

JULY-AUGUST 1971

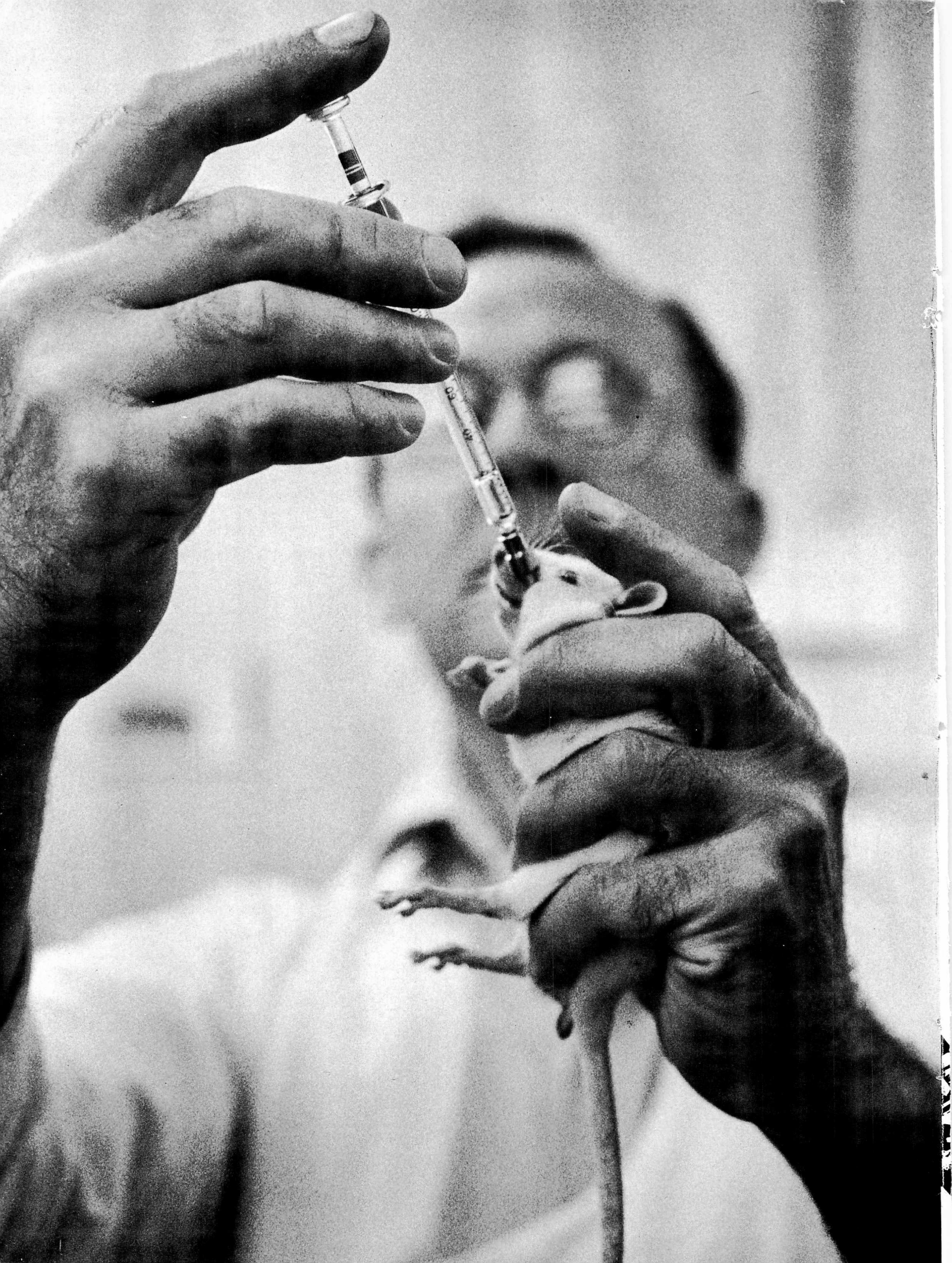
FDA PAPERS

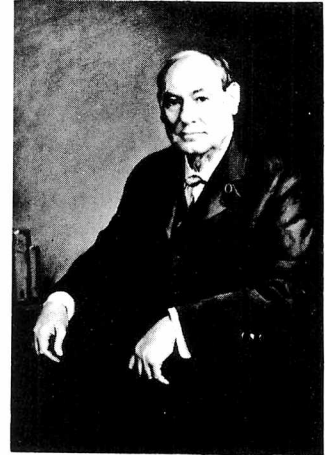
**SAFER ANTIBIOTICS
WITH LAB ANIMALS**

**IT MAY BE GOOD—BUT
IS IT GOOD FOR YOU?**

**Burn-Resistant Fabrics:
There's Hope Ahead**

UNIFORM FOOD TESTS





"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

Even though a food may be pleasing to see, smell, taste, or even to digest, its value as a nutrient is determined by the health of the eater; this may be complicated by other factors, including the amounts and kinds of other foods eaten. Finding the proof of the pudding is a great deal more subtle than most of us are able to comprehend. Man's historical tendency to alter foods makes the way food is processed one of the considerations.

It is necessary for FDA's National Center for Nutrient Analysis (see page 19) to provide the analytical expertise needed for the ultimate protection of the American consumer. To confirm man's continuing success in producing better foods, as well as to rectify his errors and sometimes his deceptions, the Center must use the best methods in evaluating the nutrient content of foods and food supplements. It not only must keep up with the food processor, but in some respects must stay ahead of him.

quotes

"I am not suggesting that FDA embark on a program of batch-by-batch testing and certification of all drugs in this country. I am not suggesting that industry embark on some sort of testing to the point of destruction—where 95 tablets out of 100 are tested to assure reliability of the remaining five tablets. What I am suggesting is that industry put into effect, where you have not already done so, all measures necessary to assure reliability. I can tell you that the Food and Drug Administration will not be satisfied until we can assure every prescriber or purchaser, public or private, that all legitimate drugs on the market, whatever the legal basis for their marketing, are, within the limits imposed by the 'State of the Art,' unequivocally reliable."

John Jennings, M.D., Associate Commissioner for Medical Affairs, at the Annual Meeting and Conference of the National Association of Pharmaceutical Manufacturers, Downingtown, Pennsylvania, June 20, 1971.

"I mentioned that we are proceeding along three tracks in nutritional labeling. The third track is listing of all ingredients on the labels of all foods. The Agency has for some time been interested in testing the worth of this concept and we found a convenient vehicle in a recent petition filed with FDA by LABEL, Inc.—an acronym for Law Students Association for Buyer's Education and Labeling. The proposal would make ingredient labeling mandatory on standardized as well as nonstandardized foods. In publishing the petition, the FDA is seeking public comment on the concept.

"We are also inviting suggestions on related subjects, such as label declarations classifying ingredients by function and source, and the way that label information should be presented."

Charles C. Edwards, M.D., Commissioner of Food and Drugs, at the Grocery Manufacturers Association Meeting, White Sulphur Springs, West Virginia, June 22, 1971.

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Commissioner of Food and Drugs

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

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

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

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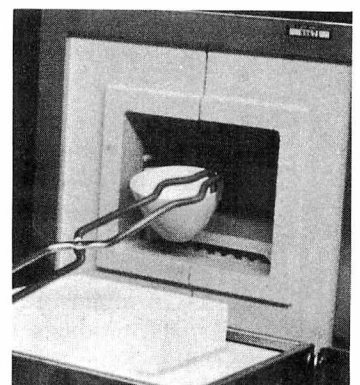
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A National Program Toward Uniform Food Testing

by Karen Gutfinski

Efforts to control microbiological health hazards in food and drugs constitute one of the major consumer protection programs of the Food and Drug Administration. A network of State and Federal food testing laboratories maintains constant surveillance over products flowing across and within State boundaries. To assess the uniformity of testing across the country by these laboratories,

the Division of Microbiology in FDA's Bureau of Foods has instituted a split food sample testing program.

Using methods, and often equipment, employed in its split milk sample testing program (see FDA PAPERS, December 1969-January 1970), the Division's Laboratory Development Section in Cincinnati prepared and shipped samples of mashed potatoes to 59 State food testing laboratories located in 44 States and Puerto Rico. Following procedures recommended by the Association of Official Analytical Chemists, 109 analysts in these laboratories examined the samples. Each sample contained a variety of bacterial types capable of causing food spoilage, loss of vital nutrients, and/or foodborne disease. Upon completion of their tests, all analysts returned their results to the Division of Microbiology for nationwide evaluation of uniformity of test results. As with the milk laboratory program, participation is voluntary.

The food testing program origi-

nated more than a year ago with realization by both State and Federal officials of the increasing need for more extensive and intensified microbiological inspection of the Nation's food supply to protect the public health. "Beyond question there are more people affected every year in this country by microbiological contamination of food than there are by any other impairment of food safety," says Dr. Virgil Wodicka, FDA Bureau of Foods director. The other causes for concern that he listed included malnutrition, environmental contaminants, naturally occurring toxins, pesticides, and food additives.

Dr. James W. Messer of the Laboratory Development Section explained that since the 1940's, food consumption patterns have shifted drastically. Commercially prepared convenience foods and ready-to-eat items have replaced many home prepared foods, thereby sharply increasing the chance of unfit food reaching consumers throughout the country. The increase in mass preparation of foods resulting from the growing practice of "eating out" also creates a greater need for regulatory activities.

Judgment of the microbiological quality of foods depends on the use of standardized methods of testing. A standardized test that is performed or interpreted incorrectly can bring about destruction of a good product and consequent waste, or can result in the shipment of a contaminated product, contributing to the more than 10 million cases of foodborne disease that occur annually in the United States. Since a single manufacturer's product may reach all parts of the Nation, it is essential that adequate testing methods are performed *uniformly* by analysts whenever and wherever food testing methods are applied.

Many of the State laboratories that participate in the present milk testing program also test additional foods. They requested that the FDA implement a laboratory standardization program for food testing similar to that for milk. To determine how widespread was the interest for a food laboratory program of this type,

the Division of Microbiology polled the central laboratory of each State and asked if they would be interested in such a program on a voluntary basis. All of the 50 States involved in the routine testing of foods replied affirmatively.

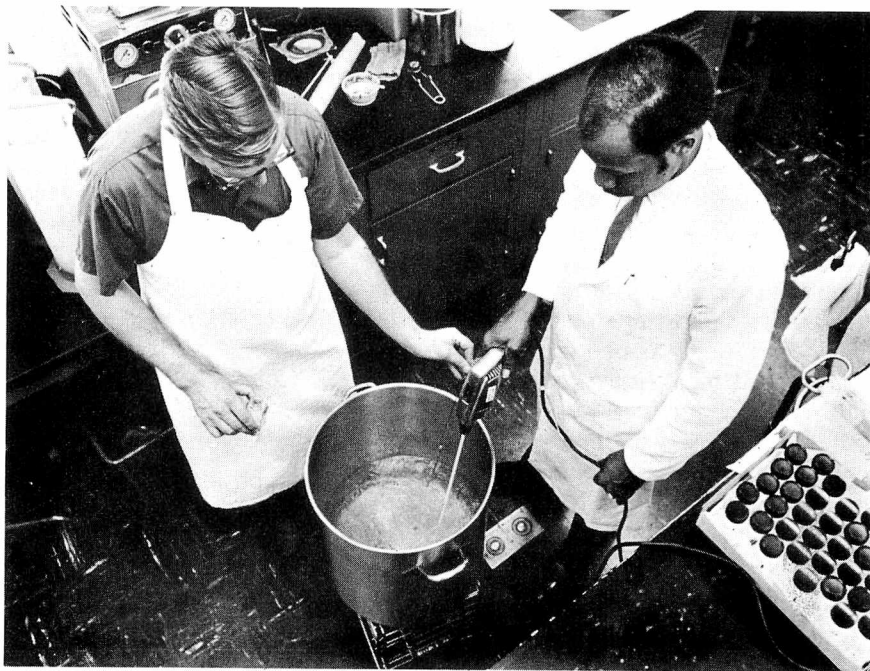
Several Federal, State, and commercial groups also saw the need for uniform application of test methods. A resolution recently passed by the Conference of State Sanitary Engineers and approved by the executive committee of the Association of State and Territorial Health Officers endorsed "the concept of . . . developing uniform microbiological examination procedures," and asked "that the Food and Drug Administration be requested to establish the mechanism to coordinate the efforts of all concerned."

The National Conference on Food Protection, which brought experts from such fields as microbiology, public health administration, and sanitation to its April meeting in Denver, Colorado, reported a similar desire for uniform performance of testing methods, as did a meeting of the Association of State and Territorial Public Health Laboratory Directors.

The U.S. Department of Agriculture, which is responsible for meat inspections, indicated its desire to inaugurate a joint testing program with the FDA for those laboratories which examine both meats and other foods. Some of these laboratories are now participating in the FDA food split sample testing program.

In addition, approximately 40 commercial food testing laboratories, all members of the American Council of Independent Laboratories, Inc., expressed an interest in a laboratory program for standardizing microbiological examination procedures for foods. Seventeen of these commercial laboratories will be included in a food split sample distribution this fall.

To avoid fragmentation and duplication of proficiency testing and correlation of results, these groups looked to a single Federal agency to provide these services. The FDA's Division of Microbiology Milk Lab-



At FDA's Cincinnati District laboratory (above), the split sample medium is prepared by microbiologists. Into a stainless steel tub containing 16 liters of water at 35° F., James Leslie (left) adds a bacteria culture. Marvin Green (right) distributes the organisms evenly with a power-driven stirrer.

Seven one-pound boxes of commercially prepared instant mashed potatoes (above) are blended into the inoculated liquid to make a 50-pound batch of sample material.

oratory Program, adopted in 1942, has produced a very high degree of uniformity in microbiological examinations of dairy products; therefore, the FDA was the logical coordinator for a similar program for foods.

In February 1970, microbiologists of the Laboratory Development Section began studies to find a substrate suitable for use as a food split sample. Out of 14 substrates studied, including such items as pudding, baby food, canned meat, gravy mix, and soup, mashed potatoes was chosen as the medium for the samples. When hydrated with water, the dried potato flakes form a consistency convenient for handling, are the lowest in naturally occurring bacteria which might interfere with the growth of the added organisms or with testing procedures, and are stable enough to maintain the test bacteria unimpaired.

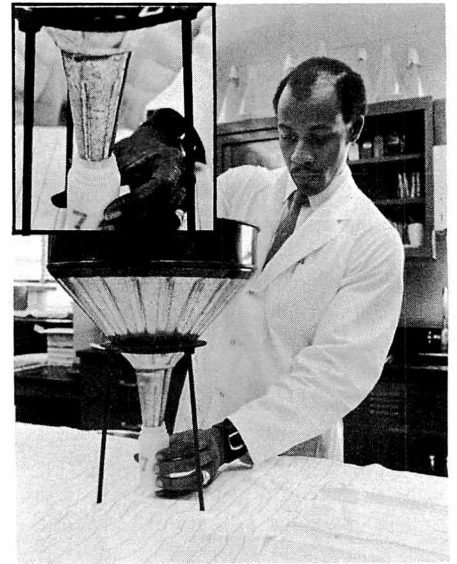
In addition to selecting a suitable substrate, 30 different kinds of bacteria were screened to find those which would remain viable during shipment and analysis of the test sample.

The laboratory's present equipment limits the mashed potato batches to 50-pound lots. The hand mixing method now being used is satisfactory, explains Dr. A. Richard Brazis, Chief of the Milk and Food Laboratory Development Section, but his group is evaluating electric commercial mixers with the intent of increasing the lot size to 100 pounds as the number of participating laboratories grows.

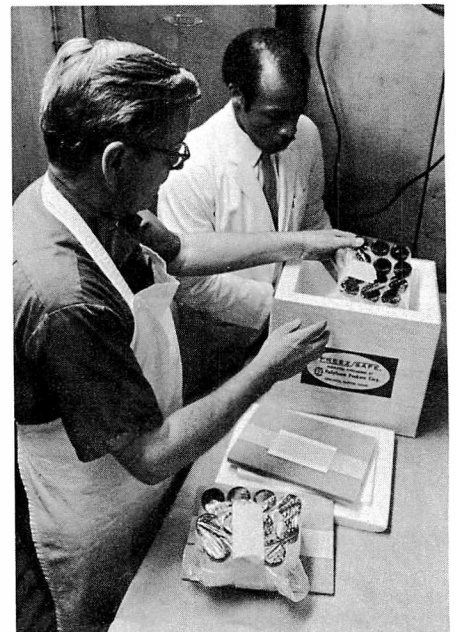
For each group of samples, Dr. Messer and his colleagues prepare four batches of substrate. Each batch is prepared by combining seven pounds of commercially manufactured instant mashed potatoes with 16 liters of water. The bacteria are added and each batch is tested for its uniformity. These tests are instituted to insure that each sample, upon arrival at its destination, will be identical to all others and will contain a predictable number of the bacterial types originally added.

Throughout the preparation procedure, the temperature of the samples is held below 40° F. to maintain

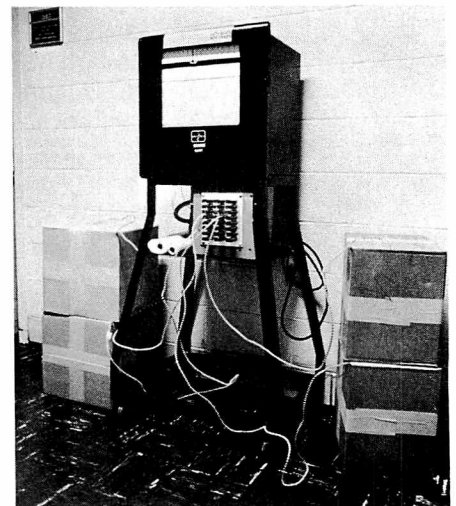
Using a large funnel (right), Mr. Green fills the plastic sample bottles (see insert) with three ounces of sample material.



In a refrigerated storage room (right), Microbiologists Leslie and Green place 23 bottles of inoculated substrate into an insulated container for shipment to a State laboratory. The unit, used in the split milk sample program as well, successfully maintains a temperature below 40° F. for the duration of the trip.



Packages of samples (right), identical to those in transit to the State laboratories, are monitored in a hallway in Cincinnati. A machine records the temperature of the samples as they are taken out of refrigeration so that FDA personnel may have some idea of the condition in which they arrive at their destination.

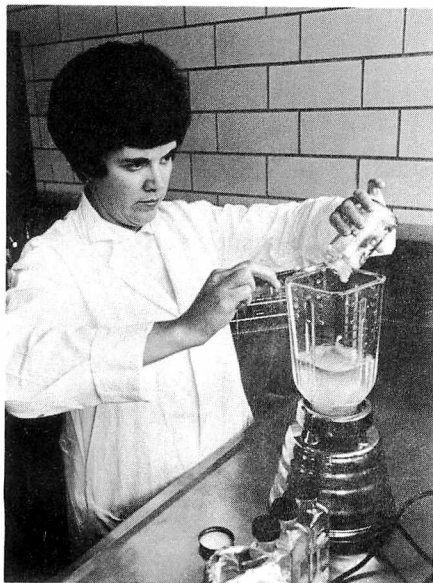




At the State laboratory in South Charleston, West Virginia, Microbiologist Evelyn Baskin (left) takes the temperature of the samples upon their arrival. An extra bottle of substrate is included for this purpose.



Rose Marie Neuhart (left), State microbiologist, weighs 50 grams of sample into a sterile container.



The measured sample (left) is then blended with 450 milliliters of sterile diluent to prepare the dilution which will be used for further testing.

stability. Since the shipping containers used in the milk testing program afforded satisfactory temperature control for 30 to 36 hours, they were used for this program.

Cultures of three types of bacteria were inoculated into the substrate: coagulase positive staphylococci, *Escherichia coli*, and a nonpathogenic food spoilage organism.

Each State laboratory received on June 7, 1971, four samples for testing. All analysts in each participating laboratory were requested to do the testing. They performed the following tests on each of the four samples: (1) an aerobic plate count; (2) a coliform count, most probable number (MPN); (3) an *Escherichia coli* MPN count; and (4) a *Staphylococcus aureus* MPN count. Testing lasted 10 to 14 days and required approximately 20 man-hours of work time.

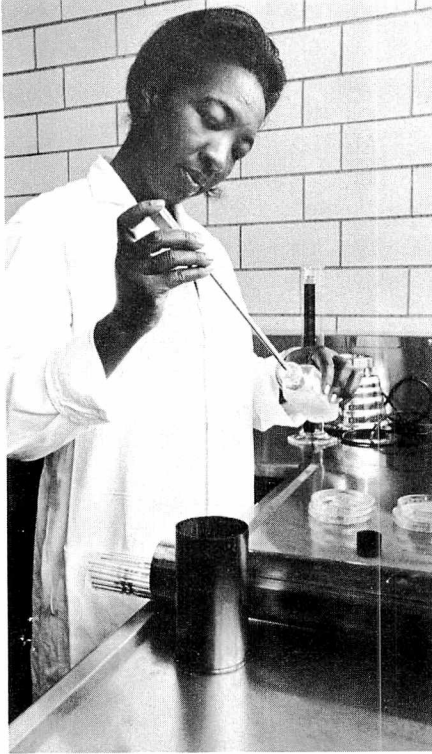
Since uniformity in following established test procedures by participating analysts is the program's goal, only the methods published in the Journal of the Association of Official Analytical Chemists were considered acceptable.

District microbiologists handled communications between the Division of Microbiology's Laboratory Development Section and the participating State laboratories. When necessary, these same District microbiologists helped the participating State laboratories overcome any analytical difficulties. Communications between the FDA District microbiologists, the Division of Microbiology, and the participating States were coordinated by the office of the Executive Director of Regional Operations.

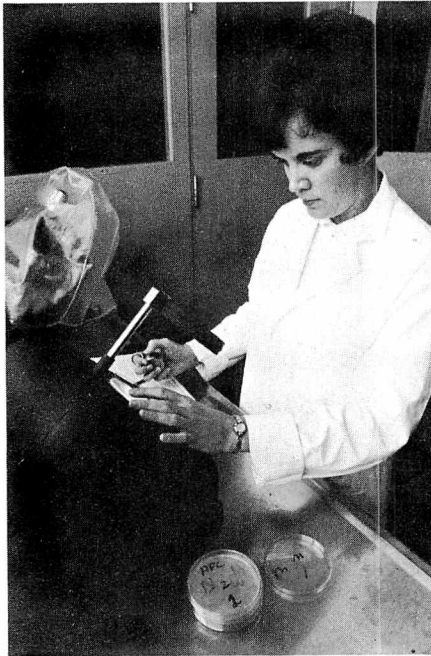
Dr. Brazis, in reviewing the results returned to the Division of Microbiology, said that all State laboratories did well in following the recommended procedures. In some instances, laboratories reported substituting other methods when prescribed methods could not be used.

Present plans for the program call for the continued issuance of one set of split samples each year for State laboratories and biannually for FDA District laboratories. It is also anticipated that samples will be in-

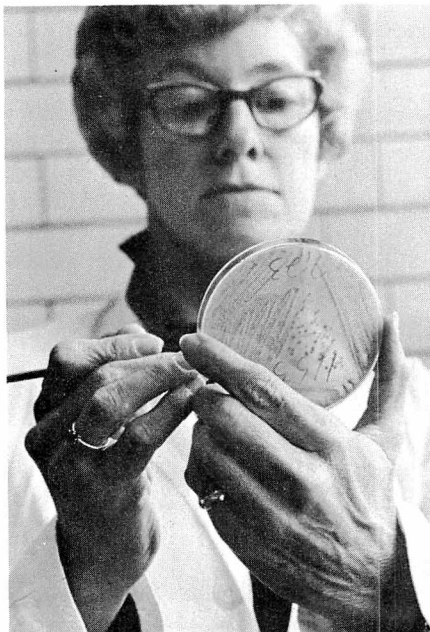
Miss Baskin (right) places one milliliter of an appropriate dilution on a plate to which she will add agar for an aerobic plate count.



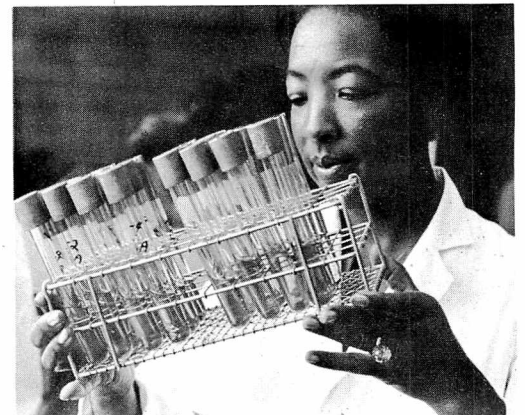
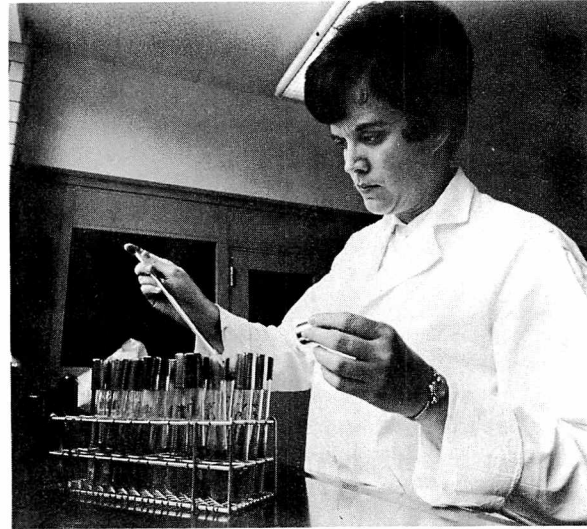
After incubation, the number of bacteria colonies (right) that have grown is counted.



