MEDICAL ADVERTISING
State of the Craft and of Regulation

FDA's 1967 LOOK
After 60 Years of Reorganization

Salmonella
Control of the Ubiquitous Bug

ECOLOGIC EFFECTS
OF ANTIBIOTICS
"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

The author of our quotation is well known to most readers. Harvey Washington Wiley was 23 years old when he delivered, in language he later described as "mighty fine ritin," his commencement address, "Life and the Coming Time." Both the title and content were prophetic. Young Wiley told his classmates he intended to become a physician who, he said, "can at least help to make the three score years and ten, full of healthful food for the finer frame, full of health and happiness and hope." Forty years later, in 1907, Dr. Wiley became the first head of the Government agency that is now FDA.

In this first issue of FDA PAPERS it is appropriate to remind ourselves that while much has changed in the past 60 years, unchanged is Harvey W. Wiley's charge of life protection.

We intend to publish the quotation in each issue, alongside a photographic reminder of today's beneficiaries. To food and drug officials it will be a reminder that their first duty is life protection. To responsible industry leaders we hope it will be a reminder that business judgments must be made knowing that at the end of the long research–development–production–distribution–marketing chain there are lives at stake.
The professions must be able to rely upon a drug without regard to the name by which it is sold. This is not always possible today. We have found too many instances involving both brand- and generic-named drugs, in which the product was not of proper quality. This situation will be corrected. The FDA will apply the good manufacturing practice provisions of the drug law fairly and forcefully to all manufacturers. If a manufacturer cannot or will not put out good drugs, he does not belong in the drug business, and we will help him get out.”

Deputy Commissioner Winton B. Rankin, to the Ninth Annual Pharmacy Clinic, University of Rhode Island, November 17, 1966.

Advertising prescription drugs should be a very special operation—wholly unlike advertising the 1967 model automobiles or the tars and nicotine of cigarettes. It should be based on the scientific data that allowed the drug to enter the market—you need look and can look no further than the official brochure for the allowable claims and the required warnings. As tempted as you may be by a new piece of investigative work that may be whispered to you to mount a new campaign to capture an entire market, you must remember that the approved claims are the limits beyond which promotion cannot go.”


Modern scientific technology is rapidly changing our concept of what constitutes toxicology. Since continuous and rapid change is inevitable and normal, the task is to remain open-minded to accommodate these rapid changes . . . . It is imperative then that animal testing procedures be modified and thoroughly developed so that their technical performance will yield results reflecting more closely human characteristics and reactions.”


PHOTOGRAPHY: John Crane, inside front cover, 1, 9, 11, 12; FDA, 13, 22, 29; Black Star, 15.
Medical Advertising  State of the Craft and of Regulation  
A review of events leading to FDA's regulatory position in 1967.

FDA's 1967 Look  After 60 Years of Reorganization  
On its 60th anniversary, a presentation of FDA's new makeup.

Salmonella  Control of the Ubiquitous Bug  
A layman's view of the Salmonella universe and how to control it.

Ecologic Effects of Antibiotics  
Has man adversely affected his environment with antibiotics?

Field Reports  
State Actions  
Seizures and Prosecutions  
Notices of Judgment
The year 1967 will mark the fifth anniversary of the Kefauver-Harris Drug Amendments to the Federal Food, Drug, and Cosmetic Act.

During the extensive investigative and legislative hearings which preceded the passage of the Amendments, a great deal of attention was paid to advertising as a primary source of medical information for the physician. It was shown that busy doctors frequently must rely on the claims made by the pharmaceutical manufacturers about various new or established drugs. Congress decided that medical advertisements lacked a balance of information about possible bad effects as compared with the claims for benefits from use of the drugs.

"The physician," Congress said, "must have the whole truth about therapeutic usefulness."

The recent history of medical advertising practices shows a disappointing level of industry compliance with the spirit and letter of the Kefauver advertising amendment. There have been formal charges of violation of the advertising amendment and consequent legal actions. Additionally, FDA spokesmen have informally told advertisers, in general and specific terms, that journal advertisements and other Rx drug promotion do not meet the requirements of frank and fair disclosures called for by the regulations.

In its widest sense, the concept of advertising to the medical profession cannot, of course, be restricted merely to the formal...
Medical advertising is quite unlike the advertising for consumer goods competing for a share of the market. Claims for soap, margarine, or washing machines are expected to deal in hyperbole because they do not, beyond a certain minimum, provide an informational basis on which the life of a person may depend. Medical advertising, on the other hand, must be expected to be an informational service to which few of the traditional advertising criteria used in other areas can be applied.

Unfortunately, much of today's medical advertising does not assume its responsibility for full information and disclosure; there is evidence to show that some such advertising is grossly misleading.

