STATE - FDA
PERSONNEL EXCHANGE

PROGRESS IN FOOD

Essential Trace Elements

THE BLUE CRAB
"We are carefully to preserve that life which the Author of nature has given us, for it was no idle gift."

Harvey W. Wiley, 1844-1930
Father of the Federal Food and Drugs Act of 1906
From his commencement address
“Life and the Coming Time”
Hanover College, 1867
Procedures set up by this administration will allow a fair and equitable resolution of these problems in the months ahead. No precipitate actions will be taken and whatever actions are taken will be guided by the results of detailed and fair analysis of adequate scientific data. Given the magnitude of the task we feel that in all fairness industry should be given a reasonable amount of time in which to provide such data.

"A new and high standard has been established for establishing proof of drug efficacy. This alone should be a major factor in improving therapeutics in this country. In time, ineffective drugs and irrational formulations will be removed from the market. The effective drugs remaining will be clearly and accurately labeled so that physicians will have available to them the balanced information they need for rational drug use. Where possible this information will be derived from adequate and well controlled clinical studies."

Henry E. Simmons, M.D., Director, Bureau of Drugs, at the American Society for Clinical Pharmacology and Therapeutics, Atlantic City, New Jersey, April 30, 1971.

The so-called Swann Report: 'Joint Committee on the Use of Antibiotics in Animal Husbandry and Veterinary Medicine Report,' which was released November 1969, has sounded a clear warning of the threat of microbial resistance to antimicrobial drugs. A task force of the Food and Drug Administration is completing an evaluation of the potential threat of infectious resistance in this country; this report should be available soon and it will add to the urgency for holding as small as possible the substrates infected with microbial organisms.

Dale R. Lindsay, Ph.D., Associate Commissioner for Science, at the opening session of the American Public Health Association, Denver, Colorado, April 5, 1971.
State-FDA Personnel Exchange  Under a new law, Federal and State staffers can learn more about the importance of working together.

The Essential Trace Elements  More and more is being found out about the role of trace elements in nutrition.

Food in Flight  Assuring sanitation of food and drink served to air passengers.

The Blue Crab Industry  The nature of the product and the way it's used makes proper sanitary practices essential in processing.

The Challenges of Progress in Food  Some suggestions for industry to meet changing conditions.

Field Reports
Product Safety Report
News Highlights
State Actions
Seizures and Postal Service Cases
Notices of Judgment
by H. Thompson Price, Jr.

A new chapter in State-Federal cooperation, authorized by the "Inter-governmental Personnel Act of 1970," was initiated May 3 when FDA's Baltimore District and Virginia's Department of Agriculture and Commerce began the first phase of a supervisory inspector exchange. Field Supervisor Howard R. Haynie of VDAC's Food Regulatory Section has been detailed to Baltimore District's Inspection Branch from May 3 through June 25. The current plans are to complete the exchange this fall with the assignment of a Baltimore District supervisory inspector to VDAC in Richmond.

Such an exchange, the first of its kind for FDA, is intended to foster even closer relations between Virginia and FDA and help both agencies improve the effectiveness of their consumer protection programs.

The new landmark legislation is Public Law 91-648, signed by President Nixon on January 5, 1971. It was passed by the 91st Congress to improve intergovernmental cooperation between the Federal Government and State and local governments. Title IV of the Act provides for the temporary assignment of personnel between Federal and State or local agencies. The Congress recognized "that effective State and local governmental institutions are essential in the maintenance and development of the Federal system in an increasingly complex and interdependent society." Section 3 states that "the authorities provided by this Act shall be administered in such manner as (1) to recognize fully the rights, powers, and responsibilities of State and local governments, and (2) to encourage innovation and allow for diversity on the part of State and local governments in the design, execution, and management of their own systems of personnel administration."

The key word is innovation. This exchange will permit both the State and FDA to get a closer look at one another. It will provide an opportunity for both to reevaluate the effectiveness of current cooperative programs with an eye toward innovative changes which will strengthen and streamline existing programs to an even greater degree and assure improvement in the accomplishment of consumer protection objectives.

The Virginia Department of Agriculture and Commerce, under the leadership of Commissioner Maurice B. Rowe, has been a leader among State agencies across the United States from the earliest conception of cooperative State-FDA inspectional programs. VDAC's Division of Regulatory Services, directed by B. W. Southall, entered into agreements with Baltimore District in 1968 and 1969 to assume major responsibility for inspectional coverage of food warehouses, bakeries, bottling plants, candy firms, flour mills, and canneries throughout Virginia. An earlier such arrangement, beginning in 1967, covers medicated feed mills.

Baltimore's Inspection Branch has worked closely with A. Lee Turner, supervisor of the Division's Food Section, in administering and strengthening the effectiveness of the food programs. Mr. Turner, who is current president of the Association of Food and Drug Officials of the United States, has been largely responsible for encouraging the continued improvement of cooperative programs and has enthusiastically supported this new venture.

During his detail Mr. Haynie will be assigned to the Baltimore District office under the direction of M. L. Strait, deputy regional food and drug director, Region III, and under the immediate supervision of Baltimore's Inspection Branch chief, J. Donald Sherry. He will work closely with the supervisory inspector who coordinates the cooperative programs with Virginia. He will be exposed to FDA procedures through actual participation in District operations.

Mr. Haynie will learn about
In Richmond (top photo), an agreement for Howard R. Haynie (left), field supervisor, Food Regulatory Section, Virginia Department of Agriculture and Commerce, to participate in State-Federal personnel exchange, is signed by VDAC Commissioner Maurice B. Rowe (center) in the presence of M. L. Strait (right), deputy regional food and drug director heading FDA's Baltimore District. In a Richmond beverage bottling plant (second from top), Mr. Haynie (right) instructs VDAC Inspector-Trainee James Curtis. Here they examine bottles before filling for foreign objects and for chips and cracks. Mr. Haynie (left) and Mr. Curtis, in the same plant (third from top), check the strength of a caustic cleaning agent used in the bottle soak solution by adding a reagent. At a bottle filling machine in the plant (bottom left), Messrs. Haynie (in hard hat) and Curtis (left) watch employees operate the equipment. Back at the office (bottom center), Mr. Haynie (left) makes observations on the inspection to his boss, A. Lee Turner, supervisor of VDAC's Food Regulatory Section. Later on, in a conference at the Richmond office (bottom right), Mr. Haynie (center) talks about the scheduling of inspections with Mr. Turner (left) and Ray Vanhuss (right), assistant supervisor of the Food Regulatory Section.
At FDA's Baltimore District (top left), M. L. Strait (right), deputy regional food and drug director, welcomes Mr. Haynie as he begins his period of familiarization training with the Agency. Gathering (above, right) to talk shop with Mr. Haynie (right) are J. Donald Sherry (center), chief inspector, Baltimore District, and H. Thompson Price, Jr., supervisory inspector. Mr. Haynie (third from right) sits in on a Baltimore District staff meeting (second from top, right) called by Deputy Regional Food and Drug Director Strait (end of table). Some details of a legal case are explained (below, top left) to Mr. Haynie (left) by Norman Kramer, Ph.D. (center), chief of the Compliance Branch, and Robert Case (right), food and drug officer. In the District's microbiology laboratory (below, bottom left), Mr. Haynie (third from left) watches microbiologist Joseph Taddio (second from left) count bacterial colonies during examination of a food sample as the technique is explained by William O. Hebert (left), supervisory microbiologist. Microbiologist William Jordan (right) is using a microscope. At Baltimore District terminal connected to a computer system at FDA headquarters in Washington (below, right), Mr. Haynie discusses the system with Irene Cheswick, project planner.
FDA's automatic data processing system by helping prepare annual and monthly operational plans and schedules and by working in the District's data processing unit during the actual processing of data and preparation of information printouts. His orientation in this data processing will be completed during a tour in FDA's headquarters in Rockville, Maryland, where he will be shown the uses made of information retrieved from its system.

VDAC's inspection reports have been feeding information into FDA's system for two years. Observation of the uses made of data so compiled may enable the State to discover possible uses in its own planning and budgeting operations for the information it supplies for FDA's system.

With the completion of the exchange in the fall, the two agencies hope they will have gained sufficient information about their respective systems to permit a merger of planning operations. The resulting increase in compatibility would facilitate future information and data exchange.

Mr. Haynie's experience will extend into the several major phases of an FDA District operation—inspectional, analytical, regulatory, and administrative. During his detail he will accompany inspectors during food plant inspections and sample collections, will work with microbiologists in the examination of food samples for bacteriological contamination, will assist a supervisory inspector in report review and endorsement, will note the food and drug officer's function in initiating impact actions, and will observe the administrative functioning of the office through attendance at staff meetings and planning sessions.

An area of increasing concern to VDAC is bacteriological contamination of food products and its documentation during inspections. Mr. Haynie will accompany an inspector-microbiologist team from the District office during an inspection of a seafood processing firm. He will assist in the collection of in-line samples, observing FDA's aseptic sampling procedures at first hand. He will follow the movement of a sample from the collection through completion of its examination in the microbiology laboratory. Likewise, he will work with the inspector in writing the report and with the supervisor responsible for its endorsement in reviewing the report and recommending action.

If legal action is indicated because of inspectional or sample results or both, he will learn FDA's procedure for initiating legal action by working in the District's Compliance Branch during the completion of the report's processing.

VDAC is also interested in the extent of coverage by FDA of the usage of colors and food additives in food products. Mr. Haynie will be along during an inspection of a bakery to observe the methods an inspector uses to determine the levels of additives used in the bakery's products.

Mr. Haynie is responsible for the field training of VDAC inspectors. His experience with Baltimore District will enable him to supplement the training his inspectors have received from FDA inspectors and university professors. He will also learn about FDA training programs and methods. In the training area an exchange of methods should benefit both agencies as the Baltimore District learns more about VDAC training programs.

A week's trip to a District resident post will provide Mr. Haynie with insight into the maintenance of an inspection office away from the District office. He will observe communication and supply lines between the post and the District and will learn how problems of sample shipment to the District laboratories are resolved. Here, too, exchange of ideas may lead to benefits for each agency, since VDAC inspectors are also stationed away from the home office and laboratories.

During the detail he will have the opportunity to meet officials of other States in the District and will thus learn of formats and procedures different from VDAC's that might be advantageously applied to its operations. Such encounters could tend to strengthen FDA's agreements with other States through discussions about the mutual rewards of a successful viable program such as that currently enjoyed with VDAC.

Mr. Haynie's attendance at two professional association meetings—Baltimore Conference of Food and Drug Officials in Baltimore June 8 and Central Atlantic States Association of Food and Drug Officials in Philadelphia May 26-28—will also give him an opportunity to meet and exchange views with officials from neighboring States in other FDA Districts.

The detail will conclude with a week at FDA's headquarters in Rockville and Washington. During his time in the Office of the Assistant Commissioner for Field Coordination, Mr. Haynie will learn something of the relationship between headquarters and FDA's Field Districts. In his work with the State Services Staff of ACFC, he will become familiar with the nationwide relationships that exist between FDA and its counterpart agencies in the States. Mr. Haynie also will spend time in other headquarters offices working with compliance officers and learning about FDA's regulatory philosophies and procedures.

If this first exchange of personnel between FDA and a State agency is successful in achieving this Agency's objective of producing a more effective force for consumer protection, it may signal the way for similar exchanges that will further strengthen State-Federal cooperation to the consumer's benefit.
The Essential Trace Elements

by M.R. Spivey Fox, Ph.D.
Among the elements and minerals that are required for optimal health of human beings, there is a group that is known as the “trace” elements. These include chromium, selenium, fluoride, molybdenum, copper, zinc, iron, iodine, and manganese. There is some evidence that tin, nickel, and vanadium may soon be included in this list. The essential trace elements are so named because each element is itself required in the diet and the quantities needed are very small, “trace amounts.” The daily requirements for man range from a few micrograms for the first named elements above to a few milligrams.

The Food and Drug Administration sets standards for the addition of specific nutrients to certain foods, such as the addition of iron to some cereal products. To carry out this activity a broad base of scientific information is required. This includes knowledge of dietary intakes by the U.S. population, incidence of nutritional deficiencies, the many facets of nutrient requirements, effect of environmental toxicants on nutrient need, and the nutrient composition of foods.

Functions in the Body. The trace elements have unique chemical properties that set them apart from other required nutrients. Most of these elements never occur in free form in the body. They bind chemically to an extensive range of organic compounds but each element usually prefers to bind to specific types of chemical groups that are part of large organic molecules. Thus the trace elements are generally dependent on organic molecules for transport, storage, and actual function. This characteristic binding behavior can lead to antagonisms if high amounts of some nonessential and essential elements are present in the diet.

Like the vitamins, which are also required in small amounts, the trace elements function in many types of chemical reactions in the body. In many cases, the elements function in maintaining the proper structural configuration required for enzymic activity in carrying out these reactions. Other functions of trace elements involve important physiological processes, such as transport of glucose across cell membranes. As a result of some of these fundamental processes, the trace elements perform functions of prime significance in every tissue and organ of the body. Deficiencies of individual elements can result in such diverse abnormalities as extreme tiredness, anemia, one type of diabetes, delayed sexual development, impaired wound healing, and goiter.

Detailed consideration of the nutritional significance of all the trace elements is too extensive to present here. Rather, we will consider FDA activities and important related information.

Research on Trace Elements. An active research program on the human requirement of trace elements has been under way for several years in the Division of Nutrition. We have studied iron, zinc, selenium, and...
chromium as well as effects of the environmental toxicant cadmium, which interferes with metabolism of the required elements. Much of the work has been carried out with experimental animals in our own laboratories; however, we also have investigated human deficiencies of trace elements in Jordan, Nigeria, and Iran. This work was done in cooperation with scientists in those countries and elsewhere in the United States.

Some of these studies on each element are described below.

**Iron.** It has been recognized for many years that anemia responsive to iron therapy does occur in the U.S. population. The most vulnerable groups have been considered to be infants, young children, and women of the childbearing age. Results from the National Nutritional Survey, conducted in the late 1960's and directed by Dr. Arnold E. Schaefer of the Health Services and Mental Health Administration, show that anemia is quite common in many geographic regions. It occurs both in families that are victims of poverty and those that are not, affecting men as well as women and children.

Concern about the anemias has prompted a reevaluation of the iron enrichment of flour and cereal products. Extensive evaluation of the iron compounds suitable for such purposes has been carried out in the Division of Nutrition. A wide range of iron compounds and the naturally occurring iron found in selected foods have been investigated. Studies with chicks and rats have shown that the relative utilization of iron from various compounds and foods ranges from near 0 to 100 percent, when compared with ferrous sulfate, an optimally available form of iron. Approximately 15-50 percent of the ferrous form is absorbed, depending on the dose and physiological condition of the animal. Ferric orthophosphate and sodium iron pyrophosphate, which are widely used to fortify cereals, were very poorly available in animal studies of the compounds themselves. From the range of compounds tested it has been possible on a preliminary basis to identify good, mediocre, and poor sources of iron. This type of information is very valuable in revising standards for iron enrichment of cereals, but must first be extended to include studies of enriched food products and of assimilability in man.

**Zinc.** For many years it was said that there was no evidence of zinc deficiency in the United States. Studies of delayed wound healing and loss of sense of taste, both of which respond to supplemental zinc, suggest that zinc intake of the general population may not always be adequate.

A severe form of zinc deficiency in the Middle East causes dwarfism and markedly delayed sexual development in both boys and girls. Dwarfism in Iran affects about 4 percent of the boys and an undetermined number of girls.

---

*At left, an animal caretaker collects Japanese quail eggs from the breeding colony. The eggs are used for hatching to keep a supply of birds on hand for trace elements study. At right, samples of tissue from a Japanese quail are “wet ashed.” In this procedure the tissues are mixed with nitric acid and heated in vials to free trace metals from tissue for atomic absorption analysis.*
Scientists from the Division of Nutrition cooperated with scientists at Pahlavi Medical School in Shiraz, Iran, and the Veterans Administration Hospital in Washington to investigate the presence of less severe forms of zinc deficiency in Iran. One study involved a supplementation program of moderately malnourished Iranian boys, aged 12-14 years. It was shown that zinc given with a concentrated supplement of other essential nutrients increased the rate of sexual development over that produced by the essential nutrient supplement without zinc. This study shows that dietary zinc is important for men and suggests that marginal zinc deficiency in forms less severe than dwarfism is widespread in the Middle East. Zinc deficiency may contribute to retarded growth in this country; however, this has not been investigated. In experimental animals we have found that dietary protein can rapidly decrease the plasma level of zinc. We are investigating this further to standardize conditions for using plasma zinc level as an indicator of zinc nutriture of an individual. We also are investigating the possibility that protein (or the constituent amino acids) may influence zinc requirement.