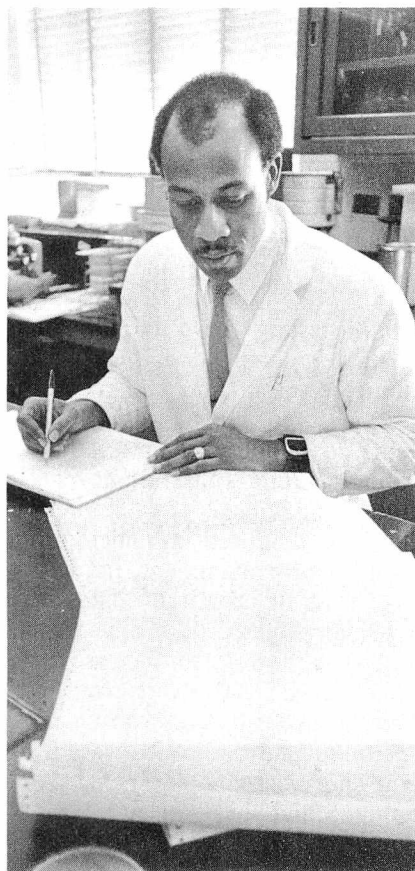
Material from those tubes showing positive coliform results is streaked on plates (right). Miss Neuhart examines one of these.



For the coliform test, Ann Hopkins (below) inoculates a Most Probable Number (MPN) series of tubes with the sample.

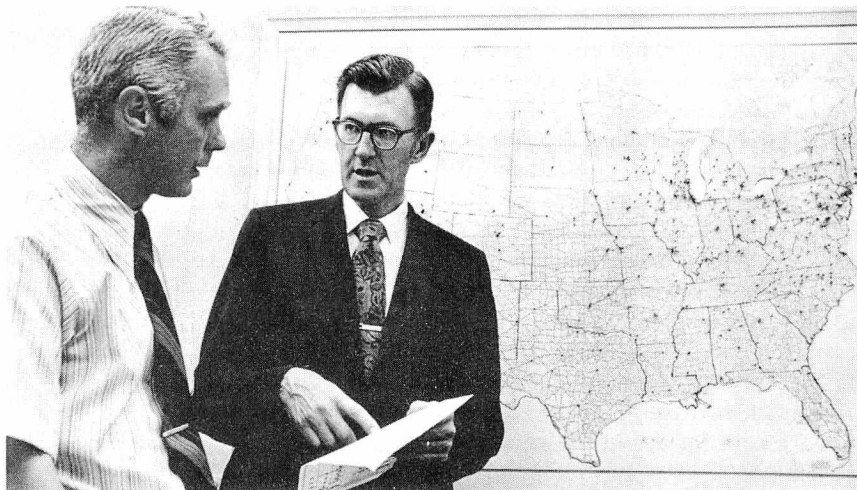


MPN tubes (above) are checked for growth of *Staphylococcus aureus*.



At Cincinnati once again (left), the results of the State laboratory analyses are compiled by Mr. Green for nationwide evaluation of uniformity of testing procedures.

Below, the split food sample testing program directors, Dr. James W. Messer (left) and Dr. A. Richard Brazis (right), discuss the degree of uniformity the tests have found. Behind them is a map pinpointing the locations of State laboratories.



cluded for *Salmonella* determinations as the program develops. Additional procedures which may be added to the program include isolation and typing of *Clostridium botulinum*, enumeration of *Clostridium perfringens*, testing foods for staphylococcal enterotoxin, isolation of *Shigella*, and the enumeration of *Vibrio parahaemolyticus*.

Future plans for the program call for visits to participating laboratories by members of the Laboratory Development Section. These visits would provide information about the types of equipment available in the laboratories, methods being used, and problems encountered by the State food analysts. Resulting information could help speed correction of deficiencies in testing procedures and facilities.

The Laboratory Development Section is an integral part of the FDA's total effort of furnishing assistance and guidelines to State and local agencies in the interest of more effectively reducing the hazard to the public health from unsafe foods.



Karen Gutfinski, a student at Simmons College, Boston, Massachusetts, is a Summer Aide with FDA's Publications Services Staff.

Using Lab Animals To Assure Safer Antibiotics

by Gaylord B. Castor

The National Center for Antibiotics Analysis (NCAA) is charged with conducting the various tests that lead to batch certification of antibiotics and antibiotic products. The certification requirements and test methods are described in the Code of Federal Regulations, Title 21, parts 146 through 151.

The Antibiotic Biological Branch of the Center carries out tests that require the use of small laboratory animals for detection of contaminants of microbial origin. In terms of space, the largest operation is that of testing for pyrogens and involves permanent housing for some 600 rabbits as well as two separate rooms for the test itself. Next is the toxicity test, which requires housing space for approximately 2,800 mice and shelf space for keeping the injected mice under observation for periods ranging from two to 14 days. Finally, a small number of cats are kept for use in the vasodepressor test.

Housing and care of the animals conform to the standards and requirements of the Animal Welfare Acts of 1966 and 1970. The Branch staff includes a doctor of veterinary medicine who keeps the animals under constant observation and provides medication for minor ailments. His services are also available, on request, to other animal laboratories in the FDA laboratory building.

Day-to-day care of the animals is provided by a crew of five laboratory animal research helpers under the direction of a foreman and supplemented by three other subprofessional laboratory aides. A number of these workers have completed courses sponsored by the American Association for Laboratory Animal Science in the proper care and handling of animals.

Members of the professional staff are classified as biologists. All are college graduates (some have advanced degrees), with majors in various biological sciences. All participate periodically in in-service training by attending courses in biological sciences and, where appropriate, in management practice.

Of the total staff of 19 persons, only five have been employed in the Center for less than five years. The remaining periods of service range from five to 28 years, giving the Branch a valuable resource in its pool of experienced personnel.

Antibiotics are not the only drugs tested by the Branch. Certain nonantibiotic parenteral (injectable) preparations are required by the USP and NF to be tested for pyrogens by the manufacturer. Samples of these products come to the Branch through the FDA

District offices for pyrogen testing for a number of reasons, including consumer complaints, suspected violations of good manufacturing practice, and routine surveillance sampling.

To understand the work of the Branch, one should realize that antibiotics and certain other drugs and biologicals may become contaminated with different types of harmful substances produced by microbial growth. The medically important contaminants fall into three groups: (1) a large class of chemically different (in intimate structure) but physiologically similar substances that produce, upon injection, an increase in body temperature and that are collectively referred to as "pyrogens"; (2) a heterogeneous class of substances that lower the blood pressure and are called vasodepressors, the most potent and most common being the simple chemical, histamine; and (3) the microbial toxins. The last group is rarely encountered, but toxic manifestations from other sources are a distinct possibility.

The danger to humans and animals from pyrogens, toxic factors, or vasodepressors depends on the nature of the offending substance and, of course, the amount present. Histamine produces a rapid but transient vasodepression when injected in small quantities; large amounts can prove more serious, although counter measures can be taken at once. Pyrogens, conversely, require an hour or more to make their presence known and a sufficiently large dose may result in shock and even death.

Pyrogens and vasodepressor substances may become contaminants at the production source. For example, antibiotic-producing molds are also efficient pyrogen producers; some biologicals are derived from animal tissues and excretions and these too may contain pyrogens as original contaminants. A number of the antibiotic molds also have been shown to produce histamine in the initial fermentation process. In the course of purification, all of these impurities are normally completely removed.

Pyrogens, vasodepressors, and perhaps toxins may appear after purification and packaging of antibiotics and other parenterals should micro-organisms gain entry into the package by way of loose stoppers, cracked vials, and other physical or manipulative portals.

The introduction of extraneous pyrogens is also a persistent threat when there is improper cleaning and sterilization of utensils, vials, ampuls, hypodermic

syringes and needles, tubing, and other implements used in the processing, packaging, and administration of parenterals.

Last, the widespread use of rubber tubing, plastic bags, plastic tubing, and plastic syringes for transfusions and infusions introduces the possibility of contamination of these items by toxic residues from plasticizers and chemical sterilizing agents.

How these problems are specifically dealt with is not treated in this article. Except for product purification techniques, which are usually trade secrets, the means of preventing or eliminating contamination by microbial growth products are standard procedures—well publicized and well known to the drug industry and regulatory agencies alike. Testing is based on the relevant scientific principles involved.

The pyrogen test is quite simple. A predetermined, measured dose of the product to be examined is injected into the ear veins of a group of three rabbits and the changes in body temperature of each is monitored over a period of three hours. An excessive rise in temperature that is repeated on retesting is a basis for condemning the product batch.

The precautions against laboratory contamination in conducting the pyrogen test are, on the other hand, quite elaborate. Every item of equipment (flasks, graduates, pipettes, syringes, needles) that comes into contact with the sample being tested must not only be clean and sterile but also pyrogen-free at the time of use. Pyrogens are quite resistant to destruction and air heated to a high temperature is used on all metal and glass equipment to accomplish that end. Water used in diluting samples to test strength must be distilled, sterile, pyrogen-free and, for USP testing, must meet various other conditions as to purity. Sterile technique is used in preparing test dilutions to avoid contaminating the stock solutions, test solutions, or the original sample if it is in a multidose container. The animals must be healthy, calm, their feeding withheld, and their temperature patterns even prior to injection. The test is a cooperative undertaking—the rabbits' systems detect any pyrogen present, but human judgment and scientific accuracy are required to eliminate any doubts as to its source.

The toxicity test in which mice are used is more properly a safety test, since it is based on a single dose administration and is designed to detect any noxious activity by the sample, whatever its origin. The dose

for each mouse is predetermined to rule out the possibility of any toxic effect from the properly compounded drug preparation. If reactions or deaths occur among the mice, the cause is presumed to be from such sources as extraneous contaminants, degradation products, or errors in formulation.

With a few exceptions, safety tests are performed almost exclusively on antibiotics. Transfusion and infusion assemblies and a few nonantibiotic drugs, however, are tested in the Branch by the methods specified in the USP. The route of administration to the animal depends on the antibiotic. In the case of packaged parenteral products, the entire formulation is given intravenously. As for oral dosage forms, only the antibiotic contained therein is tested. If it is a water soluble antibiotic, administration is intravenous; if insoluble, it is prepared as a suspension and given orally. In addition, one antibiotic is tested by intraperitoneal injection and two by subcutaneous injection because of certain physical properties of these products.

The criterion of safety is survival of the test animals throughout the period of observation, the period varying with each antibiotic. The minimum and usual period is 48 hours; the maximum, seven days. Two anticancer drugs that have antibiotic properties are also tested routinely, but these are subjected to an LD₅₀ determination—a process that yields a quantitative estimate of the actual toxicity of each batch.

In terms of quantity, the safety or toxicity test is the largest operation of the Branch. Pyrogen and histamine testing are exclusively for injectables, whereas the safety tests embrace products for injection, oral administration, and ophthalmic use.

The designation of the test for vasodepressor substances has been simplified to "histamine test," since this is the only blood pressure depressant thus far positively identified as occurring in the growth cultures of some antibiotic-producing molds. At the present time, 11 antibiotic parenteral products are subjected to histamine testing.

In this test, a cat is placed under moderately deep anesthesia and maintained at that level throughout the day. Blood pressure is recorded continuously on paper, so that every change is immediately visible and measurable. Injections are made into a leg vein through an indwelling plastic catheter. Test samples are injected alternately with a standard histamine solution. Evaluation of each sample is made by comparison of the fall

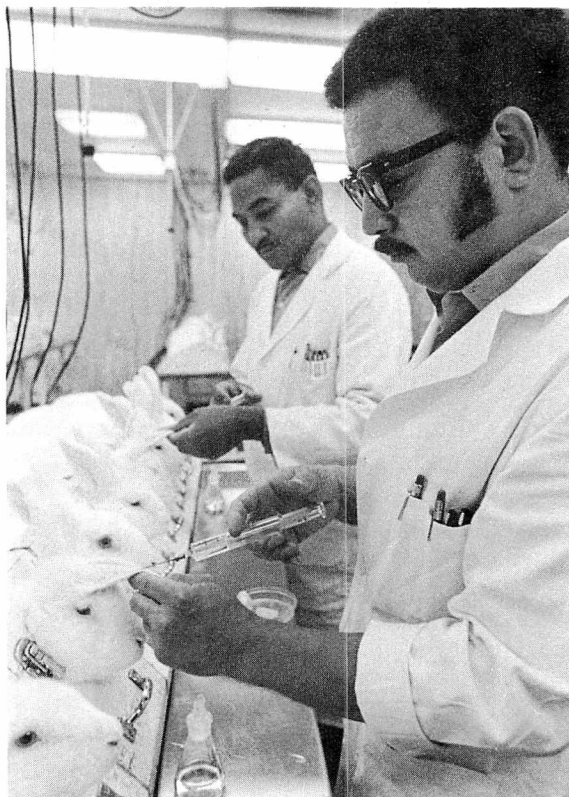
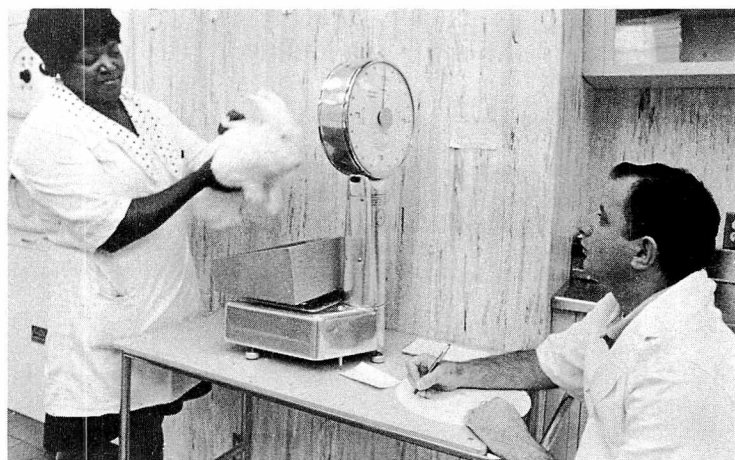
in blood pressure (if any) produced by the test sample with that produced by the standard histamine. The blood pressure drop produced by the antibiotic may equal but may not exceed that produced by the standard histamine.

Why are animals used in these tests?

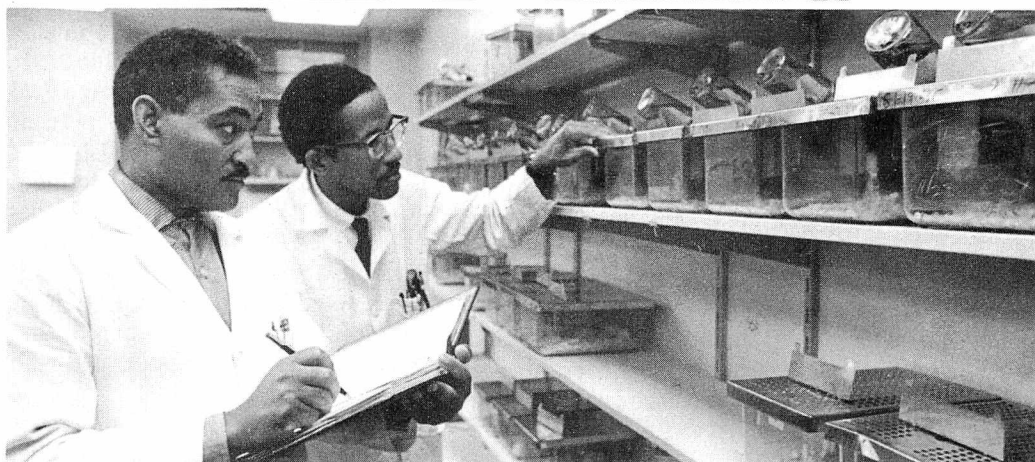
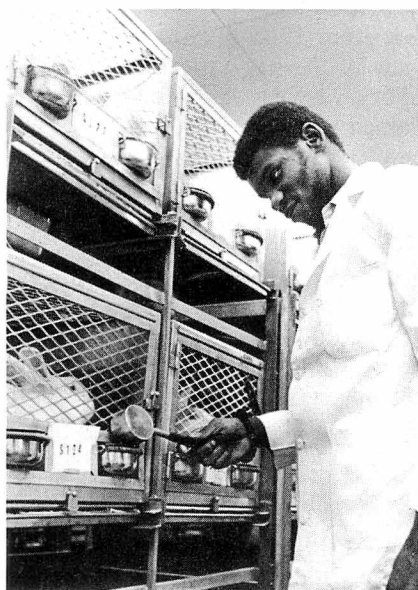
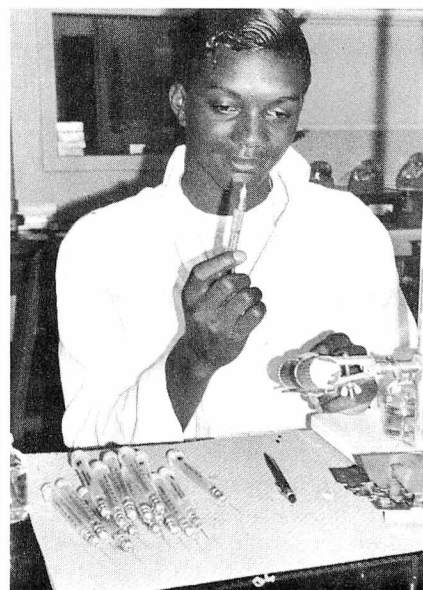
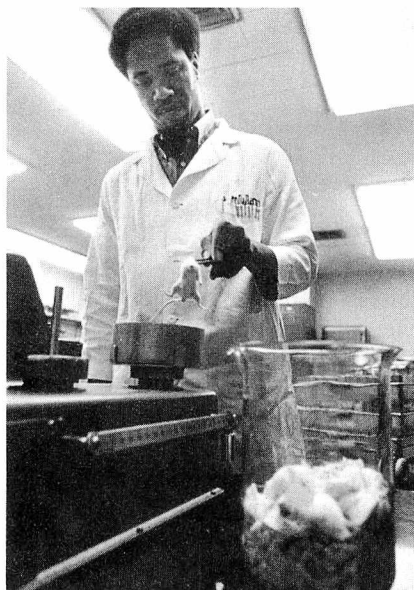
There are a number of reasons. One is the diversity of actual or potential impurities that may be involved. In the case of pyrogens, these impurities are presumably as numerous and as different as the microbial species that produce them. There is probably not now a single microbial pyrogen that can be specifically identified by chemical analysis; yet the systems of the rabbits can detect the presence of any of them.

Another reason is that we are testing for an effect instead of an individual contaminant, namely, for pyrogens rather than for Pyrogen X or Y, for toxicity rather than for ethylene oxide residues, for vasodepression rather than for histamine. Even if every possible contaminant could, like histamine, be easily identified chemically, to assay for each one separately would add an intolerable cost burden that would be passed on to the consumer.

The list of certifiable antibiotics, like that of other medicaments, is growing longer each year. Should a new contaminant appear in one of them, its physiological action could only be surmised from its chemical nature and it might at first escape detection altogether were it not for the animal tests. The animals, however, are not easily fooled, and the public benefits by receiving drugs of higher quality and safety.

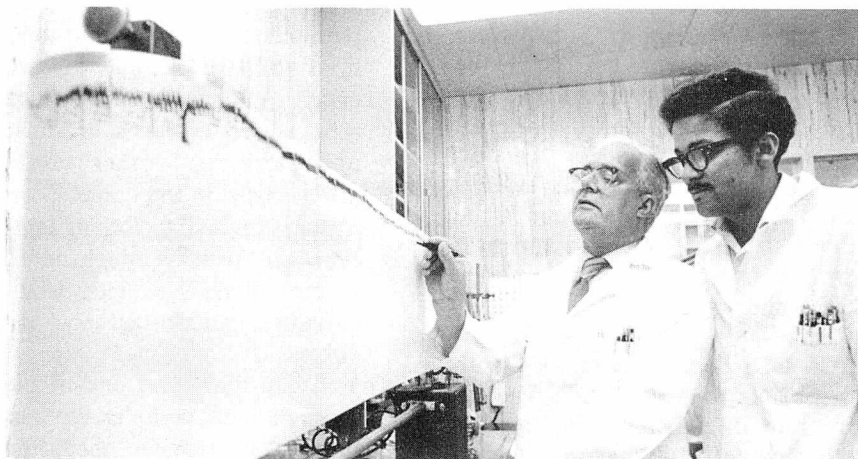


Top: A laboratory worker (left) and a biologist weigh a rabbit for the pyrogen test. Second top: Beginning the pyrogen test, a biologist takes an initial reading on a recording device of the rabbits' rectal temperatures, which are transmitted to the recording device in the cabinet through heat sensors at the tips of the suspended wires. Later readings are taken at set intervals. Bottom left: A biological aide prepares a syringe prior to the rabbit injections. Bottom right: Biologists make the pyrogen test injection into the rabbits' ear veins.



Top left: The foreman (center) and two of the laboratory animal research helper crew empty a bag of food for rabbits into a can. The small scoop is used to feed each animal a measured ration. Second top left: A laboratory animal research helper empties a scoopful of food into the feeding tray. Top center: In the antibiotic safety test, the laboratory animal research helper in charge of the mouse colony and

cat quarters inspects and weighs each mouse used in the test. Top right: A summer aide learning scientific skills prepares to make a safety test injection into a mouse's tail vein. The animal is held in the tube to keep it immobile during the injection. Middle right: Biologists check groups of mice for mortality results in safety test.



Above: A veterinary medical officer (left) and a laboratory technician inspect the histamine test recording of blood pressure changes of a cat. The chart displays the difference in responses between the standard histamine solution and the sample being tested.



Gaylord B. Castor, research biologist and assistant chief, Antibiotic Biological Branch, Bureau of Drugs, came to FDA in 1948.

Burn-Resistant Fabrics: There's Hope Ahead

by Carol Young

To tolerate the thousands of preventable injuries to our citizens each year from burns is roughly analogous to tolerating the presence of a preventable infectious disease. Most of the clothing we wear is flammable. There are known techniques to render most of it flame retardant. Why aren't we using what we know? Where do we stand on burn-resistant fabrics?

Statutory authority for carrying out the provisions of the 1967 Flammable Fabrics Act is divided among four Federal agencies: the Department of Health, Education, and Welfare is responsible for conducting a continuing study and investigation of deaths, injuries, and accidents; the Department of Commerce is authorized to promulgate flammability standards and to conduct related research; the Federal Trade Commission is responsible for enforcing the Act; the Treasury Department (Customs Service) has jurisdiction over shipments of imported products.

Within DHEW the responsibility for administering the Act rests with FDA's Bureau of Product Safety, which has begun an accelerated program of data collection and investigation of flammable fabric cases. Over 800 cases have been studied and forwarded to the Department of Commerce's National Bureau of Standards for its use in promulgating standards.

In describing the state of affairs in fabric flammability, let's first put the problems in perspective. Fires and burns are the leading cause of death from nontransport accidents to children one to four years old and the second leading cause to age groups five to 14 and 45 and over. About 8,500 such fire and explosion deaths occur each year. These death rates are higher for nonwhites than

whites, higher for males than females, higher for Indians than for other nonwhite races, and higher for white foreign born than the native born. Over 80 percent of the deaths occur in the home and over half occur during the winter months—November through March. The rate is higher in nonmetropolitan than in metropolitan counties. The highest rates occur in the South and Southwest. About 3,000 of these deaths involve the ignition of clothing.

An article in the *British Medical Journal* in 1956 related 80 percent of all burn deaths of English children to the ignition of clothing. Another article in the *British Journal of Plastic Surgery* in 1965, describing a study of 850 burned children, noted a scald-to-flame etiologic ratio of 1.25 to 1 and reported that 57 of 61 deaths were associated with burning clothing.

An estimated two million persons each year suffer nonfatal burns that are serious enough to require medical attention or to restrict usual activity for a day or more. About 100,000 require hospitalization. There are about 1.5 million work days lost each year because of injuries from burns. About 260,000 persons are injured each year by burns from fires and explosions. Persons in the 15-24 age group experience the highest injury rate, and the rate for males is higher than for females. About 35 percent of the injuries from fire and explosion occur in the home; about 35 percent happen at work; the remainder are in public places and in vehicles.

There are 1.3 million persons injured each year from contact with hot objects or open flame. The injury rate is higher among families with incomes under \$4,000 and is higher in urban than rural areas. About 75 percent occur in the home. Females have a higher injury

rate than males. Ignition of clothing is involved in about 150,000 burn injuries each year.

