

FDA PAPERS

CLEANING UP AFTER CAMILLE

Joint Effort Softens a Heavy Blow

ARTIFICIAL SWEETENERS

Fair Packaging and Labeling

Taking the Guesswork Out of Buying

THE PILL: A SECOND LOOK





"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

If you had to go through a dark and dangerous alley, who would you prefer to have along with you? The answer is someone that you know you can rely on, from past experience, to do what has to be done when the going gets rough. That's the way State authorities and FDA Inspectors and others on the line felt about each other late in August as they tried to create orderly and safe sources of food and drugs from the chaos wrought by Hurricane Camille (see page 4).

In all, five FDA Districts and sanitation engineers from the Shellfish Sanitation Program in Region IV, totaling nearly 50 men, took part with State and local authorities in helping remove what could have been a menace to public health under what may be described, at the very sunniest, as trying conditions. Blocked roads and bridges, poor or nonexistent communications, alternating rain and sun, difficulties in locating owners of wrecked firms and missing inventories required patience and tenacity, skill and tact.

The established trust and respect between State and FDA people was the bright spot that illuminated the task and made a thorough job possible. In Mississippi, particularly, the FDA Inspectors were able to go about their work and make recommendations in the assurance that State authorities would follow through with prompt and judicious action under the emergency powers they were granted during the state of martial law declared by the Governor. That the potential threat to public health from unsafe food and drugs was almost completely eliminated within a two-week period amid the devastation left by the hurricane is a credit to the concept of State and Federal cooperation.

quotes

“With the transfer of the Milk, Food, and Interstate Travel Program from the Environmental Control Administration to the Food and Drug Administration, which became effective several months ago, the Department's consumer protection programs pertaining to these areas plus product safety, pesticides, and shellfish have for the first time been brought together in one Administration. Since all of these programs have significant involvement with our State counterparts, we feel the placement of these programs within FDA will greatly enhance our efforts to coordinate State-Federal cooperation in these critical areas. These new responsibilities will, of course, entail adjustment in resource reallocation within FDA, but we at FDA feel the result will be highly beneficial to the consumer.”

Paul A. Pumpian, Director, Office of Legislative and Governmental Services, to the Annual Meeting of the Division of Food, Drug, and Cosmetic Law of the American Bar Association, August 13, 1969, Dallas, Texas.

“Medical devices are often the most critical items in diagnosis and treatment. Physicians, however, are trained in pharmacology to understand drug action, not electronics or metallurgy or polymer chemistry, which would enable them to judge the safety and effectiveness of many devices they encounter and use in their practice. The achievements in medical technology have introduced an array of devices that are new, not only in purpose, but often in the very materials used in their manufacture. Surgical implants, contact lenses, artificial kidneys, and nylon arteries are examples. The current interest in the development of artificial hearts previews another momentous forward step.

“While research and innovation must be encouraged to insure the further development of life-saving and life-sustaining devices, the patient, as well as the physician, is entitled to the assurance that a particular device has been adequately tested and proved safe, reliable, and effective. Today, unfortunately, this assurance cannot be given.”

Herbert L. Ley, Jr., M.D., Commissioner of Food and Drugs, in his speech “The Regulation of Therapeutic Devices: 1969” presented to A National Conference on Medical Devices, sponsored by the Association for the Advancement of Medical Instrumentation, Bethesda, Maryland, September 6, 1969.

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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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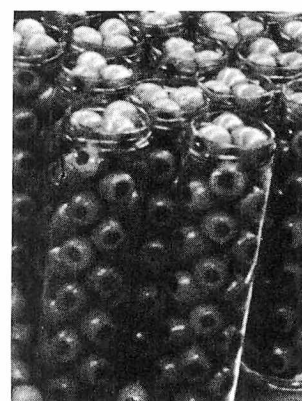
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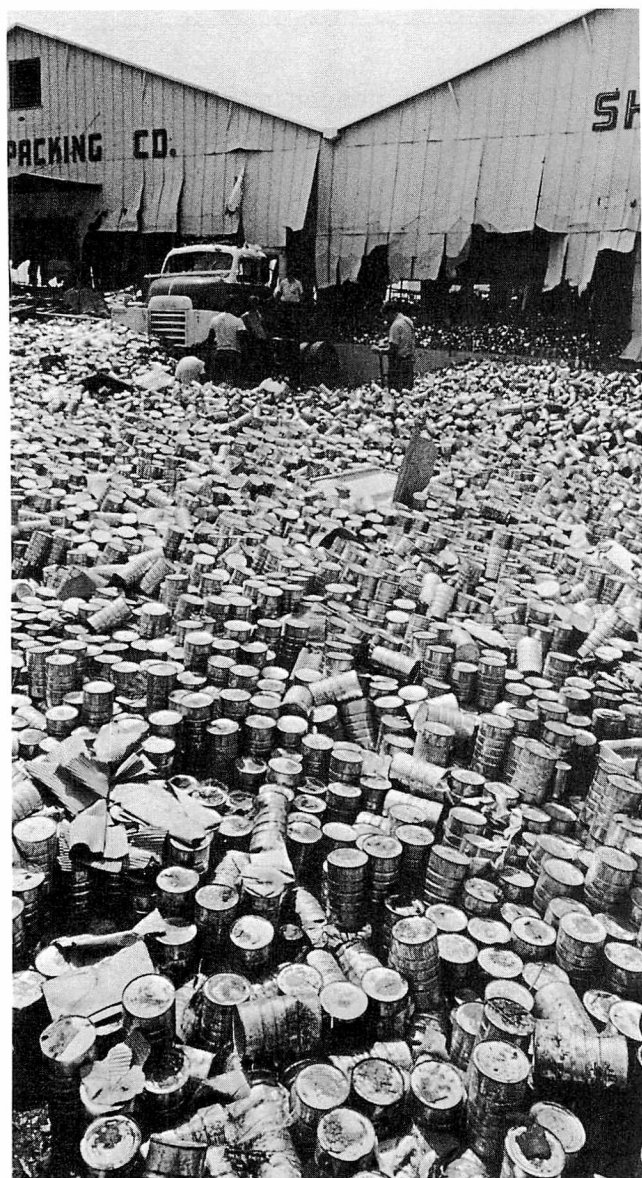


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CLEANING UP AFTER CAMILLE



After building steadily to full intensity for several hours, Hurricane Camille's Sunday punch came at 10 p.m. August 17, striking the Gulf Coast with unprecedented 200-miles-an-hour winds that continued unabating until 2 a.m. Monday. Although the entire coastal area felt some of the hurricane's impact, its biggest was against the coasts of Mississippi, southeast Louisiana, and Alabama, destruction by winds ranging in some places up to 200 miles inland. Along the Mississippi and Louisiana coasts tidal waves up to 20 feet high slammed impartially into the works of man and nature alike, destroying, flooding, and killing.

Within 48 hours the same hurricane was to carry torrential rains as far as central Virginia, precipitating flash floods there that brought further death and destruction, before heading out to sea to die in the Atlantic.

On the Gulf Coast the hurricane, its potential death toll kept down only by hurried, partial evacuation of the most dangerous areas, had left thousands homeless

and jobless, had wiped out almost the entire economies of some cities that were built largely on seafood processing and the tourist trade, and had so flattened the mostly residential Mississippi city of Pass Christian that it was later almost entirely reevacuated of returning inhabitants. It had left almost all the immediate coastal areas without electric power, telephones, gas, passable roads and bridges, potable water supplies, workable sewerage, safe food, and adequate medical facilities and supplies.

The winds and tidal waves had downed or defoliated trees small and large, had twisted steel and concrete structures and undermined pavements and seawall, and had even beached three oceangoing freighters docked and lashed together at Gulfport, Mississippi, along with many smaller vessels. In most areas waterfront structures were flattened or in ruins, including those of the extensive seafood packing industry along the coastline, where these products in cans were scattered and exposed to the elements and to hungry human scavengers.

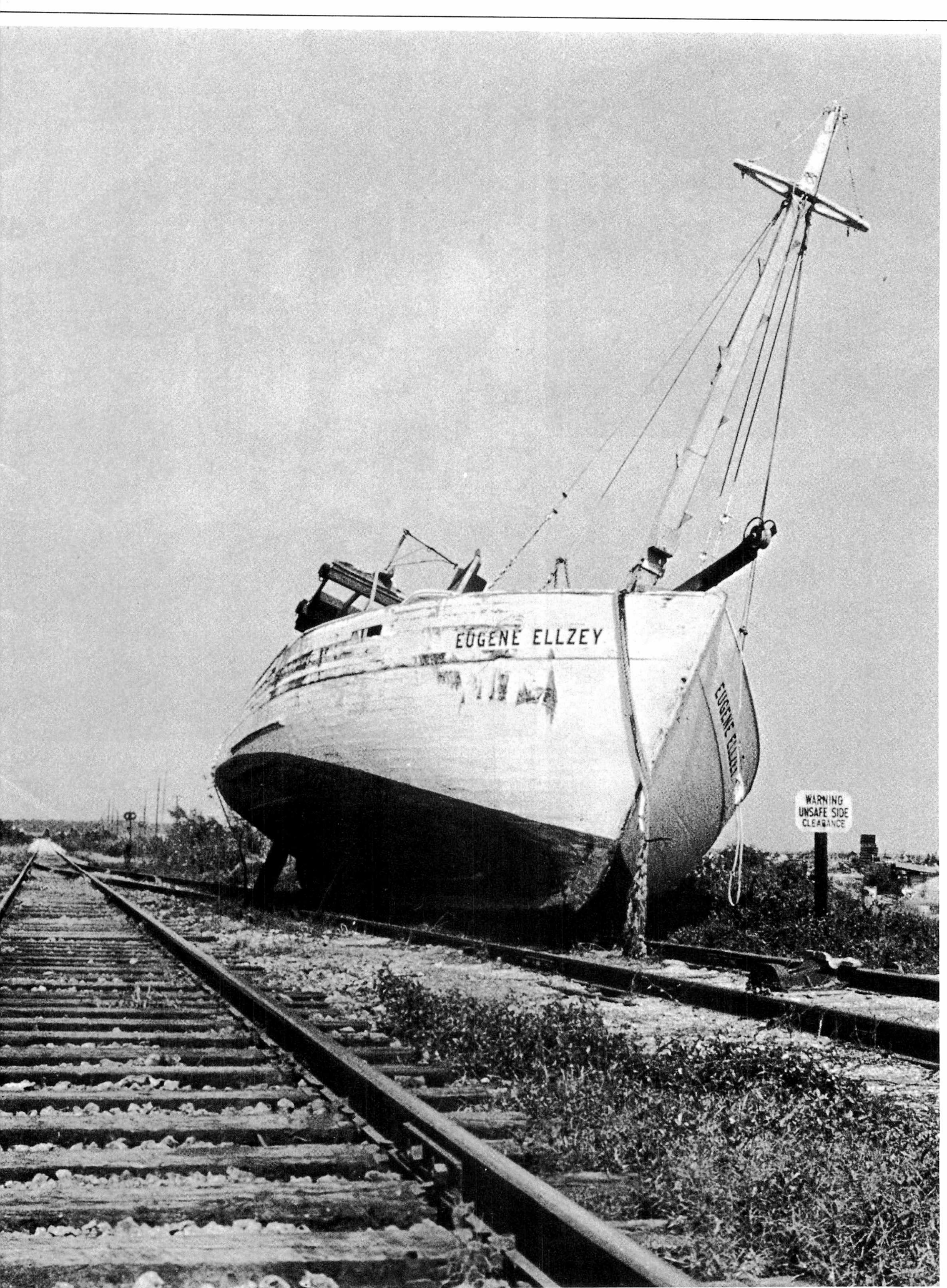
Flooded, mosquito-breeding areas, dispossessed rats, snakes, and other vermin, and the unburied bodies of animals and humans, unfit drinking water, unrefrigerated perishable foods, the lack of public eating and sleeping accommodations, together with intermittent spells of rain and hot sun, posed the threat of famine and disease. Clearly, the hurricane had left in its wake a public health problem of the worst order, one that called for the utmost and combined efforts of State, local, and Federal health, law enforcement, and civil defense officials, the military, and the citizenry.

On Monday morning the Food and Drug Administration's New Orleans District, whose territory includes all the devastated coastal area, began to put into operation its prearranged plan for meeting natural disaster, together with the improvisations needed to meet the particular emergency conditions resulting from the hurricane's pattern and intensity. Under Director Nevis Cook, the District first moved to establish contacts by whatever communication systems were available with the appropriate State and local health and civil defense officials in Mississippi, Louisiana, and Alabama to determine the areas of worst destruction and the kind and extent of help these officials needed. This information was evaluated and summarized and forwarded to FDA in Washington against the possibility that the District would need additional help from outside.

Under the plan, the District's three supervisory inspectors were to be responsible for coordination of FDA effort in the District's four States: James R. Dupre in Louisiana, Hans A. Aye in Alabama, and Richard J. Davis in Mississippi and western Tennessee. Teams of inspectors were sent into those areas of southeast Louisiana not under water to reconnoiter and evaluate the extent of food and drug damage. The District's entire work force of inspectors and import inspectors, chemists, microbiologists, and others were placed on alert to go into the disaster areas when needed.

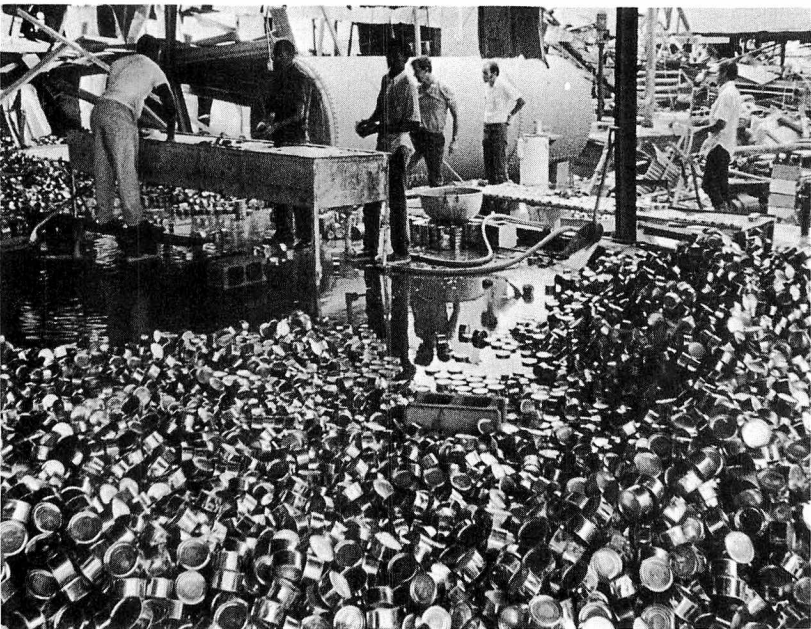
In Jackson, the State capital of Mississippi, Resident







Scenes like the beached shrimp trawler and the scattered cans of seafood and fruit drinks on the two preceding pages were repeated all along the Mississippi Gulf Coast after Hurricane Camille. Above, top left and top center, Inspectors Ray Jira and Lee Cabes respectively check ruined seafood canning facilities and equipment at waterfront packing and processing plants. Top right, Inspector Mike Becker (back to camera) talks to the president of a drug sundries warehouse flooded and damaged by tidal waves at Gulfport. Bottom left and center right, employees of seafood packing plants wash and sanitize cans of seafood in salvage operations. Bottom right, bulldozer covers over fishmeal and canned cat food flooded at port of Gulfport as workers in the background spread lime on products not yet buried. The three freighters in the background, which had been lashed together at the docks for protection before the hurricane hit, were lifted by tidal waves and deposited on dry ground.

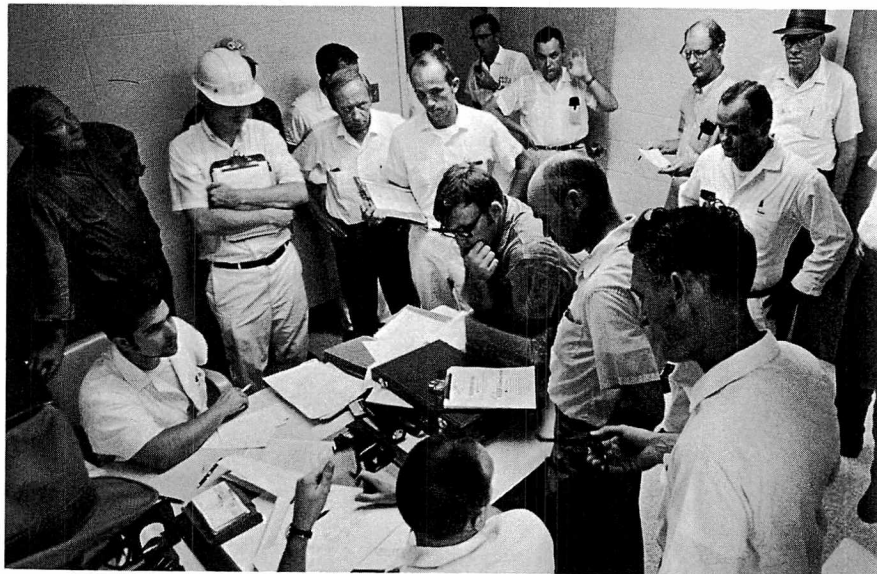


Inspector Thomas Hooker was directed to take whatever time was needed to survey firms in the central State area where the hurricane had caused some damage, and to maintain continuing liaison between the District and State health and other government officials at Jackson, then to report the following week to supervise FDA operations at its emergency headquarters in the Harrison County Health Department offices at Gulfport. In Mobile, Resident Inspectors Lewis Sikes and James Sandelin were instructed to complete similar surveys of the seafood processing and other food firms where flooding and other damage had occurred in that vicinity before moving to the Mississippi disaster area where Mr. Sikes was to head a team of inspectors.

On Tuesday, District Inspectors moved into Plaquemines Parish in southeast Louisiana, the hardest hit area in that State, where floodwaters had receded enough to make surveys of destruction, and to take actions in conjunction with State and local health authorities to assure safe food and drug supplies. On Tuesday also, two District Inspector teams totaling 12 men, headed by Memphis Resident Inspector Anthony J. Whitehead, picked their way around blocked roads into the Mississippi disaster area to make quick surveys of the destruction and to determine the kind and extent of help that would be needed in these coastal cities, including Pass Christian, Bay Saint Louis, and Long Beach on the west, and Gulfport, Biloxi, Ocean Springs, and Pascagoula toward the east, plus several smaller coastal and nearby inland communities.

By Wednesday night the quick survey teams had completed this work and reported that not only would the bulk of the District's work force be needed but additional help from adjacent Dallas and Atlanta Districts, whose Directors had offered assistance and had men standing by to depart.

On Thursday nine inspectors from Dallas District and six from Atlanta District arrived, were briefed, and were on the Mississippi scene and in action by mid-afternoon. Three sanitation engineers from FDA's Shellfish Sanitation Program at HEW Region IV in Atlanta, two of whom had been at Mobile when the hurricane struck, were dispatched to the Mississippi disaster area at State officials' request to advise and assist in assuring safe water supplies, to help cope with sewerage problems caused by backed-up water, and to assist in control of rodents. A force of five sanitation engineers from the Environmental Control Administration under James Westbrook were sent from Region IV in Atlanta to assist the State and municipalities with insect and rodent control, disposal of garbage and other solid wastes and dead animals, sewerage improvement, safe water supply assurance, disposition of dangerous spilled chemicals, and other environmental problems. Walter Hughes of the Public Health Service's Health Service and Mental Health Administration acted as the chief DHEW representative coordinating with State and local health and civil defense authorities. Daily conferences of State, local, and Federal health



At a feed store in Biloxi (three photos at top), waters 30 inches high flooded storage areas for packaged feeds and pesticides, breaking containers and mixing the two in a sodden mass. Inspector Robert Bradley (white coveralls) selects goods in the storage area to be condemned (left), supervises removal by a detail of airmen from Keesler Air Force Base (center), and collects a sample of soil from the ground nearby for analysis to determine the extent of contamination of the area with pesticides (right). The two lower center photos show (below) a contingent of inspectors from Dallas District checking in at New Orleans District offices for briefing before heading to the disaster area, and (above) one of the daily briefing sessions for inspectors at FDA's temporary headquarters in Gulfport.



representatives, including FDA, covered priorities for use of available manpower and facilities and special problems requiring cooperative action.

FDA's operations in the disaster area were carried out at the request of State and local health authorities. The Agency's primary function was to provide assistance and expertise in the food and drugs area to State and local officials in contending with emergency conditions that threatened the public health. FDA's enforcement authority under the Food, Drug, and Cosmetic Act was put aside for the duration of the emergency, and violations were referred to State authorities, who were in turn supported by the Defense Department military services and National Guard units from Mississippi and those sent by other States to assist. Mississippi Governor John Bell Williams, operating from temporary headquarters at Gulfport, had declared a state of martial law and State authorities quickly supported recommendations by FDA Inspectors.

The FDA force, which at its peak totaled 43 men, including supervisors and four inspectors in southeast Louisiana, on Thursday was divided into five survey teams operating mostly in pairs in specified geographic areas along the coast, and one reconditioning team, which followed up reports on individual firms by the survey groups. Under a system of priorities based on public health considerations, the inspectors visited all the firms on FDA's list of food and drug processors and distributors, warehouses, bottling plants, and

others operating in interstate commerce, in all about 75 firms. They also made street-by-street, door-to-door visits to all local retail groceries, supermarkets, drug-stores, restaurants, feed stores, and pesticide dealers, pest extermination firms, and others handling hazardous substances. Visits to bars and liquor stores followed when the State had lifted padlocking restrictions placed on these establishments immediately after the hurricane.

The survey teams contacted the person in charge of the establishment, if it was operating, to obtain his estimate of goods damaged or destroyed by the hurricane, or missing, inspected the stocks remaining to determine their condition in terms of hazard to public health, checked sanitation and storage and refrigeration facilities, and asked that unsafe foods and drugs be removed from shelves and placed where they would not be sold or be picked up by scavengers until they could be destroyed or reconditioned. For each firm the FDA teams made either a final report or an interim one calling for followup visits or reconditioning surveillance.

Destruction was indicated for many products that had been exposed to the elements or that had been held at temperatures high enough for spoilage to set in. Checkbacks were made at regular intervals to assure that unsafe food and drugs were not being made accessible to the public before trucks were available to haul them to a dump to be destroyed. These survey teams were headed by Dupre S. Spiller, Curtis Coker, Stanley DeSulis, Lewis Sikes, and Robert J. Jacobson.

The reconditioning team, headed by Ray Jira, kept watch over the operations of firms seeking to recondition products potentially fit for distribution into commerce. For canned seafood and other canned products, reconditioning consisted of sorting unlabeled cans by code numbers stamped on the can to identify the product, washing the can in detergent, and dipping it in a sanitizing bath. Cans beginning to rust were examined for pinholes and were required to be buffed to remove traces of rust. The reconditioning was a special problem because of the unavoidable exposure of the cans to the weather and the difficulty the firms encountered in finding qualified people to do the salvaging work.

A serious potential hazard to health was caused by the flooding of a feed and seed store in Biloxi. Some 10,000 pounds of animal feeds and about 2,000 pounds of packaged pesticides of various kinds had been washed out of the store's storage shelves and mixed together, and 1,500 more pounds of pesticides were flooded. The FDA Inspector, Robert Bradley, asked nearby Keesler Air Force Base to place a guard at the firm to keep people away from the area while a military detail under Mr. Bradley's supervision segregated the chemicals and feeds. Under direction of State authorities and with Army permission, both the feeds and chemicals were removed to an upstate military reservation and buried in a place where there was reportedly little danger of the chemicals contaminating water supplies. Later analysis of samples taken by Mr. Bradley of earth

and floor sweepings revealed contamination with pesticide residues, and efforts were continued to decontaminate the area.

At the Port of Gulfport some 800 tons of fishmeal and a million one-pound cans of cat food were flooded, and FDA Inspectors maintained surveillance over destruction by burial of all but 100 tons of the fishmeal that was removed to Louisiana for reconditioning under an agreement reached between Mississippi and Louisiana State authorities.