Pharmaceutical companies and their advertising agencies have complained that FDA rules on medical advertising are surrounded by a great deal of uncertainty; that these rules vary and are highly subjective; that they are open to interpretation.

FDA's response has been that the guidelines laid down under the mandate of the Congress are adequate; that the development of regulations of medical advertising has been consistent and the only interpretation of these rules is "what is required to adequately inform the prescriber so that he can protect the health of his patient." Within this interpretation, FDA maintains, the regulations permit ample latitude for creative, informative advertising.

For almost thirty years now, the requirements for medical advertising must tell the whole truth about drugs.
Some further confusion in non-government areas arose out of FDA's actions to differentiate the labeling of over-the-counter and prescription drugs. The courts sustained FDA's view that OTC drugs had to carry adequate directions for use: the information anyone needs to use the product for all the conditions for which it is promoted, including claims in advertisements. This meant FDA could take into account OTC advertising copy when evaluating labeling.

Prescription drugs were exempted by regulation from the "adequate directions for use" requirement, and FDA developed rules for labeling directed to physicians.

Briefly stated, the exempting regulations provided that the labeling requirements for prescription drugs would be met if adequate information for professional use of the drug was presented in the labeling directed to the physician. These exemptions led to "full disclosure" labeling requirements.

The first "full disclosure" regulation (1.106 (b) (4)), made effective in 1961, forms the basis for the package insert required for most prescription drugs. Each dispensing package, including drug samples, is required to contain the fully informative package insert.

The 1962 Kefauver hearings on administered prices in the drug industry focused attention on pharmaceutical advertising as one of the most significant factors bearing on the price of prescription drugs.

In the course of these hearings, it became apparent that major reforms were necessary. Review of prevalent drug advertisements showed that many of the good features and advantages of a drug were carefully presented; but side effects, contraindications, adverse reactions, warnings, and other limitations on a drug's usefulness were missing. The physician who wanted to be informed had to check and verify footnotes and bibliographies. He was told in the advertisement that a "full disclosure" brochure would be sent to him upon request, but few such requests were actually made. The selling parts of the ads generally featured enthusiastic testimonials which seldom included adverse experience or opinion. As a result, the careful physician found that much of journal advertising was useless as a reliable source of medical information.

The Kefauver hearings were much more concerned with the evidence that advertising expenditures amounting to one-fourth or one-third of the cost of drug distribution did not satisfy the informational role physicians expected and needed. A good part of the hearings centered around that very problem.

The advertising provision of the Kefauver-Harris bill of 1962 was a direct reflection of congressional concern and the concern of President Kennedy who requested a law which would require "that the promotional material tell the full story about the drug — its possible bad effects as well as the good — and the whole truth about its therapeutic usefulness."

Early in February 1963, the FDA published proposed advertising regulations to carry out the purpose of the Kefauver-Harris Amendments. These regulations, after comment by the PMA, the AMA, and others, were adopted with slight changes in October 1963.

The regulations do not specify the size of advertisements, the type to be used, or the pattern of their composition or graphic illustration.

The regulations do require that medical advertisements fairly show the effectiveness of the drug for the condition for which it is advertised and list all those side effects and contraindications which are pertinent for the uses recommended in the ad as well as other uses for which the drug is commonly prescribed. The law allowed this information to be presented in "brief summary" form.

The Kefauver hearings were much more concerned with the evidence that advertising expenditures amounted to one-fourth or one-third of the cost of drug distribution did not satisfy the informational role physicians expected and needed. A good part of the hearings centered around that very problem.

The advertising provision of the Kefauver-Harris bill of 1962 was a direct reflection of congressional concern and the concern of President Kennedy who requested a law which would require "that the promotional material tell the full story about the drug — its possible bad effects as well as the good — and the whole truth about its therapeutic usefulness."

Early in February 1963, the FDA published proposed advertising regulations to carry out the purpose of the Kefauver-Harris Amendments. These regulations, after comment by the PMA, the AMA, and others, were adopted with slight changes in October 1963.

The regulations do not specify the size of advertisements, the type to be used, or the pattern of their composition or graphic illustration.

The regulations do require that medical advertisements fairly show the effectiveness of the drug for the condition for which it is advertised and list all those side effects and contraindications which are pertinent for the uses recommended in the ad as well as other uses for which the drug is commonly prescribed. The law allowed this information to be presented in "brief summary" form.

To make the customary "brief summary" useful to the physician, there has to be at least mention of all the warning ideas in the official package insert, although the small size of an ad might limit the

"Fair balance" must be maintained within the promotional message
total amount of information to be presented.

There are two general kinds of "fair balance" required in advertising by the regulations. First, the information on side effects and contraindications must be adequately prominent and must be presented in reasonably close association with the information concerning effectiveness.