Dr. Irving Feller of the National Burn Information Exchange at the University of Michigan analyzed 6,000 cases admitted to 15 burn centers from 1965-69. He said, "A review of the basic mechanism of the injury reveals that 66 percent are flame burns, and another 23 percent result from scalds. Hot surface, chemical, electric, and radiation burns make up another 11 percent. Of particular importance to the group is that 86 percent of all flame burns have fabrics involved."

A study of 457 burned children admitted to Duke University Hospital classified the origins as follows: 55 percent clothing ignition; 25 percent direct contact with flame, hot ashes, or hot stoves; 15 percent gas or kerosene ignition; and five percent scald injuries.

According to Dr. George F. Crikelair, Director of Plastic Surgery at Columbia-Presbyterian Hospital, New York City, and many other medical authorities, the following facts are basic to burn injury control:

- (a) A large portion of the burns, particularly those among children and older people, involve articles of wearing apparel or fabrics used in drapes, bedding, upholstery, and other textile articles used in the home.
- (b) Burns involving clothing ignition are usually much more severe than those in which clothing ignition is not involved.
- (c) Severe burns are one of the more difficult, complex types of injuries to manage medically and have deepseated psychological ramifications affecting medical, physical, and social

rehabilitation.

- (d) Medical costs are extremely high for severe burn injuries due to the long initial period of hospitalization, followed by a series of readmissions for plastic and reconstructive surgery.
- (e) Less flammable wearing apparel and home furnishings must be made available if we are to see a significant reduction in serious burn injuries. Increased parental supervision and education will not stand alone as effective preventive programs.

On June 30, 1953, Congress enacted the Flammable Fabrics Act, outlawing the manufacture or sale of that wearing apparel "so highly flammable as to be dangerous when worn by individuals."

This statute was enacted primarily because of the widespread publicity during the midforties concerning deaths due to ignition of brushed rayon "torch" sweaters and long rayon pile "cowboy" chaps. The standard of flammability under the Act was developed by an industry committee in cooperation with the Department of Commerce, and became known as CS-191-53. It was designed to exclude from the market only those explosively flammable garments (usually a brushed rayon import) that gave rise to the original Act. Louis Segal, California's assistant fire marshal, clearly defined the issue when he said, "To put the issue in the bluntest and simplest terms possible, exceptionally flammable fabrics are not the real problem at all. . . . With very few exceptions, the clothing being ignited consists of ordinary, everyday articles that must be considered of normal, not exceptional flammability."

Enforcement of the 1953 Act was delegated to the Federal Trade

Commission. Henry Stringer, formerly an official in FTC's Bureau of Textiles and Furs, in reporting 12 years of burn injury statistics stated that only one involved fabric, of those collected and analyzed, failed to pass CS-191-53.

The weak 1953 Act was amended December 14, 1967, creating a mechanism whereby new and more effective flammability standards could be developed by the Federal Government for clothing and other household fabric items. In three years, two new rug standards were produced under the 1967 Act.

Senator Frank Moss, chairman of the Senate Subcommittee on Consumers and of the Senate Special Aging Subcommittee on Long Term Care, has challenged the pace and quality of standards development proceedings, and the quantity and quality of basic injury data.

Testimony presented at the Senate oversight and authorization hearings in June 1970 by Caspar W. Weinberger, then chairman of the FTC, urged that the law be amended to provide stiffer penalties.

A summary of the problem indicates that there are serious burn and asphyxia problems involving flammable fabrics; a significant reduction in mortality and morbidity requires effective education and legislation plus adequate, mandatory standards for fabrics used by high risk groups.

As to more recent history, 1970 was a year of remarkable achievement providing solid progress toward solving the complex problems associated with burns and flammable fabrics. Certainly the problems now are receiving the spotlight they deserve. More and better technical studies and research projects have been implemented. Deficiencies in our data collection systems are better defined. Federal funds for

operating programs, we hope, are now on the way.

Testifying before a congressional subcommittee in June 1970, Deputy Commissioner of Food and Drugs James D. Grant outlined steps taken by the FDA to carry out the responsibilities assigned to the Department of Health, Education, and Welfare by the 1967 Flammable Fabrics Act, in spite of the lack of additional personnel or funds for this purpose. Through a series of reorganizations, the Office of Product Safety was elevated to Bureau status on October 21, 1970. Mr. Grant said, "While this (proposed) action in itself will not insure more effective programs, it will afford the program visibility and recognition and does indicate the intention of our Agency to make product safety a strong and effective operation."

Investigation of burn injuries in metropolitan areas has centered in Boston and Denver, with the University of Iowa supplying data on such injuries occurring in the farm population. Through June 1970, a total of 658 flammable fabric investigations were completed. This effort was augmented considerably in the accelerated program by FDA District personnel in cooperation with fire departments, health departments, hospitals, and other community agencies which has yielded reports on over 800 cases.

Contracts have been renewed by FDA with the University of Michigan Burn Information Exchange for etiologic and economic data on burns from 22 hospitals that have special burn care units. A contract has been awarded to the University of Pittsburgh for a pilot burn investigation study to develop and test methods for rapid identification and investigation of burn cases. A special study in the U.S. Public Health Service Hospital in New Orleans

also has been agreed upon. It is designed to evaluate patient reaction to various flame-retardant fabrics, and the effects of laundering on durability.

FDA has analyzed studies and research conducted by others, including a study of death certificates to identify deaths resulting from the burning of flammable fabrics. Results of these studies are included in the First Report to the President and the Congress, prepared in 1969, and in the Second Report, released earlier this year.

The Department of Commerce is preparing the foundation for a program that shows much promise in the technical field. A 17-member National Advisory Committee for the Flammable Fabrics Act was appointed January 1, 1969, representing various related national interests. The chairman of this committee was Dr. Myron Tribus, then assistant secretary for science and technology and in that post principal advisor to Secretary of Commerce Maurice H. Stans.

The first meeting of the National Advisory Committee for the Flammable Fabrics Act was held May 2, 1969. Five meetings have been held, the latest in Washington on November 20, 1970. The Department of Commerce has issued a flammability standard for large carpets and rugs, a proposed standard for small carpets and rugs, a notice of proposed need for flammability standards for children's wearing apparel and for blankets and mattresses. On November 17, 1970, an important notice of proposed flammability standards for children's sleepwear was published in the *Federal Register*.

The Department of Commerce contracted with the Research Institute of the University of Denver to design a sampling plan and develop

a questionnaire for the collection of burn case data. Results of this project are being shared with DHEW to improve the quality and reliability of reporting and field investigations.

Seeking funds and personnel to conduct needed research, Dr. Tribus approached the American Textile Manufacturer's Institute, the National Cotton Council, and the Man-Made Fiber Producers Association, and all pledged \$25,000 apiece. The National Science Foundation matched this amount, and the result was a total of \$150,000 for research into the quantitative definition of hazards relating to wearing apparel. Forty-two organizations proposed research projects, and four contracts were awarded in October 1970.

During his tenure as FTC chairman, Mr. Weinberger stated that "both supplementary legislation and more vigorous enforcement of existing legislation are necessary."

The magazine *Consumer Reports*, in the June 1970 issue, said, "Last year alone the FTC's small corps of inspectors spotted and tested 599 textile products suspected of violating flammability standards and 111 of them failed the test." Mr. Weinberger called for a requirement for better testing of certain textile products. In addition, the FTC is now releasing information on a regular basis giving names and descriptions of fabrics that are illegally flammable. The FTC also has called for an amendment to the 1967 Act "which would provide initial civil penalties for violations of this Act in an amount not to exceed \$10,000 for each violation." In addition, FTC has proposed that, "If any person commits a willful or knowing violation of the Act, that person should be subject to a felony conviction."

A series of important conferences

on the fabric and burn problem—particularly the New York Academy of Medicine Conference in 1966—resulted in the formation of the Information Council on Fabric Flammability in 1967. This national group is made up of representatives from many segments of the textile industry, government agencies, voluntary health and safety organizations, and medical and legal groups. Its purpose is "to work for the reduction of morbidity/mortality from burns caused by flammable fabrics and related materials." All that is required to join is an interest in the problem and five dollars. Inquiries should be directed to the Council Secretary, Room 510, 1457 Broadway, New York, N.Y. 10036.

Good news is also coming from the mills and retail marketplace. Wool has always been considered the least flammable of the natural fibers. It is now being treated with flame retardant chemicals for special use situations such as the interiors of jumbo-jet airplanes. Fibrous glass by Owens-Corning and PPG Industries and modacrylic fibers such as Verel by Tennessee Eastman and Dynel by Union Carbide are being used more extensively in fabrics for draperies and interior furnishings. High temperature resistant nylon (Nomex by DuPont and Durette by Monsanto) and PFR rayon by American Viscose are available for use in high risk areas. We are told, however, that cost, flexibility, and technical problems in the mills still are deterrents to extensive use of some of the man-made fibers.

Hooker's THPC treatment for cotton and other cellulose, Ciba's Pyrovatex, Lynrus FR-1, and other chemical treatments for cotton fabrics are generally more available for fabrics this year. Sears, Penney's, and other retail catalogs and stores are now featuring flame retardant

nightwear for children up to size 6X. Some play clothes are also available with permanent flame retardant finishes.

At a meeting of the American Hospital Association in Houston in 1970 there was a notable increase in interest regarding the purchase of fire retardant fabrics made by Herculite. Guilford Mills in cooperation with Allied Chemical Company has developed a new brushed nylon knit fabric for sleepwear called "Slumber One" with a durable flame retardant finish.

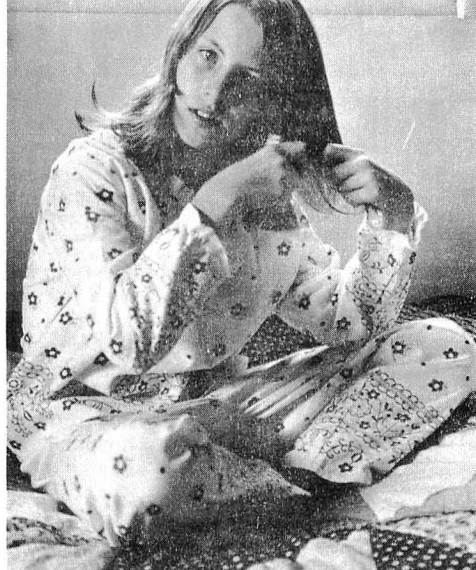
Russell Mills, Inc., has developed heavyweight cotton knit sleepwear that reportedly is sold by Sears for \$3.95. The finish is said to be effective for 50 home launderings, but fabric strength is reduced. M. Lowenstein & Sons, Inc., is now offering 100 percent cotton print cloth and terry cloth with a durable flame retardant finish similar to its flannel now being sold commercially. There are many others which it is said will be available in the not too distant future.

The burn injury problem, like the continued contamination of our air and water, is symptomatic of the overall environmental dilemma that we have created through our unrestricted use and abuse of technology.

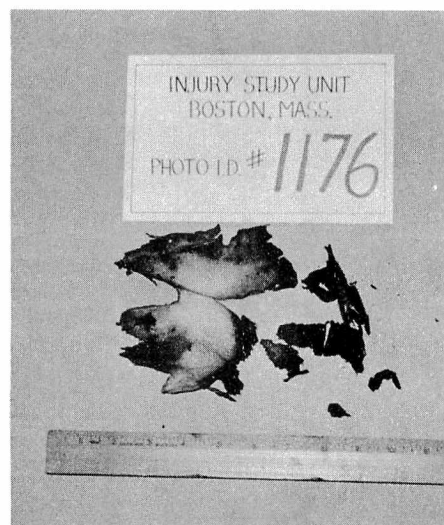
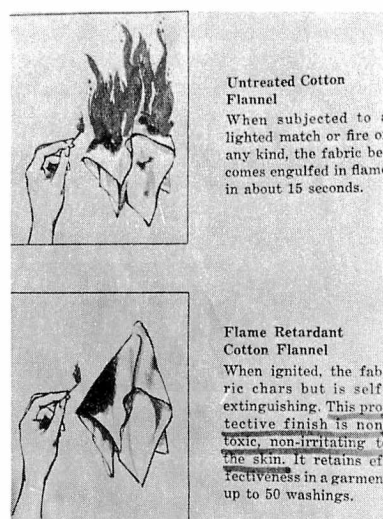
Solutions to problems of this magnitude and complexity will not be found without industry leadership, a strong and effective Federal-State partnership coupled with greatly increased citizen awareness, and an absolute refusal to continue tolerating the intolerable.



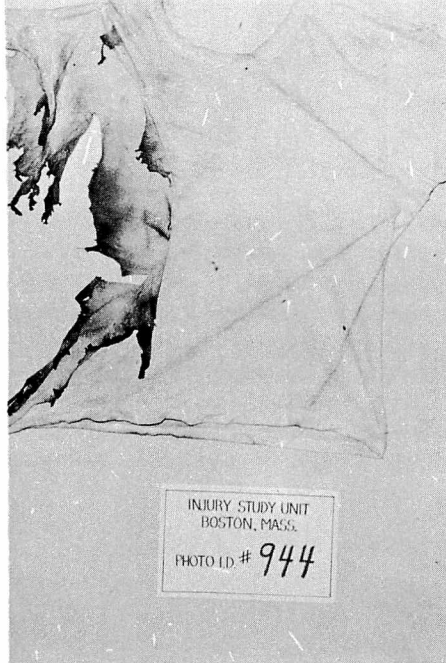
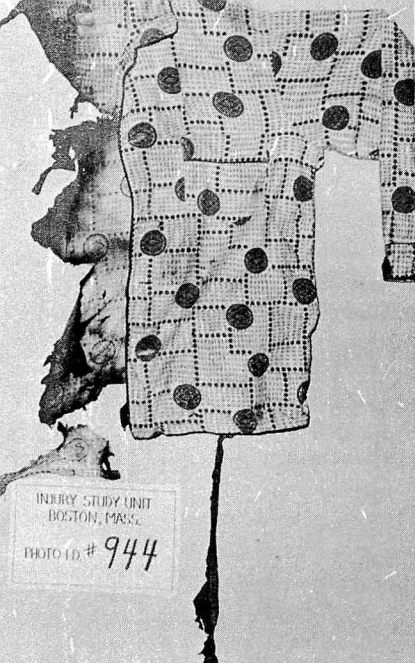
Carol Young is a staff writer in the Division of Consumer Product Safety, Bureau of Product Safety.



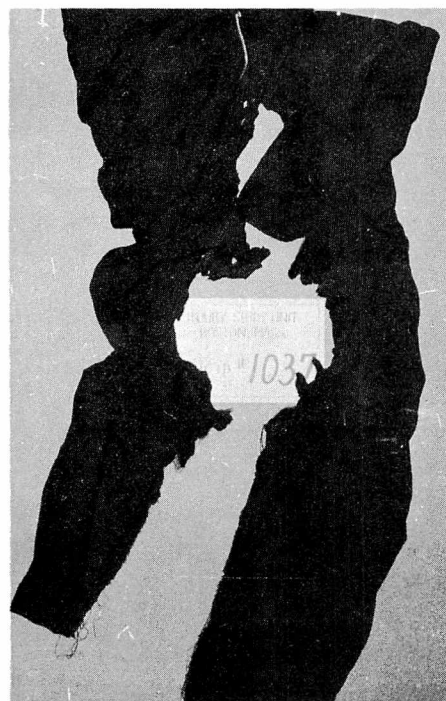
These children's cotton flannel pajamas are of the flame-retardant type. The labeling carries laundering instructions to help protect the flame-retardant finish. Accompanying literature provides additional explanation of the protection afforded by the treated fabric.



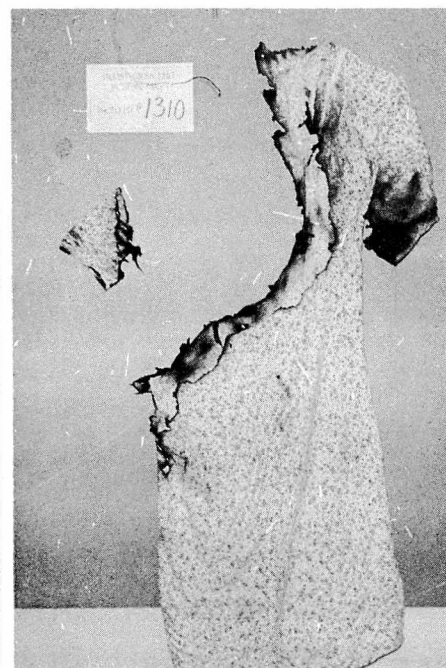
A cotton robe and gown of the kind shown were being worn by a 50-year-old woman when they were ignited from live ashes dropped from her cigarette. She suffered second and third degree burns over about 60 percent of her body and died in a hospital 22 days later. The garments were almost totally consumed by flames, as shown, although it is not known how much burning occurred after the garments were removed by her husband, who responded to her calls for help.



This cotton pajama top and T-shirt were being worn by a 10-year-old boy when they caught fire from an electric range while he was heating water to make tea. He suffered second and third degree burns on his right side and underarm and was hospitalized 31 days.



This cotton T-shirt and pants of a synthetic, drip-dry fabric were being worn by a householder when he added alcohol to a backyard barbecue fire. The flames traveled to the can of alcohol, which exploded and ignited his clothing. He was hospitalized five months with burns over 60 percent of his body and underwent five skin grafting operations.



This cotton housecoat and cotton flannel nightgown were being worn by a 78-year-old woman as she cooked breakfast on a gas stove. The sleeve of one of the garments caught fire as she reached across the stove. She suffered second and third degree burns on 33 percent of her body and died in a hospital 14 days later.

It May Be Good— But Is It Good For You?

by Mal Oettinger

A talented chef once boasted that he can tell the ingredients of any recipe if he tastes the dish several times. Finding the nutritional value of food is infinitely more complicated, requiring painstaking analyses using precise scientific methods. The expertise and equipment for doing this critical work for the U. S. Government is located in the National Center for Nutrient Analysis of FDA's Division of Nutrition.

The Center is answering the growing demand of the public (expressed in reports of the White House Conference on Food, Nutrition, and Health, for example) to know what it is eating. The Government has been active in the analysis of foods and nutritional supplements for many years, and the Center is prepared to answer the challenge that new products and growing food technology pose in a manner certain to prove beneficial not only in this country but throughout the world.

"We will develop analytical and research capabilities to keep ahead of the game," says Dr. Ogden C. Johnson, director of the Division of Nutrition. "What's happening in the marketplace? What changes are taking place? Nobody's kept up on food analysis. Technological changes often have been made without considering nutrition."

Methodology developed by the Center has a beneficial effect on the members of the food industry—not only can they satisfy FDA regulatory standards but also improve the nutritional quality of their product. With the proliferation of such new foods as enriched textured vegetable proteins, snacks, and infant foods, the public needs to know the nutrient content and, in many cases, scientists require new methods of analysis.

"We're getting into not only vitamins, minerals, and caloric content, but also protein, protein quality, and

carbohydrates. These are all part of the same question: Is this a good source of nutrition for the people eating it?" Dr. Johnson continues to stress that "We're not just interested in whether the food has what it says it has on the label—we also want to know that those nutrients will adequately nourish the consumer."

The Center had its genesis as the Vitamin Division of the Bureau of Chemistry in the days when FDA functions were in the Department of Agriculture. In FDA, it started as the Microbiological and Chemical Branch of the Division of Nutrition. It was the Vitamin Analysis Section in the Special Dietary Foods Branch before becoming the National Center. As such it retains some of the old functions but has taken on new roles as well.

The Center has both chemical and biological sections. The chemical section assays vitamin and mineral samples by chemical and physical methods and food samples for their proximate composition. It also works to develop new methods of assaying food or to improve old methods. The biological section performs assays using microbiological and rat bioassays. The section maintains a rachitic sensitive rat colony and uses 20,000 rats a year just for testing vitamin D content. It is anticipated that this colony will be used for the bioassay of other nutrients in the future. Both the rats and the micro-organisms are extremely sensitive to the nutrient for which their response is specific. For example, the organism used for measuring vitamin B₁₂ activity will show a measurable response when dosed with less than one ten-billionth of a gram of the vitamin. This section also strives to develop new methodology using as the measured response the stimulation or inhibition of the growth of micro-organisms. This information is used in analytical

studies on vitamins, amino acids, minerals, proteins, and other food factors.

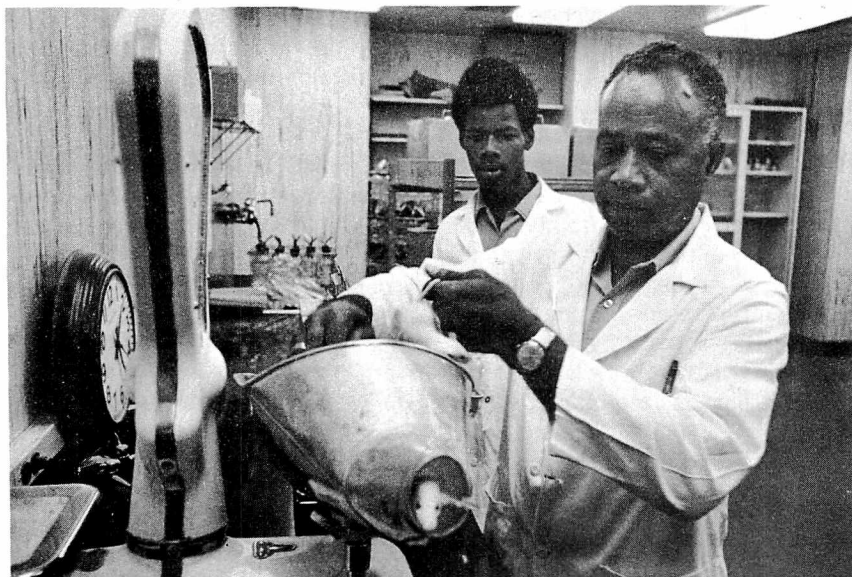
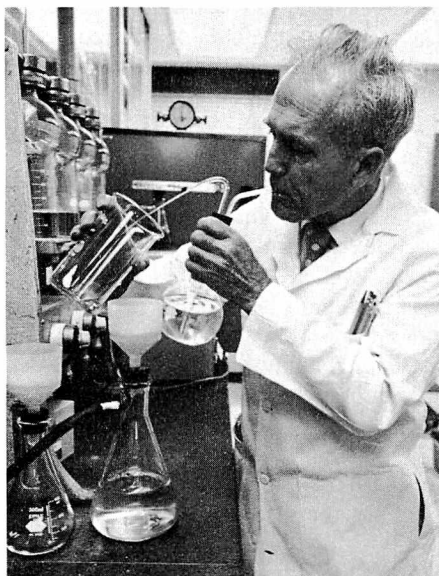
The Center's laboratories include an array of testing rooms which allow as much specific testing as most private laboratories or food industry quality-control units. These include four walk-in refrigerated laboratories, each maintaining a specific constant temperature so that samples can be studied under a variety of conditions (for example, many enzymes must be used at reduced temperatures and the Center scientists have available rooms with temperatures of 40, 30, 20, or 0 degrees Fahrenheit). There are also two elevated temperature and humidity labs and a special purpose lab where organic solvent extraction work is performed. This lab has a mechanism for quick carbon dioxide release in case of emergency.

According to the acting director of the Center, Mike J. Deutsch, rigid laboratory analytical standards are applied in conducting assays: "It is the FDA's reasoning, if feasible, that a unit should have at least two assays on each of two sub samples by each of two analysts using at least two methods (official, if possible) to establish a deficiency." This is to ensure that the results submitted are correct and will stand up in court. "We use official methods—no secrets," he points out. The Center's work results in a good proportion of the FDA's official actions.

The methods used are described in detail in such volumes as *Official Methods of Analysis* of the Association of Official Analytical Chemists (AOAC), *The U. S. Pharmacopeia*, and *The National Formulary*. As new methods are devised and approved, they are added in later editions. Mr. Deutsch is one of 54 general referees on methodology in AOAC working on developing new methods for this scientific so-



Samples arriving at the National Center for Nutrient Analysis are registered (top) before analysis begins. A washing and filtering process (right) is used as part of the procedure to determine the amount of crude fiber in a food sample. Crude fiber is one of the indicators of food quality. Laboratory rats are weighed (bottom) for setting up balanced biological test groups. Animals of 44-60 grams are used for the vitamin D assay.



ciety of the United States and Canada. His specialty is vitamins and other nutrients. He reviews the progress of associate referees, considers their recommendations on collaborative studies, evaluates reports on such research, and recommends to an AOAC subcommittee whether or not the method should be granted official status. (For further information on AOAC work and methodology, see FDA PAPERS, September 1970.)

