

September 1968

# **FDA PAPERS**

## **THE COMPLEAT INSPECTOR**

Eyes, Ears of the FDA Team

## **FOODS AND PESTICIDES**

Keeping Residues at Safe Levels

## **Antibiotics in Agriculture**

The Significance to Man's Health

## **PUBLIC ADVISORY COMMITTEES**

A Vital Reserve of Specialists







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

**Harvey W. Wiley**

From his commencement address  
"Life and the Coming Time"  
Hanover College, 1867

**T**he questions raised concerning the extent and nature of the threat to man's health from routine use of antibiotics in animal feeds are of utmost concern to farmers and food processors, commercial drug and feed manufacturers, the medical professions, and those directly responsible for the public health (see page 10).

It is obvious that the unnecessary use of antibiotics under any circumstances cannot be condoned since it may diminish the returns that can be expected from these vital drugs. This is because the bacteria against which they are aimed, and even those against which they are not aimed, can and do develop resistance—and often pass on this resistance to other bacteria.

It is truly a paradox that, although we do not know nearly as much as we ought to know about infectious drug resistance resulting from the use of antibiotics in animals, at the same time the value of antibiotics in feeds has come under question. We need massive research on both of these subjects. FDA has taken a tougher stand and requires research support for New Drug Applications to justify use in animal feeds to promote growth. FDA also has been meeting with representatives of other Government agencies and industry to determine what information is available to answer this question. Some research, in and out of Government, is being done, but the facts needed to answer the question have not been produced.

More and better research is needed. This tool which has proved so valuable to man in combating disease should not be blunted through its needless use, including use as a substitute for good animal husbandry and hygienic practices.

**Wilbur J. Cohen**  
Secretary, U.S. Department of  
Health, Education, and Welfare

**Philip R. Lee, M.D.**  
Asst. Secretary for Health  
and Scientific Affairs

**Charles C. Johnson, Jr.**  
Administrator, Consumer  
Protection and Environmental  
Health Service

**Herbert L. Ley, Jr., M.D.**  
Commissioner of Food and Drugs

**John G. Stringer**/Editor

**Harold C. Hopkins**/Associate Editor

**Sheldon Cohen**/Art Director

**Ticia Edwards**/Asst. Art Director

**Joan M. Galloway**/Managing Editor

**Frederick L. Townshend**/Production Mgr.

**PHOTOGRAPHY:** Dan O'Toole; Stockton Record, Stock-  
ton, Calif., 28.

---

**FDA PAPERS**, the official magazine of the Food and Drug Administration, is published monthly, except for combined July-August and December-January issues. Subscriptions may be ordered from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402, at \$5.50 a year (\$1.25 additional for foreign mailing).

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

Articles published in **FDA PAPERS** are in the public domain and text may be republished without permission. Use of funds for printing this publication approved by Director of the Bureau of the Budget August 15, 1966.

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.

**Advisers to the Editor\***

**H. Nelson Fitton**, Department of Agriculture;  
**Wayne Phillips**, Department of Housing and Urban  
Development; **Henry B. Montague**, Post Office  
Department; **Henry Scharer**, Department of  
Commerce; **Dr. Milner B. Schaefer**, Department of  
the Interior; **Dr. Sam Kaim**, Veterans Administration;  
**Dr. Peter V. Siegel**, Federal Aviation Agency;  
**Dr. Spofford G. English**, United States Atomic  
Energy Commission; **Dr. Harve J. Carlson**, National  
Science Foundation; **Howard J. Lewis**, National  
Academy of Sciences; **Edward J. McVeigh**, Public  
Health Service; **Arthur Settel**, Bureau of Customs.

\* The Food and Drug Administration is solely responsible for the contents of **FDA PAPERS**. The Advisers to the Editor are consultants on matters relating to the functions of the Federal Departments and Agencies listed.



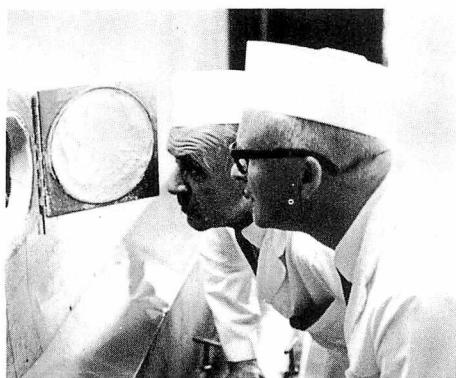
<b>The Compleat Inspector</b>	A skilled specialist serves on the front line of a highly efficient food and drug protection team.	4
<b>Antibiotics in Agriculture</b>	How buildup of bacterial resistance to antibiotics in animals may affect antibiotic effectiveness in man.	10
<b>Foods and Pesticides</b>	How pesticides used on growing foods are kept at levels safe for the U.S. consumer.	14
<b>How the Law Protects the Consumer of—A Bakery Product</b>		17
<b>Public Advisory Committees</b>	These citizen experts in special fields provide invaluable advice to FDA in many areas.	22
<b>National Food and Drug Advisory Council</b>	Advisor to FDA on policies, programs.	24

---

<b>Field Reports</b>	27
<b>State Actions</b>	30
<b>Seizures and Post Office Cases</b>	31
<b>Notices of Judgment</b>	33

---

4



14



24



*Day's work for FDA team of inspector and microbiologist, accompanied in several photos by U.S. Department of Agriculture plant inspector, begins at powdered egg processing plant with unloading inspection and sampling equipment from car upon arrival (opposite page, small photo). In large photo, microbiologist (facing camera) tests wet surfaces of eggs with chlorine-testing paper after they emerge from sanitizing bath to determine adequacy of sanitizing. At right, from top, three men check temperature of bath water, then examine egg-breaking equipment, which also separates yolks and whites. At bottom, inspector (the author) smells broken eggs in container for freshness.*

---

## The Compleat Inspector

by  
George L. Vinz

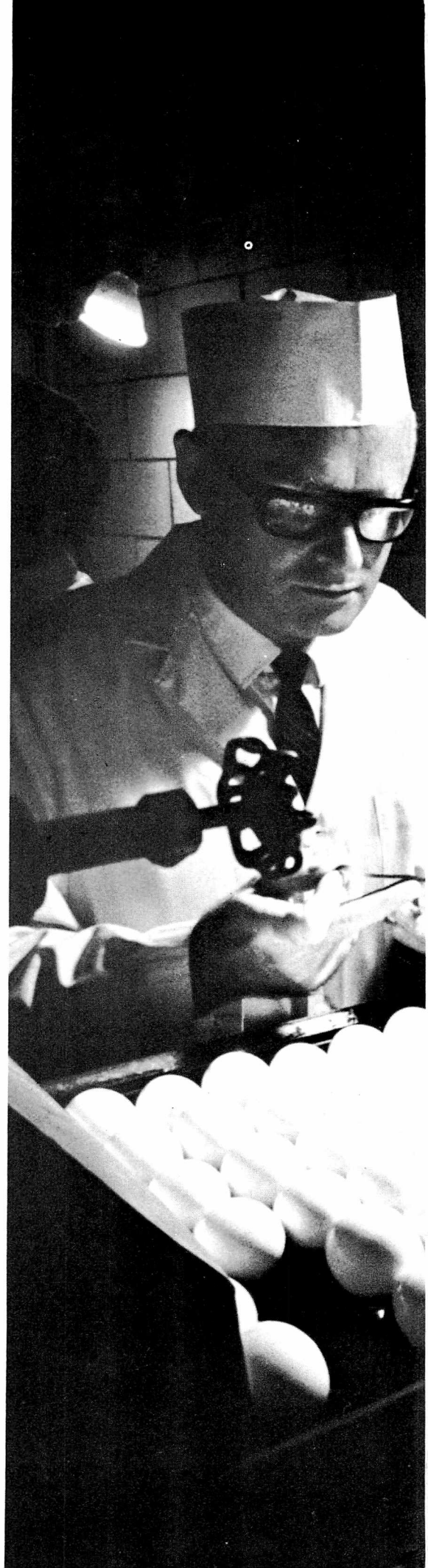
Its inspectors have often been referred to as the "eyes and ears" of the Food and Drug Administration. There is no doubt that they are key men in fulfilling the responsibilities entrusted to the Agency. But they are team workers too, supported and backed by a force of highly competent chemists, scientists, and administrators at the District and Washington levels. This "team" and its efforts provide the American consumer with the finest protection enjoyed anywhere in the world today.

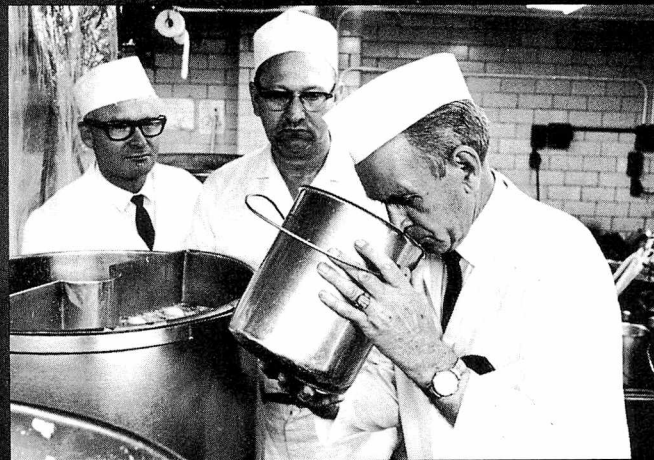
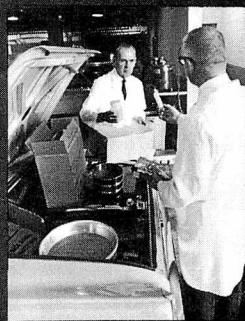
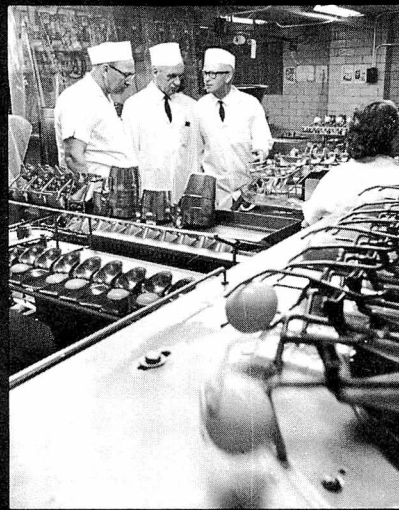
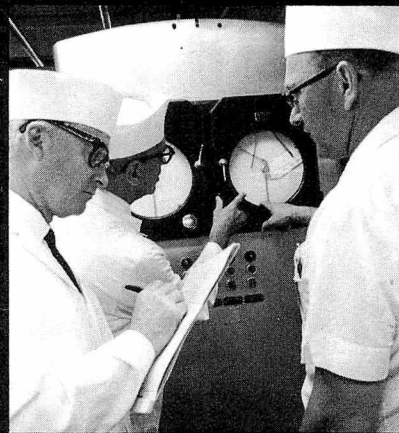
The day-by-day work of the Food and Drug Inspector is an exciting drama in which he and others apply scientific skills and common sense to protection of the public health. The inspector's work is seldom routine as he examines the sanitary conditions in food, drug, or cosmetic establishments, or checks the processing, labeling, and materials used by these firms in the production and distribution of the finished commodities. He reviews analytical work performed by scientists employed by such establishments and, when necessary, makes on-the-spot examination to detect the presence and possible cause of harmful or deceptive adulterations, contaminations, or instability of materials used in such products.

The inspector often interviews consumers, industry executives, production and research chemists, merchants, and others associated with the production, processing, packing, transporting, warehousing, and retailing of foods, drugs, and cosmetics. He may be required to trace the source and distribution of products, to make trade and consumer surveys, and to participate in cooperative enforcement work with city, State, and other Federal officials.

He may also serve as a witness in Federal court to testify on his findings and observations during a factory inspection or on the results of an investigation he has been involved in. To sum up, the inspector is a busy and dedicated individual who has the personal satisfaction of doing a job recognized by everyone as being important and necessary to the health and welfare of the Nation.

To become an inspector, a person must compete successfully in the Federal Service Entrance Examination. He must also have at least the equivalent of a bachelor's degree from a college or university of recognized standing. His curriculum must have included 30 semester hours of science, 18 of these in chemistry or the biological sciences and the rest in any combination of







such fields as pharmacy, physics, food science or technology, and the various agricultural sciences.

After selection and appointment, the new inspector enters a period of intensified training off and on the job. Competent inspectional and investigative performance depends on adequate training. He gains on-the-job experience by accompanying experienced inspectors on a variety of plant inspections. Off-the-job training often includes attendance and participation in formal programs which may involve the latest techniques relating to bacteriological contamination of foods, insect and mold contaminants, food additives, and other factors. All of these the inspector must keep in mind to consider and make judgments in the comprehensive plant inspections he will conduct as he gains experience.

Let us accompany the inspector on an inspection of a food plant. The purpose of the inspection in this instance is to determine whether the firm is operating in compliance with the requirements of the Food, Drug, and Cosmetic Act. He is ever mindful of this basic fact. If he encounters objectionable and insanitary conditions in the plant, the inspector will, because of his background and training, proceed to develop evidence to demonstrate the conditions he has encountered. He realizes too that he is responsible for detecting potential violations and for stimulating correction at the source. He is aware that he must look out for the use and misuse of unusual food ingredients, food additives, color additives, for the accuracy of the product label and for adequate packaging of the manufactured product.

The inspector, as any responsible workman, must prepare himself for a specific inspection assigned to him. He reviews the enforcement programs and guidelines for the specific project. He reviews files available at his District Office for pertinent information concerning previous inspectional and investigational findings, namely, legal status of the firm, attitude of plant management, prob-

lems encountered, and promised corrections. He must check the inspectional equipment assigned to him and assemble any special equipment he will need, such as a chlorine test kit, sterile spoons and jars, and special sampling equipment. Most District Offices equip inspectors' automobiles with identical sets of equipment, such as a variety of sample triers, sieves, flashlights, black (ultraviolet) lights, portable scales, and cameras. The vehicles also contain typewriters and dictating units which the inspector uses in preparing his reports while in travel status.

Upon arrival at the plant unannounced, at a reasonable time, the inspector will enter the office and seek out a responsible official. His behavior is dignified, authoritative, and cordial as he identifies himself by showing his credentials and issuing a Notice of Inspection as required by Section 704(a) of the Act. He invites management to accompany him on the inspection. If management has other commitments, the invitation is extended to other responsible individuals, such as the heads of sanitation or quality control departments. If representatives of other Government inspection agencies, Federal or State, are on the premises, the inspector will also invite them to accompany him. (If plant authority refuses to consent to inspection, the inspector may return later with an "inspection warrant" obtained through a Federal court.)

Prior to starting the inspection, the inspector conducts a preliminary interview with responsible management. He asks about the legal status of the firm, changes in officers, related firms, products made and distributed, trade names employed, volume of business in round figures, and percentage of goods moving in interstate commerce. He also asks about individual responsibility of the firm's officers and plant and department heads. Basically, the plant's compliance with the Act depends on execution by individuals of the operations assigned to them as well as overall coordination of their activities.

Additional information he requests during the interview includes details about the firm's ways of distribution, whether it gives or receives Food and Drug guarantees, and whether it hires consulting firms, such as sanitation consultants, analytical laboratories, and possibly labeling consultants.

At this point, management can be of real service to the inspector. Operations in many of the larger food plants today are extensive and complex, and management can help by showing or supplying the inspector floor plan charts and providing a description of the various operations in each of the charted plant areas. These same floor plans and descriptions can be of considerable value to the firm in employee training programs.

Upon completing the preliminary interview, the inspector is ready to start the inspection. Usually he will follow the plant's production flow plan, but he may deviate at times. He may, for example, have noted some condition on the outside premises during his approach to the plant, and he will proceed to check these carefully. Trash piles, scattered unused equipment, uncut weeds and tall grasses, and littered areas all provide harborage for birds, insects, and rodents, and should he find evidence of their habitat in these areas, he will intensify his efforts in looking for evidence of their presence in the plant. An unkempt exterior is a possible indication of similar conditions within the plant.

The inspector will now turn his attention to the firm's receipt, handling, and storage of raw materials. He carefully examines the various raw materials for evidence of filth, decomposition, pesticide residues, and food additives. If the plant processes fruits and vegetables, he looks for field rot or decay and evidence of insect infestation. He is aware that insect pests, for example, not only defile the raw material but also provide ingress for spoilage micro-organisms. If the firm processes cereal products or flour, he carefully ex-

amines the grains being used for evidence of rodent filth, insect infestation, and contamination. He carefully checks the handling and storage conditions for these grains. If the firm manufactures dairy products, the inspector tests the incoming milk and cream for visible filth, which can include cow manure, flies and other insects, rodent hairs and excreta, and other forms of repulsive filth. He may taste the cream for decomposition, since cream held for prolonged periods before delivery may be in an advanced stage of decomposition. If the firm processes fish, he examines the incoming raw material for decomposition, parasitic infestation, and for any evidence of diseased conditions. In most cases, evidence of decomposition and contamination is readily apparent and the inspector in examining these materials has used no particular equipment other than his normal senses of sight, taste, smell, and touch.

If the inspector observes flour or other raw materials contaminated with insects or insect filth, he is certain to ask for information concerning the lot. He may collect samples and try to determine where the infestation or contamination occurred. Receiving and storage records may provide clues. Management is entitled to collect duplicate samples and, in fact, the inspector encourages it. The inspector may take photographs of the conditions he has found and there is nothing that bars management from taking its own photographs. If the insect contamination is clear cut, management may decide to remove the lot from the premises and destroy it. In such instances, the inspector will want to witness the corrective action and include details in his report.

Occasionally the inspector may have reason to suspect that the raw material has been contaminated with pesticide residues either prior to or after receipt by the plant. He may collect samples of suspect materials to submit to his District laboratory for analysis. As required by law, the inspector issues a receipt for this and other samples collected during the

inspection. Further provisions of this mandatory procedure read:

"Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such samples for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge." A report of the sample results should reach management about 10 days after the inspection.

The inspector, in checking the sanitary aspects of a firm's operations, works from his knowledge of various factors which contribute to insanitation. His broad experience also gives him an understanding of current good manufacturing practices.

Here are some of the areas and points he considers during the inspection:

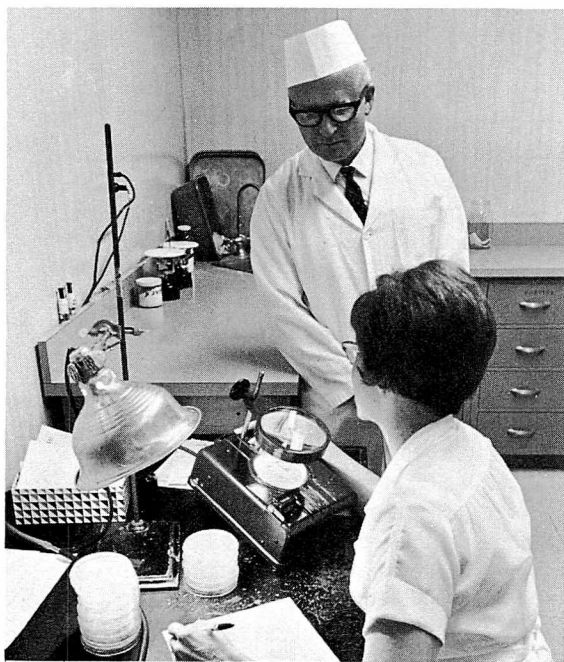
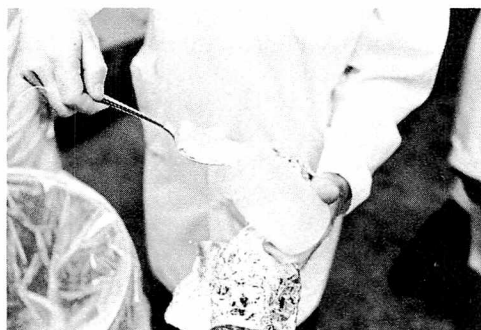
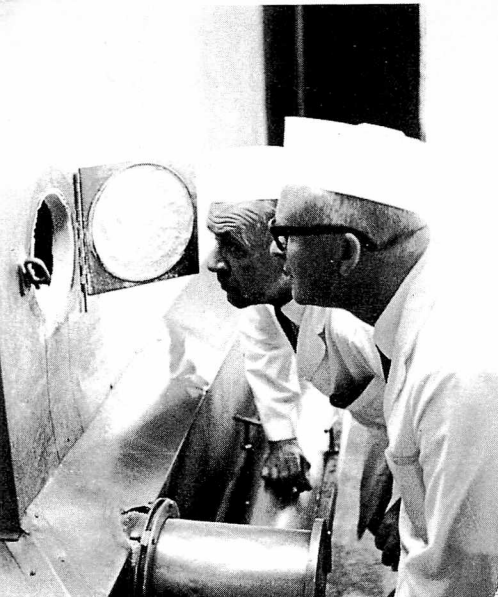
*Plant construction and design:* What is general condition, and is it suitable for the type of operation being carried on? Are floors, walls, and ceilings of such construction as to be readily cleanable, are they clean, and are they in a good state of repair? Have operations been separated by partitions or location to prevent possible cross-contamination of food products with bacteria, molds, toxic materials, filth, or other extraneous and deleterious materials? Is there adequate lighting in all areas where food or food ingredients are processed, examined, or stored? Where equipment and utensils are washed? In hand-washing areas, dressing and locker rooms, and toilets? Is there adequate ventilation with controls that prevent contamination of foods by airborne contaminants? Have windows, window wells, and doors been screened to exclude birds, dogs, cats, and vermin, including, but not limited to, insects and rodents?

*Equipment and utensils:* Are plant equipment and utensils suitable for intended use, designed and of material suitable for easy cleaning and repair, and of construction that will prevent contamination of foods with lubricants, fuel, metal fragments, contaminated water, etc.? Does installation permit ease of cleaning and sufficient space for employees to do their work without contaminating food or food-contact surfaces by clothing or personal contact?

*Sanitary controls:* Have adequate sanitary facilities and accommodations been provided? What is the source of water supply? Is the sewage disposal system adequate, including sufficient floor drains where floors are subject to flood-type cleaning or where normal operations release or discharge water or other liquid waste on the floor? Are toilet and hand-washing facilities adequate and sanitary? Are there sufficient hand-sanitizing facilities and properly prepared and maintained sanitizing solutions? What is the means of offal and rubbish disposal and is it adequate?

*Sanitary operations:* What is the condition and state of repair of buildings, fixtures, and other physical facilities? Cleaning practices and sufficiency and safety of cleaning materials and sanitizers in use? Type and effectiveness of animal and vermin control in the plant? Types of insecticides and rodenticides used and type of control? Adequacy of cleaning of equipment and utensils? Adequacy of sanitization of equipment and utensils? Are sanitizing agents effective and safe for intended use? What are the storage and handling practices for clean equipment and utensils?