One of the most difficult problems encountered by the FDA teams came from attempts by insurance firms and salvage dealers to quickly remove affected stocks of food and drug products out of the disaster area without FDA Inspectors determining first whether they were fit to salvage. The Mississippi State Board of Health issued an order that no food and drug products could be carried out of the disaster area without a permit from the Board, issued and signed by an FDA Inspector, who first satisfied himself that the operation was legitimate, that the food was salvageable, and that the FDA District where the reconditioning work was to take place was appropriately notified. Without these precautions, unsafe stocks of food could have become hazards to health elsewhere. Roadblocks were set up by the military and State law enforcement authorities to check truckers' permits. Drivers who did not have the permits were turned back or detained until an FDA Inspector could be brought to the spot.

Another task of immediate health concern was surveillance of relief food and drug supplies brought into the area by various volunteer groups using many kinds of transportation, some carrying perishables under inadequate conditions of refrigeration or sanitation. The inspector's job was to check these goods to make sure those for whom the supplies were intended were not harmed instead of helped.

The FDA team leaders made daily reports on each firm visited and on the special problems they were encountering. The information was then relayed to New Orleans District offices, which reported overall progress and problems to FDA in Washington.

As of two weeks after the hurricane on the Gulf Coast, FDA had spent 1,500 man-hours and \$25,000 in salaries at the rate of 11 hours per man per day for seven days a week. The FDA teams had completed reports on 360 Mississippi firms and supervised destruction of unsafe food and drugs valued at \$1.8 million. They had issued 23 permits, mostly to salvage dealers, for removal of products out of the area for reconditioning. These reports on destruction of damaged and unfit products do not account for those goods totally destroyed in the hurricane, nor for damage to plants and equipment.

The FDA's disaster force was reduced as of September 5 to three men operating out of District offices in New Orleans, continuing with followups and salvaging and reconditioning work. Some of the original group were relieved late in August by a fresh group of



five inspectors from Minneapolis District, where they had worked under somewhat similar conditions during the floods in that District last spring. The three FDA men were scheduled to continue until State and local officials feel they have brought food and drug sanitation under normal control and there is no longer a danger to health.

In central Virginia, rains on both slopes of the Blue Ridge Mountains flooded areas in Richmond, Waynesboro, and a half-dozen other communities. FDA's Baltimore District had five inspectors working with their counterparts in the Virginia Department of Agriculture and Commerce, checking damage to the food and drug supply. Miscellaneous food damaged or rendered unfit for use in stores and warehouses as a result of flooding, and to be destroyed under surveillance, totaled a thousand tons, according to FDA and State estimates. Some \$215,000 worth of drugs or cosmetics, including 1.5 million surgical needles, were to be similarly destroyed. A lot of 71,400 bushels of grain or feed ingredients at a co-op in Richmond was being withheld from sale voluntarily by the co-op pending determination of its salvageability. Another quantity of liquid sugar totaling 680,000 pounds was under embargo in a Richmond refinery awaiting determination as to whether it can be reconditioned. By permission of State authorities, one salvage firm was removing 4,000 to 5,000 cases of various canned foods from a Richmond warehouse to Kansas for reconditioning.

In terms of preventing a major threat to the public health, FDA's Project Cleanup on the Gulf Coast and in the Virginia area can be called a success, and the experience gained may be useful in some future disaster.





FDA's inspectors placed their expertise in food and drugs at the service of their State and local counterparts to help protect public health. Top left, FDA Inspector Mike Becker and Salvation Army Major John Jordan check a temperature recording device on a truck carrying perishable foods for hurricane refugees. In the three lower photos, inspectors check destruction at restaurants and nightclubs on the beach to assure that no unfit food or drink reaches the public. In the top right photo, State and Federal representatives confer (clockwise from left): Joe D. Brown, Director, Division of Sanitary Engineering, Mississippi State Board of Health, acting as the Board's Environmental Control and Administrative Officer at the scene; Anthony J. Whitehead, FDA Inspector; James A. Westbrook, Sanitation Engineer, Region IV, Environmental Control Administration; R. H. Andrews, MSBH Laboratory Director; Richard J. Davis, Supervisory Inspector, New Orleans FDA District, coordinating FDA activities; Gary D. Hutchinson, Water Hygiene Representative, Region IV, ECA; V. T. Hawkins, Advisory Sanitarian, MSBH, directing vector control; and Clyde Copeland, Advisory Sanitarian, MSBH, directing general sanitation activities.

Artificial Sweeteners

by John J. Schrogie, M.D.

In the 1940's, studies of possible new antipyretic drugs at the University of Illinois yielded an unexpected result: certain derivatives of cyclohexylsulfamic acid (cyclamate) being tested were remarkably sweet. Further studies showed that these chemicals were at least 30 times sweeter than an equivalent quantity of sugar but were nonnutritive; that is, they were not metabolized by the body to energy-producing compounds as is ordinary table sugar.

Although a more potent nonnutritive sweetener, saccharin, had been in general use for several decades, its consumption was somewhat limited because of a bitter aftertaste that followed ingestion of larger quantities. It soon became evident that when cyclamate was added to saccharin, reduced quantities of the latter could be used to produce sufficient sweetness without an unpleasant taste. The advent of cyclamates stimulated the development of a number of food products containing cyclamate-saccharin combinations or cyclamate alone and many new industrial producers were influenced to enter the field.

Thus, during the early 1950's, a variety of food products were developed primarily for use in the special diets needed, for example, in the treatment of diabetes mellitus. The purpose of such foods was to reduce the quantity of calorie-producing components in a controlled dietary regimen. It was also found that the addition of cyclamates yielded certain technologic advantages in food processing, and so the list of cyclamate-containing foods grew longer. Yearly production of cyclamates increased nearly fivefold during the early 1960's.

Laboratory and clinical studies of the pharmacology and toxicology of these compounds were carried out, of course, before and during the earliest marketing phases. Normal human volunteers, patients with a variety of diseases, and several animal species were tested at various dose levels. Except for the production of softening of stool at the higher doses tested, the cyclamates appeared to be virtually inert physiologically.

Taking such observations and the relatively limited initial use of artificially sweetened foods into consideration, the Food and Drug Administration in 1958 placed the cyclamates on the Generally Recognized As Safe (GRAS) list, thus defining no specific limitation on use in food products. However, labeling of such products was required to indicate that such foods should be used by those who should restrict their intake of calories.

As indicated earlier, however, a remarkable rise in consumption of artificially sweetened products has oc-

curred during the past seven or eight years. The introduction of such a wide variety of products generally coincided with a trend to encourage the desirability of bodily leanness for both esthetic and medical reasons. Extensive popular acceptance of the available products stimulated further product development. Advertising campaigns implied that simple substitution of "low calorie" products in the regular diet would be sufficient to produce weight control or loss without reference to total caloric intake versus requirement.

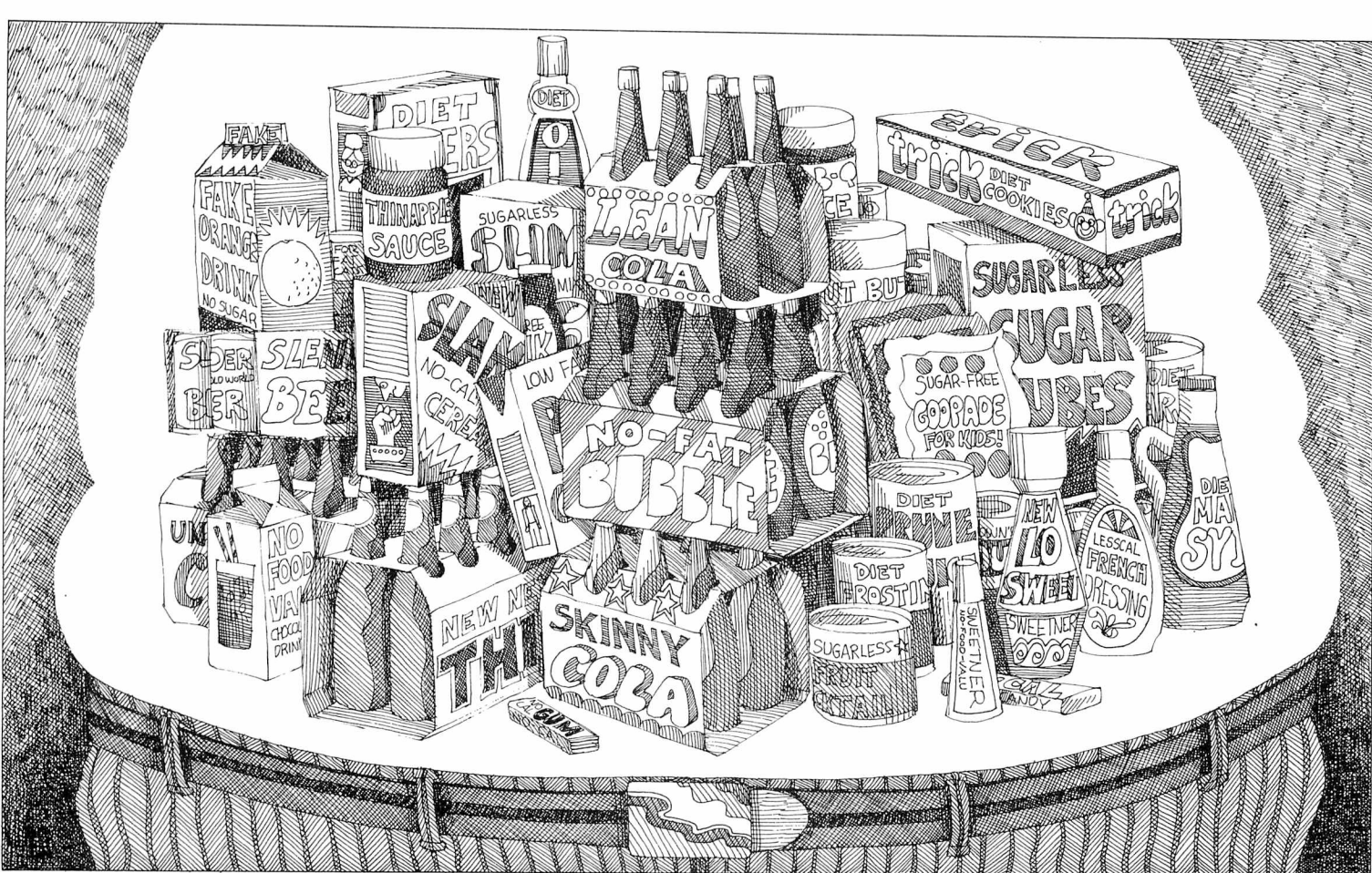
Reacting to this suddenly increased and diversified utilization of artificial sweeteners, the Food and Drug Nutrition Board of the National Academy of Sciences-National Research Council reevaluated the status of the cyclamates in 1962. Its report questioned the use of artificial sweeteners by the general public as a weight-reducing procedure, emphasized that these compounds have no direct effect on body weight, and suggested that they are useful only in closely controlled and supervised feeding regimens. The Board also questioned whether sufficient information was available to assure the safety of these substances under such widespread and indiscriminate use. This report, however, seemed to have little practical impact on the public.

Research on safety by industrial, university, and FDA groups nevertheless was proceeding because of the questions raised. New approaches and methodologies were being evaluated in parallel with scientific advances in other fields. Because of the sharp interest by scientific investigators in possible effects of chemicals on growth and reproduction that was stimulated by the thalidomide disaster, and assuming a considerable use of artificial sweeteners in women of childbearing years, studies were performed in a variety of animal species.

Unfortunately, results in animals to date have failed to yield a consistent pattern. Although retardation in number and growth of offspring has been observed in small animals, consistent results between species or investigative groups have not been achieved. Other studies on the possible direct effects of cyclamate and a metabolite, cyclohexylamine (CHA), on chromosomes



John J. Schrogie, M.D., Director of the Division of Research and Liaison in the Bureau of Medicine, joined FDA from the Public Health Service in 1967.



from animal and human cells have been more consistently positive. Although such studies are provocative and stimulating, the relevance of these observations to the human under ordinary conditions of use is, at present, simply unknown. Valid questions for further investigation have been raised by the application of these new and imaginative techniques.

Other improvements in investigative technique have unearthed information that calls for more direct action. Through the development of certain chemical assay procedures, the presence of appreciable quantities of CHA have been observed both in finished food products and as a metabolic product in humans and animals following cyclamate ingestion. Commercially, CHA is used as the precursor substance from which cyclamate is synthesized; physiologically, CHA is produced by many humans fed cyclamates, probably originating as a breakdown product in the gastrointestinal tract. Although CHA is known to have several potent and toxic effects, the direct significance of ingestion or production of the small quantities noted so far is uncertain, especially in view of the known rapid clearance of CHA from the body. However, because of these potentially adverse effects, the FDA has proposed specific limitations on CHA content of cyclamates in food products. The possible effects of CHA formed metabolically are now under study.

In addition, recent comprehensive Government supported studies at the Albany Medical College of the possible effects of cyclamates on a variety of physiological systems in the human have yielded essentially negative results.

Because of the new scientific information being gathered, the Commissioner of Food and Drugs requested that the Food and Nutrition Board again evaluate the available data. In an interim report delivered in November 1968, the Board recognized no new information that would substantially alter its previous position. It did emphasize more strongly, however, the data supporting a stool softening effect in humans and specifically recommended that an adult not exceed a daily intake of approximately 5 grams per day of cyclamates. Similarly, the Food and Agricultural Organization of the World Health Organization, in its earlier review of the situation, had recommended that daily adult intake not exceed 3.5 grams per day.

Taking these general recommendations and the general background of data into consideration, the Commissioner of Food and Drugs then proposed that a prudent daily intake for an adult not exceed 3.5 grams for a 154-pound adult and 1.2 grams for a 54-pound child. Appropriate statements were published in the *Federal Register* in April 1969 to cover the necessary labeling changes as well as CHA tolerances. Comments are now being reviewed and a final order being prepared by FDA.

Although many questions about the safety of artificial sweeteners have been raised, few have been resolved. Largely left out of the public controversy has been the issue of their effectiveness in weight reduction; none of the few controlled studies reported to date have established a useful role for nonnutritive sweeteners as weight-reducing aids except under the most carefully controlled conditions.

The Pill: A Second Look

by Louis M. Hellman, M.D.

This summary by Dr. Hellman of the Second Report on the Oral Contraceptives by the FDA's Advisory Committee on Obstetrics and Gynecology appears on the opening pages of the report itself and is adapted here in slightly condensed form.

Since the publication of the last Report on the Oral Contraceptives in 1966, scientific as well as public interest in this method of family planning has remained high. The reservations of the first report appear to have been justified. Concern about the immediate and long-range side effects of the hormonal contraceptives has increased as scientific investigations have uncovered a host of diverse biologic effects, and as the drugs have become available to increasingly large segments of the world's population.

Adverse reactions are continually reported in the scientific literature and the lay press. Since the vast majority of the reported adverse experiences are conditions which occur spontaneously in women of reproductive age, identification of an etiologic relation has been difficult and slow.

An increased risk of thromboembolic disease attributable to the use of hormonal contraceptives has now been defined in both Great Britain and the United States. Other risks, such as those of hypertension, liver disease, and reduced tolerance to carbohydrates, have not been quantitated with the same precision. Some of the risks have been recognized by isolated clinical observations, whereas others have been predicted on the basis of experiments with animals or merely on theoretical grounds.

Controversy has centered about two areas: the scientific data required to establish an etiologic relation and the balance between acceptable risk and potential benefit. The voluntary submission of reports by individual doctors to scientific journals, to the pharmaceutical industry, or directly to the Food and Drug Administration is fragmentary at best. Since the data on the natural incidence of the disorders in question is not available, it is impossible to ascertain whether the haphazard voluntary reporting of an adverse reaction in fact represents an increase in the suspected complication. The limitations as well as the value of a voluntary reporting system for providing an initial warning of serious complications have been noted frequently. There is no easy escape from this dilemma. The current aggregate pharmacological experience with the oral contraceptives is unique, however, in that large numbers of healthy young women are using potent drugs for a purpose

other than the control of disease. An improvement in national reporting of some of the alleged complications is therefore merited. If the annual national rates of incidence of the various complications thought to be associated with hormonal contraceptives were known, trends presently unsuspected might be quickly uncovered.

This pharmacological experience is unique also in the attention it has received by the press throughout the world. Particularly in Great Britain and the United States the press has attempted to keep the public informed of each discovery and each reported difficulty. Such reporting is the quickest way to satisfy the public's right to know.

The task of conveying complicated scientific information to the public is a responsibility requiring well-informed and accurate reporting, based on a judicious appraisal of data. Neither the public nor the press is well served if information is exaggerated, mitigated, or suppressed. In the final analysis, both the physician and the layman must evaluate the risks of the hormonal contraceptives in comparison with other methods of contraception or no contraception at all. They can do so wisely only when they have access to all available information, accurately and dispassionately presented.

It is difficult to separate fact from fiction at the forefront of scientific discovery. Evaluation in the area of hormonal contraception has proved formidable to the best informed scientists. The epidemiological problems are unique, requiring refinements in technique not yet fully realized. Case reporting, particularly isolated experiences, may be inconclusive. Thromboembolic disease is but one example. Eight years were required from the time of the first reported death to establish the relative risk and an etiologic relation to the hormonal contraceptives. By reviewing a welter of scientific studies of varied value, the press has acquired an increasing awareness of the problems through hard work and study. So too have physicians and the public. This difficult course could have been shortened and made more efficient by periodic, well structured, and responsibly led impartial conferences of scientific writers. The pattern was established 11 years ago by the American Cancer Society, when its science writers seminars were created.

The task of balancing the risk against the benefit to the individual and to society must eventually be met. As contraceptive practices spread to all segments of our society, it becomes virtually essential that the requirements of effectiveness and safety, and the desirability of inexpensiveness and lack of association with coitus be satisfied. Oral contraceptives have proved to be highly

acceptable to many couples who had found other methods inconvenient or impractical.

ACTION ON 1966 RECOMMENDATIONS

The Committee is gratified by the prompt response of the FDA to the majority of its previous recommendations as follows:

I. A large case-control (retrospective) study of the possible relation of oral contraceptives to thromboembolism. *Result:* A study was developed at Johns Hopkins University School of Hygiene and Public Health with FDA support. Results document an increased risk in the drug users, roughly comparable to that observed in the epidemiological studies in Great Britain.

II. Continuation and support of studies such as the ones being carried out by the Kaiser Permanente group in California and the University of Pittsburgh group in Lawrence County, Pennsylvania. *Result:* The Kaiser study is operating under support from The National Institute of Child Health and Human Development. FDA support to the project in Lawrence County was discontinued for administrative reasons, but a locally sponsored central audit of prescriptions is operating.

III. Support of additional controlled population prospective studies utilizing groups of subjects that are especially amenable to long-term followup, such as married female employees of certain large industries and graduate nurses. *Result:* A prospective study of the effects of oral contraceptives on cervical epithelium has been underway since 1967. Other prospective studies of effects of contraceptives on cervical cytology have been initiated recently. Corollary studies of possible effects on the breast will also be implemented.

IV. Continuation and strengthening of the present surveillance system of the FDA. *Result:* At the present time, all adverse reactions to the oral contraceptives reported to the FDA from the Hospital Reporting Program, manufacturers, consumers, and physicians are collected and reviewed by the Division of Drug Experience, Bureau of Medicine, where they are coded and stored in a computerized facility. Reports are then transmitted to the Division of Metabolic and Endocrine Drug Surveillance, Office of Marketed Drugs, where serious reactions are collected separately in a card file. This Division is responsible for preparation of a yearly tabulation of these serious adverse effects which is submitted to the Commissioner. A separate listing is also made by staff in the Office of Marketed Drugs.

V. Review of the mechanism of storage, retrieval, and analysis of surveillance data. *Result:* The data is stored by both computer and hand-tabulated forms. The data still cannot be retrieved easily or quickly. In addition, there is a serious difficulty with followup of individual cases because there is no uniform indexing or coding method between source and recipient. Thus, reduplication of reports or difficulties may result. Data is

analyzed according to simple criteria of drug used, age of patient, severity and nature of adverse reactions, etc., but further statistical analysis is not useful, since the total population providing the data is not known.

VI. A conference be held between the FDA and the respective drug firms concerning uniformity and increased efficiency of reporting. *Result:* Not held.

VII. Priority be given to support laboratory investigations concerning all aspects of the hormonal contraceptive compounds. *Result:* The FDA and the National Institutes of Health are supporting several studies on carbohydrate metabolism, lipid metabolism, renal function, blood coagulation mechanisms, potential carcinogenic effects, and other studies in animals and man.

VIII. Uniformity in labeling contraceptive drugs. *Result:* Accomplished.

IX. Discontinuance of time limitation of administration of contraceptive drugs. *Result:* Accomplished.

X. Simplification of administrative procedures to allow reduction in dosage of already approved compounds. *Result:* Although no formal policy has been enunciated, the sponsors of new products that represent either reductions in dosage or changes in dosage schedule have been permitted to submit reduced quantities of preclinical and clinical information. It has been suggested, however, in view of these reduced requirements, that the quality of the studies submitted in support of efficacy be improved; that is, the majority of studies should include patients beginning therapy rather than those being switched over from another hormonal contraceptive and should not generally include postpartum patients or those who are breast feeding.

UTILIZATION

American women are sufficiently interested in oral contraceptives to continue their use despite some alarming reports in the national press. By early 1969, 20 preparations of oral contraceptives, combined and sequential, were being distributed in the United States at the rate of approximately 8.5 million cycles per month. Combined progestin-estrogen products prescribed in 20- or 21-day cycles account for 80 percent of this total. As a result of the gradual trend toward the use of lower dosages, over 90 percent of the combination tablets now prescribed contain 2.5 mg. or less of the synthetic progestin. The estimates of use for 1969 are twice as high as those listed in the national fertility survey of 1965. This apparent doubling of the numbers suggests a much wider use among older women and those of limited education. Such a trend could be forecast from the increased availability of contraceptive services in many of the poorer areas of our big cities.

The use of oral contraceptives has spread in foreign countries as well. Among the countries without laws prohibiting the distribution of contraceptives, only Japan and the U.S.S.R. now proscribe the general dis-



Answering questions from newsmen about the Second Report on the Oral Contraceptives by FDA's Advisory Committee on Obstetrics and Gynecology during a news conference in Washington September 5 are (left to right) Louis M. Hellman, M.D., Professor and Chairman of Obstetrics and Gynecology, State University of

New York, Brooklyn, who is Chairman of the Committee and author of this summary of its report; Herbert L. Ley, Jr., M.D., Commissioner of Food and Drugs; and Philip E. Sartwell, M.D., M.P.H., Professor of Epidemiology, Johns Hopkins School of Hygiene and Public Health, Baltimore, a Committee member.

tribution or sale of these drugs. The estimate of worldwide distribution of oral contraceptives is now approximately 18.5 million cycles per month.

All available evidence indicates that the continuation rates of oral contraceptives are higher than those of traditional methods of contraception, such as the diaphragm, and lower than those of intrauterine devices. In its previous report the Committee indicated an anticipated use of 6 million cycles monthly in the United States in 1970. If the present estimate of 8.5 million cycles is correct, the Committee's projections were conservative.

EFFICACY

The theoretical effectiveness of the combined hormonal contraceptives is reflected in a pregnancy rate of approximately 0.1 per hundred women per year. The theoretical effectiveness of the sequential oral contraceptives appears to be somewhat lower as indicated by a pregnancy rate of 0.5 per hundred women per year. The usually given pregnancy rates, reflecting "use-effectiveness," average 0.7 per hundred women per year for the combined regimen and 1.4 per hundred women per year for the sequential regimen.

Effectiveness, judged by the total number of pregnancies, is significantly higher with oral contraceptives, combined or sequential, than with intrauterine devices or any of the traditional methods. The pregnancy rates among users of diaphragms with contraceptive paste thus appear to be 10 to 30 times higher than those among users of oral contraceptives; those among users of intrauterine devices are 2 to 4 times higher.

METHODS UNDER EVALUATION

Since the Committee's last report, pharmaceutical firms have continued to investigate synthetic progestins and estrogens in an effort to reduce side effects while maintaining maximal efficacy. For example, the most recently approved combination product contains one-third the dose of estrogen and about one-tenth the dose of progestin as was present in the original contraceptive. Steroids that are stored in and slowly released from adipose tissue after oral ingestion are currently under study with the aim of creating a pill that may require administration only once a month. Unpredictable uterine bleeding remains a problem, however.