Where does the food come from that the Center analyzes? There are several routes and several criteria. For instance, the Center does not analyze products that are not yet on the market. Center personnel will advise industry on methodology so that the control laboratory may assay nutrients in their food products, but they won't do their work for them. One route by which food reaches the Center is the FDA's continuing program of product surveillance. Field inspectors from each of FDA's 17 Districts follow programs drawn up by the Administration and submit samples of foods or supplements to be tested. The Center tests to be certain that the nutrients declared on the label are, in fact, contained in the product. Such factors as incompatibility of excipients, the length of time a product has been on the shelf, local humidity or heat, and storage conditions can speed up deterioration of the product after it has left the factory.

In addition to continuing surveillance under the Center's program, products can be submitted by field inspectors who have received complaints about them from consumers or for any other reason they believe the product is not complying with FDA regulations (for example, a routine factory inspection might indicate that vitamins are being added to a product haphazardly or not at all). The Center provides expert testimony in court cases as well as appearing at hearings to establish nutritional guidelines, food standards, or other regulations concerning nutritional components.

Another major source of samples to be tested is from other Govern-



Enriched standardized food products.



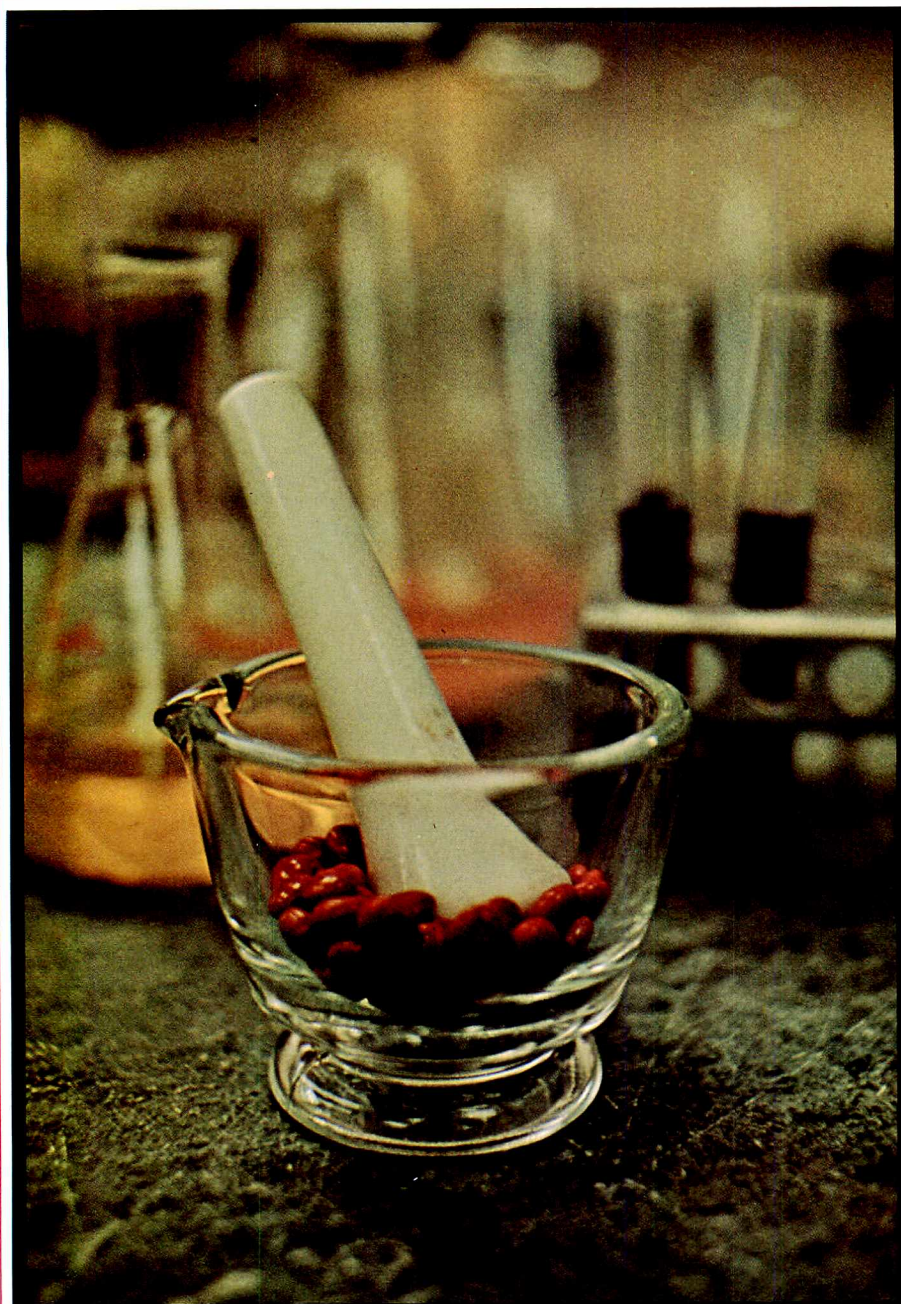
Composite display of enriched food samples, including a frozen multicomponent meal.



Enriched cereal breakfast foods.



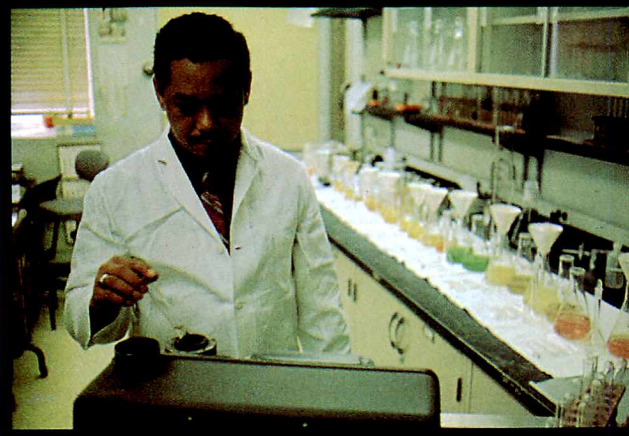
Vitamin and mineral food supplements.



Left: Vitamin tablets ready for grinding to make a composite sample.

Below left: A spectrophotometer is read in assay for vitamin B₆ in food supplement to determine the quantity of vitamin. A deficiency of this vitamin results in retarded growth, anemia, epileptic-like convulsions, and partial baldness.

Below right: The Kjeldahl digestion for determining protein content of foods is monitored. This unit is used to convert the nitrogen in proteins contained in food samples into a compound that can be measured. Mike J. Deutsch (*left*), acting director of the National Center for Nutrient Analysis, observes the operation.

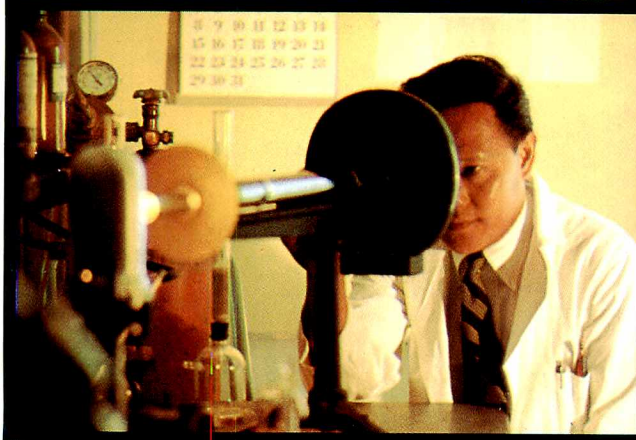




Left: A burette is filled with a solution of a compound which will indicate the quantity of *L*-ascorbic acid (vitamin C) in a food sample. A severe deficiency of this vitamin in humans produces scurvy.

Below left: A polarimeter is used to determine rotation of light due to the presence of vitamin E compound in a food sample. Vitamin E is essential to human nutrition, although minimum daily requirements have not been established.

Below right: An assay solution of riboflavin (vitamin B₂) from a food sample is inserted into a fluorometer to measure the amount of the vitamin present. A deficiency of vitamin B₂ is associated with inflammatory conditions of the mouth, tongue, and eyes, scaling of the mouth surface and fissuring in the corners, indistinct vision, and sensitivity to light.

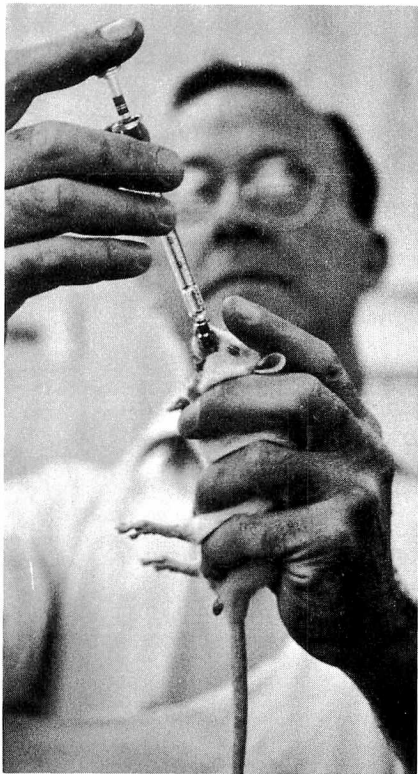




Left: USP reference standard cyanocobalamin is being diluted in the spectrophotometric assay for vitamin B₁₂. This vitamin is beneficial to normal blood formation, neural functions, and normal growth.

Below: Extraneous material is filtered from a solution containing nutrients for subsequent measurement.





A vitamin D sample is stomach-tubed to a test animal with a syringe (left). Dissected, split, and stained bones from the forelegs of rats fed vitamin D (above) can show, by the degree of healing, the amount of vitamin D received. The width and solidity of the black line across the clear cartilage is compared against a scoring chart. An animal that received an insignificant amount of vitamin D in a sample is indicated by the second pair from left at top.

ment agencies with which the Center cooperates. The U.S. Postal Service submits samples of vitamins for assay to ascertain that the health claims made by a supplier who sells by mail are not fraudulent. The Federal Trade Commission wants analytical assurance that advertising claims are not exaggerated. The Veterans Administration buys vitamin products for its hospitals and depends on the Center's analyses to ensure that the products meet VA specifications. The Defense Department is concerned with the quality of products sold in post exchanges. A challenging assignment for the Center was its evaluation of methodology for the assay of special foods to be used by astronauts.

The Center teaches visiting scientists how to perform nutrient assays. Trainees are from other Federal and State agencies, foreign countries, and the industry.

Knowledge-sharing works both ways. "You never can tell who will come up with something new next," Mr. Deutsch says. "There's a continual exchange of information with scientists from other countries—they inform us of their endeavors and it

can come on an unexpected basis."

In the past month, he has corresponded with colleagues from Ireland, Israel, Hungary, Yugoslavia, and India. Two Indian scientists were planning to visit the Center in June to study methodology. The work experience of foreign visitors is arranged so that their time at the Center will be of the greatest benefit to them in solving the particular food analysis problems encountered in their country.

The Center conducts conferences and workshops on methodology, usually on the more complicated assays. Scientists from Government, industry, and consulting laboratories come to learn what Mr. Deutsch calls "the art as well as the skill." A two-day workshop includes lectures, demonstration assays, and practical laboratory work by the participants.

The Center also cooperates with the National Institutes of Health and, in unusual cases, with hospitals. A physician at a university hospital recently consulted the Center on research in rickets. Some cases do not respond to the usual vitamin D therapy. It was necessary to find out how much vitamin D was in the

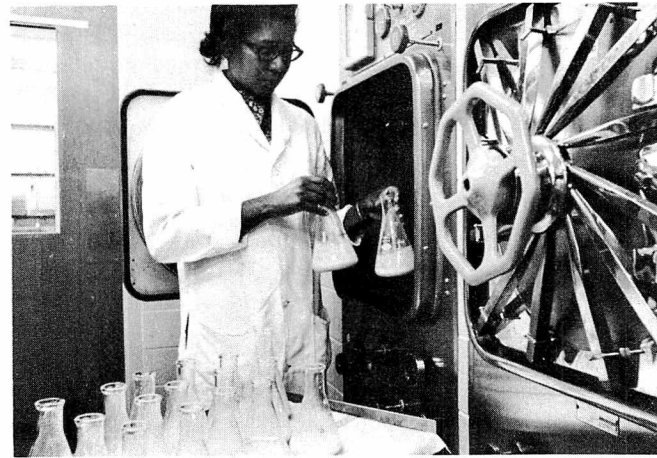
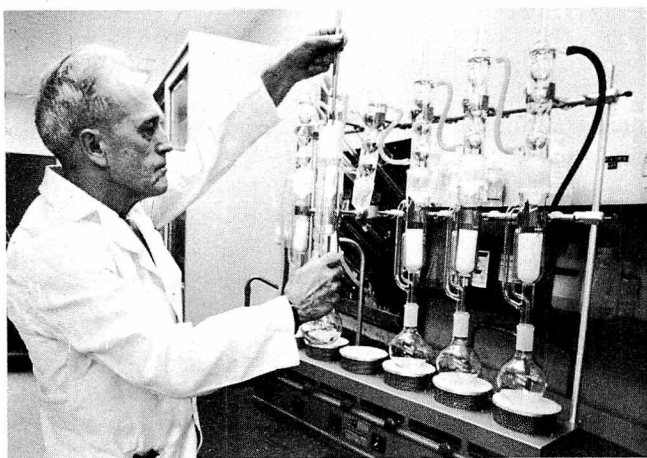
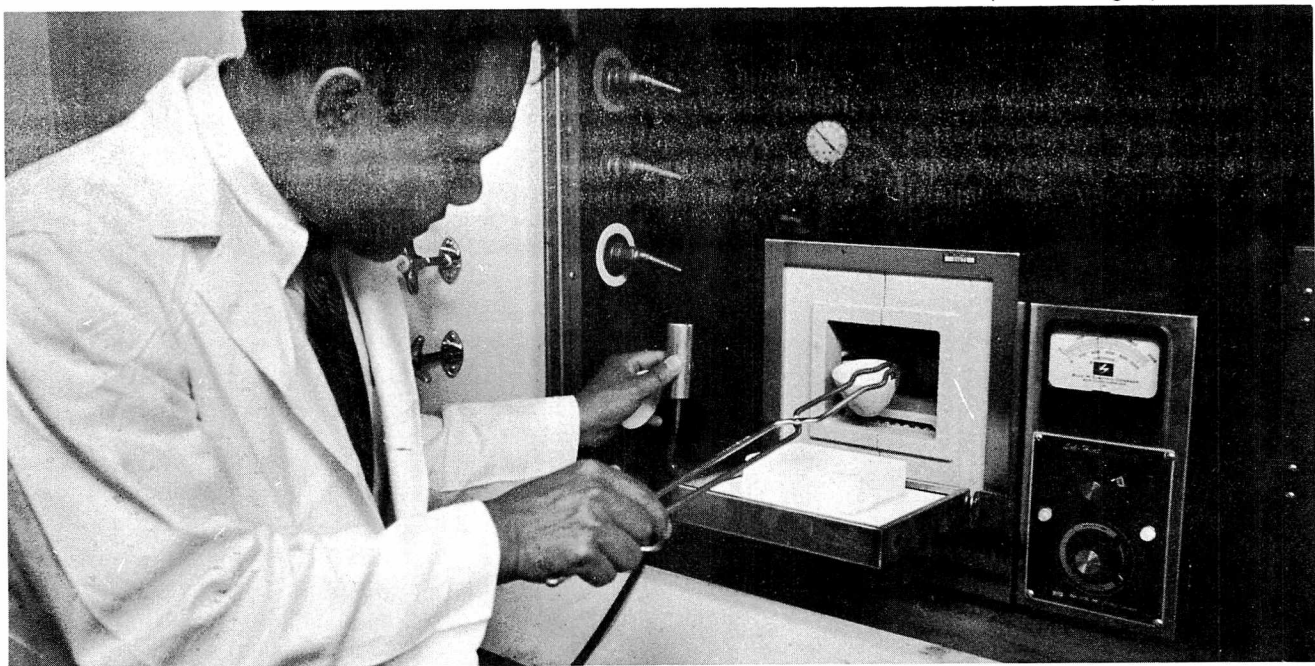
blood of patients treated with a new antirachitic compound. The hospital sent refrigerated blood samples which were picked up at the Washington airport and assayed.

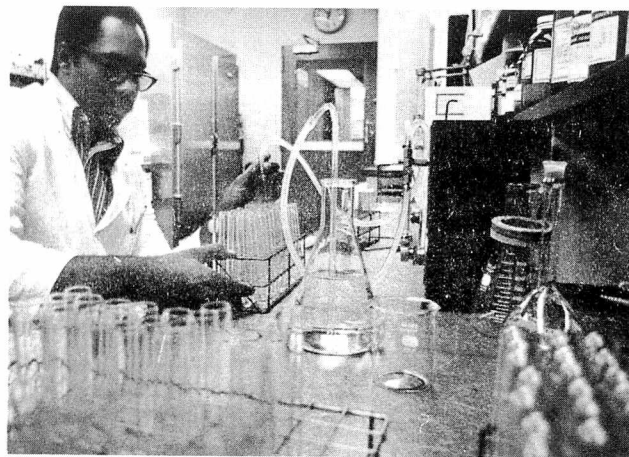
The assay is time consuming. Two groups of rats are maintained for the determination; both groups are fed a vitamin D-free diet. In about three weeks, the deformed limbs of rickets are apparent. One group is then fed the USP Vitamin D Reference Standard and serves as the control. The other group gets vitamin D from the samples under assay. Leg bones of the rats are removed and cleaned. They are then sectioned and treated with silver nitrate. The pattern of bone healing produced by the dose of vitamin D is compared with a chart in the official methodology and the amount of vitamin D present is calculated.

The spirit of cooperation pervades much of the Center's work. Industry and universities participate in formulating methods of assay. Mr. Deutsch says, "It is good if industry helps to accomplish what the consumer, the Government, and industry itself needs—the more participation, the better." Education is



A column is packed (left) to be used in removing impurities from a sample in oil-soluble vitamin assay. Food sample is "dry ashed" in a muffle furnace (middle) to remove organic material in analysis for minerals. A Soxhlet extraction bank is employed (bottom left) in a procedure for determining the fat content of a food sample. Food samples are placed in an autoclave (pressure cooker) to extract nutrients (bottom right).





The amount of nutrients present in a food may be determined by measuring the growth of test micro-organisms used in assays. These micro-organisms to be used in future assays (left) are being transferred to maintain their virility. Extracts from food samples are being pipetted (above) for microbiological assay of nutrients.



Mal Oettinger, a free-lance writer, is a former magazine staff writer and television network public information official.

an important part of the regulatory process and the Center helps companies apply methods of assaying the ingredients of their products, advising the companies' own labs, if they have them, or the firms' consulting labs.

Another area in which the Center's work has international impact is formulation of U.S. recommendations to the Codex Alimentarius (of the World Health Organization). The United States submits official position papers on international food standards which contain descriptions of analytical methods that often have been developed by the Center.

Considering the enormous diversity of work the Center is called upon to do, Mr. Deutsch points out, it is still essential that even such

mundane equipment as chemical glassware be accurate. "We use certified volumetric glassware in our work, which we feel is necessary for regulatory or methodology measurement. It eliminates errors." Formerly such lab equipment was certified by the National Bureau of Standards, but when it "went out of that business," the Center began calibrating its own equipment, using the same stringent standards.

Although the Center's analytical work essentially establishes what *is* currently in certain foods, it also assists others in FDA who look to establish guidelines for what *ought to be* in those foods. It aids in determining how long foods retain their expected nutritional value. This information is useful as a basis for recommending dating of perish-

able or semiperishable items and for the review of fortification practices.

The Center is growing. There are plans to add more chemists and specialists. Dr. Johnson points out that there are some 50,000 food producers and a great many vitamin product companies. The FDA cannot match them in manpower resources, but the Center feels that if it can help the food industry do a good job in supplying nutritive products, then this will accomplish its public interest mission better than any amount of police work.

As the late Elmer Nelson, former chief of the Division of Nutrition, once put it: "A number of scientists discussing matters of public importance over the conference table can accomplish more than a number of lawyers over the bench."

field reports

ATLANTA DISTRICT A workshop for the Sterile Disposable Medical Device Industry and Hospital Personnel was held by Atlanta District at the American National Red Cross Center, Atlanta Chapter, Atlanta, on May 19. A capacity crowd of 100 attended, including representatives from approximately 25 firms located in Region IV, and from firms throughout the United States and Canada. Earle G. Maseth, Division of Industry Services, Office of Compliance, Bureau of Drugs, assisted in organizing the workshop and arranged for industry speakers for the program. The industry speakers, Dr. Armand Marinaro and Richard E. Burgess, informed the District that this was by far the liveliest workshop they had attended. HEW Region IV Director Frank J. Groschelle also addressed the group with a kickoff speech. Members of the program were Richard E. Burgess, director of technical services, Pharmaseal Labs, Inc., Glendale, California; Jack B. Forbragd, chief, Compliance Branch, FDA Atlanta District; Dr. Carl R. Hartrampf, Jr., president, Atlanta Plastic Surgery Clinic; Harold V. Leininger, director, National Center for Microbiological Analysis, Minneapolis District; Dr. Armand Marinaro, assistant to the director, Research Division, Johnson & Johnson, New Brunswick, New Jersey; Earl G. Maseth; and Leslie O. McMillin, regional food and drug director, Atlanta District. The morning session was monitored by Joseph J. Milunas, deputy regional food and drug director, Atlanta District; the afternoon session by Richard J. Dawson, chief inspector, Atlanta District.

Chief Chemist Sol Cohen and Chief Inspector Richard J. Dawson were participants in a May conference at Auburn University, Auburn, Alabama, on the theme "Federal-State Cooperation—Is It Possible?" The conference, sponsored jointly by the Alabama State Department of Agriculture, State Agriculture Extension Service, and FDA Region IV, concluded that such cooperation is possible and "that communications, coordination, and cooperation are currently on-going and they are steadily improving."

BALTIMORE DISTRICT District officials seized lots of Diet Matzos in Baltimore on May 12. Manufactured and shipped by A. Goodman & Sons, Inc., Long Island City, New York, the product was misbranded under the Food, Drug, and Cosmetic and the Fair Packaging and Labeling Acts. The principal display panel failed to bear declaration of net quantity of contents. Statements suggesting the product is of special dietetic value in

calorie-restricted diets were false and misleading.

BOSTON DISTRICT Warren Baking Co., Cambridge, Massachusetts, was found guilty in Federal court in Boston of operating an insanitary bakery. The firm allowed flour received in interstate commerce to become contaminated with insect filth by placing it in insect-infested flour conveying systems. A four-day trial was held and Judge Anthony Julian imposed fines of \$2,500 against the Warren Baking Co. and \$5,000 against its treasurer, Salvatore Giacchetto, on April 20. The defendants were given ten days to pay the fines. Mr. Giacchetto was also given a one-year suspended jail sentence and was placed on three years' probation.

BUFFALO DISTRICT A carload of fresh celery, valued at \$1,786, was seized in Buffalo, New York, on May 5. The product contained a combined residue of 2.54 parts per million of methyl parathion and parathion and 0.26 parts per million toxaphene. The seizure was the result of close cooperation between Atlanta and Buffalo FDA Districts and the Florida State Department of Agriculture, after the State agency found a pesticides drift problem on the premises of the grower, Fancy Farms, of Sarasota, Florida, and Clanton, Alabama.

Buffalo District has caused several products to be seized. Four lots of swordfish containing high levels of mercury valued at approximately \$2,225, were seized when the owners declined to dispose of the fish voluntarily. The owners were Slade Gorton Co., Boston; J. C. Murray, New York; and J. D. Smith Interocean, Inc., New York (two lots).

A lot of Jarts, a dart-like lawn game, shipped by Kaufman Brothers, Inc., Pittsfield, Massachusetts, was seized as a hazardous substance, since the product had not been relabeled with adequate warnings.

Four lots of dried bean and pea products, valued at about \$2,900, were also seized when they were found to be rodent contaminated at the repacking firm. The repacker, Allen V. Smith, Inc., Marcellus, New York, initiated recall of products packed during the approximate 30-day period during which products shipped by the firm contained rodent filth as evidenced by District sample results.

CHICAGO DISTRICT The Special Programs Branch, Chicago District, has made agreements final for joint Interstate Travel Sanitation work with the States of Ohio, Minnesota, and Wisconsin. Agreements with In-

diana, Illinois, and Michigan have been submitted to the respective States for review and comment. These agreements are intended to minimize duplication of effort by FDA and State and local agencies, and to facilitate work planning to fulfill the FDA responsibilities under the Interstate Quarantine Regulations.

Among the many programs administered by FDA is the practice of awarding special citations to railroad and vessel companies in recognition of their efforts to upgrade sanitation levels on railroad food service cars and vessels. Railroads with headquarters in Region V that qualify for special citations are Santa Fe, Milwaukee Road, Rock Island, Burlington-Northern, and Illinois Central. Vessel companies operating on the Great Lakes with headquarters in this region and which have qualified for special citations are Ford Motor Company, U.S. Steel Corporation, Cleveland-Cliffs Iron Company, Interlake Steamship Company, Hanna Mining Company, Bethlehem Steel Corporation, Republic Steel Corporation, and Inland Steel Company.

