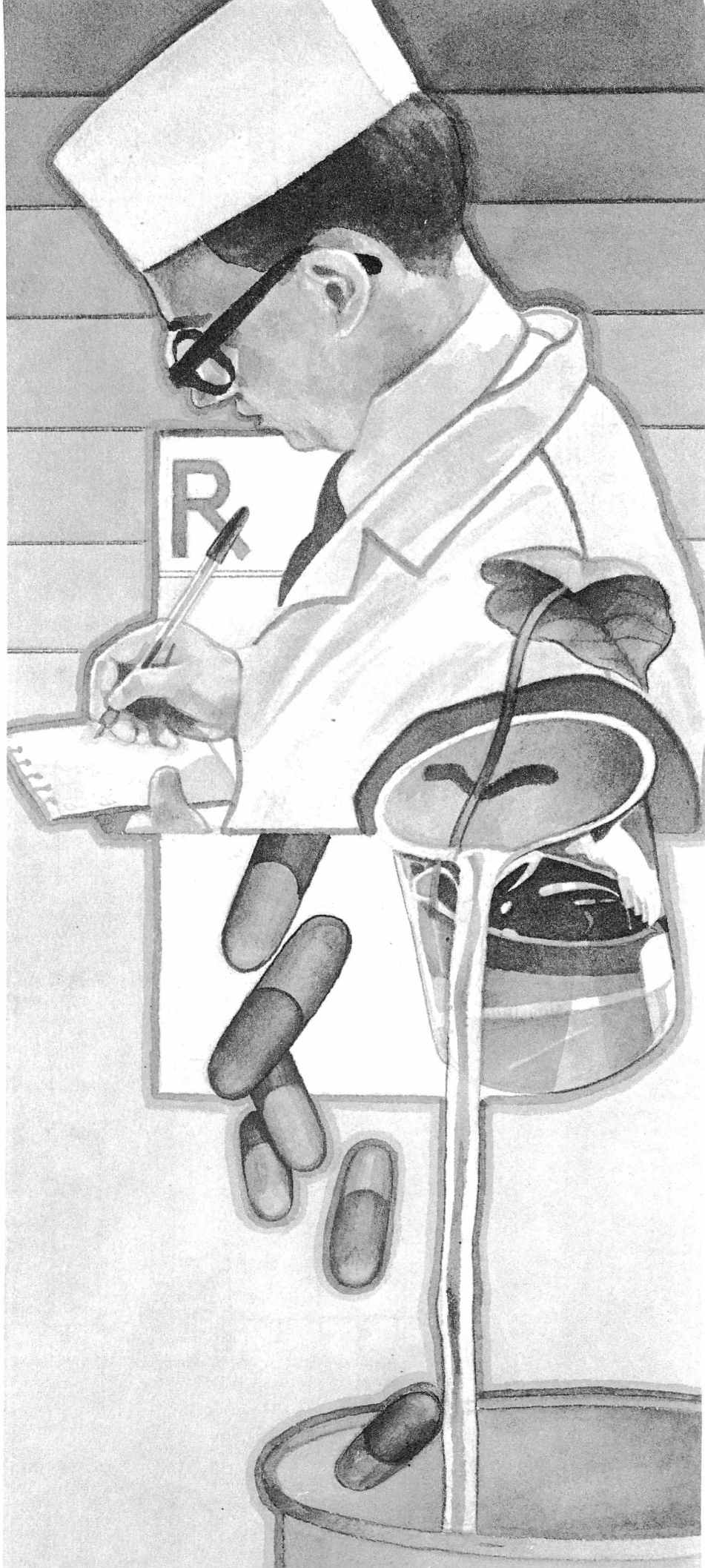
Both pesticides and drugs are metabolized by a variety of enzymes in the livers of the mammalian organism. Some pesticides can increase the activity of many of these enzymes and a number of drugs have the same enzyme-inducing ability. Chlorinated hydrocarbon pesticides such as aldrin, chlordane, and DDT stimulate the production in the liver of "processing" enzymes that metabolize drugs, pesticides, and other substances entering the liver through the portal blood. These enzymes make possible the performance of such chemical reactions as hydrolysis, reduction, oxidation, and hydroxylation. Administration of the sedative phenobarbital to man and certain animals induces the same drug-metabolizing activity in the liver. The physiological importance of enzyme induction and its relationship to the toxicity of a drug or pesticide are still being investi-

gated. When enzymes are induced, a fraction of the liver cells known as the microsomal fraction is enlarged. Since each cell is enlarged, the total liver size is enlarged. This may be a manifestation of an attempt by the body to adapt to a foreign substance. The condition is often reversible and thus does not necessarily represent a detrimental effect on the animal organism.

There are instances of beneficial effects from drug-pesticide interaction. K. P. Dubois, a pharmacologist at the University of Chicago, found that the toxicity of various organophosphate insecticides was decreased in rats when the rats were pretreated with phenobarbital. Others have reported that pretreatment of rats with the organochlorine chlordane or DDT decreased the hypnotic effect of the drug hexobarbital, and decreased the incidence of the gastric lesions that can be produced by high doses of phenylbutazone, a drug normally used to reduce fever.

The enzyme-inducing action resulting from administration of organochlorine pesticide generally lasts longer than that from administration of drugs, since these water-insoluble pesticides are not rapidly metabolized and excreted by the body but are stored for varying periods in the fatty tissues of animals and man. Allan H. Conney of the Wellcome Research Laboratories found that metabolism of hexobarbital in rats remained stimulated for 65 days after DDT had been administered and did not return to control values for 90 days. It is not known whether "normal" amounts of DDT in man increase the rate of metabolism of drugs, nor is anything known from direct experimentation in man about the effects of organochlorine insecticides on drug metabolism.

In addition to pesticides that in-



teract with drugs, agents known as pesticide synergists may have an effect on drug action. These chemicals may or may not have insecticidal action, but may enhance the insecticidal effectiveness of many pesticides. Piperonyl butoxide is an insecticide that can act as a synergist by interfering with the metabolism of some other insecticides and thus, when it is combined with certain other pesticides, it is possible to obtain more effective insecticidal action. But piperonyl butoxide can also alter the pharmacological action of drugs. B. C. Fine and J. O. Molloy of the London School of Hygiene and Tropical Medicine found that animals exposed to the sedative pentobarbital in the presence of piperonyl butoxide sleep longer (lengths of sleeping periods are used to measure the hypnotic effect of a drug).

FDA research on drug-pesticide interaction has consisted chiefly of potentiation studies in animals in which the doses of drugs and pesticides were high enough to produce a physiological effect. The amount of pesticide used is usually far in excess of that encountered by man in normal channels of exposure. L. R. Weiss, an FDA pharmacologist, found that the acute toxicity to rats of the carbamate carbaryl and the organophosphate parathion was increased by the administration of central nervous system depressants such as chlorpromazine and hexobarbital. In one study of a long-term feeding of parathion to rats, Dr. Weiss found no changes in the animal's responses to the administration of several sedative drugs. In a short-term (30-day) feeding of the organochlorine pesticides dieldrin, chlordane, and DDT to rats, the sleeping times after hexobarbital administration were reduced.

In a recent experiment conducted at FDA by P. R. Datta, rats were

fed low dietary levels of DDT for 4, 8, 12, 16, and 20 weeks. When the sedative drugs methylprylon, meprobamate, and chlordiazepoxide were administered at each interval, the sleeping times of the rats were reduced. But 12 weeks after DDT had been removed from the diet the sleeping times after these same drugs were administered were gradually increasing.

E. J. Van Loon, another FDA pharmacologist, is currently studying interactions between the chlorinated hydrocarbon pesticide lindane and the sedative phenobarbital when both are administered to dogs. The latter compound induced liver microsomal enzymes in the dogs. Lindane, in contrast to many other chlorinated hydrocarbon pesticides, not only did not induce liver microsomal enzymes but decreased the ability of phenobarbital to induce such enzymes. In experiments with phenobarbital and lindane in miniature swine, Dr. Van Loon found that swine fed phenobarbital chronically at levels producing no apparent physiological abnormalities became markedly ataxic (failed to coordinate properly) when lindane was added to the diet.

C. Cueto, an FDA pharmacologist formerly with the Public Health Service's Communicable Disease Center in Atlanta, found during experiments there that the drug phenobarbital decreased the rate of storage of the organochlorine dieldrin in the fatty tissues of rats.

The measurement of behavioral responses to various stimuli provides a sensitive means of monitoring interactions between drugs and pesticides. Although the relationship of such behavioral responses to the general toxicity of the compounds involved is not thoroughly understood, FDA is carrying on some experimentation in this area. The published findings thus far indi-

cate that behavioral interactions—such as a decrease in an animal's normal responses or an increase in his spontaneous activity—do occur, but only at doses of pesticides and drugs considerably above normal exposure levels.

Long-term studies to measure the effects of low-level exposure to pesticides in the presence of drug administration, along with variables such as sex, age, diet, and environmental temperature, represent one area where further FDA investigations are needed.

At the present state of our knowledge of drug-pesticide interactions, there appears to be a wide margin of safety for the health of the general population under normal environmental conditions. One of the important factors underlying drug-pesticide interaction involves the stimulation of the drug-detoxifying enzyme systems in the liver microsomes. The weight of evidence implies that this type of interaction is one in which man or animals adapt themselves to the environment if the stress is not too sudden and is not detrimental to the organism. For individuals highly exposed occupationally or accidentally to pesticides, it is possible that normal therapeutic treatment with some drugs may be hazardous. The various environmental health agencies in the U.S. are continually monitoring this kind of multiple exposure.



Clara Williams, Ph.D., Acting Chief, Residue Toxicology Branch, Division of Pesticides, Bureau of Science, joined FDA in 1964.

Flamma Fabrics

Tragedy struck quickly and unexpectedly, as it often does, in a young farmer's family one evening last fall.

The father, his wife, and their two small children had just returned from a visit with relatives nearby. The father went to the barn, the mother stepped outside for a moment, and the two children were in the house alone.

When the mother returned, she found the 18-month-old daughter standing near the kitchen, her jacket on fire. She threw the child to the floor and tried unsuccessfully to smother the flames with her own coat, then tried to beat the flames away from the child's face with her hands.

Responding to a shout from the 3½-year-old son, the father rushed to the house. He helped beat out the flames and slit the child's jacket open at the waist and neck to remove it because the zipper was closed up to her neck and the hood tied securely around her head.

The child's clothing, of synthetic materials and cotton, was in flames only about a minute. Melted substances were found on a stool near the stove. She apparently had pulled the stool to the stove, a modern electric model, and somehow turned on one of the heating coils—possibly while lying across the coil on her stomach.

The little girl was admitted to a hospital which specializes in treatment of burns with second and third degree burns over about 45 percent of the body. Many burn victims do not survive burns of this severity over this much body area.

Since arm and hand burns were involved, reconstructive surgery could take several years and cost 40 to 50 thousand dollars. At least some psychological effects and emotional scars are a virtual certainty. She will carry many of the physical scars the rest of her life.

This is an actual case in the files of burn investigations in FDA's Office of Product Safety. It is one of many costly, tragic burn investigation cases there.

The child's jacket in this case

probably would fit into the category of "moderately flammable" clothing—the biggest troublemaker in flammable fabrics, since most clothing fabrics and almost all the clothing involved in fire casualties fall within this category. Many people are completely unaware that so much ordinary clothing is as flammable as it is.

This is a recent case, but the problem of flammable fabrics has a long history. Efforts to control the hazards associated with flammable fabrics began much more recently and came about as a result of young boys being burned, some fatally, in fires involving cowboy chaps made from a fabric that had a long pile surface. This popular boys' costume was sold throughout the country in large numbers during the 1940's. Shortly after these dangerously flammable garments reached the market, reports began to come in of burn injuries involving them.

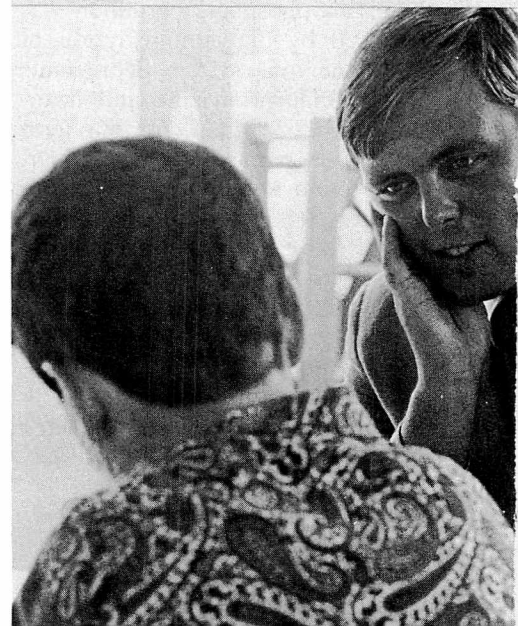
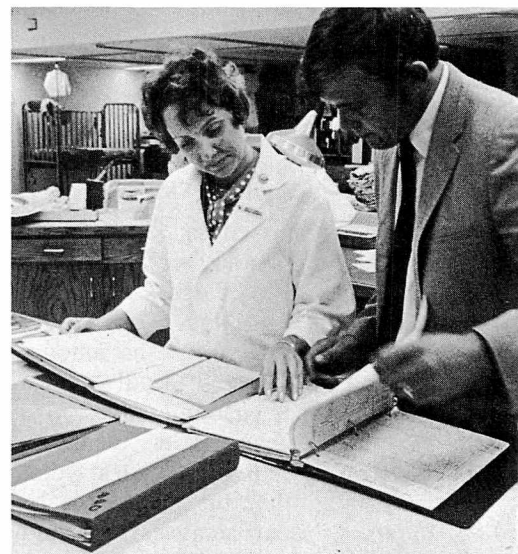
Later, in 1951, another popular clothing item that came to be known as the "torch" sweater created even greater publicity. These were sold by the millions and, as in the case of the cowboy chaps, consisted of a piled rayon fabric. These resulted in burn injuries to many wearers because they quickly ignited from lighted cigarettes and other fire sources.

The Federal Flammable Fabrics Act was enacted in 1954 following concern over the rash of burn accidents involving these two popular clothing items. This law set legal limits on the flammability of certain wearing apparel items only, but did serve to rid the country of so-called explosive clothing.

Amendments to the original Act were signed into law December 14, 1967. They broaden the category of wearing apparel to include hats, gloves, and footwear, and extend coverage to include interior furnishings of homes and public buildings.

The amendments define the term "article of wearing apparel" as any costume or article of clothing worn or intended to be worn by individuals. They define "interior furnishing" as any type of furnishing made

In photos below, Robert H. Gilman, investigator with FDA's Boston Injury Study Unit, obtains information on burn cases from Boston Shrine Burn Institute records with the nursing supervisor's help. Gilman also interviews a young burn patient and his mother for details of the circumstances surrounding his injury to include in an in-depth report to the Office of Product Safety. Gilman is one of a team of seven investigators who seek information on all product-related injuries treated in Boston area hospitals. Psychiatrist counsels wheelchair patient in rehabilitation treatment that follows many burn injuries. Open, spacious wardroom is cheerful and offers patients opportunities for companionship with one another.