*Processes and controls:* What are the kind, condition, handling, and storage practices of raw materials? Suitability of containers and carriers of raw ingredients? Fitness of ice used when such types of raw materials necessitate such means of preservation? Sanitary condition of processing equipment, accessibility to individual machines for cleaning, and thoroughness of cleaning pro-



*At top left, FDA team looks into machine that dries fresh egg materials. In small photo and photo at top right, they collect and weigh out aseptic samples of finished product. In center photo, FDA Microbiologist is shown with plant microbiologist, who is making bacterial count of egg product. In bottom photos, FDA and USDA men (left) check cleanliness of conveying equipment broken down for washing at end of workday, and (right) use chlorine-testing paper to determine strength of sanitizer in water used to clean equipment.*

cedures? Effectiveness of control procedures to minimize potential for bacterial or other micro-organic growth, toxin formation, or deterioration or contamination of processed products or ingredients? Do controls provide for careful monitoring of physical factors such as time, temperature, humidity, pressure, flow-rate, and such processing operations as freezing, dehydration, sterilization, and refrigeration? What are the testing procedures employed and the disposition of unfit finished products? Sanitary condition of packaging processes? Are materials being used in compliance with food additive regulations? What coding system and method of record keeping are employed? Are storage and transportation of finished products adequate?

*Personnel:* What are the plant control policies and practices concerning personnel affected by disease in communicable form, boils, sores, infected wounds, etc.? Cleanliness and general appearance of employees? Do employees wear effective hair restraints while working at processing operations? Do employees remove jewelry, etc., when manipulating foods or components by hand? Do employees follow plant rules in washing and sanitizing hands before returning to work station? Does the firm provide appropriate training for food handlers and supervisors in proper food-handling techniques and food-protection principles?

Usually inspectors conduct inspections alone, but where bacterial contamination may be a problem, the team approach is often used; that is, an inspector and a microbiologist working together. A bacteriological





inspection is often referred to as a comprehensive sanitary inspection, for which the preparation and approach will be much the same as has been discussed to this point. The conduct of the team inspection is intensive and the following summarizes the inspection operations.

The personal cleanliness of the inspection team is essential. They may follow the firm's sanitation program for employees, but often go beyond these requirements. They wear clean clothes and sometimes change several times during the inspection. Disposable coverings for the head are worn, and hands are washed frequently. Disposable coverings for hands and feet are used in areas where cross-contamination may be a factor. The inspector uses aseptic techniques in collecting raw material and in-process and finished product samples for bacteriological examination.

The inspectors check carefully for any evidence of rodent, insect, and other vermin infestation. They examine raw materials for bacteriological contamination and determine the source and nature of the water supply and the method of in-plant treatment, if any. They check the source and condition of the air throughout the plant, observe sanitizing practices, and evaluate their effectiveness. They inspect toilet facilities for cleanliness and adequacy of supplies. They note the appearance and practices of all employees, such as clothing worn, use of head coverings, the wearing of ornaments and jewelry, evidence of colds, sores, bandages, and any improper contact with the product in process. They also determine how such items as brushes, scrapers, brooms, containers, wiping cloths, etc., are used and stored.

Delays during the manufacturing process are noted in particular, since the inspectors are aware that some foods are sensitive to processing delays. Ingredients such as raw natural cheese, raw eggs, or raw or incompletely cooked vegetables may contribute high total bacterial counts, *Escherichia coli*, staphylococci, and

*Salmonella* to the finished products. They carefully observe cleaning practices. Poorly cleaned equipment and accumulated material left on it may subsequently result in contamination of otherwise clean food during the process.

The inspectors check products subject to drying, aging, tempering, or other holding operations by determining time-temperature relationships in each case. They note and record the sufficiency of cooking operations, cooling and storage of cooked raw materials, and packaging and freezing practices. The inspectors are constantly aware that good manufacturing practices may be negated by poor controls anywhere along the line, from raw material, plant conditions, and personnel practices to and including the finished product.

At the conclusion of the inspection, the inspector or inspector team prepares a written report of his or their observations to leave with management as required by law. The report is furnished only when, in the inspectors' judgment, a food, drug, or cosmetic consists in whole or in part of a filthy, putrid, or decomposed substance, or is held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health. The report also includes results of any field tests carried out, such as milk sediment tests, examination of fruits or vegetables for rot, or examination of wheat for rodent and insect filth.

Besides preparing the Report of Observations, the inspector or inspector team sits down with management and discusses the significance of the items listed. The law, fairness, and common courtesy require such a detailed discussion. Management should be so informed of existing conditions that corrective action on its part can be made as quickly as possible. It must be remembered that the inspector does not specify what action should be taken or how it should be done. Methods of correction should be effective and

should not create new problems.

The inspectors also at this stage point out other findings not required to be confirmed in writing. These include, for example, net weight deficiencies, obvious labeling discrepancies, and questionable use of food additives. The inspector refrains from discussing complex labeling matters and tells management that comments on this should be directed to the District or Washington offices. The inspector should encourage management to make known to him or to the District any disagreements with the inspector's observations, written or oral. It is perfectly proper for management to point out areas of disagreement and so advise the inspector and to make sure that the inspector understands the reasons for his disagreement.

After completing the inspection and the post-inspection discussion, the inspector returns to his office and writes his report. He follows a specified format, and his report includes all details of his findings and observations, samples collected, and photographic exhibits of insanitary conditions. He identifies the samples he has collected and submits them to the laboratory for specified analysis, to be correlated with his observations and findings during the inspection. An analysis may be for filth, decomposition, chemical contamination, bacteriological contamination and pesticide residues, or any of these. Sample findings and the inspector's completed report receive critical review at the District Office, and legal action, if any, emanates from this point.

The inspector is now ready for his next assignment. Such is the inspector's role as part of the team dedicated to safeguarding the Nation's food, drug, and cosmetic supply.



*The author (center) and microbiologist (left), who are Supervisory Inspector and Senior Microbiologist respectively, at Kansas City District, go over some of their observations with plant manager.*

# Antibiotics in Agriculture and the Health of Man

The introduction of antibiotics brought with it the hope that bacterial diseases, historically one of man's major health hazards, could be finally eliminated. Today, after more than 20 years of experience with these drugs, we are wiser, but still hopeful. Antibiotics have dramatically altered the practice of medicine and enhanced man's life expectancy; many bacterial diseases formerly prevalent are now rare, others easily curable.

But bacterial diseases still produce much suffering and a significant percentage of the hospitalizations and deaths in the United States. At the Children's Hospital Medical Center in Boston in 1967, for example, a bacterial disease was the primary illness of approximately 17 percent of the 12,100 children admitted. A significant number of these children were permanently affected and 77 died.

Many factors are involved in such struggles between man and invasive bacteria, but one of the most important is that bacteria have an amazing capacity to become resistant to antibiotics and, therefore, cannot be easily eliminated from infective lesions by these wonder drugs. It is not surprising, therefore, that those concerned with the public health have questioned how bacteria become resistant to antibiotics, where such bacteria originate, and what can be done to improve this health problem. The study of these questions has recently brought attention to several areas of interaction of bacteria, antibiotics, and man which have fallen from focus. One such area of interaction is the agricultural use of antibiotics.

More than a thousand tons of antibiotics are used annually on farms in this country. These drugs have direct contact with animal bacteria, some of which are potentially pathogenic for man and may have direct or indirect contact with him. Thus, it is appropriate to ask if the use of antibiotics in agriculture can affect the health of man.

Of several possible mechanisms by which this use of antibiotic in agriculture could affect man, three seem most probable.

by David H. Smith, M.D.

(1) *Antibiotic residues in foodstuffs causing allergic responses or altering bacterial ecology in humans.* Foodstuffs prepared from animals that have been given antibiotics might retain biologically significant quantities of those drugs. If these residues were not destroyed in the preparation or digestion of the food, they could allergically sensitize the person ingesting them or provoke a response varying from skin rashes to dangerous anaphylactic reactions in those already sensitized.

Antibiotics ingested along with foodstuffs would reach the lower intestinal tract of the person and come into contact with the billions of bacteria of many species which normally reside there. Present in sufficient concentration, the drug could alter the ecology of this flora of bacteria by destroying sensitive strains, thereby permitting the overgrowth of resistant organisms. This taken alone might have no deleterious effect on the person. But the bacteria from this flora occasionally gain entrance to other areas of the body, and produce disease. If resistant to antibiotics, they may be difficult to eradicate. Recent studies indicate that the bacteria which produce infections of the bladder and kidney, for example, are generally normal residents of the intestinal tract.

Such potential risks from antibiotic residues in foodstuffs are apparent, but the extent of the hazards to man cannot be adequately estimated or evaluated from existing data. Studies of this problem should be extended and expedited.

(2) *Drug-resistant bacteria of agricultural origin causing human disease.* The use of antibiotics in agriculture might permit the ascendancy of drug-resistant bacteria in the normal floras of animals; such organisms, in turn, might be transmitted to man, multiply, spread, and cause disease. The drug-resistance properties of the invading bacteria could interfere with effective antibacterial therapy.

(3) *Drug-resistant bacteria of agricultural origin transferring their*

*capacity to resist antibiotics to potentially pathogenic bacteria of man.* This mechanism implicates the same sequence as the foregoing, but resistant animal bacteria transfer their genetic potential for drug resistance to the bacteria of man's flora, which at some later time produce disease. The end result could be similar to that above: difficulty in eradicating invasive drug-resistant bacteria.

Are these more than fanciful suggestions? Let us review some of the evidence which bears on the last two of these proposals.

Animal bacteria are transmitted to man and do occasionally produce human disease. The qualitative and quantitative aspects of such exposures depend, however, upon the human population-at-risk. Farm personnel, for example, have considerable direct contact with animal bacteria. Certain skin, intestinal, and systemic diseases of some farm personnel have been clearly shown to have been caused by animal staphylococci, streptococci, Erysipelothrix bacilli, salmonellae, and Brucella organisms, to name a few. Unfortunately, the extent of incidence of these infections is not known since most are not reported to public health authorities.

Urban populations are infected by animal bacteria only after indirect contact. Thus, the intestinal disorders produced by salmonellae are the best documented and most frequent examples of diseases produced by animal bacteria in urban populations. Salmonellae can be isolated from a significant number of retail foods, particularly poultry products. Cooking usually reduces the concentration of viable bacteria to subpathogenic concentrations and most salmonellae infections are caused by contaminated foodstuffs that require no cooking, as with certain dairy and egg products, and canned meats.

More than 20,000 salmonellae infections have been reported annually since 1964 in the United States; 64 deaths were reported in 1966. This data, however, grossly underestimates the importance of this health problem. First, all authorities agree that the reported cases repre-

sent only a fraction of the total cases. In Hawaii, for example, where local public health officials have devoted extraordinary efforts to epidemiological surveillance of this problem, the reported incidence of salmonellae infections is about 12 times that reported nationally, although the ratio of positive to total cultures examined is similar to that found nationally.

Furthermore, because of the type and manner of preparing foodstuffs used in institutions, many of those diseased by salmonellae are hospitalized or institutionalized persons. Finally, approximately one of five afflicted by salmonellae are wage-earning or salaried employees and most of these lose at least a few days of work due to their diseases. The total effect of salmonellae infections on the national economy, therefore, must be significant.

How much of the salmonella problem is due to bacteria reaching man from animals? This cannot be answered accurately because of the problems of reporting and because many isolates are not sufficiently tested to determine their origin. Such information is available in Hawaii, however, and the data indicates that most of the human infections are caused by bacteria transmitted to man from animals, particularly from hogs.

Since animal bacteria do cause human disease, any antibiotic resistance these bacteria may have takes on a new meaning. Here it should be noted that some of the antibiotics most commonly used on farms are those commonly used in medicine. Thus, if antibiotic-resistant animal bacteria do cause a human disease requiring antibiotic therapy, they will very likely be resistant to one or more of the drugs a physician would use to treat the disease. Accordingly, the importance of the antibiotic resistance of animal bacteria cannot be minimized.

Antibiotics are used on farms to treat and prevent animal disease, and for so-called "growth stimulation." High concentrations of antibiotics are used for short periods in treatment, while low concentrations (20 parts per million) are added to

animal feeds and used regularly for "growth stimulation." Critics' attention has generally focused on the "growth stimulatory" use, since this accounts for most of the antibiotics used on farms and the intended results are considered to be debatable by some. The possibility that these low concentrations of antibiotics might facilitate the outgrowth of resistant bacteria was not sufficiently evaluated before this practice was commercially instituted, although the lethal action of these low concentrations on detrimental intestinal bacteria was one of the favorite, but unproved, proposals for the "growth stimulatory" effects.

One of the first of many studies indicating that animal bacteria can become resistant to antibiotics and that this resistance is related to the use of antibiotics in animal feeds was presented by Williams-Smith and Crabb in Great Britain in 1957. These scientists examined the feces of pigs and fowl kept under commercial conditions for *Escherichia coli*, one of the most common bacteria in the intestines of all animals, including man. They found that the numbers of *E. coli* in the feces were not altered by exposure to antibiotics in feeds, but whereas only 1 percent of the specimens were resistant to tetracycline when the animals did not receive this antibiotic, 95-98 percent of the specimens were all or largely resistant when the animals were receiving feed with tetracycline at "nutritional" levels. Furthermore, the degree of resistance possessed by the resistant strains was high, varying from 100-1600 micrograms per milliliter, and was not related to the concentration of antibiotic in the feed. Finally, tetracycline-resistant strains were still carried by the animals 7 months after the use of the feeds containing tetracycline was discontinued.

Although these studies were of *E. coli*, an organism which is only infrequently pathogenic for man, a direct correlation between feeding animals antibiotics and antibiotic resistance has also been found for bacteria with greater pathogenicity for man, such as salmonellae and *Staphylococcus aureus*. Edwards

and his coworkers at the National Communicable Disease Center at Atlanta have found that a progressive increase of antibiotic-resistant salmonellae isolated from animals has followed the increase usage of antibiotics in agriculture. All strains of *S. typhimurium* isolated before 1948, when antibiotics were seldom used on farms, were sensitive to tetracycline; 30 percent of strains isolated from poultry in 1962 were resistant to tetracycline, while 94 percent and 57 percent of strains isolated from cattle and hogs were resistant to tetracycline. Manten and coworkers in Holland and Anderson in Great Britain obtained similar data from extensive surveys of salmonellae isolated in those countries.

The pattern of antibiotic susceptibility of *S. aureus* isolated from animals and, more importantly, their human attendants, has also been correlated with the use of feeds containing antibiotics. Pogorzelska and Wencel in Poland in 1965 isolated *S. aureus* from the upper respiratory tract of 54-57 percent of 354 farm attendants studied. Of those strains isolated from attendants on farms where feeds containing oxytetracycline were used, 58 percent were resistant to that antibiotic. Only 3.6 percent of the strains isolated from attendants on farms where the feeds did not contain this antibiotic were resistant to oxytetracycline. In another study, drug-resistant *S. aureus* from animals fed antibiotics were found to cause disease in farm attendants and their families. The risk to man of drug-resistant animal bacteria would appear, therefore, to be real, and related to the feeding of antibiotics to animals. The actual risk cannot be quantitated, however, from existing data.

I have stressed the potential hazards of animal bacteria pathogenic for man but nonpathogenic strains may also be a problem. Within the past few years, a transferable genetic element capable of mediating clinically significant levels of resistance to one to ten of the most commonly used antibiotics has been defined in nonpathogenic as well as pathogenic, gram-negative, or enteric bacteria. This element,



called the Resistance (R) Factor, was originally defined in *Shigella* isolated in Japan, but it has since been found in a worldwide distribution. The R-Factor is now the most common basis for drug resistance among all enteric bacteria isolated from patients. Indeed, surveys of bacteria isolated over the past several years suggest that much of the recent medical literature on the clinical problems imposed by bacterial drug resistance has been describing resistances mediated by R-Factors.

The R-Factor is a self-regulated unit of genetic material or DNA which can transfer between all types of enteric bacteria, but not to staphylococci or streptococci, by a mating process involving temporary contact between two bacteria, and known as conjugation. Within minutes after receiving the R-Factor, bacteria become antibiotic resistant and acquire the potential to donate a copy of the factor to other (sensitive) bacteria. The R-Factors apparently do not affect recipient bacteria in any other way; e.g., they do not affect bacterial growth rates or pathogenicity. Since enteric bacteria are the major causes of life-threatening bacterial disease in this country, and yet are the most common bacteria found in the intestine of animals and man, the potential importance of this phenomenon is evident. Upon introduction into a person's intestine, for example, animal bacteria carrying R-Factors theoretically could convert the antibiotic-sensitive bacteria in that flora to antibiotic-resistant strains.

Is there any evidence which bears on this proposal? First, surveys of enteric bacteria isolated from farm animals in Great Britain by Anderson, Walton, and Williams-Smith indicate that most of the antibiotic-resistant isolates contain R-Factors. Second, although the transfer of R-Factors between bacteria is more efficient under laboratory conditions, it can be demonstrated in experimental animals. That such transfer is a low frequency event, as predicted by the rigorous requirements of pH, oxygenation, etc., required for transfer *in vitro*, and by the fact that only a few bacteria

in nature are infected by R-Factors, is evidenced by the results of two preliminary studies.

In one study, patients entering a local hospital were found to be frequently colonized with a strain of *Klebsiella* carrying an R-Factor. The bacterial floras of such patients were examined at periodic intervals to determine if these *Klebsiella* could transfer their R-Factors to other enteric bacteria. In another study, *Salmonella choleraesuis* was fed to pigs on a farm where antibiotics were used as feed additives. The pigs have been found to carry R-Factors in the enteric bacteria of their gut, presumably due to the antibiotics in their feed. Fecal specimens from these animals were examined at intervals for evidence of R-Factor transfer to the *S. choleraesuis*. No R-Factor transfer was demonstrated in either study.

It must be emphasized, however, that these preliminary results were obtained from only approximately 120 test situations in which transfer to or from only a certain species of bacteria was studied. Finally, it must be emphasized that bacteria carry R-Factors only because the element has been transferred to that organism; bacteria cannot make R-Factors. The prevalence and widespread distribution of R-Factors provide proof, therefore, that these genetic elements are able to transfer between bacteria in nature, even if at a low frequency.

In conclusion, it is obvious that there are more questions than answers to the relationship between feeding antibiotics to animals and the health of man. Animal bacteria, however, clearly do cause human disease, may become resistant to antibiotics used in medicine, are usually resistant because they are infected by potentially transferable R-Factors, and are affected by the concentrations of antibiotics added to animal feeds for "growth stimulation." As indicated, the potential hazards of this practice cannot be assessed from the existing data and further, extensive studies are needed.

Should these theoretical objections prevail against the practice of feeding antibiotics to animals? If

the evidence favoring the practice were conclusive, the answer would clearly be "no"! At present, however, several questions persist regarding the value of the practice.

First, many of the earlier experiments depicting this beneficial effect of antibiotics were not conducted under today's standards of scientific experimentation, and many critics seriously question whether antibiotics actually do provide the alleged "growth stimulation." Second, some studies that were conducted several years ago were made before the present breeding techniques and hygienic practices were incorporated into production practices.

Indeed, some feel that these improvements might have eliminated any benefits originally derived from antibiotics in feed. But since proponents of the practice hold that the world cannot hope to provide a sufficient dietary protein to the populations anticipated in the future without the "growth stimulation" provided to animals by antibiotics, the practice cannot be rejected without justification. It therefore would seem logical to rigorously reevaluate the benefits of antibiotics as "growth stimulants" for animals at the same time that the potential hazards of this practice are being studied. Only when the actual hazards can be balanced against defined benefits, can the problem be resolved.

There is another reason for attention to this problem: It provides a philosophic dichotomy to other federally regulated practices affecting consumers, particularly in the area of drugs. Thus, an antibiotic to be used in medicine is approved for commercial release only when its use can be shown to be beneficial and free of significant hazards. Is it not a paradox that antibiotics are now approved for use in animal feeds for "growth stimulation," even though the beneficial effects have not always been clearly demonstrated? And even though potential hazards have not yet been defined?

---

*The author is Chief of the Infectious Disease Unit of Pediatrics, Children's Hospital Medical Center, Boston, and Assistant Professor of Pediatrics, Harvard Medical School.*

# A JOB EVER CHANGING, NEVER COMPLETED

George Potter Larrick 1901-1968

A mother takes her child's temperature but gives no thought to the accuracy of the thermometer. She does not know that the Food and Drug Administration has a program for the sampling and testing the accuracy of clinical thermometers.

A man who has a heart ailment must avoid foods containing salt or sodium. An FDA regulation spells out the information given on labels of

**A** special dietary foods enabling him to plan his diet and control his sodium intake.

A doctor prescribes an antibiotic for a patient who is threatened with pneumonia. Neither the doctor nor the patient has any concern about the purity or the potency of the drug. But in this building, the Food and Drug Administration continuously tests and certifies the quality of all antibiotic drugs used on human patients in this country.

Accurate dosage of insulin is of life or death importance to several million diabetic people in this country. Every batch of insulin that is manufactured is tested in the FDA laboratories to ensure that it has the exact strength stated on the label.

Today many chemicals known as "food additives" are used to make foods more attractive, better tasting, and more economical. But none of these may be used in foods unless they have been checked and cleared for safety by the Food and Drug Administration.

Increasingly, pesticides are used to grow better

crops and protect the health of livestock. Medicated feeds enable animals to grow faster and keep down the cost of food production. But these potent chemicals must be carefully and correctly used. Scientists in this Agency have the great responsibility of establishing what amount of residues may safely be permitted in the foods going to market.

Prevention of food poisoning by infectious organisms is a major program of the Food and Drug Administration. Scientists of this Agency have dedicated their lives to improving methods for detecting and preventing these hidden dangers.

This building houses a major part of this Agency's scientific staff concerned with the carrying out of these activities and many, many more. It represents a significant advance in consumer protection—by providing the Food and Drug Administration with a scientific structure that is designed specifically for the work to be done. Every person in the Nation will benefit from the creation of these facilities.

Speaking for the Food and Drug Administration, I would like to express our gratitude to all

**F** the people who were involved in the planning, design, and construction of this building. From all of you—and from the American people—we receive this building with a pledge—that we here dedicate ourselves to a job that is ever changing—always challenging—but never completed.

*—From the last official address by Food and Drugs Commissioner George P. Larrick, given shortly before his retirement, at dedication ceremonies on November 23, 1965, for FDA's new Washington headquarters building and laboratories. Mr. Larrick, who died August 11, 1968, served 42 years with the Agency, joining as an inspector and rising through the ranks to Commissioner, a post he held for his last 11 years of service.*

# FOODS AND PESTICIDES

by  
Reo E. Duggan

**T**hroughout history man has been concerned with the control of pests affecting his health and welfare. He has constantly sought better means to minimize the diseases and losses of crops and other resources caused by the many forms of animals, insects, and plants classified as pests. His success in controlling pests may be measured by the present attention being directed to the control of the pest control agents. It is reasonable to speculate that more has been written and said, pro and con, about pesticides in food and in other parts of the environment during the past decade than in all previous ages. It is also reasonable to assume that public knowledge and interest are greater than ever before.

The relatively simple pesticide chemicals and other methods used for pest control during the early part of the 20th century have been replaced in less than 25 years by a large number, over 800, of different pesticidal compounds and several biological control systems involving insect diseases, predators, and sex sterilization.