The metal cadmium is an environmental contaminant that has long been known to be an antagonist of zinc. Cadmium has been postulated as being an etiological factor in hypertension in the general population. Industrial workers exposed to relatively large amounts of cadmium may develop anemia, kidney damage, and respiratory problems. There is no known beneficial effect of cadmium in the body, although such a possibility cannot yet be excluded. Small amounts of cadmium enter the body from the air, cigarette smoke, and water, but the principal direct source is from foods. The quantities are quite low in most foods. Those with the highest concentrations are liver, kidney, and oysters. Cadmium in the soil can be taken up by plants, and animals store small amounts of cadmium in their tissues from foods.

Cadmium, in addition to its effect on zinc, interferes with the metabolism of iron, copper, and calcium. Recently we have found that it also decreases the concentration of manganese in tissues of experimental animals. We found that feeding ascorbic acid markedly improved growth rate and decreased the anemia and poor mineralization of the bone in experimental animals that were fed cadmium. Our work and other studies suggest that adequate intakes of zinc, iron, copper, calcium, manganese, and ascorbic acid are important to resisting the adverse effects of cadmium.

Chromium. This trace element has been shown to be required for normal glucose metabolism in the rat. A scientist from the Division of Nutrition collaborated with investigators in Jordan and Nigeria in assessing the chromium requirement of infants. Infants suffering from a severe form of malnutrition,
kwashiorkor, were the subjects. Glucose tolerance tests showed that glucose utilization was impaired. Supplements of only 250 micrograms of chromium (as trivalent chromium) given with milk in the evening produced an improvement in glucose utilization by the following morning. This finding indicated that the infants were deficient in chromium. In Jordan other malnourished infants from a nearby location had normal glucose tolerance curves. It was found that these infants had a water supply that was high in chromium as compared to low chromium in the water for the other group. All received the same diet. Evidence of chromium deficiency was also obtained in Nigeria.

Selenium. Selenium is an important essential trace element. Selenium deficiency has occurred in significant numbers of lambs in certain areas of the Pacific Northwest where concentrations of the element in the soil and plants are low. A scientist from the Division of Nutrition studied the selenium requirement of infants in Jordan. When infants suffering from kwashiorkor were given adequate calories and protein, their anemia persisted. A small supplement of selenium produced an increase in newly formed red blood cells, suggesting that selenium may be important in red blood cell formation in human beings. It has not been possible to date to carry out extensive studies to firmly establish the effect.

The range between required and toxic intakes of selenium is relatively small. In some areas of the United States excess amounts of selenium occur in soils and in plants grown on them. Studies in the Division of Nutrition have shown that toxicity of selenium in rats may be lessened by diet. Incorporation of linseed oil meal in the diet protected rats against liver damage even though the total quantities of selenium in their livers were two- to four-fold higher than the concentrations of selenium in unprotected rats receiving a casein diet. The reason for the protective effect of the linseed oil meal is not known. It is critical for an animal to receive adequate selenium and it is equally critical that the animal or man be protected from excess intake.

A New Experimental Animal. The use of Japanese quail (Coturnix coturnix japonica) for trace element studies has proved advantageous in the work of the Division. The body weight at hatching is approximately 6.5 grams. The quail grow very rapidly so that they weigh 80 grams by 4 weeks of age. Because of this rapid growth rate, they are very sensitive to nutrient deficiencies. Most of our current experiments can be concluded when the birds are 2 weeks of age. The females begin laying eggs at 5½ to 6 weeks of age, compared with 6 months for chickens.

Since the quail are small, their total requirements for space and diet are quite modest. This results in great manpower and economic savings for FDA through minimizing purification of dietary ingredients and the
problems associated with providing a clean environment uncontaminated by the trace minerals under study. The quail have been used for investigations of zinc, iron, cadmium, manganese, and copper.

**Trace Elements in Foods.** The quantities of trace elements in foods have not been adequately determined and there is no compilation of existing published values. Iron is the only trace element included in Agriculture Handbook No. 8, "Composition of Foods," which was compiled by the U.S. Department of Agriculture. Even though several research workers have assayed a variety of foods for a wide range of mineral elements, this is still an area where a great deal more information is sorely needed. The effects of current agricultural practices and food processing on trace element content of foods have not been adequately evaluated.

Foods that are rich sources of trace elements tend to vary from element to element. One generally good source is the cereal and vegetable seeds. The trace elements are there for a very good reason, to nourish the young seedling during its rapid growth phase before an adequate root system is established. In the case of the cereal grains, the trace elements are concentrated in the germ and bran. Milling and refinement of cereals results in losses of most of the trace elements present in the original grain.

The seeds are also rich in phytic acid, particularly those sites within the seed where the trace elements are found. Phytic acid (inositol hexaphosphate) binds a variety of minerals, particularly calcium, magnesium, and some of the trace elements, and thus can make them unavailable. Phytic acid can decrease the intestinal absorption of zinc in experimental animals. Prolonged moist heat treatment can destroy phytic acid; however, there are still significant amounts present in whole wheat bread. The extent to which phytic acid makes zinc and possibly other minerals unavailable for absorption in man is not known.

**New Foods and Trace Elements.** The vegetable protein products are expected to become important protein sources in the future and they will probably have a significant effect on the trace mineral status of many persons. These products will be prepared from soybeans, cereal grains, and other seeds in varying degrees of refinement. We have analyzed a small number of these products for several elements. The amounts of copper, manganese, and magnesium are several times higher than those in lean meat (calculated on the basis of the same moisture content). The amounts of iron are about the same as meat and there is slightly less zinc. The zinc would probably be less available if phytic acid is also present. Fortification with iron has been considered desirable and it would appear that the same may be true for zinc. It is doubtful that our analyses are adequately representative and the extent to which these
trace elements are available is not known. It appears, however, that these foods could be important sources of trace minerals.

Requirements and Deficiencies in the United States. Iron and iodine are the only trace elements for which recommended dietary allowances have been established by the Food and Nutrition Board of the National Academy of Sciences/National Research Council. Otherwise, a few balance studies are the best guides available to suggest required intakes for manganese, zinc, copper, and molybdenum. The minimal intake for balance may not be adequate for optimal health. The amounts of fluoride in drinking water to prevent dental caries but avoid mottling of tooth enamel are well established. No other clear-cut function of fluoride is known; however, there is information to indicate that high fluoride intake can reduce osteomalacia and aortic calcification in aging individuals. The quantitative requirements of selenium and chromium are unknown.

It has already been noted that iron deficiency is relatively common in this country. Studies of wound healing and the sense of taste suggest that zinc deficiency also occurs. It is possible many cases of diabetes that begin in middle age may be due to chromium deficiency or may at least be related to such a deficiency. We are only now developing the scientific base that will let us assess accurately the nutritional status of population groups with respect to these trace elements.

It is reasonably certain that the health of many persons in the United States could be improved by increasing their intake of some essential trace elements, namely, iron, and possibly zinc. From present knowledge we can take positive steps in requiring fortification of specific foods with some elements. A great deal remains to be learned about requirements of the "newer" trace elements and possibly others that are not yet known to be essential.
As the Federal agency primarily responsible for administering the Interstate Quarantine Regulations, the Food and Drug Administration is charged with assuring that disease is not spread by interstate carriers from one State to another and that the interstate traveler is protected from foodborne disease.

FDA's Interstate Travel Sanitation Branch in the Bureau of Foods carries out this responsibility for the Agency. Although this unit is responsible for protection of travelers on all interstate carriers, in the past several years it has given increased attention to sanitation of food and drink on the Nation's airlines because of the heavy air travel, the large quantity of food prepared for serving aboard airplanes, and the logistics conditions involved that may provide a potential for microbiological or other contamination of food served in flight.

Unlike trains and ships, where food historically has been prepared on board, food served to airline passengers is supplied from catering services on the ground where meals are prepared ahead of time and then held for varying periods to be loaded, in ready-to-eat form, on the plane for serving in flight. The holding of prepared meals introduces the possibility of a potential hazard because the food must be stored, both on the ground and on the plane, under temperatures and other conditions, that will make it safe to eat. The advent of the jumbo plane intensified the problem because in longer flights longer storage is required for greater quantities and varieties of food, often for more than one meal.

The Interstate Travel Sanitation Branch is concerned with the sources, storage, processing, and handling of food and water used aboard aircraft and with sanitary disposal of wastes. It is responsible for assuring that design, performance, and operation of equipment used by the caterers and the airlines are in compliance with the requirements of the Interstate Quarantine Regulations and FDA equipment standards for cleanability and for nontoxicity of surfaces that come in contact with food and water. It is concerned with the times for which and temperatures at which food is held, and with the individual sanitary practices of catering and in-flight personnel who prepare and serve food and drink. The unit also conducts educational programs aimed at teaching proper food handling and storage methods to these personnel. In short, the unit seeks to assure proper and sanitary handling from source to consumption to assure the air traveler that the food and drink he is served aboard the aircraft is wholesome and safe.
Examining the area where an airline catering establishment receives and stores raw food materials, the FDA sanitarian checks for proper storage of food products, evidence of insect or rodent infestation, and cleanliness of the area.

In the catering firm's refrigerated storage area (above), the sanitarian examines the labels of milk to assure that the producer's name is on the list of approved sources. In the cold storage area (right) he makes similar checks, in this instance, of a special frozen meal prepared in a kosher food plant that is on the list of approved sources.
Where large numbers of meals are prepared (above), a food catering firm's food preparation area may be quite large. This firm is capable of preparing 20,000 meals a day. The FDA sanitarian notes the temperature of entrees prepared and waiting on a table (top left), then (bottom left) observes the sanitary conditions under which two employees (on either side) wrap the entrees in metal foil.
In another part of the food preparation area (top left), the sanitarian (in hat) observes the loading of a tray with items other than the entree (cup, silverware, napkin, roll, etc.), completing a tray setup to which entree will be added aboard the plane. The sanitarian checks the condition and appearance of desserts (top right) stored on trays in bulk refrigeration before they are placed on tray setups. In this check of refrigeration equipment at the catering establishment (left), the sanitarian has just removed his own thermometer from refrigeration unit after allowing it to reach temperature inside the unit and is checking it against the thermometer on the refrigerator unit for accuracy of the latter. With the manager of the catering firm (below, left), a sanitarian (at left) examines the functional design and cleanliness of tray carriers or modules. An employee of the firm charges galley modules with dry ice (below) to maintain refrigerated temperatures. The modules, with the food they contain, are loaded intact on the plane.
Two FDA sanitarians examine the interior of one of the modules (left). These modules, in the top part, contain such items as beverages, entrees, and other items. At bottom they hold serving carts loaded with tray setups. These are the same carts that the airline stewardess will roll down the aisle to serve passengers. As dishes emerge from a dishwasher (below), the two FDA sanitarians, with the catering firm's manager (center), visually examine a dish as a check on the machine's performance.

After the meals are assembled and placed in modules, they are held in a refrigerated area (left) at a temperature of 45°F or lower pending transportation to the aircraft. Here the sanitary checks temperature. Frozen foods similarly are held in freezers. Aboard the vehicle (above) that transports assembled meals to aircraft, the sanitary checks general conditions such as protection of food from contamination and maintenance of refrigerated temperatures.
After his inspection of the catering establishment, the sanitarian meets with the firm's manager (below) to report the conditions he has noted. On board the aircraft (right) the sanitarian examines the galley equipment for cleanliness and performance. Here he is looking at an oven with the airline's service representative (at left), who coordinates loading of food on the plane and is responsible for sanitation of galley areas.

The stewardess removes tray setups from the refrigerator (above) and will add the entrees, which are being heated in high-speed electric convection ovens. The food finally reaches its destination as the stewardess (center, right) serves meal to an air passenger. The sanitarian observes the sanitary methods used in removing lavatory wastes from a large airplane to a truck (right). He also checks the loading of potable water aboard the aircraft.
The Blue Crab Industry

by G. Edward Damon

Man has learned much about crabs since their first meeting—from how not to hold a live and unhappy crab to how to enjoy crabmeat in many ways.

Crabmeat is a delectable food, the subject of much praise both historical and promotional. For example, according to "Ye Maryland Chronicle," a featured column in the Baltimore Sun in 1933, a yearning for the bountiful Maryland crab was the main reason for Captain John Smith's visit to the Chesapeake Bay in 1607, and Lord Baltimore first smacked his lips over Maryland crabcakes in 1634.

It is true that crabs were so abundant and easily caught in the early days that the only market for so common a product was in the big cities. Prior to 1878 all crabs were sold alive and for about 10 cents a dozen. As early as 1855 there was an important soft crab fishery in New Jersey. The first out-of-state shipment of Chesapeake Bay soft crabs left Crisfield, Maryland, for Philadelphia by train in 1873. In 1878 canning experiments were begun and a year later a crab cannery opened at Oxford, Maryland, employing 170 men and processing 12 to 15 thousand crabs a day. The pickers were paid 2 to 3 cents a pound. Fresh-cooked crabmeat in iced, unsealed cans was not made available until 1883.

The business has grown. Landings in 1900 were estimated at less than 10 million pounds. In 1968 blue crab landings—live weight—totaled 115,797,000 pounds, compared to 82,038,000 pounds for king crab and 49,970,000 pounds for Dungeness crab landings. The value of blue crab landings that same year was $12,157,000.

Today's blue crab plants (often called crab houses) number less than 200 and range in size from one-man operations to those employing more than a hundred workers. Most plants are family owned and many are located in rural areas. Crabs are received at a dock or a loading platform almost universally by boat, although some arrive by truck. Due to the nature of the industry the methods of catching crabs and processing crabmeat are much the same as they have been for nearly a hundred years. Some progress is being made in developing "picking" machinery with various water pressure, vacuum, shaking, and centrifuging techniques.

All crabs are cooked and then cooled before being picked. This means that every plant must have some system for cooling, and cooling practices vary widely, from large holding rooms using commercial refrigeration units to concrete platforms on which the hot, cooked crabs are dumped and hosed down with cool water.

Hand picking requires many workers and the largest room in the plant. Crab pickers most commonly pick the meat directly into 12-ounce or one-pound cans and take the filled cans to the adjacent weighing and packing room when five pounds are picked. Almost all crabmeat today is packed in cans in crushed ice, placed in barrels or boxes, and shipped quickly. Ten days is considered a normally safe span between picking and consumption of fresh crabmeat.

The Food and Drug Administration has learned much about crabs and crabmeat since 1922—the year the Agency began inspecting crab plants. Out of eight Notices of Judgment in the records for that year, two involved decomposition and six short weight. The economy of the times was reflected in the short-weight fines of $10 to $100, although the offenses would be considered quite gross by today's standards—five pounds claimed for crabmeat weighing as little as 4 1/4 pounds!

FDA inspection of blue crab
Below, the inspector observes sanitary practices at a table where a worker is picking crabmeat from crab claws. At right, the inspector uses a paper containing reagent to check the strength of chlorine in a pan in which workers dip hands after washing and before handling crabmeat. Similar pans contain a stronger solution in which utensils are dipped.

Plants involves four Districts: Baltimore and Atlanta, which share slightly more than 90 percent of the inspectional load; New Orleans; and Dallas. The sanitation problems encountered reflect not only the peculiarities of a given industry but the general problems resulting from human behavior en masse as it affects food production. For example:

1. The crabs themselves arrive at the plant live, and with many, varied bacteria. Some with a potential for causing diseases are *Clostridium botulinum*, type E; *Staphylococcus*; *Salmonella*; *Vibrio parahaemolyticus*; and *Shigella*. Proper cooking kills these pathogens.