Illinois Director of Agriculture Gordon L. Ropp, received a commission under the Federal Food, Drug, and Cosmetic Act March 30. Director Ropp expressed enthusiasm over his commissioning and the protection afforded by the Department's coverage of medicated feed mills.

Twelve inspectors of the Department's Division of Feeds, Fertilizers, and Standards are making medicated feed inspections. Their efforts will result in industry improvement.

CINCINNATI DISTRICT A total of 1,363 cases of canned fruit manufactured by a firm at San Francisco, California, was seized at Toledo, Ohio, because the product contained cyclamates. The cans were shipped before the FDA cyclamate ban was put into effect and had remained in possession of Oscar Joseph Stores, Inc., until their discovery June 23. They were destroyed by Community Sanitation Service of Toledo.

DENVER DISTRICT Seizure was made in April of E-Z Breathe, an electronic air cleaner, manufactured in Yankton, South Dakota. The unit purported to be effective enough to filter the air in a 15 x 15-foot room in 18 minutes. It was advertised as a boon to those who suffer from asthma, hay fever, and emphysema. The unit was actually a smaller version of an industrial static precipitator, and does not remove all airborne particles. Routine operation of the device also produces ozone and other potentially harmful gases.

Cottonseed meal contaminated with aflatoxin was seized in the possession of consignees at Draper, Utah. The 17 tons of meal, valued at \$1,600, was manufactured by Casa Grande Oil Mill, Casa Grande, Arizona. The cottonseed meal was to have been included as an ingredient in animal feed. Had this been done, the toxin may have entered the human food chain in meat or milk.

DETROIT DISTRICT An FDA Quality Assurance Survey of two firms resulted in a State seizure of rodent-defiled bins of wheat mixed with navy beans, barley, and oats by the Michigan Department of Agriculture. Since the firms, Ovid Farmers Elevator Co., Ovid, Michigan, and Durand Milling Co., Durand, Michigan, were not engaged in interstate sales, Detroit District inspectors notified Michigan agriculture personnel, who seized the grain, valued at an estimated \$33,000, and required that the firms correct the violations by destroying the contaminated grain and preventing rodent access to the bins.

KANSAS CITY DISTRICT Uniformity in food and drug salvage operations was the main theme of a day-long training session for 43 city, county, State, and Federal enforcement officials from the Omaha, Nebraska-Council Bluffs, Iowa, area at Omaha this spring.

The purpose and objectives of the meeting were discussed by George L. Vinz, assistant to the director for Federal, State, and Industry Affairs, who also served as moderator. Regional Food and Drug Director C. A. Armstrong told the group of recent happenings and developments in FDA and the Kansas City Region.

Speakers on the topics of salvage problems, laws, and regulations were Warren G. McCubbin, chief, Bureau of Dairies and Foods, Nebraska Department of Agriculture; Everett Hart, chief, Food Products Control, Iowa Department of Agriculture; Frank A. Mosebar, FDA Kansas City District; Ray A. Moore, sanitarian, Sioux City, Iowa, Health Department; Lawrence J. Arent, chief, Commodity Operations Division, USDA Minneapolis Office; Maurice V. Ewing, officer in charge, Program Review & Compliance Staff, Consumer & Marketing Service, USDA Kansas City Office; Orville DeFrain, assistant director, Division of Environmental Health, Lincoln-Lancaster County Health Department; Justin Dierks, director, Omaha-Douglas County Health Department; Robert Carson, Council Bluffs City Health Department; and C. M. Saunders, corporate secretary, Chicago Underwriters Salvage Co.

Participants in the session named as cochairmen Wayne A. Downie, sanitarian, Omaha-Douglas County Health Department, and Major Robert L. Flentge, Offutt Air Force Base, Omaha. The group also indicated a desire for another training session by early fall.

LOS ANGELES DISTRICT Alfred M. Lewis, Inc., Las Vegas, Nevada, was found guilty after trial in U.S. District Court on five counts charging storage of food under insanitary conditions and allowing it to become contaminated with insects. Inspection of the wholesale grocery warehouse had shown generalized insect infestation, and insects were found in samples of cornmeal, corn flour, and macaroni products.

Actual trial of the case was delayed pending court hearings on the admissibility of inspectional evidence.

The firm had contended that the inspection was made without a warrant and that the defendant's constitutional rights had been violated. The Circuit Court of Appeals upheld the Government's position, and trial on the evidence was then held in early May.

Judge Roger D. Foley, who found the firm guilty, imposed a fine of \$1,000 on each count on May 28.

MINNEAPOLIS DISTRICT The Milwaukee resident office found a bakery supply warehouse under inspection in Milwaukee, Wisconsin, to be overrun by mice. The rodents were so numerous and bold that, in one instance, a mouse ran across a desk in the firm's office while an inspector was using the telephone to report the situation. The firm is located in a former seed warehouse that structurally is not suited for food storage. With the cooperation of the Wisconsin Department of Agriculture Food Division and the Milwaukee Health Department, the building has been shut down and will not be permitted to open until it meets structural requirements for food storage and the rodent population is exterminated. All stocks of flour and spices stored in the warehouse were embargoed for eventual destruction or segregation. The value in food loss is unknown, but is expected to run into thousands of dollars.

NEW ORLEANS DISTRICT The port of New Orleans was flooded in April with imported seed corn. The corn was purchased by major seed houses of the country who are in search of disease-resistant corn after last year's corn blight in the Midwest. Special arrangements were made by New Orleans District office to expedite the movement of the corn into the country in time for planting. New procedures were developed to speed the corn to its destination without relinquishing the control necessary to assure that no pesticide-treated corn finds its way into food or feed channels.

A major increase in the amount of tea imported through New Orleans is expected until October. The reason for the increase is an anticipated strike in the tea industry that will sharply curtail tea imports. Firms therefore are stockpiling the product.

NEW YORK DISTRICT New York District International Section's pilot study of ship-to-ship coverage of imports is proving successful and is expanding since its implementation in early May. The program places the inspector at the pier to examine or sample shipments as they are discharged from their carriers onto the piers. It reduces time previously spent in locating entries after delivery, and prevents informal entries from passing undetected through the customs house.

A one-ton step-in van has been equipped as a mobile laboratory to increase the inspector's field examination capability. When electrical modifications of the vehicle are completed, inspectors will be able to perform tests on the decomposition of fish. A second mobile laboratory is being painted and equipped and will join the

ship-to-ship project at the Buffalo office.

Eight import inspectors are engaged in the program. During the first week, their field examination of five entries of brazil nuts resulted in the detention of 3,100 cases, valued at \$70,000, because of insect infestation. The inspectors uncovered a shipment of vinyl stuffed rabbits which have been ruled to be banned hazardous toys and were the subject of a recall. Five hundred bags of adulterated cocoa beans were also found.

The program's accomplishments during the first month total approximately 700 actions by the Section. They consisted of samples collected for laboratory analysis, samples examined in the field and either referred directly to Case Management Branch for action or released as a result of the examination, nearly a hundred wharf examinations under the New York District Import Spice Program, and additional wharf examinations covering other commodities.

The ship-to-ship pilot study has expanded its area of coverage from the original 12 piers involved in the inspections to include Sealand Container Depot, located at Port Elizabeth, Newark, New Jersey. The depot, one of the largest of its kind on the East Coast, has provided inspectors with adequate space for examination and is installing a telephone for their exclusive use.

Weems L. Clevenger, Director of Food and Drugs for FDA Region II, was the surprised recipient of the 1971 award presented annually by the Central Atlantic States Association of Food and Drug Officials at its 55th annual convention May 27 in Philadelphia.

Mr. Clevenger was cited for outstanding achievement in the field of food and drug law enforcement and for his contributions to the Association. He was unaware, until the presentation was made by Dr. Angel Alberto Colon, a professor at the University of Puerto Rico, that he had been nominated for the award. Dr. Colon, formerly of the Commonwealth of Puerto Rico's Department of Health, came from San Juan to participate in the ceremony.

The Association is composed of food and drug officials from Connecticut, Delaware, Maryland, New Jersey, New York, Pennsylvania, Washington, D.C., and West Virginia.

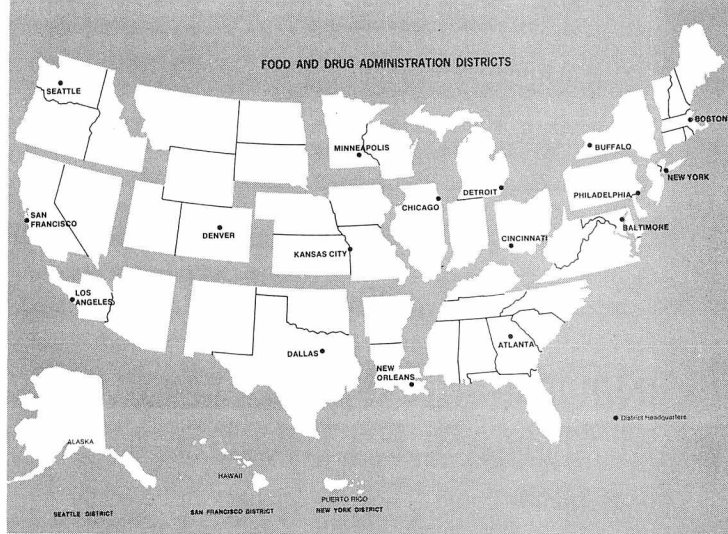
PHILADELPHIA DISTRICT The confirmed finding of a mouse sliced up in a loaf of bread purchased by a Delaware consumer resulted in fines totaling \$8,000 for the firm at fault. Fined on May 19 by U.S. District Court Judge James H. Gorby in Philadelphia was General Host Corp., trading as Bond Baking Co., Philadelphia, which had pleaded nolo contendere to eight counts charging shipment of bread containing a filthy substance and prepared under insanitary conditions, as well as holding raw material in a building accessible to rodents. James E. Wolfe, vice president in charge of production, Bond Baking Co. division, and Joseph Schafer, former plant superintendent at the firm's plant on Market Street, Philadelphia, were each

ined \$4,000 after entering nolo contendere pleas. A six-day inspection of the firm in February 1970 by Philadelphia District revealed extensive mouse infestation, which continued to progress even during the inspection. Inspectors saw 25 mice during one day of the inspection. Raw materials they had sampled and resealed one day were recontaminated two days later when it was noticed the mice gnawed through the tape seals. The firm continued use of such raw materials during the inspection, but eventually destroyed 11,500 pounds of materials.

SAN FRANCISCO DISTRICT San Francisco District conducted an in-house survey in March of pottery submitted to the laboratory by District personnel. The results showed three items of pottery contained excessive lead. One item contained 20 parts per million of lead and was categorized as severely hazardous. The District was advised by the firm from which the item was originally purchased that it will initiate a recall of the product.

Two different styles of cups imported from Italy by Holt Howard Associates during the period of 1968 to 1969 were found to contain 580 and 1,000 parts per million of lead, respectively. The items had all been sold and were not available for recall, but on April 28 the District issued a press release carrying a public warning of the potentially severe hazard involved in the use of the cups.

A third item, a mug purchased by a District inspector in Mexico several years ago was found to contain 1,100 parts per million leachable lead. There was no way of tracing the item to any on the market in this country.



SEATTLE DISTRICT Seattle District personnel, representatives of the Bureau of Foods, National Marine Fisheries Service, National Fisheries Institute, and members of the halibut industry met recently for the preliminary planning of steps to insure that halibut containing mercury residues above .5 parts per million do not reach the market. Many of the same firms handling halibut were also dealers in frozen swordfish, and are greatly concerned that the marketing of halibut be carried out in a more orderly manner.

An investigation by Seattle District of shipments by the Earl Fruit Co., Di Giorgio, California, involving rodent-infested peanuts resulted in the seizure of 39,710 pounds of peanuts and the recall and destruction of 1,227 cases of peanut butter manufactured from the peanuts by an Oregon food manufacturer. A Washington State firm which had also received a shipment from the California shipper destroyed 12,540 pounds of peanut butter which it had produced from the adulterated peanuts.

FDA DISTRICT OFFICES

ATLANTA 60 Eighth St., N.E.
Atlanta, Ga. 30309

BALTIMORE 900 Madison Ave.
Baltimore, Md. 21201

BOSTON 585 Commercial St.
Boston, Mass. 02109

BUFFALO 599 Delaware Ave.
Buffalo, N.Y. 14202

CHICAGO Main Post Office Bldg.
Rm. 1222 433 W. Van Buren St.
Chicago, Ill. 60607

CINCINNATI 1141 Central Pkwy.
Cincinnati, Ohio 45202

DALLAS 3032 Bryan St.
Dallas, Tex. 75204

DENVER New Customhouse Bldg.
Rm. 5604/20th & California Sts.
Denver, Colo. 80202

DETROIT 1560 E. Jefferson Ave.
Detroit, Mich. 48207

KANSAS CITY 1009 Cherry St.
Kansas City, Mo. 64106

LOS ANGELES 1521 W. Pico Blvd.
Los Angeles, Calif. 90015

MINNEAPOLIS 240 Hennepin Ave.
Minneapolis, Minn. 55401

NEW ORLEANS U.S. Customhouse
Rm. 222/423 Canal St.
New Orleans, La. 70130

NEW YORK 850 3rd Ave. (at 30th St.)
Rm. 700/Brooklyn, N.Y. 11232

PHILADELPHIA U.S. Customhouse
Rm. 1204/2nd & Chestnut Sts.
Philadelphia, Pa. 19106

SAN FRANCISCO Federal Office Bldg.
Rm. 518/50 Fulton St.
San Francisco, Calif. 94102

SEATTLE Federal Office Bldg.
Rm. 5003/909 First Ave.
Seattle, Wash. 98104

HEW REGIONAL OFFICES I-X

BOSTON J. F. Kennedy Federal Bldg.
Boston, Mass. 02203

NEW YORK 26 Federal Plaza
New York, N.Y. 10007

PHILADELPHIA 401 North Broad St.
Philadelphia, Pa. 19108

ATLANTA 50 7th St., N.E.
Rm. 404/Atlanta, Ga. 30323

CHICAGO New Post Office Bldg.
433 W. Van Buren St./Chicago, Ill. 60607

KANSAS CITY 601 E. 12th St.
Kansas City, Mo. 64106

DALLAS 1114 Commerce St.
Rm. 911/Dallas, Tex. 75202

DENVER Federal Office Bldg.
19th & Stout Sts./Denver, Colo. 80202

SAN FRANCISCO Federal Office Bldg.
Rm. 416/50 Fulton St.
San Francisco, Calif. 94102

SEATTLE Arcade Plaza Bldg.
1321 2nd Ave., Seattle, Wash. 98101

product safety report

INJURIES ASSOCIATED WITH FLAMMABLE LIQUIDS

A flammable liquid is any liquid that can be easily ignited and that burns rapidly—such as gasoline, kerosene, lighter fluid, denatured alcohol, starter fluid, and turpentine.

Fires and burns resulting from ignition of flammable liquids kill hundreds of children and adults and permanently scar many more. An estimated 60,000 burn injuries occur each year in the United States due to flammable liquids. The Bureau of Product Safety estimates annual injuries to be 40,000 from gasoline, 10,000 from lighter fluids, and 10,000 from other flammable liquids.

During the past several years, FDA's Injury Study Units in Boston and Denver have conducted 318 comprehensive investigations of flammable liquid accidents. These accidents account for some of the most extensive and severe burn injuries, especially to the very young and the very old. Gasoline was the flammable liquid involved in 201 cases investigated. This product is felt to present a particularly serious problem in view of its extreme flammability and widespread availability.

Following are two accounts of injuries involving flammable liquids taken from cases investigated by the Injury Study Units. Although Bill and Bob are not the real names of the injured in these cases, the accounts are based on actual accident sequences reported in the investigations.

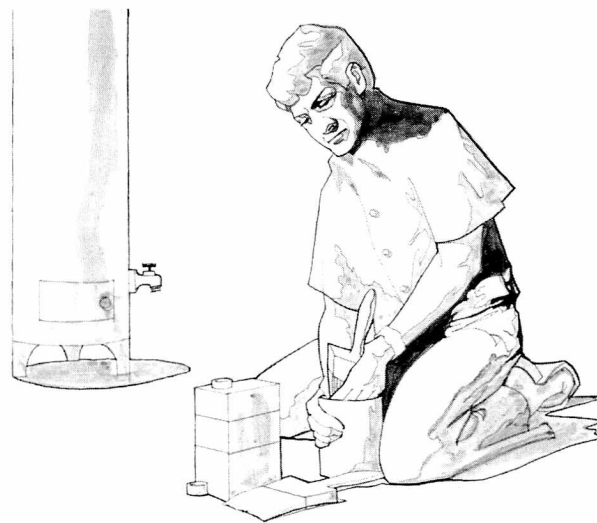
Case #1 investigated by the Boston Injury Study Unit: Bill returned home from work and, after relaxing about an hour, began preparing for a backyard cookout. Unsuccessful in his first efforts to light a charcoal fire in his small hibachi-type grill, he removed the grates and charcoal and rebuilt the fire using papers and denatured alcohol. When the fire was relit, it flared for a few minutes and then started to die down. Concerned that the fire was about to go out again, Bill took the can of denatured alcohol and sloshed more fuel onto the fire. As he did this, the vapors immediately ignited, and the flames traveled to the can, igniting it. Just as he started to throw the flaming can, it exploded, spraying him with flaming liquid which ignited his clothing. With burns over approximately 60 percent of his body, he underwent five skin grafting operations during 111 days in the hospital and was unable to work for a year.

Case #2 investigated by the Denver Injury Study Unit: On Sunday afternoon, Bob was painting his small

utility room, located off the kitchen and adjoining the garage. He had both the garage and kitchen doors open to provide a draft to carry the paint odor away. When he finished painting, he soaked a rag in gasoline to remove paint spilled on the floor. He was scrubbing the floor in front of the washing machine when he heard an explosion. Bob was wearing only a pair of shorts. He suffered first and second degree burns on his scalp, face, and both legs and was admitted to a hospital for treatment of burns to approximately 10 percent of his body.

The washing machine was not operating at the time of the ignition and Bob did not hear the burner of the hot water heater in the utility room come on. He claimed he recognized the potential danger of flammable liquids being near a flame source, but felt he was protected from the water heater's pilot light because the washing machine was between him and the water heater. Presumably the source of ignition was the pilot light of the water heater, and the gasoline vapors probably were carried to the pilot light by the draft from the kitchen to the open garage.

There is increasing evidence that the general public has neither an understanding of the characteristics of gasoline nor an awareness of dangers associated with its uses.

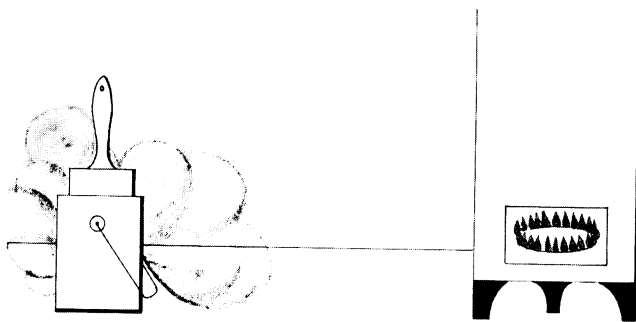


Michael Oliva, director of the Denver Injury Study Unit, reports that the most frequent gasoline ignition accidents found in the Denver investigations were gasoline vapors ignited by a natural gas appliance located nearby. (*Illustration 1*) In most cases, the gasoline was being used to clean paint brushes, auto parts, or greasy parts from some other equipment, and was being used in a basement or utility room—

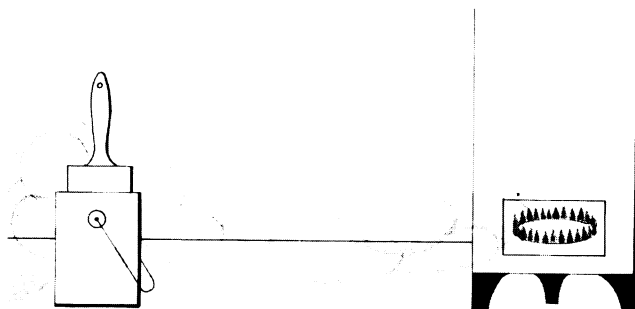
or in a kitchen—where a gas appliance was in the same vicinity. Some investigations have indicated that the victim may not have realized that there was a flame source in the area. The Boston and Denver units have investigated 29 accidents in which 31 persons were injured in this type of situation. Nine other accidents of this nature have been investigated in which a flammable liquid other than gasoline was involved.

Variations in the accident sequence in flammable liquid ignition:

1. Vapors are produced from an open gasoline container. They accumulate around the container and, if enough vapors accumulate, they eventually spread to the pilot light and ignite.
2. In the cleaning process, the individual spills gasoline from the container, increasing the gasoline surface area. This causes a rapid increase in the production of vapors and the entire area becomes saturated with vapors in a few moments. Under these conditions, the vapors spread rapidly to a source of ignition, such as a pilot light.

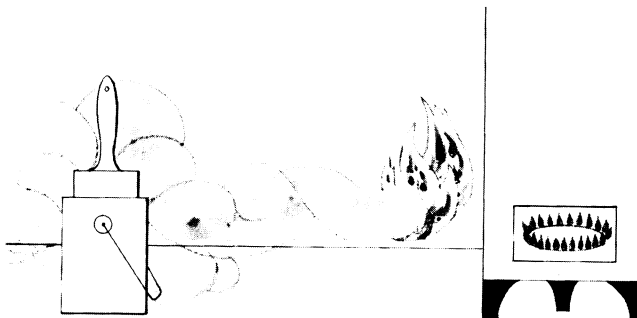


3. Vapors accumulate at a rather slow rate around the container and remain in the immediate vicinity of the container. (*Illustration II*) However, the thermostat in the water heater in the room calls for heat, and the gas burner turns on automatically. This burner requires a source of oxygen which is obtained from the air in the room. Air starts to flow from various parts of the room to the heater to feed the burner. Gasoline vapors in the room are drawn by the air current to the gas burner. (*Illustration III*)



When the vapors reach the burner, they ignite, and a flame front burns back to the gasoline container. (*Illustration IV*) If the victim is not holding the container or has no gasoline on him or his clothing,

he may not be seriously injured, but if he is holding the container and sloshes some of the burning gasoline back on himself or his clothing, or if he has spilled some gasoline on his clothing or hands, this gasoline also will ignite, and he may suffer extensive injuries. If he had spilled a large quantity of gasoline on the floor, he may be standing in an inferno of vapors and, after the flash flame has subsided, he may still be in an uncontrolled house fire.



Knowledge of three basic facts about the characteristics of gasoline could initiate precautions in its use which would decrease the number of injuries from such accidents. For example, persons using gasoline should be aware that:

1. Gasoline gives off vapors continuously even at very low temperatures (-45°F.).
2. Gasoline vapors are heavier than air. They accumulate at floor level, and in a basement or closed room it may be difficult for them to escape. They will not rise and escape through open basement windows or furnace flues.
3. Gasoline vapors will travel on air currents and ignite from a flame source some distance from where the gasoline is being used.

Gasoline should not be used for cleaning, for starting or boosting barbecues or other fires, or for filling the tank of a lawn mower while it is running or when it is still hot from having been operated.

Because of its characteristics, gasoline should not be stored or used in basements or utility rooms where there are gas appliances such as water heaters, furnaces, and clothes dryers.

Gasoline and other flammable liquids should be stored in the house only if there is no other place to store them, and then out of the reach of children and away from any source of heat or flame. They should never be stored in glass containers. Nor should a flammable liquid be stored in metal or plastic containers which do not meet requirements established in nationally recognized standards such as those issued by Underwriters' Laboratories, the National Fire Protection Association, or the National Bureau of Standards. Standards may vary somewhat among these groups, but generally safety containers meeting requirements will be made of heavy gauge metal or plastic, will have spring-loaded closures, and will be identified by an appropriate symbol or label.

news highlights

Appeals Court Upholds FDA's Position Charging Detergent Improperly Packaged

The Colgate-Palmolive Co. began immediately to remove from the market all existing stocks of its product Palmolive Crystal Clear, an automatic dishwashing detergent packaged in milk-type cartons, the Food and Drug Administration announced August 3.

Commissioner of Food and Drugs Charles C. Edwards, M.D., said representatives of Colgate-Palmolive have initiated a total recall of the product in 11 western States in which it was being test marketed. The action followed a decision August 2 by the U.S. Court of Appeals for the District of Columbia Circuit affirming the FDA's position that the product is "improperly packaged in a food container."

The Appeals Court upheld an earlier decision July 30 by a U.S. District Court. In both court actions the company had sought to restrain FDA from seizing the product. FDA contended that the product violated the Federal Hazardous Substances Act, which forbids hazardous household substances from being packaged in identifiable food packages. The action does not involve the product, but only its packaging.

Colgate-Palmolive representatives said 86,000 cases of Crystal Clear are being recalled.

The 11 western States in which the product has been test marketed are California, Washington, Oregon, Utah, Idaho, Nevada, Arizona, Montana, Wyoming, Alaska, and Hawaii.