HOSPITALS IN INJURY SURVEILLANCE SYSTEM

Flagstaff Community Hospital Flagstaff, Arizona	Northwest Hospital Des Moines, Iowa	Hillcrest Hospital Mayfield Heights, Ohio
St. Joseph's Hospital Phoenix, Arizona	Sacred Heart Hospital Ft. Madison, Iowa	Sacred Heart Hospital Eugene, Oregon
Pima County General Hospital Tucson, Arizona	Ottumwa Hospital Ottumwa, Iowa	Western Lane Hospital Florence, Oregon
Parkview Baptist Hospital Yuma, Arizona	St. Joseph Mercy Hospital Sioux City, Iowa	Josephine General Hospital Grants Pass, Oregon
Enloe Memorial Hospital Chico, California	St. Lukes Hospital Sioux City, Iowa	Gresham General Hospital Gresham, Oregon
Grossmont Hospital La Mesa, California	Schoitz Memorial Hospital Waterloo, Iowa	Willamette Falls Community Hospital Oregon City, Oregon
Feather River Hospital Paradise, California	Hazard Appalachian Regional Hospital Hazard, Kentucky	St. Anthony Hospital Pendleton, Oregon
Penrose Hospital Colorado Springs, Colorado	St. Francis Cabrini Hospital Alexandria, Louisiana	Good Samaritan Hospital and Medical Center Portland, Oregon
Saint Mary-Corwin Hospital Pueblo, Colorado	Burbank Hospital Fitchburg, Massachusetts	Lower Umpqua Hospital Reedsport, Oregon
Logan County Hospital Sterling, Colorado	Metropolitan Hospital Detroit, Michigan	Douglas Hospital Roseburg, Oregon
Meriden Hospital Meriden, Connecticut	Highland Park General Hospital Highland Park, Michigan	Mercy Hospital Roseburg, Oregon
Halifax District Hospital Daytona Beach, Florida	Hennepin County General Hospital Minneapolis, Minnesota	Salem Memorial Hospital Salem, Oregon
Broward General Hospital Ft. Lauderdale, Florida	St. Paul-Ramsey Hospital and Medical Center St. Paul, Minnesota	McKenzie Willamette Hospital Springfield, Oregon
Shands Teaching Hospital and Clinics Gainesville, Florida	General Hospital Greenville, Mississippi	Charleston County Hospital Charleston, South Carolina
Baptist Hospital Pensacola, Florida	North Mississippi Medical Center Tupelo, Mississippi	Holston Valley Community Hospital Kingsport, Tennessee
Escambia General Hospital Pensacola, Florida	Children's Mercy Hospital Kansas City, Missouri	Baptist Memorial Hospital Memphis, Tennessee
Naval Air Station Hospital Pensacola, Florida	Kirksville Osteopathic Hospital Kirksville, Missouri	John Gaston Hospital Memphis, Tennessee
Sacred Heart Hospital Pensacola, Florida	Barnes Hospital St. Louis, Missouri	Methodist Hospital Memphis, Tennessee
Tampa General Hospital Tampa, Florida	University of Nebraska Health Center Lincoln, Nebraska	Obion County General Hospital and Nursing Home Union City, Tennessee
Grady Memorial Hospital Atlanta, Georgia	Johnston City Memorial Hospital Smithfield, North Carolina	R. E. Thomson General Hospital El Paso, Texas
Cobb General Hospital Austell, Georgia	Forsyth Memorial Hospital Winston-Salem, North Carolina	Memorial Baptist Hospital, Southeast Houston, Texas
Glynn-Brunswick Memorial Hospital Brunswick, Georgia	Albany Memorial Hospital Albany, New York	St. Elizabeth's Hospital Houston, Texas
Kennestone Hospital Marietta, Georgia	Leonard Hospital Albany, New York	University of Vermont College of Medicine Burlington, Vermont
Ashton Memorial Hospital Ashton, Idaho	Samaritan Hospital Albany, New York	Stevens Memorial Hospital Edmonds, Washington
Bingham Memorial Hospital Blackfoot, Idaho	Peekskill Community Hospital Peekskill, New York	Children's Orthopedic Hospital and Medical Center Seattle, Washington
Valley County Hospital Cascade, Idaho	Golden Valley County Hospital Beach, North Dakota	King County Hospital Seattle, Washington
Community Hospital Council Bluffs, Idaho	Bismarck Hospital Bismarck, North Dakota	University Hospital Seattle, Washington
McCall Memorial Hospital McCall, Idaho	St. Alexius Hospital Bismarck, North Dakota	Central Washington Deaconess Hospital Wenatchee, Washington
Gritman Memorial Hospital Moscow, Idaho	St. Joseph's Hospital Dickinson, North Dakota	Ear and Eye Hospital of Wenatchee Wenatchee, Washington
Mercy Hospital Nampa, Idaho	Dakota Hospital Fargo, North Dakota	St. Anthony's Community Hospital Wenatchee, Washington
Bannock Memorial Hospital Pocatello, Idaho	St. John's Hospital Fargo, North Dakota	Madison General Hospital Madison, Wisconsin
St. Anthony Community Hospital Pocatello, Idaho	St. Lukes Hospital Fargo, North Dakota	Johnston Municipal Hospital Milwaukee, Wisconsin
Bonner General Hospital Sandpoint, Idaho	Grand Forks Deaconess Hospital Grand Forks, North Dakota	Aquidilla Hospital Puerto Rico
Sun Valley Village Hospital Sun Valley, Idaho	St. Michael's Hospital Grand Forks, North Dakota	Arecibo Hospital Puerto Rico
Marion County General Hospital Indianapolis, Indiana	Haven Memorial Hospital Haven, North Dakota	Fajardo Hospital Puerto Rico
Davis County Hospital Bloomfield, Iowa	Mandan Hospital Mandan, North Dakota	Ponce Hospital Puerto Rico
Mercy Hospital Burlington, Iowa	St. Joseph's Hospital Minot, North Dakota	San Juan Dispensary Puerto Rico
Mercy Hospital Cedar Rapids, Iowa	Trinity Hospital Minot, North Dakota	San Juan Hospital Puerto Rico
Jane Lamb Memorial Hospital Clinton, Iowa	Mercy Hospital Valley City, North Dakota	Charles Harwood Memorial Hospital Virgin Islands
Jennie Edmundson Memorial Hospital Council Bluffs, Iowa	Deaconess Hospital Cincinnati, Ohio	Ingor Nesbitt Memorial Hospital Virgin Islands
Broadlawn Polk County Hospital Des Moines, Iowa	Jewish Hospital Cincinnati, Ohio	Knud Hensen Memorial Hospital Virgin Islands
Mercy Hospital Des Moines, Iowa	Our Lady of Mercy Hospital Cincinnati, Ohio	Morris-De-Castro Clinic Virgin Islands



by Carol Young

in whole or in part of fabric or related material and manufactured, sold, or intended for use in homes, offices, and places of assembly.

A fabric is defined as any material—except fiber, filament, or yarn for other than retail sale—that is woven, knitted, felted, or otherwise produced from or in combination with any natural or synthetic fiber, film, or substitute for use in any article of wearing apparel or interior furnishing. Related material is defined as that made of paper, plastic, rubber, synthetic film, or synthetic foam for use in any article of wearing apparel or interior furnishing.

Interior furnishings include upholstered furniture, draperies, ornaments, bedding (including bed clothes), rugs and carpeting, and so forth, and the fabrics and related materials from which they are made.

The amendments allow for flammability testing procedures and standards to be adjusted without new legislation, and provide research funds for statistical studies, testing techniques, and development of flame retardant fabrics.

The legislation directs the Secretary of Health, Education, and Welfare, in cooperation with the Secretary of Commerce, to study and investigate deaths, injuries, and economic losses resulting from accidental burning of products, plastics, and related materials. It directs the Secretary of Commerce, in cooperation with other appropriate groups, to conduct research into the flammability of products, fabrics, and materials; to conduct feasibility studies on the reduction of flammability; to develop flammability test techniques; and to offer appropriate flammability test training. The legislation also clarifies the enforcement authority of the Federal Trade Commission over sales, or deliveries after a sale or shipment in interstate commerce. FTC is specifically authorized to require that records be kept of commercial transactions covering commodities subject to the Act and to prevent importation of nonconforming commodities.

HEW's responsibilities under the amended Act are being met through activities of the Office of Product Safety, established last December within FDA.

Data is available from several sources: surveillance teams in Boston, Cincinnati, and Denver, and through Government grants and contracts with universities. For example, the Office of Product Safety maintains a contract with the University of Michigan Hospital, which operates the National Burn Information Exchange. Some 20 burn-treatment centers cooperate in supplying the Exchange with case management data on serious burns, their treatment, and their costs as measured in hospitalization, aftereffects, and mortality. The Exchange began investigating clothing ignition cases in 1967.

Preliminary data from this source indicates that two of every three "flame" burns investigated at the time involved fabric ignition and that 84 percent of the garments ignited were reported to be cotton. In those cases where it could be determined, 75 percent of the victims had more severe burns on the body areas covered with clothing than on the uncovered areas.

Besides these sources for data on burn injuries and deaths, the Office of Product Safety recently began to establish a national surveillance network that will obtain information from every part of the country on all product-related injuries. Agreements with 126 hospitals have been made to report injuries seen in their emergency rooms on an established-frequency basis. Some hospitals report daily; some every other day; others every three, five, or ten days, depending on the hospital's patient load. The Office of Product Safety plans to increase the number of hospitals reporting each year as resources permit until a national representation of hospitals are included.

This system supplies information on the types and seriousness of injuries and the products usually associated with these injuries. Data is being compiled to pinpoint problems and determine which products

are most frequently at fault. Program goals are a representative national sampling source and a capability for product testing and research as a basis for safety criteria or standards.

The reports are recorded by hospital emergency room personnel on special forms adaptable to automatic scanning and data processing devices. This minimizes hand processing and speeds up analysis. Selected reports are investigated in depth by field personnel to determine the circumstances of the injury and to obtain information concerning the product involved. Burn injuries are assigned first priority in follow-up investigations made on a representative part of the more serious injuries.

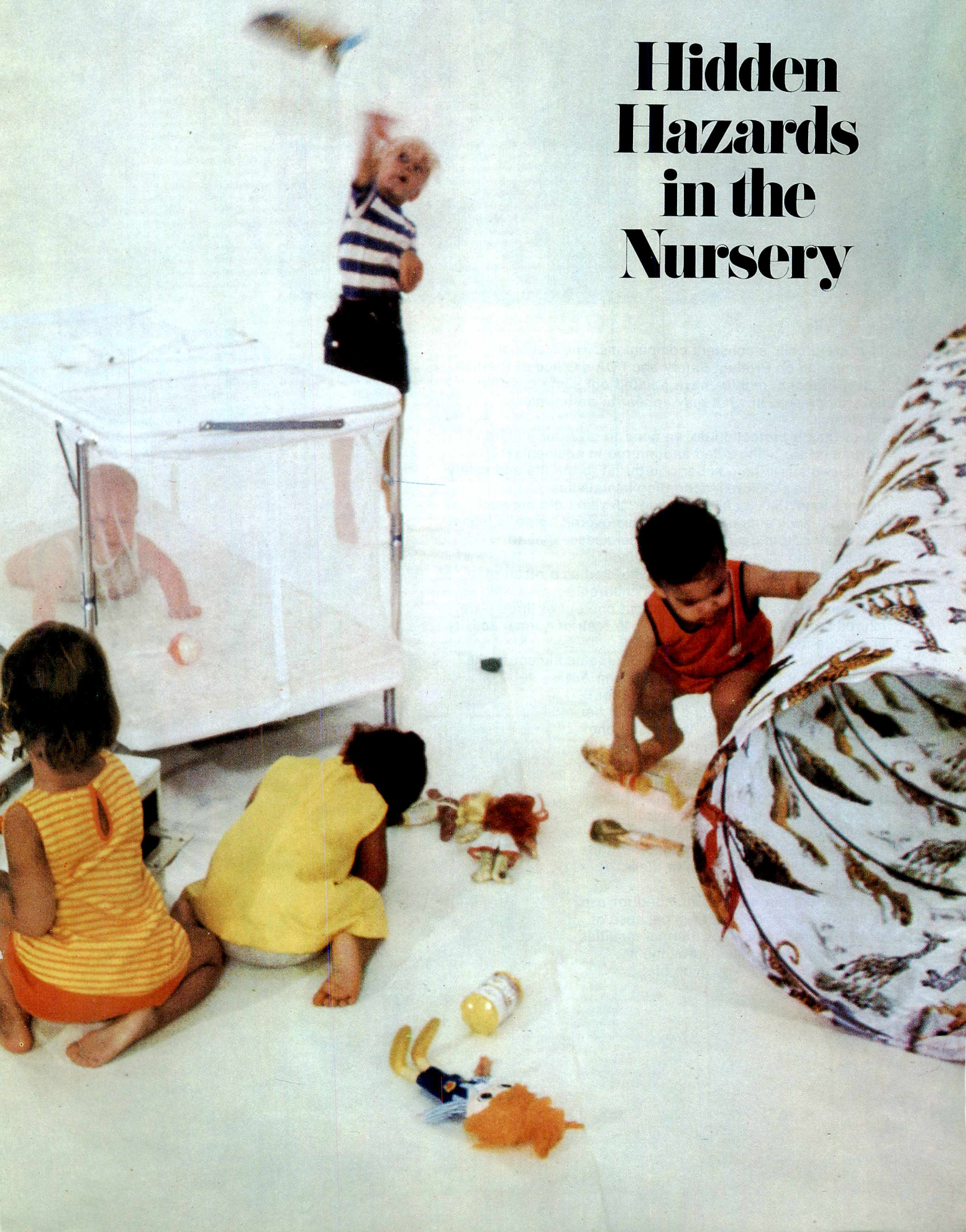
Of all accident victims, those who are burned represent by far the most difficult medical challenge and require the greatest care, attention, time, and expense. Visible disfigurement often subjects a victim to a psychological burden even if his physical recovery is complete. Clothing fires account for a substantial number of these victims. A tragic aspect of fabric burns is that many of the victims are those least able to help themselves—the aged, the disabled, and the very young.

Burns from fire and explosion are generally more serious than burns from contact with hot objects and hot liquids, primarily because of the ignition of clothing. The heat generated by the burning of any ordinary clothing produces the most serious form of deep burning. A deep burn, over a large area, explains the clinical severity of such cases.

An estimated three to five thousand die and 150 to 250 thousand are injured annually from burns involving flammable fabrics. The best way to reduce this loss is through development and use of fabrics offering protection against ignition.

Efforts to make textiles flame resistant are not new, but early research was limited to the use of water-soluble compounds. Borax, boric acid, diammonium phosphate,

Hidden Hazards in the Nursery





Toys are a child's constant companions. The National Commission on Product Safety and FDA's Office of Product Safety in recent months have pointed out some possible hazards present in what may appear to be harmless playthings.

How much protection do we need to give our children? How many are being killed and injured in accidents?

Accidents are the number one threat to the life and safety of our Nation's children, according to statistics.

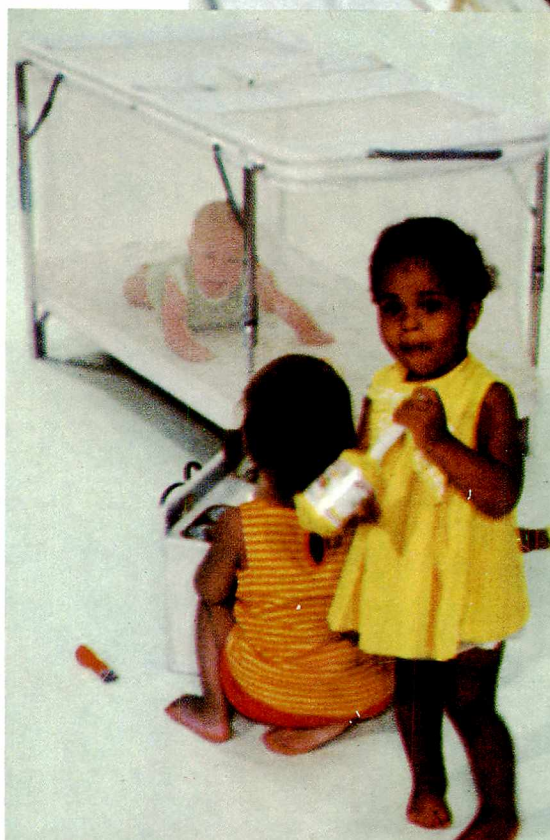
More than 15,000 children under 15 years old die each year from accidents of all kinds. This overall figure is higher than deaths from cancer, contagious diseases, heart diseases, and gastroenteritis combined.

More than half of the children who died as a result of accidents in 1966 were preschool children.

Seventeen million children—about one out of three—are injured severely enough each year to restrict normal activity or require medical attention.

The Child Protection Act of 1966, an amendment to the Federal Hazardous Substances Labeling Act of 1960, extended the Act to provide for consumer protection beyond what can be realized through labeling. As a result, the word "labeling" has been deleted from the title of the Act. It also gave FDA regulatory authority to ban toys or other articles intended for use by children if hazardous because of a chemical, flammable, pressurized, or radiational nature. Accordingly, FDA has taken action in the past against toys hazardous in these respects.

Toys and other articles intended for use by children that pose hazards because of electrical, mechanical, or thermal qualities are presently being studied by the Commission and FDA's Office of Product Safety.





The sharply-beaked bird toy (far left) may become a dangerous projectile when catapulted by a slingshot apparatus.

Cribs with widely-spaced slats (top left) present danger of strangulation.

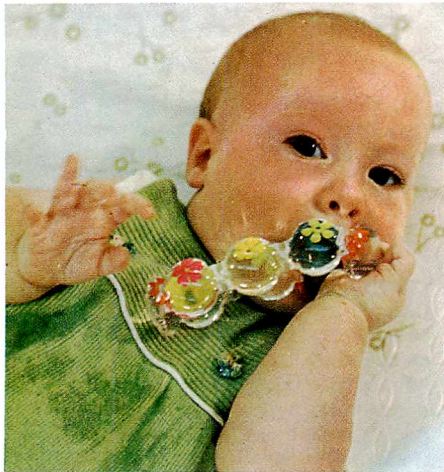
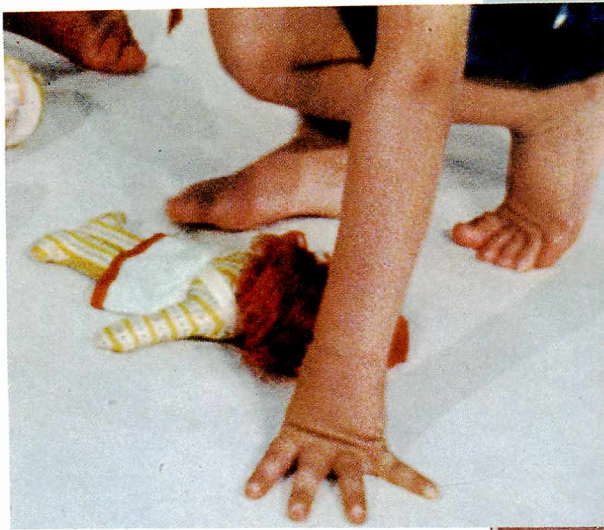
Baby rattle held by little girl (foreground, bottom left) easily comes apart to reveal sharp spikes inside. Hinged playpen presents danger of strangulation of the infant between the top and top edges. Two deaths have been reported to the Commission from this type of strangulation.

Children love playing inside the toy tunnel (center), but cloth is highly flammable.

Little girls must play house, but toy stove (background, above) produces temperatures high enough to cause burns. Clock toy (foreground) is educational, but flimsy construction makes sharp wire inside a danger.

Youngster (bottom) plays with a balloon in which there is a whistle that can be easily detached and swallowed.





Dolls with flammable hair and faces (top) were recalled from the market as a hazard several years ago under the Federal Hazardous Substances Act.

Water-filled teething rings (above) were recalled by the distributor because of bacterial contamination of water.

Toy tunnel (right) was recalled under the Federal Hazardous Substances Act because of flammability of cloth.

Costume jewelry made of jequirity beans (below) was recalled because of toxicity of beans.



and ammonium sulfamate impart resistance to flame, but because they are water soluble, laundering removes the fire retardant finishes. Several of these treatments are still valuable for such infrequently washed items as curtains, draperies, potholders, and upholstery padding.

A major breakthrough in the development of a satisfactory, durable, flame retardant finish for cotton was made at the Southern Regional Research Laboratory (one of the laboratories of the U.S. Department of Agriculture's Southern Utilization Research and Development Division) about 1950 when tetrakis (hydroxymethyl) phosphonium chloride, known as THPC, was used. This finish can be applied with standard chemical-finishing equipment. The process was commercialized in 1956 and several finishing mills in the United States and Great Britain are now using processes based on it for making fire-resistant cotton fabric. This finish on a textile withstands laundering. Its main disadvantages are cost, stiffness in some fabrics, and formaldehyde odors released during curing.

