CONSUMER PROTECTION
An Environmental Problem

WHAT'S HAPPENING AT BLUE EARTH?

Food Standards Committee
Venerable but Vibrant

BETTER PROTECTION, WIDER RESPONSIBILITIES
"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

To the veterans of the Food and Drug Administration, pollution is an old and wily adversary. They have met him in battle uncounted times where his name was filth, contamination, insanitation, toxicity, impurity, and others yet more unpleasant. A generation or more ago, and increasingly in modern times, they have closed with him under some of his other names—organic pesticide residue, household hazard, mispotency—and his fellow blackguards, misbranding, economic deception, therapeutic inefficacy.

These encounters have been on the battleground of food, drugs, cosmetics, and therapeutic devices, and the enemy has been turned back, but remains unvanquished. He will always be there at the edge of the wood, and the price of keeping him at safe distance will be eternal vigilance, as the orators say. The worldly flux in which we live, stirred by the chemical-electronic-technological revolution and the expanding population it makes possible, has made this vigilance inevitable. It has also signaled the approach of a bigger monster that threatens to cancel out much of human progress and in many ways leave man again a naked, unprotected babe. Pollution is his name, deadly pollution of the entire terrestrial and atmospheric environment; and he must be outwitted and outfought, not outrun.

FDA is joined with two other Federal agencies of the Consumer Protection and Environmental Health Service (see pages 4 and 13), a David that the citizenry will now send forth with whatever weapons it can muster against this hulking, terrifying Goliath. The FDA will be there in the thick of it, doing what it knows how to do, and looking for ways to do it better.
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PHOTOGRAPHY: Burk Uzzle—Magnum, inside front cover; NAPCA, top 4 and 6; Ted Jones—Stuart Finley Films, bottom 4 and 8; Chamber of Commerce, Newark, N.J., 5; New York City Department of Health, bottom 6; ECA, 7; FDA, remaining photos.

FDA PAPERS, the official magazine of the Food and Drug Administration, is published monthly, except for combined July-August and December-January issues. Subscriptions may be ordered from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402, at $6.00 a year ($1.50 additional for foreign mailing).

Address for editorial matters: FDA PAPERS, Food and Drug Administration, 200 C St., S.W., Washington, D. C. 20204.

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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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What's Happening at Blue Earth?  Interim reports by the principals on the Green Giant Co. self-certification pilot program.

Better Protection, Wider Responsibilities  FDA gets an expanded consumer protection mandate under a reorganization and new responsibilities.

Analytical Entomology  Assuring that food is free of filth from insects means knowing insects’ anatomy, habits, and how to isolate them.

Food Standards Committee: Venerable but Still Vibrant  Input and counsel from the States help FDA in setting better food standards.

Field Reports  State Actions  Seizures and Post Office Cases  Notices of Judgment
Consumer Protection: An Environmental Problem

by Charles C. Johnson, Jr.

The Department of Health, Education, and Welfare last July established the Consumer Protection and Environmental Health Service to make possible a more effective and systematic approach to a major problem of our time—the problem of maintaining an environment conducive to human health and well-being in a world undergoing profound and accelerating change.

We stand at a point in history when our capacity to alter the environment has reached awesome proportions, but we have not yet fully learned to use this capacity for the benefit, rather than the harm, of our own and future generations. We have overwhelmed many of Nature's processes for environmental stability and have misused, without knowing it, biological processes upon which the preservation of life depends. Furthermore, the pressures of our industrial culture produce threats to social and psychological welfare, many of which are essentially environmental problems and raise serious questions of man's ability to successfully adapt.

In the "closed system" which is our planet and its atmosphere, cer-
tain environmental changes already affect our lives adversely and pose an even more serious potential for the future. Nuclear testing is only the most dramatic example of the radiation hazards we are confronted with; large-scale application of nuclear energy, laser and microwave technology, electronic products in the home, and medical application of radiation are creating sources of radiation throughout the environment. Ingestion of chemicals from pesticides, drugs, food additives, and polluted air and water present known hazards to human health and pose sinister genetic threats which we are barely beginning to understand. Discharge of chemical, bacteriological, and radiological wastes into the earth's water supply raises the specter of contamination which could defy purification processes.

Every year, pollution gets worse, rather than better; problems of unsafe food, drugs, water, and a variety of consumer products become increasingly complex; the quality of American life, particularly urban life, is deteriorating in a morass of environmental problems, many of which are related to social and cultural unrest.

In spite of tremendous advances in medicine, science, engineering, and technology, and in spite of affluence and high standards of living, we seem in danger of creating a physical, social, and cultural environment in which the quality of life is diminished rather than enhanced. Increasingly, uneasiness about these matters has created a strong demand for more sensible use of the environment. Universities and other private organizations have turned their attention to the problem. State and local governments have established programs to cope with various aspects of it. Industry is showing increasing awareness of its responsibilities. Throughout the Federal structure, agencies charged with such matters as transportation, natural resources, city planning, and agriculture, are thinking in terms of environmental impact and are striving to reconcile their actions with some elusive principle of ecological wisdom. Private groups long watchful over particular aspects of man's environment—advocates of conservation, consumerism, health betterment, and beautification—are now recognizing that their areas of concern are part of a larger, more
complex problem which will not yield to piecemeal solutions. In recent years, the Department of HEW became increasingly aware that the rigid categorical approach which had characterized its environmental and consumer protection efforts in the past was no longer adequate to deal with the multitude of subtle, complex stresses which simultaneously impinge on man today.

The Consumer Protection and Environmental Health Service was established, therefore, to provide in the Department a single agency which could take into account the relationship of all environmental problems, coordinate the several programs of the Department established to deal with them, and provide leadership to a national effort to maintain optimum environmental conditions. Its most important concern is to assure that the health and welfare of man will become, and remain, the primary focus of these efforts.

The structure of the CPEHS is derived from a plan first formulated within the Food and Drug Administration. It brings together, in a relationship in which they can be mutually supportive, the principal activities of the Department that deal with consumer and environmental problems. It makes possible a coherent research effort which recognizes the combined, and often synergistic, effects of various environmental stresses and provides the means for developing broad criteria to protect man against such multiple threats. It provides the mechanism by which we can weigh the strong, and often conflicting, demands of divergent interest groups, establish sound priorities for action, and give new impetus and meaning to all our efforts.

It must be remembered that, just as all men breathe the air and drink the water, so all men are consumers of food, drugs, and manufactured products. In fact, the products we consume or use form an important part of our total milieu and must be considered, along with other influences in our surroundings, in any meaningful assessment of human environmental stress.

The chemical barrage to which modern man is subjected, for example, may reach him through fertilizer or pesticide residues—on the food he eats or in the water he drinks; it may consist in part of prescribed therapeutic drugs, drug residues in animal foods—or an increasing burden of drug and hormonal wastes which find their way into his drinking water; it is released into the air he breathes from industrial plants, burning dumps, and the auto in which he rides; it may reach him from the fumes and dusts he is exposed to at work. Harmful radiation may be present in various parts of his environment—in the air; in food, milk, or water; in electronic products used in the home; in diagnostic and therapeutic medical processes; in the mine or factory. Bacteriological contamination may invade his food in the manufacturing process—or it may be generated by a lack of sanitation in the store, restaurant, or home.

The living organism cares little what is the source of the insult it receives. It does not separate and classify by origin or route of entry to suit the convenience of the administrator or the researcher. It receives a total impact, which we who would protect human health and well-being must seek to understand and guard against. We know little of the interaction within the human body of the various environmental stresses. We do know that the intended effects of certain medications can be vitiated, intensified, or transformed by other environmental impacts. We know that radiation, smoking, certain pollutants in the air, and various chemicals encountered in the occupational setting can all play a part in the development of cancer. We need to know much more about these and other bodily responses to single and multiple influences. Readers of FDA Papers are, of course, familiar with the Food and Drug Administration's traditional programs. Certain new functions have been transferred to FDA to provide a more integrated program approach—shellfish san-
tation, product safety, pesticides research, and poison control. It may be useful, however, to outline briefly the responsibilities of the other CPEHS Administrations, to show how, together, the three agencies form a cohesive unit in which each part complements and reinforces the other.

The Environmental Control Administration conducts a broad range of environmental programs, directing specific attention to such hazards as improper housing, noise, rodent and insect vectors, radiation, waste accumulation, improper sanitation, and occupational disease and injury. It develops recommended codes and ordinances covering sanitary requirements. It seeks to improve the Nation's health by assuring high quality drinking water; it develops the Public Health Service Drinking Water Standards, approves municipal water supplies serving interstate carriers, and performs research on chemical contaminants and other health problems relating to water. It conducts and supports research and training, provides technical assistance, and offers demonstration and planning grants, for solid waste management.

The National Air Pollution Control Administration conducts a comprehensive program of research and training, financial and technical assistance to State and local agencies, and abatement and control activities to help protect the American people from the harmful effects of air pollution.

It administers a regulatory program aimed at controlling pollution from motor vehicles. The application of national standards for new motor vehicles began with the 1968 models.
Under the Air Quality Act of 1967, effective air pollution control from stationary sources has now been initiated on a regional basis. The program includes designation of air quality control regions, the development of air quality criteria covering the effects of air pollution on health and welfare, and the publishing of information on techniques for controlling pollutants at their source. State governments will be expected to use the criteria and control technology information as a basis for developing regional air quality standards and plans for implementing and enforcing those standards.

It is apparent that FDA, ECA, and NAPCA are concerned with separate but closely related problems which, in many cases, require a joint or coordinated effort. Pesticides, for example, engage the attention of all three agencies and present a problem with endless ramifications. With a soaring population, meaning more hungry mouths to feed, how does the world weigh the unquestioned benefits to agricultural production against the immediate and potential hazards of pesticide build-up in the environment? We in CPEHS have an obligation—to our Nation and the world—to provide sound information on which such judgments can be made, and to provide it soon.

The Food and Drug Administration is concerned with pesticide residues in food and the effects of pesticides on human health; NAPCA is concerned with pesticides as an air pollutant; ECA monitors and guards the health of industrial and farm workers who may be exposed, and must also guard against pesticide contamination of drinking water. Acting together, CPEHS and its three Administrations can achieve an understanding of the total problem which would be impossible for any one of the Administrations alone, assess the long-range effects of ingestion by man, and evaluate the control measures required. In dealing with a problem of such far-reaching significance for this and future generations, any fragmentation
of effort that could delay or hamper our progress is unthinkable.