2. Sanitation is less than ideal in some plants. For example, 1970 FDA inspection reports include the following observations:
   - Crabs on picking tables up to 6 hours at room temperature
   - Crab fat or oil on tables, preventing the penetration of sanitizing solutions
   - Chlorine sanitizing solutions below effective bactericidal levels
   - Dirty or rusty can lids in contact with crabmeat
   - Crabmeat stored at 60° F.—no ice

3. Employee work habits often indicate the need for education and enforcement of food sanitation requirements. Some offenses observed:
   - Failing to sanitize hands after using toilet
   - Picking up crab claw from floor and returning to picking table
   - Using knives with tape-wrapped or wooden handles which cannot be sanitized
   - Allowing excessive crab waste to accumulate on picking tables
   - Failing to sanitize can lids
   - Wrapping tape on fingers
   - Failing to wear hairnets
   - Placing pocketbooks and personal possessions on picking tables
   - Wearing street clothes with no apron

Despite the nature of these reports, which of course list only faults, many crab plants are clean and sanitary, indicating that their managers are well aware of the need for careful attention to prevent bacteriological problems. When sanitation problems do exist, the reasons are usually apparent to trained inspection teams. Many of the problems in both sanitation and production are intertwined with the economics of the crabmeat industry:

- Most crabmeat production is seasonal. Although a few fish for crabs the year around, most plants either close part of the year or change to oyster shucking, shrimp processing, or handling fish products.
- The labor supply is dwindling; crab picking, with its relatively low wages, fails to attract young people. Machine picking is still in the experimental and developmental stages and costs are high.
- The supply of crabs is dwindling
in many areas, possibly due to water pollution. It is now claimed, for example, that residual fuel oil is the most insidious of the whole scope of petroleum products in terms of destroying seabeds, marshlands, shellfish, and crustaceans.

- Few crab plants have laboratories equipped to pinpoint sanitation flaws, or trained sanitarians as employees.
- Programs describing precise sanitation practices usually do not exist nor are there planned programs for training employees to follow good sanitation practices.
- Crabmeat production begins with live crabs accompanied by various bacteria, many of which are harmful. Proper cooking destroys almost all bacteria. The extensive hand-handling of crabs and crabmeat frequently reintroduces bacteria in and on crabmeat, making the personal hygiene habits of employees the most important part of plant sanitation. This is particularly important when one realizes that much crabmeat is used in salads without further cooking.

The blue crab industry continues to experiment with methods of extending the shelf life of the product that it hopes will not alter flavor and texture and will not add to the possibility of bacterial contamination. Canning, which would be ideal from a bacteriological standpoint, alters flavor and texture to an evidently unacceptable degree. Freezing is not considered a satisfactory process because, upon thawing, the product is often claimed to be tough, discolored, watery, and to have a taste unlike fresh crabmeat. It has been reported that tests involving the addition of edible chemicals that would cause less drip on thawing and the addition of flavor enhancers do not improve the frozen meat.

State regulations governing the commercial production of crabmeat vary widely, but all require a permit to operate. A certificate of health from all plant employees is required by some States. All States in which crabs are processed specify that in-plant water supplies must be approved by a regulatory authority, and most States also specify adequate lighting, smooth, easy-to-clean wall surfaces, and adequate toilet and other sanitary facilities.

Several States require that a steam cabinet or comparable device be used for sterilizing all picking equipment and other utensils used for handling crabmeat. Sanitizing solutions may be controlled. One State specifies that chlorine dips be 100 parts per million for hand sanitizing and 200 parts per million for the sanitizing of utensils. Others may require only that sanitizing solutions be of "approved strength."

The boiling of live crabs is not permitted in two States, which contend that open boiling does not allow thorough cooking, although one does allow steaming without pressure. Other States permit boiling and one State requires that crabs be cooked only in steam-pressure retorts.

FDA's Baltimore District provides a good example of successful cooperation with State authorities on behalf of the crab industry. It was decided that the first need was for joint conferences between Federal and State inspection staff personnel. The first was held in Easton, Maryland, early in 1969 and a similar meeting was held a month later in Whistestone, Virginia. At these meetings each group explained inspection techniques and procedures that would make future joint in-
During a workshop in Maryland for crabmeat picking employees, a Baltimore District microbiologist demonstrates Petri dishes containing bacterial colonies resulting from samples taken 48 hours earlier of various types of exposure situations.

In March and April, FDA and State inspectors began making initial inspection visits of greater value to everyone concerned. For example, FDA inspectors advise plant managers about general sanitation needs without making specific recommendations, while State inspectors can do so and discuss specific equipment and facilities that might help the plant do a better job.

After the initial meetings, work shops were planned for plant owners and managers and then for plant workers. During the next four months George R. White, food and drug officer for Baltimore District, worked with L. Frank Hobbs, Maryland Supervisor for Shellfish Sanitation, in conducting four workshops in Maryland, and with Cloyde Wiley, director of the Bureau of Shellfish Sanitation, Virginia Department of Health, in conducting one workshop in Virginia.

Two significant trends soon became obvious: At Crisfield, Maryland, where 90 crab plant workers were expected, 300 came; and every workshop made it more apparent that visual aids—slides, films, and publications oriented to crabmeat sanitation problems—were needed.

FDA headquarters was consulted about the possibility of making a crabmeat sanitation film and "Clean Crabmeat and You" was completed in December 1970. The 16-minute film stresses the pride employees should take in doing a good job, an understanding of bacteria and what they do, and sanitation and personal hygiene techniques.

The film’s short length makes it possible for an inspector to show it during a noon lunch period, and it is already being used successfully as part of a multiple approach at workshops attended by crab plant workers. The following report by H. Thompson Price, Jr., supervisory inspector, Baltimore District, is presented as a pattern for workshops on sanitation in food plants, needing only adaptation to the product involved:

"... Each workshop included a brief introduction in which I explained the importance of the role the pickers play in helping FDA and Maryland State health officials protect the public health. The movie, ‘Clean Crabmeat and You,’ was then shown and followed by the instructional series, ‘Clean Hands’ (a new FDA sound-slide show on the importance of workers keeping their hands clean). The workshop concludes with the demonstration of agar plates previously inoculated by unclean and by washed and sanitized hands, by hair, fingernail dirt, coughing, and air; and of contact plates contaminated by toilet seats, door knobs, unsanitized table tops, coat sleeves, and unsanitized cans.

"This demonstration is very effective in illustrating to the pickers how bacteria can be introduced into crabmeat and in impressing upon them the need for proper sanitation and care to prevent bacterial contamination. For most, such a demonstration provides a first look at actual bacterial growth. The demonstration supplements the films quite well. . . . The film and slides are excellent tools for use by the Districts in their efforts to improve compliance levels in the crabmeat industry and, when combined with the agar plate demonstration, result in a complete instructional package which effectively reaches the crabmeat picker."

The blue crab industry will continue to benefit from adequate surveillance, improved educational programs for management and workers, better processing techniques and equipment, and continued communication in the interest of consumer safety and satisfaction.

The Challenges of Progress in Food

by James D. Grant

We have entered a new era in food consumption which is both a challenge and an opportunity. We are living in an age of change—perhaps, radical change—and involving new progress with our food supply which we perceive only dimly now. However, within this uncertainty we have the opportunity to reach decisions about the future nature and scope of the food supply which will have a profound effect on our society for some time to come.

To understand the significance of the changes involving our food supply, three areas of developments in our societal structure need to be examined. These are science, technology assessment, and consumer and social responsibility of corporations.

Science. The first critical area from the standpoint of the Food and Drug Administration is the scientific activity in the 70's. FDA has under way a number of new initiatives with respect to the food safety side of scientific activities. The most important of these is a review of substances classified as GRAS (generally recognized as safe) for addition to food. A project manager has been appointed to review the GRAS list. He is responsible for assuring that all GRAS list actions taken by the various operating units within FDA are properly coordinated, one with the other.

There are three separate but interrelated lines of endeavor currently under way in the review of the GRAS list. The first involves sending a questionnaire to the manufacturers, formulators, and users of GRAS items requesting information concerning the output of each, and pertinent toxicological information from their files. The second activity is a review of the toxicological literature published over approximately the past 50 years on each of the GRAS items. The third line of endeavor involves a number of FDA laboratory and administrative operations, including screening tests for teratogenicity, mutagenicity, and reproduction, that are necessary contributions to completion of the total review of the entire GRAS list.

The investigation involving industry response to the questionnaire is intended to provide information on the amount of the substance being consumed as well as to obtain any toxicity information available to the firm. The volume of use of a particular additive is important in judging the available toxicological information to determine if the latter provides sufficient assurance of the safety of continued use in food.

The review of the toxicological literature is intended to collect all pertinent safety information on each of the GRAS items so that it may be related to the consumer hazard identified by the results of the questionnaire.

The results of each of these lines of investigation will be brought together and the available information for each substance will be reviewed to determine what status it should have under the law.

FDA has already published proposed administrative criteria by which we will judge the eligibility of a substance for classification as GRAS. FDA also is developing improved toxicological guidelines for future scientific studies. We also expect a trend towards more positive control of substances through the food additive mechanism rather than the GRAS mechanism. However, the changes may not be too significant. In due course, the GRAS review will inevitably lead to an examination of all food additives. Of crucial concern is the development of procedures and scientific criteria so that all may know how scientific decisions about food safety will be reached.

We have taken two other steps. In the 1972 budget there is proposed a transfer to FDA of the U.S. Army's chemical and biological warfare facility at Pine Bluff, Arkansas. This facility will become a National Center for Toxicological Research. The purpose of this facility is not to relieve the manufacturer from the burden of establishing reasonable proof of safety, but to develop general scientific guidelines and protocols, and to do those types of applied scientific studies which are correctly within the province of the Federal Government. We believe that the activities at Pine Bluff will produce a positive incentive to private testing, both by individual firms and by private testing centers and laboratories in the commercial and in the academic sectors.

There are other important considerations concerning the Pine Bluff facility. It is to be a national facility. Initially, the Environmental Protection Agency will be involved, but it is also planned that other Government agencies will participate. We hope that the methods of managing scientific research in this facility will serve as a model for interagency scientific cooperation. In addition, FDA hopes to involve the academic and commercial sectors in the objectives of research at Pine Bluff. To assure that these objectives are successfully accomplished, we are vitally concerned in finding an effective management concept for the facility.

Another important part of our safety objectives is to improve our surveillance and enforcement activities. In the coming months we plan to make significant changes through improving statistical sampling techniques, which will be more effective because they will directly tie the results of inspections to specific acts of enforcement.

FDA has made progress with its Good Manufacturing Practice activities. In the 1972 budget we have proposed an expanded Quality Assurance Program which, if authorized, will result in developing improved quality control techniques by manufacturers.

To cope with the increasing demands on our re-
sources and expertise, FDA must have more comprehensive knowledge about the food industry. We urgently need to employ innovative approaches to maintain a reasonable level of surveillance and to effect timely compliance with the law.

FDA is developing and testing systems that will enable it to characterize the establishments and products within its jurisdiction so that it can:

1. Identify with more confidence the establishments that require intensified regulatory efforts and those that only require a spot check of some kind, such as a review of quality control records;

2. Isolate the "key indicators" of product quality in various types of establishments, thereby enabling FDA to focus inspections on the most critical aspects of production; and

3. Develop baseline information about conditions in the food industry that will reveal the impact of specific regulatory measures on product quality and on establishment conditions, thereby providing the means of measuring program effectiveness.

Nevertheless, we must come back to the basic problem of uncertainty in science. We are not reviewing toxicology information on GRAS substances and improving our surveillance because we believe foods are unsafe. Our reason for the review is to be certain that we are applying 1971 scientific criteria to earlier decisions and present practices. The difficulty is that there are many unknowns in our scientific endeavors. More importantly, there is always uncertainty in proving safety. In dealing with the public we are attempting to explain the nature of scientific inquiry. We are trying to get the public to recognize the extensive safety factors which science can assure as well as the limitations of science in achieving absolute safety.

Technology Assessment. In the July 4, 1970, report of the National Goals Research Staff, titled "Toward Balanced Growth: Quantity With Quality," there is an excellent discussion of technology assessment, which is an inherent part of our consideration of science. The report defines technology assessment as basically the stance whereby one examines technology and its impact on the biological, ecological, and social (including economic) system at work in our country and our world. It is not a precise science, but it is a methodology worthy of consideration by private organizations and companies.

If a firm wants to engage in technology assessment, how does it go about doing so? There is no easy formula, but here are a few possibilities.

Technology assessment must become a conscious effort before a product is introduced into commerce. This may seem obvious, but it is equally obvious that it is not being done. In general, corporations should ascertain, through appropriate testing, that a product is safe for its intended use before it is introduced into commerce.

Food manufacturing firms, for example, should review the scientific and toxicology literature related to particular products they desire to introduce, including the constituent components and the ultimate use of the product. The methodology of technology assessment would need to be modified for particular products or industries. In situations where the scientific literature does not adequately describe problems, or where there are unknowns, testing should be done so as to limit the scope of scientific uncertainty as much as possible.

Usually a market analysis would indicate expected sales, cost, and economic impact on the firm. This concept of marketing analysis should be expanded to examine the impact of the action on the economy. It should include an assessment of the costs and benefits as well as the possible options related to the introduction of the particular technology or product. The economic implications will obviously be different if the product is being introduced as a substitute product to another industry's product, or as a competitive response to a firm in the same industry, or as a totally new product initiative.

Research and development on new products, especially those which produce true autonomous investment and resultant economic growth, should be encouraged. However, it seems to me that self-restraint should be exercised by firms where the technology assessment indicates the possibility of undesirable direct or indirect consequences—such as plant effluent problems.

Manufacturers should assume the responsibility for the scientific, economic, environmental, biological, and social changes brought about through their products. To some extent, manufacturers do respond to consumer demand in the form of producing products consumers want, but I suggest that manufacturers shape that demand through the introduction of many products.

Manufacturers who make their technology assessment public will probably find it a useful marketing tool. The thoughtful consumer will appreciate it. The thoughtless consumer will certainly benefit from the information provided by the technology assessments. Manufacturers may see obvious objections to making the study public. One objection is that if the technology assessment is made, competitors may well use it. However, the manufacturer who performs this type of technology assessment will have such a jump on competition that he will have a superior market position anyway.

A second objection might be that consumer groups would use the technology assessment data to the detriment of the manufacturer releasing it. However, I be-
lieve consumers and government will increasingly be concerned with the impact of technology on our society. Industry has the option of taking a leadership role in providing this information; if industry fails to do so, through either inertia or reluctance, others will do the job.

Trade associations could compile industry technology assessment from member corporations for public distribution. Companies could learn what government research is being conducted in their areas of interest and provide input on the effects of technology. There are many ways these assessments could be communicated to the consumer, i.e., through independent scientific or nonprofit organizations.

Technology assessment is not a rigid system. Rather, it is a conceptual way of thinking about the introduction of technology which merits industry and public discussion.

Every manufacturer should take into account the burden of technology assessment before his product is introduced into commerce. It represents a deliberate and cautious approach to the introduction of technology, taking into consideration the direct and side effects of technology. It can help the manufacturer delineate the options, benefits, and costs encompassing economic, health, and environmental, and social considerations.

I am convinced that if individual private companies could engage in technology assessment, the demands of the public sector on the private sector for later corrections would significantly diminish. Indeed, technology assessment by the private firm now may preclude more stringent public regulation later.

Consumer and Social Responsibility of Corporations. To meet the new demands of consumers, FDA is conducting new initiatives. The Agency is working to improve the quality of food and is developing nutritional guidelines for various classes of foods. In the near future FDA will publish the first set of guidelines dealing with formulated main dishes such as frozen dinners, totally canned dinners, etc. In addition, FDA is attempting to make a more conscious effort to introduce nutritional quality in setting food standards. Another initiative of vital concern to the consumer input side is our present effort in nutrient labeling. We are experimenting to find ways of identifying calories, carbohydrates, proteins, fats, type of fat, vitamins, and minerals—on the label—in a system which will not be so complex that it won’t be used, but won’t be so simplified that it is meaningless. The key to any effective nutrient labeling is an effective consumer education program. For this program we are seeking the support of the private sector in both nutrient labeling experiments and in consumer education activities.

If FDA has correctly gauged the current concern of consumers, they are demanding not only safe foods, but also foods that are more effective from the standpoint of their nutrient quality, and foods that are better labeled as to their benefits.