Intramuscularly injected steroids with a prolonged effect that may last for one or more months have been

widely studied. Although these compounds may suppress ovulation, uterine bleeding is often an unpredictable complication. The delay before resumption of ovulatory cycles often lasts from 12 to 21 months. There is considerable variation among patients. To regulate the uterine bleeding some investigators have administered oral and parenteral estrogen. Doing so, however, detracts from the simplicity of this purely progestational regimen.

Low-dose continuous progestin therapy has been investigated in several countries. Drugs of this kind exert their contraceptive effect without the addition of estrogen and without the inhibition of ovulation. The pregnancy rate appears to be approximately 2 per hundred women per year. Approximately two-thirds of the women studied have some cycle irregularity.

The contraceptive action of low-dose progestins provides for the first time the possibility of long-term, reversible control of fertility by single administration of a hormone. Steroids may be released at a low and constant rate from capsules, made of various silicones, that are small enough to be inserted under the skin with a hypodermic syringe and that may last possibly as long as three years. Such implants could be removed if subsequent fertility were desired. If the clinical studies that have recently been initiated prove fruitful, this form of hormone administration may well become an important development in contraception.

THROMBOEMBOLIC DISORDERS

An etiologic relation between oral contraceptives and an increase in some thromboembolic disorders has been disclosed by several groups of investigators using retrospective methods of inquiry and studies of mortality trends. In 1967 the Royal College of General Practitioners in Great Britain undertook interviews of young women with vascular disease. By comparing patients with superficial thrombophlebitis with a suitably matched series of controls, it could be shown that the risk of developing thrombophlebitis was tripled in women who used oral contraceptives. In a second study, M. P. Vessey and R. Doll investigated young women admitted to several hospitals in the northwest of London with a diagnosis of idiopathic thrombophlebitis. These patients also were matched with suitable controls. A third study involved all of the deaths that occurred in England, Wales, and Northern Ireland during 1966 in women between the ages of 20 and 44 whose death certificates referred to thrombosis or embolism of the pulmonary, cerebral, or coronary vessels.

According to these British investigators, in the absence of other predisposing causes, the risk of developing deep vein thrombosis, pulmonary embolism, or cerebral thrombosis is increased about eight times by the use of oral contraceptives, while the risk of developing coronary thrombosis is apparently unchanged. The results of these three studies led FDA to order the following change of labeling for the oral contraceptives:

"1. The physician should be alert to the earliest manifestations of thrombotic disorders (thrombophlebitis, cerebrovascular disorders, pulmonary embolism, and retinal thrombosis). Should any of these occur or be suspected, the drug should be discontinued immediately.

"Studies conducted in Great Britain and reported in April 1968 estimate there is a seven to tenfold increase in mortality and morbidity due to thromboembolic diseases in women taking oral contraceptives. . . .

"No comparable studies are yet available in the United States. The British data, especially as it indicates the magnitude of the increased risk to the individual patient, cannot be directly applied to women in other countries in which the incidences of spontaneously occurring thromboembolic disease may be different."

Since that time Vessey and Doll have continued their retrospective study to include a larger group of patients matched with controls. The results of this study confirm the findings of the previous investigation.

Another retrospective study of cases of thromboembolism and an equal number of matched controls has been completed. This study necessitated a search for cases in five large cities in the United States. The subjects were women of reproductive age who were discharged alive over a recent three-year period from 43 teaching hospitals. Additional requirements for inclusion in the study were the absence of a history of any acute or chronic condition that might predispose to thromboembolism, absence of a history of a prior attack of the disease, reasonable certainty of diagnosis, and presumption of fertility. The controls were women admitted to the same hospitals in the same six-month period. These controls were matched by race, age, marital status, parity, residence, and hospital-pay status. The controls were in good health prior to hospitalization and free from evidence of sterility. The cases and the controls were interviewed in their homes after discharge from the hospital to ascertain whether they had used oral contraceptives before hospitalization. Other topics were included in the questionnaires.

Most of the acceptable cases had thrombophlebitis, pulmonary embolism, or both; a few had cerebral or retinovascular disease. The risk of thromboembolism to a woman using hormonal contraceptives was estimated by indirect methods to be 4.4 times that of the nonuser. The excess risk did not persist after cessation of use, nor did prolonged continuation of use enhance the risk. No striking differences among contraceptive products were found except for an excess of the use of sequential compounds among the cases, as compared with the controls. The excess relative risk was calculated for each diagnostic grouping and for each demographic class of subjects in which the numbers were large enough to permit evaluation. The findings of this study are in general agreement with those previously reported from Great Britain.

These studies together establish an etiologic relation between thromboembolic disorders and the use of oral contraceptives. Quantitatively they suggest that the mortality from thromboembolic disorders attributable to the oral contraceptives is about three per 100,000 women per year, adding slightly less than 3 percent to the total age-specific mortality in users of these drugs.

CARCINOGENESIS

Much indirect evidence suggests that steroid hormones, particularly estrogen, may be carcinogenic in man. This data is derived from experiments on laboratory animals in which long-term administration of estrogen resulted in cancer in five species. Although all physical and chemical agents that are carcinogenic in man produce malignant tumors in experimental animals also, evidence of the carcinogenicity of estrogen in other species cannot be transposed directly to man. Suspicion lingers, however, that the results in laboratory animals may be pertinent to man. Many difficulties arise in the epidemiological elucidation of this suspected relation. The principal obstacle is the long latent period between the administration of a known carcinogen and the development of cancer in man. Thus far, no properly devised prospective or retrospective studies have provided an adequate solution to this problem.

The Committee has focused its attention on three target organs: cervix, endometrium, and breast. Estrogens may produce a variety of epithelial changes in the human cervix of uncertain prognostic significance. A study of women attending the Planned Parenthood Clinics in New York City has revealed a higher prevalence of epithelial abnormalities that the investigators considered to be carcinoma *in situ* among women using oral contraceptives than in those who use the diaphragm. The Committee believes that this study does not prove or disprove an etiologic relation between the oral contraceptives and these cervical changes. The epidemiological and diagnostic problems inherent in these studies are discussed in the Task Force Report.

Although estrogen causes epithelial changes in the human breast, its carcinogenic effect on that organ has never been proved. Even in women with frank mammary carcinoma, estrogen produces variable changes in the clinical course of the disease. For example, ovariectomy leads to regression of metastatic breast carcinoma in approximately half of premenopausal women. Exogenous estrogens cause either regression or stimulation of similar tumors in menstruating women but induce regression in about half of postmenopausal women. The reasons for these paradoxical effects of estrogen on breast cancer are not clear.

In accordance with suggestions in the last report, FDA has required mandatory testing of all currently licensed and investigational hormonal contraceptives on monkeys throughout their lifetimes and on dogs for

seven years. Thus far the presently licensed compounds have not produced tumors in these two groups of laboratory animals. Two estrogen-progestin combinations have, however, induced mammary tumors in beagles. Because these two compounds offered no clear therapeutic advantage over previously available hormonal contraceptives, clinical investigation was discontinued. This decision still leaves unresolved the question of similarity in hormonal induction of mammary tumors in a highly susceptible canine strain and in man. Continued testing of the presently available drugs is indicated.

Currently available data on death rates from genital and mammary cancer in women in the United States does not clarify the problem of association between steroids and carcinoma. The long latent period of action of known carcinogens (10 years) and the length of time between diagnosis and death eliminate vital statistics as a source of information about this association until the mid-1970's or later.

The massive program of prophylaxis launched against cervical cancer in this country has accomplished a steady decline in deaths from the disease. The common practice of repeating cervical smears, annually or semiannually, in women taking oral contraceptives has contributed to the decline, but it has clouded the question of the effect of oral contraceptives on cervical cancer.

Since there is no method of early detection of mammary carcinoma comparable in efficacy to that of the cervical Papanicolaou smear, the problem of the possible carcinogenic effect of oral contraceptives on the breast remains unresolved. The Committee suggests that carefully designed retrospective studies using a case-control method similar to that employed in the investigation of thromboembolism may answer this perplexing question. A pilot study to ascertain feasibility is already in progress at the Johns Hopkins Hospital. If this method proves successful, several larger studies should be immediately initiated.

Lacking conclusive information about the applicability of existing animal data to women and sufficient observations of human disease, the Committee concludes that potential carcinogenicity of the oral contraceptives can be neither affirmed nor excluded at this time. Clinical surveillance of all women taking oral contraceptives must be continued. A major effort to resolve the questions about steroid-induced neoplasia in human beings should be undertaken.

METABOLIC EFFECTS

Hormonal contraceptives produce numerous effects on many organs, for example, the liver, the thyroid, and the adrenal. They also affect some of the body's homeostatic mechanism; for example, they produce changes in salt and water metabolism and occasionally induce hypertension. Recently, morphologic changes in blood vessels have been described. In many areas where al-

teration in function or structure has been noted, basic information is lacking. Little is known, for example, about the effects of the oral contraceptives on water metabolism or renal function.

Observations that large doses of estrogen hasten epiphyseal closure in girls has created fear that oral contraceptives may limit growth. Such concern is unjustified, however, because these drugs are usually prescribed only after the growth spurt and in doses far smaller than those required to stunt growth.

There is no evidence at this time that any of these drug-induced metabolic alterations pose serious hazards to health. The systemic effects of the drugs are so fundamental and widespread, however, that continued medical surveillance and investigation is required.

RECOMMENDATIONS

The Committee recommends that:

1. Well-designed studies be initiated and supported to elucidate or eliminate the relation of the hormonal contraceptives and carcinoma of the breast and uterus. The relation of exogenous steroid hormones to the induction of cancer in man is the major unsolved question in the widespread use of the current hormonal contraceptives. Funds to investigate this relation are urgently needed. An international conference on epidemiologic design of projected studies should be beneficial.

2. Long-term support be supplied to investigate the basis and prognosis of the metabolic alterations produced by the hormonal contraceptives. The Task Force Report on Metabolic Effects of the hormonal contraceptives reveals a paucity of basic knowledge. Substantial research support is needed to close these information gaps.

3. Substantial support be supplied to develop new methods of contraception. The current methods of contraception have inherent risks and disadvantages. These are enhanced when modern contraceptive methods are introduced into underdeveloped countries. Generous research support to discover new methods with decreased risks and fewer disadvantages is essential.

4. The National Institutes of Health support a National Fertility Survey in 1970. Adequate data on contraceptive usage is not available after 1965. Support for a quinquennial survey should be established.

5. Financial support be made available to make possible local reporting of certain diseases. Reporting of certain diseases such as cancer from selected localities would be of obvious benefit. The annual incidence of cancer reported from Connecticut is currently available only as late as 1962 while the report from New York, exclusive of New York City, is more up to date. These reports, if current and if extended to include adequate samples of the general population, could be used to indicate trends. With the rapid proliferation of very potent therapeutic agents, such reporting be-

comes more of a necessity.

6. FDA assure adequate surveillance of approved contraceptive drugs. The inadequacy of surveillance of contraceptive drug use in the United States and other countries is apparent. Voluntary reporting of adverse reactions tends to be capricious and may be misleading. The Committee recommends setting up test centers utilizing large contraceptive clinics, with identical record systems and good followup to record and report adverse reactions. In addition, the Committee recommends the implementation of an international conference to discuss ways and means of promoting rapid and accurate transmittal of information about adverse drug reactions to responsible authorities.

7. The surveillance system of the FDA be strengthened. This recommendation from the previous report has not been satisfactorily implemented. A system should be devised so that when adverse reaction reports are received, they are made readily and immediately accessible.

8. An annual conference of scientific writers on contraceptive knowledge and accomplishment be held under auspices of FDA or the Department of Health, Education, and Welfare. Years ago, the American Cancer Society sought by means of annual conferences of science writers to make available data on research, treatment, and etiology of malignant disease. These conferences made for a vastly better informed press. In view of the public interest in population and its control, similar conferences in this area appear to have merit.

CONCLUSION

Although the Kefauver-Harris Amendments of 1962 indicate that the term "safe" has reference to the health of man, nowhere do they define safety. Discussing this subject before the Subcommittee of the Committee on Government Operations of the House of Representatives in 1964, the Commissioner of Food and Drugs pointed out that no effective drug can be absolutely safe. Therefore, evaluating safety of a drug requires weighing benefit against risk.

The Advisory Committee on Obstetrics and Gynecology has continued to assess the risk of oral contraceptives in this light, weighing knowledge of potential hazards against benefit. It has periodically reviewed the labeling of these compounds, repeatedly advocated strict surveillance by physicians, and recommended the accumulation of additional information about biological action and clinical effects. This report states the benefits of these compounds compared with those of other contraceptives.

Specific risks as well as requisite practices for follow-up of patients have been detailed in the labeling of all hormonal contraceptives. When these potential hazards and the value of the drugs are balanced, the Committee finds the ratio of benefit to risk sufficiently high to justify the designation safe within the intent of the legislation.

Fair Packaging and Labeling

by Walter R. Moses

On November 3 this year, the Fair Packaging and Labeling Act (FPLA) will be three years old. This is a good time to review what has been done and what still needs to be done toward fulfilling the promises of this Truth-in-Packaging Law. When President Johnson signed the bill, he said it was to tell the consumer exactly what is in the package, who made it, just how much it contains, and how much it costs as compared to competitive products. It was also to end the use of labels that lie and packages that confuse. Admittedly, much remains to be done if all these purposes are to be achieved.

The requirements of the FPLA apply in general to packaged consumer commodities. The Food and Drug Administration (FDA) was made responsible for administering only those provisions of the FPLA that apply to foods, drugs, devices, and cosmetics as defined in the Federal Food, Drug, and Cosmetic (FDC) Act. Even with respect to these there were important exceptions, since the FPLA specifically excluded from its provisions the following:

Meat and meat products.

Poultry and poultry products.

Tobacco and tobacco products.

Economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act.

Commodities subject to the Virus-Serum-Toxin Act.

Habit-forming drugs.

Drugs restricted to dispensing by or on the prescription of a physician.

Insulin.

Alcoholic beverages subject to the Federal Alcohol Administration Act.

Commodities subject to the Federal Seed Act.

The Federal Trade Commission administers the provisions of the FPLA with respect to the packaging and labeling of consumer commodities other than foods, drugs, devices, cosmetics, and the exempted commodities listed above. The Department of Commerce is responsible for administering provisions concerning undue proliferation of package sizes and weights.

An FDA proposal published in the *Federal Register* of March 17, 1967, included new regulations to implement the FPLA with respect to label statements for foods and to bring up to date the general regulations issued under the FDC Act more than a quarter of a century earlier. Interested persons were invited to comment. Over 300 comments were submitted by Federal and State officials and industry representatives. These included many constructive comments and helpful suggestions that required careful study. Since the FPLA supersedes State laws regulating label declarations of the quantity of contents on containers of consumer commodities, the FDA felt it was advisable to consult State officials, whose co-

operation is essential to effective enforcement of this law. The Committee on Laws and Regulations of the National Conference of Weights and Measures and the Executive Committee of the Association of Food and Drug Officials of the United States were consulted. By the time this could be done and revised regulations drafted, the effective date had passed.

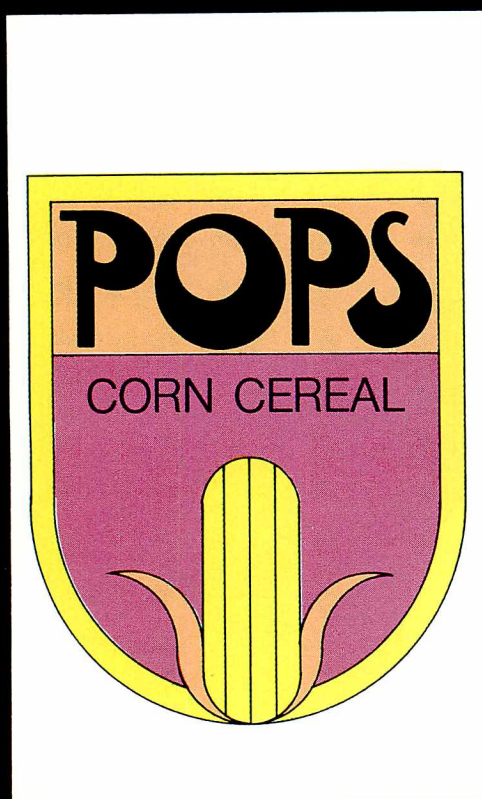
Revised regulations were published on July 21, 1967, and in accord with rulemaking procedures prescribed by law, interested persons were given an opportunity to file objections and request a public hearing. At the same time, the Commissioner of Food and Drugs exercised the option provided in FPLA to permit postponement of the effective date. July 1, 1968, was to be the effective date for all packages introduced into interstate commerce.

It soon became apparent that nearly all food labels needed revision, and that label manufacturers could not make all the new plates, print the labels, and supply these to food packers by the July 1, 1968, deadline. Therefore, the Commissioner published a statement of policy prescribing the conditions under which existing stocks of labels, complying with the FDC Act but not with all FPLA requirements, might be used after July 1, 1968. More than 3,300 firms met the prescribed conditions and were granted permission to use existing labels until new labels could be obtained, but not beyond June 30, 1969.

On September 20, 1967, a final order was published in which the Commissioner ruled on objections and requests for a hearing. Some regulations were revised, and the meaning of others was clarified.

These regulations are intended to further help consumers to know what food is in a package, who packs or distributes it, and how much it contains. However, the

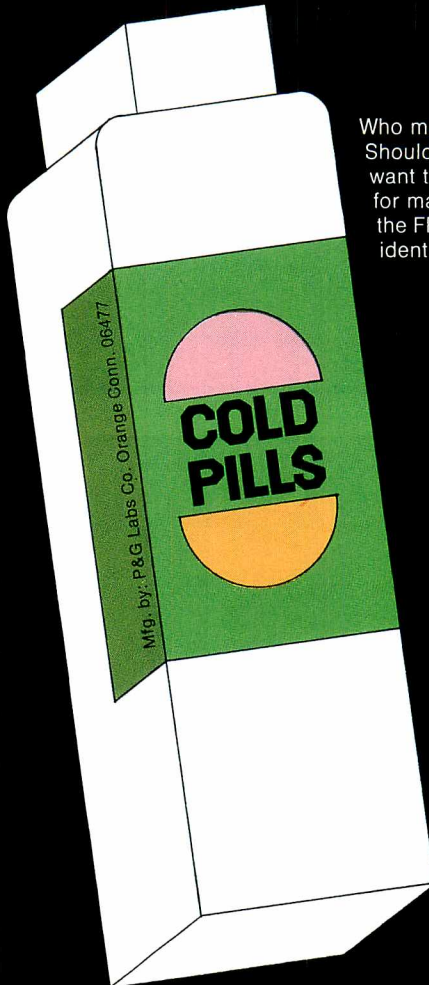
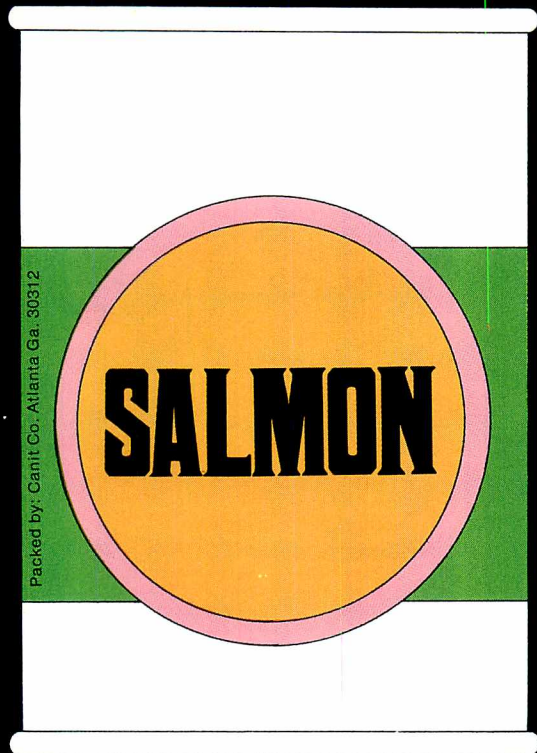




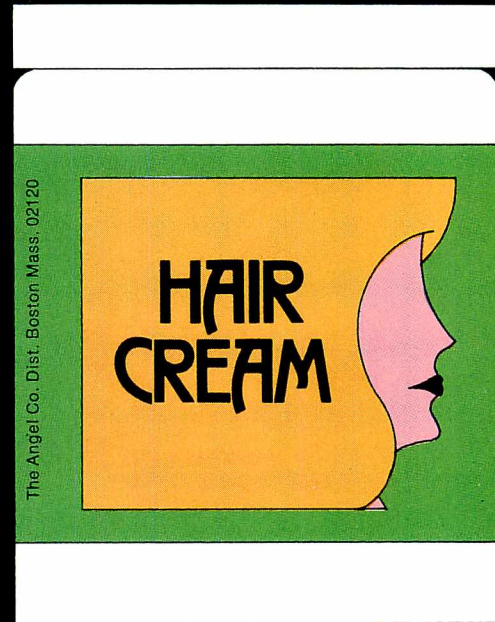
What's in the package? So that the purchaser will be in no doubt about what he's buying, the FPLA requires an identity statement in bold type on the main display panel in a size and position easy to read.



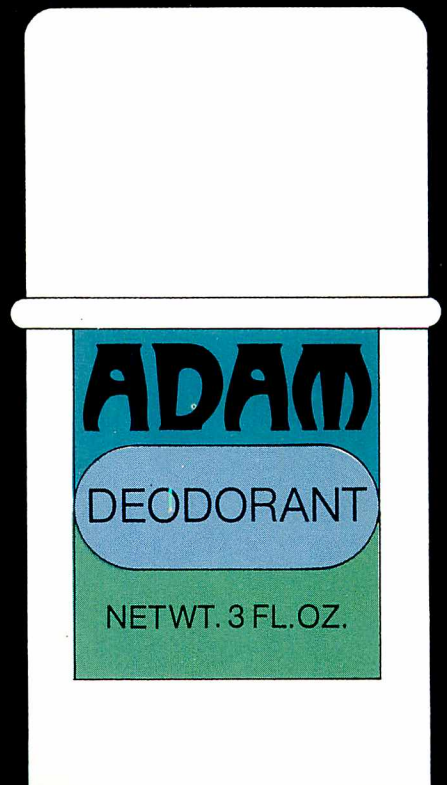
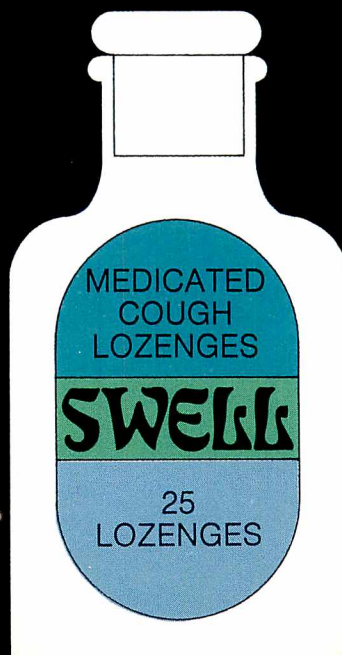
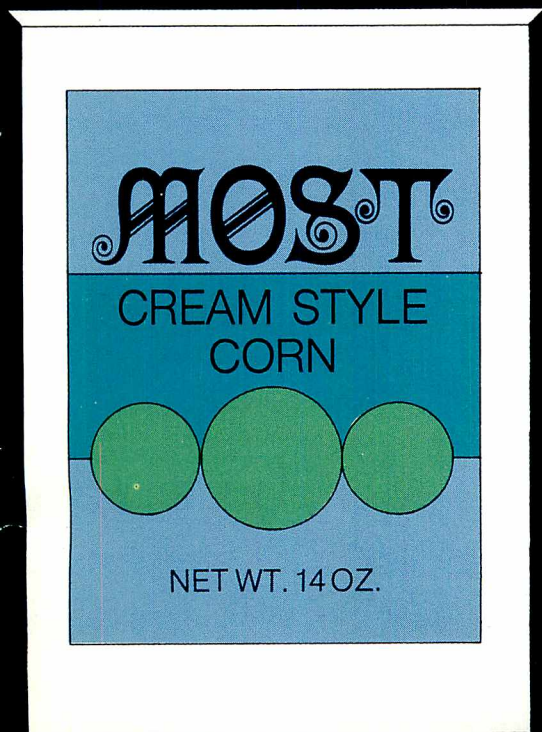
What is the food made of? To inform the purchaser of a processed food product of the ingredients it contains, the FDC Act requires a declaration on the label listing each ingredient in the order of its quantity in the product to indicate the proportions of each ingredient used. This declaration is not required in the case of some common foods for which FDA has set standards of identity that specify minimum proportions of basic ingredients.