Second, and even more important, is the requirement that a "fair balance" must be maintained within the promotional message of the advertisement. The advertisement must avoid partial disclosure of effectiveness and misleading half-truths. It must adhere to principles announced by FDA in November 1964 (see panel). It must avoid the common failings in advertising which FDA had observed up to that time.

Preclearance of an advertisement is required only when the manufacturer has failed to develop and follow an adequate program to notify the medical profession, promptly, of any newly discovered hazard involving the risk of serious injury or death.

As a result of these regulations, it seemed, by January 1964, that medical advertisements had distinctly improved. The typical layout of many ads showed that some attention had been paid to the fair balance between indications and warnings; the "brief summary" was more explicit than it had been earlier; some ads even showed a more discriminate use of the graphic arts.

It soon became evident, however, that the changes in medical advertising had more shadow than substance. There was an appearance of more careful adherence to the formal requirements of the regulations, but too often it was mere appearance. Careful perusal of many advertisements during 1966 indicated that some were more unreliable and misleading than ever.

The graphic arts made noisy declamations, unwarranted claims, and unproven implications. Suggestions were made that drugs which may have excellent validity in selected areas were applicable to a vast spectrum of medical problems. These and other violations were the basis of FDA charges made during legal actions taken in 1966.

The FDA faces a difficult problem today. On the one hand, advertisers and their agencies insist that advertising regulations cannot be too specific without creating the danger of destroying creativity and imagination; on the other hand, they also say that the present regulations are not specific enough to tell them exactly what must be said and what must be avoided.

The issue of specificity versus general rules was sharply outlined during the discussions at the two joint workshops held last fall: in Washington by FDA and the Food and Drug Law Institute and in New York by the FDA and the Pharmaceutical Advertising Club.

At the first meeting in Washington, advertising executives complained that FDA views and rules were entirely too general; that they gave no specific guidance on advertising problems.

At the second meeting, held in New York, FDA spokesmen were asked to present specific medical advertisements, with slides, pointing out their shortcomings, misstatements, and vital omissions. The result was an immediate charge that FDA was unfair to expose advertisers and their agencies to public criticism, and that the FDA, instead of showing these ads, should have confined itself to general observations applicable to all medical advertising.

FDA has repeatedly said it is opposed to any plan for preclearance of medical advertising. And

**COMMON FAILINGS IN MEDICAL ADVERTISING**

- Extension or distortion of the claims for usefulness beyond that approved in the product's final printed labeling.
- A quotation from a study intended to imply improperly that the study is representative of much larger and general experience with the drug.
- The selection of research papers of questionable quality that are favorable to the product, and omission of contrary evidence derived from much better research.
- Prominent citation of data previously valid but made obsolete or false by subsequent findings.
- Quotation out of context from a seemingly favorable statement by an authoritative figure, but omission of unfavorable data from the very same article.
- A favorable quotation from an obviously authoritative source, but no quotation from other differing experts in the same field and of equal standing.
- Data from papers that report no side effects, and omission of reports on side effects in other papers published contemporaneously.

*FDA Papers / February 1967 / 7*
the agency has appealed to the advertising profession to demonstrate to their clients that it is not only possible to be creative, but that it is also possible to create advertising that fulfills its purpose.

Some firms have taken the position that they have only two choices: (1) use advertising space to publish the approved package insert, or (2) not to use advertising space at all. One firm said that it was following the second alternative to the limit and canceling journal advertising.

Such action is hardly constructive. There is no benefit to the firm, to the agency, to the media, and least of all to the physician. FDA maintains that the majority of the pharmaceutical firms' advertising agencies are seeking constructive approaches to preserve creativity in medical advertising.

FDA recognizes the realities of advertising, however. One of these is the use of “creativity” as a competitive force among agencies. Perhaps it is time for FDA, drug firms, and advertising agencies to agree that medical advertising is unique and requires some limitations on “creativity.” Therefore, FDA is drafting revisions of the regulations.

The present FDA view is that some of the advertising regulations can be revised to be more specific without being so restrictive as to take away the creative genius of copywriters, artists, and ad designers. The FDA anticipates that, among other things, revised regulations could treat all promotions of prescription drugs under one concept, regardless of whether the promotion is classified as labeling or journal advertising; that revised regulations could take into account the length of promotions, as well as types of media, in establishing whether they will be subject to the prescription drug advertising or the labeling regulations; that criteria could be written into the regulations which would help determine whether “fair balance” has been achieved or whether the promotion is false or misleading; and that more practical interpretive and descriptive definitions can be included in the regulations.

NOTICE:
FDA will soon publish "A Primer on Medical Advertising." The contents will include excerpts from the FDC Act and regulations, significant speeches by FDA personnel, Libels of Information, letters, statements, and major communications on medical advertising issued by FDA since 1962. The primer will be available through the Superintendent of Documents, Government Printing Office; publication date and price will be announced later.