In October 1956, the Southern Utilization Research and Development Division announced one of the most effective and durable flame retardants—APO-THPC. APO is the abbreviation for tris(1-aziridinyl)-phosphine oxide. This imparts a very durable flame resistant finish and is satisfactory for use on all-cotton fabrics except tightly constructed lightweight fabrics and those weighing less than about 3 ounces per square yard. It is effective also on rayon and silk, and on blends of these fabrics, but not on cellulose acetate, nylon, or polyester fibers.

Variations of the APO-THPC treatment have been developed, and research is continuing on the development of flame retardant finishes to improve the application process and adapt them to fabrics of all weights. Some flame retardant garments have been marketed here, but flame resistant fabrics for night-

wear and children's clothing have been widely available for some time in England. Vigorous publicity is given to their advantages by the manufacturers as part of England's national fire prevention campaign. That country has had a law since 1964 prohibiting the sale of any but durable flame retardant night-dresses for children.

Of course, a number of fabrics on the market have inherent resistance to flame. Several factors determine the flammability of a fabric—its physical properties, including weight, weave, and construction (smooth and flat or brushed, napped, or piled surface); its thermal properties, which are important because most synthetic fibers, although flame resistant or slow burning, do melt or even turn to a searing liquid under fire exposure; and the chemical properties of the fiber itself, which determine its basic burning characteristics. Many textiles also have special permanent finishes intended for such purposes as wrinkle resistance, stain resistance, softness, water repellency, and washability. These also influence flammability. And many fabrics contain more than one type of fiber. All of these factors make for a wide variety of burning behavior.

Based on these factors, extremely flammable fabrics would include those made of the most readily combustible fibers woven into a physical form most conducive to rapid burning: that is, cellulose fibers in a very sheer, lightweight, or open-textured material, or in material with a deep-brushed, napped, or piled surface that exposes countless tiny fiber ends. In the latter case, the hazard is in surface construction that permits extreme ease of ignition and incredibly rapid flash burning as with the cowboy chaps and the sweaters.

Considerably more information is needed about the relative merits of various materials which are made or can be made commercially. Studies are needed on the protection offered by different fibers, weaves, and constructions; the esthetic and medical acceptability of various materials;

and comparisons of the durability and economic advantages of different fibers that are available for the same use.

The Office of Product Safety, in cooperation with other agencies of the Public Health Service, is now researching the value and acceptability of various flame resistant materials in a special study at the Public Health Service Hospital in New Orleans. Hospital sheets, blankets, pillow cases, patient gowns, robes, and cubicle curtains in three classifications—regular cotton, flame retardant treated cotton, and flame retardant treated synthetic fibers—are being evaluated. Records are being kept of durability, clinical and patient acceptability, and comfort. Economic comparisons and laboratory testing are carried out periodically for physical strength and flame retardancy.

The study began in July and is expected to run two years. The results should yield substantial knowledge of the value of flame retardant fabrics. Although the study is still in an early stage, we hope that ultimately it will stimulate the commercial availability of flame retardant materials and their use in all care institutions, places of public occupancy, and eventually in the home itself.

In terms of financial loss, available data indicates the yearly total from burns involving flammable fabrics exceeds a quarter of a billion dollars. Studies have shown that the



Carol Young, Staff Writer, Office of Product Safety, moved to FDA in September 1968 from the Injury Control Program of the Public Health Service.

samples obtained from the investigated fabric ignition cases either meet the existing standard for flammability of garments or that the fabric is not covered by the existing standard.

Government agencies responsible for carrying out the mandate of the Flammable Fabrics Act as amended agree both revised and additional standards may be needed. Testing procedures established for the existing flammability standard are considered technically inadequate to protect the public against unreasonable risk of burn accidents resulting in death or injury or significant property damage.

Among the technical inadequacies of the existing standard are (a) the lack of a provision for testing samples of less than the minimum area presently specified—for fabrics or related materials used in

smaller items or parts of wearing apparel, such as narrow strips, ribbons, tapes, fringes, small irregular shapes, loose fibers, or other forms from which the minimum size test specimen can be obtained; (b) the lack of a provision for measurement of such hazardous qualities as melting, dripping, disintegrating into flaming brands, or other hazards associated with the burning of fabrics or related materials used in wearing apparel; (c) the lack of quantitative measurement of flame intensity, heat generation, or heat transfer; (d) the lack of quantitative measurement of ease of ignition; (e) the lack of a provision to permit measurement of flame-spread time as distinguished from ignition time; (f) the lack of a provision to insure that all potentially hazardous materials are ignited in tests, particularly those that might ignite slowly, but

once ignited, burn rapidly.

DHEW has made recommendations (shown below) to the Department of Commerce in response to the latter's invitation for comments on the possible need for revised and new standards.

The recommendations made by DHEW for flammability standards for wearing apparel are almost equally applicable to standards for carpets and rugs and for other categories of interior furnishings covered by the amended Flammable Fabrics Act.

Much work has been done toward offering the public protection against flammable fabrics. Much remains to be done. New standards must be set, more flame retardant fabrics in clothing and furnishings must be made available, and the public must be made aware of the benefit of owning these fabrics.

INJURY SURVEILLANCE RECORD

(Please read instruction sheet and coding guide before marking form)

RECORD NO 000131

AGE IN YEARS IF 2 YEARS OR OLDER									
0	1	2	3	4	5	6	7	8	9
AGE IN MONTHS IF UNDER 2 YEARS									
0	1	2	3	4	5	6	7	8	9
SEX									
<input type="checkbox"/> MALE <input type="checkbox"/> FEMALE									

RECORD NUMBER									
DO NOT MARK IN THIS AREA									

NATURE OF INJURY (ALPHABETICALLY; INSULT (ONLY ONE RESPONSE))									
<input type="checkbox"/> BURN <input type="checkbox"/> SCALD <input type="checkbox"/> LACERATION <input type="checkbox"/> CONTUSION <input type="checkbox"/> ABRASION <input type="checkbox"/> FRACTURE <input type="checkbox"/> DISLOCATION <input type="checkbox"/> AMPUTATION <input type="checkbox"/> OTHER									

RECORD NO 000131									
RECORD NUMBER									
DO NOT MARK IN THIS AREA									

COLOR RACE									
<input type="checkbox"/> WHITE <input type="checkbox"/> BLACK <input type="checkbox"/> OTHER									

MARITAL STATUS									
<input type="checkbox"/> SINGLE <input type="checkbox"/> MARRIED <input type="checkbox"/> DIVORCED <input type="checkbox"/> WIDOWED									

MONTH OF INJURY									
<input type="checkbox"/> JAN <input type="checkbox"/> FEB <input type="checkbox"/> MAR <input type="checkbox"/> APR <input type="checkbox"/> MAY <input type="checkbox"/> JUN <input type="checkbox"/> JUL <input type="checkbox"/> AUG <input type="checkbox"/> SEP <input type="checkbox"/> OCT <input type="checkbox"/> NOV <input type="checkbox"/> DEC									

DATE OF INJURY									
<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9									

YEAR OF INJURY									
<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9									

DAY OF WEEK INJURY OCCURRED									
<input type="checkbox"/> MON <input type="checkbox"/> TUE <input type="checkbox"/> WED <input type="checkbox"/> THU <input type="checkbox"/> FRI <input type="checkbox"/> SAT <input type="checkbox"/> SUN									

TIME OF INJURY									
<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9									

ACCIDENT LOCATION									
<input type="checkbox"/> HOME <input type="checkbox"/> WORK <input type="checkbox"/> SCHOOL <input type="checkbox"/> OTHER									

NATURE OF ACTIVITY									
<input type="checkbox"/> SLEEPING <input type="checkbox"/> EATING <input type="checkbox"/> DRINKING <input type="checkbox"/> OTHER									

PATIENT DISPOSITION									
<input type="checkbox"/> ADMITTED <input type="checkbox"/> RELEASED <input type="checkbox"/> DECEASED <input type="checkbox"/> OTHER									

CONTACT AGENT									
<input type="checkbox"/> YES <input type="checkbox"/> NO									

SOURCE AGENT									
<input type="checkbox"/> YES <input type="checkbox"/> NO									

VEHICLE/VECT OF AGENT									
<input type="checkbox"/> YES <input type="checkbox"/> NO									

All fabrics for wearing apparel should have properties which retard ignition and burning. Whether the flame retardant property in wearing apparel fabrics, and related materials is inherent in the fabric or added by processing is immaterial.

Different standards and test procedures should be set for different types of garments, taking into consideration intended use, expected life of the garment, and similar factors. Standards and tests should closely reflect and approximate conditions and ignition hazards foreseeable in ordinary use of the wearing apparel or fabric.

Standards and tests should take into consideration the extent to which different garments will be cleaned and methods for cleaning them, with attention to the manufacturers' direction for cleaning.

The IND Procedure: Assuring Safe and Effective Drugs

by William J. Gyarfas, M.D., and Armond Welch

The Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act in 1962 increased governmental regulatory authority over clinical testing of new drugs in order to minimize hazards inherent in new drug development and to insure as far as possible a responsible concern for the safety of the subjects involved. The amendments also provided a firm basis for promotion of improved methods and evaluation of standards in the investigation of new drugs and required a demonstration of the substantial efficacy of a drug before marketing. By law, a new drug cannot be distributed in interstate commerce without approval by the Food and Drug Administration with regard to safety and efficacy. Furthermore, the submission of a Notice of Claimed Investigational Exemption for a New Drug (Form FD 1571), known as IND, is required to permit the interstate shipment of investigational new drugs for clinical studies.

The legal definition of a new drug is important. The law defines a new drug as any drug not generally recognized—among experts (qualified by scientific training and experience to evaluate the safety and effectiveness of drugs)—as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling. In addition, a drug that has been recognized as safe and effective for use under certain conditions as a result of clinical investigations, but that has not been used to a material extent or for a material time under such conditions, will still be regarded as a “new drug.” Any chemical or substance not previously used in man for the treatment of disease is obviously a new drug. Combinations of approved drugs or of old drugs may be regarded as new drugs even though the individual components are not new drugs.

A new indication for an accepted drug or its manufacture in a new dosage form or a new method of application requires investigation to show that it is safe and effective as claimed. The use of a drug *in vitro* as a diagnostic agent when this use will influence the diagnosis or treatment of disease in a human patient may cause the product to be regarded as a new drug. Under the legal definition of a new drug, the employment of an *approved drug* for uses other than those approved makes the drug a new drug.

The Federal Food, Drug, and Cosmetic Act, however, does not attempt to regulate the practice of medicine. A practitioner, in his practice of medicine as licensed by his State, may use an *approved drug* in nonapproved uses in both the therapeutic and investigational category without being legally required to submit an IND, but he may be responsible under civil law for any ill consequences arising from such use. The manufacturer, however, may not ship an approved drug across State lines for unapproved use without an IND. Also, the use of an investigational new drug—a nonapproved drug that is shipped interstate—requires submission of an IND by the physician, although he uses the drug only in his practice of medicine.

Although it is not legally required, the Food and Drug Administration does encourage the voluntary submission of an exemption (an IND) for nonapproved uses of *approved drugs* in the private practice of medicine to enable the Agency to accumulate data about the safety and efficacy of the drug. This is especially encouraged when large numbers of patients are involved. Voluntary submission of IND's under these circumstances will allow the FDA to become a useful repository on the hazards of

compounds when applied for new uses; information on significant toxicity is transmitted readily to those persons who have submitted an IND.

Investigational clinical studies are divided into three phases. The first two are described as clinical pharmacology. In Phase 1, the drug may be administered to healthy volunteers, the object being to determine toxicity, metabolism, absorption, and elimination, other pharmacological action, preferred route of administration, and safe dose range. Such studies involve a comparatively small number of subjects and are ordinarily conducted under carefully controlled circumstances by persons trained in clinical pharmacology. The proposed clinical plan may allow considerable flexibility.

When phase 1 demonstrates satisfactory results, the sponsor may proceed to Phase 2, initial trials in the treatment or prevention of the disease for which the drug is intended. Here the drug is administered to carefully supervised patients to determine safety and effectiveness. Additional pharmacologic studies, performed concurrently in animals, may be necessary to indicate safety for the Phase 2 extension of the investigation.

Finally, if the data obtained in Phases 1 and 2 provides reasonable assurance of safety and effectiveness or suggests that the drug may have a potential value outweighing its hazards, proposals for Phase 3, or extensive clinical trials, are in order. Besides work by experienced investigators, Phase 3 may, where practical, involve well-controlled studies by other groups, including practicing physicians whose training and experience in drug evaluation has been less, and whose facilities may not be so elaborate. Studies should

be carefully monitored, no matter how extensive. The regulations, which are based on the Kefauver-Harris Amendments, are designed to prevent exposure of an unnecessarily large number of patients to risk by requiring adequate evidence of safety based on earlier studies. By the Phase 3 trials, also, controls for the manufacture of the new drug should be well established.

Before starting tests of a new

drug in human beings, the sponsor, who is usually a pharmaceutical firm but may be an individual physician or a research institution, must supply to the FDA the information specified in section 130.3 of the Federal Food, Drug, and Cosmetic Act by submitting a Notice of Claimed Investigational Exemption for a New Drug (an IND), in triplicate. Once the IND has been submitted, the investigation may

proceed, unless the FDA presents an objection. If there appears to be an unwarranted hazard in continuing the ongoing clinical studies, the sponsor may be required by FDA to modify or discontinue clinical testing until further preclinical work has been done. An important function of the FDA reviews is to inform the sponsor regarding further investigation before extending the clinical testing to another phase.

The IND is required to include, among other things:

a Complete chemical and manufacturing information.

b Results of all preclinical investigations, including animal studies. Initially, these should be directed toward defining the safety of the drug rather than its efficacy. The data should demonstrate that there will not be unreasonable hazard in initiating studies in human beings. Further animal studies may be conducted concurrently with clinical studies.

c A description of the investigations to be undertaken.

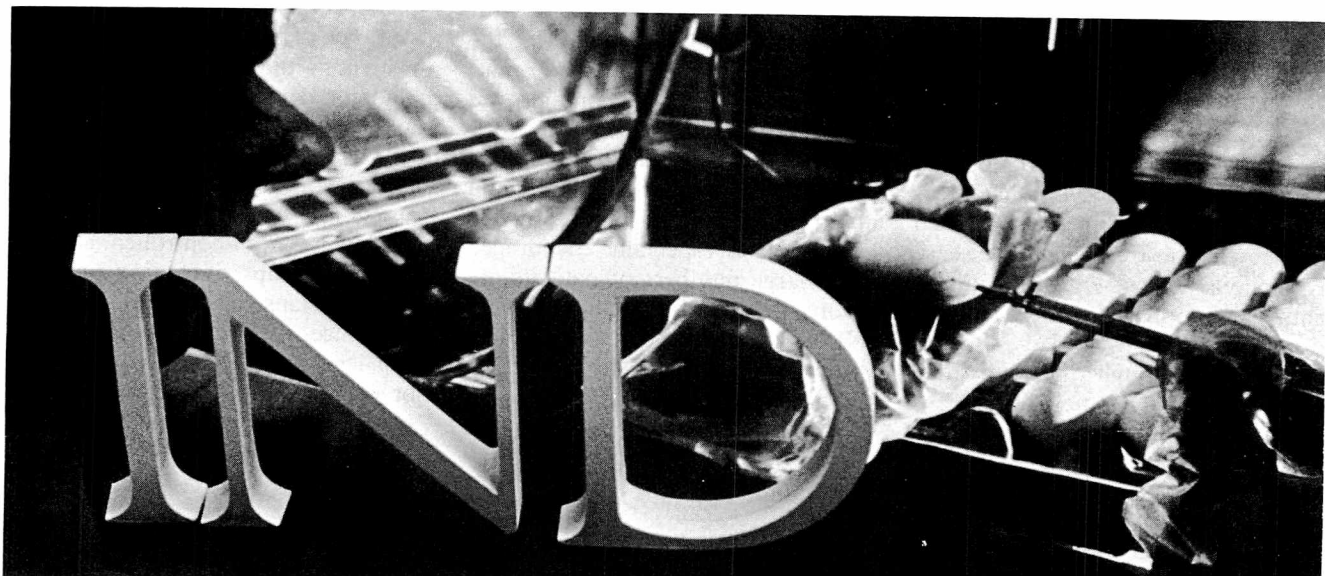
d Information regarding the training and experience of the investigator.

e Copies of all informational material supplied to each investigator.

f An agreement from the sponsor to notify the FDA and all investigators if any adverse effects arise during either the animal or human tests.

g Certification that "informed" consent will be obtained from the subjects or patients to whom the drug will be given.

h Agreement to submit annual progress reports and commitments regarding disposal of the drug when studies are discontinued.



Although the sponsor ordinarily may inaugurate clinical testing as soon as the IND is submitted to the FDA, there are certain exceptions calling for preclearance. Before starting an investigation in any of the following categories, he must obtain FDA approval:

- a. Investigations of hallucinogenic drugs, such as LSD.
- b. Investigations of certain listed drugs so toxic that their use may be justified only under special conditions.
- c. Reactivation of a study terminated by the FDA.

If a sponsor, either a firm or an individual, has a question as to whether a drug or compound he seeks to test in humans is a new drug, he may make inquiry to the Assistant for Industry Coordination, Office of the Director, Bureau of Medicine, Food and Drug Administration, as to its new drug status to determine if the submission of an IND is required. The inquiry should contain complete information about the formulation and intended use of the drug or compound. The Office of New Drugs, Bureau of Medicine, is always available to meet with prospective sponsors of IND's to discuss their proposed submissions and their plans for testing new drugs, and to offer advice, guidance, and recommendations as indicated.