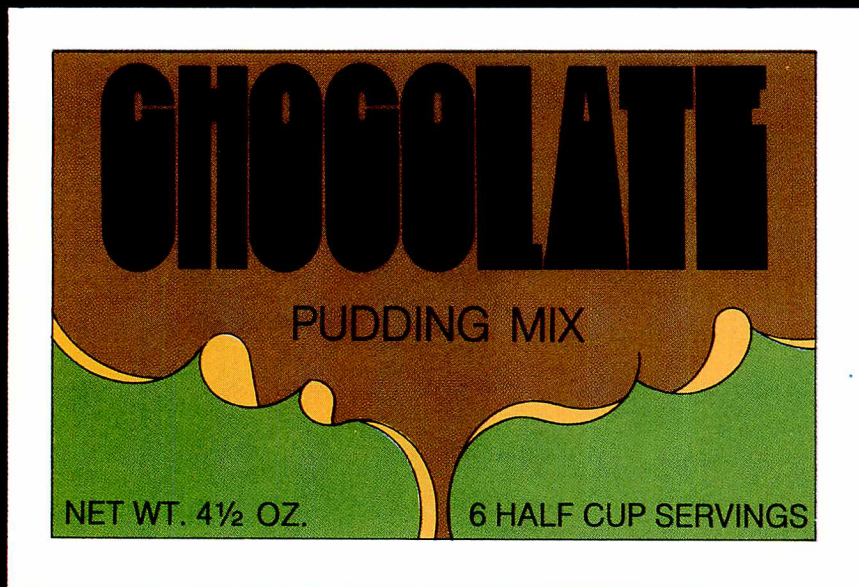


Who makes or distributes it?
Should a consumer for any reason
want to know who is responsible
for marketing a product, both
the FPLA and the FDC Act require
identifying information.

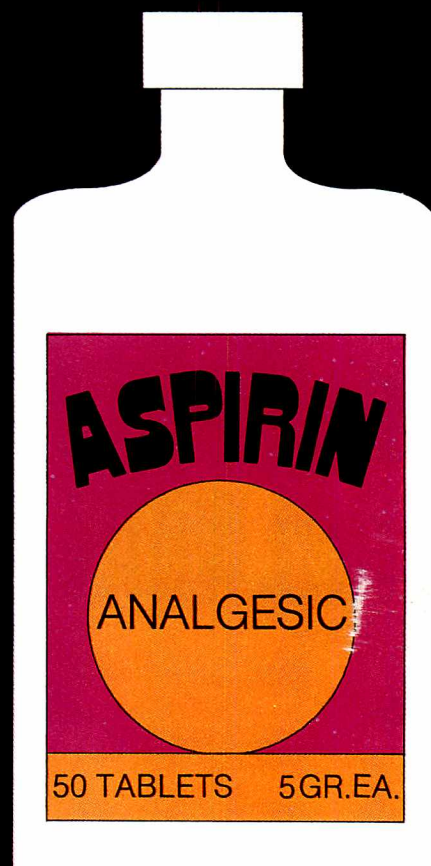


How much is in the package? To
let the purchaser know how much
he is getting, the FPLA requires a
statement of the quantity of
contents: in type of a size, shape
and contrast that makes reading
easy; in a place on the front of
the package that makes it easy to
find; and in terms that are easy
to understand and compare
with other products.





How big a serving? If the label of a food product lists the number of individual servings in the package, the FPLA requires that the amount of each serving be listed along with total quantity.



What's the drug for? What size units and how many? A consumer buying an over-the-counter (nonprescription) drug needs to know the kind of drug he's getting or what it will do, as well as the strength or quantity of each dosage unit and the total number. The FPLA requires this information on the label.



How many and what kind of devices? Labels of packages containing the various medical devices are required by the FPLA to describe the number of devices in the package as well as information about weight, measure, or size.

FPLA provides that the Secretary may exempt particular commodities from the requirements if he finds that, for good and sufficient reason, full compliance is not necessary to adequately protect consumers. The FDC Act also provides for exempting regulations under certain conditions. Exemptions have been granted for some foods when petitioners submitted proof that the proposed exemption was reasonable, did not impinge on the consumer's right to information essential to value comparisons, would not promote deception or unfair competition, and that full compliance was impracticable or otherwise unnecessary. Individually wrapped pieces of "penny candy" and pieces of candy weighing less than one-half ounce per piece sold in bags or boxes have been exempted from all labeling requirements provided the containers bear the required statements. A proposal published January 17, 1969, and published again in revised form July 10, 1969, would extend this exemption to chewing gum pieces weighing less than one-half ounce.

To tell consumers *what* is in a package, the FPLA requires that commodities be labeled with an identity statement. The regulations for the package require that this be in bold type, on the principal display panel of the package, in a size reasonably related to the most prominent printed matter on such panel, in lines generally parallel to the base on which the package rests. If the food is marketed in various forms, the identity statement must describe the form (such as sliced, diced, minced, whole, etc.), unless the form of the food is visible through the container or is accurately pictured on the label. Soft drinks in bottles are exempted from the required declaration on the principal display panel parallel to the base if the identity appears conspicuously on closures (lids or cov-

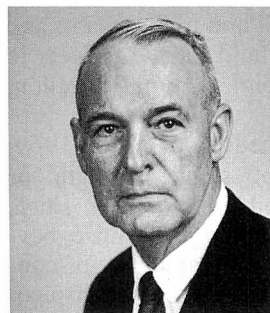
ers). Multiunit retail packages of such soft drinks (such as six-packs) are exempted if the identity statement on unit containers is not obscured by the multiunit package. Continuous label copy wrapping for butter in 4-ounce, 8-ounce, and 1-pound packages need not be parallel to the base provided the statement is not difficult to read as displayed at retail.

To provide purchasers with more information about *what* is in the package, the FPLA authorizes the promulgation of regulations regarding the declaration of ingredients on labels for fabricated consumer commodities other than foods. Foods are subject to the FDC Act, which requires that fabricated foods, other than those for which standards of identity have been established, must be labeled with a listing of ingredients by their common or usual names, but that spices, flavorings, and colorings may be declared as such without naming the specific spice, flavor, or color. The FDA has established identity standards for certain common foods. These prescribe which ingredients must be used, and sometimes how much, as for example, at least 45 parts fruit to 55 parts sugar in jams and jellies. The standards may also prescribe certain labeling statements, including which optional ingredients must be declared. For other fabricated foods, a new FDA regulation requires that ingredients, including water, be listed in order of decreasing predominance. Furthermore, the proportion of an expensive ingredient must be stated if its presence has a material bearing on price or consumer acceptance, and if the absence of such a declaration may create an erroneous impression that the food contains more of the ingredient than is actually the case. The entire list of ingredients must appear on any appropriate single panel of the label—it need not be

on the principal display panel.

The FPLA requires that labels for consumer commodities must bear the name and place of business of the manufacturer, packer, or distributor. The FDC Act has a similar requirement. Regulations require that this include the street address, unless this is listed in a current city or telephone directory. When new labels are printed, the Postal ZIP Code must be included. Regulations also require that the name of the firm, if it is not that of the manufacturer, be qualified to show his relationship, as for example, "Packed for . . ." or "Distributed by . . ." This name and place of business must be conspicuous, but the statement need not be placed on the principal display panel. In case of bottled soft drinks, the declaration may appear on the top or side of the closure. It may be omitted on multiunit retail packages for soft drinks (such as a six-pack) provided the declaration on the unit containers is not obscured, or the multiunit package bears an explanation that the name and place of business of the bottler can be found on the unit containers.

The FPLA requirement that labels tell just *how much* packages contain has had the greatest impact. Most food labels have had to be revised to comply with this provision and the regulations to implement it.



Walter R. Moses, Chief, Food Case Branch, Division of Case Guidance, Bureau of Compliance, joined FDA as a seafood inspector in July 1937.

The only packages exempted from bearing a declaration of the quantity of contents are:

(1) Food in bulk containers, if at retail outlets it is accurately weighed, measured, or counted within sight of the purchaser or to his order.

(2) Individual serving-size packages containing less than ½ ounce or ½ fluid ounce for use in restaurants, institutions, or passenger carriers.

The quantity-of-contents declaration must be located on the principal display panel (or panels). Except as noted below, it must be positioned in the lower 30 percent of the label panel in lines generally parallel to the base on which the package rests. The following are exempted from the 30 percent placement requirement:

(1) Containers with a principal display panel of 5 square inches or less.

(2) Random food packages and uniform weight packages of cheese products bearing labels stating net weight, price per pound or specified number of pounds, and total price.

(3) Soft drinks packaged in bottles with the other required information only on the closure and the quantity of contents declaration blown, formed, or molded into the surface of the bottle near the closure.

(4) Ice cream and certain other frozen desserts and milk, cream, and certain other fluid dairy products in standard ½-pint, 1-pint, ½-gallon, and 1-gallon containers. (A proposal published June 26, 1969, would exempt single strength or undiluted and less than single strength or diluted fruit juice beverages provided the quantity-of-contents declaration appears conspicuously both on the closure and blown, formed, or molded into the glass or plastic container at or above the shoulder.)

(5) Wheat flour products in conventional 2-, 5-, 10-, 25-, 50-, and 100-pound packages.

(6) Corn flour and related products in conventional 5-, 10-, 25-, and 100-pound bags.

(7) Eggs in cartons of one dozen designed to be divided, provided the declaration is on the principal display panel in such position that it will be destroyed when the carton is divided. The divided portions are exempt from labeling requirements.

(8) Margarine in 1-pound rectangular packages, except whipped or soft margarine or packages that contain more than four sticks.

(9) Butter (but not whipped butter) in 8-ounce and 1-pound packages. (Continuous label copy for butter in these sizes and 4-ounce packages is exempted from requirement that the declaration be generally parallel to the base provided it is not difficult to read as displayed at retail.)

The quantity-of-contents declaration must appear in bold face type of specified size as related to the area of the "principal display panel" of the package (not the label), in distinct contrast to the background. It must be separated from other printed information by specified distances. The only foods exempted from the type-size requirements are those in random food packages, and cheese and cheese products bearing labels which declare the net weight, price per pound or per specified number of pounds, and total price.

The quantity-of-contents declaration must be in terms of net weight, net volume, or count, and such combination of these as is needed to tell how much food is in the package. To facilitate comparisons, the number of ounces or fluid ounces must be stated on packages containing less than 4 pounds or 1 gallon. This declaration must include no qualifying terms such as "jumbo quart" or "full gallon." Packages containing 1

pound or more but less than 4 pounds must bear a dual declaration, first in terms of ounces, and then in terms of pounds and ounces or fractions. Such dual declaration is required on packages containing 1 pint or more but less than 1 gallon. For example, a package containing 56 fluid ounces should be labeled:

"Net 56 fluid oz. (1 qt. 1½ pt.)"

or

"Net 56 fluid oz. (1 qt. 1 pt. 8 fl. oz.)" but not

"Net 56 fluid oz. (1 qt. 24 fl. oz.)"

The following exemptions have been granted from the dual declaration requirement:

(1) Ice cream and certain other frozen desserts and milk, cream, and certain other fluid dairy products, if packaged in standard 1-pint, 1-quart, ½-gallon, or 1-gallon containers. Containers of 8 fluid ounces may be labeled simply "½ pint" and 64 fluid ounces as "½ gallon." (A proposal published June 26, 1969, would provide the same exemptions for single strength and less than single strength fruit juice beverages.)

(2) Butter in 1-pound packages may be declared simply as "1 pound" or "1 lb."

(3) Margarine in 1-pound packages may be declared as "1 pound" or "1 lb."

(4) Wheat flour products in 2-pound packages if labeled in terms of pounds.

Neither the FDC Act nor the FPLA requires that labels state the number of servings in a package. Both the FPLA and regulations require, however, that if the label bears any representation as to the number of servings, the net quantity of each serving must be stated. This must be in terms of weight, volume, or count, but need not be in terms of ounces or fluid ounces. It may be stated in such terms as "½ cup,"

"two tablespoons," or similar terms commonly used by housewives to describe serving sizes.

Even a casual survey of items on retail grocery shelves will reveal many labels that do not comply with these regulations. Although foods entering interstate commerce since June 30, 1969, are expected to comply, it may be weeks or months before all foods bearing old labels disappear. Congress made clear its intent that stocks already in channels of commerce when an FPLA regulation becomes effective should not be removed for failure to comply with that regulation, assuming that the labels complied with the rules in effect at the time of shipment.

The number and proportion of items bearing revised labels should increase rapidly. Even those industry members who opposed passage of FPLA have tried diligently to revise their labels by the effective date.

The Label Manufacturers National Association, Inc., after a survey among its labelmaker members, reported that over 100,000 new plates had been made and that as of July 1, 1969, they had supplied 40 billion labels for foods and beverages which were in full compliance. Other billions of revised labels have been printed and are being put into use.

As yet no regulations have been issued to implement those provisions of the FPLA dealing with such things as "cents-off" promotions and "packages that deceive" because of nonfunctional slack-fill. How soon the FDA can draft and issue such regulations will depend upon how much, if any, money is made available for this purpose.

Regulations covering over-the-counter drugs, devices, and cosmetics are not yet effective. Proposed regulations were published August 22, 1967. Over 50 comments were received. After these were carefully evaluated, an order

was published on January 11, 1968. About 25 firms and trade associations filed comments or objections, some accompanied by requests for a public hearing. After studying these, the Commissioner of Food and Drugs concluded that the major issues might best be resolved by canceling the order and publishing a final order to revise and clarify some sections. The new final order was published June 28, 1968, and the effective date was set as July 1, 1969.

Publication of this order was followed by objections and requests for a public hearing from one firm and one trade association. An order ruling on these objections was published by FDA on March 6, 1969. To permit manufacturers time to make label revisions, FDA has changed the effective date to December 31, 1969.

The regulations pertaining to over-the-counter drugs, devices, and cosmetics are similar to the corresponding food regulations with some important exceptions.

The statement of identity for a drug shall be in terms of its established name followed by a statement of its general pharmacological category. If the drug is a mixture with no established name, the requirement may be satisfied by giving its general pharmacological category or principal intended action, as for example, "antacid," "analgesic," or "decongestant."

The statement of identity for a cosmetic shall be in terms of its common or usual name, an appropriately descriptive name, an appropriate illustration representing the intended cosmetic use, or, when the nature of the cosmetic is obvious, a fanciful name understood by the public to identify the cosmetic.

The statement of identity for a device must include its common name followed by a statement of its principal intended action.

The declaration of the quantity of contents for over-the-counter drugs in tablet, capsule, ampule, or other unit form must be expressed in numerical count. If necessary to give accurate information about the strength of the drug, this should be augmented by some declaration such as "25 tablets, 5 grains each," or "100 capsules, 250 milligrams each."

The quantity-of-contents declaration for devices shall be in terms of numerical count, augmented when necessary with accurate information about weight, measure, or size, as for example, "100 tongue depressors, adult size," or "1 rectal syringe, adult size."

Adhesive tape in package form must be labeled in terms of linear measure (length) and width.

Requirements concerning ingredients declarations on drugs are quite involved. In general, the listing of ingredients is intended to supply information needed by users of the drug. Persons who are interested in preparing labels should obtain copies of the Acts and regulations.

As the FPLA enters its fourth year, we may expect its impact on packages and labels to be more visible. State food and drug officials and those responsible for enforcing weights and measures laws will be giving increased attention to the enforcement features. The FDA has prepared a manual to assist these State officials and to promote uniform interpretation of the FPLA and regulations. Consumers can help by reporting suspected violations. Reports may be forwarded to the appropriate State officials or to the nearest of the FDA District offices listed on page 37.

Fulfillment of the promises of the FPLA will depend on the continued active participation and cooperation of the regulated industries, label designers and manufacturers, State and Federal officials, and consumers.

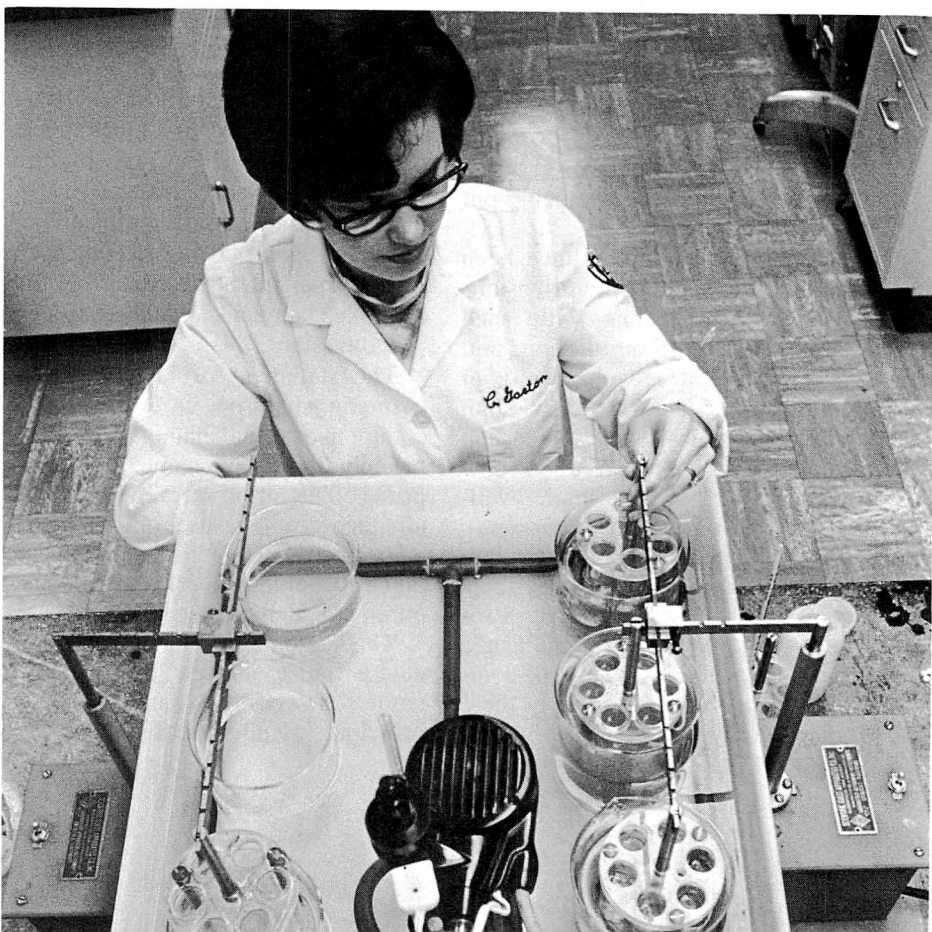
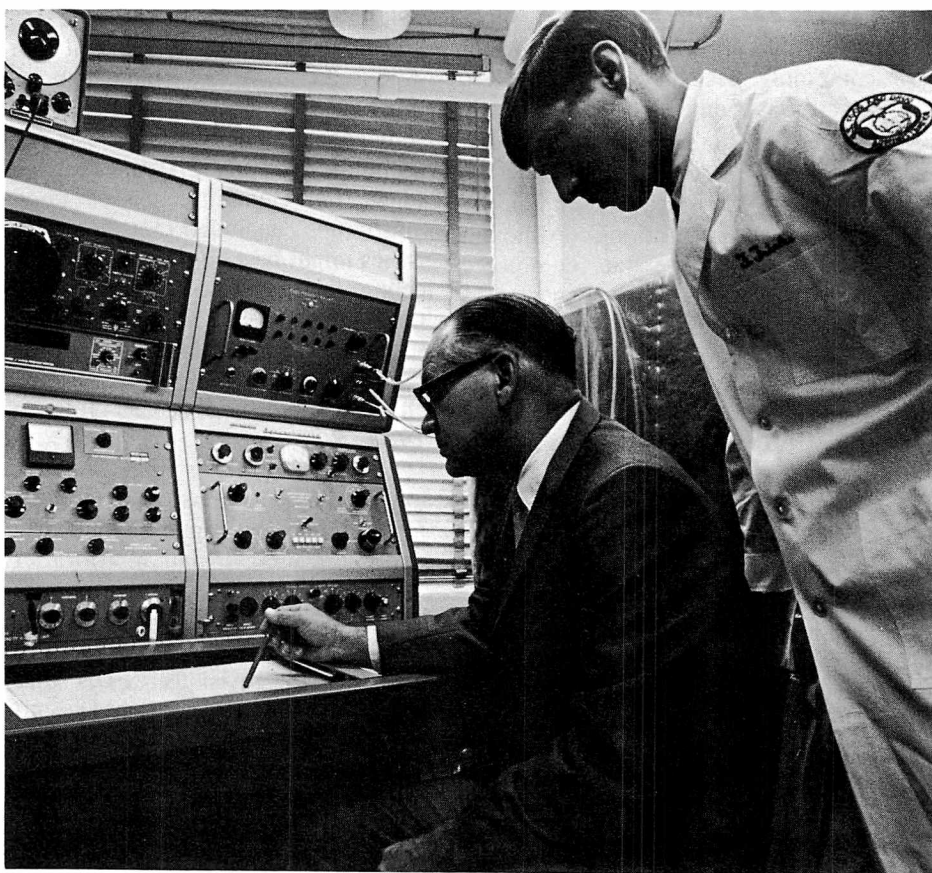
Cincinnati District: A Study in Diversity

by T. C. Maraviglia

In this age of specialization, Cincinnati District's activities under the Food, Drug, and Cosmetic Act are a study in diversity. From the Appalachian Mountains on the east to the Illinois border on the west, from Columbus, Ohio, to Chattanooga, Tennessee, the Cincinnati District is an agglomeration of agriculture, industry, geography, and history. Within its boundaries are bustling industrial centers such as Cincinnati, Indianapolis, and Louisville, as well as the rural hills of Kentucky and Tennessee. There is a combination of north, south, east, and west, including Kentucky, the eastern three-fourths of Tennessee, and the southern two-thirds of both Ohio and Indiana. Industries run the gamut from two large manufacturers of substitute milk formula for infants to small producers of greenhouse vegetables; from a processor of Chinese frozen dinners to prescription drug manufacturers.

The combination of geography and history fertilized the growth of numerous industries in the Ohio Valley. Nearly 170 years ago, the more adventurous pioneers came over the Allegheny and Appalachian mountains to settle the virgin territory surrounding the Ohio River. The rich soil offered the agricultural basis needed for colonization, and the river a channel of commerce for establishing trading and later industrial centers. The new breed of Americans parlayed Nature's assets of soil and river into embryonic industries that flourished, including the Nation's third largest food retail chain; the world's largest producer of soaps, detergents, fats, oils, and allied products; and the country's largest drug manufacturer.

Responsibility for enforcing FDA's consumer-protection laws in this 116,000-square-mile area is the job of the District's 102 people, based in seven resident posts and





Top left: District Chemist Fred Fricke (standing) and Dr. Joseph Klingenberg, District Science Advisor, work with a Nuclear Spectrometer, at Xavier University. Bottom: A District aide runs a disintegration test on enteric-coated tablets. This page: A monkey used in IND studies is examined by Dr. S. F. Mattingly (back to camera), Director, Laboratory Medicine, College of Medicine, University of Cincinnati; Dr. Homer R. Smith (left), District Veterinarian; and Tom Hatcher (right), Supervisor of Animal Facilities at the College.

the District's two-story brick building in Cincinnati. The resident stations are at Chattanooga, Knoxville, Nashville, Columbus, Evansville, Indianapolis, and Louisville.

The District has come a long way from its establishment in 1908 as the site of one of the first food and drug laboratories. Then it had a staff of three. Today there are four labs (one food, one microbiological, and two drug) staffed by 32 chemists and four bacteriologists. There is a staff of 31 inspectors, including 13 at resident posts. District headquarters administrative and clerical staffs support these activities.