A full discussion of the complex subject of pesticides is beyond the scope of this article, even when further limited to pesticides related to foods.

The statutory authority for the control of pesticide residues in food began with the Food and Drug Act of 1906. This authority was strengthened generally by the Food, Drug, and Cosmetic Act of 1938, and more specifically in the Pesticide Chemicals Amendment to the Act in 1954.

The Federal regulation of pesticides is a joint responsibility of the Department of Agriculture and the Food and Drug Administration of the Department of Health, Education, and Welfare. No pesticide chemical can be legally shipped in interstate commerce without registration by the Department of Agriculture. For a petitioner to obtain a registration, the chemical must not be injurious to man and animals when used as directed and must control the pests named on the label without harming the crop being treated. If the use will result in residues on a food or feed crop, the chemical cannot be registered until the Food and Drug Administration has established a safe tolerance for the remaining residues.

The industry or firm promoting the use of the chemical is responsible for obtaining proof that the residues remaining on food are safe for the consumer. The Food

and Drug Administration is responsible for the scientific judgment concerning the safety of a tolerance. In arriving at a decision that the proposal is safe, Food and Drug scientists use all available information, in addition to that supplied in support of the petition for a tolerance.

FDA may establish temporary tolerances for experimental field testing to determine if the pesticide can be useful without destroying the crop. The total amount of the pesticide to be used is limited. There must be adequate data showing that the residues remaining on the food are safe.

For many years, zero tolerances were established or pesticides were registered on a "no residue" basis where the presence of residues could not be found on the food at harvest. Extremely sensitive analytical methods have been developed in recent years which show that in many cases minute amounts of the pesticide were actually present at the time of harvest. In 1965, a committee of the National Academy of Sciences-National Research Council (NAS-NRC) recommended that the "zero" tolerances and "no residue" registrations be replaced insofar as possible with negligible residue tolerances—residue levels which have no toxicological significance. Negligible residue tolerances are being established insofar as practicable to replace the zero tolerances and the "no residue" registrations. However, only zero tolerances can be established for carcinogenic compounds.

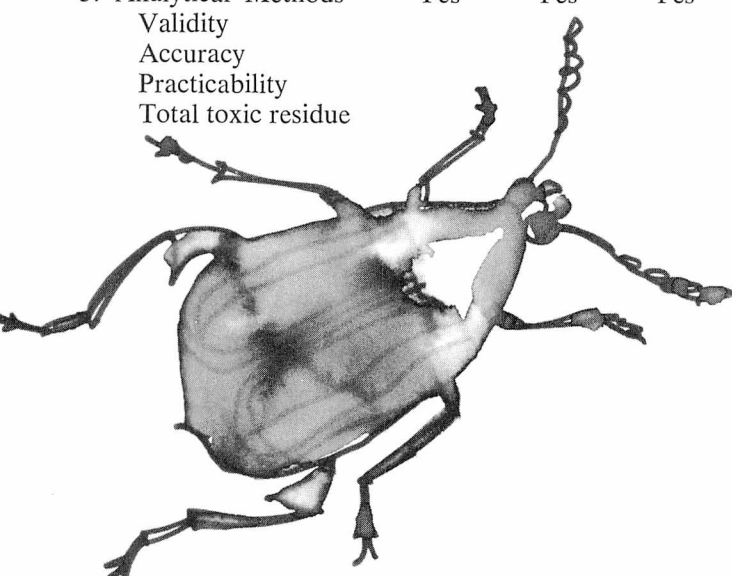
Negligible residue tolerances may be established on groups of similar type crops listed in the regulations. Most tolerances are for higher levels of residues, the other major type of tolerance, and are established for individual crops.

The accompanying table summarizes the major data requirements for each of the three kinds of tolerances, but this summary table is not intended to inform petitioners for tolerances in detail of all the data required to support a pesticide petition. It is obvious that the requirements for tolerances having some toxicological significance are most stringent. Even so, additional information may be required because of the toxicity of the general class of compounds or because of results obtained during the studies to fulfill the basic requirements.

Data requirements forming the basis for tolerances are subject to continued review by FDA, which con-



## DATA REQUIREMENTS FOR TOLERANCES

Data	Tempo- rary	Type Negli- gible Residue	Higher Resi- dues	Data	Tempo- rary	Type Negli- gible Residue	Higher Resi- dues
1. Chemical Specification	Yes	Yes	Yes	5. Acute Toxicity	Yes	Yes	Yes
Identity				LD <sub>50</sub> -several species			
Composition				animals			
Chemical name				Signs of toxicity			
Common name				(chemical, gross,			
2. Conditions of Use	Yes	Yes	Yes	histological)			
Directions				6. Sub-Acute Toxicity	Yes	Yes	Yes
Limitations				2 species			
Restrictions				90-day duration			
3. Analytical Methods	Yes	Yes	Yes	3 dose levels			
Validity				Clinical tests			
Accuracy				Laboratory tests			
Practicability				Gross examinations			
Total toxic residue				Microscopic examinations			
				7. Chronic Toxicity	Yes	No	Yes
				(started not	completed)		
				2 species			
				2-year duration			
				3 dose levels			
				Clinical tests			
				Laboratory tests			
				Gross examinations			
				Microscopic examinations			
				8. Reproduction Test	Yes	No	Yes
4. Residue Data	Yes	Yes	Yes	(started)			
Conditions of use				1 species			
Maximum rate				2 or 3 generations			
Maximum number of				3 dose levels			
applications				Teratogenic and			
Geographical				mutagenic observations			
distribution				Microscopic examination			
Reduction of residue in				of final litter			
processing				9. Other tests when	Yes	Yes	Yes
				appropriate, such as			
				enzymatic, demyelinating,			
				cataractogenic, etc.			



Reo E. Duggan  
is Deputy  
Associate  
Commissioner  
for Compliance.

siders new scientific data and advances in the evaluation of safety data. For example, reproduction studies were not required before 1963.

Tolerances are established on a crop-by-crop basis, except for the groupings permitted for negligible residues. Tolerances for pesticides which have related pharmacological effects are not additive. For example, if there are individual tolerances of 7 ppm (parts per million) for toxaphene and 7 ppm for DDT on apples, this does not mean that 14 ppm of toxaphene and DDT combined is permitted. In such cases, the amount of residue of one member of the class proportionately reduces the amount of residue of other members of the same class of pesticide which may legally be present.

The Food and Drug Administration has several programs in progress concerned with pesticide residues. The basic purpose of all of these programs is to insure the safety of the Nation's food supply. These programs include a total diet study, as well as research, surveillance, and enforcement programs.

FDA obtains market basket (or total diet) samples of foods from retail stores bimonthly in five regions of the country. The samples are prepared for consumption and examined for pesticide residues at sensitivity levels substantially lower than those used in the examination of surveillance and enforcement samples. Much additional analytical time is required to obtain these lower levels of sensitivity and to confirm the results. The proportion of individual food items used in this study was developed by the U. S. Department of Agriculture's Household Economic Research Division, based on the high consumption level of a 16- to 19-year-old male. The quantity of this diet is approximately double that of a normal individual. The results obtained from this study during the past 3 years are encouraging. In no case does the daily intake of any pesticide chemical exceed the acceptable daily intake recommendation of the Food and Agriculture Organization of the United Nations—World Health Organization (FAO-WHO). For practically all pesticide chemicals the daily intake is substantially lower than these recommendations.

The Food and Drug Administration surveillance and enforcement programs were expanded substantially beginning with fiscal year 1963. For several years, the FDA examined approximately 25,000 samples, in addition to inspecting the food growing areas, to determine

the actual practices being followed. Limited resources, coupled with relatively low incidences of violations in most food categories, has resulted in a reduction in the sampling and inspection program. Quantitative multi-residue methods of analysis capable of detecting residues at a level of 0.03 ppm were in general use beginning with fiscal year 1964. These multiresidue methods can detect and measure more than 60 of the common organochloride and organo-phosphate pesticide chemicals that may occur in samples. A majority of the samples collected and examined under these programs were classified as objective, which means they were collected without suspicion of excessive residues or misuse of pesticides.

Although about half of the samples were found to contain residues of one or more pesticide chemicals, only about 3 percent were found to contain residues in excess of the legal tolerance, or in the absence of legal tolerances, administrative guides for excessive residues. Shipments of food found to contain excessive residues are removed from food channels where possible. Followup procedures are used to prevent other portions of a lot found to contain excessive residues from reaching the consumer.

Shipments of foods imported into this country are also sampled and examined. There are no substantial differences in residues in the foods produced in the United States and those imported from other countries.

Although approximately one-half of the samples contain residues, a majority of the residues are at very low levels. Over 75 percent of the individual residues found were 0.10 ppm or less and 95 percent of the residues were 0.50 ppm or less. This general pattern of residue levels is observed when the data are considered by specific pesticide chemical, food category, domestic or imported products, or on an annual basis. In general, foods sampled under surveillance and compliance programs undergo further processing or preparation prior to consumption, and this processing generally lowers the residue level still further.

The Food and Drug Administration also carries out extensive research programs on pesticides. These research programs are designed to support and strengthen FDA's capabilities to establish and enforce pesticide residue tolerances. FDA's research activities fall into the major areas of chemical and biological research.

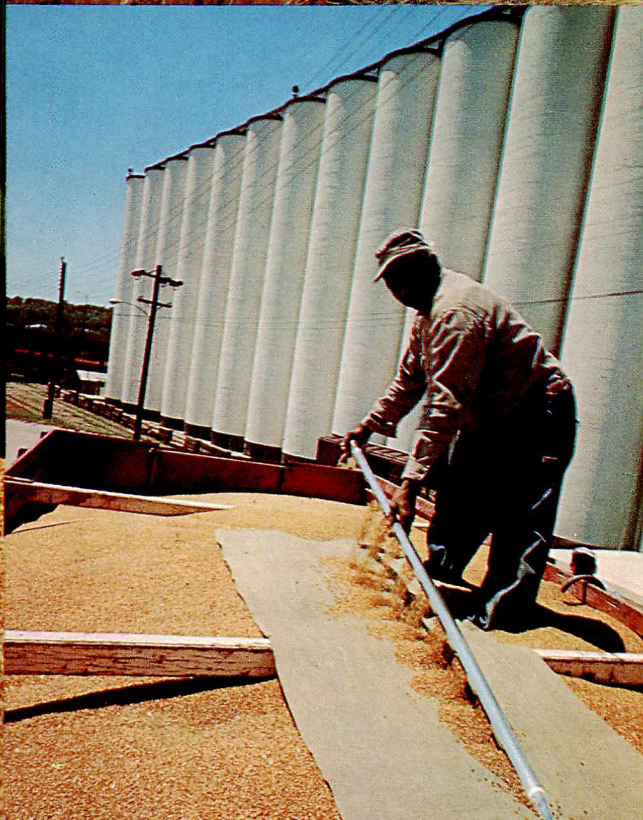
*continued on page 21*



# How the law protects the consumer of A BAKERY PRODUCT



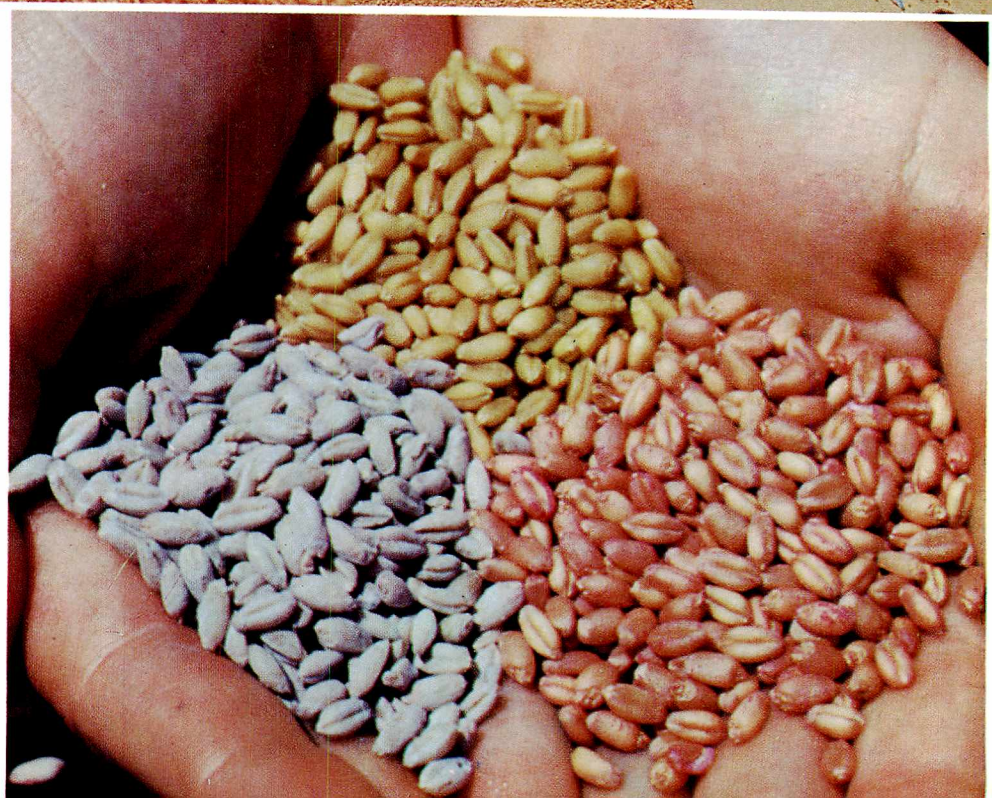




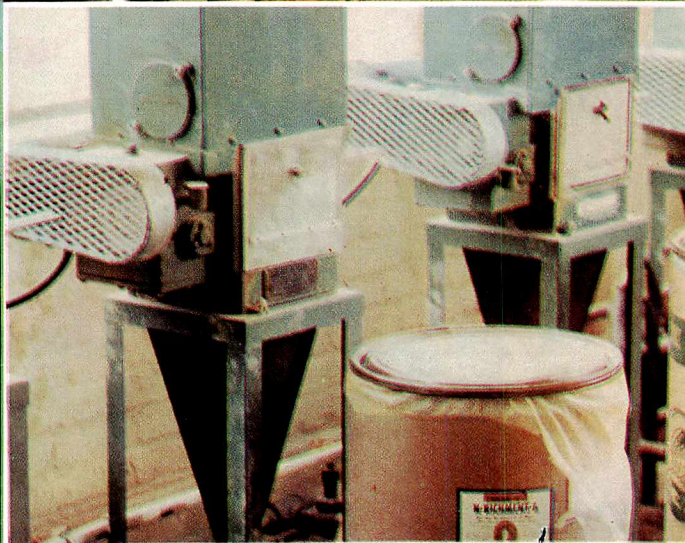
The laws administered by the Food and Drug Administration form a comprehensive pattern of protection to the consumer's health and welfare. In the case of such basics as bread and other bakery products, for example, this protection extends through the several steps in production to the finished article that appears on the consumer's table.

It is the FDA's task, under the Pesticide Chemicals Amendment to the Food, Drug, and Cosmetic Act of 1938, to assure that pesticides on food products do not exceed tolerances the Agency establishes as safe for a given pesticide on a given raw agricultural product or group of products. The U.S. Department of Agriculture regulates the labeling and marketing of pesticides employed in production and storage of the crop. The two Agencies thus work together in developing sound practices that will control the pest, yet be safe for the consumer.

For fungicidal treatment of seed that is also usable as food or feed, FDA requires that, where there is no tolerance or where the fungicide on seed is in excess of the tolerance permitted for food or feed, a dye be used to clearly mark the seed so inspec-



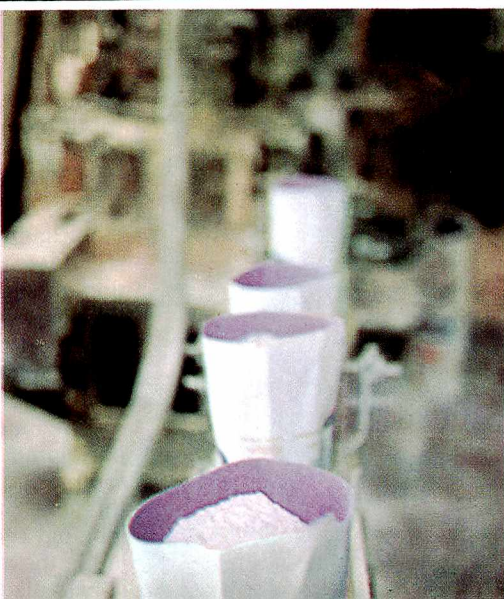




tors or others can identify it at a glance as unsafe for use in actual food or feed processing. The photo at the bottom of page 18 shows untreated wheat along with that treated with hexachlorobenzene (blue) and a mercurial fungicide (pink).

The FDC Act defines food in interstate commerce as adulterated if it is deleterious, unclean or decomposed, or exposed to insanitary conditions that may contaminate it or render it injurious to health. Photo at center right of page 18 shows an instrument used to take wheat samples from the pile at several levels for FDA analysis for pesticide residues, evidence of insects, rodents, or other deleterious conditions. FDA Inspectors maintain surveillance over storage and transportation of grain used in interstate commerce to guard against further contamination (photo page 19, left), as well as at flour mill (photo, top right, page 19) to assure that adequate sanitation practices and other safeguards are followed. Flour labeled as "enriched" must contain specified amounts of certain vitamins and minerals and FDA checks, by both inspection and analysis, to see that adequate amounts are present. Machines (center right, page 19) measure enrichment ingredients into flour.

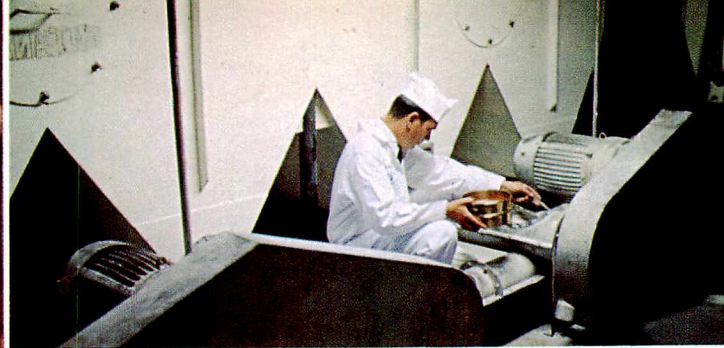
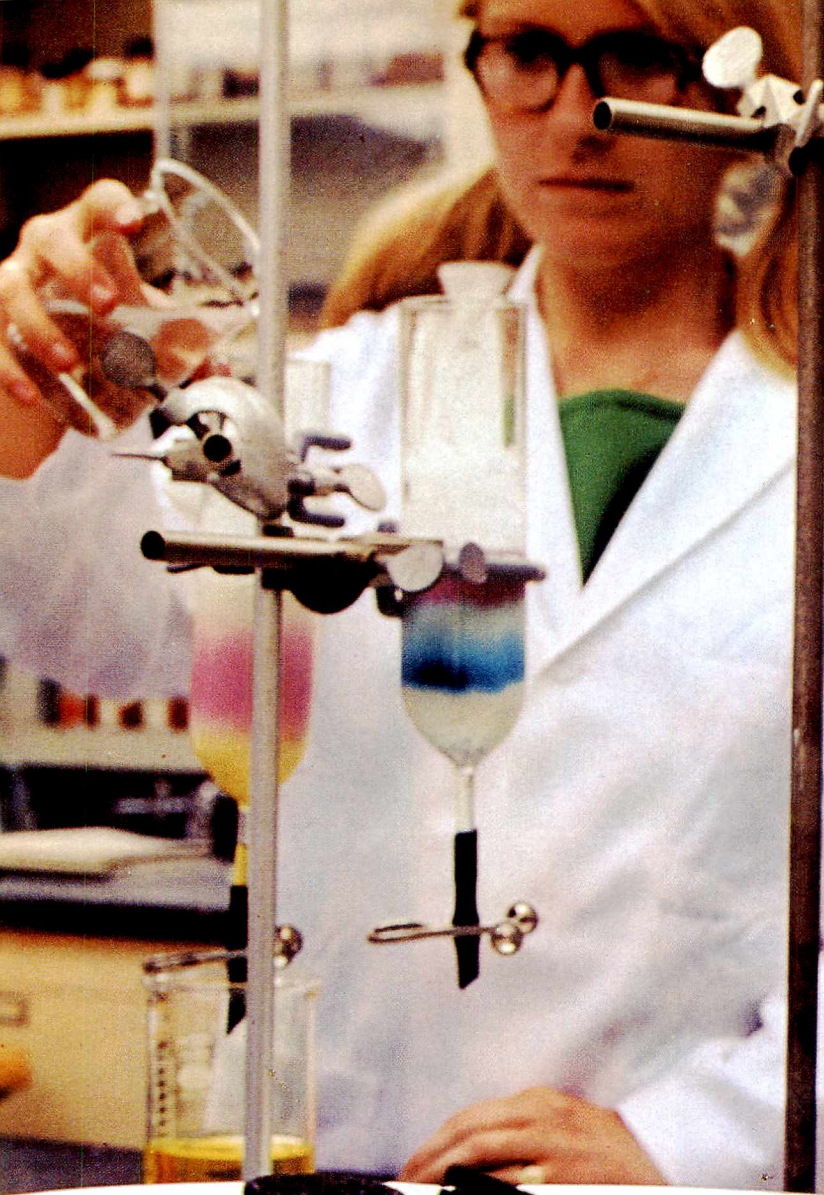
At the bakery (photos, top right, page 20), FDA Inspector checks the plant's storage areas, the



production line, equipment and facilities, and sanitation practices for evidence of conditions that may result in contamination. Besides visual examination, he takes samples of suspected materials from various areas along with ingredients and in-line and finished products to be analyzed. In laboratory (bottom left, page 20), biologist checks flour sample for contamination by filth.

The Food Additives Amendment to the FDC Act provides for FDA to establish a regulation for any food additives to be used by a manufacturer that may directly or indirectly become a component of the food or otherwise affect its characteristics, upon a finding that it is safe, based on scientific evidence submitted by the proposed user and that available to the Agency. The regulation may limit the amount of the substance that may be present on the food, specify the foods on which it is permitted, prescribe the manner of use, and specify any required labeling. Food additives include substances which may become components of food by their intended





uses in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding the food, and any source of radiation proposed for these uses. Exceptions are substances generally recognized as safe, those used under approval prior to 1958, or pesticides (covered by other parts of the law).