On the basis of a number of assumptions related to consumers, we believe that future emphasis on selling food products will continue to shift toward techniques in marketing, especially with respect to convenience, product quality, and nutrition, rather than simple production. Food products will be increasingly promoted to fill a complex of needs, both nutritional and psychological. The complexities of consumer buying will continue to increase in number and types of consumer products. The complexities will tend to remove further products from the consumer’s ability to make knowledgeable choices based on his own observations unless he receives assistance through effective education.

The American consumer wants both more protection and more information. If he is provided the necessary education, he will learn to use such tools as unit pricing and nutrient labeling to make better purchases from the standpoint of value-cost comparisons.

With respect to the food industry and consumer input, there is a need to evoke industry’s consciousness on a grand scale in dealing with consumers.

If we can build a better scientific base, we can reduce some of the uncertainty in decisions, and thus mitigate the severity of unexpected problems. Nevertheless, we are still going to have to base decisions on the best scientific data available, recognizing the limitations. If the resources are made available by the food industry to exercise corporate responsibility with respect to technology assessment and effective response to consumer demands, we think that these efforts by industry, coupled with improved science from a safety standpoint, will go a long way toward assuring that we are laying a base to deal effectively with the food challenges facing us in the future.

James D. Grant, Deputy Commissioner of Food and Drugs, joined FDA in that position in the spring of 1970.
ATLANTA DISTRICT As the result of a recent joint investigation, FDA, North Carolina, and South Carolina officials, through Federal seizures and State actions, have been instrumental in removing over 1,500 pounds of pesticide-treated seed corn from animal feed distribution channels. The investigation started last fall (see FDA PAPERS, April 1971) when it came to the District's attention that seed treatment firms, grain dealers, and farmers were selling treated seed corn which was then being channeled for use as animal feed. Officials from the North Carolina Department of Agriculture and from the South Carolina Department of Health collaborated with FDA in that part of the investigation involving their States. North Carolina Inspector Fred Nooe along with FDA Inspectors Loyd McEwen and William Carlton, from resident posts in Charlotte, North Carolina, and Charleston, South Carolina, respectively, carried out the field investigations. The State officials have also monitored the slaughter of hogs fed the treated seed corn to ensure that no meats containing pesticide residues would enter human food channels.

A fourth inspector from the State of Alabama Department of Agriculture and Industries received training in the District office during the first week of February. The training covered such pertinent areas as warehouse inspection, life cycles and identification of common storage insects, labeling requirements, sample collection techniques, and photography. The program of training for State inspectors was started last fall at the State department's request.

BOSTON DISTRICT FDA regional shellfish consultants and a Massachusetts State sanitarian visited a Boston dealer recently after local Customs Service officials reported to the District that the dealer had received a consignment from Canada of approximately 1,800 pounds of uncertified Canadian quahog (clam) shellstock. Upon arriving at the firm, officials found the shipment still intact, and the State official informed the dealer the lot was not from a certified shipper and therefore was illegal in Massachusetts. The dealer called the shipper, and after the telephone conversation, decided to return the entire lot to him through Customs officials in Portland, Maine.

Cod substituted for haddock resulted in a recall recently. The Division of Food Protection and Sanitation, State of Rhode Island, reported to the Boston District office January 22 that it had discovered a shipment of a different type of fish being substituted for haddock under the label of a nationally known chain store. A follow-up sample was taken by District inspectors and examined in the District laboratory by the electrophoresis method, which showed the product to be cod instead of haddock. When the District informed the dealer firm, it initiated a recall of the lot from its retail outlets.

Robert Kilpatrick, District product safety consultant, made a presentation on flammable fabrics to the staff of Plimoth Plantation, a tourist attraction in Plymouth, Massachusetts. The educational program was a result of concern that arose from an accident around Thanksgiving of 1970, in which one of the hostesses, dressed in Pilgrim garb, was seriously burned when her dress was ignited from an open fireplace. The staff is now planning to use flame-retardant fabrics for the hostesses' costumes. The District plans similar programs where hazardous costuming is used at other tourist attractions in the same area.

BUFFALO DISTRICT The Rich Products Co., Buffalo, has spent or contracted to spend about $35,000 for renovation of its plant and equipment to help prevent any recurrence of a recent problem that led to recall and destruction of 81,322 pounds of dried coffee whittener. The product had become insect contaminated during production.

CINCINNATI DISTRICT Deputy Regional Food and Drug Director Clifford G. Shane and Chief Inspector Carl R. Baueerlen participated in an informal early spring conference with the new director of the Ohio Department of Agriculture, Gene R. Abercrombie, his deputy director, M. David Urmston, and chief of the Division of Foods, Dairies and Drugs, Dr. David A. Hill. They discussed several topics of mutual interest.

District employees assembled March 5 to hear Gerry Padzensky, Ph.D., president of Inter-Dynamics, Inc., Chicago, speak on the Equal Employment Opportunity program and its meaning, value, and advantages. Dr. Padzensky has been engaged by the Regional Training Center for the Civil Service Commission to train EEO counselors and officers.

Supervisory Inspector John W. Blue of the Cleveland resident post made a talk to the Consumer Institute at Cleveland entitled, "The Food and Drug Administration and Consumer Protection." The Consumer Institute is sponsored for union members by the American Federation of Labor-Congress of Industrial Organizations and the Federal Trade Commission.

The District contacted the Ohio Department of Agriculture, Division of Foods, Dairies and Drugs, to offer Federal assistance after a tornado hit Columbus on February 21. State officials informed District members that damage was confined to residential areas and that
the State did not anticipate the need for such assistance. No problems involving products under FDA jurisdiction have materialized.

DETROIT DISTRICT The U. S. District Court in Detroit has refused to approve a motion to reduce sentences imposed on the Detroit Vital Foods Co.; Lelord Kordel, president; and Alfred Feldten, vice president. They were convicted in 1965 on Federal charges of misbranding drugs, and their appeals to the 6th Circuit Court and to the U. S. Supreme Court were denied. They have now been ordered to surrender for imprisonment and pay fines totaling $17,000.

Dow Corning Corp., Midland, Michigan, and one of the firm's officers have pleaded no contest to an indictment brought in August 1967, charging illegal distribution and misbranding of a medical silicone fluid for purposes of breast augmentation and body contouring for women. A grand jury had returned the indictment alleg ing the defendants violated the Food, Drug, and Cosmetic Act by the interstate shipment of silicone fluid, which was a new drug without an approved New Drug Application or Investigational New Drug Application, and by misbranding the drug, since it lacked both adequate directions for use and warnings. The court has accepted the no contest plea and sentencing has been deferred pending investigation by the probation officer.

KANSAS CITY DISTRICT The Greater St. Louis Area Metropolitan Conference of Food and Drug Officials began its second year with an all-day training session and election of officers on February 18. The meeting was held at the Ralston Purina Company's Research Building in St. Louis and was attended by over 50 enforcement officials from FDA, from local, county, and State health groups, and from industry. Elected officers included Gerald Dean Baker, chief of food control, St. Louis Health Division—president; Raymond K. Hedblad, FDA resident inspector, Edwardsville, Illinois—president-elect; R. Frank Brittingham, St. Louis County Health Department—vice president; and Harry E. Menges, Missouri Division of Health—secretary.

William Dunston and Dr. Russell Marino from the Quality Assurance and Sanitation Department of Ralston Purina Co., spoke on “Quality Assurance of Food Products” and “Food Industry Sanitation.” George E. McDonald, assistant to the director, FDA's Chicago District, opened the afternoon session with a discussion on “The Role of the Inspector.” T. L. Huge, president, American Sanitation Institute, Division of Huge Co., spoke on the “Role of a Sanitation Consultant in Industry.” The meeting concluded with a tour of the Ralston Purina laboratories.

Combining the talents of industry, the university community, and State and Federal food and drug law enforcement agencies resulted in a successful Cheese Manufacturer's Seminar held February 24 at Waterloo, Iowa. Registration showed 102 attended the one-day meeting sponsored by the Iowa Cheese Manufacturer's Association, the Dairy Division of the Iowa Department of Agriculture, and FDA's Kansas City District. Cheese makers and other dairy plant operators from nearby Illinois and Wisconsin also attended.

Featured speakers on the seminar program were Dr. J. Bryan Stine, Kraft Foods, Chicago; Robert Hohman and Irvin Marshall, Borden Co., Columbus, Ohio; Dr. George Reinbold and Professors Tom Barta and Earl Wright, Iowa State University, Ames; John A. Kedzior, FDA, Washington, D. C.; Iowa State Dairy Inspector Bernard Snitker and FDA Inspector Spencer Sorenson. Richard C. Dennler, director, State Dairy Division, and George L. Vinz, FDA's Kansas City District, were moderators.

FDA and U. S. Department of Agriculture inspectors monitored food salvage and destruction operations following flash floods in Iowa and Nebraska that resulted from a heavy snow cover and mild mid-February days. Ice jams developed on a number of small streams, damaging bridges, flooding farm lands and, at a Nebraska point, damaging an estimated half million dollars worth of egg products ready for shipment.

LOS ANGELES DISTRICT Microbiological contamination of cosmetics was the main topic of a workshop for the cosmetic and drug industries held February 27 at Los Angeles. The California Chapter of the Society of Cosmetic Chemists and the Los Angeles District sponsored the workshop, which was attended by 125 persons, most of whom were production and laboratory personnel from the cosmetic industry. Speakers from FDA and the industry covered good manufacturing practices, microbiological controls, laboratory testing for safety and bacteriological contamination, and legal requirements.

A 15,000-pound lot of cottonseed, shown by FDA analysis to be contaminated with aflatoxin while held for sale, was seized at the Hollandia Dairy in San Marcos, California, after shipment by a cottonseed products firm in Harquala, Arizona.

The District consumer specialist, Elaine Roentgen, has been active recently in both radio and television presentations. She discussed the problem of mercury in fish on radio station KOOL in Phoenix, and on the “Muriel Stevens Show” on a Las Vegas TV station. She also talked about fair packaging and labeling on television station KTVR in Phoenix, and made a videotape on flammable fabrics at the Phoenix educational television station. The tape will be distributed commercially throughout the western States.

Under the sponsorship of the Los Angeles School System, Adult Education Division, the District presented a program on foods for children to mothers of preschool children at Wilmington, which has been so well received that it will be repeated in coming months.

FDA Papers / May 1971 / 29
MINNEAPOLIS DISTRICT  Because of increased concern in the Upper Midwest about the pollution of Lake Superior, a public hearing was held on February 17 in Duluth, Minnesota, on proposed water quality standards. Deputy Regional Food and Drug Director Henry P. Roberts of the Minneapolis District presented a prepared statement approved by Commissioner of Food and Drugs Charles C. Edwards, M.D.

The District reports an incident in De Pere, Wisconsin, early in February that shows how even a seemingly harmless toy can become a lethal weapon. A six-year-old boy received a "Johnny Eagle Skeet-Shooter" for Christmas. His four-year-old brother decided to play with the toy gun, but instead of using it in the usual manner, he removed a 20-gauge shotgun shell from his father's gun cabinet and placed it in the toy ahead of the dart normally shot from the gun. The dart hit the primer of the shotgun shell, exploding it. Although the plastic toy withstood the blast fairly well and no injury occurred, some furniture was damaged.

NEW ORLEANS DISTRICT  A Federal District Court in Baton Rouge, Louisiana, had not yet reached a decision by mid-March as to whether it would enjoin a local animal by-products rendering plant. After FDA allegations that the firm had shipped *Salmonella*-contaminated meat meal in interstate commerce, District officials had appeared in court in February to ask for a temporary injunction prohibiting the firm from introducing contaminated products into interstate commerce.

The District's import detentions for February prevented the entry into commerce of $7,500 worth of misbranded olive oil, about $300 worth of misbranded canned carrots, $3,200 worth of short-weight canned tuna, about $1,000 worth of inadequately cleaned frozen flounders, $2,300 worth of decomposed canned tomatoes, and $340 worth of hazardous toys.

NEW YORK DISTRICT  Ciba Pharmaceutical Co., Summit, New Jersey, mailed 70,000 recall letters to all trade accounts on February 18-19 after discovering a sub potency problem with trasentine HCl tablets and trasentine-phenobarbital tablets. The firm became aware of the problem through stability studies run as a follow-up to a complaint of discoloration in the products. Although similar complaints had been received in the past, previous studies had not been made of these older products, for the complaints had been discounted due to the age of the lots involved. Prior to this action, the firm had scheduled stability studies as the result of an inspection conducted by New York District's Newark Section, but had assigned a low priority to these products. Because of the recent complaint it then became necessary to raise the priority and run the study. The firm is now recalling all lots and is shipping replacement stock bearing a 15-month expiration date to all consignees. The lots being recalled do not bear an expirational date.

Dr. Ernesto Colon Yordan, Secretary of Health in the Commonwealth of Puerto Rico, has fully concurred with the District's selection of Supervisory Inspector Alex Labonski, Newark Section, to replace Robert J. Martin as Director of Drug Programs in the Commonwealth's Department of Health on loan from FDA. Mr. Martin is now Region II deputy regional food and drug director in charge of the New York District. He and Mr. Labonski visited with Dr. Colon Yordan and the Drug Programs' staff late in March, and Mr. Labonski expected to assume his duties in Puerto Rico sometime in April.

Most of the chemists in the District's Pharmaceutical Section had some input into the District presentation of a two-week course, "Modern Drug Analysis for Inspectors," that ended early in March. Inspectors from the Brooklyn, Newark, and San Juan Sections participated in the course, which consisted of a broad review of the techniques and instrumentation available in a modern quality control laboratory.

PHILADELPHIA DISTRICT  The Metlox Potteries, Inc., Manhattan Beach, California, instituted a recall of suspect items in one of its lines of pottery following the death in February of a 17-month-old boy in Pennsylvania. State Health Department officials in Pennsylvania notified the Philadelphia District February 18 of the boy's death resulting from lead poisoning. During its follow-up inspection, the State found that the boy regularly had been fed grape juice kept in an earthenware pitcher. Both the State Health Department and the District analyzed the grape juice, diluted and concentrated, and found insignificant amounts of lead, but in analyzing the glaze on the pitcher, they found excessive amounts of lead. The pitcher had been purchased in Los Angeles about six years ago, but regular distribution of this type of pottery has been nationwide, including the Philadelphia area. FDA's Los Angeles District was notified and has been conducting a further investigation, which has led to the recall.

A Philadelphia-based Conference of Paramedical Teams representing hospitals throughout the Delaware Valley was held February 9 in Philadelphia at the Albert Einstein Hospital. Jeanne Devers, the District's consumer specialist, presided at both afternoon and evening sessions devoted to FDA and consumer protection. About 1,100 persons attended.

Representatives of the Philadelphia television station WCAU, channel 10, taped a special program on testing of fish for mercury March 2 at the District laboratory.
as part of the evening news shown March 14. For the
taping, Jean B. Hill and Georgia Voytush, District
chemists, demonstrated analytical technique, and
WCAU commentator Gene Crane interviewed Eugene
R. Stanley, District laboratory director.

SAN FRANCISCO DISTRICT For different reasons, a
U. S. marshal made two separate seizures in March
at the Fresco Food Products, Inc., South San Francisco.
On March 5 the marshal took into custody a hundred
32-pound sacks of whole Mexican oregano and seven
110-pound sacks of Turkish sage leaves because of
FDA charges that the products consisted in part of a
filthy substance due to the presence of rodent urine.
On March 30 a lot of 40 112-pound sacks of whole
Brazilian black pepper was seized at the same firm when
found to be contaminated with Salmonella. Seizures of
these items, valued at approximately $3,000, followed
FDA's inspection of the firm's premises, where the
inspectors found gross insanitary conditions.

FDA caused the seizure of an estimated 212 tons of
cottonseed held by a dealer at Hanford, California,
because it contained aflatoxin. The cottonseed, valued
at $20,000, had been shipped to California by a firm
in Arizona for use as dairy cattle feed.

SEATTLE DISTRICT Joan Bergy, District consumer
specialist, and representatives from the Division of
Health, Washington State Department of Social and
Health Services, presented a comprehensive workshop
titled, "Maxi Foods with Mini Money," on March 2, 3,
and 4 in three areas of Southwestern Washington. The
workshops were a pilot project to increase a public
assistance caseworker's knowledge of nutrition and food
buying, and were attended by 143 caseworkers from
the State Department of Public Assistance as well as
other community workers concerned with food buying

problems faced by poverty groups. After evaluation, it
is anticipated that the project will be repeated in other
parts of the State. The State Department of Public
Assistance is expected to recommend that the nutrition
training become part of the caseworker's orientation
education.