CPEHS has a variety of tools to use in achieving our goals. They range from demonstration and simple persuasion to court action. We will use the regulatory powers vested in each of the three Administrations vigorously, objectively, and fairly. We intend to make full use of the other important mechanisms available: education and training, demonstration projects, technical assistance to industry and government, enunciation of criteria, development of model codes and ordinances. The problems confronting us require the broadest possible approaches, marked by a willingness to innovate and a sense of urgency to get the job done.

Each of the Administrations now plays a vital role in a larger, more comprehensive attack on a major problem of our time. Without loss of identity or change in specific program orientation, each is in a position to contribute meaningfully to the solution of this larger problem and to gain in like measure from the holistic approach.

There can be no illusions, however, about the difficulty of the task. CPEHS cannot manage the environment. No single agency of government can do so. We can, however, by working together, consolidate all that we know today, and all the knowledge we can develop in the future, into a sensible, revealing picture of what is happening to man in the contemporary environment. And we can provide leadership to a national effort to protect the consumer and maintain a healthful environment, now and in the years to come.

What we do in CPEHS can make a major contribution to the health and well-being of our own generation. It may well determine the kind of world our children, and our children's children, will live in.

Charles C. Johnson, Jr., was appointed as Administrator of the Consumer Protection and Environmental Health Service on July 1, 1968, after serving from March 1967 as Assistant Commissioner of Health for Environmental Health in the New York City Health Department. He began his career as an Officer in the Public Health Service in 1947.
WHAT'S HAPPENING AT BLUE EARTH?

Will self-certification work in the food processing industry? Will it work as a practical matter in all food processing plants? What do working level FDA officials think of the concept in these early stages? How receptive are State officials responsible in the pertinent areas? What reservations does industry have or may it be expected to have about self-certification as a way of life? What room is there for improvement in self-certification for quality assurance as it has developed so far?

Early in 1968 the Green Giant Co. decided that it couldn't afford to ignore the implications in a concept that had been under study by the FDA for some time and was already undergoing limited pilot testing in an arrangement between FDA and another large food processing firm, General Foods. Green Giant's next step was to see how self-certification might work in its own backyard. Whereupon the company, despite reservations about some features and a little uneasiness about the whole new concept of an industry-Government partnership in quality assurance, let FDA know it was willing to give self-certification a fair try for a limited number of products at its plant in Blue Earth, Minn.

The agreement that resulted included the Minnesota Department of Agriculture as an active participant, since MDA under State law is responsible for covering canning plants. The three-way pilot plan, agreed upon in June 1968, has been under way ever since, and the participants—Green Giant, MDA, and FDA's Minneapolis District—have gained some definite impressions and reached some tentative conclusions from their separate points of view about self-certification as a working tool and how it has affected their interests or responsibilities so far. These remarks, passed on in informal narrative to Nathaniel L. Geary, Special Assistant for Quality Assurance in FDA's Bureau of Compliance, are recounted on the following pages.

The Industry Viewpoint
By C. B. Way

When we first heard about the Self-Certification Program, many of us had doubts about any such cooperation with a regulatory agency. The food industry had always resisted FDA attempts to get at its records. The attitudes prevailing between inspectors and inspected have been standoffish, to put it mildly. The Self-Certification Program goes against all this; thus, most of the food industry looked askance at such a program.

However, we cannot really be for or against something with which we are unacquainted. Since one company with a proven quality assurance program had, at least tentatively, accepted a Self-Certification Program, it made sense to us to investigate it. This was all we had in mind when we visited FDA in January 1968. Just to find out what it was all about.

Soon after, we tried setting up a model program for a peas and corn plant just to see how it might look. There were no definite plans by either party to implement it at that time. However, one thing led to another, and by June of 1968 we had an agreement, all duly signed, to proceed with a pilot program.

One of the philosophies we developed during this “investigation” of the program was that we thought FDA ought to know more about our business insofar as its operation affected the consumers' health. The old business of “let them do it the hard way” changed to “let us show you.” It was not necessary to disclose any classified information, or to give away the keys to the vault, so to speak. We felt that if FDA were to know more about our business, it could write more realistic laws and regulations, and, more importantly, be in a better position to determine the need for various laws and regulations; or so we reasoned. To put it another way, voluntary compliance is one way to keep from being legislated or regulated out of business. Thus, while we were quite reserved about giving out information at first, these reservations soon disappeared.

During the course of this investigation, some differences had to be overcome. One was a “language barrier” or divergence of terminology. To a canner, “raw product” is the green produce as it is harvested. To an FDA'er, it is any product fed into the system, such as tin cans, salt, water, etc. Other differences of opinion as to which areas were “critical” or potentially hazardous had to be settled.

Early in the planning it was suggested that the Minnesota Department of Agriculture (MDA) be a part of this program and, thereafter, the planning meetings became three-way sessions. The agreement was signed in June 1968 by Dr. Goddard of FDA, Mr. Schwandt of MDA, and Mr. Cosgrove of Green Giant. It covered one plant, canning only peas and whole kernel corn.

Basically, the agreement provides that Green Giant will (1) make certain pertinent quality control records available to MDA and FDA, (2) submit monthly reports listing any deviations from the agreed-on specifications, (3) give to FDA and MDA a copy of all corporate quality assurance inspection reports, and (4) submit to FDA and MDA copies of any complaints.
received from any source about products covered by the agreement. It also says that FDA and MDA will give to Green Giant copies of their full inspection reports and complaints they receive from any source on the products covered by the agreement.

The specifications which go with the agreement are not public information. What they do is establish preventative courses of action to be taken in such areas as fill of container, pesticide residue, foreign objects, etc. They also set up courses of action to be taken when a deviation occurs or is suspected. These courses of action are all part of the company standard operating practices, and no changes were made as a result of this program. It should be noted that the program concerns itself only with product safety, not product elegance.

A very important part of the agreement is that a deviation from the agreed-on specifications does not necessarily constitute a violation of the law.

One of the things we pressed for, and which we still feel is important in selling this program to the food industry, is the complete absence of publicity, if it is ever found necessary to recall a product from the market. Normally seizures, detentions, and the like are a matter of public record. Our theory was that we were giving FDA and MDA otherwise confidential information which they would not normally have and therefore we ought to be able to recall a product from the market, if necessary, without it being a matter of public record. At this writing, no basic laws have been changed, but a change along these lines is under consideration.

Some results of the self-certification trial program have been that there is an open channel of communications between MDA, FDA, and Green Giant; there has been no increase in quality costs to the company; inspection costs to the taxpayer will ultimately be reduced; concentration of regulatory agencies' resources can be placed in areas where serious health hazards exist; and an air of mutual trust and respect among the participating groups has developed.

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**The State Viewpoint**

By G. H. Steele

Minnesota Department of Agriculture has been working with Minnesota canners in both a regulatory and service manner since 1921 when our canny license law was first enacted.

Services rendered include quality grading, incubation for keeping quality, bacteriological and chemical analyses of ingredients and finished products, and periodic inspections of plants for sanitation compliance.

When we first learned of FDA’s intention to inaugurate a pilot study for Self-Certification in Minnesota, we speculated as to what effect this might have on our canny program and whether or not this might be Federal intervention or creative federalism.

We were invited to participate in the study by contributing to the limit of our resources and capabilities. As a result, we performed in our usual manner, leaving to FDA whatever laboratory and inspection work we were not able to perform.

Our philosophy always has been that every processor must carry out quality and sanitation control to the utmost of his ability to assure the best possible product for the consumer. To this end, the Minnesota Department of Agriculture should interfere only to assist and advise the processor or to take regulatory action when necessary.

The Self-Certification pilot study supplied for the first time the opportunity for FDA, MDA, and Green Giant Co. each to examine his capabilities and to evaluate procedures and methodology in use to determine if they should be continued or discarded.

At the same time, open discussion of our philosophies and programs gave each participant a more intimate knowledge of the others and made working together much more meaningful.

For the most part, the study program as originally initiated was continued, procedures being discontinued only when they appeared to serve no useful purpose. This was done only after open discussion at monthly meetings or by notification from one of the participants.

What has this study accomplished?

It resulted in mutual trust and respect for each other, thus providing a good climate for further cooperation.

It revealed to each participant what the other was attempting to accomplish.

Certain procedures were found to have little or no value and a need for others became apparent.

Each participant saw his ideas and program evaluated by the others and for the State at least this
will guide us in updating our cannery program.

The format of the agreement had to be simplified and the language of the specifications had to be given in layman's terms (the layman often being the regulatory official).

As more experience was gained in the pilot study, it became apparent that not every canner can take part in Self-Certification to the same degree as others who have greater quality control resources. Consequently, some means must be developed to supply such canners, as well as other food processors having limited control resources, with services from qualified agencies, so they can install adequate Self-Certification Programs.

From our experience, we feel that every food processor needs his own Self-Certification Program so he can give assurance from day to day that his products will retain their position in the market. Nothing short of resident inspection would accomplish this end if it were to be supplied by Government. Therefore, a processor must perform quality and sanitation control of his own products if he is to assure the best possible products for the consumer.

The Self-Certification Program appears to be the most desirable and efficient way to meet this need.

The FDA District Viewpoint

By Horace A. Allen and James A. Davis

Minneapolis District became involved in a self-certification program after Green Giant made preliminary inquiries of FDA in Washington early in 1968.

Most of the groundwork in setting up the agreement was handled by FDA in Washington, and in April the District made a precertification evaluation of the plant and facilities at Blue Earth, Minn. At about this time it became apparent that any agreement entered into by Green Giant and FDA should include the Minnesota Department of Agriculture, since this department is required by State law to cover the State's canneries. The self-certification concept was discussed with the Minnesota Department of Agriculture, and a three-way agreement was signed on June 26, 1968. This agreement covered a pilot study of self-certification at Green Giant's Blue Earth plant involving the production of canned peas and whole kernel corn.

The general requirements by FDA to protect the consumer by insisting on approved processing steps are, of course, public information. But the specific action taken by industry to put these general requirements into effect may constitute or involve trade secrets. Also available to the public is information about products recalled by industry after they leave the processor's warehouses and enter the normal distribution system to wholesalers and other distributors.

Initially the pilot study required more FDA manpower than would be given to any one plant during a normal canning season. However, we felt this was necessary to become thoroughly familiar with the plant and its operation and to be in a position to evaluate reports and information the firm would be expected to furnish when the pilot study was extended into an operational program.

As the program progressed, all parties to the agreement developed greater respect for each other's problems and abilities, and a freedom of communication evolved that has not historically characterized industry-Government relations. During some of our early meetings, occasional reservations developed, but these were quickly allayed by the frankness of our discussions. We learned that industry, because of its familiarity with a plant, was in a position to give us knowledge and information that could never be obtained through our unilateral inspections.