These are some of the ideas currently under consideration. FDA will continue formulation of revisions until the agency is prepared to publish a proposal in the Federal Register. At that time, FDA will solicit the views of all interested persons before the revisions are put into effect. Meanwhile, FDA will continue to discharge its responsibility within the framework of the law and current regulations.

While internal discussions continue, FDA is also continuing its dialogue with industry representatives and the advertising profession. Several meetings have been held to discuss new proposals for voluntary compliance with the present regulations. The participants in these discussions have taken cognizance of the industry's failure to live up to its code of advertising and of the problem facing an industry when competitive factors impoverish the richest code.

The Food and Drug Administration is sympathetic to industry leaders who would not only establish a good code of medical advertising practices but also find the means for assuring compliance with that code. The agency is also hopeful that industry leaders will seize the initiative, apply the business acumen, the creativity, and the resources to (1) bring faulty medical advertising practices under immediate control, and (2) set up a surveillance and "self-evaluation" system which will prevent the publication of violative advertisements.

The impetus of such action and the effectiveness of the industry plan will be observed carefully while FDA weighs the alternatives to correction of the present non-compliance with a law which will be five years old in October.

**Competitive forces can impoverish the richest code**
The Food, Drug, and Cosmetic Act is sixty years old in 1967. The infant law of 1906, which became effective in 1907, has matured and so has the FDA.

During these sixty years FDA has grown from a bureau in the Department of Agriculture to an agency of the Department of Health, Education, and Welfare; from 300 to 4,600 employees.

In 1906, Congress passed the first food and drug law to prevent interstate commerce of adulterated, misbranded, poisonous, or deleterious foods, drugs, and liquors and to regulate traffic therein. The Bureau of Chemistry of the Department of Agriculture, headed by Dr. Harvey W. Wiley, was assigned authority to enforce the new law.

In 1912, a separation between regulatory and research services gave early recognition to FDA's dual make-up. By this time, FDA had a staff of 312 and a budget of $763,000.

In 1927, FDA became a separate USDA law-enforcement agency, the Food, Drug, and Insecticide Administration. In 1930, the name was changed to the Food and Drug Administration.

In 1912, the Sherley Amendment was passed; the Gould Amendment in 1913; the McNary-Mapes Amendment in 1930; the Caustic Poison Act in 1927; and the Seafood Amendments in 1934.

The need for further protective legislation was part of the social awakening of the depression years. In 1933, President Franklin D. Roosevelt authorized a revision of the Food and Drugs Act. Five years of study, hearings, industry discussions and modifications followed with little prospect of any other Congressional action. Then a product called Elixir of Sulfanilamide caused 100 deaths. Congress reacted by passing the 1938 Food, Drug, and Cosmetic Act, broadening FDA's scope of authority. The new law retained the best features of the 1906 Act while adding important new ones.

The passage of the 1938 Act caused organizational changes and, by 1940, FDA's full-time employees numbered 873. In the same year, FDA moved to the Federal Security Agency.
In the late 40's and early 50's Congress enacted several amendments expanding FDA's responsibilities: the Miller Amendment in 1948, and the Durham-Humphrey Amendment in 1951. In 1948, penicillin was required to be certified for safety and efficacy. All of these factors should have meant corresponding changes within FDA. This was not the case. What changes did occur in the early 50's were negative. In 1953, FDA's budget was cut by $700,000 to $5,000,000; 1954 brought another cut of $100,000.

FDA was an obscure Federal agency. With some slight ups and downs, the FDA appropriations and manpower were the same in 1955 as in 1940. It became alarmingly clear that something had to be done. The situation was repeatedly called to the attention of budget officials and the Congress. Finally, in 1955, a Citizens Advisory Committee reported that the Food and Drug Administration did not have sufficient funds, staff, and facilities to meet its essential responsibility of protecting the public health. A threefold to fourfold expansion to take place within a period of five to ten years was strongly recommended, such expansion to be authorized by increased appropriations. This report became the catalyst for a period of rapid change and growth.

Under Commissioner George P. Larrick, the Food and Drug Administration began to catch up with its great responsibilities. A major reorganization took place in 1956. As the graph shows, the growth of FDA from 1956 to the present has been phenomenal. In 1955, there were only 1,000 full-time civil service employees. As of October 31, 1966, there were over 4,650. Appropriations have increased from approximately $5 million to $60 million for fiscal year 1967.

New and specially designed laboratory buildings have been provided for most of the 18 District Offices. At headquarters, a building was completed and occupied by 1965, containing most of FDA's laboratory facilities.

Congress continued to pass new laws—legislation changing in nature from punitive to preventive. The concept of establishing safety before marketing, which began in 1938 with new drugs, was expanded.