60 Seizures Remove Large Quantities Of Illegal Fireworks From Market

Tons of illegal fireworks have been removed from the market in 60 seizure actions this year, the Food and Drug Administration announced.

In the largest action, 310,000 units of fireworks valued at \$35,000 were seized June 25 by Federal agents of FDA and the Internal Revenue Service, at Miller Fireworks and Novelty Co., Inc., 501 Gengary Road, Holland, Ohio. The owner, John F. Miller, has been arrested by IRS agents and charged with illegal purchase of black powder and illegal manufacture of explosives.

FDA said the Ohio firm supplied fireworks to a majority of the 55 retail outlets which have been charged with selling illegal fireworks in 1971. FDA has banned explosive fireworks containing more than 2 grains of powder such as cherry bombs, M-80 salutes, and aerial

bombs under the Federal Hazardous Substances Act.

Charles C. Edwards, M.D., Commissioner of Food and Drugs, said the Agency is making every effort possible to prevent needless injuries and deaths from illegal fireworks. The enforcement problem is complicated by a substantial "bootleg" operation supplying illegal products from portable roadside stands and by illegal sale of mail-order "do-it-yourself" kits.

Commissioner Edwards said investigations confirm that eight persons were killed and 41 seriously injured in accidents involving banned fireworks during the past three years.

In addition, thousands of other injuries involving fireworks have been reported during the same period, but have not been investigated and confirmed by the Agency.

Commissioner Edwards pointed out that 18 States have banned all fireworks, allowing only caps and cap pistols. Eight other States allow only sparklers. The remaining States permit the sale and use of some or all fireworks not banned by Federal law.

An exemption to the Federal regulation provides for the use and sale of crop protection fireworks used for agricultural purposes. Large fireworks intended for public displays are also exempted from the ban.

FDA Cancels D.C. Physician's Permit For Methadone Treatment After Abuses

The Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs of the Department of Justice on June 28 rescinded the permit of a third physician to operate a methadone treatment program for narcotics addicts.

The Agencies canceled the IND (Investigational New Drug Exemption) held by Dr. Thomas W. Moore, who practices in Washington, D.C.

Dr. Moore has been barred from starting new patients on methadone treatment since April 23. He was allowed until July 19 to terminate care of patients already in his treatment program. They will be transferred to treatment at other methadone facilities in Washington. Nationally, more than 270 programs are operated under FDA-BNDD approval.

Dr. Moore's program permit was cancelled because his clinical investigation was not being conducted in accordance with the test plan approved by FDA and BNDD, and there was lack of supervision of drug administration and patient follow-up.

In earlier action, FDA withdrew the experimental permits for Dr. F. Wayne Hollinger of Detroit, Michi-

gan, and Dr. M. Rafiq Jan of New York City. The permit withdrawals took place in late May and early June.

Prior to the actions taken in New York and Detroit, the FDA had notified State and local authorities that a number of methadone maintenance programs were being investigated to determine if their practices conform to legal requirements. At that time the Agency warned that "we have reason to believe that these investigations will result in FDA's requiring some sponsors and investigators to either amend their procedures or have their investigational exemptions terminated. . . ."

"Such action is essential to prevent abuse and to avoid having the entire methadone maintenance program discredited," said Commissioner Edwards.

First 'FDA Drug Bulletin' Published With Timely Data for Physicians

The Food and Drug Administration has published the first in a series of *FDA Drug Bulletins* designed to advise physicians and allied health professionals of developments and trends in the drug field. Future issues will be published as needed.

The initial issue, published June 23, contains background information on the Drug Efficacy Study and details of a new requirement for labeling disclosure for drugs rated less than effective by the study; an explanation of FDA's fixed combination drug policy; and a report on labeling changes and other developments from the University Group Diabetes Program's study of hypoglycemic agents.

"We are keenly aware of and determined to meet the need to reach practicing physicians with timely information about the programs of FDA and their effect on physicians," said Charles C. Edwards, M.D., Commissioner of Food and Drugs.

FDA Issues GRAS List Criteria, Proposes Saccharin Reclassification

The Food and Drug Administration has published a final regulation establishing specific criteria for classifying food substances as either GRAS (Generally Recognized as Safe) or as regulated food additives.

The new regulation, published in the June 25 *Federal Register*, will aid the FDA in its current review of all of the 600 substances on the present GRAS list. The Agency said the review is necessary because of new scientific knowledge, the development of modern toxicological techniques, and the expanded usage of some GRAS substances in recent years.

As its first step in reviewing the GRAS list under the new criteria, the Agency also published a proposed regulation to remove saccharin from the GRAS list, and to issue a food additive regulation for the substance.

FDA's GRAS criteria provide that substances of natural biological origin that were widely consumed in the United States prior to 1958 may be considered

GRAS even though altered by conventional processing. No published reaffirmation of safety will be required for such substances.

All other substances on the GRAS list are being subjected to a systematic safety evaluation by FDA and either reaffirmed as GRAS or given a food additive regulation if eligible.

FDA is developing a further regulatory proposal prescribing the type of toxicological data needed to determine the safety of a substance.

The saccharin proposal would place the artificial non-nutritive sweetener in a provisional food additive regulation status. It follows a National Academy of Science-National Research Council report in July 1970 which found saccharin safe if used within specified limitations equivalent to one gram per day for an average adult. The proposal would also require disclosure on the labeling of products containing saccharin in milligrams per fluid ounce for beverages, and milligrams per serving for other foods, as well as label disclosure on manufacturing mixes.

Abbott Labs Resumes Its Sale, Distribution of Intravenous Fluids

The Food and Drug Administration announced June 23 that commercial sale and distribution of Abbott Laboratories' intravenous fluids has resumed.

Earlier this year FDA halted the use of Abbott fluids in hospitals when infections in patients were traced to bacterial contamination of caps used to close the fluid bottles (see FDA PAPERS, April 1971). Before the contamination problem halted production, Abbott produced nearly half the 8 million units of IV fluids used monthly in U.S. health care facilities.

Abbott Laboratories IV products are now being marketed using the rubber stopper closure system of Cutter Laboratories of Berkeley, California. In exchange for use of the Cutter closure, Abbott will produce intravenous fluids for the Cutter firm at Abbott's facilities.

In an intensive effort over the past several months, FDA inspectors and scientists have:

- developed rigorous manufacturing and testing protocols;
- reviewed proposed manufacturing facility changes involving production and control procedures;
- inspected Abbott facilities to assure acceptable operation; and
- collected and examined product samples from new trial production to verify sterility.

'Childproof' Container Regulations Proposed for Public Comment

A major step to protect children from accidental poisoning by requiring "childproof" containers for dangerous household substances was announced by FDA.

Commissioner of Food and Drugs Charles C. Edwards, M.D., said new regulations are being offered for public comment in the *Federal Register* of July 20. These will establish methods for evaluating the effectiveness, as well as feasibility, of safety packaging.

"The annual number of fatalities resulting from accidental ingestion of poisonous substances by children under 5, has been reduced from 454 to 284 in recent years," Dr. Edwards said. "Much of this substantial reduction is the direct result of the work of the Poison Control Center and of activities under the Hazardous Substances Act. The new regulations being proposed today are the next logical step in further reducing the hazards to children from toxic household substances."

The Poison Prevention Packaging Act of 1970 is the authority under which FDA is moving to establish scientific methods for special packaging which will be child resistant. When established, these methods will serve as the basis for standards to which "childproof" containers must conform.

The procedure proposed by FDA testing would test 200 children between the ages of 42 and 51 months inclusive, evenly distributed by age and sex, to determine the ability of a closure to resist opening by children. The ability of adults to open the special packaging also would be tested. All data would then be evaluated by FDA.

The percentage of effectiveness, established by the tests, would determine if a package can be legally designated as a safety package. It is anticipated that the standard may vary from product to product depending on the danger to children.

Bon Vivant Products Being Removed From Shelves After Botulism Death

The Food and Drug Administration and the U.S. Department of Agriculture on July 7 joined in action to remove from retail shelves all soups, sauces, and other canned food products manufactured by Bon Vivant, Inc., Newark, New Jersey. The move came after the death of a man in New York State and the severe illness of his wife from botulism caused by eating the contents of a can of vichyssoise, a potato soup produced by the company. Analysis revealed botulin toxin in that can and in four other cans of the same coded lot of the soup, as well as underprocessed and leaking or swelled cans among others of the company's products.

Two weeks later, on July 23, FDA and the National Canners Association announced joint action to accelerate the pickup of the company's products canned under its own and a number of private labels. More than a million cans of food were involved, under the Bon Vivant label and more than 30 private labels. The company distributes about four million cans of food a year. Bon Vivant agreed to the total recall and was cooperating fully to expedite stock withdrawals.

Underprocessing was blamed for the presence of bot-

ulin toxin in the Bon Vivant vichyssoise, Code V-141/USA 71. Cans from other codes of vichyssoise found also to be underprocessed were V-154, V-174, V-175, V-179, and V-180, all produced in June 1971, and the company's black bean soup, coded BB-112, also canned in 1971. Commissioner of Food and Drugs Charles C. Edwards, M.D., expressed FDA's concern about the further findings of underprocessed foods, but added that "It should be equally well understood that neither FDA nor NCA has found botulinum toxin to this time in any code or in any product other than the Bon Vivant vichyssoise code V-141/USA 71."

Underprocessing at first had been thought confined to the V-141 code. Recall of all other Bon Vivant product lines nevertheless had been requested on July 7 by FDA and undertaken voluntarily by the company as a precautionary measure.

Milan D. Smith, executive vice president of the National Canning Association, met with Commissioner Edwards on July 23. On the basis of the new information, he offered immediately to support the FDA fully in its efforts to secure removal of all Bon Vivant products by establishing additional collection points around the country to accumulate stocks of Bon Vivant products and by committing trucks, labor, and support facilities, including technical people, to the task.

Dr. Edwards said that the precautionary recall being carried out since July 7 by Bon Vivant is proceeding well in locating and recovering large lots of products from primary consignees at both the wholesale and retail level.

"The unmet need at this time is to reach beyond the larger lots in the hands of large outlets, to be certain that stocks still held in the stockrooms of smaller retail and wholesale establishments also have been withdrawn, and to physically move the food to collection points," said Dr. Edwards. "This takes more resources than the company has been able to muster."

"FDA," he added, "is grateful for the prompt and full response of the NCA and the canning industry to the problem."

Dr. Edwards emphasized that FDA "is assured within all reasonable expectations" that Bon Vivant products are virtually all off the retail shelves. FDA, he said, with assistance from U.S. Department of Agriculture, State, and local officials has personally visited 28,000 wholesale and retail establishments since the first week in July.

As of July 23, FDA had accounted for 82 percent or more than 5,300 of the 6,440 cans of the code V-141 vichyssoise. "Every precaution is being taken to account for all cans in this code," said Dr. Edwards, "but it is virtually impossible to find every can. This means," he said, "we can never guarantee against a single can being in somebody's cupboard. We urge that the public remain alert to this possibility."

He again asked consumers who find cans of the V-141 soup or any of the six additional codes identified above to contact the nearest FDA office.

state actions

Tornado Follow-Up State and local enforcement officials in the Joplin, Missouri, area supervised the disposition of approximately \$13,500 worth of storm-damaged foods following the May 5 tornado. Salvage of foods was also being accomplished at Pittsburg, Kansas, the site of another tornado, under supervision of the Food and Drug Division of the Kansas State Board of Health. Tornadoes in north central Missouri were reportedly responsible for the derailing of a freight train. State officials examined that area for damage to foods and drugs.

Network Addition The Bureau of Food and Drugs, New York City Department of Health, joined the Region II Teletype Alert Network (Tan-Two) on April 27. Messages from FDA headquarters and District offices to the New York agency are being sent via the New York District communications center.

Announces Ban Ohio Governor John Gilligan announced a 60-day ban May 5, to be effective immediately, on commercial fishing for white bass in Lake Erie waters due to high mercury contamination of the fish. A public hearing was scheduled to be held during the 60-day period to determine if the ban should be continued.

Marine Patrol Report The Florida Marine Patrol, Florida Department of Natural Resources, responsible for controlling illegal harvesting of shellfish in the State, issued 387 warnings and made 24 arrests during the period of July 1970 to March 1971, principally for the harvesting of oysters from prohibited waters. More than 26,000 patrol hours were expended in covering 8,426 miles of tidal shoreline, which includes approximately a million acres of prohibited waters and 101,460 acres

classified as "conditionally approved." The daily patrol logs of some 100 marine patrol officers are submitted on a monthly basis to FDA's Atlanta District to compile the annual evaluation of each coastal State's activities, which is a part of FDA's Shellfish Sanitation Program.

Grocery Firm Charged The California Bureau of Food and Drugs charged the Market Wholesale Grocery Co., Modesto, California, with storing adulterated food on its premises. A nonjury trial was held in Modesto Municipal Court on April 27, at which time Judge Norman S. Reid found the general manager of the firm innocent of the charges. An amended complaint was submitted, however, naming the corporation as the defendant, and the corporation was found guilty and fined \$100 for violating the State Health and Safety Code.

Health Foods Conviction The advertising of health foods as being beneficial for cancer, heart conditions, and stomach ulcers has resulted in conviction of Kurt W. Donsback, operating as Nature's Way Health Food Store, Westminster, California. The action was taken by the California Bureau of Food and Drug Inspections under the California Health and Safety Code, after a five-month investigation by the Bureau. Mr. Donsback pleaded guilty on April 9 to practicing medicine without a license, and was fined \$750, was ordered to make \$2,000 restitution to the State Food and Drug Bureau, and was placed on two years' probation period.

Decomposed Canned Tomatoes Noticing abnormal cans in a lot of canned tomatoes, Kansas State Food and Drug Inspector Oscar Honomichl collected a sample of the product during an inspection of a large

wholesale grocery firm in Wichita, Kansas, in March. The State laboratory confirmed evidence of decomposition. The lot was embargoed by the State and 148 cases of 303-size canned tomatoes were destroyed.

Unapproved Drugs Inspectors from the Pennsylvania Office of Plant Inspection, State Health Department, on April 21 ordered 9,000 sulfathiazole tablets destroyed and 44 vials of Landex amphetamine solution returned to the manufacturer. The drugs were judged new drugs as determined by the National Academy of Sciences-National Research Council study and had been shipped without benefit of New Drug Approval. State personnel were alerted by inspectors from FDA Philadelphia District.

Clam Program Discussion The Alaska Health Department, in cooperation with other State agencies, held a meeting in Juneau in April to formulate elements of a program for raising razor clams under the National Shellfish Sanitation Program. Due to the high incidence of paralytic shellfish toxin in Alaskan waters, however, such a program has been slow in development.

Franklin D. Clark, Region X food and drug director; David Clem, director, Shellfish Sanitation Division; and Robert Stott, regional shellfish consultant, were among those at the meeting.

Meat Fines The New York State Department of Agriculture and Markets reported a total of \$13,975 in penalties collected for various violations of food laws from 194 cases settled during the month of May. A Mount Vernon meat processing firm was fined \$1,000 for ten violations; two firms in the Buffalo area were jointly penalized \$1,200 for processing meat without inspection.

seizures & postal service cases

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

A total of 76 actions to remove from the consumer market products charged to be violative were reported in May. These included 53 seizures of foods: 28 involved charges concerning poisonous and deleterious substances, 22 involved charges concerning contamination, and 3 involved

charges concerning economic and labeling violations. Other seizures included 2 of food additives, 1 of vitamins and dietary food, 15 of drugs (including 6 of veterinary and medicated feed), 1 of devices, and 4 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD / Poisonous and Deleterious Substances		
Bass, white, fresh/Detroit, Mich. 5/14/71	Sandusky Fisheries, Inc./Sandusky, Ohio (S)	Contains excessive mercury.
Bonito/New Bedford, Mass. 5/27/71	Woodfield Fish and Oyster Co./Galesville, Md. (P)	"
Celery, fresh/Buffalo, N.Y. 5/6/71	Fancee Farms/Sarasota, Fla. (Grower, S)	Contains residues of parathion and toxaphene, pesticide chemicals in excess of tolerance.
Cottonseed, whole/Paramount, Calif. 5/18/71	Western Consumers Feed Co./Paramount, Calif. (D)	Contains aflatoxin, a poisonous substance, which may render it injurious to health.
Calipatria, Calif. 2/9/71	Producers Cotton Oil Co./Calipatria, Calif. (D)	"
Eatwell Bonito chunks/Milwaukee, Wis. 5/7/71	Star-Kist Foods, Inc./Terminal Island, Calif. (Distributor, S)	Contain excessive mercury.
Egg noodles/Toledo, Ohio 4/27/71	Viviano Macaroni Co./Carnegie, Pa. (M,S)	Contain Salmonella micro-organisms.
Marlin, frozen, black/Honolulu, Hawaii 5/11/71	Imported from Japan	Contains excessive mercury.
Meat and bone meal/Horsey, Va. 5/26/71	Keystone Rendering Co., Inc./Philadelphia, Pa. (M,S)	Contains Salmonella micro-organisms.
Pepper, black, whole/ S. San Francisco, Calif. 3/30/71	Imported from Brazil	"
Snapper fillets, red, frozen, Geisha brand/ Milwaukee, Wis. 4/30/71	Imported from Taiwan	Contain excessive mercury.
Swordfish/Los Angeles, Calif. 4/7/71	Caught in the waters of the Pacific Ocean outside the territorial limits of the State of California (S unknown)	Contains excessive mercury.
Los Angeles, Calif. 3/29/71	"	"
chunks, unlabeled/San Pedro, Calif. 4/30/71	"	"
San Pedro, Calif. 4/29/71	"	"
San Diego, Calif. 4/14/71	"	"
San Diego, Calif. 5/13/71	"	"
San Diego, Calif. 4/14/71	"	"
San Diego, Calif. 4/14/71	"	"
Wilmington, Calif. 4/29/71	"	"
frozen, whole/San Pedro, Calif. 4/30/71	"	"
whole and chunks/Santa Barbara, Calif. 5/4/71	"	"
Santa Barbara, Calif. 5/7/71	"	"
Tampa, Fla. 3/17/71	Pocasset Food Sales, Inc./Cranston, R.I. (S)	"
Cranston, R.I. 3/2/71	Imported	"
Boston, Mass. 5/4/71	"	"
Brooklyn, N.Y. 5/11/71	"	"
Newport Beach, Calif. 3/31/71	Caught in the waters of the Pacific Ocean outside the territorial limits of the State of California (S unknown)	"
Contamination, Spoilage, Insanitary Handling		
Alaska peas, California pink beans/ Santurce, P.R. 5/26/71	Caribe Warehouse Corp./Santurce, P.R. (D)	Held under insanitary conditions; bird and rodent contaminated.
Beanland's Best pinto beans/San Francisco, Calif. 5/3/71	R. J. Whitman Sales Co./San Francisco, Calif. (D)	"
Buttermilk powder/New Orleans, La. 5/11&13/71	Joseph Jurisich Transfer & Storage, Inc./ New Orleans, La. (D)	"
Cane sugar/Erie, Pa. 5/26/71	Nickel Plate Mills, Inc./Erie, Pa. (D)	"

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Contamination, Spoilage, Insanitary Handling (cont'd)		
Cheddar cheese/Pocatello, Idaho 4/22/71	Hi-Land Dairyman's Association/Richmond, Utah (M,S) shipped from Murrco, Utah	Rodent contaminated; made from filthy milk.
Crabmeat, canned/Somerville, Mass. 3/31/71	Imported from Japan. Nozaki Associates, Inc./New York, N.Y. (S)	Contains crab hairs (setae).
Flour/Liberal, Kans. 4/14/71	Ideal Stores Co./Liberal, Kans. (D)	Held under insanitary conditions; rodent contaminated.
Hattiesburg, Miss. 5/5/71	Shelby Wholesale Co./Hattiesburg, Miss. (D)	"
Garlic butterfly crisps/St. Paul, Minn. 4/15/71	Admiral Merchants Motor Freight, Inc./St. Paul, Minn. (D)	Held under insanitary conditions.
Ginger, split/Brooklyn, N.Y. 5/28/71	Gel Spice, Inc./Brooklyn, N.Y. (D)	Partly moldy and decomposed.
Jelly bird eggs/Erie, Pa. 3/24/71	Farley Candy Co./Skokie, Ill. (M,S)	Contain wood chips.
Peaches, canned/Nashville, Tenn. 4/2/71	Cherokee Products Co./Haddock, Ga. (P,S)	Have a phenolic or disinfectant-like taste and odor.
Peanuts, Spanish/Beaverton, Oreg. 4/12/71	Earl Fruit Co./Di Giorgio, Calif. (S)	Rodent contaminated.
Pecans/New York, N.Y. 4/9/71	Nut Tree Pecan Co./Albany, Ga. (P,S)	Packed under insanitary conditions; E. coli.
shelled/St. Louis, Mo. 5/5/71	Dasher Pecan Co./Valdosta, Ga. (P,S)	Prepared and packed under insanitary conditions; E. coli.
Piqua, Ohio 4/13/71	"	"
Grand Rapids, Mich. 5/5/71	"	"
Pickles/Bronx, N.Y. 3/24/71	Merchants Food Distributing Coop./Bronx, N.Y. (D)	Held under insanitary conditions; contained decomposed pickles.
Rice/Santurce, P.R. 5/26/71	Caribe Warehouse Corp./Santurce, P.R. (D)	Held under insanitary conditions; rodent contaminated.
Mobile, Ala. 4/20/71	Alabama State Docks/Mobile, Ala. (D)	Partly decomposed and moldy; fire damaged; contains glass particles.
Saimin (oriental type alimentary paste product), Chow Funn (wheat)/Los Angeles, Calif. 4/28/71	Modern Macaroni Co., LTD/Honolulu, Hawaii (M)	Prepared and packed under insanitary conditions; insect and rodent contaminated.
Walnut pieces/Suffolk, Va. 5/12/71	Continental Nut Co./Chico, Calif. (P,S)	Prepared and packed under insanitary conditions; insect contaminated.

Economic and Labeling Violations

Blueberry bars, Jewel Bakery Shop cookies, Old Style sugar cookies, Windmill assortment/Denver, Colo. 4/13/71	Jewel Cos., Inc./Barrington, Ill. (M,S)	Not in conformity with the Fair Packaging and Labeling Act.
Pretzels, extra thin/Chillicothe, Ohio 5/6/71	Quinlan Pretzel Co./Denver, Pa. (M,S)	"
Shrimp Newburg/Buffalo, N.Y. 5/21/71	Freezer Queen Foods, Inc./Buffalo, N.Y. (D)	" ; misleading vignette showing 18 to 19 shrimp or shrimp pieces, but article contains less.

Food Additives

Applesauce, sliced peaches, fruit cocktail, grapefruit sections/Toledo, Ohio 5/12/71	Oscar Joseph Stores, Inc./Toledo, Ohio (D)	Contain cyclamate, an unsafe food additive not in conformity with regulation.
Pottery skillets/Fort Worth, Tex. 4/13/71	Imported from Mexico (Ramon C. Gonzalez (S))	Lead leaching from earthenware skillets.