Although the Kefauver-Harris Amendments did not become effective until June 1963, 1,066 IND's were submitted in the period from February through June 1963 in anticipation of the amendments becoming effective. By the end of the Fiscal Year 1969 (June 30, 1969), a total of 5,903 IND's had been submitted to the FDA. Of these 5,903 original IND's submitted, 2,808 remain active—a number of these have been reinstated after having

been terminated or discontinued. The following chart shows the receipt of IND's since the submission of IND's became a requirement for

the clinical testing of new drugs.

Of the 2,780 IND's discontinued by the sponsors, the most frequent reasons given were completion of

FISCAL YEAR	
1963	(1/31/63 – 6/30/63)
1964	(7/1/63 – 6/30/64)
1965	(7/1/64 – 6/30/65)
1966	(7/1/65 – 6/30/66)
1967	(7/1/66 – 6/30/67)
1968	(7/1/67 – 6/30/68)
1969	(7/1/68 – 6/30/69)
TOTAL	

1,066

875

761

715

671

859

956

5,903

It is interesting to note the disposition of the 5,903 IND's received by the end of fiscal 1969. The following chart presents a breakdown by fiscal year:

Fiscal Year	Discontinued by Sponsor	Terminated by FDA	Transferred to Div. of Biologics Standards	Other Disposition
1963	6	2	8	4
1964	215	8	3	10
1965	306	26	9	0
1966	580	188	1	0
1967	627	18	10	3
1968	564	11	7	19
1969	482	8	0	18
TOTALS	2,780	261	38	54

studies, lack of commercial interest, and apparent lack of effectiveness. The FDA terminated 261 IND's, some because of indication of hazard outweighing possible effectiveness of the drug, but mostly because of the failure of the sponsor to submit additional information as required and requested. Submission of 38 IND's was made to FDA, although by the nature of the drug involved, they should have been submitted to the Division of Biologics Standards, National Institutes of Health, under Title III of the Public Health Service Act.

When IND's were first required for the conduct of human clinical testing of new drugs, many were found inadequate because of incomplete information and because of poor quality of information submitted. At the time that the Kefauver-Harris Amendments became effective, many IND's were hastily compiled to cover studies already underway. These reflected no plans for capable scientific evaluation of new drugs but appeared to be a collection of data and information readily available to the sponsor. During this early period of IND regulations, the Bureau of Medicine attempted to educate sponsors as to the nature of an IND and the information required. These Bureau efforts consisted of personal contact by Bureau staff with sponsors, conferences, and publication of infor-

mational bulletins and guidelines. At this time, the Bureau, to meet the increased workload, was increasing its personnel strength and was in a constant state of reorganization. During fiscal 1966, the increase in staff reached the desired level and was further bolstered by the assignment of a group of Public Health Service Medical Officers and Pharmacists to the FDA for a period of two years. After reorganization and a better understanding by the staff of the regulations, the Bureau carried out an intensified review of all IND's submitted to date.

In the fiscal year of 1966, the requirement of high quality information resulted in the termination of 188 IND's because they were grossly inadequate or inactive so that the safety of the drug under study could not be ascertained. Now the Bureau makes an initial screening of all IND's to determine their adequacy in complying with the regulations before submission is acknowledged.

The handling of IND's is one of the principal responsibilities of the Bureau's Office of New Drugs. The Office contains six divisions, each handling drugs in a particular specialty area. Each division contains medical officers, pharmacologists, and chemists who work together to complete the review of each IND, meeting a time-frame of 60 days. In addition, medical consultants in all specialty areas are

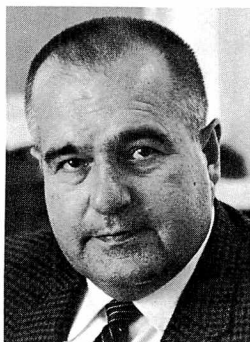
available for consultation on an ad hoc basis. Specialty advisory committees have also been set up or are being appointed in each of the major medical specialties to advise the Bureau.

As IND's are received they are screened to determine if they are complete and respond to all requirements for information. This procedure saves considerable time and effort by eliminating from the workload those IND's grossly inadequate or incomplete. Since September 1966, when this screening procedure became effective, 219 IND's have been rejected upon receipt (FY 67—40, FY 68—60, FY 69—119). When an IND is rejected, the sponsor is immediately notified by telegram. The rejected IND is returned to the sponsor (the Office retaining one copy for record) along with a letter explaining the deficiencies to enable the sponsor to make his IND acceptable.

Of the 219 IND's rejected, the deficiencies fall into three areas related to toxicology and pharmacology, chemistry and manufacturing controls, and clinical protocols. During Fiscal Year 1969, the 119 rejected IND's were deficient in various categories, as shown in the chart on the opposite page (each reject consisted of several categories).

The procedure of initially screening all IND's and rejecting those grossly inadequate has contributed to the overall improvement of the quality of IND's submitted. The rejection of inadequate IND's also reduces the number eventually terminated because of being inadequate to substantiate the clinical testing of the drug in humans.

The Kefauver-Harris Amendments of 1962 have been in effect now for over six years, requiring, among other things, the submission of IND's to perform clinical testing



William Gyarfas, M.D., Acting Director, Office of New Drugs, Bureau of Medicine, joined FDA in July 1963. Armond Welch, Chief Food and Drug Officer, Office of New Drugs, Bureau of Medicine, joined FDA in 1946.



1. Descriptive name	5
2. Components	53
3. Composition	55
4. Source	29
5. Production standards	77
6. Preclinical	60
7. Labeling	58
8. Investigator qualifications	31
9. Investigator file	31
10. Protocol	50
11. Discontinuance agreement	39
12. Discontinuance/investigator	41
13. Commercialization	42
14. Signature	18

**Toxicology
and
Pharmacology**

1. Descriptive name
6. Preclinical
7. Labeling

**Chemistry
and
Manufacturing
Controls**

1. Descriptive name
2. Components
3. Composition
4. Source
5. Production standards
7. Labeling

**Clinical
Protocols**

1. Descriptive name
7. Labeling
8. Investigator qualifications
9. Investigator file
10. Protocol
11. Discontinuance agreement
12. Discontinuance/investigator
13. Commercialization

14. Signature of sponsor

of new drugs in humans. During these six years, the Bureau of Medicine has continually improved its efficiency in review and evaluation of the IND submissions through experience and the establishment of higher requirements criteria. The Bureau also has cooperated with sponsors by means of correspondence or personal contact, publications and informational bulletins, statements of policy, and participation in workshops such as one held recently in which members of FDA participated with members of the Pharmaceutical Manufacturers Association. This joint effort by the FDA and sponsors has resulted in a continued improvement in IND submissions. However, despite this effort to upgrade the quality of IND submissions, there is still a continued need for improvement.

The IND is a guide for the testing of new drugs in humans and is providing immeasurable protection, despite frequent charges that it restricts or limits drug development and testing. The IND has restricted the uncontrolled testing of hazardous drugs or drugs for which inadequate information is available to ascertain reasonable safety for testing; it also has limited the needless exposure of individuals to new drugs. The IND requires the use of systematic, scientifically valid methods and procedures for developing and testing new drugs and provides a useful mechanism for accumulating data and information derived from drug testing. It may be reasonably concluded that the steps taken to improve the quality of the IND submission over the past six years have brought marked protection to the consumer or test subject and has improved standards for drug evaluation. At the same time, however, the need for further progress is apparent and FDA is moving in that direction.

field reports

ATLANTA DISTRICT The District detained an imported lot of 500 copper bracelets, valued at \$600, because the labeling included false and misleading claims for relief of pain from arthritis and rheumatism. Detention was June 12, at Charlotte, North Carolina, where the lot was offered for entry. The product had been shipped from Sabona Co., Ltd., London, England, to Deux-R Enterprises, Inc., Castle Hayne, North Carolina.

BALTIMORE DISTRICT Three lots of pasteurized crabmeat, consisting of 168 cans valued at about \$350, were destroyed June 27, because they had been left on a Baltimore dock for over 24 hours without re-icing.

The South Carolina packer volunteered to destroy the crabmeat after the District informed him that samples analyzed from the lot showed an elevated aerobic plate count (APC).

BOSTON DISTRICT Boston Inspectors participated in the fourth joint meeting of the Commissioned Officers Association and Clinical Society of the U. S. Public Health Service by manning the FDA information booth, titled "Safe and Effective Drugs Thru Team Effort." About 100 people visited the booth during the three-day meeting held in June in Boston. Physicians, dentists, pharmacists, and physiotherapists, as well as Government and industry representatives, attended. The moderator was Frank Tetzlaff, Regional Associate Administrator, Consumer Protection and Environmental Health Service. Dr. Paul Dudley White, noted heart specialist, delivered the keynote address.

Delegates from the American Home Economists Association Convention visited the District office in June, and heard a brief talk on the "History of FDA" by the hostess, Yolan Harsanyi, Consumer Specialist, Consumer Protection and Environmental Health Service. The 44 visitors also saw the film "Health Fraud Rackets." The group, primarily home economists, included a consumer specialist from the province of Nova Scotia's Department of Health and Welfare.

BUFFALO DISTRICT Buffalo radio station WWOL recently broadcast three weekly programs concerning the consumer protection activities of the FDA and the Consumer Protection and Environmental Health Service. The programs were part of a series on governmental agency activities, sponsored by the Public Affairs and Community Relations Committee of the Niagara Frontier Federal Executive Association. District personnel who participated in the program series included District Director Curtis R. Joiner on the May 24 broadcast;

Chief Inspector Frederick R. Carlson and Chief Chemist Felix J. Sabatino, jointly on the June 7 program; and Lois M. Meyer, Consumer Specialist, Region II, CPEHS, on the May 31 broadcast.

In June, the District detained three import shipments in Buffalo of a sterile powder and a sterile liquid intended for use in bone therapy, charging the articles were new drugs without an effective NDA (New Drug Application). The articles, called "Surgicz' Simplex," were labeled as being manufactured by North Hill Plastics, Ltd., London, England, and were shipped to this country by Down Bros., and Mayer & Phelps, Ltd., Toronto, Ontario, Canada.

CHICAGO DISTRICT Over \$11,000 worth of contaminated frozen breaded onion rings produced by one Chicago firm have been destroyed in two separate actions by the District. One seizure, and subsequent destruction by burial, involved merchandise worth \$1,000, which was contaminated with *E. coli* coliforms, and which showed a high aerobic plate count. On May 15, the manufacturer voluntarily destroyed 1,800 cases of the onion rings, worth about \$10,000, and similarly contaminated. Since the first violative inspection at the firm, the management has invested some \$2,000 in capital improvements and has drastically overhauled its manufacturing and cleanup operations.

CINCINNATI DISTRICT Supervisory Inspector Philip Brodsky received the "Federal Employee of the Year" Award in the professional and scientific category from The Federal Business Association of Greater Cincinnati. The award is based on his leadership in improving manufacturing practices in the drug industry. Mayor Eugene Ruehlmann of Cincinnati presented Mr. Brodsky a framed certificate and a desk pen set on behalf of the association, which represents over 14,000 Federal employees in the Cincinnati metropolitan area.

A food storage warehouse in Nashville pleaded nolo contendere to charges of insanitary food storage and was fined \$1,200 in the second offense action against the corporation in two years. The company, C. B. Ragland Co., Inc., was fined previously for similar charges in March 1967.

DALLAS DISTRICT In separate actions June 13, two medicated feed firms each were fined \$500 on charges involving adulteration and misbranding of medicated feeds. Both Evergreen Mills, Inc., Ada, Oklahoma, and Durant Milling Co., Durant, Oklahoma, entered pleas of nolo contendere to charges that the strength of the feeds differed from that which they purported and

were represented to possess, and the facilities and controls used in their manufacture, processing, and packing did not conform to current good manufacturing practices.

DENVER DISTRICT U.S. marshals seized 33,000 pounds of green split peas when FDA charged the lot may have been contaminated by rodents while held for sale after shipment in interstate commerce. Mountain States Bean Co. stored the peas in a Denver warehouse.

DETROIT DISTRICT Multiple seizures and publicity through the news media have reduced the number of Res-Q-Aire brand emergency aid devices in consumer channels after the two distributors of the device refused to issue a recall. An estimated 40,000 units were distributed throughout the United States. The product is a plastic bellows with an air vent at the top and a mouth piece with shield at the bottom. It has been widely sold to rescue squads and similar emergency care units.

Crown Products Co., Cleveland, formerly distributed the device, now marketed by Res-Q-Aire, Inc., Canton, Ohio. Both FDA and the Emergency Care Research Institute of Philadelphia evaluated the "Res-Q-Aire" as ineffective and dangerous, especially when used on infants and children.

News media have cooperated to warn the public of this health hazard. Seizure recommendations charged that the device's labeling was false and misleading and failed to bear adequate directions for use; that it was impossible to write directions for safe, effective use; that labeling failed to bear adequate warnings where use of the device might be harmful; and that the device is dangerous to health when used as the labeling recommends.

KANSAS CITY DISTRICT Illegal fireworks caused a heavy workload for State and District personnel prior to the July 4 holiday. At Kearney, Nebraska, two brothers were arrested for the illegal sale and distribution of illegal fireworks and fined \$100 each plus costs, and approximately \$1,000 worth of fireworks were confiscated and destroyed. In Derby, Kansas, the efforts of the Kansas Deputy State fire marshal and Sedgwick County deputy fire chief resulted in voluntary destruction of 22 gross of Cherry Bombs and Silver Salutes, valued at more than \$12,000. Local and county officials brought actions and confiscated \$1,500 worth of illegal fireworks in north central Missouri. Kansas City District Compliance Branch requested seizure of class B fireworks in possession of six retail fireworks stands in northwest Missouri. Samples collected included stocks of M-80's, Cherry Bombs, aerial bombs, Silver Salutes, 2-inch firecrackers, and 1-pound sky rockets.

Sample analysis by FDA, following inspection of the

Missouri manufacturer, resulted in the destruction of four vats of cheese worth over \$2,000, which was contaminated with staphylococci and filth. The consignee destroyed the cheese.

A nonfat dry milk manufacturer destroyed almost 14 tons of his product at Hannibal, Missouri, after FDA recalled the dry milk because of *Salmonella* contamination.

LOS ANGELES DISTRICT A considerable area of farm land in Salt River Valley, Phoenix, is contributing to endrin contamination of carrot crops. The soil contains endrin apparently applied about 1964 to cotton or other crops. The contamination is spotty, producing some carrots with illegal levels of endrin. Growers, shippers, and distributors are alert to the problem and make frequent soil and carrot analyses. The screening analyses program failed on one lot of 90,000 pounds, valued at \$4,500, which was sampled in transit and found to contain .065 parts per million of endrin. The lot was seized at Buffalo, New York.

The District supervised voluntary destruction in Los Angeles of 68 cases of candy contaminated with a zinc nitrate solution. Contamination occurred when a shifting truckload blocked doors which had to be forced open. When the door opened, two drums of 30 percent zinc nitrate solution were punctured, and contaminated the load.

Short-weight violations of frozen egg noodles recently resulted in a Denver District recommendation for seizure. Los Angeles District complied, seizing 35 cartons of 420 12-ounce packages, valued at \$108. The seizure was recommended because the manufacturer, L. A. King Food Products, Denver, had disregarded numerous warnings by Denver District. The seizure took place at the dealer's location in Los Angeles.

MINNEAPOLIS DISTRICT The District cooperated this summer with several colleges by participating in teacher education workshops. Such workshops are effective in offering current information about the consumer protection activities of the FDA. Colleges and workshops included Mankato State College—for home economics, industrial arts, health, and business education teachers, on consumer education; River Falls State University—for teachers and school administrators, to teach the safe use of drugs; Stout State University of Menomonie, Wisconsin—for home economics teachers, on family consumer trends; St. Cloud and Bemidji State Colleges—for teachers, on mood-modifying drug substances.

NEW ORLEANS DISTRICT Resident Inspector Tom Hooker met recently with Mississippi officials to discuss plans for eventual State-Federal agreements on division of work areas to avoid duplication.

During June, Chung-Juo Hsiung, a specialist with the

office of planning and programming, Joint Commission on Rural Reconstruction, Taipei, Taiwan, Republic of China, visited the District Compliance Branch. The purpose was a discussion of the requirements of the Food, Drug, and Cosmetic Act and the Hazardous Substances Act, as they apply to U. S. imports and exports.

On July 2, the District's seizure action to control misbrandings of Kay-eze, a device for which false arthritic cure claims were made, was terminated with a consent decree calling for destruction of the offending literature. A consent injunction was also approved to restrain the promoters, Kay-Cee Products Co., Jackson, Mississippi, from making representations and suggestions that the article will cure or control arthritis.

NEW YORK DISTRICT In August the District opened a new resident post in Port Chester, New York. The residency services the upstate New York area bordering the Hudson Valley to the Buffalo District line. In addition to routine compliance work, the new post serves as a focal point for State/Federal cooperative efforts in the upstate area.

FDA's enforcement of the Federal Food, Drug, and Cosmetic Act is strengthened in Puerto Rico through a provision of the Commonwealth's industrial tax exemption statute. This provision was the topic of a speech presented by Hector S. Blandino, Office of Industrial Tax Exemption for Puerto Rico, at the Pharmaceutical Manufacturing Practices seminar held April 14 and 15 at San Juan, Puerto Rico.

Mr. Blandino said all the grants issued by the Office of Industrial Tax Exemption and approved by the Governor of Puerto Rico require that the grantees comply with certain statutes, including the Federal FDC Act. If an industry subject to this act fails to abide by its requirements, the firm may lose any tax exemptions that have been granted. The Association of Pharmaceutical Industry of Puerto Rico sponsored the seminar in cooperation with the New York District.

Weems L. Clevenger, Regional Food and Drug Director, Region II, addressed the American Spice Trade Association's annual convention May 25 at Jacksonville, Florida, in behalf of Commissioner of Food and Drugs Herbert L. Ley, Jr. In the presentation, Mr. Clevenger described the industry's proposed guidelines for levels of extraneous matter in bulk imported spices, and emphasized certain points. The guides are not static, and it is expected that they will be modified because of improved harvesting and handling in the countries of origin. Blending to lower or raise a lot to a given guideline mark will not be tolerated, he said. All importers are expected to comply on their own initiative in cases where the District stamps off the entry. If adulterated spices are found in domestic commerce, FDA will recommend legal action. FDA will work with the spices trade to its resource limit, he said.