A Pesticides Amendment was passed in 1954; a Food Additives Amendment in 1958; Color Additive Amendments in 1960; and, in 1961, the Hazardous Substances Labeling Act, which was amended last year and is now known as the Federal Hazardous Substances Act.

In 1962, a European medical tragedy was avoided in the United States. But the thalidomide episode motivated Congress to pass the Kefauver-Harris Drug Amendments requiring that drugs be proved not only safe but effective for intended use before they could be released to the public.

During the same year, another study of FDA organization and operations was made by a second Citizens Advisory Committee. A general reorganization of FDA, in 1963, followed some of their recommendations.
There is a need for a strengthening and reorientation of management.

There is a need to elevate the level of scientific competence.

The Committee said, "Each of the three problems is made more acute by the intense pressures surrounding operations of the Food and Drug Administration. Because of these pressures, the Agency must achieve a high standard of excellence, must be skillfully managed, must be clear as to policies, must function with spotless integrity."

Secretary Gardner made this report public on January 17, 1966, when he administered the oath of office to the new Commissioner of Food and Drugs, James L. Goddard, M.D.

Addressing an FDA audience, Secretary Gardner said the Committee has "observed that rapid growth and the sudden shouldering of unexpected responsibilities had caused the FDA to suffer growing pains from a management standpoint. Putting the matter bluntly, they asserted that the FDA must be far better managed in the future. This is not an indictment of those who carried it through the difficult days of expansion... But, whatever the record of the past, we must set goals for the future. Given the life or death character of so many of FDA's decisions, laxity in management cannot be tolerated."

In his response, Commissioner Goddard acknowledged the difficulty of FDA decision-making. The Commissioner's chair, he said, is one of the hottest of hot-seats in the Government. But he left no doubt of his determination to make decisions in the public interest. "There is no question in my mind, our greatest effort is always protecting the public. It must be. Who else does the public have?"

Ten days later, Dr. Goddard sent a memo to all FDA employees asking their help in "strengthening and reorganizing the agency." During the past year the following changes were made:

First, in order to elevate FDA's scientific capabilities, the Bureaus of Scientific Research and Scientific Standards and Evaluation were combined into a new Bureau of Science. This eliminated overlapping functions, improved intracommunication of scientific data, and expedited application of research to solving regulatory problems.

Second, to increase the speed of review of new drug and investigational new drug applications, an inter-disciplinary team approach was instituted in the Bureau of Medicine. Under the new system, one-step processing now takes place. A team follows the history of drugs which are similar in structure. This team is responsible for monitoring the drug through investigational and new drug application stages.

Third, increased authority and responsibility were delegated to FDA's 18 District Directors who report directly to the Commissioner. The Directors also have direct working contact with the headquarters Bureaus.

Fourth, the function of providing industry advice was transferred to FDA's Bureau of Regulatory Compliance, facilitating coordination between the staffs providing advisory opinions and processing enforcement actions.

Fifth, to strengthen FDA's internal direction and leadership, a number of changes were made in the Office of the Commissioner.

The above chart depicts the organization of FDA today. Following is a brief description of the primary responsibilities of the major FDA units which appear on this chart:

The Bureau of Medicine (MED) evaluates, reviews, approves, and maintains surveillance over new drugs, their labeling and advertising. In addition, the Bureau ad-
vises on medical aspects of FDA’s regulatory work.

The Bureau of Veterinary Medicine (BVM) conducts research and tests of veterinary products, evaluates veterinary new drugs, and acts on medicated feed applications. The Bureau also advises on the veterinary medical aspects of FDA’s regulatory work.

The Bureau of Science (SCI) provides scientific support to FDA’s regulatory work. Through laboratory research, the Bureau develops methods of product and chemical analysis, information concerning component substances of a food, drug, or cosmetic; and evaluates product safety. Food standards are developed and claims for dietary foods and supplements evaluated. Food additives, pesticides, and color additives are evaluated for safety, residue, and intended use, and antibiotics and insulin certified for potency and purity.

The Bureau of Regulatory Compliance (BRC) develops regulatory programs for the Districts and collects and analyzes statistics on field compliance programs. Legal actions are reviewed and approved in cases where authority has not been delegated to the District Offices, where guidelines have not been established, and in cases of national scope requiring headquarters coordination.

The Bureau of Drug Abuse Control (BDAC), through the activities of nine field offices, audits records of manufacturers and distributors of amphetamines, barbiturates, hallucinogenic and other psychotoxic drugs. Social studies and non-punitive programs are developed to deal with this drug abuse problem and criminal investigations are designed to stop the illegal distribution and sale of such drugs.

The Bureau of Education and Voluntary Compliance (BEVC) promotes voluntary compliance by industry through workshops, seminars, exhibits, and literature.