Vitamins—Dietary Food

Diet matzos/Baltimore, Md. 5/12/71	A. Goodman & Sons, Inc./Long Island City, N.Y. (M,S)	False and misleading claims to be of special dietary value in calorie-restricted diet; not in conformity with the Fair Packaging and Labeling Act.
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DRUGS / Human Use

Atro-Dote injection/Baton Rouge, La. 4/21/71	Hart-Delta, Inc./Baton Rouge, La. (D)	Superpotent; not in conformity with good manufacturing practice.
Estrand-Gens #5 S.C. yellow tablets/Philadelphia, Pa. 4/19/71	Richlyn Laboratories, Inc./Philadelphia, Pa. (M)	Subpotent; contained approximately 80 percent of declared methyltestosterone.
Isoniazid tablets, 300 mg./Perry Point, Md. 4/2/71	Repacker/Baltimore, Md. (P)	Below USP standard for strength; contain 90 percent of declared amount of isoniazid per tablet.
Linger ointment, lot "290"/Chicago, Ill. 5/26/71	National Sanitary Labs., Inc./Chicago, Ill. (Repacker, S,D)	Contains Pseudomonas denitrificans.
M-Cal-M multiple vitamin preparation/Springfield, Mo. 4/14/71	E. W. Heun & Co./St. Louis, Mo. (M)	Not in conformity with good manufacturing practice; below labeled strength.
Pluronic F-68, flakes, powder/Denver, Colo. 4/8/71	Dr. Bruce C. Paton/Denver, Colo. (D)	Below purported quality and purity; new drug not approved for safety and efficacy.
Sedatans tablets, Hy-Po-Tone tablets/Philadelphia, Pa. 5/6/71	High Chemical Co./Philadelphia, Pa. (M,P, D) (manufactured and packed by dealer from raw materials shipped by various companies)	Not in conformity with good manufacturing practices; inadequate directions for use.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
DRUGS / Human Use (cont'd)		
Testosterone Enanthate w/Estradiol Valerate injection, Estradiol Valerate injection/ Los Angeles, Calif. 5/25/71	Titan Pharmacal Co./Los Angeles, Calif. (D)	Estradiol Isovalerate has been substituted for Estradiol Valerate.
Vitamin E—100, I.U. 200, 400, and 600/ Denver, Colo. 4/14/71	Health-Rite Nutritional Products/Los Angeles, Calif. (M)	New drug not approved for safety and efficacy.
Veterinary / Medicated Feed		
CAP-CHUR-SOL/Modesto, Calif. 5/11/71	Palmer Chemical & Equipment Co., Inc./ Douglasville, Ga. (M,S)	New animal drug not approved for safety and efficacy; not in conformity with good manufacturing practice; inadequate directions for use; no "Caution" statement.
DAP tablets/Baton Rouge, La. 5/11/71	Linden Laboratories/Los Angeles, Calif. (M,S)	New animal drug not approved for safety and efficacy.
Furazolidone/Danbury, Conn. 5/19/71	Davis-Edwards Pharmacal Co./Danbury, Conn. (M,D)	"
Dr. Mayfield Oxytet (oxytetracycline HCl/ Norfolk, Nebr. 4/26/71	Dr. Mayfield Laboratories, Inc./Charles City, Iowa (M,S)	"
Talodex/Honolulu, Hawaii 5/6/71	Diamond Laboratories, Inc./Des Moines, Iowa (M,S from Calif.)	"
and syringes/Modesto, Calif. 4/30/71	" (M,S)	"

MEDICAL DEVICES

Sizatometer/Las Vegas, Nev. 4/27/71	OSIRIS/San Francisco, Calif. (S)	False and misleading claims to be effective for stretching and increasing the size of the user's penis; inadequate directions for use; dangerous to health when used as recommended.
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HAZARDOUS SUBSTANCES

EPO panel & dry wall adhesive/St. Louis, Mo. 4/15/71	Commercial Chemical Co./Cincinnati, Ohio (M,S)	Extremely flammable; lacks consumer protection information required by the Fed. Hazardous Substances Act.
Jarts missile game/Robbinsdale, Minn. 4/20/71	R. B. Jarts, Inc./Fort Edward, N.Y. (M,S)	Banned hazardous substance; lack consumer protection information required by the Fed. Hazardous Substance Act.
Cheektowaga, N.Y. 4/26/71	Jarts Co./Fort Edward, N.Y. (M)	"
Lawn darts/Detroit, Mich. 5/24/71	King Athletic Goods Corp./Philadelphia, Pa. (M,S)	"

U.S. POSTAL SERVICE

actions taken in medical cases under provisions of the Postal Fraud Statutes as reported by the Assistant Postmaster General.

False Representation Orders Issued by Judicial Officer Under 39 U.S.C. 3005

May 6, 1971: False Representation Order issued against **Behavioral Science Laboratories**, 7100 Baltimore Avenue, College Park, Maryland 20740. Advertising and sale by mail of "Excite-X" liquid capsules represented as an aphrodisiac or sexual stimulant.

May 21, 1971: False Representation Order issued against **Buchanan**, 152 West 42nd Street, Suite 536, New York, New York 10036, and **P.O. Box 239**, Suite 1, Gary, Indiana 40401. Advertising and sale by mail of Spanish Fly "Make Them Hot" pills represented as an aphrodisiac or sexual stimulant.

Complaints Filed by the Law Department Under 39 U.S.C. 3005 (False Representation)

May 21, 1971: **Trim-Tights G-25**, 6311 Yucca Street, Hollywood, California 90028. Advertising and sale by mail of a "Sauna Girdle" represented as enabling subscribers to spot reduce.

May 25, 1971: **Thornwood Laboratories**, 10 Burnside Avenue, Congers, New York. Advertising and sale by mail of "Slenro Capsules" represented as enabling subscribers to lose ten pounds in one month.

May 26, 1971: **Barbizon Weight Control Systems, Inc.**, Suite A, 20 North Van Brunt Street, Englewood, New Jersey 07631. Advertising and sale by mail of "Barbizon Skini-Mini Capsules" guaranteed as enabling subscribers to lose ten pounds in two weeks.
June 1, 1971: **Suprema Products**, P.O. Box 267, Neptune, New Jersey 07753. Advertising and sale by mail of "Pink Champagne" formula promising dramatic weight losses.

notices of judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

Lettuce, Singh, at Utica, N. Dist. N.Y.

Charged 11-18-70: when shipped by Rala Singh Farms, Glendale, Ariz., the article contained the pesticide chemical, parathion, in excess of the prescribed tolerance; 402(a)(2)(B). Default decree ordered destruction. (1)

Swordfish steaks, at Memphis, W. Dist. Tenn.

Charged 2-12-71: when shipped by Mogelberg Foods, Inc., Jersey City, N.J., the article contained the poisonous and deleterious substance, mercury; 402(a)(1). Default decree ordered destruction. (2)

FOOD / Contamination, Spoilage, Insanitary Handling

Almond pieces, Blue Ribbon, at Hopkins, Minn.

Charged 11-27-70: when shipped by Continental Nut Co., Chico, Calif., the article contained insect filth; 402(a)(3). Consent decree authorized release to the shipper for reconditioning. (3)

Cashew nuts, salted, Fairmont Snacktime, at Little Chute, E. Dist. Wis.

Charged 11-23-70: when shipped by Johnson Nut Co., Div. of Fairmont Foods Co., Hopkins, Minn., the article contained insect filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (4)

Cornmeal, at Robertsdale, S. Dist. Ala.

Charged 9-25-70: when shipped by Murphy Grain & Milling Co., Owensburg, Ky., the article contained insect filth and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the shipper for conversion to animal feed. (5)

Flour, at Cedar Lake, W. Dist. Mich.

Charged 11-16-70: while held by Cedar Lake Foods, Cedar Lake, Mich., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (6)

Macaroni and egg noodles, at Little Rock, E. Dist. Ark.

Charged 9-2-70: while held by Jay Freeman Co., Inc., Little Rock, Ark., the articles contained insect filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (7)

Noodle mix, Noodle-Roni Parmesano, at Miami, S. Dist. Fla.

Charged 5-25-70: when shipped by Golden Grain Macaroni Co., Bridgeview, Ill., the article contained bacterial filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (8)

Noodle products, at Los Angeles, C. Dist. Calif.

Charged 10-19-70: when shipped by Greenfield Noodle & Specialty Co., Detroit, Mich., the articles, labeled in part "Greenfield's . . . Egg Drop Farfel" and "Streit's . . . Noodles . . . National Distributor Aron Streit, Inc., New York, N. Y.," contained insect filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (9)

Nutmegs, at New York, S. Dist. N.Y.

Charged 6-9-69: while held for sale, the article contained moldy decomposed nutmegs; 402(a)(3). Consent decree authorized release to Gel Spice Co., Inc., Brooklyn, N.Y., for reconditioning. (10)

Nuts, mixed, Johnson's Home Treat, at Boise, Idaho.

Charged 11-17-70: when shipped by Johnson Nut Co., Div. of Fairmont Foods Co., Hopkins, Minn., the article had been prepared and packed under insanitary conditions; 402(a)(4). Default decree ordered destruction. (11)

Potato flakes, at Houston, S. Dist. Tex.

Charged on or about 10-10-70: while held by Houston Central Warehouse & Cold Storage Co., Houston, Tex., the article contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (12)

Rice, at Sacramento, E. Dist. Calif.

Charged 11-6-70: while held by North American Foods Distributors, Sacramento, Calif., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree authorized delivery to an eleemosynary institution for use as animal feed. (13)

Rice, macaroni rings, and egg noodles, at Toledo, N. Dist. Ohio.

Charged 9-23-70: while held by Toledo Terminal Warehouse, Inc., Toledo, Ohio, all of the articles contained insect filth, and the rice was rodent gnawed; and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (14)

Salmon, canned, at Seattle, W. Dist. Wash.

Charged 11-6-69: when shipped by Kenai Packers, Kenai, Alaska, the article had been prepared and packed under insanitary conditions; 402(a)(4). The shipper as claimant filed a motion for change of venue to Dist. of Alaska which was denied, and thereafter a consent decree was entered for the release of the article to the claimant for export for use other than for human consumption. (15)

Shrimp, cooked, frozen, El Dorado, at Omaha, Dist. Nebr.

Charged 10-3-69: when shipped by New England Shrimp Co., Inc., Cambridge, Mass., the article contained bacterial filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). After the shipper was permitted by the court to withdraw its claim and answer upon the payment of certain costs, a default decree was entered ordering the destruction of the article. (16)

Shrimp meat, pasteurized, at Burlingame, N. Dist. Calif.

Charged 5-5-70: while held for sale, the article contained decomposed shrimp; 402(a)(3). Consent decree authorized release to Metro-Fresh Sales Co., San Carlos, Calif., for salvaging. (17)

Spaghetti rings, LaRosa, at Milwaukee, E. Dist. Wis.

Charged 11-27-70: when shipped by LaRosa & Sons, Inc., Westbury, N.Y., the article contained insect filth; 402(a)(3). Default decree ordered destruction. (18)

Walnut pieces, Johnson's Snacktime, at Boise, Dist. Idaho.

Charged 11-17-70: when shipped by Johnson Nut Co., Div. of Fairmont Foods Co., Hopkins, Minn., the article contained insect filth and moldy nuts and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (19)

FOOD / Economic and Labeling Violations

Candy coconut chews and coffee chews, at Tacoma, W. Dist. Wash.

Charged 10-27-70: when shipped by Ed & Don's Candies, Honolulu, Hawaii, the articles were short weight (coconut chews approx. 5.4 percent, and coffee chews approx. 4.0 percent)—403(e)(2); and the articles were in violation of the Fair Packaging and Labeling Act in that the label statement of net quantity of contents on the principal display panel of each article was not separated from other label information appearing above such statement; and such label statement did not contain letters and numerals in the established type size as required by regulations, since the principal display panel had an area of more than 5 but less than 25 square inches and such label statement contained letters and numerals less than 1/8 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Pursuant to stipulation of the parties, an order was entered authorizing donation of the article to a charitable institution. (20)

Herring in wine sauce and herring, pickled, at Pittsburgh, W. Dist. Pa.

Charged 11-24-70: when shipped by Sea Fare Foods, Inc., Detroit, Mich., the articles, labeled in part "Ma Cohen's Imported Party Snack in Wine Sauce [or 'Home Made Pickled Schmaltz Herring'] . . . City Smoked Fish Co., Detroit, Mich.," were in violation of the Fair Packaging and Labeling Act, in that the pickled herring's declaration of quantity of contents was not separated from other printed label information appearing above or below the declaration—15 U.S.C. 1453(a)(2); and in that the quantity of contents of the articles were expressed as "Net Contents 1 Lb. 8 Oz. 1 Lb. 4 Oz." and "Net Contents 1 Lb. Avd.," instead of "Net Wt. 24 Oz. (1 Lb. 8 Oz.);" and "Net Wt. 16 Oz. (1 Lb.);" and the quantity of contents of the articles was stated in a type size less than 1/8 inch high on the principal display panel areas larger than 5 square inches—15 U.S.C. 1453(a)(3)(A)(i), 1453(a)(3)(C)(i). Consent decree authorized release to Cantor & Smolar Co., Inc., Pittsburgh, Pa., for relabeling. (21)

Macaroni and egg noodle novelty product, Mrs. Sostrin, at Milwaukee, E. Dist. Wis.

Charged 10-28-70: when shipped by Sostrin Food Products, Lincolnwood, Ill., the articles were in violation of the Fair Packaging and Labeling Act in that the quantity of contents declaration was stated in a type size less than 3/10 inch high; the quantity of contents declaration was expressed as "1 Lb. Net Weight" instead of "Net Wt. 16 Oz. (1 Lb.);" the declaration of quantity of contents of the macaroni only was not placed within the bottom 30 percent of the area of the principal display panel; and the quantity of contents declaration was not separated from other printed label information appearing above and below; 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(3)(C)(i). Default decree ordered destruction. (22)

Shortening, vegetable, yellow, Saute Vegetable Butter Brand, at Detroit, E. Dist. Mich.

Charged 7-5-67 and amended 11-20-67: while held by American Shortening & Oil Co., Detroit, Mich., who manufactured the article from oils shipped in interstate commerce, the article's labeling statements "butter" were false and misleading as applied to an article which consisted of various vegetable oils, artificial coloring, and other ingredients, and which was, in fact, an artificially colored vegetable shortening; the article was offered for sale under the name of another food, "butter," when it was not butter; the article lacked the common or usual name of its ingredients; and the article contained an artificial coloring and its label failed to state that fact; 403(a), 403(b), 403(i)(2), 403(k). The dealer filed an answer to the charges denying that the article was misbranded. The Government served interrogatories on the dealer. Thereafter the Government moved for summary judgment. In finding for the Government, the court said:

"Defendant's contention is based upon its belief that (1) the labeling is not misleading to the consumer in that the word 'butter' is preceded by the adjective 'vegetable'; (2) the artificial coloring is used, not to deceive, but to avoid a prejudice against a greasy food product that is white or gray.

"The court disagrees with the position espoused by defendant. The labeling of the product as 'vegetable butter' is false and misleading. The product manufactured by defendant contains no ingredient similar to or identical to those set forth in 21 U.S.C. §201(a), defining 'butter'. Defendant's product is not and cannot constitute butter under the Food, Drug, and Cosmetic Act. The word 'butter' used in conjunction with the word 'vegetable' is misleading. It gives the consumer the impression that he is purchasing a product made from butter. When an individual shops for food staples he does not take time, in most instances, to read the labels so as to apprise himself of the ingredients. The consumer relies on the description on the package. If it states that it is 'peanut butter' the consumer expects it to be made from peanuts without reading its label as to its ingredients. If the item states that it is 'vegetable butter,' the average consumer takes it as being composed of a mixture of vegetable oils and butter.

"'Butter' is defined in 21 U.S.C. §321(a) as a product 'made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.' Defendant admits that its product does not satisfy the statutory definition for butter; that its product is made primarily from vegetable oils and contains no milk or cream. Despite these discrepancies, its product is manufactured to be similar in appearance to butter since it is yellow-colored and semisolid.

"In *Libby, McNeill & Libby v. United States*, (C.A. 2d, 1945), 148 F.2d 71, a food standard case where the product labeled 'tomato catsup with preservative' was found to be misbranded because the standard for 'tomato catsup' did not permit a preservative, the court stated at page 73:

'If producers of food products may, by adding to the common name of any such product mere words of qualification or description, escape the regulation of the Administrator, then the fixing of a standard for commonly known foods becomes utterly futile as an instrument for the protection of the consuming public.'

The defendant has done that which was forbidden in the *Libby* case. He has added the word 'vegetable' to the common name of his product.

'Similarly, in *United States v. Vitasafe Formula M* (D.C. New Jersey, 1964), 226 F. Supp. 266, the court held that 'Any single false, misleading, exaggerated, ambiguous or over-emphasized statement or representation in labeling of either a drug or a food misbrands the articles within the meaning of either 21 U.S.C. § 343(a) or § 352(a).' (p. 278) [Emphasis supplied.]

"In the case at bar defendant holds his product out to the consumer as being 'vegetable butter'. Defendant has admitted that the word 'vegetable' is used to qualify or describe the type of butter. The defendant purports his product to be something which it is not. Defendant has attempted to negate the effect of using the word 'butter' by putting the phrase 'Not A Dairy Product' on its label. This, however, is not sufficient to completely minimize the effect its product's name will have on the consumer.

"The use of the word 'butter' for a yellow-colored vegetable shortening is misleading and contrary to the intent of Congress as expressed in the statutory definition for butter, 21 U.S.C. §321(a). Defendant is correct in stating that there are other products on the market which use the name butter in some form (such as apple butter, peanut butter, etc.), which obviously do not conform to the statutory definition of butter. However, apple butter and peanut butter do not look like butter, whereas the product involved in this case is identical in appearance and consistency to butter. Because of the similarities between defendant's product and butter, its product obviously lends itself to deceptive promotion and use as butter. It is not unreasonable to presume that defendant added the artificial yellow coloring to its product so that it would appear similar to butter and thereby lend itself to deceptive use and not to use solely for frying and cooking purposes."

The claimant subsequently filed an appeal, however, the appeal was dismissed for lack of prosecution. (23)

VITAMINS / DIETARY FOODS

Dr. Bronner's dietary foods, at Detroit, E. Dist. Mich.

Charged 8-13-70: when shipped by E. H. Bronner & Associates, Escondido, Calif., the label of the dulce sea lettuce was false and misleading, since the article was not effective, as represented, to promote greater health and physical fitness because of its iodine content, the statement "Crude protein rich in natural hormones" on the label of the carrot syrup was false and misleading, since it was contrary to fact, the label of the vegetable-amino-broth organic seasoning contained false and misleading claims that such article would provide a significant amount of protein in the daily diet and was adjusted to contain a natural sodium and potassium chloride balance, the label of the organic-mineral-salt seasoning contained false and misleading claims that such article would build teeth and that all minerals and trace found in man were supplied in a balanced proportion in the article, and the label of the organic mineral bouillon contained false and misleading claims that such article would provide instant energy, a full meal, and all nutrients needed by the body—403(a); the labels of the organic-mineral-salt seasoning and the organic mineral bouillon failed to bear the common or usual name of each ingredient in the articles—403(i)(2); the labels of all articles other than the organic mineral bouillon lacked required information concerning their purported dietary properties—403(j); and the dulce sea lettuce contained the nonconforming food additive, iodine—402(a)(2)(C). Default decree ordered destruction. (24)

Videtts multivitamin and mineral capsules, at Houston, S. Dist. Tex.

Charged 1-12-71 and amended 1-28-71: while held by Videtts Pharmaceutical Corp., Houston, Tex., the labeling of the article contained false and misleading claims that the article would bring back the vigor and vitality of youth, that the article contained all vitamins and minerals essential to health, that the article would supply the nutritional value of all foods pictured in an accompanying newspaper insert, including such foods as butter, liver or beef, enriched bread, broccoli, oysters, milk, cabbage, tomatoes, and eggs, and that the article was capable of promoting a healthier, happier, and more dynamic life; that the ingredient vitamin D was declared on the label without stating its source; and that the article's label lacked required information concerning its purported special dietary uses; 403(a) 403(i)(2), 403(j). Consent decree authorized release to the dealer for relabeling. (25)

FOOD ADDITIVES

Beverages, Dietetic No-Cal, at Lexington, E. Dist. Ky.

Charged 3-27-70: when shipped by Anthony Sales Co., Connaminson, N.J., the article contained the nonconforming food additive, calcium cyclamate; 402(a)(2)(C). Default decree ordered destruction. (26)

Mackerel, canned, Rose Bowl, at Garden City and Queens, E. Dist. N.Y.

Charged 6-11-69: when shipped by J. R. Barry & Co., Terminal Island,

Calif., the article contained the nonconforming food additives, DDT, DDE, and DDD; 402(a)(2)(C). Default decree ordered destruction. (27)

DRUGS / Human Use

Absorbent gauze "sponges" U.S.P., Bay's Readi-Wrap, at Atlanta, N. Dist. Ga.

Charged 6-17-69: when shipped by Parke, Davis & Co., from Greenwood, S.C., the article's quality fell below the U.S.P. standard for absorbent gauze, since it was not packaged individually so that the sterility of each unit was maintained until the package was opened for use; 501(b). Following the filing of an answer by the claimant, Parke, Davis & Co., the Government filed a motion for summary judgment. The court in granting such motion found that there was no genuine issue as to any material fact. The court also stated "a U.S.P. item must conform to the standards of the U.S.P. whether or not it provides a test. Cf. *U.S. v. Lessor, et al.* (C.A.2d, 1933) 66 F.2d 612. We feel that packaging not only involves quality but purity as well.

"The argument that two gauze sponges constitute a single unit which is packaged individually, thus coming within the packaging requirement of U.S.P. VII is likewise without merit. On page 262 of the U.S.P. it is required that 'Absorbent Gauze . . . is so packaged individually that the sterility of each unit is maintained.' The common sense meaning of individually is 'one' or 'by itself'.

"This article is a drug recognized by an official compe[n]dium, contrary to claimant's contention, for the description of Type VII is set out in the U.S.P. It seems obvious to the Court that the words 'sponge' and 'absorbent' are so synonymous that the difference is but a play on words for the purposes of the Act. Being so recognized by the U.S.P. there was a failure to package the gauze in accordance with the standards of the U.S.P. Were the description 'U.S.P. Type VII (20/12)' not on the envelope a genuine issue as to a material fact might be raised.

"The argument that the difference between the packaging requirements under the U.S.P. and the packaging of this article is 'plainly stated' on the label or envelope does not carry the burden. 21 CFR §1.100(c) requires a drug as defined in the U.S.P. and having a statement that it differs in strength, quality or purity from the standard set forth in the U.S.P. to show all the respects in which the drug so differs and the extent of such difference. As noted in *United States v. 5 one-pint Bottles, etc.* (S.D., N.Y., 1934) 9 F. Supp. 990, if a manufacturer wants to use a compendium title for a non-conforming product, it is his duty to give the public unmistakable notice of the departure from the official standard."

Thereafter a decree was entered ordering that the article be released to a charitable institution for use for purposes not requiring sterility after the envelope of the article had been opened and reclosed. (28)

Bovik's Aloe Vera Gel Juice, at Clovis, Dist. N. Mex.

Charged 7-16-69: when shipped by Valley Aloe Vera, Inc., Weslaco, Tex., the article was a new drug without an effective approved New Drug Application; 505(a). Dr. Ellis G. Bovik, Weslaco, Tex., filed an answer denying the charge, and the Government filed a motion to strike such answer on the ground that he had not filed a claim of ownership. Thereafter, Dr. Bovik filed a claim and the motion to strike was denied. Subsequently, with the consent of the claimant, a decree was entered ordering the destruction of the article. (29)

Chorionic gonadotropin injection, at Houston, S. Dist. Tex.

Charged on or about 10-7-70: when shipped by Glogau & Co., Inc., Chicago, Ill., the article lacked its declared strength, since it contained approximately 74 percent of its declared chorionic gonadotropin; 501(c). Default decree ordered destruction. (30)

Diethylstilbestrol enteric-coated tablets, U.S.P., at Fort Lee, Dist. N.J.

Charged on or about 12-11-69: when shipped by Strong Cobb Arner, Inc., Cleveland, Ohio, the article's quality fell below U.S.P. standards, since the article failed the disintegration test; 501(b). Default decree ordered destruction. (31)

Digoxin tablets, U.S.P., at Woodside, E. Dist. N.Y.

Charged on or about 10-9-69: when returned to Davis Edwards Pharmacal Corp., Woodside, N.Y., from Cleveland, Ohio, the article's strength differed from, and its quality fell below, U.S.P. standards for content uniformity, since more than one tablet out of 30 was outside the limits of 85 percent to 115 percent; 501(b). Default decree ordered destruction. (32)

First aid cream, at New York, S. Dist. N.Y.

Charged on or about 1-2-70: when shipped by Suburban Sales Co., Philadelphia, Pa., the article, labeled in part "Double Antibiotic First Aid Cream Kalton . . . on minor burns, insect bites, and minor skin infections . . . Allantoin, Bithionol, Eucalyptol, Benzyl Alcohol, Diphenol Hydrochloride . . . Tyrothricin Gramicidin," was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (33)

Obital Timecaps amphetamine and thyroid combination capsules, at Mansfield, N. Dist. Ohio.

Charged 3-1-68: while held by Caldwell & Bloor Co., Mansfield, Ohio, after repackaging by such firm, the labeling contained false and misleading claims that the article was an adequate and effective adjunct in treatment of simple obesity; and the labeling lacked adequate directions for use and failed to comply with the Rx drug requirement for disclosure of information; 502(a), 502(f)(1). Consent decree ordered destruction. (34)

Reserpine tablets, U.S.P., at Melville, E. Dist. N.Y.

Charged 1-7-70: when shipped by Seaway Pharmacal Co., Muskegon Heights, Mich., the strength of the article, labeled in part "Tablets Reserpine Alkaloid 0.1 Mgm . . . Manufactured For Wolins Pharmacal Corp. Farmingdale, New York," differed from the U.S.P. standard and the label statements of strength were false and misleading, since the article contained approximately 80 percent of its declared reserpine; 501(b), 502(a). Default decree ordered destruction. (35)

Thyroid-thyroid-digitalis tablets and capsules, Thyroidig Anterior Pituitary thyroid-digitalis combination tablets, and thyroid tablets, at Denver, Dist. Colo.