A large percentage of the District's man-years go to drug inspections and laboratory analysis. Allocations for fiscal year 1970 call for about two-thirds of the total manpower to be devoted to drug work.

The District has about 20 medium to large drug manufacturers, plus a large manufacturer who produces special formulations on individual order. A complete listing includes several hundred drug and drug-related establishments producing such items as antibiotics, prescription and over-the-counter drugs, large-volume injectables, veterinary drugs, ophthalmic ointments, vitamins, and also includes drug control and research groups.

Activities to assure the safety and effectiveness of drugs are varied and include collecting samples of single component drugs for the FDA's National Center for Drug Analysis in St. Louis.

One drug firm turns out over 80 percent of the insulin produced in the United States. It forwards samples of each batch to FDA's Center for Antibiotic and Insulin Analysis in Washington.

Insulin is only one of the so-called specialty drug products in the District. The larger drug firms produce large numbers of drug prod-

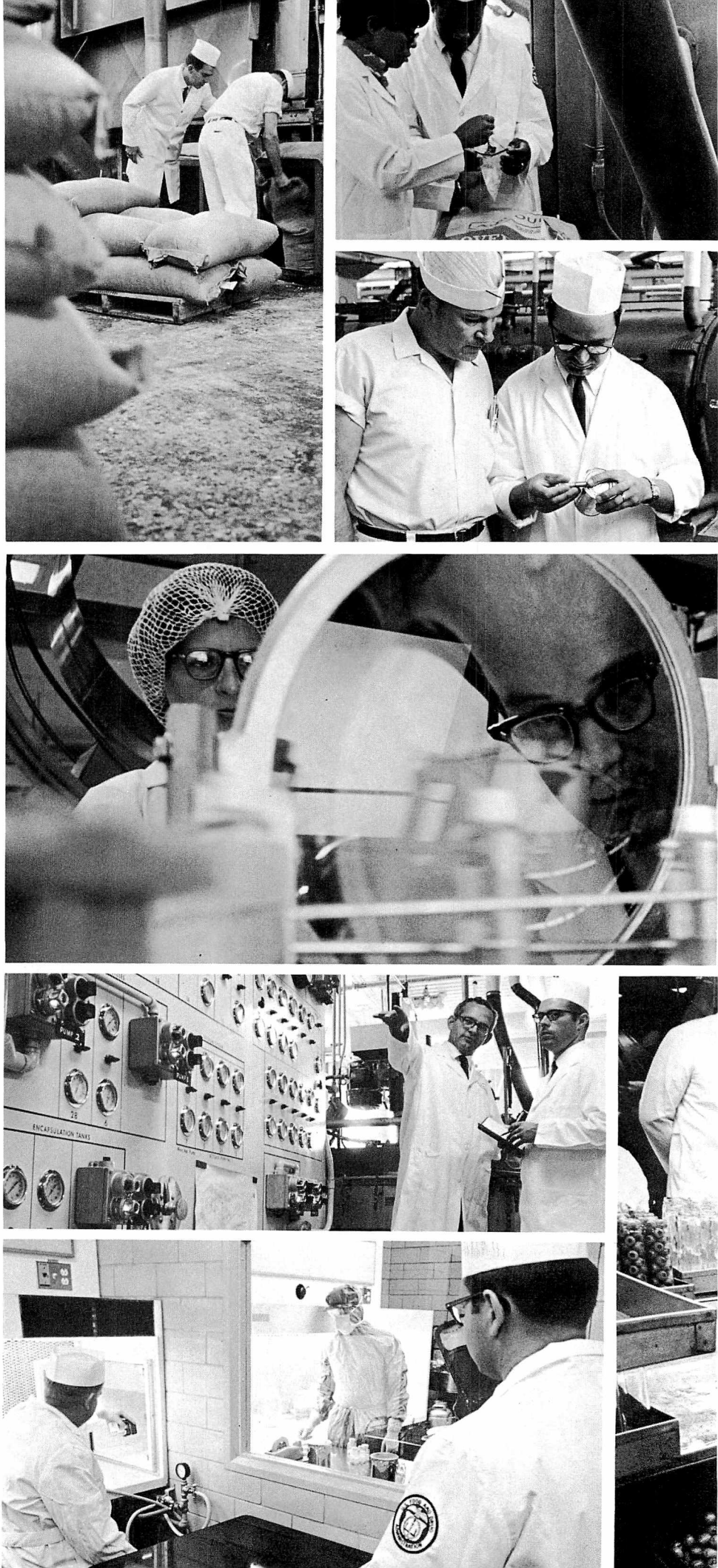
Top, clockwise from left: A District Inspector (in smock) looks for mold in peanuts used in manufacture of peanut butter; a District bacteriologist (foreground) and an inspector collect samples of ingredients used in cake mixes; FDA Inspector (left) checks tomatoes with a greenhouse operator; and a District Inspector (right) checks seam security of cans used in an infant formula plant. Center: An FDA Inspector views a detail of a drug plant's bottling line

ucts, including new drugs as well as antibiotics. Surveillance samples representing various manufacturers' products are collected and analyzed, including prescription and nonprescription drugs, antibiotics, and classes within these product areas such as vitamins and ophthalmic ointments, all of which have particular requirements.

Another aspect of drug inspectional work done in cooperation with FDA headquarters involves New Drug Applications (NDA's). When a drug manufacturer develops a new drug, it must be approved by FDA's Division of New Drugs. Approval depends in part on laboratory and analytical testing information developed by the manufacturer. The District, when requested, provides headquarters with results of field investigations and findings based on our day-to-day contact with the drug firms.

Under the Intensified Drug Inspection Program, half of the inspections initiated with District firms have been completed to date. An essential aspect of the District's IDIP program is its coordination, which is handled by a nonsupervisory manager.

The importance of the daily workload of drug inspection and analysis can never be underestimated. The prime goal, of course, is protection of the American consumer. Cincinnati District is proud of helping avert a national tragedy some years ago through participation in investigations of the drug thalidomide, manufactured in Europe and later linked with an epidemic of birth deformities in European countries. A firm in Cincinnati District proposed to manufacture and sell the drug in the United States, but first had to submit data to the FDA as part of its New Drug Application. While FDA carefully investigated the data, the drug's





through a magnifying glass. Bottom, clockwise from right: Women employees in a food plant handpack olives as a District Inspector observes the operation. In a sterile room, a District Inspector (right) watches a drug firm employee pass a bulk antibiotic sample through an ultraviolet lock to the sample room. A District Inspector and the section head of the drug firm's manufacturing lab discuss operation of the control panel for microencapsulation of aspirin.

connection with the European birth deformities was established and the firm withdrew its NDA.

The majority of drug manufacturers are fully aware of their public responsibilities under the food and drug laws. Early in 1969, one large manufacturer placed an emergency telephone call on a Sunday morning to the District Director's home to inform him of some difficulty involving a batch of penicillin. The penicillin had been contaminated with a sulfa product, and the case had serious implications because the penicillin product was intended for use by patients otherwise sensitive to sulfa. The manufacturer was in process of recalling the contaminated product from the market. The District helped by monitoring the recall and checking its effectiveness.

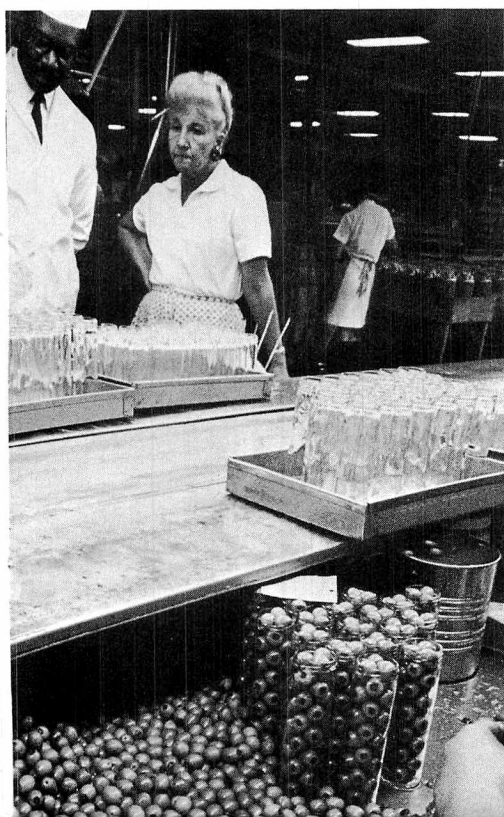
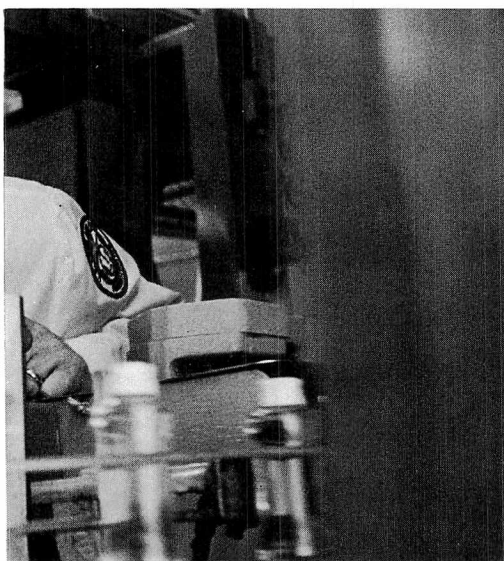
Another manufacturer's voluntary recall this year involved ammonium chloride tablets. This tablet has an enteric coating that delays disintegration until it leaves the stomach. Cincinnati District laboratory tested the tablets in a simulated gastric juice bath (similar to digestive fluids of the stomach). The tablets began disintegrating in less than one hour which doesn't happen to a true enteric-coated tablet. The manufacturer, advised of the findings, recalled the shipment and destroyed it under the eyes of an inspector.

District food responsibilities are also varied. A total of 900 food establishments were inspected in fiscal 1969, and 1,166 food samples collected. Food industries encompass a variety of general processors and canners, including two large manufacturers of milk substitutes for infant feedings, a freeze-dried food processor, a large processor of mushroom products, a spice and condiment processor who ranks among the top five in the country, and one of the largest pro-

ducers of margarine. More greenhouse vegetables, including tomatoes and bibb lettuce, are grown in Hamilton County, Ohio, than any county in the country.

Although pesticide residues are checked in many foods, the greenhouse industry in the past has provided some unusual District inspection and investigational work. A large Indiana greenhouse producer—30 acres under glass—grew and marketed quantities of bibb lettuce that had unacceptable residues of the pesticide PCNB (pentachloronitrobenzene). This pesticide has no tolerance level. Investigation revealed that the producer had followed pesticide application directions provided by the pesticide manufacturer. However, the pesticide application schedules had not taken into account that greenhouse production differs from field production—there are no weathering processes in greenhouse growing, whereas, in open field production, sun, wind, and rain combine to reduce the level of pesticides on a crop. The District cooperated with the State of Indiana and the lettuce producer in destroying the contaminated lettuce.

The milk and dairy industry in the District is a large one. Both Kentucky and Tennessee have sizable cheese industries. The District has 240 producers of dairy and other milk-based items, such as butter, ice cream, dried milk, and cheese. These firms also are an inspectional obligation and sometimes problems arise. One occurred when a lot of cottage cheese was tested in Cincinnati and excessive residues of the pesticide dieldrin were found. Investigation showed that the cottage cheese was produced from milk carried by one particular tank truck, which had collected milk from 12 to 15 producers. In tracking down the herd responsible, the District received cooperation from officials



Right: The District's woman inspector checks effectiveness of cleaning operations on cosmetic bottles. Far right: A District chemist explains a slide sample which is being shown via the closed circuit TV unit. Center, left to right: In a joint State-Federal inspection of an Ohio medicated feed manufacturer, an FDA Inspector collect samples of drug ingredients from hanging bins; the supply clerk, who doubles as District photographer, enlarges a picture in the District's photo darkroom; and a District chemist con-

ducts a flammability test of the contents of a pressurized container. Bottom, clockwise from left: A District chemist prepares to examine, under a polarizing microscope, particles that have been filtered from injectables. District Director T. C. Maraviglia (at easel) conducts a monthly management training seminar for first line supervisors and branch managers (left to right): Carl R. Baeuerlen, Chief Inspector; William H. Munday, Supervisory Chemist; Robert E. Keating, Food and Drug Officer; Loren Y. Johnson, Chief Chemist; Marcella Feeley, Ad-

in Kentucky and Ohio. When the herd was located in Kentucky, the source of the milk was temporarily shut off until the situation cleared up. Periodic tests for pesticide residues are now being run by the milk marketing association involved.

Sometimes food contamination can have tragic results. Such was the case several years ago involving botulism in smoked fish. An antitoxin is used in treating botulism poisoning. The antitoxin manufacturer has a warehouse in Cincinnati and automatically calls the FDA District office when requests for antitoxin are received. That is how the District learned of the outbreak of food poisoning from smoked fish in Tennessee and Kentucky involving 24 persons and resulting in seven deaths. All reported illnesses were traced to one lot of smoked fish. Largely as a result of this outbreak, the FDA established an advisory committee on botulism hazards, which established criteria for smoking and treating fish to avert future outbreaks.

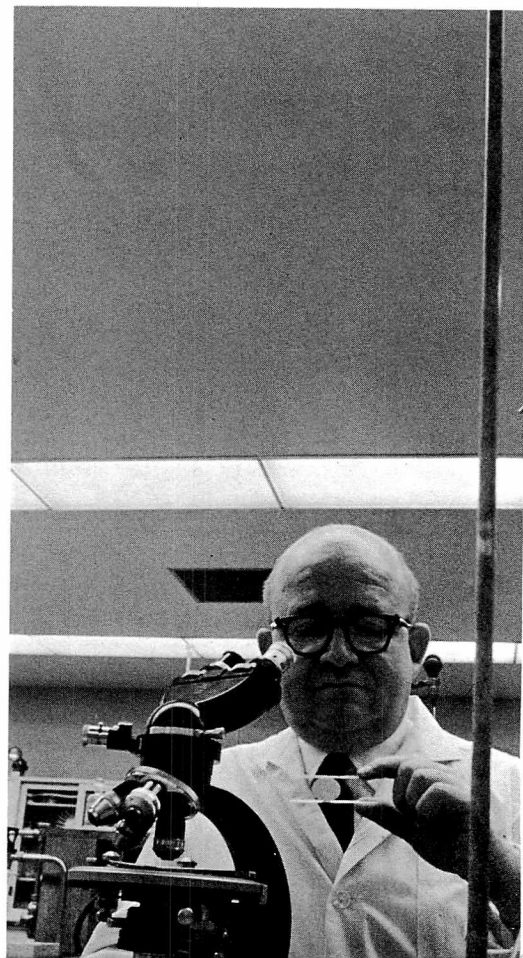
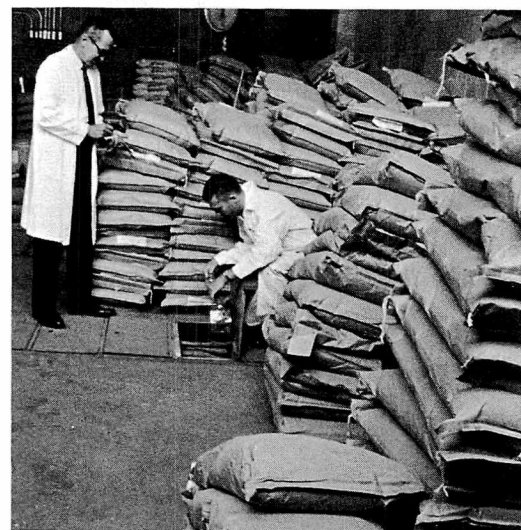
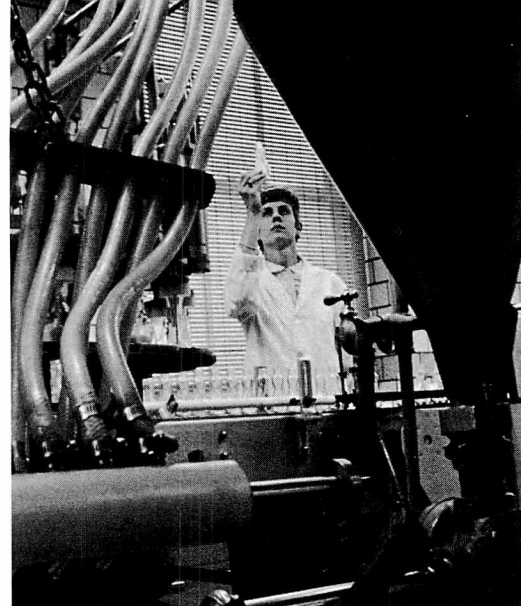
As other Districts, Cincinnati must establish priorities to use manpower to the fullest. In the food area, those plants producing items susceptible to bacteriological contamination, and so presenting a potential hazard to health, receive top priority for inspections. Two years ago the District supervised destruction of over 510,000 pounds of retail size packages of instant non-fat dry milk because of *Salmonella* contamination.

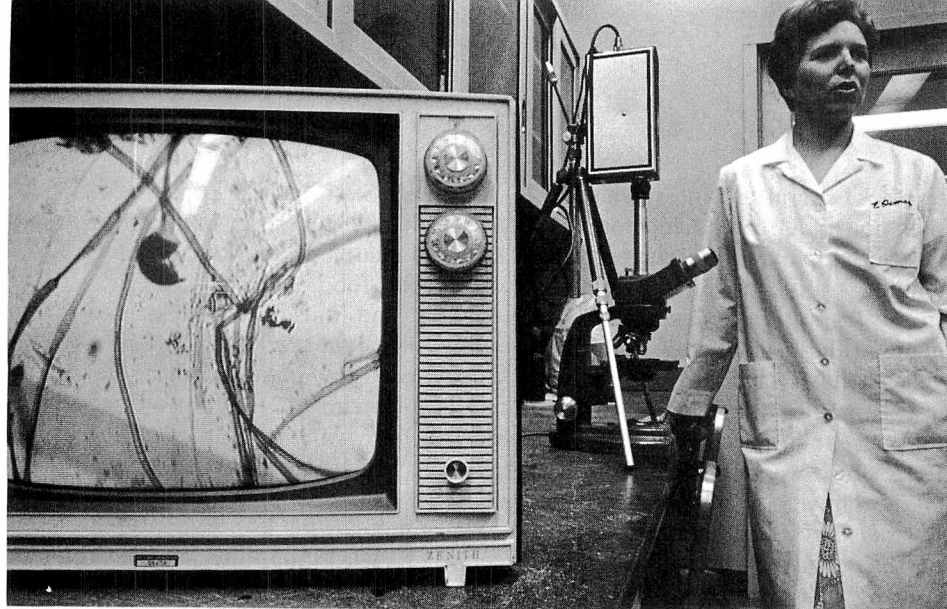
Another important facet of District work involves food sanitation. To avoid duplication, the District has signed a joint agreement with the State of Kentucky whereby inspections of food storage warehouses, flour mills, and bakeries are shared by the two agencies. During a training period, State and FDA Inspectors conducted joint inspections.

Both Kentucky and the District since have worked out a cooperative workload division under which Kentucky also is responsible for inspecting bottling plants. Work-planning meetings are held every two months when new inspection work schedules are assigned and the previous two months' work evaluated.

Another cooperative agreement includes Cincinnati District, the State of Indiana, and Detroit District. This agreement aims at avoiding duplication in cannery and bottling plant inspections in Indiana. The State covers these two industries and supplies FDA with inspectional reports. FDA in turn furnishes assistance when asked, and, in special situations, will notify the State if it plans investigations. This agreement also includes the area of pesticides. The State and FDA exchange pesticide analysis reports. Under another agreement with Cincinnati and New Orleans Districts, the State of Tennessee inspects bottling plants.

Joint District-State cooperation extends also to medicated feeds, of which there are over 1,300 producers in the District. If there is too much of a drug in feed, it could be dangerous to the animal or, more important, contribute to a residue that would carry over to human food. Too little drug would make the feed ineffective for the intended use. The District helps train State employees in proper inspectional techniques, permitting District personnel to be diverted to other assignments. Indiana has seven men commissioned by FDA and four others are being trained for eventual commission. Two have received commissions in Kentucky and eight are being trained; in Ohio, one has been commissioned and nine are being trained; and, in Tennessee, one is commissioned and ten are being trained. Indiana has taken





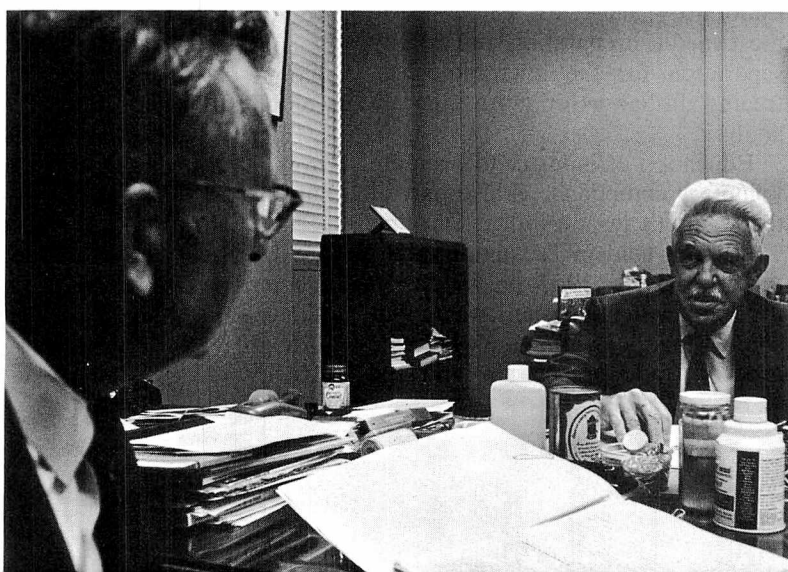
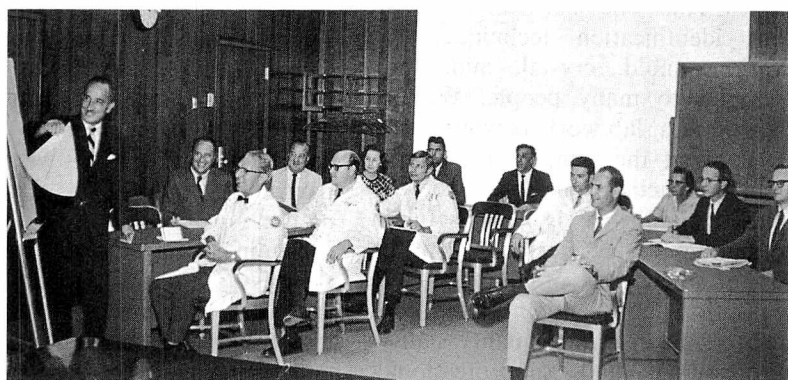
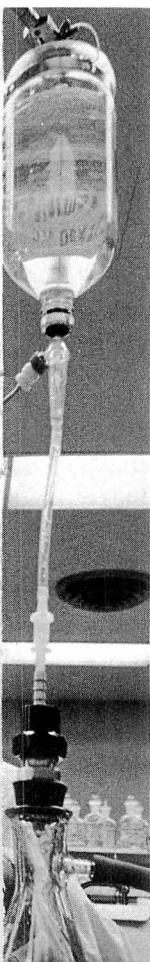
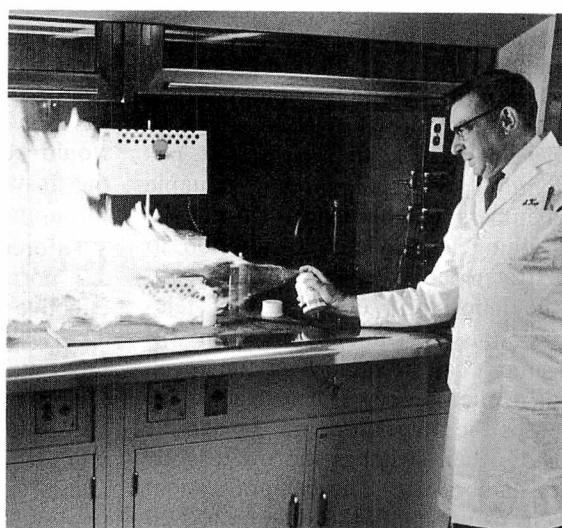
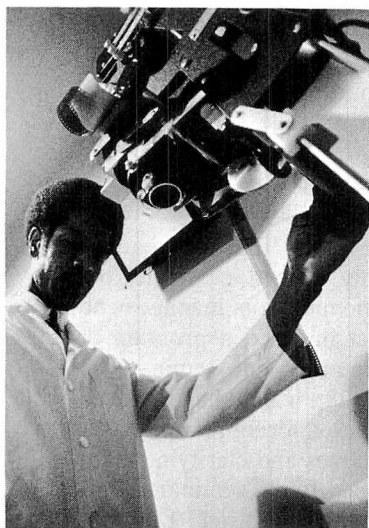
ministrative Assistant; John R. Wessel, Supervisory Chemist; Dale Lawson, Supervisory Inspector; Philip Brodsky, Supervisory Inspector; Joseph Brucciani, Supervisory Chemist; George Masters, Supervisory Inspector; Jewell Gilmore, Office Services Supervisor; Robert C. Mysonhimer, Administrative Officer; and Alan L. Hoeting, Deputy Director. Food and Drug Officer George Meeks (left) talks with Frank E. Fisher, Director, Bureau of Food and Drugs, Indiana State Board of Health, about mutual enforcement problems.

over responsibility for inspection of most of its firms, FDA inspecting the few which ship interstate.