The District Offices, located in 18 cities throughout the United States, carry out all field activities necessary for enforcement of the laws under FDA’s jurisdiction, with the exception of activities relating to drug abuse control. Legal action is taken in cases where authority has been delegated to the Districts, and recommendations are made on legal actions in cases where authority has been retained by headquarters.

The Regional Assistant Commissioners (RAC), to be located in the HEW Regional Offices, are concerned with the effectiveness of FDA–State programs.

The Associate Commissioner for Science (ACS) is the principal adviser to the Commissioner on scientific matters. He has responsibility for promoting scientific competence and integrity within FDA, appraising FDA’s research activities, coordinating the scientific aspects of FDA’s regulatory activities, and developing an integrated science information system.

The Associate Commissioner for Compliance (ACC) is the principal adviser to the Commissioner on compliance matters, and coordinates FDA’s regulatory and regulation-making activities.

The Assistant Commissioner for Education and Information (ACEI) is the principal adviser to the Commissioner on public information and education. He coordinates FDA’s contacts with the news media and provides publication services.

The Assistant Commissioner for Planning and Evaluation (ACP) provides leadership in long-range planning and coordinates and issues FDA’s five-year plan.

The Assistant Commissioner for Administration (ACA) is the principal adviser on organization and management and provides services in the areas of financial management, personnel management, general services, and management systems.

The National Advisory Food and Drug Council is composed of a group of distinguished private citizens who advise the Commissioner concerning FDA’s programs and policies.

The Field Liaison Officer (FLO) acts for the Commissioner in coordinating District Office activities.

The Office of International Affairs (OIA) provides leadership concerning FDA’s role in international affairs and is concerned with the quality of food, drug, and cosmetic imports.

The Office of Policy Management (OPM) is concerned with internal security and the protection of trade secrets in documents submitted by industry.

The Office of Legislative and Governmental Services (OLGS) is concerned with FDA’s relationships with State governments and the coordination of legislative matters.

This is the shape of FDA after 60 years of reorganization. As Commissioner Goddard reported to Congress last year, “This is the direction in which the Food and Drug Administration is moving, in order to be a more effective, more responsive, and more responsible agency of the Government.” Because of the increased responsibility placed upon it, the FDA will no doubt continue to adapt and reorganize as conditions change.
In a bakery an FDA Inspector and bacteriologist take a sample of dried egg to be analyzed for Salmonella.

Salmonella is not a newly discovered organism; nor is it an old one that has lately adapted itself to modern living conditions. In its hundreds of configurations, it has been with man since time immemorial—perhaps since man himself arose from the primeval slime.

And because Salmonella has been with man for so long, he has finally lost patience with it.

In the past, salmonellosis, the bacterial infection of the intestines caused by the Salmonella organism, has usually resulted from man's own contamination of his environment. As long as the environment was relatively restricted, no serious harm was done. The ailment would run its course through the community; it would usually be mistaken for intestinal flu or an upset stomach, and would rarely have serious consequences. As a result, it would soon be forgotten as one of those things whose arrival and departure defy explanation.

If, however, the community is a hospital, a school, or a nursing home for the elderly, an outbreak of salmonellosis can be far more serious. The resulting gastroenteritis can kill the very young as well as the old.

Medical authorities have encountered great difficulties in estimating the incidence of sal-
monellosis among the population. A great many cases are reported as "food poisonings"; other explanations range from "upset stomach" to "changes in the weather."

There are a few ground rules of which medical authorities are certain. Thus, man is almost invariably infected by the oral route; within 8 to 48 hours there is nausea, vomiting, stomach pains, and persistent diarrhea. After about 5 days of quiet suffering, the symptoms subside and the victim tells family and friends that he had an attack of the "24-hour flu." Some victims recover only to become carriers and pass the infection along.

It is estimated that, in 1966, some two million Americans, or 1 percent of the population, suffered from attacks of salmonellosis. If the average duration of each incidence is only 2 days—and this, statistically, would be the very minimum—then, a total of 1.5 million work days was lost among the labor force. There is evidence that the duration of illness is substantially higher: according to one source, each member of the working population is disabled an average of 51/2 days a year through sickness. The primary causes are colds and influenza, amounting to one-third of the lost time. The secondary cause is "digestive disease" which is often self-diagnosed as the "24-hour flu" or "stomach upset," but which in many cases may be salmonellosis.

The economic loss incurred by the Nation through the high incidence of salmonellosis is serious enough; but the increasing evidence of the possibilities of nation-wide salmonellosis epidemics is a matter for grave medical concern.

It has been known since 1885 that the primary route for salmonellosis infection is from animal to man. The 1963 edition of a standard medical textbook relates the vast majority of Salmonella infections of man to the enormous reservoir of Salmonella in animals. The text suggests that poultry and poultry products are primary sources of Salmonella, and adds that "up to 50 percent of raw meat purchased in retail markets is contaminated with salmonellosa."