Our experience during this pilot study has shown us that as a regulatory agency, we can have a greater degree of confidence in the quality of the firm's product by evaluating its in-plant controls than by routine regulatory inspections and collection of samples.
BETTER PROTECTION,
WIDER RESPONSIBILITIES

by Herbert L. Ley, Jr., M.D.

The creation last summer of the Consumer Protection and Environmental Health Service, with the Food and Drug Administration as one of its three constituent agencies, was the beginning of a new Federal effort to provide stronger and more cohesive protection for the American consumer.

Under the reorganization, FDA's major responsibilities remain basically the same—to develop a uniform system of enforcement to assure that foods are safe, pure, and wholesome; that drugs and therapeutic devices are safe and effective; that cosmetics are safe; and that such products are honestly and informatively labeled and packaged.

In addition to continuing our traditional regulatory activities, however, FDA has assumed an expanded role in helping to solve today's environmental health problems, such as those related to pesticides and poison control. These new responsibilities have had the most direct impact on FDA's Bureau of Medicine. Within the Bureau, we have established a new Office of Product Safety consisting of five divisions, two of which are concerned with pesticide activities.

The Division of Community Studies is carrying on the essential work of determining, through epidemiological-oriented community
studies in a number of States, the effects of pesticides on man.

The second division dealing with pesticide problem areas is the Division of Pesticide Registration, which has the responsibility of reviewing pesticide labels submitted for registration and advising the Department of Agriculture concerning the human health implications of registration applications. This Division will also cooperate with other units of the Consumer Protection and Environmental Health Service and with other Departments in evaluating pesticide use and in recommending labeling that will reduce potential hazards to man.

The other divisions of the Office of Product Safety are concerned with hazardous household chemicals, the national network of poison control centers, and the safety of household appliances and other consumer products. Along with the creation of the new Office, the Bureau of Medicine's advisory committee structure has been strengthened by the establishment of 10 committees, allowing FDA to draw upon a broad range of scientific expertise in specific subject areas.

A new Division of Pesticides also has been set up within the Bureau of Science to assume responsibility for the other pesticide functions formerly carried out by the Communicable Disease Center as well as those which were already part of the work of the Bureau of Science. The development of new or improved methods for the analysis of pesticide residues and the investigation of the mechanisms of underlying chemical reactions will be among the Division's responsibilities. Exposure studies and the study of pesticide poisoning incidents also will be sponsored by the Division as part of the effort to evaluate the health hazards associated with the use of economic poisons. In addition, the Division will review petitions on pesticides, evaluating adequacy and reliability of information on chemical identity and purity, stability, residue data, intended effect data, and methodology.

These new functions are compatible with those previously carried out by the Agency, but our success in administering both the new and old responsibilities of FDA still must depend primarily upon continued cooperation from industry and our own concern for exceptional performance. In 1944, for-
mer FDA Commissioner Dr. Paul Dunbar recognized, as I do today, that the Agency's most critical resource is its personnel. As an indication of his feeling, Dr. Dunbar called upon every employee to strive from the moment of joining FDA to develop a reputation for dependability, for careful and direct thinking, and for personal responsibility. I am making every effort to see that this concept of personal responsibility continues to be an essential part of our Agency development.

This concept of self-responsibility is applicable to industry as well.

When one considers that our drug recalls, for example, have continued spiraling upward—from 651 recalls in Fiscal Year 1967 to 722 recalls in Fiscal Year 1968—we can only conclude that the drug industry is faced with and must solve a very difficult problem. The record shows that 78 percent of these drug recalls were attributable to deficiencies in manufacturing practices. It is also part of the record that the Defense Department, in conducting 714 preaward surveys of manufacturers over the past 4 years, rejected 44 percent (most of them drug manufacturers) for quality control and housekeeping deficiencies.

Although FDA has assumed new and expanded responsibilities, the Agency will not let up in the performance of its food and drug regulatory activities. For more than half a century the Agency and the regulated industries have had to work together, to solve mutual problems together, and to do what must be done to protect the consumer. We will continue to be responsive to industry; and we fully expect industry to be responsive to FDA. But both Government and industry must also be responsive always to the consumer or each has failed in its responsibilities.

If FDA and industry continue
working in an atmosphere of mutual respect, our mission will not only be easier to accomplish but can be exceedingly productive as well. FDA scientists have achieved extraordinary advances in analytical methodology and will continue to work in areas of pioneering research. Industry, as well as FDA, benefits from these achievements. Other FDA projects, such as vitamin analysis, drug equivalency studies, and the Intensified Drug Inspection Program also aid industry in solving specific problems.

It is important to underscore that today's technological changes are providing the tools which industry and Government both must use to strengthen their scientific understanding and to develop a common scientific language. This is an essential element in dealing effectively with the broad range of medical and environmental problems that we face today. How we meet and how quickly we solve these problems, as diverse and as complicated as they are, will affect, for good or bad, the lives and health of every American.

The best way FDA can serve the public is through consistent and imaginative programs that upgrade scientific competence, that build a strong bridge between the scientific activities of FDA and the outside community of science, and that strengthen our State-Federal relationships in carrying out shared consumer protection obligations. We must also continue to seek the cooperation and support of the industries we regulate.

Herbert L. Ley, Jr., M.D., joined FDA in 1966 as Director of the Bureau of Medicine and became Commissioner of Food and Drugs on July 1, 1968. His career covers service in several medical activities of the U.S. Army and professorships and administrative posts at George Washington University and the Harvard School of Public Health.
In the Food and Drug Administration's endeavors to assure that food in interstate commerce contains no filthy, putrid, or decomposed substance or is otherwise unfit for food, and that it is not prepared, packed, or held under insanitary conditions by which it may become contaminated with filth or rendered injurious to health, analytical entomology is an important and necessary implement in the Agency's regulatory mission.

The Microanalytical Branch headed by William V. Eisenberg, in the Bureau of Science's Division of Microbiology, is responsible for developing analytical methods to detect filth in foods, including insect contamination, a major source of filth; for providing scientific expertise to FDA Districts on unusual problems involving filth contamination; for studying the various food processing methods and conditions to determine the sources and routes of contamination; and for working out bases for establishment of Good Manufacturing Practice guidelines. The Branch thus is staffed with microanalysts or other experts trained to isolate and identify insects or their fragments and their eggs or excreta in food material of plant origin. They must not only extract insects or fragments from the food, but must also be able to identify them. For by identifying the insect, they not only establish that the food is contaminated, but also can tell whether the contamination took place during the normal production of the crop or during some later stage in processing, based on the kind of insects that might infest the food at each source. Since some insects are not normally found in food in the field, identification of one or more of these insects can help to establish that contamination took place during processing, and, by extension, that the food was prepared, packed, or held under insanitary conditions, thus providing a firm basis for regulatory action.

Proper identification requires a thorough knowledge of insect morphology—the anatomical structure of a given insect and the body parts, sculpturing, markings, or other physical characteristics that make positive identification possible.

Some of the methods used by the Branch's Analytical Entomology Section, headed by Paris Brickey, to extract or differentiate the insect and its fragments from the food or plant material include oil flotation, in which various oils that adhere to insect cuticle but not to plant matter are finely dispersed in aqueous or alcoholic solutions containing the food material and float the insect material; sieving through fine mesh screens; filtration of soluble foods to isolate fragments; X-ray examination of such food as whole cereal grains to detect insect infestation; direct examination of food samples by the naked eye or through low-power or high-power microscopes; sedimentation techniques to separate insect eggs and excreta from food material; and differentiation of insect and food materials through staining techniques (see FDA PAPERS, March 1968).

Analytical Entomology

The insects above are representative of the various flies, beetles, and moths that infest foods. From the left: The vinegar fly or Drosophila, found in canned tomatoes and tomato products, peppers, fruits, and pickled products; the rice weevil, which infests macaroni, wheat, corn, oats, barley, buckwheat, and other grain products; the red-legged ham beetle, found in cheese, dried egg yolk, copra, cacao beans, and other products containing fats and proteins; the larger cabinet beetle or dermestid, which infests nutmeats, dried fruits, cereal products, and dried milk; and the Indian meal moth, found in cereals, dried fruits, herbs, milk chocolate, powdered milk, nuts, and seeds.
The microscopic photos above show fragments of several insects as they appear in various foods. Top left photo, in granulated almonds, are (at right) the wing cover or elytron (top) and head (bottom) of the larger cabinet beetle, and (at left) two leg fragments of the Indian meal moth. Top right photo, darker objects in flour are (top) a leg fragment and (bottom) the snout of the rice weevil, and (center, left and right) elytron fragments of the cadelle beetle. Bottom left photo, in seedless raisins are (center left and near top right) the head and elytron of the dried fruit beetle and (barely visible, center) the wing of the vinegar fly. The dark objects in this picture at top left and bottom right are aborted raisin seeds. Bottom right photo, in cocoa, the two larger, orange colored objects in the upper left center are elytron fragments of the coffee bean weevil and the darker objects at left are (top) the mandible or tooth of the coffee bean weevil and (bottom) a head fragment of the red-legged ham beetle.

The photos below show fragments of various insects with their distinctive characteristics and markings as they appear under a high-power (100-X to 200-X) microscope. Left photos show (top) the pronotum (area behind the head) of the red-legged ham beetle and (bottom) a fragment of the larger cabinet beetle. Center, left and right photos are elytron fragments of the cadelle beetle.
Center photos show (top) a leg from the Indian meal moth, with a characteristic spine protruding from the joint area, and (bottom) a mandible or tooth of the dried fruit beetle, with the cutting edge at upper right.

Right photos show (top) a leg of the rice weevil, with its setaceous growth and characteristic tibial spur, and (bottom) a wing of the vinegar fly.
In the photo at top, almonds are cracked and examined under low-power magnification for signs of insect infestation. The instrument to the left is a nutcracker. Below, at left, a microanalyst decants oil containing insect fragments into a beaker following oil flotation procedure. This material containing insect fragments is then filtered on ruled paper and (top) examined under a wide field microscope. The microanalyst is using a probe to search for fragments and using a hand-operated counter to keep up with the total of fragments. At bottom, a high-power microscope is used to identify insect fragments.
Food Standards Committee: Venerable But Still Vibrant

by Mal Oettinger

There are areas in which the Food and Drug Administration is expected to assume the position of a man with his ear to the ground, his nose to the grindstone, his eye to the future, and the bit firmly between his teeth. Uncomfortable, to say the least. One area where vigilance and industriousness are vital is in the promulgation of national food standards. It was recognized as early as 1885 that here was an area where the Federal Government needed cooperation and advice from the States. It was from this that the idea of a Food Standards Committee (FSC), composed of experts from all parts of the country, grew into realization. Today the Committee functions as a source of advice and consultation to the Commissioner of Food and Drugs in the discharge of his statutory responsibility for food standards development.