The District has 219 firms that manufacture products covered by the Federal Hazardous Substances Act. These firms are subject to District inspection, as are potentially hazardous products entering from other States or countries. Where harm or injury is caused by a product manufactured in a State outside the District, the case is referred to the involved FDA District. This happened, for example, when a 2-year-old child died in Tennessee, after drinking a rust remover. Cincinnati District investigated, when notified by the local Poison Control Center, and determined that the product label warning should have been more prominent. Checking the store where the original rust remover was purchased, inspectors found other, presumably newer, bottles of the product on which revised labels carried more prominent warnings. Since the manufacturer was in Iowa, the case was referred to the Kansas City District.

In another recent case involving hazardous substances, early this year the District detained a lot of tear gas guns and cartridges imported from Germany through the Indianapolis airport. The immediate containers of the tear gas and cartridges were unlabeled. All other labeling was in German. Since the law requires that appropriate cautionary labeling be printed in English on the immediate container, the outside container, and the accompanying literature, the tear gas guns and cartridges were declared misbranded, and corrective action followed.

Misbranding has been the basis of District enforcement action in another area—phony therapeutic devices. Such devices bilk the consumer by promising “miracle” cures, or “protection” from certain



diseases. A device seized last year purported to be an "anti-fatigue" device for use in automobiles or trucks. This metal box, containing high voltage electronic components, operated off the car's electrical system, and supposedly fended off fatigue, eliminated drowsiness, increased mental and physical efficiency, and prevented fear on the part of the driver. Among other claims, the device was said to prevent cancer, and the manufacturer claimed it had been used in space by at least two U.S. astronauts to keep alert and mentally active.

The 68 therapeutic device industries in the Cincinnati District include a large thermometer importer, which calibrates them before marketing. A large hospital supply firm is also in the District. Inspectional responsibilities here include spot sterility checks of supplies such as surgical dressings and sutures.

The cosmetic industry is well represented. Several large and well-known manufacturers of cosmetic products, such as lotions and shampoos, are in Cincinnati. The largest manufacturer of extrusions—in the hundreds of millions—for cosmetic eyeliners, eye pencils, and lip-liner pencils is in Tennessee. Several years ago, inspection showed certain pencils were made with coal-tar colors not allowed under the FDC Act, since they have not been proved safe for use around the eye area. The pencils were recalled from the market.

THE District's broad scope of activities, including every facet of food and drug work, provides fundamental and varied training for personnel. Many District alumni have moved from Cincinnati District training to more advanced FDA positions. More than 25 percent of the total number of District Directors, Deputy Directors, Chief Chemists, or Chief Inspectors now in FDA's 17 field offices have worked in Cincinnati District in the past.

The District's strong career development program gives all employees an opportunity to move forward. Under a program sponsored

by the Federal Businessmen's Association of Greater Cincinnati, 11 District employees are currently attending college on their own time. In the Inspection Branch, plans are made at the beginning of each fiscal year to have each inspector attend at least one training course. Each of the present inspectors has attended FDA's four-week Basic Drug School at the University of Rhode Island. In the Cincinnati laboratories, 11 persons have taken advanced courses in chemistry and basic theories, and 22 are currently enrolled in a correspondence course at the University of St. Louis in the pharmacology and toxicology series.

One primary District mission is to develop people to their fullest potential and make them valuable members of the team. On-the-job training is provided in addition to extracurricular college training. In the laboratory, closed circuit television is a valuable tool. The TV camera can be fitted over the "eye" of a microscope. The instructor focuses the microscope on the sample slide, then switches the microscope to camera use. The camera's zoom lens can magnify the slide up to 800 times. Thus, one instructor can point out identification techniques for various mold, crystal, and urine samples to many people. Without the camera, lab workers would have to look at the sample and receive their instructions one at a time. The closed circuit TV is also useful in orienting all lab personnel on the use of a new piece of equipment.

Both training and the team concept result in a high quality staff—professional and subprofessional. Laboratory aides, for example, do most media preparation and colony separation for the microbiologists, freeing the latter for more intricate analysis.

Education of industry to promote voluntary compliance is also part of the District's responsibility. Our first workshop, held in Lexington, Kentucky, early in 1967 on sanitation for food warehousemen, was sponsored jointly with a wholesale grocery trade association and the

Kentucky State Health Department. Since then, the District has planned and conducted 21 workshops, ranging from food sanitation to drug GMP's and hazardous substances. Only the four workshops in Kentucky did not involve other Districts. Cincinnati District shares jurisdiction with New Orleans District in Tennessee, and with Detroit District in both Indiana and Ohio.

Beginning with last year's January 11 workshop on medicated feeds, the District initiated a new practice to make the workshops more valuable. We circularized industry well in advance to find out what information it wanted from the seminar, then made sure personnel would be present who would have the answers. Industry's response to this approach has been favorable.

Enforcement of the law requires not only trained personnel but effective guidance from management. The District initiated a program of monthly management seminars in October 1968, which have proved successful in exploring new management techniques and clarifying managerial roles. Each seminar is attended by the District Director, Deputy Director, the Food and Drug Officers, Chief Inspector, Chief Chemist, supervisory inspectors, and supervisory chemists, as well as the Administrative Officer, and other staff members who may be particularly affected by the subject matter.

Seminars have dealt with such subjects as statistics, performance appraisal, self-management, problem solving techniques, motivating and management of people, and communications. The rotating chairman sees that all members of the seminar receive subject materials well ahead of the meeting for study.

Engendering thought not only through the management seminars but also through our daily activities is essential to the team concept that is the operating philosophy of Cincinnati District. We work together to protect the consumer through all the facets that our industries and the law provide.

field reports

ATLANTA DISTRICT FDA action resulted in seizure of 38 tons of decomposed frozen eggs, further adulterated by the presence of *Salmonella* and *Arizona* microorganisms, in late summer at a cold storage warehouse in Columbus, Georgia. The eggs, which were intended for animal food, had been packed and shipped by the Golden Egg Products Co., Inc., Oneonta, Alabama, on various dates earlier in the year and were in reused cans bearing various brand name labels. Some of the cans bore U.S. Department of Agriculture plant inspection shields and others were labeled "unfit for human consumption." None of the product, which consisted of reject eggs, had been suitably denatured, as required by law, to prevent its possible later diversion to human food use.

BALTIMORE DISTRICT Prosecution was concluded recently against J. H. Andrews & Sons, Inc., Baltimore, and a U.S. District Court judge at Baltimore imposed a fine on each of four counts, totaling \$1,200. The local candy warehouse/distributor firm pleaded nolo contendere to FDA's charges that the candy products were rodent- and insect-infested.

Maryland crabmeat workers in the northern areas of Dorchester and Talbot Counties attended a sanitation workshop in late summer cosponsored by FDA and the Maryland State Health Department, at which the significance of bacterial contamination in foods and techniques for sanitary food processing were major topics discussed.

BOSTON DISTRICT Representatives from the District's Injury Study Unit are investigating the death of a Connecticut teenager. The youth reportedly was electrocuted while using a small electric drill, the cause being attributed to faulty wiring of the drill. The accompanying extension cord and the drill have been collected as an official sample and forwarded to FDA headquarters for study.

What was labeled by the District's Shellfish Consultant as a naturally occurring ecological control measure was supported by FDA's analytical findings. During the late spring and early summer, surf clams began washing ashore on Easton Beach, Newport, Rhode Island, in increasing numbers and dying there. By early July so many were being swept ashore that bulldozers in removal operations at the beach could not keep up with the "clam tide." The FDA Ecologist at the time labeled it as one of Nature's "control measures" used to maintain a normal balance of fish life when a surplus occurs. The clams nevertheless presented a potential

health hazard in that several hundred people were harvesting them to eat, unaware that the large number of gulls drawn to the beach for the same purpose could, by their prolonged presence, create a sanitation problem leading to *Salmonella* contamination of the clams. FDA, State public health, and State natural resources officials discussed the problem areas, and samples of the clams were collected by FDA's Shellfish Sanitation Branch and analyzed for bacteria. A public warning was issued by State officials that those clams found on the beach should not be eaten. When FDA released its analyses, the State and local boards of health were notified that water pollution was not a contributing cause of the clam deaths; nevertheless, the clams on the beach were still subject to *Salmonella* contamination and should not be eaten.

BUFFALO DISTRICT Various drugs valued at over \$1,400 have been seized in possession of Jenkins Laboratories, Inc., Auburn, New York. FDA alleged that the drugs, which included "Fever Jr.," "Palmosan," "Sed-A-Cel," and "Hemophos," were misbranded when introduced into, while in, and while held for sale after receipt in interstate commerce because of false and misleading claims in labeling and because the labeling failed to bear adequate directions for use. When shipped by C. M. Bundy, Cincinnati, the drugs were not labeled correctly. After the New York laboratory received and repacked the drugs, they were still in violation.

CHICAGO DISTRICT G. E. McDonald, State/Federal coordinator for the District, was the District's representative at the commissioning of Glenn E. Yard, Superintendent of the Illinois Division of Feeds, Fertilizers and Standards, as an officer of the Food and Drug Administration. The Illinois Director of Agriculture, John W. Lewis, who was commissioned in the spring, presented the commission to Mr. Yard.

CINCINNATI DISTRICT The District has concluded its investigation of interstate shipment of milk contaminated with the pesticide dieldrin. A Kentucky producer had furnished the contaminated milk to a Cincinnati milk marketing association, which sold the milk to a local dairy producing cottage cheese in which the dieldrin was first detected. The subsequent investigation and resolution of this problem ultimately involved the Food and Drug Program of the Kentucky State Health Department, the Ohio State Health Department, the Cincinnati Board of Health, and the Food, Drug, and Dairy Division of the Ohio State Department of Agriculture. The last-named organization has made its lab-

oratory facilities available to the milk marketing association on a fee basis, and samples are now routinely analyzed on a continuing schedule that allows for periodic screening of milk from each producer selling it in the Cincinnati market.

DALLAS DISTRICT The District assisted the Region VII FDA Interstate Carrier Sanitation Consultant in an investigation of a complaint that spoiled food was served on a flight of an airline from Houston to Washington. The airline caterer had received a 500-pound shipment of beef, some of it partially thawed, from a Chicago meat processor. Portions of this beef were served on several flights and many complaints were received that the roast beef had a putrefactive odor and was tough. The District and Houston City Health Department laboratories collected samples for analysis. Results of the analyses, along with tests made by the Compliance and Evaluation staff of the U.S. Department of Agriculture indicated that the spoilage was not uniform throughout the shipment, and that some roasts were in good condition. However, based on recommendations from USDA, the caterer agreed to destroy the remainder of the lot.

DENVER DISTRICT A local manufacturer of dry mix products for bakery use and its president pleaded nolo contendere recently to charges of preparing, packing, and holding doughnut mix under insanitary conditions that allegedly contributed to adulteration of the mix with insects. Rust Sales Co., Denver, was fined \$500 and Maurice A. Rust was placed on two years' probation.

DETROIT DISTRICT After intensive surveillance by FDA, a manufacturer of frozen stuffed baked potatoes is resuming production this fall with completely new equipment and processing procedures. The local firm, which had been inspected several times over a six-month period, was informed after the first inspection that inadequate facilities and equipment and poor manufacturing practices created a potential for microbiological contamination. Subsequent inspections and analyses pinpointed the sources of bacterial contamination and confirmed that the product was affected. After receiving the laboratory results of samples of the product taken on the production line and after FDA had ordered seizure, the firm remodeled facilities, removed unsuitable equipment, increased the frequency of equipment sanitation, hired a qualified bacteriologist, and began an employee sanitation training program. In addition, the firm is withholding 21,000 cases of the potatoes from the market until results from 800 analyses now in progress by the firm show that the product is free from bacterial contamination.

KANSAS CITY DISTRICT The District is sponsoring a four-State interlaboratory quality assurance pro-

gram that started in late July. State laboratories in Kansas, Missouri, Iowa, and Nebraska are participating in an effort to upgrade the overall quality of laboratory performance in their areas of responsibility. The program will provide a mathematical basis for the confidence placed in the assay results of regulatory samples in the area of pesticide residues, medicated feeds, and extraneous materials.

LOS ANGELES DISTRICT A U.S. District Court judge levied a \$300 fine against a Phoenix firm because of excessive residues of toxaphene and parathion on lettuce shipped by the firm in November 1966. FDA-analyzed lettuce samples showed 22 parts per million of toxaphene and 1.8 ppm of parathion. The firm, Western Growers Distributing Co., pleaded nolo contendere to one count, and the court dismissed two other counts alleging excessive pesticides in two other shipments of lettuce made by the firm about the same time.

MINNEAPOLIS DISTRICT The District faces a multitude of problems caused by grain contaminated by armyworms, which are taking a large toll in small grain and corn crops in eastern South Dakota and southwestern Minnesota. Recently harvested oat crops containing a large number of the worms are being rejected by grain elevators because, in addition to adulterating the grain, the worms create a moisture problem that contributes to spoilage. Other grain handlers report the worms in such number that they plug the combines, and moisture from the worms causes dirt to adhere to the oats, making them unsuitable for any use except possibly in animal feeds.

NEW ORLEANS DISTRICT During a period of several months, the District has seized a number of bulk carloads of fishmeal contaminated with *Salmonella*. The meal was seized after it passed through conveying and loading equipment at the Alabama State Docks, in Mobile. The dock authorities now plan to install terminal heat-treating facilities and dock repairs to make quarters tight against bird and rodent entry. These improvements could eliminate the *Salmonella* problem in this area.

NEW YORK DISTRICT District seminars and numerous inspections for and with the Chinese noodle industry failed to produce satisfactory results in attempts to clean up the plants and reduce bacteriological and other contamination of the products. Consequently, charges were brought against Asia Noodle Manufacturing Co., Inc., a New York City firm, the firm's manager, Edward Eng, and the secretary-treasurer, Wing Wong Wu. The prosecution alleged interstate shipment of wonton skins that were adulterated with *E. coli* and other organisms and of fried noodles adulterated with insect parts. The firm and individuals pleaded guilty, so there was no trial.

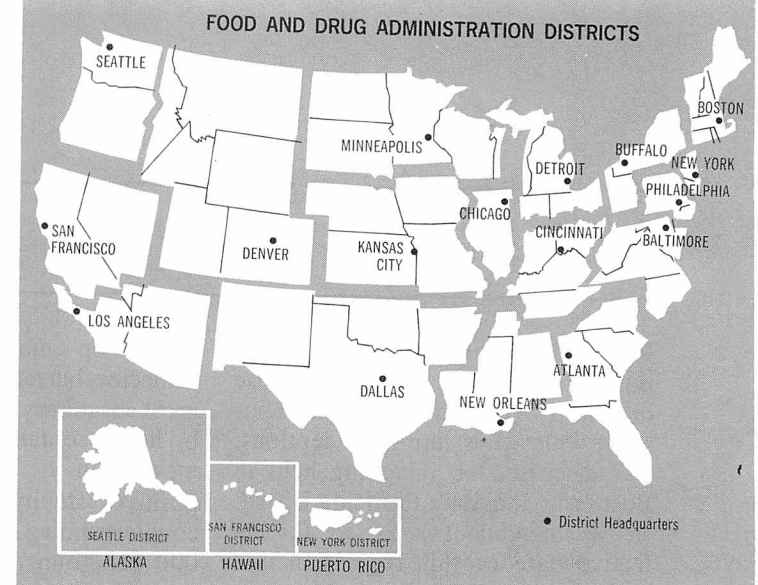
Fines levied against the firm and two officers totaled

\$2,300, and one of the individuals, Mr. Eng, was placed on a year's probation. Part of the probation's condition was that FDA inspect the firm and furnish a report to the probation officer within six months. This action's effect would be to make compliance activities more successful in other segments of the industry. Future inspections in this area will be conducted under the State/Federal Single System Program. Nevertheless, FDA responsibility for goods in interstate commerce will continue.

PHILADELPHIA DISTRICT Twelve of the District's female employees were the subject of a Sunday feature article on Women in Career Government Services, carried recently in the *Philadelphia Evening Bulletin*. The women employees included 11 inspectors and one technician.

SAN FRANCISCO DISTRICT A U.S. marshal recently seized a lot of 25 Res-Q-Aire Emergency Respirator devices valued at approximately \$140. These devices, shipped by Crown Products Co., Cleveland, were declared a danger to health after an independent study and an FDA conclusion indicated the devices were ineffective and dangerous if used for the purpose for which they are intended, and are therefore misbranded. Other seizures of the device are pending.

One of the District's 59 July detentions included 750 cartons containing 40 ampules each of a product called "Shensei's Stamina Choco." The product, imported from Japan, consisted of a plastic ampule-shaped container full of multicolored confectionery pellets the shape of BB shot. A pink plastic straw, running down into the container of pellets, is used for sucking the



confectionery out of the container. The same product under the brand name of "Hippy Sippy" was the subject of a national recall earlier this year monitored by FDA's New York District. The product has been classified as a possible serious health hazard, since sucking the candies through the straw may result in pellets being drawn into the bronchial tract.

SEATTLE DISTRICT The Oregon State Food and Dairy Division requested a discussion with FDA on the requirements of the Fair Packaging and Labeling Act and this resulted in a one-day workshop held by the District at Portland in late July. Representatives included the Oregon agency, the Washington State Department of Agriculture's Food and Dairy Division, Washington and Oregon State Weights and Measures officials, and Federal Trade Commission representatives at Seattle. State officials have requested a second meeting, to be held in about six months.

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
Boston, Massachusetts 02203

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

Pesticide Ban Discussed A proposed amendment to ban the use of "hard" pesticides in Massachusetts, with a few limited exceptions, was discussed at a hearing held in Boston by the State Pesticide Board. If the amendment is passed, the effective date of this regulation will be January 1, 1970. Representatives from government, industry, conservation groups, FDA's Boston District, and the public at large attended the hearing.

City/County Cleans Up Local city and county health officers of northern Cincinnati and suburbs were efficiently handling cleanup and salvage operations following a tornado in August that cut an 8-mile swath through the area. Despite the extensive damage, estimated at up to \$20 million, the death toll was low, although 265 were injured. National Guard troops were called in to patrol the area, and Federal financial assistance was requested.

Compliance Follows Legislation After a lot of crabmeat prepared under insanitary conditions had been ordered destroyed, a violative processing plant in Port Bolivar, Texas, cleaned up in compliance with the requirements of a bill passed May 21 in the State legislature. The bill governs the picking, storing, transporting, and selling of crabmeat. Dudley Johnson, Chief of the Division of Marine Resources, Texas State Department of Health, who is in charge of the licensing of all the crabmeat plants in the State, currently is checking, inspecting, and licensing approximately 17 plants.

Also at this time, FDA's Dallas District, in cooperation with the Agency's Division of Microbiology in Washington, is participating in a nationwide survey of current practices and of the bacteriological picture of this industry. During an inspection of the above processing

plant, Top Quality Seafood Co., an inspector/bacteriologist team found gross insanitary conditions, reflected by heavy contamination of the crabmeat with *E. coli* and coagulase positive staphylococci and plate counts running as high as 16,000,000 per gram in the finished product. Since crabmeat is especially perishable and is often consumed with no further processing, the District called for Mr. Johnson's cooperation. His office immediately contacted the Galveston County Health Department, which embargoed all crabs and crab products on the plant's premises.

The following day two Division of Marine Resources Inspectors from Austin inventoried the products in storage at the plant and ordered the destruction of 1,600 pounds of boiled crabs and 930 pounds of crabmeat. Mr. Johnson reported later that the firm has cleaned up the physical facilities and instituted tight personnel supervision control, and that the bacteriological results of recent samples show the products to be in compliance with the law and the plant to be operating under sanitary conditions.

Corn/Pork Adulteration Idaho authorities have destroyed approximately 600 pounds of corn, and the U.S. Department of Agriculture has directed that approximately 25,000 pounds of pork and pork products be destroyed after corn allegedly fed to the hogs was sampled by FDA's Denver District and was found to contain residues of the pesticides dieldrin and aldrin.

Adulterated Peas Embargoed The Wisconsin State Department of Agriculture has embargoed 1,800 cases of canned peas found to be adulterated with lubricating grease during can handling and seaming and has cited the firm for a hearing. The adulteration was found during a routine FDA Minneapolis District

inspection of the cannery. Since none of the pack had been shipped, Wisconsin State authorities were advised. All further lots found to be adulterated by the State will be embargoed.

Annual Conference Florida's Department of Agriculture held its Sixth Annual Pesticide Residue Conference in July. Conference attendance was by invitation, and Federal and State representatives at the meeting, held in Sanford, included those from Texas, Louisiana, Alabama, Georgia, and Virginia. Each attendee was scheduled to participate by giving an oral presentation to the conference, thus encouraging a valuable exchange of information.

State/Federal Discussion Bernhard Larson, Director of the Pennsylvania Bureau of Foods and Chemistry, recently visited the FDA Philadelphia District to discuss State-Federal relations, programming, and training. The meeting resolved several issues that could be helpful to the State agency in securing additional resources, and that could lead to more meaningful agreements in food inspection areas.

Inspector Wears Two Hats In addition to his regular duties, a Wisconsin State Food Inspector recently donned the "hat" of a peace officer. In a State Court in Two Rivers, the State filed a charge against an individual alleging the operation of a fish-smoking plant under insanitary conditions. The individual pleaded guilty and promised the judge he would discontinue the smoked fish business. He was fined \$50 and costs or 10 days in the county jail. When he chose to serve the time in jail, the judge, not finding a peace officer available, assigned the inspector the added duty of escorting the prisoner to jail and having him booked.