PHILADELPHIA DISTRICT On June 27, Virginia K. Knauer, Special Assistant to the President for Consumer Affairs, appointed Jeanne M. Devers, Consumer Protection and Environmental Health Service Consumer Specialist stationed at the Philadelphia District, as an Associate Director for Field Operations with the President's Committee on Consumer Interests. Miss Devers' assignment includes the promotion and development of local, State, and national consumer programs. She was one of the 1968 recipients of the FDA's Merit Award.

SAN FRANCISCO DISTRICT The San Francisco Consumer Desk is working closely with local educators to set up consumer protection workshops and seminars for 200 teachers in November in the Oakland Unified School District. Credit for the seminars will be offered under the California teacher's in-service training program.

Consumer Specialist Una Wood says the workshops, which are a continuation of the San Francisco and Sacramento seminars organized by FDA last fall, are being expanded to include informational materials from all agencies in the Consumer Protection and Environmental Health Service.

A workshop planning committee, made up of representatives from the home economics, life sciences, and health education fields, was to announce the seminar's details in August.

The U. S. marshal for the District of Hawaii seized 22 30-pound cans of frozen whole eggs on June 26 in Hawaii after analysis revealed the presence of *Salmonella* and Arizona hinshawii. A Los Angeles District firm shipped the eggs to Hawaii. The eggs were valued at approximately \$145.

A long-standing problem may be on the way to solution! Large amounts of cassia are imported through the District each year, and it has been almost routine to detain this product because of the presence of insect filth and mold. Some time ago, one of the larger local users of this product forwarded machinery to Padang, Indonesia, for reconditioning cassia prior to shipment. Early this year, the equipment was assembled and cleaning of the product began. In May, three entries of precleaned cassia were sampled by the District and released.

Over 17 tons of green coffee were seized in San Francisco on June 12, because samples collected during an inspection of the storage firm showed the presence of rodent urine. The District also alleged that the coffee, valued at \$11,700, had been held under insanitary conditions.

District detentions in San Francisco during June included a lot of 6,250 176-pound sacks of sesame seed that were contaminated with the pesticide chemical aldrin, and a lot of 82 109-pound bales of sage leaves. The bales had a white powder on the exterior which laboratory examination identified as antimony and

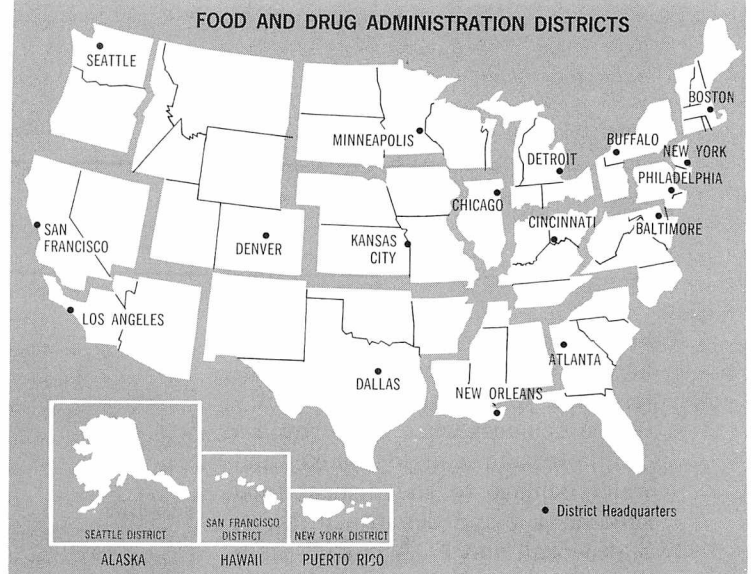
arsenic. Contamination probably occurred during unloading operations, when sacks of the poisonous powder broke, spewing contents over the bales.

SEATTLE DISTRICT A representative of the vegetable canning industry met with District staff members June 4 to discuss mutual problems. The representative, William Clyde, is Corporate Quality Control Director of Lamb-Weston Co., Portland, Oregon. The company operates a number of vegetable canneries in Oregon and Washington.

The District participated in a bit of drug history June 12 when all the area drug manufacturing industries sent representatives to Portland, Oregon, to plan a two-day Good Manufacturing Practices Drug Workshop for October. Stanley Drug Products was host at the planning meeting, attended by Portland Resident Inspector Loren Peterson and Industry Education Officer J. Kenneth Kinney.

During the fall of 1968, 80,000 pounds of frozen whole salmon was seized in Bellingham, Washington, because of decomposition. The legal procedure having run its course, the U. S. marshal has now reported to the District that the frozen salmon was "laid out to be thawed and then plowed under the soil."

A multilevel attack has been initiated against a canned tomato juice problem involving a District packer. Food poisonings have been attributed to consumption of the tomato juice made by Snokist Packers of Yakima, Washington. The National Canners Association (NCA), with the complete cooperation of the packer, took the lead and convened a meeting in Portland, Oregon, on June 13 to try to assemble all the facts.



Participants included FDA, State health and agriculture departments of Oregon and Washington, and the company. In the hope that combined efforts would be productive, the meeting assigned various responsibilities to each participant.

The District recently discussed preliminary plans to incorporate food and inspection data from the States of Oregon and Washington into the District's data processing system. The District met June 6 with the Oregon State Department of Agriculture, Dairy and Consumer Services Division, and on June 11 with a representative of the Washington State Department of Agriculture. The preliminary discussions concerned the FDA proposed State establishment inspection forms. The District already has food inspection agreements with both States. Both Oregon and Washington State representatives are responsive to the idea and plan to meet with District people again as soon as the proposed State inspection forms are approved.

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

CPEHS REGIONAL ASSISTANT ADMINISTRATORS' OFFICES REGIONS I-IX

BOSTON J. F. Kennedy Federal Bldg.
Government Center
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NEW YORK 26 Federal Plaza
New York, New York 10007

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

Fire Damage A fire in a Charlotte, North Carolina, shopping center in late spring caused over \$630,000 in damages when it destroyed a drugstore and caused smoke and water damage to an adjacent food supermarket and department store. State, local, and FDA officials handled the investigation, and supervised destruction of damaged products.

The drugstore was unable to salvage anything except some ladders and fertilizer. Its losses were estimated to be around \$600,000. A firewall between the drugstore and the supermarket saved the latter from extensive damage. Water seeped through the wall, however, and damaged bread, eggs, and dairy products. Meat wrapped in cellophane absorbed some of the smoke and had to be destroyed also. Although the supermarket's coolers were not damaged, meats hanging there were contaminated with an off-odor from a deodorizer product used in an adjacent stock room and thus were ordered destroyed. Ira Verble, inspector with the Charlotte-Mecklenburg County Health Department, supervised destruction of damaged food products, valued at \$30,000. Damaged merchandise was buried in a city dump.

Officials stationed guards at the stores until cleanup crews removed damaged merchandise.

California Closes Firm State action resulting from FDA San Francisco District referral during the week of June 23 closed a firm that distributed herbs for use as aphrodisiacs. The firm, Kama Sutra West, San Francisco, advertised in such publications as the "Berkeley Barb," a so-called underground newspaper, to distribute its product. FDA's Los Angeles District brought the firm's operations to the attention of the San Francisco District, which investigated and, finding no direct interstate jurisdiction in the matter, re-



Contaminated beef being loaded into truck on its way to the city dump for burial.

ferred it to the Bureau of Food and Drug, California Department of Public Health.

Illinois Enforces The Illinois Department of Public Health, Division of Milk Control, initiated a program to insure that manufacturing plants achieved compliance with the new State inspection regulations. The regulations became effective last March 28. In April the Division of Milk Control checked all Illinois dairy plants to determine the degree of compliance prior to annual renewal of Certificates of Approval. Plants not operating under satisfactory conditions were denied certification pending reinspection. In May the Division checked to determine if corrections and improvements had been made. Many firms showed marked improvement, a result of substantial expenditures of money and manpower.

Pesticide Sampling Agreement Under a new State-Federal agreement, the Wyoming Department of Agriculture on July 1 started collection of all pesticide surveillance samples for FDA within the State. The Department pays for the

samples, and ships them to Denver District laboratories for examination. The agreement, developed by Wyoming officials and FDA personnel, provides for use of State and Federal resources, and aids in avoiding duplication of effort.

AFDOUS Elects John C. McClellan, administrator for the General Laboratory Division of the Wisconsin Department of Agriculture, is the newly elected president of the Association of Food and Drug Officials of the United States. Mr. McClellan succeeds Eaton E. Smith, this year's AFDOUS president, who is director of the Food and Drug Unit of the Connecticut Department of Consumer Protection.

Texas Embargoes Shrimp The State of Texas embargoed and witnessed the destruction of 1,650 pounds of green headless shrimp on June 19 after FDA Dallas District Inspectors found the shrimp in a state of decomposition at a seafood company in Port Lavaca. The District laboratories had confirmed inspectional findings of decomposition, and, since the shrimp was not shipped interstate, the Texas Department of Health was called in.

Wiley Award to Hawaii Official

The Food Commissioner and Analyst for the State of Hawaii, George H. Akau, received the 1969 national Wiley Award for outstanding service in consumer protection. The Association of Food and Drug Officials of the United States presented the award to Mr. Akau at its annual banquet on June 18.

Mr. Akau became Administrator of Food and Drug Laws for the Hawaii State Department of Health in 1944. He also served as acting district chief for the FDA, as well as a consultant on FDA's Food Standards Committee.

The Wiley Award is presented annually in honor of Dr. Harvey W. Wiley, who is credited with successfully obtaining enactment of the Food and Drug Act and the Federal Meat Inspection Act, both passed by the Congress in 1906.

District/Federal Agreement Dr. Murray Grant, Director of the District of Columbia Health Department, and Maurice D. Kinslow, Regional Food and Drug Director, Department of Health, Education, and Welfare Region III, signed an agreement July 3 in which the D. C. Health Department assumes responsibility for inspecting bottling plants and investigating consumer complaints concerning bottled beverages. The agreement also provides for training D. C. personnel, and for joint inspections involving D. C. and FDA's Baltimore District to evaluate the program.

Flood Damage Tennessee State authorities ordered destruction of water-damaged meats, vegetables, flour, and other nonsalvageable food items after a flash flood struck Red Boiling Springs on June 23. Two children drowned in the flood, which caused an estimated several million dollars damage.

Feed Inspectors Trained Nine Iowa Department of Agriculture Feed Inspectors have finished training in FDA medicated feed inspection techniques and are now being processed for FDA commissions. The Iowa group, headed by Secre-

tary of Agriculture L. D. Liddy, represents the third State in the District's territory to carry on the cooperative feed inspection program. Both Kansas and Missouri are already conducting feed mill inspections.

Commissioning in Illinois John W. Lewis, Director of the Illinois Department of Agriculture, and 12 inspectors of the Department's Division of Feeds, Fertilizers and Standards received commissions April 22 under the Food, Drug, and Cosmetic Act. The commissions climaxed a week-long training session with the FDA's Office of Legislative and Governmental Services and a series of joint inspections with Chicago District Inspectors. Mr. Lewis, who is a former Speaker of the Illinois House of Representatives, was awarded the first commission by Samuel M. Hart, Regional Food and Drug Director. Mr. Lewis then presented commissions to the State Inspectors. After the presentation, Mr. Lewis said: "The testing of livestock feeds that contain medication gives the farmer more assurance than ever that the merchandise he buys has the proper amount of medicines in it and that the feed will do the job he wants done."

Train Wreck Cooperation A train wreck in the early morning of May 7, north of Alhambra, Illinois,

brought a period of massive cooperation among State and Federal units to protect the consumers' health. Tank cars of anhydrous ammonia and propane as well as five carloads of soybean meal and three cars of corn sirup were included in the train. Several cars of propane exploded and burned. In this dangerous situation, personnel from various State agencies worked to protect the public from the hazards of possible adulteration of foodstuffs. Joint protection efforts were made by the Illinois Division of Feeds, Fertilizers and Standards, Department of Agriculture; Division of Food and Drugs, Department of Public Health; the State Police; and FDA's Chicago District. State Inspectors, under the supervision of Division of Feeds, Fertilizers and Standards Superintendent Glenn E. Yard, made sure the damaged car of ammonia was not moved precipitately. An inspector from the State's Division of Food and Drugs and one from FDA Chicago District checked soybean meal. Since the meal was not contaminated, it was sold to a local livestock feeder. One sirup car was ruptured, one was undamaged, and a third had a broken valve that had allowed half the car's contents to escape. The remainder of the sirup from this third car was embargoed and sampled.



State-Federal personnel at wreck site to determine extent of damage to foodstuffs.

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 actions to remove adulterated, misbranded, and unsafe products from the consumer market were reported in June/July. These included 35 seizures of foods: 7 because of poisonous and deleterious substances, 27 because of contamination, and 1 because of economic violations. Other seiz-

ures included 1 each of food and color additives, 13 of drugs (including 1 of veterinary and medicated feeds), 6 of medical devices (including 1 of prophylactics), and 4 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD / Poisonous and Deleterious Substances		
Carrots/Buffalo, N.Y. 6/26/69	Bodine Produce Co./Phoenix, Ariz. (P,S)	Contain endrin pesticide residues for which there is no tolerance.
Eggs, frozen/Honolulu, Hawaii 6/26/69	Weksler Egg Co./Vernon, Calif. (P,S)	Salmonella.
Fishmeal (bulk)/Waldron, Ark. 6/2/69	Imported from Norway, Wilbur-Ellis Co./New York, N.Y. (S)	"
Mobile, Ala. 6/9/69	Wilbur-Ellis Co./New York, N.Y. (S)	"
Mobile, Ala. 7/2/69	Shipped from Lima, Peru.	"
Morehead City, N.C. 5/23/69	Imported from Peru, International Proteins Corp./Fairfield, N.J. (S)	"
Jack mackerel, canned/Brooklyn, N.Y. 6/17/69	J. R. Barry Co./Terminal Island, Calif. (S)	Contains DDT, DDE, DDD, pesticide chemicals not in conformity with regulations.
Contamination, Spoilage, Insanitary Handling		
Beans/Gretna, La. 6/23/69	Gulf Puerto Rico Lines/Gretna, La. (D)	Held under insanitary conditions.
Black-eyed peas, canned/Muncie, Kans. 6/7/69	Allen Canning Co./Siloam Springs, Ark. (M,S)	Contain stones.
Cashew(s), whole/St. Paul, Minn. 5/28/69	Imported from India, J. F. Braun & Sons, Inc./New York, N.Y. (S)	Insect and rodent contaminated.
brittle/Sunbury, Pa. 6/17/69	Strazer Candy Co./Denver, Colo. (M,S)	Prepared and packed under insanitary conditions.
Coconut/Tampa, Fla. 6/11/69	Lorenzen Coffee Service/Tampa, Fla. (D)	Held under insanitary conditions.
Coffee, green/San Francisco, Calif. 6/12/69	Matson Terminals, Inc./San Francisco, Calif. (D)	"
Halibut pieces, frozen/Seattle, Wash. 5/27/69	Rainier-Port Cold Storage/Seattle, Wash. (D)	Decomposed.
Seattle, Wash. 6/5/69	From unknown fishing vessel.	"
Nutmeg/New York, N.Y. 6/10/69	Fidelity Warehouse/New York, N.Y. (D)	Moldy.
Peanuts, shelled/Los Angeles, Calif. 6/18/69	Gust Picoulas & Co./Los Angeles, Calif. (D)	Held under insanitary conditions.
Peas, green, split/Denver, Colo. 6/25/69	Mountain States Bean Co./Denver, Colo. (D)	"
Pepper, black/Brooklyn, N.Y. 6/10/69	J. Raphael & Sons Corp./Brooklyn, N.Y. (D)	Moldy.
Pinto beans/Los Angeles, Calif. 5/14/69	Bean Growers Warehouse Association, Inc./Buhl, Idaho (P,S)	Prepared, packed, and held under insanitary conditions.
Rice/Gretna, La. 6/23/69	Gulf Puerto Rico Lines/Gretna, La. (D)	Held under insanitary conditions.
Cairo, Ill. 5/21/69	Greaney Brokerage Co./Cairo, Ill. (D)	"
Wheeling, W. Va. 5/29/69	Wheeling Wholesale Grocery Co./Wheeling, W. Va. (D)	"
and wheatcakes/Los Angeles, Calif. 5/27/69	American National Mercantile Co./Los Angeles, Calif. (D)	"
Sardines, canned/Baton Rouge, La. 6/5/69	North Atlantic Packing Co./Jonesport, Maine (M,S)	Decomposed.
Sesame seed/New York, N.Y. 6/10/69	Fidelity Warehouse Co./New York, N.Y. (D)	Insect contaminated.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Contamination, Spoilage, Insanitary Handling (cont'd)		
Shrimp, breaded/Memphis, Tenn. 5/6/69	Trade Winds Co./Thunderbolt, Ga. (P,S)	Prepared and packed under insanitary conditions.
Orangeburg, S.C. 5/13/69	"	"
Florence, S.C. 5/26/69	"	"
Los Angeles, Calif. 5/16/69	National Shrimp Processors, Inc./Browns- ville, Tex. (P,S)	Decomposed.
dried, shredded/Phoenix, Ariz. 5/8/69	La Victoria Products Co./Rosemead, Calif. (P)	Insect contaminated.
meat, frozen/Seattle, Wash. 7/8/69	B & B Fisheries, Inc./Kodiak, Alaska (P,S)	Excessive coagulase positive staphylococci.
Tomato paste/Columbus, Ohio 6/19/69	William W. Callif & Sons, Inc./Columbus, Ohio (D)	Partly decomposed.
Walnuts, black, shelled/Reading, Pa. 6/2/69	Continental Nut Co./Chico, Calif. (P,S)	Prepared and packed under insanitary conditions; E. coli.
Economic Violations		
Egg noodles, frozen/La Habra, Calif. 6/18/69	Alpha Beta Acme Markets/La Habra, Calif. (D)	Inaccurate quantity of contents statement.
Color Additive		
Maraschino raisins/Miami, Fla. 5/12/69	Kitchen Craft Foods Co./Brooklyn, N.Y. (M,S)	Contain an unsafe color additive, FD&C red, and labeling fails to state that chemical preservatives benzoate of soda and sulfur dioxide were added.
Food Additive		
Tricaine methanesulfonate powder/Scotts- dale, Ariz. 5/27/69	Crescent Research Chemicals, Inc./Scotts- dale, Ariz. (D)	Inadequate directions for use in fish and other ani- mals to be used for human food.
DRUGS / Human Use		
Codeine phosphate injectable/Jackson, Mich. 6/25/69	Intra Products Co./Dayton, Ohio (M,S)	Faulty needle shields fail to assure sterility; not packaged as prescribed in USP.
Cosanyl extract/Detroit, Mich. 6/4/69	Parke, Davis & Co./Detroit, Mich. (D)	Prepared under insanitary conditions.
Cratil butabarbital sodium tablets ½ gr./ Lisle, Ill. 6/26/69	Bates Laboratories, Inc./Chicago, Ill. (M,S)	Not in conformity with NF standard for strength.
Crinex formula/Rochester, N.Y. 4/24/69	Crinex, Inc./Rochester, N.Y. (D)	Not prepared in registered establishment; inadequate warnings; false claims for stimulating hair growth and for scalp therapy.
Fever Jr. tablets, Palmosan tablets, Sed-A- Cel, Hemophos tablets/Auburn, N.Y. 7/8/69	Jenkins Laboratories, Inc./Auburn, N.Y. (D)	False and misleading claims as urinary antiseptic (Palmosan); inadequate directions for use (Fever tablets, Sed-A-Cel, Hemophos tablets).
Ni-Kur/Barberton, Ohio 5/12/69	Selador, Inc./Barberton, Ohio (D)	New drug not approved for safety and efficacy.
Obetabs/Detroit, Mich. 5/26/69	Plymouth Labs., Inc./Plymouth, Mich. (M,S)	Below labeled potency; methods used, facilities, and controls not in conformity with good manufactur- ing practice.
Reserpine/Mansfield, Ohio 5/16/69	"	Below USP standard for strength.
Robese gel/Phoenix, Ariz. 5/27/69	East Phoenix Wholesale Drug/Phoenix, Ariz. (D)	New drug not approved for safety and efficacy; false and misleading claims for gastrointestinal tract, dysmenorrhea, hypotension; inadequate informa- tion for such use.
Squill, white/Detroit, Mich. 6/4/69	Parke, Davis & Co./Detroit, Mich. (D)	Insect contaminated.
Kola nuts, cherry bark/Detroit, Mich. 5/16/69	"	"
Trio Reducing Pac/Minneapolis, Minn. 5/28/69	Super Products/Chicago, Ill. (Distrib.)	New drug not approved for safety and efficacy; false and misleading claims as a necessary adjunct to diet control to achieve weight loss.
Veterinary/Medicated Feed		
ZEV (veterinary cough syrup)/Elgin, Ill. 5/23/69	Strong Cobb Arner, Inc./Cleveland, Ohio (M)	New drug not approved for safety and efficacy.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
MEDICAL DEVICES		
Dynabelt Electronic Exerciser/Kansas City, Mo. 5/5/69	Dynatone Electronics Corp./Wichita, Kans. (M,S)	False and misleading claims for reducing inches and exercising muscles effortlessly; inadequate warnings against use.
Gauze sponges/Atlanta, Ga. 6/26/69	Parke, Davis & Co./Greenwood, S.C. (M,S)	Below USP standard for quality; not sterile.
Res-Q-Aire emergency respirator/Seattle, Wash. 7/8/69	Machsa, Inc./Cleveland, Ohio (M)	False and misleading claims to be effective for resuscitation; inadequate warnings against use in conditions such as obstructions in the mouth and throat, aspirated objects, dentures, and use in infants and children where air volume would be excessive; dangerous when used in the prescribed dosage, frequency, and duration.
Jackson, Miss. 7/9/69	Crown Products Co./Cleveland, Ohio (S)	"
Surgical gloves/Tyler, Tex. 6/24/69	Affiliated Hospital Products/St. Louis, Mo. (M,S)	Labeled "Sterile" and "Pure Latex Surgeon's Gloves" but contained metallic particles and holes.