The Color Additive Amendments to the FDC Act define a food,



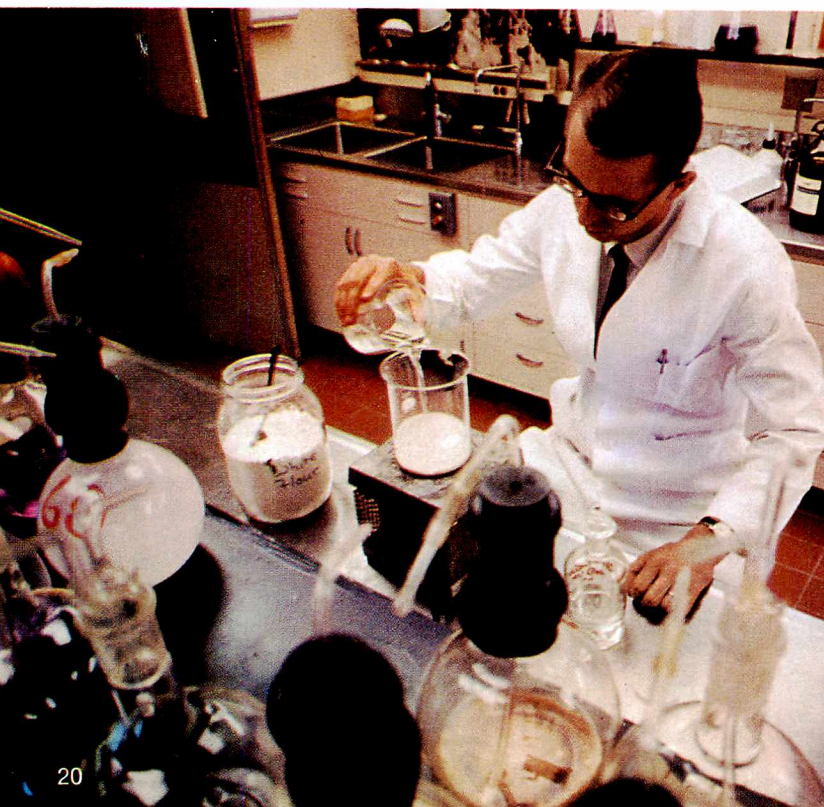
drug, or cosmetic as adulterated if it contains color additives which have not been accepted by FDA as safe for the intended use. FDA issues regulations listing permitted color additives, and limitations to their use, if necessary. FDA tests each batch of color to be used by a manufacturer and certifies it before use is permitted, except for those color additives specifically exempted by regulation from certification. The photo at top left of page 20 shows an FDA chemist testing colors used in the displayed cookies by matching them against FDA's standard colors.

Under the Act, FDA sets standards of identity, quality, and fill of container for certain bakery and other products to be sold under common or usual names. Such products must comply with the specifications set as well as with the requirements for all foods under the law.

Labeling, under the FDC Act, must not be false or misleading. Damage or inferiority must not be concealed and one food may not be sold under the common name of another. Containers must not be misleading through package shape or fill of contents. Label information must be conspicuously displayed and easy to understand. The label must contain the name and address of the manufacturer or distributor and an accurate statement of the amount of food in the package. Ingredients must be listed in descending order of their predominance in the food except those foods for which FDA has set standards of identity, in which case ingredient listing is in accordance with the prescriptions of the standards. Special dietary foods require additional information on vitamin, mineral, and other dietary properties. If artificial flavoring or chemical preservatives are used, this must be stated on the label. Any use of artificial coloring must be stated except for butter, cheese, and ice cream. Imitations must be labeled as such.

The Fair Packaging and Labeling Act of 1966 requires certain additional anti-deception packaging and labeling for food. FDA has established regulations for enforcement of this law. Briefly, the law provides additional packaging and labeling requirements to make it easier for the consumer to judge the value of the product he is buying.

FDA also is in the process of developing Good Manufacturing Practice Regulations, based on the FDC Act, for the food industry in general, and for specific food industries. These regulations are intended to help the food industry to understand good manufacturing practices, since these are not specified in detail in the law.







continued from page 16

FDA's chemical research on pesticide residues in foods includes: (1) establishing the chemical identity of the residue including significant conversion products; (2) developing, improving, and validating methodology for measuring the amount of such residues; and (3) occasional checking of the validity of data submitted in pesticide petitions.

The biological research program is directed toward evaluating the hazards of pesticide residues and their conversion products by acquiring information on the effects of these materials on animals and man. This research work is applied research directed to the support of pesticide tolerances and to the development of scientific facts to furnish an increasingly sound basis for FDA policies.

The biological research effort includes the following areas: (1) the development of data on new types of pesticides to facilitate FDA guidance of commercial work for support of petitions; (2) a more detailed examination of specific toxic effects for their impact on safety evaluation; (3) examination and development of new toxicological methods for use in evaluating safety; and (4) resolution of conflicting data for a sounder evaluation of safety of pesticide residues in foods.

The results of all of these programs indicate that this country has no major problem with the direct use of pesticides in the production of our food supply insofar as the presence of unsafe residues is concerned. The low level of samples having residues exceeding tolerances or guidelines, the low level of residues found in the total diet study, and the low level of residues found in the surveillance and enforcement programs generally all are indicative of this fact. But this does not mean that problems do not exist. Nearly 75 percent of the total daily intake of chlorinated organic pesticides is from dairy and other animal products. There are few registered uses of pesticide chemicals known to result in residues in meat and poultry. No registrations have been granted which are calculated to result in residues in milk, but a number of petitions for pesticide residue tolerances in milk to cover such registrations are under consideration by FDA. Therefore, these are environmental factors contributing residues to these commodities indirectly.

New pesticide chemicals, formulations, and other

methods of insect control are being developed. Some of these new control measures will replace or reduce the need for older, less effective chemicals. New tolerances are required and existing tolerances must be reviewed in terms of current good agricultural practice and need, in keeping with the policy that tolerances should not be higher than necessary for safe and effective use.

For example, FDA has recently published an order to reduce DDT tolerances. This action was initiated by a review of the analysis of a large number of samples over the past several years which indicated that the level of DDT found on most fruits and vegetables is far below the 7 ppm tolerance for that pesticide. The difference between the levels found and the tolerance was so great as to raise a question as to the need for so high a tolerance. Although tolerances cannot be established on the basis of regulatory samples because the amounts of the pesticide chemical and the time of application are not known, such data can be used as an indicator of need for review of the tolerances. Most DDT tolerances were set on the basis of public hearings held in 1950, and data such as that required for present day tolerances was not available at that time.

The intent of the order is to establish DDT tolerances no higher than needed in current good agricultural practices. The order also suggests that a 1 ppm tolerance is adequate for most crops, and indicates that if a higher tolerance is needed, data on usage and residues to support such higher tolerance should be presented to FDA by January 1, 1969.

In other cases, new information concerning the toxicity or pharmacological effect may result in a review of existing tolerances. After a review of aldrin and dieldrin by the Pesticides Residues Committee of the NAS-NRC in 1965, certain tolerances were reduced, some uses were discontinued, and additional research was initiated. The results of this additional research will be submitted to FDA during the summer of 1968 for a further evaluation of the current tolerances.

As our information on safety and actual levels of residues in foods expand and changes in agricultural practices in the use of pest control agents occur, we may expect other changes in tolerances. Our tolerance system must keep abreast of the changes if we are to continue to have a safe and adequate food supply.



# Public Advisory Committees

by Clem O. Miller, Ph.D.

It is common practice today for the Food and Drug Administration and other Federal agencies to establish public advisory committees to supplement the expertise of their respective staffs. Although agencies intend to maintain an able staff, problems and questions do arise that require immediate knowledge in areas beyond the competence of the respective staffs.

Thus, the use of such committees is an acknowledgment that outside the agencies are citizens with recognized superior cognizance in specialized fields who are willing to contribute this expertise to their Government. Because the need for these consultants is infrequent, it would be a waste of scientific manpower to hire such experts as full-time members of agency staffs. An advisory committee made up of such specialists is a convenient method of collecting evaluated information for agency decisionmaking.

The extensive use of public advisory committees by Federal agencies started soon after World War II. During the war most of the defense research programs were developed under the aegis of the National Academy of Sciences-National Research Council. After World War II, Federal agencies came to recognize that incorporation of public advisory committees into the administrative framework of the agency improved communication between members of the agency staff and of the committee, developed a feeling among the committee members of involvement in the agency's affairs, and was generally more effective. Close association with the members of the committee helped upgrade the staff.

Prior to 1963, the FDA had only two public advisory committees on a continuing basis. The Food Standards Committee was established in 1938 and the Board of Tea Experts dates from 1897. Before 1963 the FDA held that it had certain statutory responsibilities it could not delegate and that regulatory decisions by FDA required an intimate knowledge of precedents and the Agency's unique mission. FDA officials felt that since they were responsible for the hard decisions, they should make the decisions themselves. Furthermore, they felt that referring a question to an advisory committee to obtain a recommendation for action was tantamount to accepting it as a basis for action. These leaders believed that there would be times when they would be unable to take the recommended action, even though they might agree with the merits, because to do so might conflict with existing Government-wide policy or be inopportune at the time because of pragmatic realities.

There also may have been some misunderstanding of the respective functions of advisory and executive committees. The recommendations of an advisory committee are, of course, advisory only, and such a committee's recommendations are not mandatory in nature.

There is a feeling by some that agencies have used public advisory committees as a shield to protect themselves from the responsibilities of making tough decisions or those that might elicit subsequent public criticism. The FDA had no desire to evade criticism for the consequences of its actions by attributing them to a committee of eminent scientists or citizens.

For a few years immediately prior to 1963, FDA occasionally used *ad hoc* advisory committees on specific problems for short periods of service, 90-180 days. These *ad hoc* committees included:

Prophylactic Use of Antimicrobial Agents Advisory Committee, Safety of Folic Acid in Multivitamin Preparations Advisory Committee, Menadione Advisory Committee, Aramite Advisory Committee, and Methoxychlor Advisory Committee.

Since the passage of the Federal Food, Drug, and Cosmetic Act in 1938, and especially since the Kefauver-Harris Amendments of 1962, the thrust of FDA's effort in consumer protection and the philosophic approach have been shifted. Early regulatory problems dealt largely with sanitation in food and drug manufacturing and the esthetics of food manufacturing processes. With the introduction of many new and complex drugs and the wide use of pesticide chemicals and additives, safety has become an even more important factor in consumer protection. More recently, the effectiveness of drugs and the nutrient value of foods have come to the fore in the consumer protection program.

During the 1950's and early 1960's there was a growing opinion among public-spirited citizens that FDA would be able to perform its mission more effectively if it used public advisory committees on a continuing basis. An advisory committee established by the National Academy of Sciences-National Research Council in 1960 at the request of the Secretary of Health, Education, and Welfare included this proposal among its recommendations. The Second Citizens Advisory Committee, 1962, recommended that FDA set up a National Advisory Food and Drug Council.

In 1963, Food and Drugs Commissioner George P. Larrick decided to initiate a program of using continuing advisory committees. Committees were to be established as needed and as wanted by FDA Bureaus or Divisions.

The first committee established on a continuing basis was the Investigational Drug Advisory Committee in 1963. Its first meeting was held in June 1963. After the promulgation of regulations for enforcement of the Kefauver-Harris Amendments in 1962, there had arisen misunderstandings and anxiety on the part of the scientific community. Over a period of 2 years, the Committee was of valuable assistance in improving com-

munication between FDA and the scientific community, in interpreting the regulations, and in allaying the concerns of many.

The National Advisory Food and Drug Council was established in March 1964 by formal determination of the Secretary. It held its first meeting December 1, 1964. The Council members represent consumer groups, science, industry, law, medicine, pharmacy, veterinary medicine, education, agriculture, communications, labor, government, voluntary health organizations, and women's organizations. The Council deals with problems and questions before FDA in the area of public policy and public affairs.

The Secretary approved establishment of the Medical Advisory Board in April 1964, and it held its first meeting March 2-3, 1965. This Board considers broad medical problems and matters before the Bureau of Medicine. The members are eminent physicians and medical scientists with wide experience and represent several medical disciplines.

More recently the Veterinary Medicine Advisory Committee (November 1964) and the Research in the Biological and Physical Sciences Advisory Committee (September 1964) were established in the Bureau of Veterinary Medicine and Science respectively.

The Department has issued a manual on committee management and FDA has issued a supplement to it. The first step in establishing a new advisory committee is the preparation of statements by the requesting group of need and of the areas of expertise to be represented by the committee's members. Approval is requested from the Secretary through the Commissioner. Candidates for membership on the committee are selected with considerable care. They should be eminent experts in their respective fields and be recognized by their peers for good judgment. All candidates must be cleared with the Department's Office of Internal Security. Nominees for membership are required to list ownership of securities which might constitute an apparent conflict of interest as well as to furnish a statement of employment, either full-time or part-time or as a consultant, and research grants or contracts they may have received from companies regulated by FDA.

Standing and continuing committees are set up for periods of 2 years. Each committee may be continued 2 additional years on adequate justification.

Congress has provided by law that manufacturers of pesticide chemicals and food or color additives may request FDA to establish *ad hoc* advisory committees to set tolerances for the presence of specific chemical compounds in certain foods. These are called statutory committees and do not require approval by the Secretary. Statutory committees are allowed 60 to 90 days

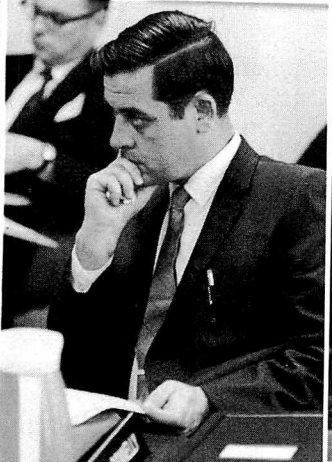
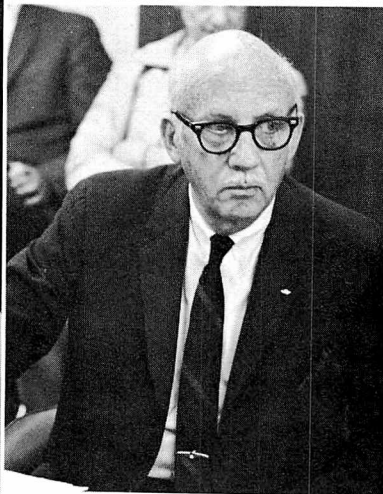
*continued on page 26*

## The National Advisory Food and Drug Council

The National Advisory Food and Drug Council, made up of citizens representing a number of fields of interest, was established in 1964 to provide FDA a source of competent knowledge and experience that will help to plan, develop, and execute the Agency's programs.

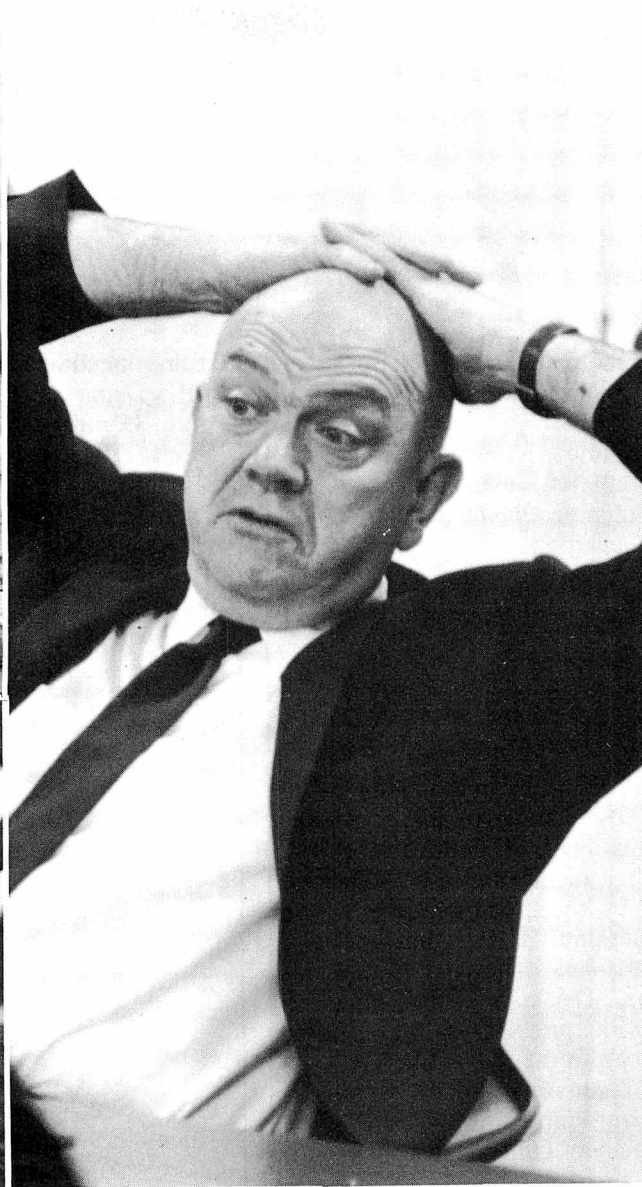
The 17-member group was established on the recommendation of the President's Second Citizens' Advisory Committee during the administration of Commissioner George P. Larrick. The Council's membership represents such interests as consumer groups, science, industry, law, medicine, pharmacy, veterinary medicine, education, agriculture, communication, labor, government, voluntary health organizations, and women's organizations.

The Council meets twice a year or more often to deal with special problems on the call of the Commissioner of Food and Drugs, who serves as its Chairman. It advises the FDA on attitudes, interests, and values of such groups as consumers, industry, the general public, and the scientific community, and about trends on advances in science and technology and development of new products. The Council also studies economic, demographic, and political trends and recommends new FDA programs and changes in existing programs and areas of emphasis. Appointments are made on a 3-year rotating basis.



At left, June L. Sears (top) is an extension home economist with Michigan State University Cooperative Extension Service; Barbara Reagan (being sworn in, below left), Ph.D., is a Professor of Economics at Southern Methodist University, Dallas, Tex.; Vincent Donnelly is President of Philadelphia Laboratories, Philadelphia. In center, Charles G. King (top), Ph.D., is Associate Director of the Institute of Nutrition Sciences, Columbia University, New York; Frederick D. Lascoff (middle) is President of J. Leon Lascoff & Son Apothecaries, New York; George C. Poppenseik (bottom), V.M.D., is Dean of New York State Veterinary College, Cornell University, Ithaca. At right, Thomas Christopher, S.J.D., is Dean of the School of Law, University of New Mexico, Albuquerque.





In top row, left to right, Dorothy S. Brady, Ph.D., is Professor of Economics, Wharton School, University of Pennsylvania, Philadelphia; James P. Dixon, Jr., M.D., is President, Antioch College, Yellow Springs, Ohio. Alfred M. Boyce, Ph.D., is Dean, College of Agriculture, University of California, Riverside. Center row, left, Stanley E. Cohen is Vice President, Advertising Publications, Washington. At bottom, left to right, Anne Draper is Research Associate, AFL-CIO, Washington; Orville G. Brim, Jr., Ph.D., is President, Russell Sage Foundation, New York. Not present when photos were made: Chauncey W. Cook, Chairman of the Board, General Foods Corp., White Plains, N.Y.; Kenneth B. Willson, President, National Better Business Bureau, Inc., New York; F. J. L. Blasingame, M.D., Executive Vice President, American Medical Association, Chicago; Charles A. Byrley, Director of Federal-State Relations, National Governors' Conference, Washington.



continued from page 23

to prepare their reports recommending a tolerance for FDA action. These groups terminate automatically at the end of 90 days.

A public advisory committee, as defined in the Department's manual for committee management, is any committee, board, commission, council, conference, panel, task force, or similar group, formed by a department or agency of the Federal Government in the interest of obtaining advice or recommendations, or for any other purpose, and which is not composed predominantly of members or representatives of a single industry or group of related industries, or of any subdivision of a single industry made on a geographic, service, or product basis.

The chairman of an advisory committee may be an FDA official or a non-FDA member of the committee appointed by the Commissioner of Food and Drugs. The executive secretary is a member of the FDA staff. The agenda is prepared by the executive secretary in cooperation with the chairman, if he is not an FDA employee, or by the chairman, if he is an FDA employee. A member of the FDA staff attends all meetings of the committee with authority to adjourn the meeting when he considers it in the public interest. During their time of service, members of advisory committees are special Government employees.

The Committee Management Office is responsible for establishing a committee and for appointment of members to it. For administrative purposes, each advisory committee is assigned to the FDA group which requested it. The official files for advisory committees are kept in the office of Committee Management.

The following standing and continuing advisory committees, of which all but two have been established since 1963, are now active:

Board of Tea Experts (1897), Food Standards (April 1938), National Advisory Food and Drug Council (February 1964), Medical Advisory Board (April 1964), Teratogenic Effect of Certain Drugs (April 1964), Veterinary Medicine (November 1964), Obstetrics and Gynecology (April 1965), Protocols for Safety Evaluation (August 1965), Clinical Research Contracts (Biometric and Epidemiological Methodology) (November 1965), Respiratory and Anesthetic Drugs (March 1966), Research in the Biological and Physical Sciences (August 1966), Hematology (January 1967), Joint FDA-PHS Psychotomimetic Agents (March 1967).

The Drug Nomenclature Advisory Committee was established as a standing Committee in September 1967. It has not met, but will when the need arises.

The Abuse of Depressant and Stimulant Drugs Advisory Committee was established by statute and held

its first meeting in December 1965. It was transferred to the Department of Justice with the Bureau of Drug Abuse Control in April 1968.

Since 1963, the following *ad hoc* advisory committees have been established. They have completed their assignments and have been discharged.

Possible Nephrotoxicity from Phenacetin Misuse (December 1963), Daroil and Daroil Emulsions (February 1964), Review Tolerances for Aldrin and Dieldrin (August 1964), Aminopyrine and Dipyrone (August 1964), Investigational Drugs (September 1964), Veterinary Medical and the Non-Medical Uses of Antibiotics (November 1964), Penicillin Contamination (December 1964), Endrin and Aldrin-Dieldrin Residues (May 1966).

**E**stablishment of the following specialty advisory committees has been approved by the Secretary, and the first meeting dates will be set when the need arises:

Anti-Infective Agents (August 1967), Cardiovascular and Renal Disorders (August 1967), Dental (August 1967), Dermatology (August 1967), Drug Experience (August 1967), Endocrinology (August 1967), Neuropharmacology (April 1967), Oncology (August 1967), Ophthalmology and Otorhinolaryngology (August 1967), Radioactive Pharmaceuticals (August 1967).

The Bureau of Medicine has requested one other specialty advisory committee, on Pediatric Nutrition.

The Food and Drug Administration is gratified to observe the patriotic response of private citizens when invited to serve on a public advisory committee. They have accepted the invitation as a recognition and as an opportunity to contribute their experience to helping FDA assure that food is wholesome and nutritious and that drugs are safe and effective.



Clem O. Miller, Ph.D.,  
is Committee  
Management Officer  
in the Office of  
the Commissioner.

---

**ATLANTA DISTRICT** A lot of approximately 652,-200 pounds of fishmeal shipped from Lima, Peru, was detained by the District on June 13 at the port of Savannah, Ga., because of *Salmonella* contamination. The lot, valued at \$35,100, was destined for a New York importer. When informed of the contamination, the importer started negotiations to have the fishmeal reconditioned by a heat process to destroy the *Salmonella* micro-organisms.

Fireworks with a wholesale value of more than \$3,500 were seized in the possession of various South Carolina dealers on June 28 after FDA filed 21 separate civil actions charging that the fireworks were banned hazardous substances while held for sale after shipment in interstate commerce, within the meaning of the Federal Hazardous Substances Act. The massive roundup and seizure involved 97 lots of articles commonly known as M-80's, cherry, aerial, repeat, and flash bombs, sky rockets, bursting comets, repeating mines, star and break shells, torpedoes, and crackerballs.