Serving on FDA's Food Standards Committee has long been considered an honor. It was in recognition of this that the Committee in 1938 recommended that membership terms be limited to 4 years so more State representatives could participate in the work of this important advisory body. Since 1938 the Committee members have been appointed by the FDA Commissioner. Its recommendations have never had the force of law, but the Committee has great prestige. It has always been composed of senior and proficient officials from State regulatory agencies responsible for administration and enforcement of food laws. Seven State officials, with outstanding records of accomplishment, currently serve on the Committee with two FDA officials who serve as Chairman and Executive Secretary.

Although the FDA Commissioner has the input of the professionals working for the Administration in Washington and in the 17 Districts, he receives valuable viewpoints from Committee members who work on the State and regional level. In the nature of their duties, these men have contact with the grassroots in a manner that is often denied Federal officials. They are familiar with the needs and desires of consumers in their areas, with the views advanced by representatives of food industries, and with the history of legislative support at the State level. The seven State members of the FSC are regional representatives of the Association of Food and Drug Officials of the United States (AFDOUS), one from each of the seven AFDOUS geographical regions. Eaton E. Smith, a Committee member, is president of AFDOUS, in addition to his regular duties as Director of Food and Drugs in the State Department of Consumer Protection in Connecticut. Another Committee member, Evan E. Wright, Director of the Food and Drug Division of Kansas' State Department of Health, also serves as Secretary-Treasurer of AFDOUS.

All members of the FSC have had long experience on the State level in fulfilling the basic aim for which the Committee was originally established—to promote honesty and fair dealing in the interest of consumers through the promulgation of food standards. Health and nutritional considerations are taken into account by both State and Federal agencies in setting food standards, but the economic aspects remain the primary task. Through the FSC, State and Federal officials work together to assure the customer that the food products he purchases are accurately represented, that they meet certain prescribed standards of identity, quality, and fill of container. It is FSC's conviction that the consumer should be able to buy certain food staples with confidence, without having to decipher the fine print on the label, and that furthermore, the identity and quality will not vary substantially from one region or State to another or be subject to differing standards of integrity on the part of the producer.

Arriving at a standard for a food is a complicated process requiring prior notice, negotiation, and thorough consideration of the limitations on the manufacturer as well as the needs and desires of the consumer. FDA cannot—nor would it wish to—arbitrarily promulgate standards by fiat. Comments are solicited from the State members of the FSC on all proposed standards while they are still in the discussion stage. The proposed standards, which may be initiated in a number of ways, are then published in the Federal Register. Comments are invited. Responses are evaluated and an order ruling on the proposal is then published in the Federal Register. Any person who can show he is adversely affected by the order can object to it and request a formal hearing. If proper objections are submitted, the effective date of the order is stayed and a public hearing is scheduled and conducted before a hearing examiner. After the hearing, a final order based on the testimony of the hearing is published. Then if any party (such as a representative of the food industry concerned) is dissatisfied with the decision rendered and is prepared to demonstrate that the decision rendered is not based upon substantial evidence of record, he has the right to take it directly to the Federal Circuit Court of Appeals. If the original order encounters no objections, it will become effective on a prescribed date. This procedure was instituted by Congress for the promulgation of food standards.

The Food Standards Committee actually predates the Food and Drug Administration by a number of years. It had been recommended by the Commissioner...
Left, Evan E. Wright, Director, Food and Drug Division, Kansas Department of Health, representing the Mid-Continental Association of AFDOUS.

Below, Frank E. Fisher, Director, Bureau of Food and Drugs, Indiana Board of Health, representing Central States Association.

Right, A. Lee Turner, Supervisor, Food Regulatory Section of the Division of Regulatory Services, Virginia Department of Agriculture and Commerce, representing the Southern States.

Center left, James W. Bell, Chief, Bureau of Food and Drug Inspections, California Department of Public Health, representing the Western Association.

Left, Gary L. Beard, Committee Executive Secretary and an FDA Food and Drug Officer.


Far right, Elmer O. George, Director, Food Laboratory, Division of Food Control, New York Department of Agriculture and Markets, representing Central Atlantic States.

These photos were taken at the February 27
Below, Paul A. Pumpian, Food Standards Committee Chairman and Director of FDA’s Office of Legislative and Governmental Services.

Right, Donald J. Mitchell, State Chemist, State Chemical Laboratory, South Dakota, representing North Central States Association.

meeting of the Food Standards Committee.
of Agriculture in 1885 and he had the services of State advisers on such matters as standards for fertilizer and livestock feed. The first FSC was formed in 1897; its chairman was the chief of the Agriculture Department’s Bureau of Chemistry, Harvey W. Wiley, who has been called “Father of the Pure Food and Drug Law.” Two years later, the Committee put forth its initial report setting the first food standards in the United States.

In 1902, Congress appropriated funds for the Secretary of Agriculture to establish standards for purity of foods. But Congress never specifically bestowed official status on the Committee. Its recommendations were termed “advisory standards” because of the lack of a congressional mandate, and in two separate lawsuits of the time charging adulteration of foods contrary to the advisory standards, the Federal District courts reflected some confusion—one court finding the standards had the weight of law, the other rejecting the standards as a legal restraint.

Nevertheless, the early standards established were useful and had an effect on the way in which food was marketed. The Committee had a wide purview in those days: at a meeting in Louisville, Ky., early in the century, it considered “spiritous liquids.” The recorder’s notes preserve a motion that if any distilleries outside the city were to be visited, it must be after the Committee had completed its deliberations.

It was a branch of the food industry—the National Canners Association—which first asked Congress to pass legislation giving Agriculture’s Food, Drug, and Insecticide Administration authority to set food standards for canned goods (except meat and milk). This 1930 legislation is commonly known as the McNary-Mapes Amendment. In a more limited case, in 1923, the dairy industry had asked Congress itself to set a standard for butter and this was enacted. In 1933, pressure increased for establishment of food standards that would have the force and effect of law. Six separate bills were introduced during the next 6 years and the Food, Drug, and Cosmetic Act of 1938 (FD&C Act) gave the FDA this power.

The 1938 law made no specific mention of a Food Standards Committee. However, Walter G. Campbell, Chief of FDA at the time, recommended to his superior, Secretary of Agriculture Henry A. Wallace, that a Food Advisory Committee be made part of the mechanism by which FDA’s Chief would be provided with facts to determine what constituted fair and honest dealing in the marketplace of the day. As before, the FSC had four State and two Federal representatives. The Committee was quite active until World War II, when because of wartime pressures and restrictions on travel, it became somewhat quiescent. In the early 1960’s, membership was increased by the FDA Commissioner to seven State (and two Federal) members.

The current membership, in addition to Eaton E. Smith of Connecticut and Evan E. Wright of Kansas, mentioned earlier, includes the following State food and drug enforcement officers: James W. Bell of California; Frank E. Fisher of Indiana; Dr. Elmer O. George of New York; Donald J. Mitchell of South Dakota; and A. Lee Turner of Virginia. The Chairman of the FSC is Paul A. Pumian, Director of the FDA Office of Legislative and Governmental Services (the branch of the Agency under which the Committee functions), and Committee Secretary is Gary L. Beard, FDA Food and Drug Officer.

Although the Committee meets formally only twice a year, there is frequent communication and a good deal of correspondence between the members and the FDA. Committee members are kept in close touch as to what foods are being considered for standardization and what is motivating such actions. The members, consulting with other State regulatory officials in their AFDOUS region and with representatives of food industry or consumer groups, report their judgment of the proposed standards and suggest modifications. State officials are often more intimately aware of the problems facing certain food producers than Federal officials; they are frequently aware of industry’s desires for proposing a food standard and can comment knowledgeably on the advisability of promulgating such a standard. Some States set their own food standards; others have a provision in their constitution to adopt Federal standards. State standards vary widely—some are more stringent than Federal standards, some more lenient. If a food does not meet Federal standards, it may not be shipped in interstate commerce, although it may be consumed within the State where it was produced. Federal standards apply to staple food items in wide use; States may have their own specific needs (Hawaii, for example, has standards for poi and oriental-type noodles; in the case of the latter, Hawaiian manufacturers must have two labels, one indicating the product has met Hawaiian standards for home use, and another, more general label for distributing to the rest of the country).

The FSC members are also informed of pending international food standards being considered by the Codex Alimentarius Commission, in which some 40 countries are participating under the joint sponsorship of the Food and Agriculture Organization (FAO).
and the World Health Organization (WHO) of the United Nations. Although Committee members are not directly involved in setting international standards, FSC will consider whether the United States ought not to have its own standards for a food being considered by Codex, because unless the United States has established a standard under FDA procedures for a particular food product, it could not enforce a Codex standard for the same food. This could put American producers of this product at a disadvantage if they sought to export it. As one FDA authority on food standards put it: “If we already have a domestic standard in effect when a Codex standard comes up for consideration, we are in a strong position to influence and guide its provisions. If, on the other hand, the Codex standard is adopted before we have an FDA standard, we will be under pressure to make the provisions of any standard adopted in the future consistent with the corresponding Codex standards.” (“Food Standards,” by L. M. Beacham, FDA PAPERS, September 1967.)

Committee members are consulted before the semiannual meetings to learn what new standards or amendments of existing ones the members feel should be discussed. “Resource personnel” from FDA attend the meetings to brief Committee members and to discuss common problems. The FDA staff officers are drawn from such departments as the Office of the Commissioner, the Bureau of Compliance, and the Bureau of Science and its Division of Food Chemistry and Technology (Food Standards and Food Technology Branches). After the discussions, the Committee members meet in executive session and vote on recommendations to be made to the Commissioner.

There are certain considerations in setting food standards that the Committee studies in making its recommendations. Foods for which standards are set must be “important food”—items staple enough to make a difference in the family budget. At one recent meeting, for example, a member reported interest in his region in standards for eggnog. The discussion which followed made clear that because of the seasonal nature of the product and its limited interstate movement, it would have a low priority for standardization.

Another important consideration is the relationship between what it would cost in research and Government man-hours to set a standard and the benefit (in dollars) the public would derive. In effect, FDA considers what the taxpayer will be getting back from the dollars expended by the Agency. Although this approach seeks to assign monetary value to imponderables, within limits it can be done.

FDA is in the process of seeking a contract with outside consultants in an attempt to develop a formula that will give solid general guidelines for determining the cost-benefit ratio of food standard actions.