Charged 1-4-68 and amended 5-2-68: while held by Western Research Labs., Inc., after manufacture by that firm from active ingredients shipped in interstate commerce, the labeling of the Thyroidig tablets (1 gr., 2 gr., 3 gr., 5 gr.), Thyroidig capsules (2 gr., 3 gr.), and

Thyroidig Anterior Pituitary tablets contained false and misleading claims that thyroid safely accelerated cellular metabolic processes, that Western Research Labs., Inc., had overcome many of the thyroid disadvantages by properly balancing the thyroid dosage with digitalis and that the Western Research Labs.' Thyroidig preparations were safe and effective adjuncts in the treatment of obesity; the labeling of the thyroid tablets (3 gr., 4 gr., 5 gr.) contained false and misleading claims that the tablets would safely accelerate cellular metabolic processes, and were safe and effective adjuncts to the dietary treatment of obesity and safe and effective in the treatment of menstrual disorders, infertility, threatened abortion, and certain skin diseases; the labeling of such thyroid tablets was misleading since it failed to reveal that such tablets were not safe and effective in the treatment of obesity, menstrual disorders, infertility, threatened abortion, and skin diseases unless such conditions were associated with hypothyroidism, and that the overwhelming number of persons who suffer from such conditions are not afflicted with hypothyroidism; the labeling of all of the articles lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information; the Thyroidig tablets and capsules, the Thyroidig Anterior Pituitary tablets and the 5 gr. thyroid tablets were dangerous to health when used in the dosage and with the frequency and duration suggested in their labeling; and the portions of the articles packaged in plastic strips and plastic bags (each containing 28 tablets or capsules) lacked labels bearing the name and place of business of the manufacturer, packer, or distributor, an accurate statement of the quantity of contents, the established name of the articles, the established name and quantity of each ingredient and the required prescription legend; 502(a), 502(f)(1), 502(j), 502(b)(1)(2), 502(e)(1)(A)(i)(ii), 503(b)(4).

Western Research Labs., Inc., claimant, filed an answer to the complaint for forfeiture and thereafter various discovery proceedings by way of interrogatories, requests for admission, and depositions were undertaken by the parties. Following the institution of injunction proceedings on 11-26-68 as hereinafter reported (See Notice of Judgment No. 50), the injunction proceedings and forfeiture proceedings were consolidated. Thereafter a consent decree of condemnation and permanent injunction was entered under which the drugs seized were adjudged to be misbranded within the meaning of Sections 502(a) and 502(f)(1) and condemned with provision for their release under bond for the purpose of destroying the Thyroidig (T) and Thyroidig Anterior Pituitary (TAP) and bringing the seized thyroid into compliance with the decree. In addition the decree enjoined the defendants in the injunction action from doing the following acts:

A. Manufacturing, processing, packing, labeling, promoting, introducing, or delivering for introduction into interstate commerce, or holding for sale after shipment in interstate commerce, any article of drug designated or known as Thyroidig (T), Thyroidig Anterior Pituitary (TAP), or any drug containing a combination of thyroid and digitalis, or any drug containing anterior pituitary substance in combination with any other drug, the labeling for which represented or suggested anterior pituitary substance as being an active ingredient, unless and until an approved New Drug Application was effective with respect to any of such articles or unless and until Western Research Labs., Inc., filed an acceptable investigational plan with respect to such articles;

B. Labeling, promoting, introducing, or delivering for introduction into interstate commerce, or holding for sale after shipment in interstate commerce, any drug containing in whole or in part thyroid or digitalis, specifically for the treatment of obesity or specifically as adjuncts to the treatment of obesity;

C. Introducing or delivering for introduction into interstate commerce, or holding for sale after shipment in interstate commerce, any drug containing in whole or in part thyroid or digitalis unless and until the labeling of each such drug bore adequate information for its use for recognized general medicinal purposes; (the decree provided that this paragraph C should not prohibit changes in labeling permitted or required by Federal law or Federal regulation, except that labeling changes made by any other person as a result of approval of a New Drug Application could not be made by Western Research Labs., Inc., unless and until it also obtained approval pursuant to Section 505(a)).

The decree also required that the defendants in the injunction proceedings should recall and destroy certain written, printed, and graphic matter which specifically pertained to use of thyroid and digitalis in treatment of obesity and that Western Research Labs., Inc., should mail a copy of the decree to all persons to whom it had distributed any of its drugs or such written, printed, and graphic matter.

Following the entry of the above decree, the issue of whether the drugs packaged in small plastic bags or cellophane or plastic tear strips of 28 tablets or capsules each were misbranded under Sections 502(b), 502(e)(1)(A), and 503(b)(4) was considered by the court under motions for summary judgment filed by the parties. The court held in an opinion dated November 20, 1969 (306 F. Supp. 247), that the plastic bags and tear strips were the immediate containers of the drugs and should bear the information required under Section 502 and that the drugs in such bags and tear strips were not exempt from bearing such information by reason of Section 503(b)(2). In accordance with such opinion, an order was entered granting the Government's motion for summary judgment, and enjoining the defendants against introducing or delivering for introduction into interstate commerce, or holding for sale after shipment in interstate commerce, any drug containing in whole or in part thyroid or digitalis unless and until each plastic strip and plastic bag (each containing 28 tablets or capsules) bore a label which contained the name and place of business of the manufacturer, packer, or distributor, an accurate statement of quantity of contents, the established name of the drug, the established name and quantity of each active ingredient, and the statement: "Caution: Federal law prohibits dispensing without prescription." (36)

Thyroid 6-grain capsules and tablets, dextro-amphetamine sulfate-barbiturate-thyroid capsules, and thyroid-digitoxin capsules and tablets, at Albuquerque, Dist. N. Mex.

Charged 2-8-68: while held by Calvin Scott & Co., Inc., Albuquerque, N. Mex., for repacking and after repacking, the labeling of the thyroid capsules and tablets contained false and misleading claims concerning their safety and efficacy as an adjunct in treatment of constitutional obesity, hypothyroidism, amenorrhea, and hypomenorrhea; the labeling of the thyroid-digitoxin capsules and tablets contained false and mis-

leading claims concerning the safety and efficacy of such drugs as an adjunct in the treatment of hypothyroidism, myxedema, amenorrhea, and constitutional obesity, in increasing cellular metabolism, and in counteracting the tachycardia effect of the thyroid content; that the labeling of the dextro-amphetamine sulfate-barbiturate-thyroid capsules contained false and misleading claims concerning the safety and efficacy of such drugs as an adjunct in treatment of obesity and in providing a calorigenic effect and metabolic stimulating effect; that a number of drugs failed to bear labels containing the name and address of the manufacturer, packer, or distributor, an accurate statement of the quantity of contents, name and quantity of each active ingredient, and the required prescription legend; and that all of the drugs lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information; and the thyroid and thyroid-digitoxin capsules and tablets were dangerous to health when used in the dosage, frequency, and duration suggested in their labeling; 502(a), 502(b)(2), 502(e)(1)(A)(ii), 502(f)(1), 502(j), and 503(b)(4). Consent decree authorized release to Calvin Scott & Co., Inc., of the 6-grain thyroid drug for reworking into smaller dosage units and for compliance operations, ordered the destruction of the other drugs, and enjoined Calvin Scott & Co., Inc., against manufacturing, packing, promoting, or introducing into interstate commerce, or holding for sale after shipment in interstate commerce, any article of drug of the kind involved in this action. (37)

DRUGS / Veterinary

Honey Bloom vitamin-iron compound in honey base, at Ashland, N. Dist. Ohio. Charged 7-8-70: when shipped by Truett Labs., Dallas, Tex., and while held after such shipment by the dealer, Hess & Clark, Div. of Richardson-Merrell, Inc., Ashland, Ohio, the article was a new animal drug without an effective approved New Animal Drug Application; and its labeling contained false and misleading claims concerning its efficacy in horses to build up the red blood cell count, to promote peak horsepower, to promote breeding ability, and to bring nutritionally deficient horses to top show condition; 501(a)(5), 502(a). Consent decree ordered destruction. (38)

Vita-Jec vitamins A, D, and E injectable, at Fresno, E. Dist. Calif. Charged 11-9-70: when shipped by Diamond Shamrock Chemical Co., Denver, Colo., the article had been prepared and packed under insanitary conditions; the circumstances of the article's manufacture and packing lacked conformity with current good manufacturing practice; the article's purity and quality was deficient, since it contained particulate matter; and the labeling contained a false and misleading claim concerning the efficacy of the article in the prevention and treatment of avitaminosis caused by a deficiency of vitamin E; 501(a)(2)(A), 501(a)(2)(B), 501(c), 502(a). Consent decree authorized release to Diamond Shamrock Corp., Fresno, Calif., for salvaging. (39)

MEDICAL DEVICES

Gloves, for surgery, latex, at Tyler, E. Dist. Tex.

Charged 6-23-69: when shipped by Affiliated Hospital Products, St. Louis, Mo., the quality of the article was deficient, since it contained metallic particles and holes which made possible the transfer of foreign materials into the patient and also compromised the integrity of the sterile barrier between the physician and patient, and the label lacked the place of business of the manufacturer, packer, or distributor; 501(c), 502(b)(1). The shipper appeared as claimant after which interrogatories were served by the Government and claimant upon each other and answered in part. Motions were also filed and granted permitting each party to obtain a representative sample of the article seized, and requiring the Government to produce certain relevant documents and to produce for inspection by the claimant the gloves which the Government had examined prior to the seizure proceedings. Thereafter the claimant filed a motion for permission to withdraw its claim. Such motion was granted and a default decree was entered ordering the destruction of the article. (40)

Shala-Min water filters, at Amarillo, N. Dist. Tex.

Charged 7-17-70: when shipped by Shala-Min of New Mexico, Inc., Albuquerque, N. Mex., the labeling of the article contained false and misleading claims concerning the efficacy of the article in removing chlorine, fluoride, poisons, and metallics, adding organic minerals, reducing the aging process, in treating anemia and muscle pains in humans, and in treating cataracts, mangy sores and lump-jaw in cattle; 502(a). Default decree ordered destruction. (41)

Theromatic Model A-6DT40 electronic instrument, at St. Louis, E. Dist. Mo.

Charged 3-23-70: when shipped by Dynapower Systems Corp., Los Angeles, Calif., the device label contained false and misleading claims for infections, otitis media, fractures, bone and tissue healing, smooth muscle spasm, low back pain, arthritis, and inflammations of bursa, sinus, prostate, and liver; the labeling lacked adequate directions or information for such uses, since the article was worthless for such uses; and the article was dangerous to health when used as directed, since it was ineffective for the treatment of such serious disease conditions and by reason of its ineffectiveness, it was unsafe for such use; 502(a), 502(f)(1), 502(j). Default decree ordered destruction. (42)

PROPHYLACTICS

Prophylactics, rubber, Gold Circle, at New York, S. Dist. N.Y.

Charged 2-19-69: when shipped by Circle Rubber Corp., Newark, N.J., the article's quality was deficient and the label statement "Sold for the Prevention of Disease Only" was false and misleading, since the article contained holes; 501(c), 502(a). Default decree ordered destruction. (43)

COSMETICS / BEAUTY PRODUCTS

Dentifrice, 2 seizure actions, at Pipestone, Dist. Minn. Charged 6-24-70 and 9-2-70: when shipped by Unette Corp., Livingston, N. J., the article, labeled in part "Tween Kleen The Super Stain Remover . . . The White Company, Pipestone, Minnesota," contained a deleterious substance, pumice, which may render the article injurious to users under such conditions as prescribed in the labeling or as customary or usual; 601(a). Consent decree authorized release to the White Co. for salvaging. (44).

HAZARDOUS SUBSTANCES

Cherry bombs, M-80 firecrackers, Silver salutes, 2" firecrackers, 1 1/8" firecrackers, and repeater fireworks, at Charleston, E. Dist. Mo. Charged 7-2-70: while held by Ronnie's Trading Post, Charleston, Mo., the articles were fireworks devices which were banned hazardous substances by regulations, since they were intended to produce audible effects by a charge of more than 2 gr. of pyrotechnic composition; 2(q)(1)(B). Default decree ordered destruction. (45)

Skilcraft No. 510P chemistry sets, at Milwaukee, E. Dist. Wis. Charged 4-6-70: when shipped by Skil-Craft Playthings Co. (subsidiary of Western Publishing Co.), Chicago, Ill., the articles were banned hazardous substances, since they were hazardous substances intended for use by children, and the articles were not exempt under the regulations for classification as banned substances, since the immediate container of each chemical in the sets failed to bear adequate first-aid instructions and the instruction manual failed to bear the required caution statement; 2(q)(1)(A). Consent decree authorized release to Skil-Craft Corp. (formerly Skil-Craft Playthings Co.) for relabeling. (46)

NOTICES OF JUDGMENT on Criminal Actions

FOOD

Gateway Milling Co., a corporation, **Charles A. Pitcher**, secretary, and **Thomas M. Norman, Jr.**, treasurer, Peoria, S. Dist. Ill. Charged 6-19-70: flour was held in a building accessible to rodents and was contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (47)

William Griffith's & Sons, Inc., and **William H. Griffith**, president, Utica, N. Dist. N. Y. Charged 8-7-70: cake mix and donut flour were held in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (48)

NOTICES OF JUDGMENT on Criminal Actions

DRUGS and DEVICE

William J. Adams, t/a Vitamin Products Co. of Maryland, Baltimore, Dist. Md. Charged 9-16-66: while held for sale, Endocardiograph devices were offered for sale for use for various specified diseases, symptoms, conditions, and purposes which resulted in the devices being misbranded for failure to bear adequate directions for use for such diseases, symptoms, conditions, and purposes (Count 1)—502(f)(1); while held for sale, Pneumotrophin Cytotrophic Extract of Beef Lung (Count 2), Myotrophin Cytotrophic Extract of Beef Muscle (Count 3), and Catalyn V-P710 vitamin combination tablets (Count 10) were offered for sale for various specified diseases, symptoms, conditions, and purposes, and were accompanied by a booklet (Count 2) entitled "Schedule of Recommendations for Specific Conditions/Malnutrition," a folder (Counts 2 & 10) entitled "Therapeutic Food Company . . . Product Information for Doctors," and a book (Counts 2 & 3) entitled "Therapeutic Food Manual," which resulted in the articles being misbranded in that such booklet, folder, and/or book contained false and misleading claims for the articles in the treatment of various specified diseases, and in that the articles' labeling lacked adequate directions for use for their intended and orally represented purposes (Count 2: lung cancer prevention, lung air sac nutrition, and improved vision; Count 3: to shrink enlarged heart, to return heart to normal, and to prevent heart attack; Count 10: cure muscle cramp, stimulate protomorphogens, replace damaged liver tissue, and turn hair from gray back to normal color)—502(a), 502(f)(1); while held for sale, Collinsonia Root capsules (Count 4), Calcium Lactate tablets (Count 5), Cardio-Plus yeast, heart, and brain combination tablets (Count 6), C-Y 1721 dulse and alfalfa combination (Count 7), C-Y 1711-13-29A vitamin wafers (Count 8), Cataplex F fatty acid derivative tablets (Count 9), Zymex II enzyme capsules (Count 11), were offered for sale for use for various specified diseases, symptoms, conditions, and purposes and were accompanied by a book entitled "Therapeutic Food Manual" (Counts 4-8, 11), a booklet entitled "Schedule of Recommendations for Specific Conditions of Malnutrition" (Counts 5, 7), and a folder entitled "Therapeutic Food Company . . . Product Information for Doctors" (Counts 4, 6, 9, 10), which resulted in the articles being misbranded in that such labeling contained false and misleading claims for the drugs for specified diseases, including (Count 6) hypertension, coronary thrombosis, and tic-tac rhythm of the heart—502(a).

The defendant pleaded not guilty to all counts. The defendant moved to dismiss the information for failure of the counts to charge offenses and for willful and prejudicial delay. The defendant also moved to suppress evidence obtained by FDA inspectors at the defendant's premises consisting of tape recordings of conversations between the defendant and the FDA inspectors. The court denied the defendant's motions and the case came to trial before judge and jury. During the trial the defendant moved for acquittal and the motion was granted as to counts 4 and 11, because the Government failed to show that the drugs were held for sale, and as to Counts 5, 7, and 8, since the book entitled "Therapeutic Food Manual" and the booklet entitled "Schedule of Recommendations For Specific Conditions of Malnutrition" had been

excluded from evidence. At the conclusion of the case, the court granted defendant's motion for acquittal as to Count 1 because the Government failed to show that the device was offered for sale, and as to Count 9 because the leaflet made no specific reference to the article. The defendants were also acquitted as to Count 10. Counts 2, 3, and 6 were submitted to the jury which returned a verdict of guilty on those counts. Thereafter the defendant was placed on probation for five years. The defendant appealed. In affirming the conviction of the defendant, the Court of Appeals rendered the following opinion:

"PER CURIAM: The appellant was tried and convicted of violations of The Food, Drug, and Cosmetics Act (21 U.S.C. §331(k)). On various occasions inspectors of the Food and Drug Administration visited the appellant and represented themselves to be prospective customers. During their conversations incriminating statements made by the appellant were transmitted, via a transmitter hidden on one of the inspectors, outside to Inspector Bullard who overheard and recorded them on a tape-recorder. The appellant urges that this was a violation of the Fourth Amendment. We need not reach this constitutional question, for, at the appellant's trial, Inspector Bullard did not testify nor were the tape recordings offered in evidence. The incriminating statements were repeated in court only by the inspectors who were parties to the conversations. Even though the inspectors concealed their true identity, they were not an 'uninvited ear.' The appellant assumed the risk that the inspectors as well as all of his other customers might repeat statements he made to them.

"In avoiding the constitutional question, we do not intend to intimate that we think it one of substantiality, or insubstantiality.

"This Court has carefully considered the appellant's other contentions and finds them to be without merit. **Affirmed.**" (49)

NOTICES OF JUDGMENT on Injunction Action

Western Research Labs., Inc., **Leonard C. Tobin**, president, **Elmer J. Morgenstern**, vice president, and **Vincent Crocker**, plant manager, Denver, Dist. Colo.

Charged 11-26-68 in a complaint for injunction: that the defendants were engaged in manufacturing, packing, labeling, promoting, and selling various drugs intended for use in Western Research Laboratories' Treatment of Obesity including drugs consisting in whole or in part of thyroid, digitalis, or anterior pituitary, in distributing such drugs in interstate commerce, and in holding such drugs for sale after shipment of one or more of their components in interstate commerce; that the labeling of the drugs contained false and misleading representations that Western Research Laboratories' Treatment of Obesity was a medically proven system of weight reduction and control, that thyroid-digitalis combinations were safe and effective in the treatment of obesity and as adjuncts in the treatment of obesity and were of value in the treatment of individuals requiring the thyroid effect, and that thyroid safely accelerated cellular metabolic processes and was a safe and effective adjunct to dietary treatment of obesity; that the labeling was misleading, since it failed to reveal that thyroid-digitalis combinations are irrational drug mixtures which may be dangerous to health, that digitalis is not safe and effective in the treatment of obesity, that thyroid has no valid medical use in the treatment of obesity unless the obesity is associated with hypothyroidism, and that most persons who suffer from obesity are not afflicted with hypothyroidism; that the labeling of the drugs lacked adequate directions for use; that the thyroid-digitalis combinations were dangerous to health when used in the dosage and with the frequency and duration recommended in their labeling; and that all of the above drugs were new drugs without effective approved New Drug Applications; 502(a), 502(f)(1), 502(j) and 505(a).

The injunction proceedings were consolidated with the forfeiture proceedings against various drugs under seizure and thereafter a consent decree of condemnation and permanent injunction was entered as hereinabove reported in Notice of Judgment No. 36. (50)

CORRECTION: Notice of Judgment No. 8 in the December 1970-January 1971 issue of **FDA Papers** erroneously mentioned a firm which had no connection with the article seized. The Notice should have read as follows:

Grits, at Greenville, N. Dist. Miss.

Charged 2-12-70: while held by Itzig Co., Greenville, Miss., the article contained insects and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (8)

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

Notices of Judgment are prepared by Food, Drug, and Environmental Health Division, Office of the General Counsel, DHEW.

Published by direction of the Secretary of Health, Education, and Welfare.

Charles C. Edwards, M.D., *Commissioner of Food and Drugs*

Washington, D.C., July 1, 1971



TRIM THOSE STATISTICS!

Every year thousands of persons using electrically powered hedge trimmers suffer injuries serious enough to require medical treatment. FDA has prepared a leaflet, "Trim, Trim, Trim," describing the practices that result in injuries from hedge trimmers, telling how to choose a trimmer, and suggesting how to use it to avoid injuries. Copies are available free from the Bureau of Product Safety (PS-50), P.O. Box 8208, Southwest Station, Washington, D.C. 20204.

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Announcements

ANNUAL AOAC MEETING The 85th annual meeting of the Association of Official Analytical Chemists will be held October 11-14 at the Marriott Motor Hotel, Twin Bridges, Washington, D.C. About 230 papers will be given on new techniques, methods, and instrumentation for analysis of drugs, cosmetics, feeds, fertilizers, foods, food additives, pesticides, flavors, beverages, contamination of foods, mycotoxins, and related subjects.

Approximately 1,500 chemists, microbiologists, physicists, and their administrators are expected to attend, representing Federal, State, Provincial, and local government agencies, universities, and industries throughout North America.

The association will honor some of its outstanding members the opening day of the meeting. In the morning, six scientists and administrators who have been named to receive the 1971 "Fellow of the AOAC" award will be honored during special ceremonies. Henry A. Davis, president of the association, will present certificates to Thomas G. Alexander and Edward F. Steagall, Food and Drug Administration; I. Hoffman, National Research Council of Canada; Fred J. Baur, Procter & Gamble Co.; Albert J. Gehrt, Moorman Manufacturing Co.; and Halver C. VanDame, Merck, Sharpe & Dohme. The honorary title "Fellow of the AOAC" was established in 1961 to recognize meritorious service to the association. To be considered for the award, a member must have performed major service as an officer, referee, associate referee, or committeeman for a period of 10 years or more.

At a banquet the evening of the opening day, Dr. Charles W. Gehrke, a professor at the University of Missouri, will receive the 14th AOAC Harvey W. Wiley Award for outstanding contributions to analytical chemistry important to agriculture and public health. The \$750 award is presented annually to recognize notable achievements in development and study of analytical methodology needed for research and regulatory purposes on foods, pesticides, feeds, drugs, cosmetics, fertilizers, and related areas. It was established in 1956 in honor of Harvey W. Wiley, "father" of the Federal Food and Drugs Act of 1906 and a founder of the AOAC.

PACKAGING SEMINAR The Packaging Program of the University of California, in cooperation with the Packaging Industry Advisory Committee, will present identical seminars on "Packaging Legislation and Regulation: Current Status and Future Prospects" October 19-20. The first seminar will be held at the Burlingame Hyatt House, Burlingame, California, and will be repeated the second day at the International Hotel, Los Angeles International Airport. The seminar will feature the latest information not only on the Fair Packaging and Labeling Act, but also on other new legislation and regulations that may have great impact on the packaging industry in the near future. The keynote speaker will be Dr. Virgil Wodicka, director of the Bureau of Foods, FDA. Those speaking on "FPLA—Five Years Later" will be John Gomilla, FDA; Earl Johnson, Federal Trade Commission; Eric Vadelund, National Bureau of Standards; and Dr. John DeHoll, U.S. Department of Agriculture. In the area of other packaging legislation and regulations, Dale C. Miller, FDA, will speak on product safety legislation, and Dr. George M. Briggs, University of California—Berkeley, on nutritional labeling; at this date no speaker on the subject, "Code Dating and Unit Pricing," has been announced.

The registration fee for each one-day seminar will be \$35, which will include the seminar proceedings and lunch. For registration form, write Dr. Ming-yu Li, Deputy Coordinator, Packaging Program, University of California, Davis, California 95616. Telephone number: Area Code 916-752-1142.

CASE STUDY BOOKLET The Division of Industry Services, FDA, has compiled a variety of previously published Drug Recall Case Studies in a single booklet, categorized by specific problem areas. Since the introduction of the Drug Recall Case Study program in 1968, the Division's mailing list has steadily increased to a present total of approximately 1,200. Because of the many relatively new subscribers among this number who received none of the early issues, the Division has had numerous requests for back issues. The booklet will fill such a need.

The compilation may be used as teaching/resource material for quality assurance and in-plant training programs. Because of the limited number published, one copy only will be supplied on request from the Division of Industry Services, Bureau of Drugs (BD-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.

PHARMACY CONFERENCE The Extension Services in Pharmacy and the School of Pharmacy, University of Wisconsin, at Madison, will sponsor a conference October 24-27 on "Drug Efficacy Evaluation and Self-Evaluation by Pharmaceutical Industry." The objective of the conference is to provide a medium through which pharmaceutical scientists and managers can discuss these current and important subjects as they relate to research, control, manufacturing, and marketing of drugs. Workshop sessions will be held for a comprehensive look at FDA's New Drug Application process.

Featured speakers will be Dr. Calvin M. Kunin, University of Wisconsin; Dr. George deStevens, CIBA Pharmaceutical Co., Summit, New Jersey; and from FDA's Bureau of Drugs will be Dr. Henry Simmons, director, Dr. Herman Rosenstein, Dr. Paul A. Bryan and Jonas L. Bassen.

Additional details regarding the conference can be obtained from Dr. Melvin H. Weinswig, Conference Secretary, Extension Services in Pharmacy, 155 Pharmacy Building, University of Wisconsin, Madison, Wisconsin 53706.