Over 800 consumers attended the third annual Wash-
ington Consumer Conference held February 25 at
Seattle and cosponsored by Seattle District and other
local consumer protection agencies. "What You Can Do
About Food and Nutrition" was the theme of the con-
ference, and FDA's program topics were food safety
and nutrition labeling.

FDA recommended seizure of repacked epsom salts at
a drug manufacturing plant in Oregon because the firm
had virtually ignored all the drug good manufacturing
practices required by Federal law. When a U. S. marshal
went to the plant February 8 to seize the 1,440-pound
lot of salts, he was so appalled at the condition of the
plant that he took it upon himself to order the plant to
discontinue operations until the premises had been

cleaned up.

FDA DISTRICT OFFICES

<table>
<thead>
<tr>
<th>Location</th>
<th>Address</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATLANTA</td>
<td>608th St., N.E. Atlanta, Ga. 30309</td>
<td></td>
</tr>
<tr>
<td>BALTIMORE</td>
<td>900 Madison Ave. Baltimore, Md. 21201</td>
<td></td>
</tr>
<tr>
<td>BOSTON</td>
<td>585 Commercial St. Boston, Mass. 02109</td>
<td></td>
</tr>
<tr>
<td>BUFFALO</td>
<td>599 Delaware Ave. Buffalo, N.Y. 14202</td>
<td></td>
</tr>
<tr>
<td>CHICAGO</td>
<td>Main Post Office Bldg. Rm. 1222/433 W. Van Buren St. Chicago, Ill. 60607</td>
<td></td>
</tr>
<tr>
<td>CINCINNATI</td>
<td>1141 Central Pkwy. Cincinnati, Ohio 45202</td>
<td></td>
</tr>
<tr>
<td>DALLAS</td>
<td>3032 Bryan St. Dallas, Texas 75204</td>
<td></td>
</tr>
<tr>
<td>DENVER</td>
<td>New Customhouse Bldg. Rm. 5604/20th &amp; California Sts. Denver, Colo. 80202</td>
<td></td>
</tr>
<tr>
<td>DETROIT</td>
<td>1560 E. Jefferson Ave. Detroit, Mich. 48207</td>
<td></td>
</tr>
<tr>
<td>KANSAS CITY</td>
<td>1009 Cherry St. Kansas City, Mo. 64106</td>
<td></td>
</tr>
<tr>
<td>LOS ANGELES</td>
<td>1521 W. Pico Blvd. Los Angeles, Calif. 90015</td>
<td></td>
</tr>
<tr>
<td>MINNEAPOLIS</td>
<td>240 Hennepin Ave. Minneapolis, Minn. 55401</td>
<td></td>
</tr>
<tr>
<td>NEW ORLEANS</td>
<td>U.S. Customhouse Rm. 222/423 Canal St. New Orleans, La. 70130</td>
<td></td>
</tr>
<tr>
<td>NEW YORK</td>
<td>850 3rd Ave. (at 30th St.) Rm. 700/Brooklyn, N.Y. 11232</td>
<td></td>
</tr>
<tr>
<td>PHILADELPHIA</td>
<td>U.S. Customhouse Rm. 1204/2nd &amp; Chestnut Sts. Philadelphia, Pa. 19106</td>
<td></td>
</tr>
<tr>
<td>SAN FRANCISCO</td>
<td>Federal Office Bldg. Rm. 518/50 Fulton St. San Francisco, Calif. 94102</td>
<td></td>
</tr>
<tr>
<td>SEATTLE</td>
<td>Federal Office Bldg. Rm. 5003/909 First Ave. Seattle, Wash. 98104</td>
<td></td>
</tr>
</tbody>
</table>

HEW REGIONAL OFFICES I-X

<table>
<thead>
<tr>
<th>Location</th>
<th>Address</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEW YORK</td>
<td>26 Federal Plaza New York, N.Y. 10007</td>
<td></td>
</tr>
<tr>
<td>PHILADELPHIA</td>
<td>4th Federal Plaza Philadelphia, Pa. 19108</td>
<td></td>
</tr>
<tr>
<td>ATLANTA</td>
<td>50 7th St., N.E. Rm. 404/Atlanta, Ga. 30323</td>
<td></td>
</tr>
<tr>
<td>CHICAGO</td>
<td>New Post Office Bldg. 435 W. Van Buren St./Chicago, Ill. 60607</td>
<td></td>
</tr>
<tr>
<td>DALLAS</td>
<td>1114 Commerce St. Rm. 917/Dallas, Tex. 75202</td>
<td></td>
</tr>
<tr>
<td>KANSAS CITY</td>
<td>611 E. 12th St. Kansas City, Mo. 64106</td>
<td></td>
</tr>
<tr>
<td>DENVER</td>
<td>Federal Office Bldg. 19th &amp; Stout Sts./Denver, Colo. 80202</td>
<td></td>
</tr>
<tr>
<td>SAN FRANCISCO</td>
<td>Federal Office Bldg. Rm. 416/50 Fulton St. San Francisco, Calif. 94102</td>
<td></td>
</tr>
<tr>
<td>SEATTLE</td>
<td>Arcade Bldg. Mezzanine 1319 2nd Ave., Seattle, Wash. 98101</td>
<td></td>
</tr>
</tbody>
</table>
INJURIES ASSOCIATED WITH GASOLINE POWERED LAWN MOWERS

FDA's Boston Injury Study Unit has investigated and analyzed 41 injuries associated with power lawn mowers. Data on an additional 43 power lawn mower injuries have been collected from five hospitals and health departments in Oklahoma, Oregon, Tennessee, Texas, and Washington through contracts with FDA's Bureau of Product Safety. Data from these 84 injury cases are presented in the tables that follow.

INJURIES BY MONTH

<table>
<thead>
<tr>
<th>Month</th>
<th>Injuries</th>
</tr>
</thead>
<tbody>
<tr>
<td>February</td>
<td>1</td>
</tr>
<tr>
<td>May</td>
<td>6</td>
</tr>
<tr>
<td>June</td>
<td>20</td>
</tr>
<tr>
<td>July</td>
<td>25</td>
</tr>
<tr>
<td>August</td>
<td>14</td>
</tr>
<tr>
<td>September</td>
<td>13</td>
</tr>
<tr>
<td>October</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>84</strong></td>
</tr>
</tbody>
</table>

TYPE OF INJURY AND BODY PART INVOLVED

<table>
<thead>
<tr>
<th>Injury</th>
<th>Body Part</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laceration</td>
<td>Head 1, Face 2, Arm 3, Hand/Finger 4, Leg 16, Foot/Toe 1, Chest 56, Total 184</td>
</tr>
<tr>
<td>Avulsion</td>
<td>Head 5, Total 5</td>
</tr>
<tr>
<td>Amputation</td>
<td>Head 2, Arm 4, Total 6</td>
</tr>
<tr>
<td>Puncture</td>
<td>Head 1, Arm 2, Total 3</td>
</tr>
<tr>
<td>Fracture</td>
<td>Head 1, Arm 3, Leg 4, Total 8</td>
</tr>
<tr>
<td>Contusion</td>
<td>Head 1, Arm 2, Leg 1, Total 4</td>
</tr>
<tr>
<td>Burn</td>
<td>Head 2, Total 2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1, 2, 2, 44, 7, 27, 1, 84</td>
</tr>
</tbody>
</table>

An analysis of the 41 accidents investigated by the Boston Unit revealed the following factors concerning the behavior of individuals involved:
1. Twenty accident victims stated that they failed to recognize any risk in what they were doing at the time of the accident. Eight stated that they realized risk was involved.
2. Twenty-two indicated that they were repeating an action which previously had not resulted in injury.
3. Thirty-six indicated that they were familiar with the use of the mower.
4. Eleven indicated that they were in a hurry, fatigued, or upset about something at the time of the accident.
5. Nineteen were injured where environmental conditions were poor: heavy, wet grass, rocky areas, or inclining slopes.
6. Five who received foot or leg injuries were injured more severely than they may have been had they been suitably clothed. Improper dress included shorts, sneakers, and no shoes.
7. Power mower injuries resulted in loss of 128 work days, two school days, four days from household tasks,
Here are some “dont’s” recommended by the Outdoor Power Equipment Institute to help avoid summertime injuries from powered lawn mowing equipment.

Right: Don’t use a lawn mower in an area where children are playing and be especially careful about using a lawnmower when its tunnel or grass chute is pointed toward children or other persons. Small unseen objects in the grass can be caught by the mower’s blades and become dangerous missiles hurled great distances at high velocities.

Left: Keep children away from power mowing equipment and never leave a mower unattended when it’s running or if it can be set into operation by curious youngsters. These high-powered machines are too complicated and too unwieldy for children to handle.

Left: A prime rule for mowing safety is to wear sensible clothing and sturdy, closed shoes. Bits of clothing that do not fit the body closely can become tangled in running machinery and cause serious injury. Although heavy shoes do not guarantee protection, injuries caused when a foot is accidentally caught in a mower blade can be much more serious with sandals and lighter shoes.
and 20 summer employment days (students on vacation). These total 154 days of incapacitation from significant activities.

During the same period of time and in the same geographical area that the Boston investigations were conducted, cases of four children and one adult severely burned from ignition of gasoline stored for use in power mowers were also investigated. The extent and severity of injury, the cost of treatment, and the duration of disability associated with these five burn injuries exceeded the combined total of the 41 conventional power mower injuries. Gasoline should be stored at home only if necessary and then out of the reach of children and away from any source of heat or flame. It should not be stored in glass but in metal containers—preferably safety containers with spring-loaded caps.

The following table shows the number of injuries occurring in relationship to the use of the mower; i.e., whether or not the motor was running or the mower was in motion. The data indicates that 91 percent of the injuries occurred while the motor was running. One-third of the injuries sustained resulted from cleaning out the grass chute and adjusting the wheel for blade height. Approximately 20 percent were the result of objects thrown by the mower—wire, stone, or glass. At least four of the injured persons were bystanders. One person was injured over the eye by a piece of concrete thrown 80 feet from the mower. Nineteen percent of the victims received foot injuries which resulted when they pushed or pulled the mower over a foot or slipped a foot under the mower.

<table>
<thead>
<tr>
<th>INJURIES ASSOCIATED WITH ACTIONS INVOLVED</th>
<th>Motor Running</th>
<th>Motor Not Running</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mower in Motion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Struck by Thrown Objects</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Foot Under Mower</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Foot Caught in Drive</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Mower Not in Motion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjusting Wheels</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Clearing Chute</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Attaching Chute</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Starting Mower</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Lifting Mower</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Repairing Blade</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Contact with Exhaust</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>77</td>
<td>7</td>
</tr>
</tbody>
</table>

The power mower industry's trade association, the Outdoor Power Equipment Institute (OPEI), issues a triangular safety seal that manufacturers are permitted to display on their mowers if a prototype model has been tested and approved by an authorized independent testing laboratory as complying with the Safety Specifications for Power Lawn Mowers, which is published by the American National Standards Institute. These specifications lessen the danger of hurled objects and reduce chances of hand and foot injuries from direct contact with the blade.

OPEI currently is sponsoring a national campaign to make safety information on use of its products locally available through the industry's estimated 100,000 retail outlets. Retailers are being urged to emphasize safety while selling and to offer free copies of safety mowing rules.

Safety rules for power mower operation recommended by OPEI and FDA's Bureau of Product Safety follow:

**Before Mowing**
1. Read owner's manual and know controls thoroughly before you start. Learn how to stop machine quickly.
2. Wear proper clothing—no shorts, sandals, canvas shoes, or bare feet.
3. Fill gas tank outdoors before starting. Filling a hot tank can cause an explosion. Do not smoke while filling tank.
4. Inspect and clear lawn of all foreign objects—rocks, glass, wire, etc.
5. Clear area of children and pets. They could be targets of undetected flying debris tossed from mower's discharge chute.
6. Avoid accidental starting—be sure self-propelled mowers are in neutral before starting.

**While Mowing**
1. Do not unclog mower while it is running. *This is the most common cause of mowing accidents.*
2. Do not adjust wheels while mower is running.
3. Keep feet clear of mower's blades at all times. Use extra care to keep feet away while starting mower.
4. Keep clear of discharge chute at all times. Foreign objects picked up by the mower's blades could be hurled out the discharge chute.
5. Push, don't pull mower. You could pull it over your feet.
6. Stop engine whenever you leave the mower, even for a moment. A running mower can present a strong and dangerous temptation for a curious youngster.
7. Do not allow children to operate mower.
8. Stop engine before pushing mower across drives, walks, or roads. It might pick up and hurl a stone or loose gravel.
9. Mow steep slopes sideways. When mowing up and down, the mower could slip down on top of you. Be extra careful of footing on slopes and wet grass. For riding mowers and lawn tractors, the rule is just the opposite—mow up and down the slope for greater stability.
10. Stop engine and disconnect spark-plug wire before storing or working on mower.
11. Have mower maintained in top condition.
Consumers Warned of High Lead, Cadmium In Empoli Pottery Imported From Italy

Consumers were warned by FDA on April 16 to refrain from using Empoli brand pottery imported from Italy and sold nationally because some pieces of the pottery contain very high levels of cadmium and lead. The Agency said prolonged use of the pottery could cause severe illness or death.

The pottery, which is being recalled by the Munford Company, Conley, Georgia, is sold through 40 of the company's World Bazaar retail outlets and was imported between 1969 and August 1970. All of the pottery is stamped “Italy” with the numbers “38,” “352,” or “7/13.” The Agency said the plates are stamped “Italy/38,” fruit bowls “Italy/352,” and the gravy boats “Italy/7/13.” Mugs of the Empoli line do not contain violative levels of the heavy metals.

The FDA has made three other announcements related to lead-contaminated pottery within the last 14 months but this is the first to cite cadmium as an earthenware contaminant.

The earthenware pieces are sold separately and are of a predominantly yellow color inside and out with a blue floral design. Nearly 10,000 pieces were imported, FDA said.

The warning, which was also conveyed to appropriate State authorities, was issued after FDA analysis showed levels of leachable lead and cadmium in the earthenware ranging up to 200 parts per million lead and 30 parts per million cadmium. The Agency's action guideline for the heavy metals is 7 parts per million for lead and 0.5 parts per million for cadmium.

FDA Proposes Safety Standards to Prevent Injuries to Children From 'Clacker Balls'

Proposed regulations to minimize the danger of “clacker balls” causing injury to children have been announced by the Food and Drug Administration.

Commissioner of Food and Drugs Charles C. Edwards, M.D., said FDA is continuing to receive reports of injuries caused by flying fragments when the balls shatter. The balls also may become missiles when the cord breaks. The proposed regulations, published in the Federal Register, April 27, would require the toy to meet minimum safety standards.

The toy consists of two hard plastic balls connected by a length of cord. In use, the two balls are made to strike together sharply and repeatedly by rapid hand motion. Through popular use, the term “clackers” has become the toy’s generic name. FDA issued a public warning on February 10 and began laboratory tests to determine shatter potential and other possible hazards of the toy.

Malcolm W. Jensen, director of the FDA's Bureau of Product Safety, said that “millions of the clacker balls have been sold in recent months.” More than 100 manufacturers were estimated to be producing the toy in the United States.

The proposed regulations set forth a method of sampling, a standard testing procedure, and labeling requirements. The action is being taken under the Child Protection and Toy Safety Act, an amendment to the Federal Hazardous Substances Act.

Ritts Committee Files Final Report In Review of FDA Scientific Activities

A final report has been received from the FDA Ad Hoc Science Advisory (Ritts) Committee established to review and evaluate the total scientific efforts of the Food and Drug Administration and to advise the Commissioner of Food and Drugs on aspects of the Agency's science activities that warrant improvement. (See FDA Papers, May 1970). The complete report is being reviewed in detail, and the FDA will shortly release the report and a summary of FDA preliminary response, including implementation of some recommendations, Commissioner of Food and Drugs Charles C. Edwards, M.D., announced May 13.