The problem of Salmonella in poultry and poultry products was particularly emphasized during the First National Conference on Salmonella, called by the Communicable Disease Center of the Public Health Service in 1964. A number of papers read during the meeting underlined the pioneer work undertaken by the poultry industry to control Salmonella. While they readily admitted the gravity of the problem, it soon became apparent that more was known about Salmonella in poultry and eggs than about the ubiquity of the bug in other food products intended for human consumption.

Summing up the results of that conference, Dr. Alexander D. Langmuir said, "... we are going to have to learn more about salmonellosis if we are to be successful. For example, we do not even know whether the problem is increasing..."

Today, only 3 years later, we know that it is. While in 1964 only 800 types of Salmonella organisms were recognized, over 1,200 are known to exist today, and the list is by no means complete. The ubiquity of the bug is unquestioned.

We also know that not only food-producing animals are implicated in the spread of Salmonella: a wide variety of birds and reptiles, as well as dogs, cats, flies, roaches, ticks, fleas and other insects, are active in the Salmonella chain of infection.

Although the FDA and U.S. Department of Agriculture require that liquid, frozen, or dried eggs be pasteurized or subjected to an equivalent treatment, the FDA found in 1966 that some 26 percent of all such shipments examined were contaminated with Salmonella. And not unnaturally, this contamination has spread into foods involving the use of egg products, such as noodles, cake mix, and the like.

But not only eggs are involved: during the past few months, there have been recalls of dried yeast, yeast tablets, and special dietary products containing these contaminated ingredients.

The list of contaminated products is long. Salmonella was found in smoked fish which made some 400 people ill during a single outbreak of salmonellosis. In this case, careful investigation indicated that the processing plant was contaminated, most likely by fish that came from polluted waters.

A year ago, Salmonella invasion of dried milk was discovered, with the result that several nationally distributed products had to be recalled. The problem here, is that dried milk is not only used in many American households; it also is utilized in major quantities by commercial bakeries, with the result that salmonellosis can spread over wide areas before its source is discovered.

The Salmonella universe has been found to include even products which only indirectly are derived from animal sources. Thus, the organism has been discovered in granulated pepsin, thyroid powder, pancreatin, and desiccated glandular substances such as whole hog stomach and dried liver powder.

A red coloring made from a cochineal insect caused hospital outbreaks of salmonellosis after the dye was used for intestinal studies;
the same dye also contaminated candy and various seasoning agents in which it has been used.

As increasing evidence of massive *Salmonella* infestation of food and drugs comes in, industry, health authorities, the general public, and the FDA have decided that more intense control of this problem is necessary. Yet, among many, this growing concern is mixed with the hope that the bug will quietly go away.

It hasn’t and it won’t.

In the past, when foods rarely traveled farther than to the local market, and drugs were far less sophisticated than they are today, *Salmonella* was a local problem, rarely recognized and rarely affecting more than a relatively small group of people at any one time.

Today, in an era of nationally marketed foods, the spectre of national salmonellosis epidemics has become a distinct possibility.

The national scope of the salmonellosis problem was recognized in 1963, when the Communicable Disease Center of the U.S. Public Health Service established a surveillance program covering the 50 States, Puerto Rico, and the Virgin Islands. The program collects weekly reports of cases, and acts as an early warning system to control outbreaks. In 1965, CDC expanded participation to England, Belgium, the Netherlands, Australia, and Canada. This has led to a recommendation that the World Health Organization sponsor the establishment of an international reporting center.

Since 1885, when Dr. D. E. Salmon identified the organism, the U. S. Department of Agriculture has been interested in control of *Salmonella*. The Consumer and Marketing Service, Inspection and Grading Branch of the Dairy Division, provides inspection service to some 200 dry milk plants. The Animal Health Division of Agricultural Research Service has studied contamination of animal feed since 1961, working closely with industry associations.

The Division of Environmental Engineering and Food Protection of PHS has established and operates a Grade A milk plant inspection and certification program.

FDA works closely with these and other Federal and State agencies to avoid duplication of effort, and to expand resources for national attention to the problem. At all levels of Government there is agreement that *Salmonella* can be controlled.

FDA has concluded that action should be taken to eliminate animal-based sources of infection. The major responsibility for animal infection lies in contaminated feeds and feed mixes which utilize animal by-products and thus start the vicious chain. Investigation has shown that such feed additives as processed fish meal, poultry meal, meat scraps and meal are primary sources of *Salmonella*.

These products are processed without any regard for sanitation, simply because they are intended for animal consumption, and sanitation is considered unnecessary for such a purpose. They are the refuse of animals whose edible parts move along in a cleaner atmosphere, while the waste lies exposed to the elements and becomes a ready breeding ground for *Salmonella*.