Prophylactics

Redi-Wet/Minneapolis, Minn. 6/12/69	Dean Rubber Co./North Kansas City, Mo. (M,S)	Defective quality.
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HAZARDOUS SUBSTANCES

Ash Cans, M-80's/Sardinia, S.C. 6/24/69	Smith's Esso Station/Sardinia, S.C. (D)	Banned hazardous substances; lack consumer protection information required by the Fed. Hazardous Substances Act.
Black Cat Super Charged Flashlight Crackers, repeating bombs, flash bombs, buzz bombs / Matanuska-Susitna Borough, Alaska 7/3/69	Barbara Tallman's Retail Fireworks Stand/ Matanuska-Susitna Borough, Alaska (D) and Ruth Hand	"
Bouillants (Love Meters)/Alexandria, Va. 6/9/69	Imported by John S. Connor, Inc./Baltimore, Md. (S)	"
Bulldog Salutes, M-80's, Globe Torpedoes, Cherry Bombs/Allendale, S.C. 6/24/69	Brant's Texaco Station/Allendale, S.C. (D)	"

POST OFFICE DEPARTMENT

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

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

June 17, 1969: False Representation Order issued against **ALPHA INDUSTRIES, ARIES INDUSTRIES, INC.**, and **P.O. BOX 135**, Flatbush Station, Brooklyn, N.Y. Solicitations of orders and sale through the mails of a booklet entitled "New Found Routine of Virility Exercises for Adults," advertised as effective for enhancing sexual virility.

July 3, 1969: False Representation Order issued against **THE EVERSLIM FACTORY**, Postfach 221 at 7070 Schwaebisch Gmuend, West Germany. Solicitations of orders and sale through the mails of "The Everslim Sleep and Slim Garment," represented to reduce body weight if worn all the time you spend in bed.

Other Action

July 4, 1969: **Edward I. Winkler**, age 27, was killed in a crash on this date at Mount Evans, Colo., in an airplane piloted by him. Winkler, d/b/a **Vib-Erect Co.**, Los Angeles, Calif., was sentenced in Federal Court on July 29, 1968, to 6 months' imprisonment, fined \$6,000, and placed on probation for 5 years on condition that he not engage in any mail-order business. He had been convicted of mail fraud incident to his nationwide advertising and sale through the mails of so-called sex devices. (See FDA Papers, November 1968.)

Following his imprisonment, he was released in approximately 2 weeks, pending outcome of an appeal, but continued his mail-order business under the trade styles **DIOR** and **UNIVERSAL SALES**. The "take-in" ran into many hundreds of thousands of dollars. Thousands of complaints were received from persons alleging the brochure was obscene in itself.

notices of judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

Carrots, at Buffalo, W. Dist. N.Y.

Charged 12-30-68: when shipped by John Jacobs Farms, Phoenix, Ariz., the article contained the pesticide chemical endrin for which there was no tolerance or exemption; 402(a)(2)(B). Default decree ordered destruction. (1)

Flour and dried beans, at Prescott, Dist. Ariz.

Charged 5-12-65: while held by Thriftee Wholesale, Prescott, Ariz., flour contained rodent filth—402(a)(3); dried beans contained the pesticide chemical DDT for which there was no tolerance or exemption for post-harvest use—402(a)(2)(B); and both articles were held under insanitary conditions—402(a)(4). Default decree ordered destruction. (2)

FOOD / Contamination, Spoilage, Insanitary Handling

Cassia, at Brooklyn, E. Dist. N.Y.

Charged 5-29-68: while held for sale, the article contained insect filth; 402(a)(3). Consent decree authorized release to Imperial Commodities Corp., New York, N.Y., for salvaging. (3)

Catsup, Del Monte, at Columbus, S. Dist. Ohio.

Charged on or about 1-21-66: when shipped by California Packing Corp. Frankfort, Ind., the article contained decomposed tomato material; 402(a)(3). Default decree ordered destruction. (4)

Chili peppers, at Los Angeles, C. Dist. Calif.

Charged 1-16-69: while held by Arizona Picos Packing Co., Los Angeles, Calif., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release of a portion of the article to the dealer for salvaging; and default decree ordered destruction of the remainder of the article. (5)

Flour, at Bluffton, N. Dist. Ind.

Charged 8-14-67: when shipped by The Lock Two Grain & Milling Co., New Bremen, Ohio, the article contained insect fragments and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (6)

Flour, at Corinth, N. Dist. Miss.

Charged 2-7-69: while held by Alcorn Wholesale Co., Inc., Corinth, Miss., the article was rodent gnawed and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (7)

Flour, at Selma, S. Dist. Ala.

Charged 5-3-67: while held by Stewart, King & McKenzie, Selma, Ala., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (8)

Flour, 2 seizure actions at Charleston, S. Dist. W. Va.

Charged 12-5-66: while held by Dunbar Wholesale Co., Charleston, W. Va., the article contained rodent filth, was rodent gnawed, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decrees ordered destruction. (9)

Nutmegs, at Brooklyn, E. Dist. N.Y.

Charged 6-18-68: while held for sale, the article contained insects and moldy, decomposed nutmegs; 402(a)(3). Consent decree authorized release to George Uhe & Co., Inc., New York, N.Y., for salvaging. (10)

Pecan pieces, at Philadelphia, E. Dist. Pa.

Charged 1-16-68: when shipped, the article contained *E. coli* and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (11)

Pecan pieces, at St. Louis, E. Dist. Mo.

Charged 2-1-68: while held by Missouri Pecan Shelling Co., St. Louis, Mo., who shelled and packed the article, the article contained insect filth; 402(a)(3). Consent decree ordered destruction. (12)

Perch, frozen, breaded, at Nashville, M. Dist. Tenn.

Charged 12-4-68: when shipped by Channel Fish Co., Inc., Boston, Mass., the article contained bacterial filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (13)

Potatoes, hash-brown, frozen, Huddle House, at Atlanta, N. Dist. Ga.

Charged 6-12-68: when shipped by Idaho Frozen Foods (Div. Consolidated Foods Corp.), Twin Falls, Idaho, the article contained *E. coli* and excessive coliforms and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for salvaging. (14)

Salt, at Charleston, S. Dist. W. Va.

Charged 12-5-66: while held by Dunbar Wholesale Co., Charleston, W. Va., the article contained rodent filth, was rodent gnawed, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (15)

Seafood patties, frozen, at Dayton, S. Dist. Ohio.

Charged on or about 1-8-69: when shipped by Allen Kirkpatrick & Co., Inc., Rehoboth Beach, Del., the article contained bacterial filth; 402(a)(3). Default decree ordered destruction. (16)

Shrimp, breaded, frozen, at Atlanta, N. Dist. Ga.

Charged 1-3-69: when shipped by Apollo Foods, Inc., Tampa, Fla., the article contained bacterial filth and had been packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (17)

Shrimp, canned, at Winchester Bay, Dist. Ore.

Charged on or about 11-6-67: when shipped by Winchester Bay Seafoods, Inc., Winchester Bay, Ore., to California and subsequently returned, the article contained coagulase positive staphylococci and bacterial filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for reconditioning. (18)

Shrimp, peeled, frozen, at Crescent City, N. Dist. Calif.

Charged 9-13-67: when shipped, the article, labeled in part "Packed by Astoria Sea Food Co., Astoria, Oregon, Oregon Fancy Shrimpmeat," contained bacterial filth; 402(a)(3). Default decree ordered destruction. (19)

Tomatoes, canned, Oak Hill, at St. Louis, E. Dist. Mo.

Charged on or about 7-6-67: when shipped by Markham Bros. & Co., Okeechobee, Fla., the article contained fly eggs; 402(a)(3). Default decree ordered destruction. (20)

Walnuts, black, shelled, at Chicago, N. Dist. Ill.

Charged 5-3-68: when shipped by Woodland Nut Co., Woodland, Calif., the article contained *E. coli*; 402(a)(3). Consent decree authorized release to shipper for reconditioning. (21)

Walnuts, shelled, at Seattle, W. Dist. Wash.

Charged on or about 2-1-68: when shipped by Lindsey Nut Co., Concord, Calif., the article contained *E. coli* and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (22)

Wheat, at Minneapolis Dist. Minn.

Charged 8-2-66: when shipped by M. D. Christiansen, Kimbell, S. Dak., the article contained rodent filth; 402(a)(3). Consent decree authorized release to Fruen Milling Co., Minneapolis, Minn., for decharacterizing. (23)

FOOD / Economic Violations

Broccoli cuts, frozen, at Kansas City, Dist. Kans.

Charged 12-16-66: when shipped by Stokely-Van Camp, Inc., Mount Vernon, Wash., the article labeled in part "Kroger Broccoli Cuts . . . Distributed by The Kroger Co., Cincinnati 1, Ohio" bore a label vignette depicting whole broccoli heads which was false and misleading as applied to a product consisting of irregularly sliced and chopped pieces of broccoli; 403(a). Consent decree authorized release to the distributor for relabeling. (24)

Cheese food, at City of Commerce, C. Dist. Calif.

Charged 10-18-67: while held by Arden-Mayfair, Inc., the article had been packed by the dealer, after shipment in interstate commerce, and labeled in part "Mayfresh Kitchens . . . American Grated Cheese . . . From the Famous Mayfresh Kitchens, Los Angeles, Calif.," and the label lacked the name "grated American cheese food" specified by the identity standard and failed to state all optional ingredients, since the ingredient cheese whey solids was not listed; 403(g)(2). Default decree authorized donation to public/charitable institution. (25)

Honey, at Springfield, W. Dist. Mo.

Charged on or about 9-17-65: when shipped by C. R. Cass, Severy, Kans., the article was short weight (approx. 1.25 percent); 403(e)(2). Default decree authorized donation to public/charitable institution. (26)

Mixed nuts with peanuts, Tops, at Jacksonville, M. Dist. Fla.

Charged 5-2-68: when shipped by Pittsburgh Snax Co., Inc., Pittsburgh, Pa., the label vignette was false and misleading in representing substantial quantities of mixed nuts other than peanuts, including pecan nuts, when the article contained only small amounts of nuts other than peanuts, and no pecan nuts; the container was so filled as to be misleading, since only 66.1 percent of the available volume of the can was occupied by the nut ingredient; and the statement of quantity of contents was inconspicuous, since it was printed in white ink on a light colored and mottled background; 403(a), 403(d), 403(f). Default decree authorized donation to public/charitable institutions. (27)

Orange drink, at Phoenix, Dist. Ariz.

Charged 4-20-68: when shipped by Vita-Pakt Citrus Products Co., Covina, Calif., and while held by Vita-Pakt of Arizona, Phoenix, Ariz., the name "Orange Juice Blend" and labeling were false and misleading, since the article was not a blend of orange juice and was not adequate and effective to help prevent flu and colds as represented; and the article lacked conformity to the standard of identity for orange juice, since it contained orange juice from concentrate, water, sugar, corn sirup, dextrose, citric acid, orange extractives, and ascorbic acid; 403(a), 403(g)(1). Consent decree authorized destruction. (28)

Orange juice, at Bronx, S. Dist. N.Y.

Charged on or about 8-8-67: when shipped by Frozen Fruit Concentrates, Inc., Bayamon, P.R., the article, labeled in part "Del Frutal Brand Orange Juice Unsweetened . . . Distributed by Del Frutal Canning Industry, Inc., San Juan, Puerto Rico," failed to conform to the definition and standard for orange juice, since it contained sodium cyclamate; 403(g)(1). Default decree ordered destruction. (29)

Peanuts, shelled, processed, Peanut Crisps, at Hoboken, Dist. N.J.