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 31 seizure actions to remove adulterated, misbranded, and unsafe products from the consumer market were reported in August. These included 8 seizures of foods: 7 because of contamination, and 1 because of economic viola-

tions. Other seizures included 8 of drugs (including 1 of veterinary), 12 of medical devices, and 3 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD / Contamination, Spoilage, Insanitary Handling		
Eggs, frozen/Columbus, Ga. 7/25/69	The Golden Egg Products Co./Oneonta, Ala. (P,S)	Partly decomposed.
Monterey cheese/Salt Lake City, Utah 8/4/69	C. W. & Jay Ward, Inc./Richfield, Idaho (M,S)	Prepared, packed, and held under insanitary conditions; insect contaminated.
Peas, yellow and green split/Cincinnati, Ohio 7/14/69	Baltimore & Ohio Warehouse Co./Cincinnati, Ohio (D)	Held under insanitary conditions; insect contaminated.
Pepper, Brazilian black/Freeport, Ill. 7/9/69	Imported from Brazil, Atlantic Textile Corp./New York, N.Y. (S)	Moldy.
Peppers/Cleveland, Ohio 7/8/69	Ba-Tampte Pickle Co./Brooklyn, N.Y. (M,S)	Decomposed.
Sesame seed/Brooklyn, N.Y. 7/15/69	Triborough Transportation Corp./Brooklyn, N.Y. (D)	Insect contaminated.
Walnuts, black/Springfield, Mo. 7/29/69	Continental Nut Co./Chico, Calif. (P,S)	E. coli.
Economic Violation		
Walleye fillets, frozen/Superior, Wis. 7/25/69	Imported from Canada, Twin Ports Grocery/Minneapolis, Minn. (S)	False and misleading label "Walleye Fillets"; Northern Pike was substituted for Walleye Pike.
DRUGS / Human Use		
Aloe Vera Gel/Clovis, N. Mex. 7/22/69	Valley Aloe Vera, Inc./Weslaco, Tex. (M,S)	New drug not approved for safety and efficacy.
Conscorb capsules, Cycleze tablets, wart liquid, Nutro Lecithin/Los Angeles, Calif. 5/6/69	Nysco Labs., Inc./Long Island City, N.Y. (M,S) G & W Labs, Inc./Port Reading, N.J. (M,S) Daylin Medical & Surgical Supply, Inc. (D)	Conscorb capsules: false and misleading claims for effectiveness in maintaining nutritional needs; Cycleze tablets and wart liquid: new drugs not approved for safety and efficacy, false and misleading claims for depression, fatigue, menstrual bloating, and treatment of common warts; Nutro Lecithin: false and misleading claims as a lipotropic agent and for treatment of liver, kidneys, heart, and atherosclerosis.
Dextro-amphetamine sulfate capsules/Inwood, N.Y. 6/25/69	Plymouth Laboratories, Inc./Plymouth, Mich. (M,S)	Below labeled strength.
EZ Hair Remover/Del Ray Beach, Fla. 7/15/69	EZ Beauty Products Co./Houston, Tex. (M,S)	New drug not approved for safety and efficacy.
Meprobamate tablets/Fenton, Mich. 7/18/69	Rabin Winters/El Segundo, Calif. (M,S)	Not produced under GMP conditions; cross-contaminated with quinidine sulfate.
Rena-Spaz tablets/South Bend, Ind. 7/22/69	Standard Pharmacal Corp./Elgin, Ill. (M,S)	Not produced under GMP conditions; below labeled strength.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
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DRUGS / Human Use (cont'd)

Sodium butabarbital/Tiffin, Ohio 7/25/69	Davis-Edwards Pharmacal Corp./New York, N.Y. (M,S)	Not in conformity with NF standard for strength, contains less than 94 percent of labeled sodium butabarbital.
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Veterinary/Medicated Feed

Masti-Biotic 12, Calcium-dextrose/Jacksonville, Fla. 6/3/69	Southeastern Laboratories, Inc./Jacksonville, Fla. (M,S)	Masti-Biotic, below labeled quality, no accurate quantity statement; calcium-dextrose, inadequate directions for use.
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MEDICAL DEVICES

Res-Q-Air Emergency Respirator/ Fairfax, Calif. 8/1/69	Machsa, Inc./Cleveland, Ohio (M)	False and misleading claims for resuscitation, emphysema, bronchial asthma, strokes, heart attacks, any respiratory distress; inadequate directions for use; no warnings against use for infants, children, or persons with dentures or aspirated objects in the mouth and throat; dangerous to health when used in dosage, frequency, and duration suggested in label.
Birmingham, Ala. 7/23/69	"	"
Minneapolis, Minn. 7/17/69	"	"
San Francisco, Calif. 7/9/69	"	"
Laurel Springs, N.J. 7/23/69	"	"
Spartanburg, S.C. 7/15/69	"	"
Macon, Ga. 7/11/69	"	"
Kalamazoo, Mich. 7/16/69	"	"
Little Rock, Ark. 7/17/69	"	"
St. Petersburg, Fla. 7/16/69	"	"
Tampa, Fla. 7/16/69	"	"
New Port Richey, Fla. 7/16/69	The Campro Co./Canton, Ohio (M)	"

HAZARDOUS SUBSTANCES

Bondrite CC-15, CC-60 Contact Cement, Conolite Solvent/Lemont, Ill. 7/25/69	U.B.S. Chemical Co./Cambridge, Mass. (M,S)	Lack consumer protection information required by the Fed. Hazardous Substances Act.
Con-Bond Fast Drying Cement/Denver, Colo. 6/25/69	Columbia Cement Co., Inc./Brooklyn, Mass. (M,S)	"
Contact Cement, Solvent for Contact Cement/Temple, Tex. 5/28/69	Staley Chemical Co./Cambridge, Mass. (M,S)	"

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)

July 25, 1969: False Representation Order issued against Thomas L. Hall, Ltd., Kowloon, Hong Kong. Solicitations of orders and sale through the mails of a Japanese weight reduction system report guaranteed by promoter (U.S. citizen) as enabling subscribers to lose up to 63 pounds without any hunger pains, discomfort, or exercise. (Note: A Fraud Order was issued on September 25, 1968, against identical operation by same promoter at Tokyo, Japan.)	
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notices of judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

- Carrots, fresh**, 2 seizure actions, at Detroit, E. Dist. Mich.
Charged 12-20-68: 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). Consent decree ordered destruction. (1)
- Thyme**, at Brooklyn, E. Dist. N.Y.
Charged 1-13-69: when shipped by Sokol & Co., Chicago, Ill., the article contained an added poisonous and deleterious substance, *Salmonella* micro-organisms; 402(a)(1). Consent decree authorized release to shipper for salvaging. (2)

FOOD / Contamination, Spoilage, Insanitary Handling

- Beans, lima, and flour**, at Brooklyn, E. Dist. N.Y.
Charged 4-20-66: while held by Brooklyn Eastern District Terminal, Brooklyn, N.Y., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (3)
- Bran, cracked wheat, and rice**, at Santa Fe Springs, C. Dist. Calif.
Charged 1-9-69: while held by Safeway Stores Distribution Center, Santa Fe Springs, Calif., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (4)
- Brazil nuts, shelled**, at Oakland, N. Dist. Calif.
Charged 8-14-68: while held for sale, the article contained *E. coli*; 402(a)(3). Default decree ordered destruction. (5)
- 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 Kauders Commodities Co., Inc., New York, N.Y., for salvaging. (6)
- Chili peppers**, 2 seizure actions, at San Pedro, C. Dist. Calif.
Charged 1-22-69 and 2-10-69: while held by Crescent Warehouse Co., Ltd., San Pedro, Calif., the article in one action contained rodent filth and the article in both actions had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to California Commodities Corp., San Francisco, Calif., for salvaging. (7)
- Chorizo sausages, canned**, at Port Newark, Dist. N.J.
Charged 9-12-67: while held for sale, the article contained decomposed sausages; 402(a)(3). Default decree ordered destruction. (8)
- Cocoa beans**, at Brooklyn, E. Dist. N.Y.
Charged 9-11-67: while held by Continental Terminals, Inc., Brooklyn, N.Y., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to A. C. Israel Commodity Co., Inc., New York, N.Y., for reconditioning. (9)
- Cocoa powder**, at Collinsville, S. Dist. Ill.
Charged 12-2-68: while held by L. Bruno & Sons, Inc., Collinsville, Ill., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (10)
- Cracker meal, cornmeal mix, chicken seasoned coating mix, and whey**, at Miami, S. Dist. Fla.
Charged 11-26-68: while held by Robbins Warehousing and Distributing Co., Miami, Fla., the whey contained cockroach filth, and all articles contained insect filth, and all articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Foremost-McKesson, Inc., San Francisco, Calif., of the whey for salvaging. Default decree ordered other articles destroyed. (11)
- Dextrose, cocoa powder, and baking soda**, at Houston, S. Dist. Tex.
Charged 2-13-69: while held by Paul's Bakery, Inc., Houston, Tex., the articles contained rodent filth, were rodent gnawed, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (12)
- Eggs, frozen**, 2 seizure actions, at Landover, Dist. Md.
Charged 12-17-68 and 1-14-69: while held for sale, the article contained decomposed eggs; 402(a)(3). Consent decrees authorized release to Blue Ribbon Products Co., Los Angeles, Calif., for salvaging. (13)
- Egg yolks, frozen**, at Brooklyn, E. Dist. N.Y.
Charged 6-21-67: while held for sale, the article contained decomposed eggs; 402(a)(3). Default decree ordered destruction. (14)
- Fennel seed**, at Chicago, N. Dist. Ill.
Charged 2-7-69: while held for sale, the article contained insect filth; 402(a)(3). Default decree ordered destruction. (15)
- Ginger, whole and ground**, at Detroit, E. Dist. Mich.
Charged 10-4-68: while held for sale, the article contained insect filth; 402(a)(3). Consent decree authorized release to Vico Asmus Products, Inc., Detroit, Mich., for salvaging. (16)
- Mackerel fillets, frozen**, at Jersey City, Dist. N.J.
Charged on or about 1-20-69: when shipped by Kansas Packing Co. of Texas, Inc., Houston, Tex., who was returning the article to a New York

shipper, the article, labeled in part "Fresh Frozen . . . Mackerel Fillets Packed by Haven Sea Foods Ltd. Middle West Pubnico N.S. Product of Canada," contained decomposed fish; 402(a)(3). Default decree ordered destruction. (17)

Malt grain and coffee, green, 2 seizure actions, at Gretna, E. Dist. La.
Charged 3-4-69: while held by Gulf Puerto Rico Lines, Inc., Gretna, La., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decrees authorized release of malt grain to Pan-American Industries Corp., and coffee to Balzac Bros. & Co., Inc., New York, N.Y., for salvaging. (18)

Peanuts, shelled, at Norfolk, E. Dist. Va.
Charged 1-31-69: while held by Old Dominion Peanut Corp., Norfolk, Va., the article contained rodent urine, excreta pellets, and was rodent gnawed and held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (19)

Pecan pieces, at Cincinnati, S. Dist. Ohio.
Charged 1-21-69: when shipped by Natchez Pecan Shelling Corp., Natchez, Miss., the article contained *E. coli*; 402(a)(3). Consent decree authorized release to shipper for salvaging. (20)

Pecan pieces, at Jeannette, W. Dist. Pa.
Charged 3-17-69: when shipped by Sunshine Pecan Co., San Antonio, Tex., the article contained *E. coli* and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (21)

Pecans, shelled, at Waycross, S. Dist. Ga.
Charged 2-5-69: when shipped by Gold Kist Pecans, Canton, Miss., the article contained *E. coli*; 402(a)(3). Consent decree authorized release to Cotton Producers Association of Atlanta, Ga., for salvaging. (22)

Pecans, unshelled, and mixed nuts, unshelled, at Detroit, E. Dist. Mich.
Charged 12-11-68: while held for sale, one lot of pecans contained insect filth, all lots contained moldy nuts and shriveled nuts, and all pecan lots contained rancid nuts and empty shells; 402(a)(3). Default decree ordered destruction. (23)

Perch fillets, breaded, frozen, 0-Perch, at New Orleans, E. Dist. La.
Charged 11-26-68: when shipped by Channel Fish Co., Inc., Boston, Mass., the article contained bacterial filth and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (24)

Potatoes, french fried, frozen, at Baltimore, Dist. Md.
Charged 12-6-68: when shipped from Greeley Ice & Storage Co., Greeley, Colo., the article was unfit for food because it contained ammonia; 402(a)(3). Default decree ordered destruction. (25)

Rice, converted, at Fresno, E. Dist. Calif.
Charged 11-20-68: while held by California Sun Dry Bulgur Co., Fresno, Calif., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (26)

Shrimp, breaded, frozen, at Magnolia, Dist. N.J.
Charged on or about 1-8-69: while held by Deal's Seafood Co., Magnolia, N.J., who prepared and packed the article from ingredients shipped in interstate commerce, the article contained excessive coliforms and excessive coagulase positive staphylococci and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (27)

Shrimp, breaded, frozen, at Salt Lake City, Dist. Utah.
Charged 2-14-69: when shipped by Fishing Processors, Inc., Los Angeles, Calif., the article, labeled in part "Trophy Brand Breaded Shrimp Packed for Safeway Stores, Inc." and "Quick Frozen . . . Breaded Fantail Shrimp Packed for Regent Food Co., Head Office, Oakland, California," contained coagulase positive staphylococci and bacterial filth and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (28)

Tomato paste, canned, at Manati, Dist. P.R.
Charged 10-25-68: while held for sale, the article contained a decomposed substance; 402(a)(3). Default decree ordered destruction. (29)

Tomato sauce, canned, Mountain Pass, at Albuquerque, Dist. N. Mex.
Charged 11-19-68: when shipped by Mountain Pass Canning Co., Anthony, Tex., the article contained decomposed tomato material; 402(a)(3). Default decree ordered destruction. (30)

Walnuts, unshelled, at Dallas, N. Dist. Tex.
Charged 3-13-69: when shipped by Associated Grocers, Kansas City, Mo., the article contained rodent filth; 402(a)(3). Default decree ordered destruction. (31)

Yeast, dried, at Los Angeles, C. Dist. Calif.
Charged 12-13-68: while held by Plus Products, Los Angeles, Calif., the article contained insects and insect parts and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (32)

FOOD / Economic Violations

Crabcakes, breaded, frozen, at San Juan, Dist. P.R.
Charged 11-7-68: when shipped by Henderson's Portion Pak, Coral Gables,

Fla., codfish and shellfish had been substituted wholly or in part for the article, the label statement "Crab Cakes" was false and misleading, since the article contained codfish and shellfish, and the label lacked the common or usual name for each ingredient; 402(b)(2), 403(a), 403(i)(2). Default decree ordered destruction. (33)

Mozzarella cheese, low moisture, at Brooklyn, E. Dist. N.Y.

Charged 12-5-68: when shipped by Richmond Co-Op Association, Inc., Richmond, Va., the article lacked conformity to the standard of identity, since it contained less than 45 percent of milk fat; 403(g)(1). Consent decree authorized release to Falcone Dairy Products, Inc., Brooklyn, N.Y., for salvaging. (34)

Shrimp, peeled, deveined, frozen, at Seattle, W. Dist. Wash.

Charged 8-29-68: when shipped by Neptune Sea Food Co., Inc., Los Angeles, Calif., the label was false and misleading, since the article consisted of peeled, deveined shrimp, whereas the label declared the ingredients to be fish, wheat flour, corn flour, dried eggs, and corn starch; and the article was short weight; 403(a), 403(e)(2). Consent decree authorized release to shipper for salvaging. (35)

Sirup, 3 seizure actions at Kosciusko, N. Dist. Miss., Meridian and Columbia, S. Dist. Miss., and San Augustine, E. Dist. Tex.

Charged on or about 3-14-67, 3-20-67, and 4-10-67: when shipped by Norris Bros. Syrup Co., West Monroe, La., the article labeled in part "New Crop [or "Pure"] Ribbon Cane Syrup . . . Made for A. J. Lyon & Co. Meridian, Miss." [or "Flynt Wholesale Co., Inc., Columbia, Miss." or "V. F. Todd, San Augustine, Texas"] contained a sweetening substance other than cane sirup which had been substituted for cane sirup; the label was false and misleading, since the article contained a sweetening substance other than a cane sirup; and the label lacked the common or usual name of each ingredient; 402(b)(2), 403(a), 403(i)(2). The article was claimed by Fred I. Norris and Bobby Ray Norris, t/a Norris Bros. Syrup Co. The Kosciusko and San Augustine actions were transferred to the Southern District of Mississippi and consolidated with the Meridian and Columbia action. Consent decree authorized release to the claimant for relabeling in the two Mississippi actions. The claimant withdrew its claim and answer in the Texas action, and a default decree ordered that the sirup seized in that action be delivered to charitable/public institution. (36)

VITAMINS / DIETARY FOODS

Dietetic custard mix, gelatin dessert, chocolate and vanilla creme puddings, and french dressing, at Miami, S. Dist. Fla.

Charged 9-19-68: when shipped by Kitchen Craft Foods Corp., Brooklyn, N.Y., the labeling of the dietetic custard contained false and misleading claims for the prevention of heart disease and lacked the common or usual name of each ingredient—403(a), 403(i)(2); the label statement "sugar free" of the chocolate and vanilla puddings was false and misleading, since the articles contained the nutritive sweetener lactose, and the label lacked the common or usual name of each ingredient—403(a), 403(i)(2); the label statement "sugar free" of the french dressing was false and misleading, since the article contained the nutritive sweetener lactose, and the article was an imitation of another food and its labeling failed to bear the word "imitation"—403(a), 403(c); and the labeling of all the articles lacked required information concerning their purported special dietary uses—403(j). Default decree ordered destruction. (37)

Thiamine HCl tablets, and vitamin A and C capsules, at Canton, N. Dist. Ohio.

Charged 10-14-68: when shipped by Formulations, Inc., Milwaukee, Wis., the articles were prepared, packed, and held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (38)

Vitamin B-12 tablets, at Detroit, E. Dist. Mich.

Charged 2-20-69: when shipped by Bates Labs., Inc., Chicago, Ill., the valuable constituent cyanocobalamin had been in part omitted or abstracted, and the labeling was false and misleading, since the article was deficient in cyanocobalamin (approx. 28 percent); 402(b)(1), 403(a). Default decree ordered destruction. (39)

ANIMAL FEEDS

Cottonseed pellets, Chuck Wagon, at Ryan, W. Dist. Okla.

Charged 2-13-69: when shipped by Stamford Cotton Oil Mill, Stamford, Tex., the valuable constituent protein had been in part omitted or abstracted, and the labeling contained a false and misleading statement of protein content; 402(b)(1), 403(a). Default decree authorized donation to public institution for use as animal feed or fertilizer. (40)

Pig feed, medicated, at Shamrock, N. Dist. Tex.

Charged on or about 6-4-68: when shipped by Evergreen Mills, Ada, Okla., the bag label and the tag on the bag bore net weight statements which were inconsistent with each other; and the article contained an antibiotic, was not from a certified batch, and lacked exemption from antibiotic certification, since the bag label directed the article to be fed "free choice" with grain; 502(a), 502(i). Consent decree authorized release to C & H Supply, Shamrock, Tex., for salvaging. (41)

DRUGS / Human Use

Afla-Lite alfalfa tablets, at Forest, S. Dist. Miss.

Charged 2-17-69: while held by Pasco Products Co., Forest, Miss., who packed and labeled the article, the labeling contained false and misleading claims for arthritis, rheumatism, cancer, and other therapy; 502(a). Default decree ordered destruction. (42)

Alovera ointment, at New York, S. Dist. N.Y.

Charged 4-9-68: when shipped by Collins Chemical Corp., North Miami, Fla., the labeling contained false and misleading claims for bed sores,

for burns caused by electricity, chemicals, hot fat, steam, and fire, and for reduction of the formation of scar tissue; 502(a). Default decree ordered destruction. (43)

Amphetamine, barbiturate, and other depressant or stimulant drugs, at Hardeeville, Dist. S.C.

Charged 9-5-67: while held by Thomas B. Carroll, Jr., M.D., Hardeeville, S.C., complete and accurate inventory records and receipt and disposition records of all such drugs were not prepared and kept; 301(q)(4). Consent decree authorized release to dealer for preparation of records. (44)

Amphetamine sulfate tablets, N.F., at Detroit, E. Dist. Mich.

Charged 2-20-69: when shipped by Bates Labs., Inc., Chicago, Ill., the article's strength differed from N.F. standards and the labeling was false and misleading, since the article was deficient in amphetamine sulfate (approx. 22 percent); 501(b), 502(a). Default decree ordered destruction. (45)

Calcium gluconate injection, at Hato Rey, Dist. P.R.

Charged 8-29-68: when shipped by Austin Pharmaceuticals, Inc., Island Park, N.Y., the circumstances of the article's manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice, and the article's quality and purity fell below N.F. standards, since the liquid in some vials contained white clumps (precipitate), and in one, the liquid was discolored; 501(a)(2)(B), 501(b). Default decree ordered destruction. (46)

Contraceptive pills and vaginal foam, and therapeutic vaginal jelly and triple-sulfa cream, at Dayton, S. Dist. Ohio.

Charged 1-15-69: while in transit via McLean Trucking Co., Inc., of Winston-Salem, N.C., the articles were held under insanitary conditions whereby they may have been rendered injurious to health due to accompanying leaking drums of parathion; 501(a)(2)(A). Default decree ordered destruction. (47)

Dewate dextro-amphetamine sulfate injection, in glandular extract, at San Francisco, N. Dist. Calif.

Charged 8-27-68: when shipped by Myers-Carter Labs., Inc., Glendale, Ariz., the article was a new drug without an approved effective New Drug Application; 505(a). Default decree ordered destruction. (48)

Diatol D phenylpropanolamine HCl capsules, at Detroit, E. Dist. Mich.

Charged 8-4-66: while held by Michigan Pharmacal Co., Detroit, Mich., the dealer's label vignette and name for the article were false and misleading, since the article was not adequate and effective for weight control as represented, and the labeling lacked adequate directions for use; 502(a), 502(f)(1). Consent decree authorized destruction. (49)

Ethionamide—INH isoniazid combination tablets, at Brooklyn, E. Dist. N.Y.

Charged 3-29-67: when shipped by Reed-Lane, Inc., South Hackensack, N.J., the article (which was in part repacked in Brooklyn) was a new drug without an effective approved New Drug Application; 505(a). The drug was claimed by Amfre-Grant, Inc., Brooklyn, N.Y. Both the claimant and the Government moved for summary judgment, the former relying on 21 U.S.C. 381(d), which conditionally exempts drugs intended for export from condemnation as "adulterated or misbranded" if they meet the standards of the country of designation. The court granted the Government's motion, and said:

"The [claimant's] argument must yield to the language of the statute. The exemption of Section 381(d) applies to what would otherwise be 'adulterated or misbranded' within the other sections of the Act. On those words hinge the operation of the Act as it applies to foods and drugs that are not 'new drugs.' The 'new drug' provisions, although solidly embedded in the Act, operate separately, and it is not a necessary, nor even a probable inference that the policy considerations that led to the enactment of Section 381(d), would extend to new drug provisions."

Accordingly the export exemption was not applicable to drugs which were new drugs, and such exemption could not be claimed by the manufacturer of a new drug intended for export as justification for lacking an effective approved drug application.

The claimant had also argued that no introduction into commerce of the drug as a new drug appeared on the facts; that, when shipped in interstate commerce, the drug was labeled only by name and content and had no labeling concerning conditions for use, and that the drug was therefore not a drug the composition of which generally recognized among qualified experts as safe and effective for use under the conditions prescribed, and recommended or suggested in its labeling, i.e., the drug was not a new drug.

The court said that it was explicit that the drug seized was all intended for export for use in the treatment of disease and there was no suggestion that any of the drug shipped was ever to be used except as directed on the package and insert handed up during argument. Consequently the court found that the drug was a new drug when shipped from New Jersey to Brooklyn regardless of whether the drug was then accompanied by labeling that made the therapeutic assertions, since the new-drug character of the article depended on its intended use and not on its label.

Thereafter, the claimant moved for reargument. In denying the motion, the court said:

"It is not, at this stage, enough to show that the Claimant did not claim that it was in any case entitled to summary judgment on the ground that the compound was not a 'new drug' for the additional reason that it was 'generally recognized,' and to show that the Government, assuming that the point was not controverted, presented only an assertion and not evidence that the compound was not 'generally recognized.'"

Thereafter, a decree of condemnation ordered the destruction of the article. (50)

Ferrous sulfate tablets, enteric-coated, U.S.P., at Farmingdale, E. Dist. N.Y.

Charged on or about 4-12-68: when shipped by Seaway Pharmacal Corp., Muskegon Heights, Mich., the article's quality fell below U.S.P. standards, since it failed the U.S.P. test for disintegration; 501(b). Default decree ordered destruction. (51)

Meprobamate tablets, N.F., at New York, S. Dist. N.Y.

Charged 4-7-66: when shipped by Riverton Labs., Inc., Newark, N.J., the circumstances of the article's manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice; the article's strength differed from and the quality fell below N.F. standards, and the labeling was false and misleading, since the article lacked meprobamate (approx. 11 percent); and the article was a new drug without an effective approved New Drug Application; 501(a)(2)(B), 501(b), 502(a), 505(a). Default decree ordered destruction. (52) *

Phenobarbital tablets, at Canton, N. Dist. Ohio.