The FDA will consider any properly presented request for a food standard or modification of an existing standard. Some are recommended by the affected industry, others proposed by the Agency itself. Thorough consumer surveys give the Agency an idea of those areas where standards are most needed. They also give an indication of what consumers know and do not know about certain products and point to any need for additional labeling requirements. When the industry requests modifications that it claims will improve a food standard, the FDA frequently conducts investigations, including visiting food processing plants and making experimental food packs to determine whether the change would indeed be beneficial to the public. Another way of arriving at a food standard amounts to killing two birds with one stone. If the Agency is working on standards for frozen peas, for example, it may well conduct parallel studies on frozen beans. Of course, this procedure results in a cost-benefit saving to the consumer.

Results of consumer surveys, Agency investigations, and tests currently being conducted are made available to the members of the FSC so they can properly evaluate proposals for new standards. Thus, the Committee gets a great deal of information and research material from FDA upon which to base its recommendations to the Commissioner.

The Committee has for many years been a model for State-Federal relations in an area of great importance to both producers and consumers. It helps bring extensive expertise to bear on problems not easily resolved, bringing regional considerations that might otherwise be inadvertently overlooked into FDA’s deliberations. An FDA official who worked with the Committee over 30 years summed it up: “It is a wise and venerable institution which has served the public well.”

Mal Oettinger, a free lance writer, is a former magazine staff writer and television network public information official.
ATLANTA DISTRICT  Cucumbers contaminated with excess endrin residues presented a serious problem to the District in January. Florida Department of Agriculture officials reported to FDA on January 16 that they had analyzed a sample of cucumbers imported from Mexico, in possession of Trino Produce, Inc., Pompano Beach, Fla., and had found endrin residues at a level of 0.61 parts per million.

Subsequent investigations conducted jointly by FDA and Florida State officials revealed that the sample had been taken from a portion of a lot of 9,527 60-pound bags. This was an entire boatload of cucumbers which had been imported on January 12 through the port at Key West, from where they were transported by truck to Pompano Beach. They were then repackaged for distribution throughout the United States and Canada.

Approximately 503,000 pounds of the lot had been distributed before the State officials had completed their analysis. The approximately 68,620 pounds remaining on hand in Florida was voluntarily destroyed under State supervision on January 16. Since Trino sold the cucumbers through 35 brokers, each of whom had sold portions of the lot to several accounts, the exact number of consignees receiving the cucumbers was not immediately available. Trino Produce did instruct all brokers to contact all consignees and to have the cucumbers voluntarily destroyed for which Trino would bear the cost.

The boatload of cucumbers was the first shipment of the season from a 1,200-acre cucumber farm operating in Yucatan, Mexico, in which Trino owned a half interest. The products, part of which had been sprayed with endrin prior to harvesting, had been expected to yield a crop valued at $6 million in this year’s market.

During the time the first shipment was being destroyed, the firm offered for entry, on January 16, a second boatload containing 6,292 65-pound bags of cucumbers. This lot, which had an entry value of $40,000, was sampled in import status and found to contain endrin residues at a level of 0.15 parts per million. It was refused admission on January 20 and reexported.

A third shipment, offered for entry on January 27, contained 2,344 100-pound bags. This lot, also sampled in import status, contained endrin residues at a level of 0.08 parts per million. It was refused admission on January 20 and reexported.

In the meantime, a fourth boatload of cucumbers from the same farm was offered for entry on January 30. It, too, was sampled for analysis.

The farm reportedly has made some attempts to remove some of the excess endrin residue by various washing treatments. Reports indicate such efforts have been totally unsuccessful, and it would appear that the entire $6 million crop may be ruined.

Baltimore District  Maurice D. Kinslow, Baltimore District Director, and Buel M. Walters, Chief Inspector, met on January 16-17 with Commissioner of Agriculture Gus R. Douglass and C. Harold Amick, Director, Consumer Protection, West Virginia State Department of Agriculture, to draw up an agreement whereby that department assumes the responsibility for inspection of food warehouses as of July 1.

Harry Sherman, trading as Capitol Salad Co., Washington, D.C., was fined $500 on January 13 in the District of Columbia court of general sessions. Mr. Sherman pleaded guilty to three counts of a seven-count information charging the manufacture, packaging, and offering for sale in interstate commerce of crabcakes contaminated with bacterial filth.

Because they contained decomposed eggs, two lots of frozen whole eggs valued at $10,210 were seized in January while held by a firm in Landover, Md. The eggs were stored to the account of a baking company.

BOSTON DISTRICT  The District continues its efforts to achieve compliance in the smoked fish industry. FDA Inspectors have intensified their inspectional coverage among the New England smoked fish manufacturers in an attempt to effect voluntary compliance with Good Manufacturing Practices for smoked fish and have assisted in educating the processors to the serious bacteriological problems that can occur if smoked fish are not properly processed.

Two New England fish manufacturers initiated plant improvement programs following District inspections which showed that the firms processed fish products under conditions conducive to bacterial contamination. As an immediate result of the inspections, three large lots of frozen breaded ocean perch were seized from one firm and the other firm was cited.

The firms responded to these regulatory actions by implementing in-plant improvement programs utilizing the services of a consulting food laboratory, which plans to make inspections and collect samples on unannounced visits in a manner similar to FDA inspections.

The program is unusual in that the improvements are proceeding according to a specified timetable, at the end of which the District expects both firms to be in compliance.

BUFFALO DISTRICT  Lois M. Meyer, District Consumer Specialist, assisted in and made appearances on
a 21-program series on "Health Education for the Elementary School Teacher," presented by the State University of New York over the New York State Educational TV Network. FDA resource material was used to a great extent in the programs entitled "Protecting the Health of Consumers" and "Fraudulent Health Practices."

**CHICAGO DISTRICT** State-Federal coordinators from Chicago and Kansas City Districts were guests at a conference held February 27 in Chicago. In line with its intensified coverage of manufactured dairy products, the Illinois Department of Public Health's Division of Milk Control sent representatives to meet with those of the Missouri and Iowa Departments of Agriculture Dairy Divisions for joint planning. The FDA personnel were invited to attend as observers.

**CINCINNATI DISTRICT** Thirty cases containing 900 pounds of shelled pecan pieces, in possession of a Cincinnati bakery, were seized by the FDA because of contamination with *E. coli* organisms. The product, valued at $1,100, had been packed and shipped by Natchez Pecan Shelling Co., Natchez, Miss.

When the District detected high total bacterial counts in samples of frozen seafood patties that were held at a cold storage warehouse in Dayton, Ohio, seizure was ordered. The 44-case lot, valued at $790, had been manufactured and shipped by Allen Kirkpatrick & Co., Inc., Rehoboth Beach, Del.

The District seized 424 cartons and boxes of miscellaneous drugs and devices recently at wholesale drug warehouses in Dayton, Ohio, and Richmond, Ky. Investigation established that the items had been held under insanitary conditions whereby they may have been rendered injurious to health. The articles had been transported in a truck which was also carrying parathion, a pesticide chemical. During shipment, parathion leaked from one of the containers, exposing the contents of the truck to the chemical.

**DENVER DISTRICT** The District received a report from a Colorado trucking company that a drum containing the chemical pentachlorophenol had accidentally opened in shipment, and that 80 cases of cookies in the same trailer were possibly contaminated. FDA alerted the Colorado State Health Department, which secured a voluntary destruction order for all cookies in the shipment.

**DETAULTD DISTRICT** An analgesic and vitamin preparation claimed to be an effective remedy for the relief of the pains and swelling of arthritis, gout, lumbago, rheumatism, and bursitis was seized February 5 in Cuyahoga Falls, Ohio. FDA charged that the product, "Richards Formula 10," was misbranded and that it lacked an approved New Drug Application. Value of the 660 cases and accompanying labeling seized was placed at $6,600. The product had been manufactured and shipped to Ohio by L. Perrigo Co., Allegan, Mich.

**KANSAS CITY DISTRICT** A U.S. marshal seized 91 cases of "Nail Therapy" at Wichita, Kans., after FDA charged that the product, valued at $2,621, is a new drug that was shipped in interstate commerce without an approved New Drug Application. The product was manufactured by Bee Gee Laboratories, Los Angeles, Calif.

Shaw Pharmacal Co., St. Louis, Mo., pleaded guilty on January 13 to five counts of an eight-count information at St. Louis. FDA alleged adulteration and misbranding of various drugs. The firm was fined $5,000 on one count and placed on 3 years' probation on the remaining four counts. The judge indicated that the firm will be subject to a $40,000 fine if it fails to comply with the Food, Drug, and Cosmetic Act on these four counts.

The District's investigation of the death of a 14-year-old boy January 12 in Kansas City indicated misuse of a spray-on shortening in a pressurized container was responsible. The boy's mother said neighborhood children had been inhaling the product to temporarily change their voices. Although no autopsy was performed, the attending physician said that the death was not due to toxicity of the product but to laryngospasm. It appeared that the product was sprayed directly into the mouth, thus freezing the larynx.

**LOS ANGELES DISTRICT** The District's Consumer Specialist, Elaine Roentgen, is assisting in a study of the effect on the eating habits of senior citizens brought about by an educational program on nutrition and dietary practices. The program, supported by a Department of Health, Education, and Welfare grant, includes the serving of a weekly hot meal, at a nominal price, to three selected groups of elderly people at a Los Angeles school. Two of the groups, prior to the meal, heard a talk by Mrs. Roentgen on nutrition. The third group is a control and does not have a lecture. The experiment is intended to discover whether education will result in improving the dietary habits of the two groups.

Forty acres of carrots in the field, equivalent to 40 carloads, were voluntarily plowed under in January by John Jacobs Farms, Phoenix (Glendale), Ariz., because of suspected endrin contamination. Shipments of carrots harvested from some of the firm's fields had been seized by FDA because of excessive residues of the pesticide chemical (see Field Reports, FDA PAPERS, March 1969). The firm decided to harvest no more of the crop grown in plots of land which had endrin residues. The pesticide had been applied to other crops on the same fields 5 years earlier but
still remained in the soil and was absorbed by the carrots.

MINNEAPOLIS DISTRICT Two-day Consumer Education Workshops were held in Rochester, Morris, Mankato, Duluth, and Bemidji, Minn., during January and February. Although the workshops stressed shopping for credit. District Consumer Specialist Blanche Erkel presented information about wise use of money in purchasing those products that are under the jurisdiction of the FDA.

The University of Minnesota Extension Service, the Minnesota Home Economics Association, the Minnesota Attorney General’s Office, the Chamber of Commerce, Better Business Bureau, and Credit Union representatives cooperated in presenting these programs to educators and community leaders.