Charged 3-7-68: when shipped by Standard Brands, Inc., Suffolk, Va., the article's label contained false and misleading claims that the article contained half the calories of oil-roasted peanuts, was significantly higher in protein and significantly lower in calories than oil-roasted peanuts and roasted peanuts generally, was peanuts with 50 percent fat removed, and was of significant value for weight reduction;

403(a). Consent decree authorized donation to charitable institutions. (30)

Salad dressing, Henderson's Best, at Fort Smith, W. Dist. Ark.
Charged 2-24-69: when shipped by Henderson Coffee Co., Muskogee, Okla., the article lacked conformity to the standard of identity, since it contained less than 30 percent by weight of oil; 403(g)(1). Default decree authorized delivery to charitable institution. (31)

FOOD ADDITIVE

Rye flour, Globe Blue Ribbon, at St. Louis, E. Dist. Mo.
Charged 12-1-67: when shipped by Globe Milling Co., Watertown, Wis., the article contained the nonconforming food additive DDT; 402(a)(2)(C). Default decree authorized donation to public institution for use as animal feed. (32)

VITAMINS / DIETARY FOODS

Kolorok dietary powder and tablets, at Phoenix, Dist. Ariz.
Charged 8-24-66: when shipped in bulk drums in powder form by John A. Lyons Co., College Place, Wash., and while a portion of the article in bulk drums was held by Arizona Labs., Inc., Phoenix, Ariz., and while a portion of the article was held by N-H Distributors, Inc., Phoenix, Ariz., after being flavored, tableted, and packaged by Arizona Labs., the labeling contained false and misleading claims for child illnesses, strong muscles, clotting power of blood, and other therapy, and false and misleading claims concerning the need for supplementation of the diet with calcium and the article's special value; 502(a). Consent decree authorized release to Ira C. Hensel, Phoenix, Ariz., for salvaging. (33)

Liver Iron B-Plex tablets, at Milwaukee, E. Dist. Wis.
Charged 12-6-68: while held for sale after manufacture by Formulations, Inc., Milwaukee, Wis., from certain active ingredients shipped in interstate commerce, the article had been prepared, packed, and held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (34)

Over Fifty vitamin-mineral capsules and R-T-C Round-The-Clock analgesic tablets, at Chicago, N. Dist. Ill.
Charged 11-30-66: while held by G-R-I Pharmaceuticals, Inc., Chicago, Ill., the name "Over-Fifty Capsules" and other statements in the dealer's labeling for the vitamin-mineral capsules contained false and misleading claims: that the article would prevent tiredness, nervousness, damage to health, depression, and other diseases; that the nutritional value of the article was equivalent to that of large quantities of ordinary foods; and that the article was of special value to persons over the age of fifty—403(a), 502(a); the name "R-T-C Round-The-Clock 24 Hour Pain Relief Plan" and other statements in the dealer's labeling for the analgesic capsules contained false and misleading claims: for 24-hour relief, neuralgia, neck pain, and other therapy; for maintaining tissue supplies of vitamin C; of being composed of three different kinds of tablets, each acting in a special way for long-lasting relief from specified conditions; and of being compounded of three different, distinct analgesic-containing formulations for morning, afternoon, and bedtime use—502(a). Consent decree authorized release of the vitamin-mineral capsules for re-labeling and the donation of the analgesic tablets to public/charitable institution. (35)

Yodelca tonic and Organo Neurocerebral vitamin tablets, at Coral Gables, S. Dist. Fla.
Charged on or about 4-20-66: when the tonic and part of the vitamin tablets were shipped by Pharmaceutical Enterprises, Inc., (Reid Provident), Atlanta, Ga., and while held by Maferal, Inc., Coral Gables, Fla., who labeled some of the vitamin tablets and who furnished Pharmaceutical Enterprises, Inc., with labels for the tonic and the rest of the vitamin tablets, the Yodelca tonic contained the food additive iodine whose use was nonconforming; and the article's labeling contained false and misleading claims for promoting growth and concerning the M.D.R. of iodine furnished by the article—402(a)(2)(C), 502(a), 403(a); and the Organo Neurocerebral vitamin tablets bore a label listing and label references to calcium, bone marrow powder, and other specified ingredients which was false and misleading in representing, suggesting and implying that the article's nutritional value was enhanced thereby; the article lacked required information concerning its special dietary properties; and its label contained false and misleading claims for chronic fatigue, neurasthenia, and other therapy; 403(a), 403(j), 502(a). Default decree ordered destruction. (36)

DRUGS / Human Use

APC tablets and dicalcium phosphate tablets, at St. Paul, Dist. Minn.
Charged 8-1-68: when shipped by Formulations, Inc., Milwaukee, Wis., both articles had been prepared, packed, and held under insanitary conditions; and the circumstances of the APC tablets' manufacturing, packing, and handling lacked conformity with current good manufacturing practice; 402(a)(4), 501(a)(2)(A), 501(a)(2)(B). Default decree ordered destruction. (37)

Adhesive bandages, U.S.P., at East Killingsworth, Dist. Conn.
Charged 10-4-67: while held for sale, the quality of the article fell below U.S.P. standards, the label statement "Sterile" was false and misleading, and the article was not packaged as prescribed in the U.S.P., since the individual wrappers were incompletely sealed which could result in nonsterility of the product; 501(b), 502(a), 502(g). Consent decree authorized donation to public institution with instructions concerning the improper sealing and that the articles could not be guaranteed as to sterility. (38)

Alabin antiseptic powder and Alabin antiseptic ointment, at Erie, W. Dist. Pa.
Charged 5-23-68: when shipped by Aseptico Labs., Inc., Lockport, N.Y., the labeling of the antiseptic powder contained false and misleading claims that the article was nonpoisonous and false and misleading claims for skin irritations, oral discomforts, cold symptoms, and as a nasal spray—502(a); and the labeling of the antiseptic ointment contained false and misleading claims for nose, throat, and chest irritations, spasms, burns, bites, and other therapy; and the labeling lacked adequate warnings against unsafe use—502(a), 502(f)(2). Default decree ordered destruction. (39)

Amphetamine, barbiturate, and other depressant or stimulant drugs, at East Woodstock, Dist. Conn.
Charged 12-20-67: while held by Moore Kirk Laboratories, Inc., East

Woodstock, Conn., complete and accurate inventory records and receipt and disposition records of such drugs were not prepared and kept; 301(q)(4). Consent decree authorized release to dealer for preparation of records. (40)

Amphetamine, barbiturate, and other depressant or stimulant drugs, at Kansas City, W. Dist. Mo.

Charged 9-22-67: while held by Henry C. Haist & Co., Kansas City, Mo., complete and accurate inventory records and receipt and disposition records of such drugs were not prepared and kept; 301(q)(4). Default decree ordered destruction. (41)

Amphetamine, barbiturate, and other depressant or stimulant drugs, at Plymouth, E. Dist. Mich.

Charged 1-31-67: while held by Plymouth Laboratories, Inc., Plymouth, Mich., complete and accurate receipt and disposition records of such drugs were not prepared, obtained, and kept; 301(q)(4). Consent decree authorized release to dealer for preparation of records. (42)

Atropine sulfate injection, at Orlando, M. Dist. Fla.

Charged on or about 12-28-66: while held for sale, the article failed to bear adequate directions for use and lacked the prescription legend; 502(f)(1), 503(b)(4). Default decree ordered destruction. (43)

Bariatric Formula thyroid-digitalis tablets, at Galveston, S. Dist. Tex.

Charged on or about 5-16-68: when shipped by Bariatric Corp., Coral Gables, Fla., the article was a new drug without an effective approved New Drug Application; the labeling contained false and misleading claims for offsetting tachycardia and for constitutional obesity; the labeling lacked adequate directions and did not comply with the Rx drug exemption requirement for disclosure of information, and the article was dangerous to health when used as prescribed in its labeling; 505(a), 502(a), 502(f)(1), 502(j). Default decree ordered destruction. (44)

Boric acid solution, N.F., and boric acid ointment, N.F., at Pittsburgh, W. Dist. Pa.

Charged 5-20-68: while held by Mine Safety Appliances Co., Pittsburgh, Pa., who manufactured the boric acid solution from ingredients shipped in interstate commerce and packed the boric acid ointment, the labeling of the boric acid solution lacked adequate warnings for ophthalmic preparations and was not labeled as required by the National Formulary—502(f)(2), 502(g); the boric acid ointment was short weight (approx. 13 percent), and the labeling lacked adequate warnings for ophthalmic preparations—502(b)(2), 501(c). Consent decree ordered destruction. (45)

Calcium carbonate and aminoacetic acid combination tablets, at Kansas City, W. Dist. Mo.

Charged 4-25-66: when shipped by Richlyn Labs., Inc., Philadelphia, Pa., the label of the article labeled in part "Mylac . . . Manufactured for: Cooperative Pharmacal, Kansas City, Mo." contained false and misleading claims for the relief of peptic ulcer (gastric and duodenal); 502(a). Default decree ordered destruction. (46)

Chemband spray bandage, at Irving, N. Dist. Tex.

Charged 10-4-68: when shipped by Hysan Products Co., Chicago, Ill., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (47)

Chemicals, laboratory glassware, tablet punches, and other drug compounding equipment, at Knoxville, E. Dist. Tenn.

Charged 10-17-66: while held by Floyd S. Foreman, t/a Darigon Corp., Knoxville, Tenn., the articles were used in the manufacture, compounding, and processing of stimulant drugs at an establishment that had not been registered with the Secretary of H.E.W.; 301(p), 510. Default decree authorized donation to public/charitable institution for educational use. (48)

Conjugated estrogen tablets, at Mansfield, N. Dist. Ohio.

Charged 12-2-68: when shipped by Plymouth Labs., Inc., Plymouth, Mich., the circumstances of the article's manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (49)

Esprel Analgesic tablets, at St. Paul, Dist. Minn.

Charged 6-20-68: when shipped by Formulations, Inc., Milwaukee, Wis., the circumstances of the article's manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice, and the article's quality was deficient because of the excessive individual tablet weight variation; 501(a)(2)(B), 501(c). Default decree ordered destruction. (50)

Halco absorbent gauze, U.S.P., and gauze bandages, U.S.P., at New Haven, Dist. Conn.

Charged 1-18-68: when shipped by A. E. Halperin Co., Inc., Boston, Mass., the articles' quality fell below the U.S.P. standards, the label statements "Sterile" and "Sterilized" were false and misleading, and the articles were not packaged as prescribed by the U.S.P., since the individual wrappers were not completely sealed, which could result in nonsterility of the articles; 501(b), 502(a), 502(g). Default decree ordered destruction. (51)

Histone prednisone-chlorpheniramine tablets, Pasa prednisone-salicylamide combination tablets, and hydrocortisone ointment, U.S.P., at South Fort Mitchell, E. Dist. Ky.

Charged 12-28-66: when shipped by C. M. Bundy Co., Cincinnati, Ohio, the hydrocortisone ointment differed in strength from U.S.P. standards and its label was false and misleading, since the article contained approximately 62 percent of the declared hydrocortisone—501(b), 502(a); and the labeling of all three drugs lacked adequate directions for use and they were not exempted therefrom, since adequate information for intended use by licensed practitioners was lacking—502(f)(1). Default decree ordered destruction of the hydrocortisone ointment. Consent decree authorized release of other drugs to Blaine Co., South Fort Mitchell, Ky., for relabeling. (52)

Methampyrone sodium tablets, at Jacksonville, M. Dist. Fla.

Charged 5-11-65: while held by Delta Drug Corp., Jacksonville, Fla., who labeled the article "Ompyrone Analgesic-Antipyretic Anti-rheumatic . . . Distributed by Generic Drug Laboratories Incorporated Jacksonville," the article's labeling lacked adequate direction for use and was not exempted therefrom, since it lacked adequate information for use by licensed practitioners; and the article was dangerous to health when used as directed in its labeling; 502(f)(1), 502(j). Default decree ordered destruction. (53)

Parkquid amphetamine-thyroid combination tablets, at Wilmington, Dist. Del. Charged 2-29-68: when shipped by Milan Pharmaceuticals, Inc., Morgantown, W. Va., the labeling contained false and misleading claims for simple obesity, and it was false and misleading, since the package insert represented that the article contained dextro-amphetamine sulfate which was inconsistent with the label ingredient statement that it contained various amphetamine hydrochlorides and other drugs, and the labeling lacked adequate directions and did not comply with the Rx drug exemption requirement for disclosure of information; 502(a), 502(f)(1). Default decree ordered destruction. (54)

Piperazine citrate syrup, U.S.P., at Rio Piedras, Dist. P.R. Charged 7-28-67: while held by Laboratories Sein, Inc., Rio Piedras, P.R., who manufactured the article from piperazine citrate shipped in interstate commerce, the article's strength differed from U.S.P. standards, since it was deficient in piperazine citrate (approx. 20 percent), the labeling lacked adequate directions and did not comply with the Rx drug exemption requirement for disclosure of information, and the label lacked the prescription legend; 501(b), 502(f)(1), 503(b)(4). Default decree ordered destruction. (55)

Prednisone tablets, U.S.P., at Chicago, N. Dist. Ill. Charged 11-17-67: when shipped by United Research Laboratories, Philadelphia, Pa., who were returning the article to the manufacturer, the article's strength differed from and its quality fell below U.S.P. standards, since 5 out of 10 tablets exceeded U.S.P. limits for content uniformity; 501(b). Default decree ordered destruction. (56)

Prescription legend drugs and depressant or stimulant drugs, at Booneville, N. Dist. Miss. Charged 3-3-67: while held by Lindsey Drug Store, Booneville, Miss., the labeling of the articles failed to bear adequate directions for use and they were not exempted therefrom, since they were prescription drugs and the dealer was not lawfully engaged in handling such drugs, and the complete and accurate inventory records and receipt and disposition records had not been prepared and kept; 502(f)(1), 301(q)(4). Default decree ordered destruction. (57)

Quinine sulfate capsules, N.F., at Maryland Heights, E. Dist. Mo. Charged 2-20-68: while held by Shaw Pharmacal Co., Maryland Heights, Mo., who manufactured the article from quinine sulfate shipped in interstate commerce, the article's strength differed from N.F. standards, since the article was deficient in quinine sulfate (approx. 10 percent) the label statement "Quinine Sulfate . . . U.S.P." was false and misleading, since the article was not recognized in the United States Pharmacopeia; and the labeling also contained false and misleading claims for malaria, when the article taken in accordance with the dosage recommended on the label was not adequate and effective for malaria; 501(b), 502(a). Default decree ordered destruction. (58)

Rectal ointment, at Washington, Dist. Columbia. Charged 5-21-68: when shipped by Pharmaceutical Enterprises (Reid-Provident Labs.), Atlanta, Ga., the article, labeled in part "Hadsensa Rectal Ointment . . . Menthol, ichthammol, linseed oil, peanut oil, thymol, ointment base, Manufactured . . . for Hadsensa of America, Inc. . . . Miami 32, Florida," was short weight; and while held by District Wholesale Drug Corp., Washington, D.C., who placed a package insert in the article's cartons, the labeling lacked adequate directions for use under which a layman could use the article safely and for the purpose for which it was offered, namely, anal fissures, pruritus ani, eczema, swollen nodes, swollen rectal mucous membranes, surface erosions, and deep fissures, since such conditions cannot be diagnosed by the layman and adequate directions cannot be written for lay use; 502(b)(2), 502(f)(1). Default decree ordered destruction. (59)

Skomine-With-Phenobarbital tablets, at Patoka, E. Dist. Ill. Charged 2-7-69: when shipped by Bush Labs., St. Louis, Mo., the circumstances of the article's manufacture, processing, packing, and holding lacked conformity with good manufacturing practice; and the strength of the article was deficient, since the article was deficient in tropine alkaloids calculated as methscopolamine bromide (approx. 12.6 percent) and phenobarbital (approx. 12 percent); 501(a)(2)(B), 501(c). Default decree ordered destruction. (60)

MEDICAL DEVICES

Bardex—Foley catheter, at Brooklyn, E. Dist. N.Y. Charged on or about 6-24-66: when shipped by C. R. Bard, Inc., Murray Hill, N.J., the labeling failed to bear adequate directions for use; 502(f)(1). Default decree ordered destruction. (61)

Hydro-jet bath pump, at Milwaukee, E. Dist. Wis. Charged 4-12-66: when shipped by Boulevard Electronics, Inc., Chicago, Ill., the labeling contained false and misleading therapeutic claims; 502(a). The National Health Products Co., of Milwaukee, Wis., having withdrawn its claim, a default decree ordering destruction was entered. (62)

Toilet seat with water and air jets, at Gardena, C. Dist. Calif. Charged 2-15-66: when shipped by Croname, Inc., Chicago, Ill., and while held by American Bidet Corp., Inc., Gardena, Calif., the article, labeled in part "The American Bidet . . . The American Bidet Corp. Inc. Gardena, California . . . Manufactured under license by Croname Incorporated Chicago, Ill.," had accompanying labeling (printed on the dealer's order) that contained false and misleading claims for hemorrhoids, perineal problems, healing of proctology patients, and other therapeutics; 502(a). Consent decree authorized release to the dealer for salvaging. (63)

Top Shape plastic pocket-size barbell-shaped exerciser, at Kansas City, W. Dist. Mo. Charged 3-23-66: when shipped by First Marketing Corp., Cincinnati, Ohio, and while held for sale, the labeling contained false and misleading claims for keeping in trim and in top shape, reducing stomach, waist, and hips, and increasing the life span, and for related purposes; and the label lacked the name and place of business of the manufacturer, packer, or distributor; 502(a), 502(b)(1). Default decree ordered destruction. (64)

Weber Super-Pulse electronic-wave generator, at Greenville, W. Dist. Ky. Charged 9-9-68: when shipped by unknown shipper, the article's accompanying labeling contained false and misleading claims for arthritis, bone infection, stomach ulcers, to restore good health, and to cause human gamma globulin to be four times more effective, and the label-

ing failed to bear adequate directions for use; 502(a), 502(f)(1). Default decree authorized release to FDA. (65)

COSMETICS

Beleza medical beauty cream, at Phoenix, Dist. Ariz. Charged 2-6-69: when shipped by Moscatelli Products Co., Hollywood, Calif., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (66)

Estrogenic hormone skin cream, at Hialeah, S. Dist. Fla. Charged 7-10-68: while held by House of Starlight, Div. of Averil, Inc., Hialeah, Fla., after having manufactured the article from ingredients shipped in interstate commerce, the label lacked the established name of each active ingredient, and the labeling lacked adequate directions for use; 502(e)(1)(A)(ii), 502(f)(1). Default decree ordered destruction. (67)

HAZARDOUS SUBSTANCES

Cherry Bombs, M-80 firecrackers, and Silver Salutes, at Sullivan, E. Dist. Mo. Charged 6-28-68: while held by Kay's Park Service, Sullivan, Mo., the articles were banned hazardous substances, since they were toys which were flammable solids and generated pressure through explosion when ignited; 2(q)(1)(A). Default decree ordered destruction. (68)

Cherry Bombs, M-80 firecrackers, and tubular flash salutes, at Cherry Grove Beach, Dist. S.C. Charged 6-27-68: while held by Wood's Fireworks, Cherry Grove Beach, S.C., the articles were banned hazardous substances, since they were toys which were flammable solids and generated pressure through explosion when ignited; 2(q)(1)(A). Default decree ordered destruction. (69)

Duplicating fluid, at Seattle, W. Dist. Wash. Charged on or about 1-9-68: when shipped by Columbia Ribbon & Carbon Pacific, Inc., Portland, Oreg., the article was a hazardous substance which presented a special hazard because it consisted of methyl alcohol and it lacked the required conspicuous label statement "Keep out of the reach of children" or its practical equivalent; 2(p)(1)(J). Default decree ordered destruction. (70)