The action terminated more than a week of planning and undercover work by the District's inspectional, analytical, clerical, and administrative staffs.

An item in the May 1968 issue of FDA PAPERS concerning the seizure of 297 bags of rice contaminated with rodent urine and rodent and bird excreta at Great Southern Wholesale Grocery Corp., Miami, Fla., was misleading in that it omitted to mention that the rice was being held by the firm under insanitary conditions. There was no evidence to indicate that the contamination took place before the rice was received by the Miami firm, as might have been construed by the inadvertent mention in the item of the name of the manufacturer and shipper, Arkansas Rice Growers Co-op Association, Stuttgart, Ark.

**BALTIMORE DISTRICT** Charged with contamination of food products with insects and insect filth as a result of insanitary storage conditions, Arnold L. Adams, trading as Arnold L. Adams Wholesale Co., Rocky Mount, N.C., was fined \$500 and placed on a year's probation on June 18. Under the court's finding, the defendant will be liable for an additional fine of \$500 on each of four remaining counts, should he violate the terms of the probation.

Because of insect infestation and decomposition, 18,810 pounds of cassia bark (Chinese cinnamon), valued at \$15,800, were seized at Richmond, Va., on June 24. The cassia was shipped by Imperial Commodities Corp., New York, N. Y.

**BOSTON DISTRICT** In cooperation with the New England Fisheries Institute, the District held bacteriological workshops for the processed seafoods industry on June 25 and 27. Government and industry representatives participated in the program, which included a film on bacteriological contamination and an illustrated discussion of problems in the shrimp industry. Recent inspections had uncovered significant adverse conditions in 47 percent of the firms producing processed seafoods, which are highly susceptible to bacteriological contamination. The workshops, therefore, were timely and stressed correction of problems by voluntary compliance.

Tower Hill Bakery Corp., Lawrence, Mass., and Andrew Puglise, president and treasurer of the firm, were found guilty on May 17 of causing enriched bread to be adulterated with insect filth. The corporation was fined a total of \$2,000. The individual defendant was given jail sentences totaling 1 year; sentences were suspended with probation of 2 years.

**BUFFALO DISTRICT** A New York drug firm, its officers, agents, and employees have been enjoined from shipping adulterated or misbranded drugs in interstate commerce until good manufacturing practices have been established. All drugs on hand were ordered to be reworked, destroyed, or otherwise brought into compliance. Jenkins Laboratories, Inc., Auburn, consented to the decree of permanent injunction on June 21 and discontinued all manufacturing operations.

**CINCINNATI DISTRICT** A lot of 42,800 "Special Formula" tablets, shipped by C. M. Bundy Co., Cincinnati, Ohio, was seized recently in Indianapolis, Ind. FDA charged that the label failed to bear adequate directions for use, when shipped by the Ohio firm.

**DALLAS DISTRICT** A trial scheduled to have been held August 19 was to determine a Texas firm's future actions in the drug business.

The U.S. Attorney for the Northern Judicial District of Texas had filed a complaint on June 19 asking for a permanent injunction against the Lanpar Co., Dallas, seeking to halt the firm's continued distribution of combination thyroid-digitalis drugs for use in weight reduction regimens. At a hearing on June 26, the court denied request for a temporary restraining order and set the case for trial in August.

In June the Church of Scientology of Texas, and others, brought a civil action in the Western Judicial District

of Texas against the Secretary of Health, Education, and Welfare, the Commissioner of Food and Drugs, and FDA's Dallas District Director, to " \* \* \* enjoin seizure from the United States mails and detention of confessional aids of the Church of Scientology of Texas, its ministers and its members and students of religious instruction \* \* \*." The action is in response to FDA detentions of "Hubbard E. Meters" offered for entry from England. "E. Meters" are considered misbranded therapeutic devices by FDA (see Field Reports, Atlanta District, May 1968 issue of FDA PAPERS).

**DETROIT DISTRICT** A District-sponsored conference held at Indiana University, Bloomington, on June 17, was attended by 150 officers and delegates of the Indiana State AFL-CIO. The conference, conducted by the Detroit District Consumer Specialist, Diane M. Place, was entitled "FDA and Consumer Interests."

**LOS ANGELES DISTRICT** Failure to bear adequate directions for use, in labeling furnished by the distributor, and lack of approved New Drug Application resulted in seizure of 3,400 vials of "Robese Injection" in June. The drug, intended for use in obesity clinics, contained amphetamine salt and peptones. After shipment from Chicago, Ill., the drug was distributed by Rocky Mountain Pharmacal Co., Phoenix, Ariz. Seizure was made in Phoenix at the firm's warehouse and at two obesity clinics.

Residues of the pesticide endrin present in fresh carrots grown and packed by Henning Produce Co., Phoenix, Ariz., formed the basis for voluntary destruction of four shipments made to Houston, Tex., Boston, Mass., Sioux City, Iowa, and Chicago, Ill. The grower-packer offered to destroy the carrots after learning that FDA had found endrin in samples from outgoing shipments. FDA's investigation was made after District Inspector's discovered that the firm's own field samples showed pesticide residues. A total of 3,561 crates or bags, each containing 48 1-pound bags, was destroyed by dumping.

**NEW ORLEANS DISTRICT** The District's dollar volume of import detentions for fiscal 1968 was \$1,751,710. This was a 75 percent increase over the \$998,781 value for fiscal 1967. Included in the 1968 total is a brazil nut detention in June which alone was valued at almost \$102,000. The nuts, offered for entry at the port of Mobile, were detained because of aflatoxin content.

**NEW YORK DISTRICT** One of the first regulatory actions taken under FDA's intensified drug inspection program represents a case based solely on evidence found at a factory as the basis for alleging violations under Good Manufacturing Practice Regulations.

On July 9 a temporary restraining order was issued by a New York District court prohibiting Austin

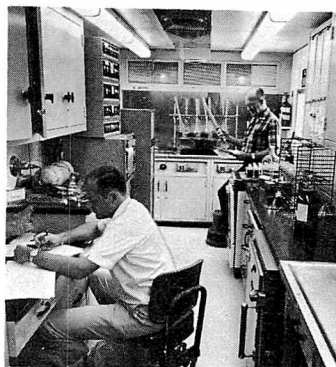
Pharmaceuticals, Inc., Island Park, N.Y., from shipping any drugs in interstate commerce pending a hearing on preliminary injunction. The hearing was held July 12, at which time the firm agreed to a permanent injunction, which was entered July 16.

Stating that the Government's evidence was overwhelming, a New Jersey District court in June found Christie Industries, Inc., Dumont, N.J., and its president, Edwin C. Christie, guilty of shipping fireworks assembly kits in interstate commerce in violation of a preliminary injunction. Mr. Christie was released on bond and was ordered to appear for sentencing on completion of a probation report.

**PHILADELPHIA DISTRICT** Over a period of 3 months, the District conducted an extensive training program to fit its inspectors to make intensified drug inspections of selected firms in the District's territory. A number of inspectors from neighboring FDA Districts participated in these sessions, which included lectures by supervisory personnel and by members of the Temple School of Pharmacy, Philadelphia. The training also included work demonstrations at these cooperating groups: General Electric Missile and Space Laboratories, Valley Forge, Pa.; Stokes Pharmaceutical Equipment Dept., Penn Salt Chemical Corp., Warminster, Pa.; and at Temple School of Pharmacy.

A Pennsylvania firm's color certification services were suspended as of June 12. Suspension was in addition to decertification of three lots of colors by FDA earlier in the year, when an investigation revealed improprieties in certification procedures at Bates Div., Crompton & Knowles, Reading.

**SAN FRANCISCO DISTRICT** A workshop for the medicated feed industry held in Fresno, Calif., on June 18 was cosponsored by the San Francisco and Los Angeles Districts in cooperation with the California Feed and Grain Dealers Association and the California State Department of Agriculture. Approximately 120 representatives of feed manufacturers, cattle and poultry producers, and veterinary products manufacturers attended.



FDA chemists (from left), Evalds Jekabsons and Paul Marshall, at work in mobile laboratory.

As part of an overall consumer safety program in which Federal, State, and county agencies participate, FDA sent one of its mobile laboratories into the San Joaquin Valley early in June to start monitoring fresh fruits and vegetables for pesticide residues.

One of four such facilities operated by FDA, the portable lab contains

equipment capable of screening for minute quantities of pesticidal agents which must not exceed established tolerances determined to be safe. After the screening, final determination is made in the San Francisco District lab as to whether the residue level is violative, and if so, what action will be taken.

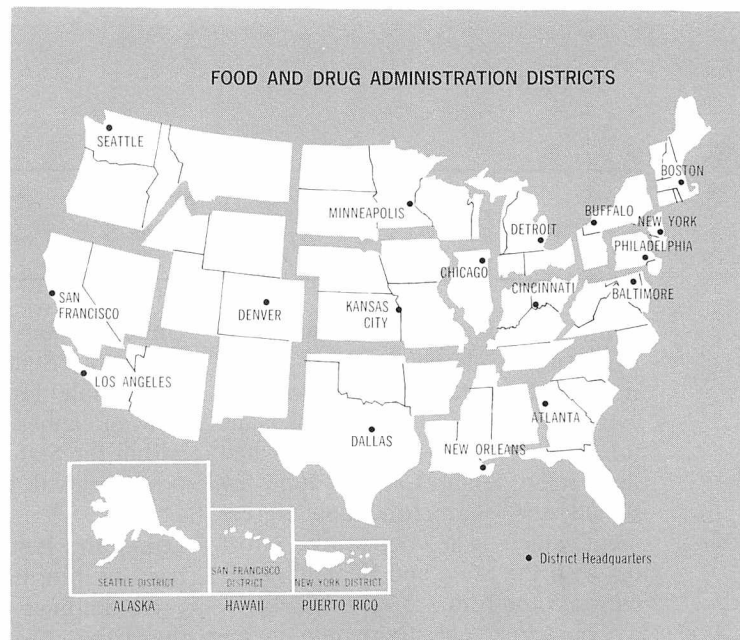
The laboratory, staffed by District chemists, was based at Stockton, Calif., until July 1, when it was moved to Salinas to begin screening of leafy and stem vegetables and strawberries until mid-August. It then was to be sent to Fresno for the grape harvest, before going to Los Angeles District for the winter vegetable harvest.

Because of the length of time lab workers must be away from home, different chemists go on duty in each place the laboratory visits.

As a result of the mobile laboratory visits, pesticide sample screening time has been reduced considerably, which is of benefit to the District as well as to the grower, shipper, or processor.

**SEATTLE DISTRICT** Tentative arrangements have been made with the Alaska Department of Health and Welfare for its inspectional personnel to accompany District Inspectors during fishery inspections. FDA hopes that this additional training, especially in the microbiological areas, will greatly increase the Alaska Department Inspector's efficiency, knowledge, and skills in inspectional and sample collecting techniques. The District has offered a standing invitation to cover the entire 1968 fishing season.

Also as part of the cooperative fishery inspection program, the Alaska Department of Health and Welfare is analyzing samples of water used in processing, col-



lected by the District during coverage of salmon canneries.

During a recent salmon cannery inspection at Alakanuk, Alaska, on the Yukon River, the District encountered operating conditions which failed by a wide margin to comply with the 1968 requirements of the Canned Salmon Control Plan. Among other things, untreated water from an obviously polluted source was being used in processing. Representatives of the firm, the National Canners Association, and Seattle District met to discuss the problem and the decision to be made. Under the 1968 requirements of the Plan, which have been agreed to by 61 companies producing more than 98 percent of the Nation's canned salmon, any participating plant not in compliance will be suspended until corrections are made.

#### FDA DISTRICT OFFICES

**ATLANTA** 60 Eighth Street, N.E.  
Atlanta, Georgia 30309

**BALTIMORE** 900 Madison Avenue  
Baltimore, Maryland 21201

**BOSTON** 585 Commercial Street  
Boston, Massachusetts 02109

**BUFFALO** 599 Delaware Avenue  
Buffalo, New York 14202

**CHICAGO** Main Post Office Bldg.  
Rm. 1222/433 W. Van Buren Street  
Chicago, Illinois 60607

**CINCINNATI** 1141 Central Parkway  
Cincinnati, Ohio 45202

**DALLAS** 3032 Bryan Street  
Dallas, Texas 75204

**DENVER** New Customhouse Bldg.  
Rm. 5604/20th & California Streets  
Denver, Colorado 80202

**DETROIT** 1560 E. Jefferson Avenue  
Detroit, Michigan 48207

**KANSAS CITY** 1009 Cherry Street  
Kansas City, Missouri 64106

**LOS ANGELES** 1521 W. Pico Boulevard  
Los Angeles, California 90015

**MINNEAPOLIS** 240 Hennepin Avenue  
Minneapolis, Minnesota 55401

**NEW ORLEANS** U.S. Customhouse  
Rm. 222/423 Canal Street  
New Orleans, Louisiana 70130

**NEW YORK** 850 3rd Avenue (at 30th Street)  
Rm. 700/Brooklyn, New York 11232

**PHILADELPHIA** U.S. Customhouse  
Rm. 1204/2nd & Chestnut Streets  
Philadelphia, Pennsylvania 19106

**SAN FRANCISCO** Federal Office Bldg.  
Rm. 518/50 Fulton Street  
San Francisco, California 94102

**SEATTLE** Federal Office Bldg.  
Rm. 501/909 First Avenue  
Seattle, Washington 98104

#### FDA REGIONAL ASSISTANT COMMISSIONERS' OFFICES

##### REGIONS I-IX

**BOSTON** J. F. Kennedy Federal Bldg.  
Government Center  
Boston, Massachusetts 02203

**NEW YORK** 42 Broadway  
New York, New York 10004

**CHARLOTTESVILLE** 220 7th Street, N.E.  
Charlottesville, Virginia 22901

**ATLANTA** 50 7th Street, N.E.  
Rm. 404/Atlanta, Georgia 30323

**CHICAGO** New Post Office Bldg.  
433 W. Van Buren Street  
Chicago, Illinois 60607

**KANSAS CITY** 601 East 12th Street  
Kansas City, Missouri 64106

**DALLAS** 1114 Commerce Street  
Rm. 911/Dallas, Texas 75202

**DENVER** Federal Office Bldg.  
19th & Stout Streets  
Denver, Colorado 80202

**SAN FRANCISCO** Federal Office Bldg.  
Rm. 416/50 Fulton Street  
San Francisco, California 94102



---

# state actions

---

**State Cooperates in Plan** The Minnesota State Department of Agriculture became the first State agency to take part in FDA's pilot plans for industry self-regulation, when the Green Giant Co. on June 24 signed the self-certification agreement which is a cooperative effort between the State and Federal agencies and the firm.

The agreement, to remain in effect for 1 year, covers the production of canned peas, whole kernel corn, peas with pearl onions, and corn with sweet red and green peppers at the firm's plant at Blue Earth, Minn.

Both regulatory agencies will continue to make inspections as they deem necessary, furnishing detailed reports to the company. Green Giant will maintain a self-inspection and quality control program, making results available to FDA and to the State agency.

Through a full exchange of information between the firm and the regulatory agencies, the goal of better consumer protection through increased industry initiative should be achieved, the participants believe.

**Florida Chemist Honored** Dr. Vincent Evans Stewart, State Chemist and Director, Division of Chemistry, Florida Department of Agriculture, received the Harvey W. Wiley Award for 1968 at the annual conference of the Association of Food and Drug Officials of the United States, held in June at Hartford, Conn.

The Wiley Award is presented annually to a member of the Association in recognition of his outstanding contributions in the field of food, drug, and cosmetic law enforcement.

**Indiana Assumes Inspections** The Food and Drugs Division of the Indiana State Board of Health and FDA's Cincinnati and Detroit Districts have signed a Memorandum of

Understanding for fiscal 1969, under which the State of Indiana will be responsible for making all inspections of canneries and bottling plants within the State. Activities involving pesticides will be shared.

**Louisiana Issues Warning** On the basis of information in copies of adverse findings letters furnished by the FDA to the Louisiana State Board of Health, Food and Drugs Division, after inspection of certain drug manufacturers, the State has notified these firms that either they must conform to requirements of the FDC Act in both labeling and manufacturing practices or their labels will be unacceptable for re-registration at the end of the calendar year.

FDA reports adverse findings in letters by certified mail to the top management of involved firms following establishment inspections where significant adverse conditions or practices are observed or are identified in subsequent review. The new reporting system, started in March 1968, gives industry the opportunity to voluntarily correct the problem without further Government action.

The State's cooperation after receiving copies of such letters brought about a recent voluntary destruction by a New Orleans drug firm of antibiotics worth more than \$1,000.

**State-FDA Extend Agreement** The Food Regulatory Section of the Virginia State Department of Agriculture and Commerce and FDA's Baltimore District have extended a Memorandum of Agreement signed earlier in the year to include the State's assumption of responsibility for inspections of wheat and corn mills and canneries, except for fish and mushroom canneries, which FDA will continue to inspect.

Both agreed that when inspections reveal continuing objectionable conditions in any of these firms, the State may request the Baltimore Dis-

trict to take part in a joint inspection to obtain corrective actions and to prevent the intrastate and interstate shipment of violative products.

It was further agreed that both agencies would explore other areas in which cooperative planning may avoid duplication of effort.

**State-Federal Agreement** The Pennsylvania State Department of Agriculture and the Consumer and Marketing Services, U.S. Department of Agriculture, have signed an agreement establishing cooperative State-Federal meat inspection services. Pennsylvania becomes the 19th State to sign such an agreement under the U.S. Wholesome Meat Act, enacted in 1967.

The agreement provides a 50-50 cost-sharing plan under which USDA will match, dollar for dollar, the money spent by the State on mandatory meat inspections. This accords with provisions of the State's new mandatory meat and poultry inspection law signed by Governor Raymond P. Shafer on July 9.

The State's new law, which replaces a 53-year-old meat hygiene law, is another important step forward in the State Department of Agriculture's broad program of consumer protection. It is described by Governor Shafer as "evidence of Pennsylvania's determination to give consumers the protection they need in the modern market place."

Unlike the meat hygiene law, which provided inspection service on a voluntary basis for butchers and packers, the new law provides for livestock and poultry inspection before and after slaughter and for inspection of sanitary conditions of slaughter plants and packing houses. It also requires reinspection of meats and poultry during manufacturing and processing and makes all meat and meat products subject to further reinspection in trade channels.

# seizures and post office cases

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

A total of 48 seizure actions to remove adulterated, misbranded, and unsafe products from the consumer market were reported in May/June. These included 23 seizures of foods:

21 because of contamination, and 2 because of economic violations. Other seizures included 17 of drugs, 3 of medical devices, 1 of cosmetics, and 4 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>FOOD / Contamination, Spoilage, Insanitary Handling</b>		
Cassia/Brooklyn, N.Y. 5/28/68	Morris J. Golombeck/Brooklyn, N.Y. (D)	Insect infested while held for sale.
Brooklyn, N.Y. 6/4/68	"	"
New York, N.Y. 5/29/68	Fidelity Warehouse Co./New York, N.Y. (D)	"
Brooklyn, N.Y. 5/31/68	Imported from Indonesia.	"
Totowa, N.J. 5/29/68	Knickerbocker Mills Co./Totowa, N.J. (D)	"
Detroit, Mich. 6/7/68	A. A. Sayia & Co., Agent/New York, N.Y. (S)	Moldy and insect contaminated.
Brooklyn, N.Y. 5/31/68	Imported from Indonesia.	"
Brooklyn, N.Y. 5/31/68	"	Insect infested while held for sale.
Cattish fillets, frozen/New Orleans, La. 5/28/68	Dahlberg-Laurent Sales Co., Inc./New Orleans, La. (D)	Decomposed.
Haddock fillets and cattfish fillets, frozen/New Orleans, La. 5/28/68	National Food Stores/New Orleans, La. (D)	"
Pecans, shelled, pieces/St. Louis, Mo. 3/22/68	Louisiana Pecan Shelling Co./Mansfield, La. (M, S)	Prepared and packed under insanitary conditions; E. coli.
Pepper, black/Brooklyn, N.Y. 5/31/68	Municipal Warehouse/Brooklyn, N.Y. (D)	Moldy and insect contaminated.
Potatoes, whole, sweet/Little Rock, Ark. 6/3/68	B. F. Trappey's Sons, Inc./Lafayette, La. (P, S)	Decomposed.
hash brown/Atlanta, Ga. 6/20/68	Idaho Frozen Foods/Twin Falls, Idaho (M, S)	Prepared and packed under insanitary conditions; E. coli, excessive coliforms.
Salmon, smoked, frozen/Everett, Wash., and Bellingham, Wash. 4/1 & 4/16/68	Northern Products Co./Seattle, Wash. (S)	Decomposed.
Sardines/Okeechobee, Fla. 5/20/68	North Atlantic Packing Co./Brookline, Mass. (S)	Swelled, leaky cans.
Shrimp, frozen/Los Angeles, Calif. 5/15/68	Kermin Frozen Foods/Los Angeles, Calif. (D)	High bacterial count.
Trout fillets/New Orleans, La. 5/28/68	National Food Stores/New Orleans, La. (D)	Decomposed.
Turkiye, T.I.S., shelled filberts/Detroit, Mich. 5/20/68	Philip Olender Co./Detroit, Mich. (D)	Rodent contaminated.
Walnut kernels, black/Cleveland, Ohio 5/24/68	Woodland Nut Co./Woodland, Calif. (P, S)	E. coli contaminated.
<b>Economic Violations</b>		
Nuts, mixed, salted/Newark, N.J. 5/14/68	Aster Nut Products, Inc./Boykins, Va.	Label vignette, depicting substantial quantities of mixed nuts other than peanuts, is false and misleading for an article consisting mainly of peanuts.
Shrimp, breaded, frozen/Los Angeles, Calif. 5/10/68	Warner Poultry Co./Los Angeles, Calif. (D)	Label vignette, depicting whole, tail-on breaded shrimp, is false and misleading for a product consisting mainly of breaded shrimp pieces.
<b>DRUGS / Human Use</b>		
Alabin Powder, Alabin Ointment/Erie, Pa. 6/5/68	Aseptico Laboratories, Inc./Lodport, N.Y. (M, S)	False and misleading claims and inadequate directions for use; ointment additionally fails to bear adequate warnings for safe use.
Aqualized Solprogel Powder Topical, Aqualized Solprogel Aerosol Powder, Topi-Stat/Dallas, Tex. 5/23/68	Truett Laboratories/Dallas, Tex. (D)	Inadequate directions and warnings against use in pathological conditions where use may be dangerous to health; label fails to bear common or usual name of each active ingredient.
Bariatric Formula Thyroid-Digitalis tablets/Galveston, Tex. 5/16/68	Bariatric Corporation/Coral Gables, Fla. (S)	New drug not approved for safety and efficacy; false and misleading claims; inadequate directions for use; dangerous to health when used in dosage or with frequency recommended.
Boric acid solution and ointment/Pittsburgh, Pa. 5/27/68	Mine Safety Appliance Co./Pittsburgh, Pa. (D)	Boric acid solution not in conformity with NF, ointment (bulk and repacked) deficient in boric acid content; repackaged ointment fails to bear adequate warnings and an accurate quantity of contents statement.
Golden-50 Tablets/Chicago, Ill. 5/9/68	Golden-50 Pharmaceutical Co./Chicago, Ill. (D)	False and misleading claims in labeling.
Hadensa rectal ointment/Washington, D.C. 5/22/68	Pharmaceutical Enterprises/Atlanta, Ga. (M, S)	Inadequate directions for use; inaccurate quantity of contents statement.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>DRUGS / Human Use (cont'd)</b>		
K-Q & Lustre Too/Columbia, S.C. 5/29/68	Bailey Laboratories, Inc./Buffalo, N.Y. (M, S)	False and misleading claims for control of dandruff, as a scalp treatment, to promote healthy hair growth; label fails to bear established name of each active ingredient. Below labeled quality; fail to disintegrate properly.
Methazem tablets/Oakmont, Pa. 5/31/68	Cowley Pharmaceuticals, Inc./Auburn, Mass. (M, S)	
Mint Glo/Chicago, Ill. 5/12/68	Larson Laboratories, Inc./Erie, Pa. (M, S)	False and misleading claims.
Panrau 50 mg. and 100 mg., Elixir Panzol, Syrup Panverm/New Orleans, La. 6/3/68	C. M. Bundy Co./Cincinnati, Ohio (M)	Inadequate directions for use.
Phenobarbital sodium capsules/Dayton, Ohio 5/16/68	Formulations, Inc./Milwaukee, Wis. (M, S)	Below USP quality standard; inaccurate statement of quantity of contents.
Prednisolone tablets/Nampa, Idaho 5/23/68	Basic Health Center & Clinic/Nampa, Idaho (D)	Inadequate directions for use; label fails to bear "CAUTION" statement.
Private Formula No. 1555 (Co-Gel tablets)/Minneapolis, Minn. 5/15/68	Formulations, Inc./Milwaukee, Wis. (M, S)	Not in conformity with good manufacturing practice; below labeled purity and quality.
Private Formula No. 1746 (Niacin tablets 100 mg.)/Chicago, Ill. 6/10/68	"	Below NF requirements for weight variation.
Sulfadiazine 1.9 gr./Auburn, N.Y. 5/20/68	C. M. Bundy Co./Cincinnati, Ohio (M, S)	Inadequate directions for use.
Thyrodig T-13, T-32, Thyroid THO-5, Thyroid Anterior Pituitary TAP-3/Houston, Tex. 5/28/68	Western Research Labs./Denver, Colo. (M, S)	New drugs not approved for safety and efficacy; misbranded.
Y-Trate capsules/New Albany, Miss. 4/19/68	Nysco Labs., Inc./Long Island City, N.Y. (M, S)	New drug not approved for safety and efficacy; false and misleading claims; inadequate directions for use.
<b>MEDICAL DEVICES</b>		
Cristofv Anti-Fatigue/Houston, Tex. 5/17/68	Electrogen Industries, Inc./Westbury, Long Island, N.Y. (M, S)	False and misleading therapeutic claims.
Med. Toothpics/Cleveland, Ohio 5/13/68	Iodent Chemical Co./Detroit, Mich. (M, S)	False and misleading claims to be effective for promoting healthy gums.
Trim-Twist Exercisor/Newark, N.J. 4/30/68	Trim Twist, Inc./Coral Gables, Fla. (M, S)	False and misleading claims to tone and firm waistline, hips, buttocks, thighs, and arms, burn up 1240 calories per hour; inadequate direction for use.
<b>COSMETIC</b>		
Dark-Eyes/Denver, Colo. 6/12/68	"Dark-Eyes" Co./Chicago, Ill. (M, S)	Contains pyrogallol and silver nitrate, color additives not in conformity with regulations.
<b>HAZARDOUS SUBSTANCES</b>		
Boom No. 0, 2, 3 Aerial Flash Bomb, Globe Torpedoes, 2 Shot Sky Bombs/Gaffney, S.C. 6/11/68	Campbell's Wholesale Fireworks/Gaffney, S.C. (D)	Flammable toys, generating pressure, and lack warning information required by the Fed. Hazardous Substances Act.
Cherry Bomb Fireworks, Bulldog Salutes Fireworks/Chesnee, S.C. 6/11/68	B. T. Ezell Fireworks/Chesnee, S.C. (D)	"
M-80 Salutes, Cherry Bomb Salutes, Super Bulldog Salutes/Canby, Oreg. 5/10/68	New Jersey Fireworks Manufacturing Co., Inc./Vineland, N.J. (M, S)	"
Shotgun shells/St. Louis, Mo. 5/14/68	Underwriters Salvage Co. of Chicago/St. Louis, Mo. (D)	Misbranded hazardous substances, since ammunition was subjected to fire and water damage and is not ready for use in a pistol, revolver, rifle, or shotgun.

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

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

May 17, 1968: Fraud Order issued against **Ray Murphy, et al.**, Highland, Mich. Solicitations of orders and sale through the mails of a program for treatment and cure of arthritis.

#### Complaints Filed by the General Counsel Under 39 U.S.C. 4005 (Fraud)

May 23, 1968: **Dalidex, Inc.**, Brooklyn, N. Y. Solicitations of orders and sale through the mails of a cure for obesity.

May 28, 1968: **Dinora Products, Inc.**, Brooklyn, N. Y. Solicitations of orders and sale through the mails of an aphrodisiac and sexual stimulant.

#### Arrests, Indictments, or Convictions Occurring Under 18 U.S.C. 1341 (Fraud)

May 10, 1968: **Wendell G. Hendricks**, an unlicensed osteopath of Los Angeles, Calif., was placed on probation for 2 years, fined \$400, plus \$1,500 to be paid to California Board of Medical Examiners. Hendricks was allegedly preparing to administer a serum to a supposedly retarded child. Fifteen such injections, at a cost of \$1,000, were supposed to cure the girl. An estimated \$15,000 to \$20,000 was filched in a continuous scheme. In this investigation, the Postal Inspection Service cooperated with State and local authorities who had had Hendricks under investigation for a number of years.



# notices of judgment

## NOTICES OF JUDGMENT on Seizure Actions

### FOOD / Poisonous and Deleterious Substances

- Cabbage, fresh**, at Louisville, W. Dist. Ky.  
Charged 9-21-66: when shipped by Horton Produce Co., Hillsville, Va., the article contained the added pesticide chemical toxaphene in excess of established tolerance; 402(a)(2)(B). Consent decree ordered destruction. (1)
- Cabbage, fresh**, at Mobile, S. Dist. Ala.  
Charged 9-29-66: when shipped by Newman Grocery & Produce Co., Hillsville, Va., the article contained the pesticide chemical toxaphene in excess of the tolerance; 402(a)(2)(B). Consent decree ordered destruction. (2)
- Egg product, dried, Bud**, at San Francisco, N. Dist. Calif.  
Charged 10-4-66: when shipped by Anheuser-Busch, Inc., Omaha, Nebr., the article contained the added poisonous and deleterious substance *Salmonella* micro-organisms; 402(a)(1). Consent decree authorized release to shipper for reprocessing. (3)
- Egg product, dried, Fortex**, at West Palm Beach, S. Dist. Fla.  
Charged on or about 1-27-67 and amended 3-20-67: when shipped by Ballas Egg Products Corp., Zanesville, Ohio, and Ballas Frozen Foods, Inc., New York, N.Y., the article contained the added poisonous and deleterious substance *Salmonella* micro-organisms; 402(a)(1). The article was claimed by Ballas Egg Products Corp. After litigation, a consent decree of condemnation authorized release to the claimant for salvaging. (4)
- Egg product, dried, Sweet-N-Lite**, at Topeka, Dist. Kans.  
Charged 10-11-65: while held for sale, the article, which had been prepared and packed by Seymour Foods Co., Div. Norris Grain Co., Topeka, Kans., from ingredients shipped in interstate commerce, contained the added poisonous and deleterious substance *Salmonella* micro-organisms; 402(a)(1). Consent decree authorized release to the packer for salvaging. (5)
- Eggs, frozen**, at Dallas, N. Dist. Tex.  
Charged 6-11-65: when shipped by Delight Certified Egg Farms, Inc., Hope, Ark., the article contained the added poisonous and deleterious substance *Salmonella* micro-organisms; 402(a)(1). Consent decree authorized release to shipper for reconditioning. (6)

### FOOD / Contamination, Spoilage, Insanitary Handling

- Almonds, shelled**, at Cincinnati, S. Dist. Ohio.  
Charged 3-30-66: while held by Baltimore & Ohio Warehouse Co., Cincinnati, Ohio, the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to California Almond Growers Exchange Co., Sacramento, Calif., for salvaging. (7)
- Beans, pinto**, at Crows Landing, N. Dist. Calif.  
Charged 4-6-65: while held by John F. Grusec Co., Crows Landing, Calif., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for reconditioning. (8)
- Beans, red**, at Los Angeles, C. Dist. Calif.  
Charged 7-15-66: while held by American Warehouse, Los Angeles, Calif., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to Nishimoto Trading Co., Los Angeles, Calif., for salvaging. (9)
- Breadier mix**, at Indianapolis, S. Dist. Ind.  
Charged 3-25-66: while held by Rolling Mills, Inc., Indianapolis, Ind., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (10)
- Butter**, at Hagerstown, Dist. Md.  
Charged 4-18-66: when shipped by United States Security Warehouse, Columbus, Ga., the article contained a smoky odor and flavor due to a fire in shipper's warehouse; 402(a)(3). Consent decree authorized release to shipper for salvaging. (11)
- Butter**, at Hartford, Dist. Conn.  
Charged 5-13-67: while held for sale, the article had an odor and flavor of a petroleum distillate due to solvent fumes from a concrete sealer used by Bozzuto's, Inc., Cheshire, Conn., to treat the floor of the article's storage area; 402(a)(3). Consent decree authorized release to Land O'Lakes Creameries, Inc., Hartford, Conn., for reconditioning. (12)
- Butter**, at St. Paul, Dist. Minn.  
Charged 11-13-67: when shipped by Rugby Creamery Co., Rugby, N. Dak., the article contained decomposed butter; 402(a)(3). Default decree ordered destruction. (13)
- Corn, canned**, at Nevada, W. Dist. Mo.  
Charged on or about 4-28-66: when shipped by Ackley Food Processors, Inc., Ackley, Iowa, the article, labeled in part "Summer Girl Brand Cream Style Gold Sweet Corn . . . Isis Foods, Inc. Distributors . . . Kansas City, Mo.," contained insects; 402(a)(3). Default decree ordered destruction. (14)
- Eggs, frozen**, at Brooklyn, E. Dist. N.Y.  
Charged 10-22-65: when shipped by Nulaid Farms Association, San Leandro, Calif., the article contained decomposed eggs; 402(a)(3). Consent decree authorized release to Pacific Growers, San Leandro, Calif., for salvaging. (15)
- Eggs, frozen**, at Brooklyn, E. Dist. N.Y.  
Charged 12-10-65: when shipped by Earl K. Riley Co., Chicago, Ill., the article, labeled in part "Whole Eggs . . . Packed by Blue Ribbon Prod. Los Angeles," contained decomposed eggs; 402(a)(3). Consent decree authorized release to L. Rudolf Co., Inc., New York, N.Y., for salvaging. (16)
- Eggs, frozen**, at Landover and Silver Spring, Dist. Md.  
Charged 2-17-66: when shipped by Olson Bros., Inc., La Habra, Calif., the article contained decomposed eggs; 402(a)(3). Decree ordered destruction and payment of costs by claimant-shipper. (17)
- Flour**, at Brooklyn, E. Dist. N.Y.  
Charged 2-16-65: while held for sale, the article had been damaged by river water and smoke due to a shipboard fire; 402(a)(3). Consent decree authorized release to S. A. Wald & Co., Jersey City, N.J., for nonfood industrial use. (18)
- Flour**, at Carthage, E. Dist. Tex.  
Charged 6-23-66: while held by Magnolia Grocery Co., Carthage, Tex., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (19)
- Flour**, at Los Angeles, S. Dist. Calif.  
Charged 3-17-66: while in transit in a rodent-infested railcar, the article was rodent gnawed and contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to California Grocery Trading Co., Inc., Los Angeles, Calif., for salvaging. (20)
- Lobster tails**, at New York, S. Dist. N.Y.  
Charged 4-29-66: while held for sale, the article contained decomposed lobster tails; 402(a)(3). Default decree ordered destruction. (21)
- Mushrooms, stems and pieces, canned**, at Kansas City, W. Dist. Mo.  
Charged 2-4-66: when shipped by Brandywine Mushroom Corp., Div. Borden Co., West Chester, Pa., the article contained decomposed mushrooms; 402(a)(3). Default decree ordered destruction. (22)
- Peanuts, raw, shelled**, at Sioux City, N. Dist. Iowa.  
Charged 7-6-66: when shipped by Luverne Peanut Co., Luverne, Ala., the article contained insect filth; 402(a)(3). Consent decree authorized release to shipper for reconditioning. (23)
- Peauts, unshelled**, at Downey, S. Dist. Calif.  
Charged 7-13-66: when shipped by Hancock Peanut Co., Courtland, Va., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to All American Nut Co., Inc., Downey, Calif., for reconditioning. (24)
- Pecans, unshelled**, at Mobile, S. Dist. Ala.  
Charged 12-21-64: [while held for sale], the article contained rancid and moldy nuts and empty shells; 402(a)(3). Consent decree authorized release to Employers Fire Insurance Co. of Massachusetts for reprocessing. (25)
- Pectin and canned corn, creamed**, at Detroit, E. Dist. Mich.  
Charged 6-13-66: while held by Arrow Salvage, Inc., Detroit, Mich., the articles were held under insanitary conditions whereby they may have been rendered injurious to health, since chlordane was present on their containers; 402(a)(4). Default decree ordered destruction. (26)
- Rice**, at Dayton, S. Dist. Ohio.  
Charged 5-28-66: while held by Peerless Storage Co., Dayton, Ohio, the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree authorized donation for use as animal feed. (27)
- Rice**, at Modesto, N. Dist. Calif.  
Charged 5-20-66: while held by Hoskings Food Products Co., Modesto, Calif., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (28)
- Rice, wild, instant**, at Chicago, N. Dist. Ill.  
Charged 8-12-66: when shipped by Walter Erickson (Arrowhead Canning Co.), Grand Rapids, Minn., the article, labeled in part "Instant Wild Rice . . . Reese Finer Foods Inc. . . . Chicago," contained *E. coli* and bacterial filth; 402(a)(3). Consent decree authorized release to Reese Finer Foods, Inc., Chicago, Ill., and Pet Milk Co., St. Louis, Mo., for reconditioning. (29)
- Sage leaves**, at Memphis, W. Dist. Tenn.  
Charged 11-16-65: while held by Vaiden Warehouse, Memphis, Tenn., the article contained rodent and insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Pee Dee Co., Memphis, Tenn., for reconditioning. (30)
- Sesame seeds, poppyseeds, and caraway seeds**, at New York, S. Dist. N.Y.  
Charged 4-19-66: while held by Railroad Stores, Inc., New York, N.Y., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Louis Furth, Inc., New York, N.Y., for salvaging. (31)
- Shrimp, breaded**, at Indianapolis, S. Dist. Ind.  
Charged 9-30-66: when shipped by Booth Fisheries Corp., Brownsville, Tex., the article contained insects and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (32)
- Strawberries, sliced, frozen, Simplot**, at Caldwell, Dist. Idaho.  
Charged 10-5-66: when shipped by Kelley, Farquhar & Co., Salem, Oreg., the article contained decomposed strawberries; 402(a)(3). Consent decree authorized release to shipper for salvaging. (33)
- Tomatoes, canned, Truworth**, at Bay City, E. Dist. Mich.  
Charged 1-5-66: when shipped by Hirtzel Canning Co., Toledo, Ohio, the article contained decomposed tomato material; 402(a)(3). Consent decree authorized release to shipper for salvaging. (34)
- Vinegar**, at Dallas, N. Dist. Tex.  
Charged 2-7-66: while held by Richard Colgin Co., Inc., Dallas, Tex., the article, which had been repacked by the dealer, contained insect filth; 402(a)(3). Default decree ordered destruction. (35)
- Wafers, vanilla**, at Marietta, E. Dist. Okla.  
Charged 6-15-66: when returned to the manufacturer, Julian Ball Industries, Inc., Marietta, Okla., the article contained rodent filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (36)
- Wheat**, at Kansas City, Dist. Kans.  
Charged 5-18-66: when shipped by Farmers Cooperative Elevator Association, Washington, Kans., to Kansas City, Mo., and reshipped to Kansas City, Kans., the article contained rodent filth; 402(a)(3). Consent decree authorized release to Farmers Union Cooperative Marketing Association for salvaging. (37)
- Wheat**, at Minneapolis, Dist. Minn.  
Charged 3-3-66: when shipped by Farmers Union Elevator Co., Minot, N. Dak., the article contained rodent filth; 402(a)(3). Consent decree authorized release to shipper for reconditioning. (38)
- Whitefish**, at Detroit, E. Dist. Mich.  
Charged on or about 6-28-66: when shipped from Canada by unknown shipper, the article contained parasitic cysts; 402(a)(3). Default decree ordered destruction. (39)
- Zucca melon balls**, at Brooklyn, E. Dist. N.Y.  
Charged on or about 4-1-66: when shipped by California Zucca Melon Products, Palermo, Calif., the article contained insect filth and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (40)

### FOOD / Economic and Labeling Violations

- Butter**, at Brooklyn, E. Dist. N.Y.  
Charged 12-19-66: while held by Sicuro Bros., Inc., Brooklyn, N.Y., the article, which had been packaged by the dealer, was short weight; 403(e)(2). Default decree authorized donation to public/charitable institution. (41)
- Candy, various kinds**, at Los Angeles, S. Dist. Calif.  
Charged 7-25-66: when shipped by G. Scaccianoce, Bronx, N.Y., the labels lacked the name and place of business of the manufacturer, packer, or distributor, and lacked a quantity of contents statement; and the labels of some of the articles lacked the common or usual name of each ingredient; 403(e)(1), 403(e)(2), 403(i)(2). Consent decree authorized release to F & M Importing Co., Los Angeles, Calif., for reconditioning. (42)
- Candy bars, Rio**, at Chicago, N. Dist. Ill.  
Charged 9-9-66: when shipped by George Ziegler Co., Milwaukee, Wis., the label statements "no sugar," "oodles of non-fat milk," and "dietetic" were false and misleading as claiming the article was of significant value for maintaining and reducing body weights; and the name and place of business of the distributor, the statement of weight, and the ingredient statement were inconspicuously placed, since they were printed on the back of the candy bar label; 403(a), 403(f). Consent decree authorized release to Ziegler Products Co., Skokie, Ill., for relabeling. (43)
- Cereal, Hidden Valley's**, at Solana Beach, S. Dist. Calif.  
Charged 3-7-67: while held by Bernard Jensen Products, Solana Beach, Calif., for purpose of repacking, the repack labeling contained false and misleading nutritional

claims and the article lacked required information concerning its purported special dietary uses; 403(a), 403(j). Consent decree authorized release to dealer for salvaging. (44)

**Cheese dips, Gaymont's**, at Cincinnati, S. Dist. Ohio.  
Charged 10-3-66: when shipped by Oscar Ewing, Inc., t/a Food Specialties, Louisville, Ky., the variously flavored articles were short weight (approx. 5 to 8 percent); 403(e)(2). Default decree authorized donation to public/charitable institution. (45)

**Clams, canned**, at Los Angeles, S. Dist. Calif.  
Charged 7-29-66: while held by Inspectors Seafood Co., Los Angeles, Calif., the label references to article as "Pismo Clams" were false and misleading, since the article was eastern sea clams and not pismo clams; 403(a). Consent decree authorized release to dealer for salvaging. (46)

**Cookies, chocolate-flavored**, at North Kansas City, W. Dist. Mo.  
Charged 9-13-65: when the article labeled in part "Oven Gold . . . Cookies . . . Distributed by American Bakeries Company . . . Chicago" was shipped by Bake Line Products, Inc., Chicago, Ill., the name and place of business of the manufacturer, packer, or distributor, the statement of the quantity of contents, and the ingredient statement on the label were inconspicuous, since they were printed in dark brown ink on the transparent package containing the dark brown cookies; 403(f). Default decree authorized donation to charitable institutions. (47)

**Fruit cocktail, canned**, at Kansas City, Dist. Kans.  
Charged 4-6-67: when shipped by Duffy-Mott Co., Inc., Pratt-Low Div., Santa Clara Calif., the article lacked conformity to the standard of identity, since it was deficient in its pear and pineapple ingredients; 403(g)(1). Default decree ordered delivery to public institution. (48)

**Fruit-drink mixes, Sun Country**, at Hazelton, M. Dist. Pa.  
Charged 2-8-67: when shipped by Crystal Foods, Inc., Toms River, N.J., the label representations that the article was made from natural fruit juices and that the ingredient "Sweet 'n Low" was a sugar substitute when it was a combination of nutritive and nonnutritive sweeteners were false and misleading, the labels failed to bear the word "imitation" and immediately thereafter the name of the food imitated, namely, dehydrated grape juice, dehydrated orange juice, dehydrated lemon juice; and the label lacked a quantity of contents statement in terms of avoirdupois ounces; 403(a), 403(c), 403(e)(2). Default decree ordered destruction. (49)

**Ice cream topping and ice cream mix**, at Indianapolis, S. Dist. Ind.  
Charged 2-27-67: when shipped in bulk bags by Glister Milling Co., Chester, Ill., and while held by Unipak, Inc., Indianapolis, Ind., who repacked and labeled portions of the articles, the bulk and repack labels of the ice cream mix failed to bear the word "imitation" conspicuously, the repacked articles were short weight, and the label of the bulk articles lacked the common or usual name of each ingredient; 403(c), 403(e)(2), 403(f)(2). Consent decree authorized release to Glister Milling Co., Chester, Ill., for relabeling. (50)

**Oil blend, Rita**, at Philadelphia, E. Dist. Pa.  
Charged 8-19-64: while held by Leonard Foti, t/a Rosa Food Products Co. and/or Giacomo Foti, Philadelphia, Pa., the article, manufactured by dealer in part from olive oil shipped in interstate commerce, had the valuable constituent olive oil in part omitted or abstracted; a blend of cottonseed and peanut oil had been substituted in part for olive oil; and the label statement "10% Olive Oil" was false and misleading, since the article contained less olive oil; 402(b)(1), 402(b)(2), 403(a). Default decree ordered destruction. (51)

**Orange juice from concentrate**, at Las Vegas, Dist. Nev.  
Charged 8-7-67: when shipped by Instantwhip Los Angeles, Inc., Lynwood, Calif., the article labeled in part "Pink's Best Orange Juice . . . Packed for Pink's Produce Company, Las Vegas" failed to conform to the standard of identity, since it contained the nonpermitted ingredient potassium sorbate, and the label lacked the required name of the food, orange juice from concentrate; 403(g)(1), 403(g)(2). Default decree ordered destruction. (52)