The chairman of the Committee was Dr. Roy E. Ritts, Jr., professor and chairman of microbiology and immunology, Mayo Graduate School of Medicine, University of Minnesota and the Mayo Foundation.

The committee, established in March 1970, was given full freedom to consider any aspects of FDA's scientific activities and had as its primary purpose the preparation of a report on methods to improve such activities. The committee's recommendations cover scientific management and planning throughout the Agency, use of extramural scientific advice, scientific contracts and grants, scientific information and recordkeeping, and the scientific activities of the Bureaus of Foods, Drugs, Veterinary Medicine, and Product Safety.

Many of the committee’s recommendations have been previously submitted to Dr. Edwards in draft form and some are already being implemented. These include suggestions to improve scientific planning, division of responsibilities among key scientific staff, contract and grant activities, and some aspects of bureau operations.

Dr. Edwards, in announcing receipt of the report, said, “I want to commend the committee for the thoroughness of their examination of the Agency and thank..."
them for the valuable contribution they have made in helping us improve the scientific operations of FDA. This will aid us in carrying out our obligations to the American consumer.”

The other members of the committee are Marion W. Anders, D.V.M., Ph.D., associate professor of pharmacology, University of Minnesota; J. Richard Crout, M.D., professor of pharmacology and medicine, Michigan State University College of Human Medicine; Willard A. Krehl, Ph.D., M.D., professor and chairman of preventive medicine, Jefferson Medical College; Lauren A. Woods, Ph.D., M.D., vice president for health sciences, Virginia Commonwealth University. The staff director is Berwin A. Cole, Ph.D., deputy associate commissioner for science, FDA.

FDA, BNDD Issue Final Regulations On Experimental Use of Methadone

Final regulations applicable to the experimental use of methadone, a narcotic drug similar to morphine, in treating synthetic narcotics addiction, were published in the Federal Register April 2 by the FDA and the Department of Justice Bureau of Narcotics and Dangerous Drugs.

The new regulations were issued to clarify the position of methadone today under current laws, to establish responsible medical-legal guidelines for its use, and to facilitate additional scientific research into methadone therapy.

Earlier this year proposed regulations and guidelines were published by the FDA and BNDD. The proposals drew considerable comment from the medical community, the National Academy of Sciences-National Research Council, authorities on treatment of drug addiction, and municipalities operating methadone maintenance programs.

Commissioner of Food and Drugs Charles C. Edwards, M.D., has met with representatives of groups concerned with the proposed requirements and accepted recommendations for a number of changes. These are primarily in the suggested plan of study (protocol) for treatment programs.

“Most of the comments made were based on an interpretation of the suggested plan as unduly restrictive on scientific investigators,” Dr. Edwards said. “This was not and is not our intention.”

“We want the methadone research program to succeed,” Dr. Edwards continued. “But there may be inherent hazards with long-term use of methadone and the drug has not yet proven its long-term effectiveness in maintenance treatment of addiction under the general Federal standards. What both FDA and BNDD want is additional, adequate, and well-controlled investigation of the usefulness as well as the hazards involved in methadone maintenance therapy.”

The new regulations will aid community groups in setting up programs to study the role of methadone in the rehabilitation of addicts and in making sure that the drug is used under strictly controlled conditions to provide additional safety and efficacy data.

The final order contains modifications included for the purpose of promoting good science and good therapy. The modifications include:

- A new section is added outlining special considerations for patients who are pregnant, who have serious physical illness, or who are less than 18 years old.
- A daily dosage of 160 mg may be exceeded when the investigator finds it essential to do so for a particular patient.
- Diagnostic examinations done on admission to a methadone program to rule out serious illness will be repeated once a year for each patient instead of every six months.

The proposed protocol is not designed to be the exclusive study plan for these investigations. Variations will be handled on an individual basis according to the needs of particular test programs.

Some objections to recordkeeping were made. Both FDA and BNDD are required by their respective laws to inspect records of drug testing and narcotic usage. FDA’s law, for example, requires adequate records in the event that a follow-up on an adverse drug reaction requires reaching patients to ensure their safety.

Prior approval will be required by both agencies before new methadone programs can begin. FDA will review each proposal for scientific merit; BNDD will consider the safeguards against diversion of drug supplies into illicit channels. As of April, FDA had approximately 275 active Investigational New Drug Applications (IND’s) for use of methadone.

FDA Seeks Bids to Set Up Pilot System To Collect and Use Drug Reactions Data

The Food and Drug Administration announced April 19 that it is seeking bids on a contract to help set up a pilot system to collect and use information about drug reactions. It is intended to serve as the basis for eventual expansion into a national drug experience reporting system far beyond the limited FDA adverse reactions program now in operation.

FDA’s ultimate goal is fast identification of unexpected and unpredictable drug reactions so that prompt corrective action can be taken to protect the patient.

Two medical environments will be involved in the pilot study:(1) Inpatient medical wards where all drugs will be carefully monitored to determine effects of short-term drug therapy.(2) A controlled outpatient-inpatient total medical care system, where several selected classes of drugs will be monitored to determine effects of long-term drug therapy.

Information for potential bidders is available from the FDA Contracts Office, 5600 Fishers Lane, Rockville, Maryland 20852. Telephone: 301 443-4420.
Cooperative Inspection Although International Consolidated, Inc., Jersey City, New Jersey, has complied with a legal order to correct insanitary conditions at its plant, the New Jersey State Department of Health will continue to keep the firm under surveillance for an undetermined time because of a record of chronic violations. The firm processes reject bakery goods into animal feed. The recent violations were discovered during a joint inspection in December by State and Federal officials. At the request of the State department, representatives from FDA's New York District office in Newark had accompanied the State officials to the plant where they found gross deviations from basic sanitary requirements conducive to insanitary conditions at its plant, the firm's manufacturing area through which chemicals had previously sifted. The State officials were satisfied that the judge's order had been complied with. The firm's management promised complete correction by the end of January 1971. FDA found that factory samples collected during the inspection were negative for Salmonella but were positive for titanium oxide contamination.

The State then filed an Order to Show Cause against the firm in the Superior Court of New Jersey (Hudson County), and requested that the FDA personnel reinspect the firm with State officials on January 27. When the inspection was made, the list of observations was practically identical to the one issued at the conclusion of the December inspection. A meeting was then held January 29 in the chambers of Hudson County Court Judge Lynch between the firm's management and State and Federal officials, at which time an order was issued listing specific conditions to be corrected by the firm within two weeks.

State and Federal officials reinspected on February 16 and found that a tremendous amount of corrective action had been taken specifically in segregating raw material and finished-product areas, which completely confined the finished product; in overall cleaning of equipment and repairing broken windows; rodent-proofing doors and walls; and repairing the wall between the chemical storage warehouse and the firm's manufacturing area through which chemicals had previously sifted. The State officials were satisfied that the judge's order had been completely corrected by the end of January 1971. FDA found that factory samples collected during the inspection were negative for Salmonella but were positive for titanium oxide contamination.

A “Don't” to Remember Under sanitation standards set by the Oregon Department of Agriculture, insects buzzing around or crawling over food in food stores, houses, or processing plants are taboo. But don't use Vapona strips or automatic time-interval-releasing insecticide dispensers to control insects in these places, warns the dairy and consumer services division of the department, which is assigned most of the department's activities directed at assuring the consumer a pure food supply.

In warning against use of these devices in control of insects, Joe Gray, who is head of the food area of the division, points out that the Food and Drug Administration also prohibits their use in areas where food is on display, stored, prepared, or served. He said the FDA requires also that labels warn against their use in kitchens, restaurants, or areas where food is prepared, displayed, or served.

Mr. Gray's advice to those with insect problems is to start solving them by destroying the breeding places. Then if control is needed, use some of the approved insecticides on the market, and while applying them, completely cover all food as well as surfaces with which food will come in contact. Among other precautions that need to be taken with all pesticides and hazardous materials to keep them from contaminating food is one to always remember: don't store them over or near food.

Teletype Alert The Bureau of Food and Drugs, New York City Department of Health, on April 27 joined the FDA Region II Teletype Alert Network (TAN-TWO), and immediately began receiving pertinent information from FDA's New York District. FDA will send messages from its headquarters and other District offices to the Bureau via the New York District communications center from where it will immediately be forwarded over the compatible, nongovernment network.

Potential Hazard The Ohio Department of Industrial Relations, Division of Bedding and Upholstered Furniture Inspection, recently ordered the return of a "Koala Bear" doll to a Georgia supplier. The order was issued because the doll's eyes were not properly attached, thus creating a potential hazard to children who play with the toy.

Agreement Directors Glenn Kreuscher and Henry D. Smith of the Nebraska State Departments of Agriculture and of Health, respectively, signed an agreement with each other in February to share inspectional responsibilities for all food service establishments in the State. Each department planned to name a Food Survey Officer, with immediate certification by PHS/FDA's Kansas City District, which would act in an advisory capacity under its Special Programs in the Food Services Branch.
**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 90 actions to remove from the consumer market products charged to be violative were reported in February/March. These included 58 seizures of foods: 16 involved charges concerning poisonous and deleterious substances, 29 involved charges concerning contamination, and 13 involved charges concerning economic and labeling violations. Other seizures included 1 of food additives, 1 of vitamins and dietary food, 20 of drugs (including 3 of veterinary and medicated feed), 3 of medical devices, 3 of cosmetics, and 4 of hazardous substances.

<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>Brewer’s yeast/Glendale, Calif. 12/1/70</td>
<td>Yeast Products, Inc./Paterson, N.J. (M,S)</td>
<td>Contains Salmonella microorganisms.</td>
</tr>
<tr>
<td>Eggs, whole, frozen/Puerto Nuevo, P.R. 2/12/71</td>
<td>J. Fleishman &amp; Co., Inc./Roxbury, Mass. (M,S)</td>
<td>contains aflatoxin, a highly toxic contaminant for which there is no tolerance.</td>
</tr>
<tr>
<td>Peanuts, shelled/Milwaukee, Wis. 2/10/71</td>
<td>Jack Gronik Co., Inc./Milwaukee, Wis. (D)</td>
<td>contains excessive mercury.</td>
</tr>
<tr>
<td>Swordfish, frozen/Newport Beach, Calif. 1/20/71</td>
<td>Caught in the waters of the Pacific Ocean outside the territorial limits of the State of California. (S unknown)</td>
<td>Held under insanitary conditions.</td>
</tr>
<tr>
<td>Milwaukee, Wis. 2/10/71</td>
<td>J. Fleishman &amp; Co., Inc./Roxbury, Mass. (D)</td>
<td>Rodent contaminated.</td>
</tr>
<tr>
<td>Produkt, Place &amp; Date Seized</td>
<td>Manufacturer (M), Packer (P), Shipment (S), Dealer (D)</td>
<td>Charges</td>
</tr>
<tr>
<td><strong>FOOD / Poisonous and Deleterious Substances</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cassia, cumin seed/Detroit, Mich. 3/11/71</strong></td>
<td><strong>A.E. Staley Manufacturing Co./Detroit, Mich. (D)</strong></td>
<td>Held under insanitary conditions.</td>
</tr>
<tr>
<td><strong>Cornmeal/Shreveport, La. 2/19/71</strong></td>
<td><strong>The Quaker Oats Co./Dallas, Tex. (S)</strong></td>
<td>Rodent contaminated.</td>
</tr>
<tr>
<td><strong>Shreveport, La. 2/12/71</strong></td>
<td><strong>Salley Grocer Co., Inc./Shreveport, La. (D)</strong></td>
<td>Held under insanitary conditions: rodent contaminated.</td>
</tr>
<tr>
<td><strong>Dragon brand, long grain rice/Phoenix, Ariz. 2/18/71</strong></td>
<td><strong>P.M. Foods, Inc./Phoenix, Ariz. (D)</strong></td>
<td>Prepared and packed under insanitary conditions; partly decomposed.</td>
</tr>
<tr>
<td><strong>Eggs, whole, frozen/Orlando, Fla. 2/8/71</strong></td>
<td><strong>Golden Egg Products, Inc./Oneonta, Ala. (P,S)</strong></td>
<td>Prepared and packed under insanitary conditions; insect-damaged nuts.</td>
</tr>
<tr>
<td><strong>Miami, Fla. 2/1/71</strong></td>
<td><strong>Johnson Nut Co./Hopkins, Minn. (M,S)</strong></td>
<td>Held under insanitary conditions, rodent contaminated.</td>
</tr>
<tr>
<td><strong>‘Fairmont Snaktime’ salted peanuts (code 5W0)/Little Chute, Wis. 1/19/71</strong></td>
<td><strong>Merchants Terminal Warehouse Co., Inc. (Hinky Dink Food Stores, Inc.)/Omaha, Nebr. (D)</strong></td>
<td>Held under insanitary conditions.</td>
</tr>
<tr>
<td><strong>Flour, sugar/Omaha, Nebr. 1/19/71</strong></td>
<td><strong>Certified Grocers of Illinois, Inc./Chicago, Ill. (D)</strong></td>
<td>Held under insanitary conditions.</td>
</tr>
<tr>
<td><strong>Ceresota/Chicago, Ill. 2/12/71</strong></td>
<td><strong>Peavey Co./Flour Mills/Altona, Ill. (M,S)</strong></td>
<td>Insect contaminated.</td>
</tr>
<tr>
<td><strong>Certified red label/Chicago, Ill. 2/12/71</strong></td>
<td><strong>Chicago, Ill. 2/12/71</strong></td>
<td>Held under insanitary conditions: rodent contaminated.</td>
</tr>
<tr>
<td><strong>Chicago, Ill. 2/12/71</strong></td>
<td><strong>Chicago, Ill. 2/12/71</strong></td>
<td>Prepared and packed under insanitary conditions; insect-damaged nuts.</td>
</tr>
<tr>
<td><strong>Flour, cheese flavored corn twists/Chicago, Ill. 2/23/71</strong></td>
<td><strong>Flour, donut base/Portland, Maine 1/12/71</strong></td>
<td>Held under insanitary conditions, rodent contaminated.</td>
</tr>
<tr>
<td><strong>mix/Holyoke, Mass. 3/21/71</strong></td>
<td><strong>Clarendon, N.H. 1/29/71</strong></td>
<td>Held under insanitary conditions.</td>
</tr>
</tbody>
</table>
### Contamination, Spoilage, Insanitary Handling (cont'd)

<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>Grits, cornmeal/Charlotte, N.C. 2/11/71</td>
<td>Statesville Flour Mills Co./Charlotte, N.C. (D)</td>
<td>Held under insanitary conditions; insect and rodent contaminated.</td>
</tr>
<tr>
<td>Onion rings, breaded/Dallas, Tex. 1/19/71</td>
<td>Randy's Frozen Meats, Inc./Okmulgee, Okla. (M); Gus’s Frozen Onion Rings/Okmulgee, Okla. (S)</td>
<td>Prepared and packed under insanitary conditions; excessive coliforms and a high total bacterial count.</td>
</tr>
<tr>
<td>Pecans, shelled/Cincinnati, Ohio 3/4/71</td>
<td>Nut Tree Pecan Co./Baconton, Ga. (M,S)</td>
<td>Prepared and packed under insanitary conditions; E. coli.</td>
</tr>
<tr>
<td>Fairfield, Ohio 3/4/71</td>
<td></td>
<td>Held under insanitary conditions; rodent contaminated.</td>
</tr>
<tr>
<td>Rocky Mount, Va. 2/18/71</td>
<td>Franklin Grocery &amp; Grain Corp./Rocky Mount, Va. (D)</td>
<td>Held under insanitary conditions; rodent contaminated.</td>
</tr>
<tr>
<td>Rice/Wichita, Kans. 1/29/71</td>
<td>F &amp; E Wholesale Grocery Co./Wichita, Kans. (D)</td>
<td>Prepared and packed under insanitary conditions; insect contaminated.</td>
</tr>
<tr>
<td>Salmi with instant soup base/San Francisco, Calif. 12/7/70</td>
<td></td>
<td>Prepared and packed under insanitary conditions; high total bacterial count.</td>
</tr>
<tr>
<td>Shrimp, breaded/Columbia, S.C. 1/6/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>frozen (codes 9970 and 10147)/Austin, Tex. 1/27/71</td>
<td>Sea Pack, Div. of W.R. Grace &amp; Co./St. Simons Island, Ga. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Jacksonville, Fla. 1/13/71</td>
<td>Trade Winds Co. (subsidiary of W.R. Grace &amp; Co.) Thunderbolt, Ga. (P)</td>
<td></td>
</tr>
<tr>
<td>Milwaukee, Wis. 3/5/71</td>
<td></td>
<td>Decomposed.</td>
</tr>
<tr>
<td>Tomatoes, stewed, canned/Denver, Colo. 3/16/71</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Economic and Labeling Violations