Rag dolls, 2 seizure actions at Brooklyn, E. Dist. N.Y. Charged 2-3-67 and 3-17-67: while held for sale after being imported from Poland, the articles were banned hazardous substances, since they were toys which were flammable substances; 2(q)(1)(A). Consent decree authorized release to A. D. Sutton & Sons, New York, N.Y., for export. (71)

Railway fuses, at Farmington, E. Dist. Mich. Charged on or about 1-4-68: while held for sale, the article was extremely flammable and it lacked a number of required conspicuous label statements; 2(p)(1)(C, E, F, J). Default decree authorized donation to public/charitable institution. (72)

Repeating bombs, flash bombs, and other Class B fireworks, at Summerton, Dist. S.C. Charged 6-27-68: while held by Stuckey's, Summerton, S.C., the articles were banned hazardous substances, since they were toys which were flammable solids and generated pressure through explosion when ignited; 2(q)(1)(A). Default decree ordered destruction. (73)

Slip Gard shower-floor treatment kit, at Knoxville, E. Dist. Tenn. Charged 6-21-68: when shipped by Reilly Chemical Co., New Orleans, La., the article consisted of display-type cartons each containing two bottles, one of which contained approximately 5.7 percent hydrofluoric acid which was toxic and corrosive, and the label of the bottle containing acid and the cartons lacked a number of the required conspicuous label statements—2(n), 2(p)(1)(E, F, G); the signal word "Danger" on the bottle containing acid was in type size less than 18 point type, and the statement of hazards "May be fatal if swallowed" on such bottle and the carton were not in capital letters and were in type size less than 12 point type—2(p)(2); and the label statements "perfectly harmless," "minor" (describing burns), and "dilute" (describing hydrofluoric acid) negated and disclaimed the required label statements—2(p)(1), 2(p)(2). Default decree ordered destruction. (74)

Sneeze powders, Squeeze/n Sneeze and Niespulver, at Greensboro, M. Dist. N.C. Charged 2-12-68: when shipped by Franco-American Novelty Co., and Syd-Art Novelty Co., New York, N.Y., the articles were irritant substances, and the Squeeze/n Sneeze plastic bottles and the Niespulver paper envelopes lacked a number of the required conspicuous label statements; and while held by Fred Alan Novelty Co., Inc., Greensboro, N.C., the statements "Harmless" and "Harmless Fun" on the bottle and tag of Squeeze/n Sneeze powder negated and disclaimed the required label statements; 2(p)(1)(A, B, D, F, G, J). Default decree ordered destruction. (75)

Thompson's Water-seal, at Seattle, W. Dist. Wash. Charged 3-30-67: when shipped by E. A. Thompson Co., Inc., King City, Calif., the article presented a special hazard because of its petroleum distillate content (approx. 76 percent), and the label lacked a number of the required conspicuous label statements; 2(p)(1)(B, E, J) and 3(b). Default decree ordered destruction. (76)

Westglas acetone and Westglas cleaning solvent, at Seattle, W. Dist. Wash. Charged on or about 11-1-67: when shipped by Western Fibrous Glass Products Co., Burlingame, Calif., both articles were irritants to the eye, the acetone was extremely flammable, the cleaning solvent was toxic by ingestion because of its methyl ethyl ketone content and also was flammable, and the articles lacked a number of the required conspicuous label statements, acetone—2(p)(1)(F, G, J), cleaning solvent—2(p)(1)(B, E, F, G); and the statements of hazard, namely, "Extremely Flammable" for the acetone and "Flammable" for the cleaning solvent, were inconspicuous in that they did not appear on the main panel of the label in the required type size—2(p)(2). Default decree ordered destruction. (77)

NOTICES OF JUDGMENT on Criminal Actions

FOOD

Farmer's Rice Milling Co., Inc., Lake Charles, W. Dist. La. Charged 10-17-67: when shipped, rice had been prepared and held under insanitary conditions; 402(a)(4). Nolo contendere plea; fine. (78)

Langlois Flour Co., and Donald R. Langolis, president, Los Angeles, C. Dist. Calif.
Charged 8-22-68: when shipped, pancake mix, labeled in part "Sambo's Deluxe Buttermilk Pancake Mix Distributed By Sambo's Pancake Houses Santa Barbara, Calif.," contained insect filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Nolo contendere pleas; fines. (79)

Sea Pack Corp., and James J. Meadows, St. Simons Island, S. Dist. Ga.
Charged 9-29-67: when shipped, breaded shrimp contained bacterial filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Nolo contendere pleas; probations. (80)

Harry Sherman, t/a Capitol Salad Co., Washington, Dist. Columbia.
Charged 1-9-69: when manufactured within the District of Columbia, crabcakes contained *E. coli* and other bacterial filth and were prepared under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea; fine. (81)

DRUGS

Walter Balachowski, mechanic, Chicago, N. Dist. Ill.
Charged on or about 2-10-67: methamphetamine drugs were unlawfully sold, delivered, and otherwise disposed of; 301(q)(2). Guilty plea; imprisonment. (82)

James A. Blankenship, truck-stop employee, Jackson, W. Dist. Tenn.
Charged on or about 8-5-67: desoxyephedrine hydrochloride tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment and probation. (83)

Byron K. Bowie and George O. Herndon, Columbia, W. Dist. Mo.
Charged 6-5-67: depressant/stimulant drugs were unlawfully sold and delivered; 301(q)(2). Guilty pleas; fines and probations. (84)

John L. Cole, truck-stop employee, Jackson, W. Dist. Tenn.
Charged 11-15-66: desoxyephedrine hydrochloride tablets were dispensed without a prescription; 503(b)(1). Guilty plea; probation. (85)

Evelyn Crump, t/a Southside Truck Stop, Waldron, W. Dist. Ark.
Charged on or about 3-13-64: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Nolo contendere plea; probation. (86)

Ernest Hugh Fountain, truckdriver, 2 criminal actions, Mobile, S. Dist. Ala. and Birmingham, N. Dist. Ala.
Charged on or about 4-25-67: depressant or stimulant drugs were unlawfully sold and delivered at Mobile, Ala., and at Birmingham, Ala.; 301(q)(2). The action in the Southern District of Alabama was transferred to the Northern District. Guilty pleas in both actions; fines and probations to run concurrently. (87)

Honeggers' & Co., Inc., Fairbury, S. Dist. Ill.
Charged 12-4-68: when shipped, the labeling of Big "H" rabbit pellet feed, Pre-Starter Pops feed, Forti-Lay Crumbles feed, Fortipoultry Plus Crumbles feed, and Pig Popper Supplement feed contained false and misleading claims as to quantity of contents and effectiveness, as follows: rabbit pellet feed was deficient in furazolidone and was therefore ineffective for prevention of *Pasteurella*-type pneumonia and mucoid and diarrheal enteritis in rabbits; the Pre-Starter Pops was deficient in furazolidone; the Forti-Lay Crumbles feed was deficient in penicillin; the Fortipoultry Plus was deficient in furazolidone, and was therefore ineffective for treatment of fowl typhoid, paratyphoid and pullorum in chickens and turkeys; and the Pig Popper Supplement feed was deficient in penicillin and streptomycin, and was therefore ineffective for prevention of bacterial swine enteritis, stimulation of growth and improvement of feed efficiency in swine—502(a); the Forti-Lay Crumbles feed and Pig Popper Supplement feed were not from a certified batch and were not exempt, since they did not contain the required amount of antibiotic drug for their intended purposes—502(l). Nolo contendere plea; fine and costs. (88)

Drew S. McClanahan, truckdriver, and **Louis Marquez, Jr.**, barber, Cudahy, S. Dist. Calif.
Charged 8-18-66: amphetamine sulfate tablets were unlawfully sold and delivered; 301(q)(2). Guilty pleas; probations. (89)

Donald Mazingo, company guard, Chicago, N. Dist. Ill.
Charged on or about 2-10-67: methamphetamine drugs were unlawfully sold, delivered, and otherwise disposed of; 301(q)(2). Guilty plea; imprisonment. (90)

John Porter Nelson, service station employee, Knoxville, E. Dist. Tenn.
Charged 5-2-67: amphetamine sulfate tablets were unlawfully sold and delivered; 301(q)(2). Guilty plea; fine. (91)

Vernon L. Robinson, truck-stop operator, Seneca, W. Dist. Mo.
Charged 12-22-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; probation. (92)

Robert L. Sevier, truck-stop employee, Jackson, W. Dist. Tenn.
Charged on or about 11-15-66: desoxyephedrine hydrochloride tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment and probation. (93)

Frank A. Shannon, truck-stop employee, Jackson, W. Dist. Tenn.
Charged on or about 8-5-67: desoxyephedrine hydrochloride tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment and probation. (94)

Shaw Pharmacal Co., Maryland Heights, E. Dist. Mo.
Charged 7-25-68: when shipped, Reserpatabs[®] (reserpine tablets) quality and purity fell below U.S.P. standard, since some of the tablets contained trisulfapyrimidines and some tablets contained phenacetin, and all tablets failed the U.S.P. "other alkaloids" tests—501(b); some of the Reserpatabs had been prepared, packed, and held under insanitary conditions—501(a)(2)(A); the strength of diethylstilbestrol tablets differed from U.S.P. standard, because of a deficiency of diethylstilbestrol—501(b); the quality of Stil-Forte tablets was deficient, since they failed the disintegration test for enteric-coated tablets—501(c); the quality of rauwolfia serpentina tablets fell below the N. F. standard, since the article failed to disintegrate—501(b); and the circumstances of manufacture, packing, and holding of all the articles lacked conformity with current good manufacturing practice—501(a)(2)(B). Guilty plea; fine and probation. (95)

John Spada and Anthony Jozapaitis, at Dorchester, Dist. Mass.

Charged 9-15-67 by grand jury: amphetamine sulfate tablets, phenobarbital tablets, sodium pentobarbital capsules, sodium pentobarbital injectable, and chloral hydrate tablets were unlawfully sold and delivered—301(q)(2); and conspiracy to sell and deliver such drugs—18 U.S.C. 371. Not guilty pleas. After trial by court, defendants found guilty; imprisonment. (96)

William W. K. Todd, t/a Todd's Drug Store, Glasgow, W. Dist. Va.
Charged 12-2-65: Dexamyl Spansule capsules, Diuril tablets, and Equanil tablets were dispensed without a prescription, and Enovid-E tablets were dispensed as an unauthorized refill; 503(b)(1). Nolo contendere plea; fine and probation. (97)

Charles Eugene Webb, produce company employee, Knoxville, E. Dist. Tenn.
Charged 5-2-67: amphetamine sulfate tablets were unlawfully sold and delivered; 301(q)(2). Guilty plea; imprisonment. (98)

DEVICES

Edward D. Olson, II, t/a Exertron of Little Rock, Little Rock, E. Dist. Ark.
Charged 6-4-68: Exertron electronic contrivances were held for sale for use in using up calories, controlling weight, toning and firming muscle groups, and trimming one's figure, and the devices were accompanied by newspaper advertisement tear sheets that contained false and misleading statements that the devices were adequate and effective for the above uses; 502(a). Guilty plea entered in M. Dist. Fla.; imprisonment suspended, fine, and probation. (99)

HAZARDOUS SUBSTANCES

Wilmington Chemical Corp., and Joseph S. Klehman, president, Chicago, N. Dist. Ill.
Charged 9-17-65: when shipped, X-33 water repellent was an extremely flammable substance that presented a special hazard due to its petroleum distillate content, and its containers lacked required conspicuous label statements; 2(p)(1)(B, C, E, F, I), 3(b). The defendants moved to dismiss the case for alleged deficiencies of form, fact, and law in the information, for the alleged failure of Government to give the appropriate notices or hearing prescribed in 15 U.S.C. 1266, and because the Government was estopped by the ventilation of the whole controversy in some 30 seizure suits, a suit by the corporation against the Government, and a proceeding before the Federal Trade Commission in which full hearings were had and the individual defendant was subpoenaed and gave testimony and in which a decision as to both defendants to "cease and desist" was rendered.

On 1-28-66, the court overruled the defendants' motion to dismiss, and at the same time granted leave to the individual to file a motion to dismiss based on the immunity provisions of 15 U.S.C. 32. Accordingly, the individual moved to dismiss the case as to himself, based upon immunity allegedly conferred pursuant to 15 U.S.C. 32 by his having testified before the FTC as to matters relating to the subject matter of the criminal information.

On 5-6-66, the court denied this motion, saying that although X-33 water repellent provided a common subject, the papers submitted on the defendant's motion failed to show that the defendant's compelled testimony given in the FTC hearing related in a "substantial" way to the subject matter of the criminal information, that the defendant's unsupported assertions were unsatisfactory, and that the defendant had been and was free to secure the record of the FTC hearing and to itemize the "substantial relationship" which the defendant claimed to be present. 254 F. Supp. 92 (1966). Thereafter, the defendant filed an additional motion claiming immunity pursuant to 15 U.S.C. 49. On 4-14-67, the court in denying the defendant's motion said that although the criminal information concerned a common subject, X-33, it did not relate substantially to the "unfair trade practices" alleged in the FTC complaint, and that the defendant's testimony involving his role in the corporation had no connection with the crimes charged in the criminal information closer than that the defendant was a vigorous force within the company, and that the defendant should not be exonerated of all crimes involving the company merely because he testified about his authority and function with it.

Guilty plea by corporation; fine. Nolo contendere plea by individual but with his right to appeal the question of immunity preserved. On 7-3-68, the Court of Appeals for the 7th Circuit said:

"At the time Klehman testified under F.T.C. subpoena there appears to have been a real possibility that he would be prosecuted individually for the corporation's unlawful shipments of X-33 as a misbranded product. The issue, in the administrative proceeding, of individual responsibility for corporate acts was seemingly identical to an issue inherent in the criminal prosecution, if brought. We think that, but for the immunity statute, Klehman would clearly have been privileged to refuse to answer the questions concerning his close control over the activity of the corporation. It follows that when he testified, the statute immunized him from this prosecution." 397 F.2d 406 (1968).

Accordingly, the judgment against Klehman was reversed and the cause remanded with directions to dismiss the information as to him. (100)

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.

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

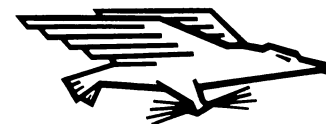
Herbert L. Ley, Jr., Commissioner of Food and Drugs
Washington, D.C., September 1, 1969.

The Pill

These two words have come to be synonymous with 'Oral Contraceptives'—a comparatively new concept in birth control. New concepts, no matter in what area of human existence, are subject to misconceptions, discussions, and detailed review. The Pill is no exception.

FDA feels the public is entitled to the most recent facts available on Oral Contraceptive research. Thus, FDA's Advisory Committee on Obstetrics and Gynecology is releasing its second report in three years on Oral Contraceptives. This new report emphasizes studies conducted since the original report. It summarizes current knowledge, both clinical and laboratory, and includes new data on metabolic effects of the oral contraceptives.

A price for the report will be announced in a later issue of *FDA Papers*, at which time copies may be obtained from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.



OFFICIAL BUSINESS

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Announcements

REVISED FACT SHEETS AVAILABLE

The following FDA Fact Sheets have recently been revised and are available in limited quantities without charge from the Division of Industry Services, Bureau of Compliance, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204:

"FDA Regulations of Interest to Food Manufacturers, Veterinarians, Livestock and Poultry Producers." The recent revision incorporates new additions to Subpart C, Title 21, Code of Federal Regulations, titled "Food Additives Permitted in Feed and Drinking Water of Animals or for the Treatment of Food-Producing Animals."

"Drug Experience Reporting by Veterinarians." This Fact Sheet was recently revised to update the names and addresses of veterinarians of the Bureau of Veterinary Medicine in FDA Districts, U.S. Department of Agriculture's Animal Husbandry Station veterinarians, and USDA Extension specialists in veterinary science for Drug Experience Reporting.

"Salmonella in Feed and Animal Industries." The major change incorporates recommendations by the National Academy of Sciences/National Research Council study, under contract with FDA and USDA, to Federal and State agencies to develop and implement programs to control *Salmonella* contamination of feed ingredients.

"Diethylstilbestrol." The major change explains that FDA has not sanctioned the simultaneous use of ear implants and feed containing diethylstilbestrol for beef animals.

"Aflatoxins and Other Mycotoxins." This has been completely revised as a result of recent findings.

"Antibiotics Used in Animals Raised for Food." This has been changed to incorporate regulations that appeared in the *Federal Register* on May 17, 1969. There is a brief explanation of why the regulations were changed and the Fact Sheet includes the change in injectable antibiotics permitted for use in food-producing animals and those injectable antibiotics not permitted for use in food-producing animals.

STATISTICAL SUMMARY OF INDUSTRY PARTICIPATION IN FDA WORKSHOPS, SEMINARS, AND CONFERENCES / FISCAL 1969

District Workshops

	No.	ATTENDANCE Firms	People
GMP—Drugs—Human	13	513	1344
Drugs—In Plant— for Employees	9	25	481
GMP—Drugs—Veterinary	2	190	285
Foods—Bacterial Contamination	27	904	2134
Foods—Chemical Contamination	6	335	492
Foods—Sanitation	15	990	1614
Foods—Economic	1	225	300
Hazardous Substances	3	86	165
Cosmetics	1	48	105
Total	77	3316	6920

Seminars and Conferences

	No.	ATTENDANCE Firms	People
Hazardous Substances (Regional)	5	339	618
Drugs—Quality Assurance (Regional)	4	199	412
Drugs—Unit Packaging (National)	1	450	650
Drugs—GMP (National)	3	345	800
FDLI—(National)	1	200	753
Therapeutic Devices (Regional)	6	421*	556
Total	20	1954	3789

*Hospital Representatives

These workshops and conferences are designed to respond to the needs of the regulated industries for information about various problems in compliance, and to clarify for industry any fine points of the laws administered by the Food and Drug Administration. Normally, these workshops are initiated in FDA Districts because they are most familiar with industry's needs in their geographical areas. The Bureau of Compliance is gratified by the cooperation from industry to date in these areas.