District representatives, Inspector Myron Day, Microbiologist Myron Crider, and Veterinarian Edward Sterner, met in February with Bob Peterson, bacteriologist for the Belgrade Superior Feed Co., Belgrade, Minn., to plan a control program on Salmonella. FDA will sample and take cultures of all feed ingredients purchased by the firm and will sample and take cultures of all finished feeds on a random basis. This important program is a good example of industry/FDA cooperation, the District feels.

NEW ORLEANS DISTRICT FDA Inspectors at the District’s Memphis resident post have, over a period of several months, accomplished special training of one State Inspector in making sanitary inspections of food warehouses and three others in the inspection of medicated feed mills. Some training in the preparation of inspection reports was included.

Arrangements by the District for training the State Inspectors in the medicated feed mills area were made with Clyde Cathey, Director, Division of Feeds, Seeds, and Fertilizer, Tennessee Department of Agriculture. The inspectors are Stoy Permenter, W. W. Scarbrough, and William Sensing, and they were trained by FDA Inspector John L. Yount.

Cooperative sanitary inspection work for the training of State Inspector Robert Kelly by FDA Inspector Michael Becker was by agreement between the District and Eugene Holeman, Director and State Chemist, Food and Drug Division, Tennessee Department of Agriculture.

Although importations through the port of New Orleans were down to a minimum during January because of a dockworkers’ strike, there were significant import actions involving the detention of frozen rock lobster tails offered for entry from Costa Rica. Due to decomposition, 844 cases containing 33,760 pounds of the lobster tails were detained.

NEW YORK DISTRICT Ralph Bernstein, Associate Regional FDA Director of Region II, Irving Berch, Director of the Philadelphia District, and Weems Clevenger, Acting Regional FDA Director of Region II, met with Dr. Roscoe Kandle, Commissioner of the New Jersey State Department of Health, in his office in January and, in an appropriate ceremony, presented him a commission from the FDA to cover his drug inspectors’ responsibilities in the inspection of drugs for humans. Dr. Kandle seemed impressed with the progress in the extension of consumer protection that the commission represents.

Arrangements have been made for all activities by commissioned State Inspectors to be reported on FDA documents so they will be accurately reflected in the FDA data system.

Kaybel, Inc., an Englewood, N.J., drug repacking firm, and its president and secretary-treasurer, Abraham Kaybel and Harry Bell, were each fined $1,000 on January 15 in a Newark District court. In the same court last November 20, a jury found the three defendants guilty of repacking and shipping Enovid 5-milligram tablets without an approved New Drug Application or supplement.

Six officials from the Canadian Department of Fisheries who recently spent a week in the District were enthusiastic in their appraisal of the District’s course in organoleptic examination of fish. The course content was altered to provide an understanding of each agency’s grading designations. As a result, the District believes there will be much less confusion with respect to re-exportations between the two countries.

The Canadian officials attending the course are: Ozzie M. Linton, Chief of Regulatory Programs, Ottawa; Gordon R. Douglas, Chief of Inspection, Winnipeg; John M. Graham, District Officer, Montreal; Paul M. Winchester, Assistant Chief of Inspection, Halifax; David C. Horne, Senior Quality Control Chemist, Halifax; and Baxter J. Emberly, Fish Quality Specialist, St. John’s.

PHILADELPHIA DISTRICT The deaths of a 54-year-old woman and a 17-year-old boy in one family from what appeared to be food poisoning led to an investigation by the New Jersey Department of Health. It revealed that during the past Christmas season, the northern New Jersey family had bought a turkey from a local market. When it was eaten a few days later, members of the family became ill, and two died. The State Health Department analyzed the turkey and found it contained Salmonella. Since the source of the processing of the turkey was in question, the State asked Philadelphia District to analyze fatty acids in the turkey meat in an effort to identify the processor. Fatty acids identified with coconut oil were found, and the New Jersey Department of Health was so advised.

SAN FRANCISCO DISTRICT As part of its routine
coverage of imported fishmeal, the District collected samples for bacteriological analyses from lots of the product offered for entry at the port of Stockton. The fishmeal, carried on the SS Santa Malta, had been loaded at Chile and Peru. When analyzed, the samples were found to contain metal ore dust. A total of 11,831 sacks of fishmeal suspected of metal ore contamination was removed from two holds of the ship where lead ore in burlap sacks had been stored over the tops of the hatches and zinc and copper ore had been stored in the holds under the fishmeal. District laboratory analyses of additional samples taken from the lots removed found lead dust on the outside of paper sacks of the fishmeal. Analyses of fishmeal in burlap sacks revealed lead contamination of the contents. Detentions were issued for the product, and reconditioning has been proposed by the consignee for the fishmeal in paper sacks. The sacks of fishmeal not involved in the adulteration have been released.

SEATTLE DISTRICT The District is preparing enthusiastically to take part in “Fish Expo 69,” a large national trade fair for the fish industry, to be held next October 5-8 at Seattle. FDA’s Boston District participated in the fair when it was held last October in Boston and encouraged Seattle District to do so this year.

District personnel, along with personnel from various Washington State agencies, attended a 4-hour driver training session in January at Seattle. The session, presented by State Trooper Jerry Campbell, was titled “Washington State Patrol Defensive Driving Program” and contained a mixture of films and questions and answers.

Auto racing fuel manufactured by Francisco Laboratories, Los Angeles, Calif., and valued at $650, was seized by the District because it was a hazardous substance.

An unpleasant odor in the town of Libby, Mont., was detectable for miles after a train derailment on January 20 involving not only a car of frozen beef and several cars of flour but also a carload of mercaptan mixtures used to deodorize natural gas. The U.S. Department of Agriculture’s Compliance Branch was alerted to decide on how to dispose of the beef. Attempts at salvaging the flour were made away from the site of the derailment because of the odor at Libby and that permeating the flour. FDA personnel supervised the removal of the flour and the subsequent attempt to salvage it.
Stop Order Issued  Nebraska State Inspector Earl Otte issued a 24-hour stop-production order pending correction of all insanitary conditions found during joint inspection of a Scottsbluff, Nebr., bakery. Inspector Otte, assisted by FDA Inspector Cliff Bryant of the Kansas City District, found generally poor housekeeping practices and evidence of rodents in the storage area; bakery equipment had not had recent cleaning; and accumulations of flour, jelly, fillings, and dough were observed on the floor, tables, and equipment.

Foodstuffs Destroyed  Clarence Smythe, Kansas City, Kans./Wyan- dotte County Health Department Inspector, supervised the destruction of 2,625 pounds of foodstuffs at a Kansas City grocery warehouse. Mr. Smythe ordered the destruction following the discovery of rodent contamination during a joint inspection with FDA Kansas City District Inspector Johnnie Nichols.

Fires Damage Merchandise  Indiana Division of Food and Drugs provided constant supervision over recent salvage operations of merchandise involved in three drug store fires. Disposal of prescription legend drugs was monitored to insure that they remained in legitimate drug channels. Merchandise destroyed was valued at $62,500 and goods salvaged at $55,500.

State Embargoes Potatoes  The Ohio Department of Agriculture’s Division of Foods, Dairies, and Drugs embargoed 80,000 bushels of potatoes because of pesticide contamination. DDT, DDE, and dieldrin were stored on an upper floor from where the pesticides were washed down on the potatoes by water used to control a fire.

Governor Issues Proclamation  Michigan Governor William G. Mil- liken declared the week of March 1-7 as Weights and Measures Week throughout the State. In doing so, he pointed out that it is fitting for a time to be set aside once a year to consider the importance of the standards and of the role of the government official in regulating their use for the welfare of the people of Michigan. He also emphasized the necessity for uniform weights and measures standards to maintain orderly and equitable commerce throughout the State.

The first weights and measures statute was enacted in the United States in 1799, and in 1836, Michigan received the official standards. In 1946, the Michigan Legislature enacted statutes relating to weights and measures, and in 1964 updated the law to provide standards for weights and measures and to regulate the packaging and advertising of certain commodities.

State Holds Conference  The Washington State Department of Health held its fifth annual Washington State Interagency Conference on Health Hazards of Pesticides January 7 at Olympia. FDA Seattle District’s Chief Inspector, William G. Kupp, participated with a discussion of FDA’s current programs and policies in the pesticide area.

Damaged Drugs Destroyed  Pennsylvania State Department of Health representatives supervised the burning in a local land fill of an entire carload of extensively damaged drugs, both prescription and nonprescription, following a fire at the Pennsylvania Railroad yard at Harrisburg. The drugs, valued at approximately $750,000, had been shipped by Wyeth Laboratories and were destined for one of the firm’s distribution houses.

Fire Leads to Destruction  Joint surveillance by Wisconsin Department of Agriculture Inspectors and FDA’s Minneapolis District Inspectors following a fire which partially destroyed the Larson Canning Co., Green Bay, resulted in the voluntary destruction of over a million cans of assorted vegetable products.

State Embargoes Shrimp  The State of Illinois embargoed a truckload of approximately 30,000 pounds of shrimp that had been involved in an accident near Mount Vernon, Ill. A State Inspector supervised segregation of the load and destruction of about 720 pounds of the shrimp on which diesel fuel had been spilled. The remainder of the shipment was to be returned to Brownsville, Tex., for further reconditioning under monitoring by the FDA Dallas District.

Board of Health Acts  The Chicago Board of Health embargoed all stock in a burned-out drug production plant following a fire which gutted the Medical Chemical Corp., at Chicago. Although finished products in the warehouse section were not directly damaged, prescription drug protection and quarantine areas were completely destroyed and raw materials and containers in the storage room were damaged by smoke and water. The embargoed stock included approximately 600 cartons of raw materials and 800 cartons of finished drugs.
seizures and post office cases

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

A total of 39 seizure actions to remove adulterated, misbranded, and unsafe products from the consumer market were reported in January. These included 25 seizures of foods: 10 because of poisonous and deleterious substances, and 15 because of contamination. Other seizures included 10 of drugs, and 4 of hazardous substances.

<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEADED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfalfa hay/El Cajon, Calif. 12/20/68 (2 shipments)</td>
<td>Gwynn Land &amp; Cattle Co./Yuma, Ariz. (S)</td>
<td>Contains toxaphene, a pesticide chemical not in conformity with regulations.</td>
</tr>
<tr>
<td>Carrots/Detroit, Mich. 12/20/68</td>
<td>John Jacobs Farms/Phoenix, Ariz. (M, S)</td>
<td>Contain endrin, a pesticide chemical not in conformity with regulations.</td>
</tr>
<tr>
<td>Detroit, Mich. 12/23/68 (2 shipments)</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
<tr>
<td>Pittsburgh, Pa. 12/27/68</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
<tr>
<td>Chelsea, Mass. 12/23/68</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
<tr>
<td>Buffalo, N.Y. 1/6/69</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
<tr>
<td>French-fried potatoes/Baltimore, Md. 1/13/69</td>
<td>J. R. Simplot Co./Caldwell, Idaho (M, S)</td>
<td>Contain ammonia.</td>
</tr>
<tr>
<td>Thyme/Brooklyn, N.Y. 1/15/69</td>
<td>Sokol &amp; Co./Chicago, Ill. (S)</td>
<td>Contains Salmonella.</td>
</tr>
</tbody>
</table>

Food / Poisonous and Deleterious Substances

- Alfalfa hay was contaminated by toxaphene, a pesticide chemical.
- Carrots were contaminated by endrin, another pesticide chemical.