Charged 10-14-68: when shipped by Formulations, Inc., Milwaukee, Wis., the article had been prepared, packed, and held under insanitary conditions; and the circumstances of the article's manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice; 501(a)(2)(A), 501(a)(2)(B). Default decree ordered destruction. (53)

Preparation No. B-2581 elixir, at Warren, W. Dist. Pa.

Charged 10-19-67: while held by Myers Labs, Inc., Warren, Pa., after manufacture from KI, ascorbic acid, sodium salicylate, and cohosh root, shipped in interstate commerce, the labeling contained false and misleading statements for the temporary relief of muscular aches and pains; the labeling lacked adequate directions for use, and such cannot be written, and lacked adequate warnings; 502(a), 502(f)(1), 502(f)(2). Consent decree ordered destruction. (54)

Rid-Odor bismuth subgallate tablets as internal deodorant, at Largo, M. Dist. Fla.

Charged 11-12-68: when shipped by United Surgical Corp., Port Chester, N.Y., the article was a new drug without an effective approved New Drug Application; 505(a). Consent decree ordered destruction. (55)

Thyroid tablets, at Brooklyn, E. Dist. N.Y.

Charged 12-3-68: when shipped by J.W.S. Delavau Co., Inc., Philadelphia, Pa., the quality of the article, labeled in part "Thyroid Tablets U.S.P. Enteric Coated . . . Manufactured for . . . Paramount Pharmacal Co. Brooklyn, N.Y.," fell below U.S.P. standards, since the article failed the U.S.P. disintegration test; 501(b). Default decree ordered destruction. (56)

MEDICAL DEVICES

Endura-Dent dental sprayer, at Detroit, E. Dist. Mich.

Charged 8-16-67: when shipped by Endura Appliance Corp., Freeport, N.Y., the carton label and insert contained false and misleading claims for providing a new way to dental health, for tooth decay and gum problems, and for bad breath, gum massage, and other oral therapy; 502(a). Upon consent of the Government and motion of shipper, the case was transferred to the S. Dist. of New York. Consent decree authorized release to shipper for relabeling. (57)

Posture Massage electric vibrator, at Dallas, N. Dist. Tex.

Charged 1-27-69: when shipped by Marketing Research Associates, Inc., Columbia, S.C., the article's accompanying labeling contained false and misleading claims for relief of tension, neck problems, arthritis, heart trouble, diabetes, ulcers, and numbness, and the labeling failed to bear adequate directions for use and adequate warnings; 502(a), 502(f)(1), 502(f)(2). Consent decree ordered destruction and enjoined the claimant, Marketing Research of the Southwest, Inc., Dallas, Tex., against selling, advertising, or introducing into interstate commerce any of the devices or accompanying labeling. (58)

HAZARDOUS SUBSTANCES

Bellini oil-painting kit, at Denver, Dist. Colo.

Charged 12-6-68: when shipped by Bocour Artists Colors, Inc., New York, N.Y., the article was a hazardous substance [a bottle of turpentine was among the artist's supplies] that presented a special hazard because of its turpentine content and it lacked a number of the required conspicuous statements on the turpentine bottle label, on the outside kit container, and in the accompanying instructional literature; 2(n)(1)(2), 2(p)(1)(E & J), 3(b). Consent decree authorized release to Michael's Artists & Engineering Supplies, Inc., Denver, Colo., for relabeling. (59)

Combs and barrettes, at New York, S. Dist. N.Y.

Charged 9-13-68: when shipped by Speert, Inc., Brugg, Switzerland, the article was a flammable substance presenting a special hazard and it lacked required conspicuous label statements; 2(p)(1)(A, D, E, I, J). Default decree ordered destruction. (60)

Cracker Ball ball-type explosive caps, at Houston, S. Dist. Tex.

Charged 6-25-65: when shipped by unknown shippers in Japan, the article was an extremely flammable solid substance that generated pressure through explosion when subjected to friction or percussion, and its containers lacked required conspicuous label statements; 2(p)(1)(A, C, E, F, I, J). The article was claimed by Alpha Enterprises, Inc., Houston, Tex., who denied that the article was either a hazardous substance or was in a misbranded package. Written interrogatories were served by both the Government and the claimant. Thereafter, at a trial before the court, the Government contended that the Cracker Balls were dangerous because of a claimed tendency on the part of children to be injured by them, resulting from the Cracker Ball's resemblance to candy or a breakfast cereal, and the tendency of a young child to put the Cracker Ball in his mouth, to bite upon it, and to cause it to explode. The claimant contended that a total of 24 nonserious injuries when almost three billion Cracker Balls had been imported was an exceedingly low incident of harm.

The court said:

"I find that the cracker ball is a hazardous substance within the terms of (f)(1)(A) of Section 1261 in that it is flammable and generates pressure through decomposition, heat or other means. While the question is not

at all free from doubt, I find that the cracker ball may cause a substantial personal injury as a proximate result of any customary or reasonably foreseeable handling or use. I find further that the cracker balls are 'in a container intended or suitable for household use.' Thus—to avoid being in a 'misbranded package of a hazardous substance'—a 'label' (as defined in § 1261(n) of Title 15 U.S.C.A.) must be affixed. The label must meet the requirements of § 1261(p)(1); and to be a 'label' in the statutory sense, the printed matter must be affixed to the 'immediate container.' The immediate container is the plastic envelope. While marked in compliance with ICC regulations, it is not marked in full compliance with 1261(p)(1). Hence the cracker balls in suit are subject to condemnation." (61)

Cracker Ball ball-type explosive caps, 14 seizure actions, at Vineland, Dist. N.J. (2 seizure actions); Elkton, Dist. Md.; Kansas City, W. Dist. Mo. (3 seizure actions); Mamaroneck, S. Dist. N.Y.; St. Louis, E. Dist. Mo.; Tulsa, N. Dist. Okla.; Nashville and La Vergne, M. Dist. Tenn.; Fort Smith, W. Dist. Ark.; Mitchell, Dist. S. Dak.; and Dillon, E. Dist. S.C.

Charged between 6-18-65 and 7-8-65: when shipped by Yaguchi Trading Co., Ltd., Yokohama, Japan; S. Mantsuna & Co., Ltd., Tokyo and Yokohama, Japan; Sanyu Co., Ltd., Shizuoka, Japan; Maison Albert David, Taipei, Taiwan, Republic of China; Hosoya Fireworks Co., Yokohama, Japan; and unknown shippers, the articles were extremely flammable solid substances that generated pressure through explosion when subjected to friction or to percussion and their containers lacked required conspicuous label statements; 2(p)(1)(A, C, E, F, I, J). Consent decrees in the Mamaroneck, N.Y., and Dillon, S.C., actions ordered destruction. Default decrees in the Kansas City, Mo., Nashville, Tenn., and Mitchell, S. Dak., actions ordered destruction. Consent decrees in the Vineland, N.J., Elkton, Md., St. Louis, Mo., Tulsa, Okla., La Vergne, Tenn., and Fort Smith, Ark., actions authorized release to New Jersey Fireworks Manufacturing Co., Inc., Vineland, N.J. (articles in the Vineland and Elkton actions), and to Atomic Fireworks, Inc., St. Louis, Mo., O.K. Fireworks Corp., Tulsa, Okla., Perks Fireworks Co., La Vergne, Tenn., Jack Warner, t/a Jack Warner Fireworks, Fort Smith, Ark., for salvaging or export to country of origin. In addition, in the cases of the claimants, New Jersey Fireworks Manufacturing Co., Inc., Atomic Fireworks, Inc., of Missouri, O.K. Fireworks Corp., and Perks Fireworks Co., it was ordered that such claimants be enjoined from introducing into interstate commerce any hazardous substance called by the name "Cracker Balls," or "Ball-type caps," or by any other name, which are irregularly shaped spheres of paper (or similar substances) which contain an explosive material that generates pressure and explodes when subjected to percussion or friction and which is extremely flammable, unless the immediate container is conspicuously labeled with certain specified consumer protection information. (62)

Potassium nitrate, dextrine, and charcoal powder and granules, at Columbus, W. Dist. Wis.

Charged 7-31-68: while held by Sheard Science Supplies, Inc., Columbus, Wis., who repacked the articles and had on hand booklets entitled "Mail Order Catalog No. 662 Sheard Science Supplies, Inc." and "Enjoyment From Pyrotechnics," the articles were banned hazardous substances, since they were toys which were toxic, flammable, or generated pressure through explosion when ignited; 2(a)(1)(A). Default decree ordered destruction. (63)

Tear gas shells, North Hollywood, C. Dist. Calif.

Charged 12-2-68: while held by G-G 31, Inc., North Hollywood, Calif., the article was an irritant substance and generated pressure through explosion when subjected to percussion, and its label and accompanying dealer literature lacked a number of the required conspicuous label statements; 2(p)(1)(B, D, E, F, G, I, J), 2(n). Consent decree authorized release to the dealer for relabeling. (64)

X-33 water repellent, at Roberts, W. Dist. Wis.

Charged 3-29-65: when shipped by Wilmington Chemical Corp., Chicago, Ill., the article was an extremely flammable substance, and its containers lacked required conspicuous label statements; 2(p)(1)(E, F, I). Default decree ordered destruction. (65)

NOTICES OF JUDGMENT on Criminal Actions

FOOD

Ritchie Grocer Co., t/a Ardis-Ritchie Grocer Co., Shreveport, W. Dist. La.

Charged 1-9-69: beans were held in a building accessible to rodents and insects and were contaminated with filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (66)

DRUGS

Ciba Pharmaceutical Co., Division of Ciba Corp., Summit, Dist. N.J.

Charged 9-23-66: when shipped, the labeling of Esidrix-K tablets and Esidrix tablets lacked adequate directions for use and such drugs were not exempt therefrom, since they were prescription drugs which were new drugs and their labeling was not substantially the same as the labeling authorized by the drugs' approved New Drug Applications; and the advertisements for the drugs in medical journals did not include a true statement of information in brief summary relating to the side effects, contraindications, and effectiveness required by regulations; 502(f)(1), 502(n). Defendant's motion to dismiss on ground a hearing was not given under Section 305 was denied. Nolo contendere plea; fine. (67)

O. M. Franklin Serum Co., Amarillo, N. Dist. Tex.

Charged 9-18-68: when shipped, dextrose solution for veterinary use contained insect fragments; 501(a)(1). Nolo contendere plea; fine. (68)

Antiocho Orlando Gonzales, medical technician, Laredo, W. Dist. Tex.

Charged on or about 9-1-65: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; sentencing suspended. (69)

Harvey E. Howard, t/a Howard Products Co., Los Angeles, C. Dist. Calif.

Charged 12-28-67: when shipped, Howard's Chewable CPL 400 enzyme di-

gestive tablets, accompanied by brochure entitled "Howard Products Bulletin," and by reprint entitled "Enzymes—Medicine's Bright Hope" was a new drug without an effective approved New Drug Application; 505(a). Nolo contendere plea; probation. (70)

Sidney Rowlette, Indiana salesman, at Denver, Dist. Colo.

Charged 4-20-67: green caffeine tablets were held, offered for sale, and delivered in unlabeled bottles as Syndrox tablets; 502(i)(3), 502(b)(1), 502(e)(1)(A)(i). Not guilty plea. After trial, the court found the defendant guilty; imprisonment.

On appeal Rowlette contended that he was entrapped into committing the offense. The Court of Appeals affirmed the defendant's conviction saying:

"Rowlette had sold amphetamines to Brown [FDA agent] on a prior occasion. He had been convicted for selling amphetamines. He testified that he willingly came to Denver. The evidence shows the government merely afforded Rowlette an opportunity to commit an offense for which he had the criminal propensity. . . . This law does not forbid . . . This is not a case where the government agent offered substantial financial reward, feigned severe illness, or appealed to the sympathies of the appellant. Brown merely requested that the drugs be sold to him. . . . Rowlette willingly took advantage of the opportunity, but the law 'will not protect the guilty from the consequences of subjectively mistaking apparent for actual opportunity to safely commit crime.' (Citations omitted). . . .

"It is significant to note that Rowlette told Brown during the telephone conversations, as well as at the airport, that he was supplying various amphetamines; in fact, he supplied caffeine. Amphetamines had been requested. Thus, Rowlette did not react to the inducement made but unilaterally availed himself of a set of circumstances to commit the crime charged." 32 F.2d 437 (1968). (71)

NOTICES OF JUDGMENT on Injunction Actions

Consumer Electronics, Inc., Arthur J. Sandone, president, Buford L. Coan, vice president, Joe S. Falco, secretary-treasurer, Dallas, N. Dist. Tex. Charged 8-22-67 in a complaint for injunction: that the defendants engaged in designing, manufacturing, promoting, selling, and delivering for introduction into interstate commerce, a device designated as "Figure Control," "Electro-Tone," "Electro-Tone Figure Control," "Figure Control Electrosizer," and "Electrosizer" which device provided electrical current intended to cause intermittent contraction of the voluntary skeletal muscles beneath the skin area to which the pads of the device were applied; that, in promoting the device, the defendants utilized instruction leaflets, warranty leaflets, and newspaper reprints that contained false and misleading claims for figure control, weight reduction, girth reduction, and significant increase in calorie consumption, and false and misleading claims that the device provided the user with a convenient, comfortable, and relaxing form of exercise to achieve such results; that the labeling was also misleading, since it suggested and created the impression that the device was suitable and safe for use without medical supervision on specified areas of the body including shoulders, chest, back, face, waist, buttocks, and the extremities, and the labeling failed to reveal the material fact that certain uses of the device in such areas might result in aggravation of specified conditions or other injury (including conditions such as appendicitis, cancer, hemophilia, arteriosclerosis, varicosities, pregnancy, angina pectoris, abscesses, cystitis, tenosynovitis, and various disorders of the abdomen, blood vessels, heart, circulation, skin, kidney, muscles, nerves, and in individuals taking anticoagulants, cortisone, and related drugs); 502(a).

The labeling lacked adequate directions for (lay) use, and such directions cannot be written because the layman cannot reliably determine when use of the device is contraindicated and may be harmful and also lacked adequate warning against unsafe use; information concerning uses and against unsafe use was not prominently placed in the labeling with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; and the article was dangerous to health when used as directed in the labeling—502(f)(1), 502(f)(2), 502(c), 502(j); and the defendants violated the law by causing the shipping in interstate commerce and holding for sale after such shipment of the devices as labeled as above. A consent decree of permanent injunction enjoined the violative acts complained of and ordered that all the defendants' stocks of the device be brought into compliance or destroyed. (72)

Irene A. Rice, Minneapolis, Dist. Minn.

Charged 9-26-66 in complaint for injunction: that the defendant engaged in selling and distributing the "Figurecare" electronic muscle stimulator, and that, while the device was held for sale after shipment in interstate commerce, the defendant made oral representations holding the device out as a prevention and treatment for the conditions specified below; and the labeling of the device lacked adequate directions for its intended use for arthritis, heart conditions, slipped disc, weight loss, increased energy, strengthen muscles, retention of youthful looks, and other therapy; 502(f)(1). A temporary restraining order enjoined the defendant from the violations complained of. Subsequently, in a consent decree of permanent injunction, the defendant was permanently enjoined with respect to the "Figurecare" device, any similar device, or any device or drug intended for use in the cure, mitigation, treatment, or prevention of disease in man while such article is held for sale after shipment in interstate commerce, from making any oral or written representations for the use of such article for the cure, mitigation, treatment, or prevention of any disease, conditions, or infection of any kind which is not stated in the labeling of such article. (73)

NOTICES OF JUDGMENT on Miscellaneous Actions

Cracker Ball ball-type explosive caps, judicial review suit, Houston, S. Dist. Tex. Charged 4-3-67: by Alpha Enterprises, Inc., in a suit for judicial re-

view of FDA refusal of import admission of the article and for injunction against interference with importation of the article, against H.E.W. Secretary John W. Gardner: that the defendant had denied the plaintiff's administrative appeal requesting H.E.W. to lift the import detention placed on an imported shipment of Cracker Balls; that, after trial of a seizure action involving Cracker Balls, the plaintiff had been authorized to label the Cracker Balls seized in that action and to sell them in interstate commerce in plastic bags bearing approved labels; that, in reliance upon such approval, plaintiff ordered 100 additional cases of Cracker Balls from Japan prior to the amendment of the Federal Hazardous Substances Labeling Act on 11-3-66; that such amendment gave the Secretary power to classify by regulation a "banned hazardous substance"; that, as of that time, "Cracker Balls" had not been classified as a "banned hazardous substance" by regulation; that such amendment was unconstitutional because of vagueness, that the defendant's acts with respect to plaintiff's article were arbitrary and capricious; and that, insofar as this shipment of Cracker Balls was concerned, the statutory amendment was *ex post facto* in nature and should not apply to this shipment.

The defendant moved to dismiss the suit. In dismissing the suit, the court said:

"... The cracker ball classification as a banned hazardous substance could only be saved by [proviso] (ii) [of 15 U.S.C. 1261 (q)(1)] if it be considered a 'common fireworks' and if, by regulation, the Secretary had determined that it could be adequately labeled to protect the purchasers and users thereof. Probably the cracker ball should not be considered as 'common fireworks.' It is not included in the exemptions referred to parenthetically in the statute, and from the congressional hearings, it would appear to be the intent to exclude cracker balls from the definition of 'common fireworks.' Again, however, there is no regulation promulgated by the Secretary which would exclude this article from the statutory definition. The Court cannot, in my judgment, by injunction require that the Secretary promulgate such a regulation. . . .

"Thus if the matter be not subject to judicial review, the Court is without jurisdiction. If it be considered subject to judicial review, the Secretary has done no more than to apply the proper statutory definition to the article in question and his action was proper." (74)

X-33 water repellent, declaratory judgment suit, Chicago, N. Dist. Ill.

Charged 10-21-63, by Wilmington Chemical Corp., in suit for declaratory judgment against H.E.W. Secretary Anthony J. Celebrezze: that the defendant threatened to seize the product manufactured and distributed by the plaintiff under a ruling by the defendant which was retroactive; that, in April of 1961, the plaintiff began manufacturing and distributing X-33; that the first 125 shipments were inadvertently not labeled in compliance with the Federal Hazardous Substances Labeling Act; that after the spring of 1961, plaintiff caused all further cans of X-33 to be labeled with the firm's current label which FDA examined in 1962 and found to be in compliance with the law; that, in the spring and summer of 1963, there were several injuries and two deaths that were allegedly caused through the use of the plaintiff's products; and that, in August of 1963, FDA advised that the current label was not in compliance with the law; and that, in September of 1963, FDA advised that unless all labels were changed, including shipments to retail dealers (amounting to 2,400 sales), seizure of all the products would be begun immediately.

The defendant moved to dismiss the action, and moved for summary judgment. The court decided to proceed directly to the propriety of the suit to decide the issues raised, irrespective of the very cogent technical objections to the maintenance of the suit against the named defendant. In dismissing the suit, the court said:

"The Court concludes that the motion to dismiss should be granted on the ground that its discretion should be exercised adversely to assuming jurisdiction to pass upon the alleged arbitrariness of defendant's action in respect to the offending labels.

"While it is understandable that plaintiff complains of defendant's retroactive change of position in respect to plaintiff's label, to its detriment, the Court believes that if the label theretofore permitted is insufficient to warn future users, it is just as inadequate and dangerous to warn users of cans previously marketed.


"If the prime purpose of the Statute is to protect the public, that protection is the paramount consideration, and it is defendant's duty to do a complete job of protection and not trust to luck that purchasers of the cans theretofore sold to dealers will be aware enough to understand the previously approved but inadequately specific label.

"The Court is also loath to substitute its judgment for the expertise of the administrative official charged with the duty of passing upon the subject. It has been held that the Declaratory Judgment Act does not confer jurisdiction to review administrative action, not final, so as to be reviewable under the Administrative Procedure Act. *Continental Bank and Trust Company*, 303 F. 2d 214." 229 F. Supp. 168. (75)

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.

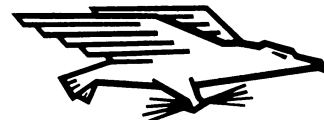
Notices of Judgment are prepared by Food, Drug, and Environmental Health Division, Office of the General Counsel, DHEW. Published by direction of the Secretary of Health, Education, and Welfare.

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



BE A COUNTRY'S DOCTOR

Not alone of course. We, the Food and Drug Administration, will be your partner in practice, and we have the largest practice in the United States. It's our job to see that the foods, drugs, cosmetics, therapeutic devices, and certain household products are safe for all American consumers. If you qualify as a Medical Officer in our Bureau of Medicine (through Board certification or eligibility), you would make medical decisions as to safety and efficacy of marketed and new drugs; give medical evidence and opinions in legal actions, coordinate medical research contracts and special studies, and review and evaluate data on adverse drug reactions. It's a big job, and a big opportunity. If you would like more information on Medical Officer positions, submit a curriculum vitae to: Deputy Director, Bureau of Medicine, P.O. Box 2000, Eads Station, Arlington, Va. 22202.



Announcements

REPRINTS AVAILABLE Single copies of reprints of two proposed regulations covering drugs, published in the *Federal Register* on August 22, 1969, are available from the Division of Industry Services, Bureau of Compliance, Food and Drug Administration, 200 C St., S.W., Washington, D.C. 20204. They are (1) Drugs; Current Good Manufacturing Practice in Manufacture, Processing, Packing, or Holding, Part 133 CFR21, and (2) Peer Group Committee Review of Clinical Investigations of New Drugs in Human Beings; Part 130.3 CFR21, New Drugs for Investigational Use in Human Beings.

FDLI-FDA ANNUAL CONFERENCE The 13th Annual Joint Educational Conference of the Food and Drug Law Institute and the Food and Drug Administration will be held December 11-12, 1969, at the Marriott Twin Bridges Motor Hotel, Washington, D.C.

The 1½-day conference will feature outstanding Government and industry speakers and individual workshop sessions on subjects of major interest to the food and drug industries.

PROCEEDINGS OF DRUG QUALITY ASSURANCE SEMINARS AVAILABLE The proceedings of each of four Regional Seminars on Quality Assurance in Drug Manufacturing, sponsored by leading universities in cooperation with FDA and the Pharmaceutical Manufacturers Association earlier this year, have been published and are now available from the respective universities.

The Seminars were conducted by faculties of outstanding experts drawn from the pharmaceutical industry, Government, and the academic field. The Seminars dealt in part with the development and evaluation of industry self-inspection programs. There also were extensive workshop discussions on the scope of current good manufacturing practices in the drug industry and FDA's Good Manufacturing Practice regulations. Principles of supervision, training, and employee motivation also were given extensive treatment by eminent industry training directors and industrial psychologists.

The first Seminar, sponsored by the University of Southern California, was held in Los Angeles February 9-12. Another, sponsored by the University of Illinois, was held in Chicago February 23-25. The additional two, sponsored by Rutgers, the State University of New Jersey, were held in New Brunswick, N.J., March 10-11 and 13-14.

The Proceedings, in paperback book form, contain not only the full texts of all faculty lectures but also summaries of group discussions and workshop sessions.

Copies of the Proceedings of the several Seminars are available from the sponsoring universities as follows:

Proceedings of the Far West Regional Seminar on Quality Assurance in Drug Manufacturing. For price information and copies write to Edward S. Brady, Associate Dean, School of Pharmacy, University of Southern California, University Park, Los Angeles, Calif. 90007.

Proceedings of the Midwest Regional Seminar on Quality Assurance in Drug Manufacturing. Paperback, 161 pages. \$3 per copy. Write to Herman Slayman, Ed.D., Division University Extension, University of Illinois, 715 South Wood, Chicago, Ill. 60612.

Proceedings of the Eastern Regional Seminars on Quality Assurance in Drug Manufacturing. (1 volume.) For price information and copies write to Joseph Czapp, Conference Department, Rutgers, The State University, Clifton Avenue, New Brunswick, N.J. 08903.

For historical perspective on the Government-industry-university educational program which led these Regional Seminars and on pending proposed revisions of FDA's Current Good Manufacturing Practice regulations for drugs, interested persons may wish to consult the Proceedings of the Seminar on Control Procedures in Drug Production, held July 17-22, 1966, at Hershey, Pa., under the sponsorship of the University of Wisconsin. Copies are available at \$2 each (quality discount of 25 percent for 10 or more copies) from: Extension Book Store, University Extension, The University of Wisconsin, 432 Lake Street, Madison, Wis. 53706.