<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>Bananas, chocolate coated, frozen/Philadelphia, Pa. 1/18/71</td>
<td>Rezende’s Frozen Foods/Riverside, N.J. (M,S)</td>
<td>False and misleading statements “chocolate covered” and “Dark Sweet Chocolate,” since coating contains fat other than cocoa fat and does not meet the standard of identity for chocolate coating; not in conformity with the Fair Packaging and Labeling Act.</td>
</tr>
<tr>
<td>Barbecue sauce, smoked/North Little Rock, Ark. 3/9/71</td>
<td>Better Foods, Inc./Dallas, Tex. (M)</td>
<td></td>
</tr>
<tr>
<td>Codfish, boned, salt/Denver, Colo. 2/10/71</td>
<td>Booth Fisheries, Inc./Chicago, Ill. (S)</td>
<td></td>
</tr>
<tr>
<td>Compliment cooking sauce/Dallas, Tex. 2/12/71</td>
<td>Pet, Inc./St. Louis, Mo. (M)</td>
<td></td>
</tr>
<tr>
<td>Herring filets, creamed/Cleveland, Ohio 1/7/71</td>
<td>City Smoked Fish Co./Detroit, Mich. (M)</td>
<td></td>
</tr>
<tr>
<td>Honey, Rita Miller’s comb/Denver, Colo. 3/4/71</td>
<td>Miller’s Honey Co., Inc./Salt Lake City, Utah (S)</td>
<td></td>
</tr>
<tr>
<td>Pecans, shelled/Memphis, Tenn. 3/10/71</td>
<td>The Roper Pecan Co./Hickman, Ky. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Salmon/Greenville, S.C. 2/5/71</td>
<td>Whitney Fidalgo Seafoods, Inc./Seattle, Wash. (S)</td>
<td></td>
</tr>
<tr>
<td>Salsa Picante, Mole Poblano, Mole Verde, Adobo en Pasta, Pipian en Pasta/San Antonio, Tex. 2/1/71</td>
<td>Productos Marpe, S.A./San Luis Potosi, Mexico (M)</td>
<td></td>
</tr>
<tr>
<td>Shrimp, Country’s Delight, breaded fantail/Chicago, Ill. 2/12/71</td>
<td>Golden Shore Seafoods, Inc./Brunswick, Ga. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Vegeburger/Collegedale, Tenn. 3/5/71</td>
<td>Cedar Lake Foods/Cedar Lake, Mich. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Walnut kernels, black/Neola, Iowa 2/2/71</td>
<td>Hammond’s Products Co./Stockton, Mo. (P,S)</td>
<td></td>
</tr>
</tbody>
</table>

### Food Additive

<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>Rantsite (crushed stone)/Hutchinson, Minn. 1/5/71</td>
<td>Carl Schmidt/Florence, Colo. (M,S)</td>
<td>Unsafe food additive; false and misleading statements to be a significant source of supplemental minerals for livestock and poultry; label fails to bear common or usual name of article.</td>
</tr>
<tr>
<td>Videts capsules/Houston, Tex. 1/13/71</td>
<td>Videts Pharmaceutical Corp./Houston, Tex. (D)</td>
<td>Represented falsely as a food for special dietary use for persons of all age groups; inadequate information on vitamin and mineral content.</td>
</tr>
</tbody>
</table>

### Vitamins—Dietary Food

<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>Videts capsules/Houston, Tex. 1/13/71</td>
<td>Videts Pharmaceutical Corp./Houston, Tex. (D)</td>
<td></td>
</tr>
</tbody>
</table>

**FDA Papers / May 1971 / 39**
<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>Adrenal Cortex extract (RecuptoD/San Francisco, Calif. 12/10/70)</td>
<td>Giogau &amp; Co., Inc./Chicago, Ill. (M,S)</td>
<td>New drug not approved for safety and efficacy.</td>
</tr>
<tr>
<td>Digitalis, Digoxin/Danbury, Conn. 3/2/71</td>
<td>Davis Edwards Pharmacoal Co./Danbury, Conn. (M,S) Returned from Flushing, N.Y.</td>
<td>Subpotent (Digitalis); fails to meet content uniformity test (Digoxin).</td>
</tr>
<tr>
<td>Digoxin tablets/Danbury, Conn. 3/2/71</td>
<td>Tek Chemicals, Inc./Mount Angel, Ore. (D)</td>
<td>Fail to meet content uniformity test.</td>
</tr>
<tr>
<td>Drugs, raw material and finished products/Chicago and Evanston, Ill. 1/26/71</td>
<td>Great Southern Drug Co./Tucker, Ga. (D)</td>
<td>Not in conformity with good manufacturing practice.</td>
</tr>
<tr>
<td>Epsom salt/Mount Angel, Ore. 2/18/71</td>
<td>Jim Ollis, Inc./Gallatin, Tenn. (M,S)</td>
<td>Strengthen differs from that purported.</td>
</tr>
<tr>
<td>Jim’s tonic/Rome, Ga. 2/16/71</td>
<td>Mirasol, Inc./Salt Lake City, Utah (M,S)</td>
<td>Not in conformity with good manufacturing practice.</td>
</tr>
<tr>
<td>Mirasol (mineral cure-all)/Ridgeland, Wis. 1/7/71 and 2/3/71</td>
<td>American Chemical &amp; Drug Co./San Francisco, Calif. (D)</td>
<td>Below USP standard for quality and strength.</td>
</tr>
<tr>
<td>Ornex capsules/West Deptford, N.J. 2/19/71</td>
<td>Marshall Pharmacoal Corp./South Hackensack, N.J. (M,S)</td>
<td>New drug not approved for safety and efficacy.</td>
</tr>
<tr>
<td>Pangavite injection (Pangamic Acid B-15)/San Francisco, Calif. 11/18/70</td>
<td>Krebs Laboratories/San Francisco, Calif. (M,S)</td>
<td>Contains 109 percent declared amount of amino-phylline.</td>
</tr>
<tr>
<td>Provitamin B-15 capsules/Richardson and Dallas, Tex. 3/24/71</td>
<td>Atlas Pharmaceutical Labs., Inc./Detroit, Mich. (M) Paul B. Elder/Bryan, Ohio (M,S)</td>
<td>Not in conformity with good manufacturing practice; below labeled strength in benzoic acid.</td>
</tr>
<tr>
<td>Som Ophyllin aminophylline/Providence, R.I. 12/14/70</td>
<td>Lincoln Laboratories, Inc./Decatur, Ill. (M,S)</td>
<td>New drug not approved for safety and efficacy; inadequate directions for use.</td>
</tr>
<tr>
<td>Trihogmogen suspension/Middletown, Conn. 2/25/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urostat tablets/Port Huron, Mich. 2/5/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viron 1/Denver, Colo. 2/18/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formula 707 Conditioner/Salt Lake City, Utah 2/24/71</td>
<td>John Ewing Co./LaSalle, Colo. (D)</td>
<td>New animal drug not approved for safety and efficacy; false and misleading claims as a conditioner for horses of all ages; to keep them in peak condition at all times; to contain best balance of vitamins, minerals, and growth-promoting ingredients; to quiet nervous horses and enable them to win races.</td>
</tr>
<tr>
<td>Super 700/LaSalle, Colo. 2/9/71</td>
<td>John Ewing Co./LaSalle, Colo. (D)</td>
<td>New animal drug not approved for safety and efficacy; not conforming to current good manufacturing practice regulations; sulfamethazine not declared on label; inadequate directions and warnings; false and misleading claims for healthier, faster growing animals at lower cost; earlier marketing; better carcasses; better coats, brighter eye; to reduce mortality.</td>
</tr>
<tr>
<td>Batronic Ventilaide/Worland, Wyo. 11/17/70</td>
<td>Batrow Laboratories, Inc./Branford, Conn. (M,S)</td>
<td>False and misleading claims for pulmonary ventilation and in treatment of emergency breathing conditions; inadequate directions for use; dangerous to health when used as recommended.</td>
</tr>
<tr>
<td>Respirex oxygen mask/New York, N.Y. 2/3/71</td>
<td>Respirex Corp./Los Angeles, Calif. (S)</td>
<td>False and misleading claims that the 38 liters of oxygen content is sufficient for first aid treatment of heart attack, stroke, drowning, shock, asthma, and smoke inhalation; inadequate directions for use; inadequate warnings against unsafe methods and duration of administration which may be dangerous to health.</td>
</tr>
<tr>
<td>Theramatic device/Indianapolis, Ind. 9/21/70</td>
<td>Dynapower Systems Corp./Santa Monica, Calif. (M,S)</td>
<td>Inadequate directions for safe use by laymen and practitioners.</td>
</tr>
<tr>
<td>PRODUCT, PLACE &amp; DATE SEIZED</td>
<td>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</td>
<td>CHARGES</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td><strong>Cosmetics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beacon Castile shampoo/Akron, Ohio 1/22/71</td>
<td>Consolidated Royal Chemical Corp./Chicago, Ill. (M)</td>
<td>Contains potassium oleate and Neutronix 600, deleterious substances which may render it injurious to users.</td>
</tr>
<tr>
<td>“Final Eyes” eye make-up/Kansas City, Mo. 3/3/71</td>
<td>Oxyn Co./Trenton, N.J. (M,S)</td>
<td>Contains pseudomonas stutzeri and staphylococci, poisonous and deleterious substances which may render it injurious to users.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HAZARDOUS SUBSTANCES</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Eco-G controlled suds/Landover, Md. 3/8/71</td>
<td>&quot;</td>
</tr>
<tr>
<td>Harrison Winter King Methanol anti-freeze/ Milwaukee, Wis. 1/20/71</td>
<td>Harrison Oil Co., Inc./Milwaukee, Wis. (D)</td>
</tr>
<tr>
<td>Silver Salute firecrackers, aerial repeater bombs/Mount Pleasant, Miss. 12/31/70</td>
<td>Mackeys Grocery &amp; Service Station/Hwy 72, Mount Pleasant, Miss. (D)</td>
</tr>
</tbody>
</table>

**U.S. POSTAL SERVICE** actions taken in medical cases under provisions of the Postal Fraud Statutes as reported by the Chief Postal Inspector.

**False Representation Orders Issued by Judicial Officer Under 39 U.S.C. 4005**

February 19, 1971: False Representation Order issued against Thy-Lac Corp., 101 34th Street, Union City, N.J. 07087. Solicitations of orders and sales through the mails of “Nu-Youth” Formula (pills), represented as enabling users to enjoy sexual rejuvenation.

March 4, 1971: False Representation Order issued against B. McFall, Box 09179, Chicago, Ill. 60609. Solicitations of orders and sales through the mails of “New Vim,” a product advertised to “activate the glands plus special treatment,” represented as being an aphrodisiac.

**Complaints Filed by the General Counsel Under 39 U.S.C. 4005 (False Representations)**

February 9, 1971: Swedish Health Shorts, Inc., Northridge, Calif. 91324. Firm places full-page advertisements in national magazines, representing that the inflatable shorts will remove up to 6 inches of unwanted waistline, hip, and thigh in about 5-10 days.

March 10, 1971: Bruce Roberts Co., 89 Worth Street, New York, N.Y. 10013. Solicitations of orders and sales through the mails of “Viran” tablets, represented as a sexual rejuvenator.

February 26, 1971: Fenaire, Inc., 18800 N.W., 2nd Ave., Miami, Fla. 33169. Solicitations of orders and sales through the mails of Vitamin E (d-Alpha Tocopheryl Acetate) represented as being an aphrodisiac.

March 11, 1971: Brewster Products and P.O. Box 906, Madison Square Station at New York, N.Y. 10010 and at Newark, N.J. Advertising and sale by mail of “Formula 11” Method promising dramatic weight losses.

March 9, 1971: Grapefruit Diet, 7046 Hollywood Boulevard, Hollywood, Calif. 90028. Firm advertised in newspapers and magazines of general circulation that grapefruit was an essential part of the diet and contributes to rapid weight loss, by acting as a catalyst to start “The Burning Process.”

March 12, 1971: Parker Publishing Co., Inc., West Nyack, N.Y. 10994. Advertising and sale by mail of a book entitled “Helping Yourself With Foot Reflexology,” represented as containing therapeutic theories and principles which are in the nature of a panacea as well as a remedy for numerous general and specific human body ailments.
NOTICES OF JUDGMENT on Seizure Actions

FOGO/Poisonous and Deleterious Substances

Digestor tankage, Eagle's, and meat and bone meal, Eagle's, at Cassopolis, W. Dist. Mich.
Charged 9-10-70: when shipped by Eagle Products, Inc., Mishawaka, Ind., the articles contained a poisonous and deleterious substance, Salmonella micro-organisms; 402(a)(1). Consent decree ordered destruction. (1)

Lettuce, Singh's, at Buffalo, W. Dist. N.Y.
Charged 11-24-70: when shipped by Raja Singh Farms, Toltec, Ariz., the article contained the pesticide chemical, parathion, in excess of the tolerance; 402(a)(2)(B). Consent decree ordered destruction. (2)

Shrimp patties, frozen, at Mandan, Dist. N. Dak.
Charged 11-17-70: when shipped by Moore's Seafood Products, Inc., Fort Atkinson, Wis., the article contained the poisonous and deleterious substance, Salmonella micro-organisms; 402(a)(1). Consent decree ordered destruction. (3)

Wheat, at Sioux City, N. Dist. Iowa.
Charged 8-24-70: when shipped by Peavey Co., Winner, S. Dak., the article contained a pesticidal chemical which was not labeled, and there was no tolerance or exemption; 402(a)(2)(B). Consent decree authorized release to reconditioner. (4)

Food/Drug/Compounding, Spillage, Insanitary Handling

Charged 8-9-70: when held by A. A. De La Torre & Sons, El Paso, Tex., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (5)

Beans, pinto, dried, at Hatton, Dist. N. Dak.