Contamination, Spoilage, Insanitary Handling

- Chicken seasoning mix coating, cracker meal, hush puppy cornmeal mix, sweet dairy whey were held under insanitary conditions and contaminated by insects and cockroach excreta pellets.
- Eggs were decomposed.
- Ocean perch were prepared and packed under insanitary conditions and contained E. coli excessive coliforms.
- Pecans, mixed nuts were insect contaminated, moldy, rancid, shriveled nuts and empty shells.
- Rice, purified bran, cracked wheat were held under insanitary conditions and rodent contaminated.
- Seafood patties were high bacterial count.
- Shrimp were prepared and packed under insanitary conditions and coagulase positive staphylococci.
- Tomato sauce was decomposed.
<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conjugated estrogens/Mansfield, Ohio 12/27/68</td>
<td>Plymouth Laboratories, Inc./Plymouth, Mich. (M, S)</td>
<td>Methods used, facilities, and controls not in conformity with good manufacturing practice.</td>
</tr>
<tr>
<td>K.O. gray hair preparation/Eau Claire, Wis. 1/17/69</td>
<td>Laser Laboratories, Inc./Minneapolis, Minn. (M, S) National Products Co., Inc./Eau Claire, Wis. (D)</td>
<td>False and misleading claims to be effective to restore natural color to gray hair, treating, controlling, and destroying dandruff; new drug not approved for safety and efficacy.</td>
</tr>
<tr>
<td>Mevatinic-C tablets/Chicago, Ill. 1/14/69</td>
<td>Formulations, Inc./Milwaukee, Wis. (M, S)</td>
<td>Prepared under insanitary conditions.</td>
</tr>
<tr>
<td>Nail Therapy/Wichita, Kans. 1/22/69</td>
<td>Bee Gee Laboratories/Los Angeles, Calif. (M)</td>
<td>New drug not approved for safety and efficacy.</td>
</tr>
<tr>
<td>Nitroglycerin USP/Los Angeles, Calif. 12/4/68</td>
<td>Dealer/Los Angeles, Calif.</td>
<td>Below USP standard of strength.</td>
</tr>
<tr>
<td>Norhist-8 (chlorpheniramine maleate USP) lot 1275/Norfolk, Va. 1/28/69</td>
<td>American Tablet &amp; Capsule Co., Inc./Brooklyn, N.Y. (M, S)</td>
<td>Below labeled quality, fail to disintegrate completely; label statement &quot;Timed Disintegration Tablets <strong>Chlorpheniramine Maleate</strong> U.S.P.&quot; is false.</td>
</tr>
<tr>
<td>Rabro tablets/Aurora, Ill. 1/14/69</td>
<td>Orbar International, Ltd./Aurora, Ill. (D)</td>
<td>New drug not approved for safety and efficacy; inadequate directions for use.</td>
</tr>
<tr>
<td>Rauwolfia serpentina capsules/Dayton, Ohio 12/17/68</td>
<td>Shaw Pharmacal Co./Maryland Heights, Mo. (M, S)</td>
<td>Below labeled strength; methods used, facilities, and controls not in conformity with good manufacturing practice.</td>
</tr>
<tr>
<td>Racing Fuel/Seattle, Wash. 1/13/69</td>
<td>Francisco Laboratories/Los Angeles, Calif. (M, S)</td>
<td>&quot;</td>
</tr>
</tbody>
</table>

**HAZARDOUS SUBSTANCES**

**POST OFFICE DEPARTMENT**

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

Complaints Filed by the General Counsel Under 38 U.S.C. 4005 (Fraud)

February 5, 1969: JMBF, San Jose, Calif. Solicitations of orders and sale through the mails of instructions on aphrodisiacs (for women).

February 10, 1969: Specialties, Seattle, Wash. Solicitations of orders and sale through the mails of a drugless method to stop headaches and of an herb tea to correct kidney and gallstone conditions.
NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

Alfalfa hay, at Ontario, C. Dist. Calif. Charged 4-16-68: when shipped by Archie Mellon, Yuma, Ariz., the article contained a quantity of the pesticide chemical parathion in excess of the tolerance; 402(a)(2)(B). Default decree ordered destruction. (1)

Egg and sirup blend, frozen, Fortex, at Detroit, E. Dist. Mich. Charged on about 12-5-66: when shipped by Dallas Egg Products Corp., Zanesville, Ohio, the article contained the added poisonous and deleterious substance Salmonella micro-organisms; 402(a)(1). Default decree ordered destruction. (2)

Seafood dinners, frozen, and crabcakes, frozen, at Salem, W. Dist. Va. Charged 3-6-68: when shipped by Henderson's Portion Pak, Inc., Coral Gables, Fla., the seafood dinners contained E. coli, and the crabcakes contained excessive cfu's. The article was packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (3)

Seafood dinners, frozen, and crabcakes, frozen, at Salem, W. Dist. Va. Charged 5-13-68: when shipped for sale, the article contained bacterial filth; 402(a)(3). Default decree ordered destruction. (22)

Walnut halves and pieces, Fein-Pak, at Chicago, N. Dist. Ill. Charged 2-16-68: when shipped by Oregon Nut Exchange, Salem, Ore., the article contained E. coli and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for salvaging. (23)


Waltz, shelled, 2 seizure actions at Cleveland, N. Dist. Ohio, and Milwaukee, E. Dist. Wis. Charged 5-14-68 and 5-3-68: when shipped by Woodland Nut Co., Woodland, Calif., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (25)

Walnuts, unshelled, at Eldorado, E. Dist. Ill. Charged 2-27-68: while held by Federal Wholesale Corp., Div. of Scott Lad Foods, Inc., Eldorado, Ill., the article contained rotten filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for reconditioning. (26)

Walnuts, unshelled, almonds, unshelled, and peanuts, unshelled, at Boston, Dist. Mass. Charged 2-7-68: while held by G. Angelo Fruit Co., Inc., Boston, Mass., the article contained rotten filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (27)


FOOD / Economic and Labeling Violations

Apricot halves, canned, at Norfolk, Dist. Nebr. Charged 1-24-67: when shipped by USP Corp., San Jose, Calif., the article, labeled in part “Our Family... Apricots...” Distributed by Nathaniel Conin Company, Minneapolis, Minn., fell below standard of fit, since the article did not contain the maximum quantity of the ingredient which could be sealed in the container without crushing or breaking 403(b)(2). Consent decree authorized donation to public/charitable institution. (30)

Cheese, cheddar, unsalted, at Los Angeles, C. Dist. Calif. Charged 1-15-65: when shipped by L. D. Schreiber Cheese Co., Inc., Green Bay, Wis., the label lacked the complete name of the manufacturer, packer, or distributor, and the article lacked conformity to the standard of identity; salted cheese; 403(k). Default decree authorized release to shipper for salvaging. (31)

Chocolate drink, at Ashtabula, N. Dist. Ohio. Charged 4-8-68: when shipped by Kohnmann's Chocolate Beverage Co., Wampum, Pa., the name “Chocolate Drink” and the label statement “Vanilla” were false and misleading, since the article contained cocoa and vanilla but not chocolate or vanilla; the label lacked the name of the ingredients water and sugar; and the labeling failed to declare the presence of the artificial colorings; 403(a), 403(k). Default decree authorized release to shipper for salvaging. (32)

Noodles, enriched, at South Portland, Dist. Maine. Charged 4-29-66: when shipped by Prince Macaroni Manufacturing Co., Lowell, Mass., the name “Butter & Egg New England Style Noodles” was false and misleading, since the article had no distinctive butter flavor or egg flavor; when prepared and served, the minimum amount of eggs required for enriched egg noodles; and the article lacked conformity to the standard of identity, since it contained butter, skim milk powder, monosodium glutamate (MSG), and flavoring, which ingredients are not permitted; 403(a), 403(g)(1). Default decree authorized destruction to public/charitable institution. (33)

Preserves, strawberry, Featherweight, at Los Angeles, C. Dist. Calif. Charged 4-16-66: when held by Kohok Queen City Seafood Corp., Buffalo, N.Y., after being processed and packed, the article lacked so as to make it appear better or of greater value; and the article lacked conformity to the standard of identity, since the article contained artificial coloring; 403(b)(4), 403(g)(1). Default decree ordered destruction. (34)

Shrimp, breaded, frozen, at Buffalo, W. Dist. N.Y. Charged 3-1-68: when shipped by Chicago Dietetic Supply House, Inc., Chicago, Ill., artificial coloring was mixed or packed in the article so as to make it appear better or of greater value; and the article lacked conformity to the standard of identity, since the article contained artificial coloring; 403(b)(4), 403(g)(1). Default decree ordered destruction. (35)
conformity to the standard of identity, since it was deficient in shrimp material and failed to bear the specified name, breaded shrimp pieces; and the article lacked conformity to the standard of identity, since it was deficient in shrimp material and failed to bear the specified name, breaded shrimp pieces; 403(a), 403(g)(1), 403(g)(2). Default decree authorized destruction to charitable institution. (36)

Spaghetti, canned, at Tulsa, N. Dist. Okla. Charged 6-17-68: when shipped by HLM Products, Alma, Ark., the article, labeled "Cannelloni Pasta and Tomato Sauce . . . " lacked conformity to the standard of identity, since it was deficient in stated ingredients and failed to bear the required nutrients to make the label false, misleading and deceptive; 402(a), 402(b), 403(a), 403(g)(2). Default decree authorized destruction to charitable institution. (36)

SHRIMP PRODUCTS

Shrimp pieces, breaded, frozen, at Los Angeles, C. Dist. Calif. Charged 3-6-68: while held by employers Phoenix Pharmacy, Phoenix, Ariz., the article, labeled "Rose Frozen Shrimp, Inc., Los Angeles, Calif., from shrimp shipped from Panama, the vignette label reading in part "Champion Brand Breaded Shrimp Portions . . . " was false and misleading, since the vignette depicted whole, tail-on breaded shrimp, and the article consisted primarily of shrimp pieces and not conforming to the standard of identity, since it was deficient in shrimp material and failed to bear the specified name, breaded shrimp pieces; 403(a), 403(g)(1), 403(g)(2). Default decree authorized destruction to charitable institution. (36)

Anaphylactic shock treatment kit, at Washington, D. Dist. Md. Charged 11-27-67: while held by Verne's Big Sky Pharmacy, Kalispell, Montana, the complete and accurate receipt and disposition records were not prepared and kept; 301(q)(4). Consent decree authorized the delivery of the drugs to the claimant, Newborn Drug Co., Kalispell, Montana, which had purchased Verne's Big Sky Pharmacy. (48)

Anaphylactic shock treatment kit, or other anaphylactic shock or burn units, at Phoenix, D. Dist. Ariz. Charged 3-6-68: while held by Shears Pharmacy, Phoenix, Ariz., complete and accurate receipt and disposition records of all such drugs were not prepared and kept; 301(q)(4). Consent decree authorized the executive to dispose of我说 that's all.