**Peach halves, canned**, at Waynesboro, W. Dist. Va.  
Charged on or about 10-7-66: when shipped by Corbett Canning Co., Tabor City, N.C., the article, labeled in part "Tommy Tucker Brand . . . Distributed by B.R.G. Co., Inc., Waynesboro," fell below the standard of quality because of excessively hard peaches; 403(h)(1). Consent decree authorized release to shipper for relabeling. (53)

**Peach halves, canned, Dixie Delite**, at Columbus, S. Dist. Ohio.  
Charged 9-16-66: when shipped by Hendricks Canning Co., Easley, S.C., the article fell below the standard of quality because of excessively hard peach units; 402(h)(1). Consent decree authorized release to shipper for reprocessing. (54)

**Pickles, dill, Forman's**, at Rochester, W. Dist. N.Y.  
Charged 3-29-66: when shipped by Benjamin Lipitz Co., Philadelphia, Pa., the article's label lacked the common or usual name of each ingredient and failed to declare the chemical preservative, sodium benzoate; 403(i)(2), 403(k). Consent decree authorized release to L. C. Forman & Sons, Inc., Pittsford, N.Y., for relabeling. (55)

**Tomatoes, canned, Lord Chesterfield**, at Lincolnton, W. Dist. N.C.  
Charged 8-24-66: when shipped by McCall Farms, Effingham, S.C., the article fell below standard of quality because of excess peel; 403(h)(1). Consent decree authorized donation to public/charitable institution. (56)

#### VITAMINS / DIETARY FOODS

**Burt's All-Purpose Gelatin in Capsules**, at Milwaukee, E. Dist. Wis.  
Charged 10-15-63 and amended 11-20-64: when shipped by All-Purpose Gelatin Products, El Segundo, Calif., and while held by Walters Food Distributors, Milwaukee, Wis., the shipper's bottle label and tag, and the reprint leaflet of the dealer, contained false and misleading claims for strong, beautiful fingernails and for significant value for special dietary supplementation by reason of high, super-rich protein content in an amount low in calories; 502(a). The article was claimed by the shipper. Subsequently the claimant, without admitting any of the issues of law or fact, consented to a decree of condemnation and destruction. (57)

**Cheese, swiss**, at Smithfield, Dist. Utah.  
Charged 11-29-66: when shipped by Cache Valley Dairy Association, Smithfield, Utah, to South San Francisco, Calif., and returned to Utah, the label statement "Salt Free" was false and misleading, and the article lacked required information concerning its purported special dietary uses as means of regulating intake of sodium; 403(a), 403(j). Default decree ordered destruction. (58)

**Colicin-Pectin laxative, Soymane and Sedamine dietary supplements, nucleic acid tablets, multi-vitamin & mineral tablets, B complex combination tablets, Profod bile salt combination tablets, Ketovite tablets and capsules, and Amino 90 amino acid-iodine mixture**, at Cedar Rapids, N. Dist. Iowa.  
Charged 2-1-67: while held by Professional Foods, Cedar Rapids, Iowa, after being repacked in part, the dealer's labeling contained false and misleading nutritional and therapeutic claims; 502(a). Consent decree authorized release to dealer for salvaging. (59)

**Di-methionine**, at Denver, Dist. Colo.  
Charged 2-24-67: when shipped by Nopco Chemical Co., Richmond, Calif., the label lacked the name and place of business of the manufacturer, packer, or distributor, an accurate quantity of contents statement, and the common or usual name of the food; 403(e)(1), 403(e)(2), 403(i)(1). Case was dismissed after the owner had properly labeled the article. (60)

**Dr. Bronner's lecithin-protein cereal, and carrot-safflower oil**, at Tulsa, N. Dist. Okla.  
Charged 10-7-66: when shipped by Dr. Bronner & Associates, Escondido, Calif., the bottle labels of the cereal contained false and misleading claims [of providing a significant quantity of protein, of the article's equivalence in the diet with butter, cheese, milk, and fat, of the 11-oz. bottle's equivalence in net weight to 1 pint, and of the nutritional enhancement of the cereal by the inclusion of lecithin, choline, dates, and other ingredients]; the label lacked required information concerning its purported special dietary uses; and the label contained false and misleading claims [of cholesterol, fat and calcium reduction, of the treatment and prevention thereby of heart and cir-

culatory diseases, and of the promotion of healthy nerves and brain cells]; 402(a), 403(j), 502(a). The oil's label lacked required information concerning its purported special dietary uses; and contained false and misleading claims [of lowering blood cholesterol and thereby preventing and treating heart and circulatory diseases, of reducing body weight, and of promoting digestion and balanced nutrition]; 403(j), 502(a). Default decree ordered destruction. (61)

**Organic Sea Plant minerals and Formula A herbal tablets**, two seizure actions at Sheboygan, E. Dist. Wis.

Charged 10-17-66: while held by Kett's Health Food Center, Sheboygan, Wis., after being repacked in part, the minerals contained the nonconforming food additive iodine, and their labeling contained false and misleading nutritional claims—402(a)(2)(C), 403(a); and the Formula A tablets contained false and misleading arthritis and neuritis claims—502(a). Default decrees ordered destruction. (62)

**Pectin, Low Sugar**, at Salt Lake City, Dist. Utah.

Charged 5-11-66: when shipped by Mutual Citrus Products Co., Anaheim, Calif., the valuable constituent, a nutritive sweetener, had been in part omitted or abstracted, an article sweetened in part by a nonnutritive artificial sweetener, sodium cyclamate, had been substituted for an article sweetened by a natural sweetener, and the name "Low Sugar Pectin," and the label statements concerning the article's content of low sugar, pectin, and sodium benzoate were false and misleading as applied to the article which contained 78 percent dextrose and no sodium benzoate; 402(b)(1), 402(b)(2), 403(a). Default decree ordered destruction. (63)

**Super Hemo tablets**, at Panorama City, C. Dist. Calif.

Charged 3-20-67: while held by Bonquet Labs., Panorama City, Calif., after having repacked the article, the valuable constituent vitamin C had been in part omitted or abstracted and the labeling was false and misleading, since the article was deficient in vitamin C (approx. 50 percent); 402(b)(1), 403(a). Default decree ordered destruction. (64)

**Vasculex dietary-supplement tablets, Amino B tablets, Nellazyme capsules, Bio-zyme tablets, Enzade digestive tablets**, at Rushville, S. Dist. Ill.

Charged 1-25-65: when shipped by Warner-Davis, Inc., Brooklyn, N.Y., the Nellazyme capsules contained duodenal and stomach substances and the Bio-zyme tablets contained stomach substances, intrinsic factors and cobalt, which were nonconforming food additives; the labeling of all of the articles contained false and misleading nutritional and therapeutic claims; the labeling of the Bio-zyme tablets lacked required information concerning their purported dietary uses, the labeling of the Bio-zyme and Enzade tablets lacked adequate directions for use and did not comply with the exemption requirements for prescription drugs for disclosure of information; and the label of the Bio-zyme and Enzade tablets lacked the required prescription legend; 402(a)(2)(C), 403(a), 502(a), 403(j), 502(f)(1), 503(b)(4). Following answers to interrogatories by the shipper as claimant and by the Government, consent decree was entered ordering destruction of the articles. (65)

**Vitamin products and dietary supplements**, at Moonachie, Dist. N.J.

Charged 1-29-62 and amended 1-2-63: when shipped, and while held by Foods Plus, Inc., the labels and the dealer's booklet "Foods Plus 1962 Vitamin Catalog" contained false and misleading therapeutic claims, and representations, including false and misleading representations that the articles were superior to similar products generally available due to their formulation and endorsement by Carlton Fredericks, that Carlton Fredericks was internationally and prominently recognized as a competent authority on nutrition, that vitamins were more effective in combination with minerals because they reinforce and supplement the effectiveness of each other, and that the nutritional requirements of people of old age are different from those of adults generally; and the labeling of the article lacked adequate directions for use for cystic mastitis, high blood pressure, multiple sclerosis, abortions, mongolian idiots, heart diseases, tartar on teeth, and other diseases and conditions for which the articles were intended, prescribed, recommended, and suggested in oral statements by Carlton Fredericks on radio programs "Living Should Be Fun"; 502(a), 502(f)(1).

Foods Plus, Inc., claimed the articles. Thereafter, claimant moved for summary judgment in favor of the libellant, upon the ground that claimant recognized that an honest difference of opinion could exist as to whether the articles were misbranded under 502(a). For this reason, claimant sought a decree holding that the articles seized were misbranded under 502(a) but authorizing their release from seizure for the purpose of relabeling by claimant in conformity with the requirements of the section. In support of this motion, claimant represented that its previous contractual relationship with Carlton Fredericks had by then terminated. Claimant persisted, however, in contending that the articles were not misbranded under 502(f)(1), and refused to consent that the suggested decree so adjudicate. Claimant's motion was denied, and libellant's cross-motion for leave to amend the libel by including a prayer for injunctive relief prevailed.

After trial by the court, the court found for the Government and ordered the articles condemned and ordered Foods Plus, Inc., enjoined. Upon appeal, the decision of the trial court that the articles were misbranded was undisturbed and propriety of the injunction was upheld, although it was remanded to cure defects in the language, the court said:

"The appellant sees in the decision of the lower court an expansion of the power and jurisdiction of the Food and Drug Administration into areas of free speech and expresses the fear that such ruling would make independent commentaries broadcast over the radio subject to regulatory control by government agencies. It would seem that this argument is based upon a misconception of what is here decided. There is nothing new or alarming in a ruling that statements made by a lecturer employed by a party and adopted by that party as its own representations may be taken in a civil action as evidence of that party's intention as to matters in which the intention is a material issue. Nor does the fact that the representations were made in a radio broadcast affect the situation.

"The appellant also complains that the injunction issued is not sufficiently specific to inform it when it would be in compliance. \* \* \* An injunction must be complete and sufficiently specific in itself to instruct an enjoined party as to what acts are prohibited. We think that in this case the defect in the injunction can be cured, including in the decree the words 'sufficient information to enable a layman to safely and effectively attempt self-medication without professional assistance.'

"The part of the decree referring to 'other conditions if any there be, for which such drug or device is commonly and effectively used' is, we believe, beyond the proper scope of an injunction. It may well be that the appellant is unaware of how a particular preparation is commonly used somewhere in the United States or, equally, it may be that the appellant does not wish or intend to recommend its drug to be used as a competitor for some other preparation even though it might work equally well. The quoted language should be deleted. \* \* \*

"The appellant contends that the injunctive provision of the decree should not have been included because the business relationship between Fredericks and the claimant was terminated more than three years ago. It is well settled that the cessation of activities, either before or after suit is begun, does not in itself bar issuance of the injunction. The matter is in the broadest sense for the discretion of the trial court which is best qualified to form a judgment as to the likelihood of a repetition of the offense." 362 F. 2d 923 (1966). (66)

#### DRUGS / Human Use

**Acetaminophen tablets, N.F.**, at Buffalo, W. Dist. N.Y.

Charged 12-15-66: while held by Direct Laboratories, Inc., Buffalo, N.Y., who had manufactured the article from acetaminophen shipped in interstate commerce, the article's strength differed from the N.F. standard, since it contained approximately 87.3 percent of the declared acetaminophen; 501(b). Default decree ordered destruction. (67)

**Amphetamine, barbiturate, and other controlled drug stocks**, at Atlanta, N. Dist. Ga.  
Charged 9-7-66: while held by Premo Pharmaceutical Labs., Inc., Atlanta, Ga., the dealer's establishment for wholesaling, jobbing, and distributing controlled drugs was not registered as required by law; complete and accurate inventory records of all stocks of amphetamines, barbiturates, combinations thereof, and chloralhydrate were not prepared, and complete and accurate receipt and disposition records were not prepared and kept; 301(p), 301(q)(4). Default decree ordered destruction except for 3 bottles authorized as exhibits for FDA. (68)

**Amphetamine, barbiturate, and other depressant or stimulant drugs, at Ames, S. Dist. Iowa.**

Charged 9-8-67: while held by Bert Adams, D.O., Ames, Iowa, complete and accurate inventory records, and receipt and disposition records, of all such drugs were not prepared and kept; 501(q)(4). Default decree ordered destruction. (69)

**Amphetamine, barbiturate, and other depressant or stimulant drugs, at Wendell, E. Dist. N.C.**

Charged 8-2-66: while held by Nowell's Drug Store, Wendell, N.C., the articles were in the possession of a pharmacy whose State license had been revoked; 501(q)(3). Default decree ordered destruction. (70)

**Amphetamine drugs, at Knoxville, E. Dist. Tenn.**

Charged 11-26-65: while held by James E. Dyson, Knoxville, Tenn., the labeling lacked adequate directions for use and was not exempt therefrom, since the article was not in possession of a person regularly and lawfully engaged in distribution of prescription drugs; 502(f)(1). Default decree authorized release to FDA. (71)

**Athco 6-hour cold capsules, yellow and black, at Nashville, M. Dist. Tenn.**

Charged 11-23-66: while held by Athens Products Co., Nashville, Tenn., who repacked and relabeled some of the article, the articles' quality and purity were deficient since the yellow capsules contained free salicylic acid and an odor of acetic acid; in the repackaging operation, the ingredient statements for the yellow and black capsules had been reversed; and the article was a prescription drug but lacked the prescription legend; 501(c), 503(b)(4). Consent decree ordered destruction. (72)

**Gingi-Pak gingival retraction cotton, cords, and kits, at Richmond, E. Dist. Va.**

Charged 8-26-66: when shipped by Surgident, Ltd., Los Angeles, Calif., the articles' strengths of epinephrine hydrochloride differed from the purported strengths (approx. 16 to 237 percent); and labels of the articles lacked an accurate statement of the quantity of contents; and some of the articles in the kit lacked the prescription legend; 501(c), 502(b)(2), 503(b)(4). Default decree ordered destruction. (73)

**Jems theophylline-caffeine combination tablets, at Miami, S. Dist. Fla.**

Charged 4-14-66 and amended 4-15-66: while held by All Products Unlimited, Inc., Miami, Fla., after manufacture on order of dealer, the labeling contained false and misleading sex energizer and other therapeutic claims; the labeling lacked adequate directions for use; and the label lacked the required prescription legend; 502(a), 502(f)(1), 503(b)(4). Consent decree ordered destruction. (74)

**LSD and DMT, at Brooklyn, E. Dist. N.Y.**

Charged 11-17-66: while held by Irving S. Wolfe, Brooklyn, N.Y., prohibited acts had occurred with respect to the articles, in that the dealer failed to register his drug processing establishment, in that controlled drugs were being processed by an unregistered and unauthorized dealer, and in that the articles were unlawfully possessed; 501(p), 501(q)(1), 501(q)(3). Default decree ordered destruction. (75)

**Mann's Ulcer Medicine, at Ottawa, Dist. Kans.**

Charged 3-10-67: while held by Seyler Drug Co., Ottawa, Kans., after manufacture from ingredients shipped in interstate commerce, the article's labeling contained false and misleading ulcer claims and failed to bear adequate directions for lay use; 502(a), 502(f)(1). Default decree ordered destruction. (76)

**Priorbarb pentaerythritol tetranitrate combination capsules, at Columbia, Dist. S.C.**

Charged 4-13-67: when shipped by Nysco Laboratories, Inc., Long Island City, N.Y., the article labeled in part "Priorbarb . . . Manufactured For: Oak Ridge Pharmaceuticals, Inc. Columbia" was a new drug without an effective approved New Drug Application; and the labeling lacked adequate directions for use and was not exempt therefrom; 505(a), 502(f)(1). Default decree ordered destruction. (77)

**Rauwolfia serpentina tablets, N.F., at Mechanicsville, N. Dist. Iowa.**

Charged 7-12-66: while held by Senyon Drug Co., Mechanicsville, Iowa, the article's strength differed from N.F. standards, since the article was deficient in reserpine rescinnamine group alkaloid (approx. 62 percent); 501(b). Default decree ordered destruction. (78)

**Sargon laxative pills, Severa's First Aid ointment, Dr. Whetzel's expectorant, Quintaline camphor-menthol & boric acid ointment, and ox bile extract & pancreatin tablets, at Warren, W. Dist. Pa.**

Charged 3-13-67 and amended 4-13-67: when the ox bile extract & pancreatin tablets were shipped by Paul B. Elder Co., Bryan, Ohio, and while held by Myers Laboratories, Inc., Warren, Pa., for repacking, their labeling contained false and misleading claims for nutritional disturbances, the listing in the labeling of pancreatin as an active ingredient was false and misleading, since the tablets were not coated to protect them from stomach acids which destroy pancreatin activity, and the labeling lacked adequate directions for use and did not comply with the prescription drug exemption requirement for disclosure of information—502(a), 502(f)(1); and while the other articles were held by Myers Laboratories after manufacture from ingredients shipped in interstate commerce or after being repacked in part, the labeling claims for use of Quintaline ointment for nasal irritation, muscular strains and bruises and Severa's ointment for frostbite were false and misleading; the repack carton label of Sargon pills lacked quantity of contents statement; the labeling of Severa's ointment lacked adequate information in a form likely to be read, since adequate directions for use did not appear in the foreign languages in which other statements in the labeling were expressed; the labeling of Sargon pills and Severa's ointment lacked adequate warnings against unsafe use; and the labeling of Dr. Whetzel's expectorant lacked adequate directions for use and did not comply with the prescription drug exemption requirement for disclosure of information, and its label failed to bear the required prescription legend—502(a), 502(b)(2), 502(c), 502(f)(1), 502(f)(2), 503(b)(4). Consent decree condemned all articles and authorized release of Sargon pills, Severa's ointment, and Quintaline ointment to the dealer for relabeling; the other articles were destroyed. (79)

**Snap-To salicylate-caffeine combination tablets for hangovers, at Milwaukee, E. Dist. Wis.**

Charged 7-20-66: when shipped by Snap-Bak, Ltd., Chicago, Ill., the article lacked an effective approved New Drug Application; 505(a). Consent decree authorized release to shipper for relabeling. (80)

**Throat lozenges, at Minneapolis, Dist. Minn.**

Charged 7-21-66: when shipped by Success Chemical Co., Inc., Brooklyn, N.Y., the article's gramicidin antibiotic ingredient was not from a certified batch; 502(l)(1). Default decree ordered destruction. (81)

## DRUGS / Veterinary

**At Last heart-worm treatment for dogs, at Pensacola, N. Dist. Fla.**

Charged on or about 10-10-66: when shipped by At Last Laboratories, Theodore, Ala., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (82)

**Calvita skim-milk booster, at Bismarck, Dist. N. Dak.**

Charged 4-7-66: when shipped by National Vitamin Products Co., Minneapolis, Minn., the article's labeling contained false and misleading claims for the prevention of bacterial calf diarrhea; 502(a). Default decree authorized donation to public/charitable institution. (83)

**Dimethyl sulfoxide, at Pawtucket, Dist. R.I.**

Charged on or about 5-24-65: while held by the Horsemen's Pharmaceutical Co., Inc., Pawtucket, R.I., the labeling lacked adequate directions for use for the purposes for which the article was intended by the dealer; 502(f)(1). Consent decree ordered destruction. (84)

**Neo-Cortef eye-ear ointment, at Minneapolis, Dist. Minn.**

Charged 7-20-66: when shipped by Upjohn Co., Kalamazoo, Mich., the article's quality was deficient, since the article contained metal particles; 501(c). Default decree ordered destruction. (85)

**Nutronic Dairy D-1 premix and Nutronic Metabol D-2 premix, at Portland, Dist. Oreg.**

Charged 7-20-66: when shipped by Ultra Life Labs. and Colchester Processing Co., East St. Louis, Ill., the labeling lacked adequate directions for use; and its labeling was false and misleading because of its claim that it could be sold only on or by the

order of a licensed veterinarian—502(a), 502(f)(1); and while held by Vetecon, Inc., Portland, Oreg., the labeling contained false and misleading claims for the prevention of acute and chronic mastitis; 502(a). Consent decree authorized release to dealer for relabeling. (86)

**Pepto-Liv liver combination injection, at Omaha, Dist. Nebr.**

Charged 10-13-66: when shipped by Anthony Products Co., El Monte, Calif., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (87)

**Super Speed Anemia Ban liver-iron combination injection, at Omaha, Dist. Nebr.**

Charged 8-29-66 and amended thereafter: when shipped by Anthony Products Co., El Monte, Calif., the labeling contained false and misleading claims for anemia in horses and other animals, the labeling lacked adequate directions for use in animals other than horses and directions as to when the drug should be used intravenously or intramuscularly, and the article was a new drug without an effective approved New Drug Application; 502(a), 502(f)(1), 505(a). Default decree ordered destruction. (88)

## MEDICAL DEVICES

**Catheters, V-Cath, and needles, at Portland, Dist. Oreg.**

Charged 5-5-67: when portions of the articles were shipped by, and thereafter returned to, Paramed, Inc., Portland, Oreg., and while a portion was held by such firm after being assembled with needles which had been shipped in interstate commerce, the articles' purported quality of sterility was deficient, since the containers of the articles contained holes, and the labeling lacked adequate directions and did not comply with the prescription device exemption requirements with respect to the caution legend and the disclosure of information; 501(c), 502(f)(1). Consent decree authorized release to Pharma, Surge, Inc., Portland, Oreg., for salvaging. (89)

**Catheters, V-Cath Simplex I.V., at Seattle, W. Dist. Wash.**

Charged 3-21-67 and amended 4-17-67: when shipped by Paramed, Inc., Portland, Oreg., the article's quality was deficient, since the article's packages were not an effective barrier to assure sterility; 501(c). Default decree ordered destruction. (90)

**Exer-genie exerciser, at St. Paul, Dist. Minn.**

Charged 3-22-67 and amended 3-30-67: when shipped by Exer-genie, Inc., Fullerton, Calif., the labeling contained false and misleading therapeutic claims; 502(a). Default decree authorized donation of article to charitable institutions after relabeling. (91)

**Figure-Control device, at Minneapolis, Dist. Minn.**

Charged 11-16-66: when shipped by Consumer Electronics, Dallas, Tex., the name "Figure-Control," and the labeling claims for spot reducing and obtaining a trimmer, more fashionable, figure were false and misleading—502(a); and while held by Hydro Massage, Inc., Minneapolis, Minn., the labeling lacked adequate directions for reducing and getting rid of wrinkles, as represented by the dealer; 502(f)(1). Default decree ordered release to FDA. (92)

**Incliner foam bed wedge, at Atlantic City, Dist. N.J.**

Charged 3-23-67 and amended 5-4-67: when shipped by Sturdi-Crafters, Inc., Philadelphia, Pa., and while held by Spencer Gifts, Inc., Atlantic City, N.J., the article's labeling, including a catalog prepared by the dealer, contained false and misleading respiratory and circulatory claims; 502(a). Consent decree authorized release to the dealer for relabeling. (93)

**Mineral Vapor steam cabinet, at Gainesville, N. Dist. Ga.**

Charged 2-13-67: when shipped by National Health System, Plymouth, Ind., the article's labeling contained false and misleading therapeutic claims and lacked adequate directions for use and adequate warnings against misuse; 502(a), 502(f)(1)(2). Consent decree authorized release to Gainesville Health Club, Inc., Gainesville, Ga., for relabeling. (94)