Charged 8-26-70: when shipped by Staley Manufacturing Co., Detroit, Mich., to San Carlos, Tex., and thereafter returned, the article contained wood chips; 402(a)(3). Default decree ordered destruction. (7)

Chilies, dried, at Vernon and Los Angeles, C. Dist. Calif.
Charged 10-23-70: when shipped by Lehat, Schwitz Shipping Corp., Staten Island, N.Y., the article contained feral mite and insect filth; 402(a)(3). Consent decree authorized release to Hsimooco (American Co.), Inc., Los Angeles, Calif., for salvaging. (8)

Cornflakes, at Phoenix, Dist. Ariz.
Charged 7-10-70: when shipped by George Walcher, Weimar, Tex., the article contained insect filth and moldy cornflakes; 402(a)(3). Default decree ordered destruction. (9)

Eggs, frozen, at St. Louis, E. Dist. Mo.
Charged 8-21-70: when shipped by Hillini Egg Products, Oliny, Ill., the article contained decomposed eggs and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (10)

Peppers, at Omaha, Dist. Neb.
Charged 11-9-70: when shipped by Chicago Pickle Co., Redgranite, Wis., the article, labeled "Allbert's Finest . . . Banana Peppers . . . Distributed by Farm Foods, Uniontown, Ala.," contained insect and rodent filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (11)

Pickle relish, sweet, and pickle chips, sweet, at Hurlock, Dist. Md.
Charged 8-20-70: while held by Hurlock Pickling Co., Inc., Hurlock, Md., the articles had been prepared under insanitary conditions, from sugar which had been imported from Ireland and which had been held in bags contaminated with amoebic ore, whereby the articles may have been rendered injurious to health; 402(a)(4). Default decree ordered destruction. (12)

Shrimp, breaded, frozen, Cold King, at Charlotte, W. Dist. N.C.
Charged 8-20-70: when shipped by Southern Frozen Foods, Inc., Monte- zuma, Ga., the article contained E. coli, coagulase positive staphylococci, and bacterial filth, and had been prepared and packed; by Gulf Gold, Inc., Tampa, Fla.) under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (13)

FOOD/Economic and Labeling Violations

Charged 7-30-70: when shipped by Grist Mill, Los Angeles, Calif., the article was in violation of the Fair Packaging and Labeling Act, since the declaration of net quantity of contents was not separated from other printed label information appearing below the declaration; and since the principal display panel and alternate principal display panel had an area between 25 and 100 square inches, and the net quantity of contents was stated in a type size less than 3/16 inch high, 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Default decree ordered destruction. (14)

Cookie wafers, vanilla, Tasty, at Mountain Grove, W. Dist. Mo.
Charged 8-14-70: when shipped by Tasty Cookie Co., Inc., Louisville, Ky., the article was in violation of the Fair Packaging and Labeling Act in that the quantity of contents declaration was not in the bottom 30 percent of the principal display panel, and was stated as "Net Weight 1 Pound" and "One Box of 16 Wafers" instead of "Net Weight 12 Oz. (2 cups); 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i). Default decree authorized donation to charitable institutions. (15)

Preserves, strawberry, at Sheboygan, E. Dist. Wis.
Charged 9-25-70: when shipped by Phillips Foods Corp., Chicago, Ill., the article, labeled in part "Gaylord Pure Strawberry Preserves Dist. by Topco Associates, Inc., Skokie, Ill., lacked conformity to the standard of identity, since it contained excess dextrose; 402(a)(1). Default decree authorized donation to charitable institutions. (16)

Charged 5-6-70: when shipped by Zestee Foods, Inc., Oklahoma City, Okla., the article, labeled "Bisquick Brand Fancy Solid Pack Alba- core White Tuna in Water . . . Packed for American Roland Food Corp., New York, N.Y.," contained decomposed tunafish; and the label statements "Fancy White Tuna" and "Fancy Solid Pack" were false and misleading, since the article was not "Fancy" because it contained flakes, some scorching, and had a poor color; 402(a)(A). Consent decree authorized release to American Roland Food Corp., New York, N.Y., for export to original foreign suppliers. (17)

Tunafish, canned, at Long Island City, E. Dist. N.Y.
Charged 6-3-70: when shipped by Japan Mercantile Co., Ltd., Tokyo, Japan, the article, labeled in part "Brand Fancy Solid Pack Alb- core White Tuna in Water . . . Packed for American Roland Food Corp., New York, N.Y.", contained decomposed tunafish; and the label statements "Fancy" and "Fancy Solid Pack" were false and misleading, since the article was not "Fancy" because it contained flakes, some scorching, and had a poor color; 402(a)(A). Consent decree authorized release to American Roland Food Corp., New York, N.Y., for export to original foreign suppliers. (18)

Waters, wheat, Venus, at Los Angeles, C. Dist. Calif.
Charged 9-22-70: when shipped by Venus Waters, Inc., Quincy, Mass., the label statement concerning the sodium content of the article was false and misleading, since the sodium contained was more than the declared amount of sodium; 403(a). Default decree ordered destruction. (19)

Whiting, headless, frozen, Seven Seas, at Alexander City, M. Dist. Ala.
Charged 10-6-70: when shipped by Neptune's Seven Seas, Inc., Gloucester, Mass., the article was in violation of the Fair Packaging and Labeling Act in that the quantity of contents was stated as "Net WT. 5 Lbs." instead of "Net WT. 48 Ounces (3 Lbs.); 15 U.S.C. 1453(a)(3)(A)(ii). Consent decree authorized release to shipper for relabeling. (20)

Yams, cut, canned, at East Putnam, M. Dist. Conn.
Charged 8-6-70: when shipped by King Pharr Foods, Inc., Cullman, Ala., the article, labeled in part "Daisy Cut Sweet Potatoes Golden Yams in Syrup . . . Distributed by Farm Foods, Uniontown, Ala.," was in violation of the Fair Packaging and Labeling Act, since the declaration of net quantity of contents was not placed within the bottom 30 percent of the area of the principal display panel, and net quantity of contents on the principal display panel and alternate principal display panel (each having an area between 5 and 25 square inches) was stated in a type size less than 1/8 inch high, and since the label lacked a statement of the net quantity of the servings referred to in the statement "3 to 4 servings.; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(ii); 1453(a)(4). Default decree ordered destruction. (21)

VITAMINS/DIETARY FDDDS

B-complex vitamin and mineral tablets, at Oakland, N. Dist. Calif.
Charged 3-5-70: while held by Lura-Glo Products, Inc., Oakland, Calif., after being manufactured from ingredients shipped in interstate commerce, the tablets contained the nonconforming food additive, sodium fluoride, and potassium iodide; the label statement "High Potency" was false and misleading; the listing on the label of the ingredients, powdered whole dried liver, dried debittered yeast, di-methionine, potassium chloride, insoluble and choline dihydrogen citrate was false and misleading, since such listing suggested that the articles were enhanced by such ingredients, whereas such ingredients were of no nutritional value and were of no nutritional significance in the article; and the article's label lacked required special dietary use information concerning its vitamin and mineral properties; 402(a)(2)(C), 403(a), 403(j). Default decree ordered destruction. (22)

Dr. Bronner's calcium food, carrot syrup, organic mineral bouillon, and organic vegetable tablets, at Oakland, N. Dist. Calif.
Charged 3-5-70: while held by Lura-Glo Products, Inc., Oakland, Calif., after being manufactured from ingredients shipped in interstate commerce, the articles contained the nonconforming food additive, sodium fluoride, and had a poor color; 402(a)(3). Consent decree ordered destruction. (23)
sugar replacement and that it contained natural ground calcium which was recognized in the United States Pharmacopeia; the label for the same product, Aknemed, stated that it was a medication for acne, or for general skin problems, and that the article's labeling lacked serious diseases regardless of their nature; 502(a). Default decree ordered destruction. (39)

Charged 6-17-70: while held by International Drug Co., Los Alamitos, Calif., after manufacture by Linden Labs, Culver City, Calif., from raw materials shipped in interstate commerce, the article was deficient in chloropropionamide, a potassium salt of chlorpropionamide; 502(a). Default decree ordered destruction. (32)

Charged 2-13-70: when shipped by B. B. Elder Co., Bryan, Ohio, the supplement contained false and misleading claims that the article had unique nutritional value as a supplement to the diet and that its phenylpyrrolidine hydrochloride content was less than that declared (approx. 20 percent); 501(1)(k), 501(c), 502(a). Default decree ordered destruction. (30)

Ginseng powder and capsules, at Chicago, N. Dist. Ill.
Charged 1-26-70: while held by Dr. Michael's Products, Chicago, III., after being shipped in powder form in interstate commerce and thereafter in part encapsulated and repackaged, the accompanying labeling contained false and misleading claims that the articles were a gonadotrophic agent favorably affecting the functions of the gonads or sex glands and that the article would stimulate physical and mental activity and help to resist serious diseases regardless of their nature; 502(A). Default decree ordered destruction. (33)

Histerol-Forte cold tablets, at Downey, C. Dist. Calif.
Charged 11-25-69: while held for sale by manufacture to Leo Linden Labs, Culver City, Calif., from ingredients shipped in interstate commerce, the article, labeled in part "Special Formula S.C. . . . Each tablet contains lodinated . . ." was deficient in phenylethylurea hydrochloride content (approx. 18 percent) and in phenylpropanolamine hydrochloride content (approx. 21 percent); 501(c). Default decree ordered destruction. (34)

Iodinated casein tablets, at Atlanta, N. Dist. Ga.
Charged 9-18-69: when shipped by Aknell Corp., Miami, Fla., the article, labeled in part "Special Formula S.C. . . . Each tablet contains lodinated . . ." was deficient in phenylethylurea hydrochloride content (approx. 18 percent) and in phenylpropanolamine hydrochloride content (approx. 21 percent); 501(c). Default decree ordered destruction. (35)

Charged on or about 7-15-70: while held by Southern Pharmaceutical Co., Gainesville, Fla., the labeling lacked adequate directions for use and the article was not exempt from such requirement, since it was a new drug without an effective approved New Drug Application and no notice of claimed investigational exemption was on file; 502(1)(k). Default decree ordered destruction. (36)

Viron 1 ascorbic acid combination powder for injection, at Denver, Dist. Colo.
Charged 7-10-70: when shipped by Lincoln Labs., Inc., Decatur, Ill., the article was a new drug without an effective approved New Drug Application, and its labeling lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information; 502(1)(k), 505(a). Default decree ordered destruction. (37)

Vitamin combination injection, at Minneapolis, Dist. Minn.
Charged 2-13-70: when the article, labeled in part "Zee Pac Histenol-Forte Cold Tablets . . . contains . . . and chlorpheniramine maleate (approx. 17 percent) and in phenylephrine hydrochloride content (approx. 20 percent); 501(a)(6), 501(c), 502(a). Default decree ordered destruction. (38)

DRUGS/Veterinary

high-Trans Stibiloral 90% trans isomer diethylstilbestrol premix, at Buffalo, W. Dist. N.Y.
Charged 4-29-70: when shipped by Elanco Products Co., Division of Eli Lilly & Co., Indianapolis, Ind., the article was a new animal drug without an effective approved New Animal Drug Application; 501(3)(f). Default decree ordered destruction. (39)

Charged 3-13-70: while held by Mixen Co., Inc., who manufactured the article from a premix containing thiazidene shipped in interstate commerce, the article was deficient in thiazidene content, since it was an animal feed containing a new animal drug, thiazidene, and no approval was in effect of an application filed pursuant to Section 512(m)(1) with respect to such animal feed; and the labeling contained false and misleading statements in the article's labeling, and packing, and holding lacked conformity with current good manufacturing practices; and the article's strength was deficient, since its vitamin D2 content was between 1 percent and 89 percent of that declared; 501(2)(B), 501(c). Default decree ordered destruction. (38)

DRUGS/Veterinary

Absorber copper bracelets and copper sheets, at San Francisco, N. Dist. Calif.
Charged 4-10-70: while copper bracelets were held by the dealer, Michael S. Colbert, doing business as "The Absorber," at San Francisco, Calif., and by the manufacturer, after manufacture from sheets of copper shipped in interstate commerce and thereafter, the manufacturer of copper bracelets for the dealer were held by the manu-
We hold that the absence of coercive circumstances and the credibility of a consent given to an inspection justify a departure from the Sherman Act rule in favor of an administratively determined waiver of warrant.

In conclusion, we hold that in the context of the exclusionary rule a warrantless inspectorial search of business premises is reasonable when entry is gained not by force or misrepresentation, but is, with knowledge of its purpose, afforded by manifestation of consent. Lack of warrant under these circumstances does not render the inspection unreasonable under the Fourth Amendment. United States v. Hammond Milling Co., 413 F.2d 608 (5th Cir. 1969), cert. denied, 396 U.S. 1002 (1970).

We have examined appellants' remaining contentions and find them without merit. Accordingly, the judgment of the district court is affirmed.

NOTICES OF JUDGMENT on Injunction Action

Chick Haven Eggs, Inc., Chick Haven Farms, Inc., and Tam S. Hutchinson, d/b/a Chick Haven Farms, were charged 8-23-67 in complaint for injunction: that the defendants were engaged in breaking, freezing, packaging, labeling, and distributing in interstate commerce, or while held for sale after shipment in interstate commerce, eggs which were all alleged to be adulterated and misbranded or otherwise violative of the law when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce; and that the defendants were ordered to cease and desist of said activities.

A consent decree of permanent injunction was entered which enjoined the defendants against the violations complained of and which required the defendants, before making any further interstate shipment of frozen whole eggs and similar articles to establish facilities and procedures to assure that such articles were not contaminated with Salmonella microorganisms or filth, to destroy or bring into compliance with the law the stock of unpasteurized frozen eggs at the defendants' plant; to recall all unpasteurized frozen eggs not destroyed; to notify the United States Department of Agriculture, the State veterinarian, and the county veterinarian of the recall of eggs.

Chick Haven Eggs, Inc., Chick Haven Farms, Inc., and Tam S. Hutchinson, d/b/a Chick Haven Farms, were ordered to pay costs of the action.

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

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

Charles C. Edwards, M.D., Commissioner of Food and Drugs
Washington, D.C., May 1, 1971
Announcements

NABP INSTITUTE The first institute for Pharmacy Law Instruction, scheduled June 20-23 at the Sheraton Oakbrook Motor Hotel in Oakbrook, Illinois, is a joint effort of the National Association of Boards of Pharmacy, American Association of Colleges of Pharmacy, Food and Drug Administration, and the Department of Justice Bureau of Narcotics and Dangerous Drugs. As a working conference for teachers of pharmacy law, the institute will consider the substance of statutes, regulations and rules of the profession, the assimilation of which is necessary for voluntary compliance by pharmacy practitioners. It will also be concerned with the ethical obligations of the pharmacist and the societal significance and impact of his function. The importance of this instruction has been noted by Sidney H. Willig, director of the institute, in his comment, “There is no force of drug officials available federally or in any State that could carry out the legislative mandate unless the largest percentage of pharmacy practitioners were law abiding.” Dr. Willig is a professor of law in the Schools of Dentistry, Pharmacy, and Law at Temple University, Philadelphia.

Plans for the institute include both workshops and lectures. Separate workshops are scheduled to study the pharmacist as a therapeutic consultant, the pharmacist as a delegator of functions within legal guidelines, and the pharmacist’s role in comprehensive health planning. Initially, the lectures include discussion of the law and ethics of the practitioner. The divergence of pharmacy practice, the interrelationship of rules, State agencies and the practitioner, and the handling of substances are a part of this first presentation. A second lecture series deals with Federal statutes, with emphasis on the jurisdiction and structure of the responsible agencies. A final set of lectures considers civil and criminal liability relative to pharmacy practice. In all, the program schedules 20 hours of lectures and six hours of workshop activity.

Additional information is available from either Fred T. Mahaffey or Howard S. Bimson at NABP, 77 West Washington Street, Chicago, Illinois 60602. If telephoning, the numbers are 312-263-6540 or 312-263-6541.

FOOD SANITATION TRAINING FILM AVAILABLE FDA recently completed production of a 16-mm motion picture film titled “Integrity of Food—A Responsible Concept of Sanitation.” The film, a 15-minute color production with sound, is designed to portray and emphasize important sanitary precautions required in the protection of food. Specifically, the basic rules are reviewed as a way of promoting efficient and proper food warehousing. The potential public health hazards resulting from careless practices in food storage are also explained.

A review copy of the new film has been distributed to all 17 FDA Districts. Arrangements may be made with each Field Office (see list at end of “Field Reports,” page 31) to have the film shown at industry meetings, or for other types of training programs. Food industry officials may find it useful in employee training because it pinpoints requirements and the importance of each person’s job in the storage of food products.

The training film is available for purchase at $62.25 per copy. Send order to Sales Branch, National Audiovisual Center (GSA), Washington, D.C. 20409. Make check or money order payable to National Audiovisual Center (GSA).

PHARMACY CONFERENCE The School of Pharmacy of the University of North Carolina will sponsor a conference July 18-21 on “Computer-Based Information Systems in the Practice of Pharmacy.” The pharmaceutical industry and profession has long recognized the need for automated systems to accommodate dramatic expansion in all areas. The UNC conference will examine in depth the information requirements that computer-based systems must meet in such areas as third-party payments for prescription drugs, drug interactions and adverse reactions, drug recalls, and other measures that affect the practice of pharmacy and patient care.

Among experts in the health care and pharmacy fields planning to attend the conference are Dr. M. Keith Weikel, director for health evaluation, Department of Health, Education, and Welfare, Washington, D.C.; Dr. Vernon E. Wilson, administrator, Health Services and Mental Health Administration, DHEW, Washington; and Dr. David P. Jacobus, vice president, Basic Research, Merck, Sharp and Dohme, Rahway, New Jersey.

Dr. George P. Hager, dean of the UNC School of Pharmacy, is conference director, and Paul D. Olejar, director of drug information programs at the School of Pharmacy, is conference coordinator.

Joseph A. Higgins, director of the Social Security Administration’s Drug Task Force, which has been studying the question of how payments for prescription drugs might be handled efficiently, will lead the workshops dealing with third-party payments.

For further information regarding the conference, write to the UNC School of Pharmacy, Chapel Hill, North Carolina 27514.