Prebiotics and probiotics for animals, at Atlanta, Dist. Ga. Charged 1-25-68: when shipped by National Co-Gel Tablets, Inc., Long Beach, Calif., from shrimp shipped from Atlanta, N. Dist. Ga., the article, labeled in part "Gutgard" in connec-
ective for the treatment of hypothyroidism and as a metabolic stimulant, and the Unitrim capsules claimed to be safe and effective for the treatment of obesity; the articles' labeling lacked adequate directions and adequate warnings; 502(a), 502(f)(1), 502(f)(2). Consent decree authorized release to A. F. Electronics, Chicago, Ill., for relabeling. (77)

Posture massage vibrator pad, at Bradentown, D. Dist. Fla. Charged 2-8-68: when shipped by R&B Distributors, Inc., Oklahoma City, Okla., the labeling contained false and misleading claims to aid blood circulation, to revitalize nerves and muscles, and for treatment of arthritis and it failed to bear adequate directions for use, and the label of a portion of the article lacked the name and place of business of the manufacturer, packer, or distributor; Section 502(a). Default decree ordered destruction. (78)

Sleep-and-Slim corset-type garment, at New York, S. Dist. N.Y. Charged 1-11-68: when shipped by Westward Industries, Los Angeles, Calif., the articles were banned hazardous substances, since they were toys which were flammable solids and generated pressure through explosion when ignited; 2(q)(l)(A). Default decree ordered destruction. (80)

Ulra Tan sun-lamp cabinet, at Kansas City, W. Dist. Mo. Charged 3-28-68: when shipped by American Ultra Tan & Sauna Co., Burbank, Ind., the labeling contained false and misleading claims for being an integral and necessary part of a diet plan for reducing, relieving "cramps" in the legs, resisting tooth decay, for eliminating the need of drugs, and for treating all body maladies, pneumonia, diabetes, gastric ulcers, heart disease, and other conditions; 502(a). Default decree ordered destruction. (81)

Hazardous Substances

Aerial bombs and other Class B fireworks, at Hamer, Dist. S.C. Charged 1-10-68: when shipped by L. Taylor Inc., Spartanburg, S.C., American Importers, Inc., Florence, Ala., and other unknown shippers outside the State of South Carolina, the articles were banned hazardous substances, since they were toys which were flammable solids and generated pressure through explosion when ignited; 2(q)(l)(A). Default decree ordered destruction. (82)

Cherry Bombs, at Waynesville, W. Dist. Mo. Charged on or about 6-30-68: while held by a fireworks stand, Waynesville, Mo., the articles were banned hazardous substances, since they were toys which were flammable solids and generated pressure through explosion when ignited; 2(q)(l)(A). Default decree ordered destruction. (83)

Cherry Bombs and other Class B fireworks, at Lebanon, W. Dist. Mo. Charged 6-24-68: while held by Anthony Products Co., El Monte, Calif., the article was a flammable substance in self-pressurized containers and was a toxic substance presenting a special hazard, and the article lacked required conspicuous label statements, lacked the statement of hazard "Flammable" on the main panel of the label, and the label required the term "Warning" on the secondary label; Section 502(a). Default decree ordered destruction. (84)

Color Spray enamel, at Jacksonville, M. Dist. Fla. Charged 2-15-68: when shipped by Chase Products Co., Broadview, Ill., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (85)

Super Absorption iron injection for horses, at Oklahoma City, W. Dist. Okla. Charged 12-7-67: when shipped by Anthony Products Co., El Monte, Calif., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (74)

Drugs

Drug/Veterinary

Drugs

Nyscaps capsules and A.P.C. tablets, N.F., at Elgin, N. Dist. III. Charged 4-23-68: when shipped by Nysco Laboratories, Long Island City, N.Y., the strength of the A.P.C. tablets differed from N.F. standards, since the average capsule weight by more than 10 percent—501(b), and while held by Joseph W. Blaszczak, D.V.M., Queens, N.Y., the article was a new drug without an effective approved New Drug Application; 505(a). Consent decree authorized release to Peter B. Wadman, d/b/a Universal Distributors, Denver, Colo., for relabeling. (75)

Coraline juicer, at Culver City, D. Dist. Calif. Charged 3-11-68: when shipped by Ketol, Ltd., Aarbog, Switzerland, the labeling lacked adequate warnings against use over swollen or inflamed areas, skin eruptions, or unexplained pain; 502(a), 502(f)(2). Consent decree authorized release to shipper for relabeling. (76)

Cherry Bombs and Silver Salutes, and other Class B fireworks, at Howardsville, E. Dist. Mo. Charged 2-11-68: when shipped by C&M Engineering, Inc., Oklahoma City, Okla., the labeling contained false and misleading claims to aid blood circulation, to revitalize nerves and muscles, and for treatment of arthritis and it failed to bear adequate directions for use, and the label of a portion of the article lacked the name and place of business of the manufacturer, packer, or distributor; Section 502(a). Default decree ordered destruction. (86)
statement “nontoxic" negated and disclaimed the required label statements; 2(p)(1), 2(p)(2), 3(b). Default decree ordered destruction. (87)

Cracker Ball ball-type explosive caps, at Lebanon, N. Dist. Ohio.

Charged 6-25-68: when shipped by F. M. West, Lebanon, Tenn., and Consignedsales Co., Kansas City, Mo., the articles were extremely flammable solids and generated pressure through explosion when subjected to friction or percussion, and their containers lacked required conspicuous label statements; 2(p)(1), 2(p)(2), 3(b). Default decree ordered destruction. (87)

Latic Key appealed on ground involving the denial of a continuance, the admissibility of incriminating statements and admissions of codefendants, the repeated claims by Government agents to the defendants' place of business, the failure of an alleged witness to the essential elements of the crime. The Court of Appeals for the Sixth Circuit held that the defendants' counsel could not be heard to claim that answers to a motion for further particulars came too late to be of use without a continuance, and that the defendants' motions for continuance were not supported by any affidavit. The court agreed that the defendants must be admitted to a joint trial and there was no claim that the trial judge had not properly instructed the jury that such evidence was not to be considered in determining the defendant's guilt or innocence, and that the information upon which Latic Key was convicted had arisen out of their receipt of drugs personally illegally dispensed (counts 11, 12, and 14); that the altered invoice was apparently known to the defense and was in the evidence against them; and that the defendants' counsel had proved and needed only to prove that the drug had been shipped in interstate commerce for sale.
FOOD MANUFACTURERS, PROCESSORS & PRODUCERS
GIVE YOUR WALLS A VOICE

Maintain required storage temperatures.

Make sure equipment is working properly.

Sanitizing hands after washing, as required.

Communicating with employees is a full-time business, and an important one, especially in your industry. To help you, FDA’s Division of Industry Services has designed a 2-color, four-part poster series on sanitation guidelines in the food industry.

Each set offers guidelines in a different area of the food industry: plant employees, raw materials, processing, and finished products. Each set has one master poster (16" x 20") listing sanitation guidelines, and several companion posters (8" x 10") illustrating these guidelines. Each set is color coded for easy identification.

Order your poster series from the Government Printing Office, Washington, D.C. 20402. Sanitation Guidelines for Plant Employees—12 posters $0.65, Sanitation Guidelines for Raw Materials—12 posters $0.65, Sanitation Guidelines for Food Processing—9 posters $0.55, Sanitation Guidelines for Finished Products—8 posters $0.50 OR—all four sets $2.35.
**Announcements**

**NEW FDA FACILITY** A new FDA Docket Clerk's Office has been set up to facilitate the handling of public requests for legal information connected with its regulatory hearings.

The new office maintains all records connected with hearings conducted by FDA, including such documents as Federal Register announcements and publications, transcripts of testimony, volumes of exhibits, files containing motions, memoranda, and briefs, and the orders issued by the Agency's Hearing Examiner.

Once FDA publishes a formal hearing notice in the Federal Register, all records concerning the matter are transferred from the Department of Health, Education, and Welfare's Hearing Clerk's Office to the FDA Docket Clerk's Office. Upon termination of the case and the submission by the Agency's Hearing Examiner of his decision or report, the records are returned to the Department for permanent custody.

The FDA facility is open from 9 a.m. to 5:30 p.m., and provides adequate accommodations for the review of public documents. It is located in Room 3015, Federal Building 8, 200 C Street, S.W., Washington, D. C. 20204.

**AFDOUS ANNUAL CONFERENCE** The Association of Food and Drug Officials of the United States will hold its 73rd Annual Conference June 16-19 at the Eden Roc Hotel, Miami Beach, Fla. This year's program will feature presentations by Federal, State, local, and industry officials and by members of the academic and medical community.

In addition, the Harvey W. Wiley Award Dinner—a highlight of the conference—will be held. The Wiley Award is presented annually to a member of the Association in recognition of his outstanding contributions in the field of food, drug, and cosmetic law enforcement.

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

**SCHEDULE OF FDA WORKSHOPS AND REGIONAL CONFERENCES MAY 1969**

<table>
<thead>
<tr>
<th>FDA District</th>
<th>Date</th>
<th>Location</th>
<th>Subject Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minneapolis</td>
<td>May</td>
<td>Madison, Wis.</td>
<td>Bacteriological Problems in Canning Industry</td>
</tr>
<tr>
<td>Buffalo (jointly with Detroit District)*</td>
<td>May 8</td>
<td>Pittsburgh, Pa.</td>
<td>Hazardous Substances</td>
</tr>
<tr>
<td>Northwestern University/ FDA/FDLI*</td>
<td>May 10</td>
<td>Chicago, Ill.</td>
<td>GMP—Drugs</td>
</tr>
</tbody>
</table>

*Seminars