**Sauna Beauty steam cabinet, at Virginia Beach and Norfolk, E. Dist. Va.**

Charged 3-22-67: when shipped by Hydro Massage Co., Chicago, Ill., and while held by Dixie Rents, Inc., Virginia Beach, Va., after receipt of accompanying labeling from G & R Merchandise Mart, Frederick, Md., the article's labeling contained false and misleading arthritis, complexion, and other therapeutic claims; 502(a). Consent decree authorized release to Dixie Rents, Inc., for relabeling. (95)

**Teething rings, water-filled, at Shreveport, W. Dist. La.**

Charged 6-14-66: when shipped by John G. Kyles, Inc., New York, N.Y., the article's purity and quality were deficient, and the labeling was false and misleading, since the article's liquid contained mold and viable micro-organisms; 501(c), 502(a). Default decree ordered destruction. (96)

**VNT photoelectric reflection gage, at Wellington and Harper, Dist. Kans.**

Charged 8-2-66: when shipped by Photo Electric Instrument Co., 1/4 Visual Nerve Tracing Instrument Co., Brockton, Mass., accompanying booklets and leaflets contained false and misleading claims for spinal analysis, nerve impingement, diseased viscera, asthma, hay fever, and other false and misleading claims for diagnosis, treatment, restoring patients to normal, and insuring patients' health; 502(a). Default decree ordered delivery to FDA. (97)

## PROPHYLACTICS

**Rubber prophylactics, Big Chief, at Dallas, N. Dist. Tex.**

Charged 4-28-67: when shipped by Allied Latex Sales Co., Inc., Dothan, Ala., the article's quality was deficient and the labeling false and misleading, since the article contained holes; 501(c), 502(a). Default decree ordered destruction. (98)

**Rubber prophylactics, Duke, at Jeffersonville, S. Dist. Ind.**

Charged 10-28-66: when shipped by M & M Rubber Co., Kansas City, Mo., the article's quality was deficient, since it contained holes; 501(c). Default decree ordered destruction. (99)

**Rubber prophylactics, Peacocks, at Los Angeles, S. Dist. Calif.**

Charged 6-8-66: when shipped by Dean Rubber Manufacturing Co., North Kansas City, Mo., the article's quality was deficient, since the article contained holes; 501(c). Default decree ordered destruction. (100)

**Rubber prophylactics, Royal Knight, at Elgin, N. Dist. Ill.**

Charged 11-30-66: when shipped by Allied Latex Sales Co., Inc., Dothan, Ala., the article's quality was deficient, and the labeling was false and misleading, since the article contained holes; 501(c), 502(a). Default decree ordered destruction. (101)

**Rubber prophylactics, Safe-Tex, at Macon, M. Dist. Ga.**

Charged 7-13-66: when shipped by Barnett's, Inc., Durham, N.C., the article's quality was deficient, and its labeling was false and misleading, since the article contained holes; 501(c), 502(a). Default decree ordered destruction. (102)

**Rubber prophylactics, Spartans, at Sparks, Dist. Nebr.**

Charged 10-12-66: when shipped by M & M Rubber Co., Kansas City, Mo., the article's quality was deficient and its labeling false and misleading, since it contained approximately 0.9 percent holes; 501(c), 502(a). Default decree ordered destruction. (103)

## NOTICES OF JUDGMENT on Criminal Cases

### FOOD

**Associated Wholesale Grocery of Arkansas, and Charles E. Toland, Little Rock, E. Dist. Ark.**

Charged 7-11-67: flour and cornmeal were placed in a building accessible to rodents and contaminated with rodent filth; 402(a)(3), 402(a)(4). Not guilty pleas. After trial by the court, judgment of not guilty as to individual and judgment of guilty as to corporation. Corporation was fined. (104)

**Carroll Food Products Co., Inc., and Robert E. Carroll, president, Chillicothe, S. Dist. Ohio.**

Charged 8-14-67: popping corn and pretzel rings were held in a building accessible to rodents and insects and were contaminated by rodent filth and insect filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Guilty plea by individual; probation. (105)



Clayton-Brown Co., Memphis, W. Dist. Tenn.

Charged 8-29-67 by grand jury: flour and sugar were held in a building accessible to rodents and were contaminated by rodent filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (106)

Coble Dairy Products Cooperative, Inc., Anderson, Dist. S.C.

Charged 7-24-67: when shipped, a food labeled in part on the top of the lid as "Orange Juice" or "The Real Thing O.J. . . Orange Juice Cobs" and at the lip of the lid "Reconstituted Orange Juice Packed For: Seco Dairies, Inc., Delant, Fla. for "Packed By: Coble Dairy Products General Offices: Lexington, N.C." failed to conform to the standard of identity for either orange juice or reconstituted orange juice, since it contained citric acid, added water, sorbate, and benzoate; its labeling was false and misleading, since it was neither orange juice nor reconstituted orange juice; it was offered for sale under the names of other foods; and it contained the artificial coloring beta-carotene and the chemical preservative sodium benzoate without the labeling so stating; 403(g)(1), 403(a), 403(b), 402(k). Guilty plea; fine. (107)

J. Fleishman & Co., Inc., Saul Fleishman, director, Arthur Fleishman, president, and Howard Fleishman, treasurer, Roxbury, Dist. Mass.

Charged 10-31-67 by grand jury: when shipped, frozen egg whites labeled in part "Egg Whites Distributed by Mountainside Butter & Egg Co. Elizabeth, New Jersey" and "Egg Whites . . . Fleishman & Co. Boston 29, Mass." contained the added poisonous and deleterious substance *Salmonella* micro-organisms and had been prepared and packed under insanitary conditions—402(a)(1), 402(a)(4); frozen eggs labeled in part "Frozen Whole Eggs . . . Distributed by Bon Ton Foods Mount Vernon, N.Y." contained the added poisonous and deleterious substance *Salmonella* micro-organisms, contained decomposed eggs, and had been prepared and packed under insanitary conditions—402(a)(1), 402(a)(3), 402(a)(4); and unlabeled frozen eggs contained decomposed eggs and had been prepared and packed under insanitary conditions. 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Guilty pleas by individuals; probation. (108)

Lunding & Co., Inc., and Frederick A. Nielsen, Jr., president, Los Angeles, S. Dist. Calif.

Charged 11-16-67: licorice candy, chocolate candy, and potato pancake mix were held in a building accessible to rodents and insects and were contaminated by rodent and insect filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Guilty plea by individual; fine and probation. (109)

Mar-Gold Corp., and Charles N. McCurdy, general manager, Atlanta, N. Dist. Ga.

Charged 10-19-67: when shipped, margarine labeled in part "June Daisy Vegetable Margarine, Distributors June Dairy Products Co., Inc., Miami, Fla." contained rodent filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Nolo contendere pleas; fines. (110)

Portales Valley Mills, Inc., and Ray O. Hill, manager, at Portales, Dist. N. Mex.

Charged 12-20-66: when shipped, shelled peanuts contained rodent urine and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Guilty plea by individual; probation. (111)

David J. Sharboneau, t/a Sharboneau Brokerage Co., Harlingen, S. Dist. Tex.

Charged 1-23-68: dried green peas and pinto beans were held in a building accessible to rodents and were contaminated by rodent filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (112)

Vivi Macaroni Co., t/a Delmonico Foods Inc. of Florida, and Peter S. Viviano, Tampa, M. Dist. Fla.

Charged 5-17-67 by grand jury: when shipped, macaroni, labeled in part "Chef-Pac Elbow Macaroni . . . Distributed by National Industrial Food Distributor Associates, Inc., Atlanta, Ga." and "Elbow Macaroni (or "Wide Egg Noodles") Delmonico Foods Inc. of Florida Tampa," contained insect filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Not guilty pleas. The defendants moved to dismiss the indictment and to strike the second paragraph of each count, on the grounds that the indictment failed to state facts sufficient to constitute an offense, and that the second paragraph of each count (which recited the labeling of the food) was highly prejudicial to the defendants without having any relevancy or materiality to the violations charged. The defendants also made other motions, including a motion for a bill of particulars, a motion for discovery and inspection of certain Government records, and a second motion to dismiss the indictment. Such second motion alleged that the grand jury was believed to have been informed of the defendants' prior Food and Drug law violation, and that such disclosure deprived the defendants of due process of law. It was noted that each count of the indictment returned by the grand jury contained a concluding paragraph in which the grand jury charged the defendants' previous conviction. The court granted parts of the defendants' motions for a bill of particulars and for discovery and inspection, and denied the remainder of defendants' motions. After trial by jury, verdicts of guilty were returned. The corporation was fined, and the individual was fined, placed on probation, and sentence of imprisonment was suspended. (113)

Zeb Vance Baucum, M.D., of New Augusta, and Harold D. Barnes, pharmacist, of Laurel, S. Dist. Miss.

Charged 8-22-67: conspiracy to sell and deliver depressant or stimulant drugs outside the ordinary and authorized course of their business, including in part: the sale of large quantities of amphetamine and methamphetamine drugs to persons who were looking for a source of such drugs, the covering by Dr. Baucum of shortages by writing prescriptions for drugs sold, and the ordering of large quantities of amphetamine and methamphetamine drugs for the purpose of sale outside the ordinary and authorized course of their business—18 U.S.C. 371, 301(q)(2). Syndrox tablets, methamphetamine hydrochloride tablets, and capsules containing dextro-amphetamine sulfate and amobarbital were unlawfully delivered; 301(q)(2). Nolo contendere pleas; imprisonment suspended, fine, and probation. (114)

#### DRUGS

Arthur Frank Blalock, truck-stop operator, and Wynona Henson Blalock, Flatwood, S. Dist. Ala.

Charged 9-14-67: amphetamine sulfate tablets were unlawfully sold and delivered; 301(q)(2). Guilty pleas; fines and probations. (115)

James Maxwell Brown, taxi driver, Kansas City, W. Dist. Mo.

Charged 3-6-67: amphetamine sulfate tablets were dispensed without a prescription—503(b)(1); and amphetamine sulfate tablets and pentobarbital sodium capsules were unlawfully sold and delivered—301(q)(2). Guilty plea; imprisonment, fine, and probation. (116)

James H. Cook, barber, Indian Head, Dist. Md.

Charged 10-9-67: capsules containing secobarbital sodium and amobarbital were unlawfully possessed; 301(q)(3). Guilty plea; imprisonment suspended, fine, and probation. (117)

Richard C. Curtis, M.D., Akron, N. Dist. Ohio.

Charged 3-15-67: methamphetamine hydrochloride tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment. (118)

Ernest M. Dunn, pharmacist, Birmingham, N. Dist. Ala.

Charged 3-31-67: dextro-amphetamine sulfate tablets were unlawfully sold and delivered; and a prescription for Amytal tablets was refilled more than 6 months after issuance; 301(q)(2), 301(q)(7). Nolo contendere plea; fine. (119)

Roger C. Erickson, Mahala A. Erickson, and William A. Lotte, Santa Ana, C. Dist. Calif.

Charged 10-13-66: LSD was unlawfully sold and delivered and was unlawfully possessed; 301(q)(2), 301(q)(3). Guilty pleas by Mahala Erickson and Roger Erickson; imprisonments suspended and probations. Guilty plea by Lotte; probation. (120)

George W. Franz and Hardy Dale Jones, Los Angeles, S. Dist. Calif.

Charged 9-3-65: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea by Franz; fine. Guilty plea by Jones; imprisonment suspended and probation. Subsequently Jones's probation was revoked and he was imprisoned. (121)

Monroe D. Fredeking, D.O., and Mildred Nunn, receptionist, Fort Worth, N. Dist. Tex.

Charged 3-13-67 by grand jury: methamphetamine hydrochloride tablets were dispensed without a prescription—503(b)(1); and desoxyephedrine-pentobarbital combination tablets were unlawfully sold and delivered—301(q)(2). Nolo contendere by Fredeking; imprisonment suspended, fine, and probation. Nolo contendere by Nunn; imprisonment suspended and probation. (122)

Joyce F. Freeman, Chicago, N. Dist. Ill.

Charged 3-1-67: methamphetamine powder was unlawfully sold and delivered and was unlawfully possessed; 301(q)(2), 301(q)(3). Not guilty plea. The defendant moved to dismiss the information on the grounds that the section of the Act charged was unconstitutional in attempting to regulate matter beyond the powers of the Federal Government and that the information was defective, since it did not charge the defendant with engaging in activities affecting or relating to interstate commerce. In a memorandum opinion, the court upheld the statute and the information and dismissed the defendant's motion. 275 F. Supp. 803 (1967). After trial, defendant was found guilty; imprisonment suspended and probation. (123)

Thomas Paul Garrison, grocery store operator, James R. Hill, service station employee, Lawrence Winston Harrington, service station operator, Joseph W. Attaway, Milledgeville, M. Dist. Ga.

Charged 8-25-66: Diphetamine tablets were dispensed without a prescription; 503(b)(1). Guilty pleas by Garrison and Hill; imprisonment.

Not guilty pleas by Harrington and Attaway. Attaway moved for severance urging: (1) The only defendant joined charged with movant is Hill who has entered a plea of guilty; (2) Movant is not alleged to have entered into a conspiracy with any of the other defendants; (3) Movant is not charged with having participated in any of the transactions in the other counts; (4) None of the other defendants, save Hill who has pleaded guilty on all counts, is alleged to have participated in the transaction with which movant is charged; (5) The transactions involved in the information are not alleged to be the same series of acts or transactions, nor are they alleged to be a series of acts or transactions; and (6) To try movant with Harrington would be prejudicial to movant.

In denying Attaway's motion, the court cited *Kivette v. United States*, 230 F.2d 749 (5th Cir. 1956) and *Scheve v. United States*, 184 F.2d 695 (D.C. Cir. 1950) "as allowing joinder of all defendants engaged in a connected course of conduct out of which arose separate crimes alleged against different persons," and said that Rule 8(b) of the Federal Rules of Criminal Procedure does not even require participation by all defendants in the same broad "transaction," since the Rule requires just participation "in the same series of acts or transactions." The court said that, with reference to participation, the identity of the act or transaction, or the existence of a series of acts or transactions constituting an offense or offenses did not need to be "alleged" or spelled out in the information or indictment. *Griffin v. United States*, 272 F.2d 801 (5th Cir., 1957), *Kivette v. United States*. The court said that a joinder can be upheld without there being any conspiracy count, and that the court was satisfied that all four defendants were properly joined in the information. As to the question of prejudicial joinder raised by Attaway's sixth ground, the court noted that this was traditionally a matter of discretion of the trial court, and that the mere unsupported assertion of prejudice is not sufficient to justify severance of properly joined defendants.

After trial by jury, the jury returned no verdict as to Attaway. Verdict of guilty as to Harrington; imprisonment. (124)

Horsemen's Pharmaceutical Co., Inc., Pawtucket, Dist. R.I.

Charged 8-4-66: when shipped, Penetro Freeze DMSO-combination veterinary drug, and DMSO were new drugs without effective approved New Drug Applications—505(a); and, while held for sale, DMSO was repacked into bottles for drug use without labeling bearing adequate directions for the drug's intended use in the cure, mitigation, and treatment of horses, and without adequate warnings against dangerous and unsafe use—502(f)(1), 502(f)(2). Guilty plea; fine. (125)

Dennis J. Janovich, Los Angeles, S. Dist. Calif.

Charged 4-27-66 by grand jury: desoxyephedrine hydrochloride was dispensed without a prescription; 503(b)(1). Upon defendant's request, case transferred to Eastern District of Missouri. Guilty plea; imprisonment. (126)

Charles B. Jones, t/a Broadway Pharmacy, Phoenix, Dist. Ariz.

Charged 1-25-66 by grand jury: while held for sale, dextro-amphetamine sulfate tablets in a package had removed therefrom a part of their label bearing the established name of the drug, the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents in terms of numerical count—502(b)(1 & 2), 502(e)(1); and dextro-amphetamine sulfate tablets were dispensed without a prescription—503(b)(1). Guilty plea; probation. (127)

Elmon Keaton, Waco, W. Dist. Tex.

Charged 8-11-67: dextro-amphetamine sulfate tablets, dextro-amphetamine-amobarbital combination tablets and amphetamine-dextro-amphetamine combination tablets were unlawfully sold and delivered, and possessed; 301(q)(2), 301(q)(3). Guilty plea; imprisonment and probation. (128)

Peyton Brooke King, truck-stop employee, Browns, S. Dist. Ala.

Charged 9-14-67: dextro-amphetamine sulfate tablets were unlawfully sold and delivered, and possessed; 301(q)(2), 301(q)(3). Guilty plea; fine and probation. (129)

Phil Levine, pharmacist, Kansas City, W. Dist. Mo.

Charged 9-15-67: amphetamine sulfate tablets were unlawfully sold; 301(q)(2). Guilty plea; fine and probation. (130)

Doyle Howard Mace, Springfield, W. Dist. Mo.

Charged 8-18-67: amphetamine sulfate tablets were unlawfully sold and delivered, and possessed; 301(q)(2), 301(q)(3). Guilty plea; imprisonment. (131)

Guy McGinnis, truckdriver, Greeley, Dist. Colo.

Charged 1-12-68: a quantity of depressant or stimulant drugs was unlawfully possessed; 301(q)(3). Nolo contendere plea; probation. (132)

Piedmont Drug Co., and John B. Woodcock, Jr., vice president, Gainesville, N. Dist. Ga.

Charged 1-4-68: a complete and accurate record of the kind and quantity of phenmetrazine hydrochloride tablets received, sold, delivered, and disposed of was not prepared, obtained, and kept; 301(q)(4). Guilty pleas; fines. (133)

Calvin L. Proctor, hotel clerk, Kansas City, W. Dist. Mo.

Charged 5-3-67: chlorthalidone hydrochloride capsules were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment suspended and probation. (134)

Leroy Russell Whisenant, bartender, Cleveland, N. Dist. Ohio.

Charged 11-21-67: amphetamine sulfate tablets were unlawfully sold and delivered; 301(q)(2). Guilty plea; probation. (135)

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.

Case summaries are prepared by Food and Drug Division, Office of the General Counsel, DHEW.

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

Herbert L. Ley, Jr., Commissioner of Food and Drugs

Washington, D.C., September 1, 1968.



**T**hrough them the Food and Drug Administration speaks to 7½ million Spanish-speaking residents of the United States and Puerto Rico.

FDA created Alberto and Maria—a typical American couple except that Spanish is their mother tongue.

Through a series of 5-minute radio dramatizations, Alberto and Maria illustrate the problems and concerns of most American consumers, and provide advice for the safe and effective use of foods, drugs, and medical devices, cosmetics, and other household products.

Have you met...

## ***Alberto & Maria?***

Twenty-six episodes in the lives of Alberto and Maria have been distributed to 200 radio stations throughout the country.

Typical comments on the series . . . "Since the Spanish-speaking people of northern California do not have . . . any other media of news . . . they look to radio for all their information. Thank you for the beautifully done dramatizations."

—San Francisco

"They really reach the heart of this . . . audience."

—Chicago

"We want to congratulate you on the content and quality of the program."

—Tampa, Florida

"We would welcome additional programs of this kind."

—New York City

"It is excellent. FDA is to be congratulated for its efforts in trying to bring their message to the Spanish-speaking population."

—Mayaguez, Puerto Rico

For more information about this radio series or other aspects of FDA's Spanish Information Program, write to: Press Relations Staff, Food and Drug Administration, Washington, D. C. 20204.



OFFICIAL BUSINESS

## Announcements

### WORKSHOP ACTIVITIES INCREASING

The current series of FDA-industry workshops, conferences, and seminars for fiscal 1968 (7-1-67 through 6-30-68) has surpassed previous records.

Of major significance to consumer protection were both national and local meetings on compliance problems relating to good manufacturing practices for drugs; microbiological contamination, chemical residues, and sanitation in foods; safety in cosmetics; and improved labeling of household chemicals and paints.

An increasing interest in FDA-industry workshops in promoting voluntary compliance is evidenced by statistics indicating that 9,480 persons from 5,097 firms attended 143 District workshops this fiscal year. In fiscal 1967, 94 workshops were attended by 8,147 persons from 2,995 firms.

FDA conducted or participated in 12 national and regional meetings in fiscal 1967 and the same number in fiscal 1968. However, the number of persons attending increased from 2,593 to 3,855. The number of firms sending representatives to these national and regional meetings increased from 1,100 to a new high of 1,703.

### DRUG INDUSTRY TRAINING FILM

Since the announcement of the availability of FDA's "Good Drug Manufacturing Practices: No Margin for Error" film in January 1968, the drug industry has shown a keen interest in its use as an employee training and motivational tool. This is evidenced by the statistical summary on the right. However, the summary does not reflect the film's total audience during this period, since it does not include data on loans from FDA Districts. The Districts are also showing the film at most of the drug GMP workshops.

FDA PAPERS, April 1968, lists loan and purchasing information. To date 40 firms have purchased prints of the film for their continuing use.

Because of the interest in a Spanish language version by a number of organizations, for example, the Mexican Pharmaceutical Association, the Pan American Health Organization, and a number of U.S. drug firms with plants in Latin American countries, FDA prepared an official Spanish language script. The Mexican Pharmaceutical Association plans to prepare a Spanish version of the film based on the official script.

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

### SCHEDULE OF FDA WORKSHOPS AND REGIONAL CONFERENCES OCTOBER & NOVEMBER 1968

FDA District	Date	Location	Subject Area
Boston	October	Boston, Mass.	GMP—Drugs-Human
	October	Hartford, Conn.	GMP—Drugs-Human
Cincinnati	October 8	Johnson City, Tenn.	Sanitation—Food Industry
	October 9	Nashville, Tenn.	Sanitation—Food Industry
	October 10	Memphis, Tenn.	Sanitation—Food Industry
Detroit (jointly with Cincinnati District)	October 1	Indianapolis, Ind.	Hazardous Substances
	October 22	Detroit, Mich.	Microbiological—Egg Users
	October 24	Kalamazoo, Mich.	Microbiological—Egg Users
New York*	October 9	New York, N. Y.	Hazardous Substances
Detroit (jointly with Cincinnati District)	November 7 or 21	Lafayette, Ind.	GMP—Drugs-Human
Los Angeles*	November 7	Los Angeles, Calif.	Hazardous Substances

\* Regional seminar on labeling of household chemicals and paints.

### STATISTICAL SUMMARY OF INDUSTRY AUDIENCE VIEWING FILM "GOOD DRUG MANUFACTURING PRACTICES: NO MARGIN FOR ERROR" JANUARY THRU JUNE 1968<sup>1</sup>

Month	Number of Showings <sup>2</sup>	Number of Persons Viewing	Average Number of Persons Per Showing
January	2	450	225
February	2	110	55
March	36	1593	44
April	56	2124	38
May	114	4390	38
June	67	2181	32
Total	277	10848	

<sup>1</sup> Statistics include only viewings based on loan of film from BVC.

<sup>2</sup> A total of 80 firms borrowed the film from BVC during the January-June period.