The processing methods used for these materials intended as feed mixes do not always kill the *Salmonella* organism; and, even if they do, the product is immediately recontaminated in *Salmonella*-loaded surroundings. And once the feed mix is contaminated, the *Salmonella* organism is assured of survival and eventual arrival in the human body, since it contaminates the animal which is fed on the mix and eventually slaughtered for human consumption.

Animal feed manufacturers insist that they cannot hope to produce *Salmonella*-free products as long as the ingredients they use arrive *Salmonella*-laden at their plants. They say that any effort to eliminate the bug from their operations is doomed as soon as the next shipment of contaminated by-products enters their premises, and they have a good case.

The fact is that these complaints have had little or no effect on the suppliers of animal by-products. There is an apparent disinterest,
or lack of economic incentive, on the part of that industry.

In recent months, the Food and Drug Administration has made various attempts to change this attitude. Thus, a letter to the major associations representing the feed industry informed them of the Agency's concern, and encouraged them to take the initiative in breaking the vicious cycle of Salmonella contamination.

This effort was followed by a statement of policy, published in the Federal Register. It formally notified the industry that the FDA would regard as adulterated any animal by-product intended for animal feed where that by-product is found to be contaminated by Salmonella. Under the law, such material is subject to seizure.

If voluntary compliance by industry and regulatory actions by the FDA result in the delivery of Salmonella-free animal by-products to feed manufacturers, then we may have reached the stage where the primary chain of contamination of animal-derived food intended for human consumption will be broken.

To arrive at that goal, the feed manufacturer cannot wait to install his own sanitary controls until after his supplier has succeeded in wiping out Salmonella contamination in animal by-products. Salmonella must be controlled wherever and whenever it is found.

The interest which the FDA has in the animal feed problem was somewhat overshadowed by the notoriety given to the recalls of dried milk last fall.

The fact is that the FDA has, for a long time, been very much concerned with Salmonella infestation of a wide variety of foods intended for human consumption. As indicated earlier, Salmonella concentration seems to be particularly heavy in dried or frozen eggs; it certainly is so in dried milk products, which are manufactured under conditions substantially different from those applied to fresh milk products.

It is becoming increasingly evident that the food industry's entire thinking on this subject may have to undergo a radical change. Speaking at the Tenth Annual Food and Drug Law Institute-FDA Educational Conference in November 1966, Robert G. Ruark, of the Corn Products Company, said that salmonellosis is poisoning by accident, and added, "it occurs where we fail to control the malevolent side of nature to our maximum ability. It occurs when we fail to use our knowledge. And the result of this failure is tragic in terms of its consequences—all the more so, because it is unnecessary."

Expressing the interest of the consumer and the intent of the Government, Mr. Ruark added, "if the food manufacturer is going to stay in business, he must be willing to pay the price required to assure a quality product. The precautions and the regulations relating to salmonella are costly, but we can be certain that better products will be flowing to the consumer in the future by proper exercise of these precautions. This is simply economic incentive enough for the manufacturer to comply with regulations and recommendations."

If it is in the interest of the food manufacturer himself to control the incidence of Salmonella infestation, it now remains for him to determine where his efforts at control can be most effective.

It goes without saying, that ordinary sanitary precautions in the food plant must be above reproach; that there must be facilities for the sterilization of food machinery, and that these facilities must be used to the fullest possible extent, at regularly planned intervals.

There is evidence, however, that, in some plants, regularly undertaken sanitary procedures have not been successful in eliminating Salmonella. In some cases, machinery was taken completely apart, sanitized, and reassembled—yet the Salmonella organism promptly appeared again in the very first products that came down the assembly line.

Where this has been the case, it may well be necessary to review the sanitary efficacy of all machinery involved in the production and packaging of food. Frequently, such machinery was designed and built 10 or more years ago when knowledge and awareness of Salmonella infestation was more limited than it is now.

It may well become necessary to embark on entirely new methods in the design and manufacture of food machinery. Perhaps such machinery should not be designed just by engineers. Perhaps food technologists, bacteriologists, even immunologists will have to cooperate in the design of such machinery to apply their combined knowledge to the elimination of bugs which, literally and figuratively, have invaded the factories.

During the past few years, the FDA, following the congressional mandate of 1962, has set up a code of good manufacturing practices for the drug industry.

Current thinking among FDA officials indicates that it may well be necessary to set up a similar code for the food industry, unless the industry itself shows its willingness to eliminate the danger of Salmonella infection and infestation.

There is no reason to believe that the Salmonella organism cannot be controlled. There is every reason to believe that it must be.
salmonella sleuthing

Detection of *Salmonella* in food is not complicated for trained microbiologists. Using standard lab equipment, FDA routinely analyzes many types of foods. A full-time microbiologist can readily maintain *Salmonella* control procedures. FDA helps firms select proper detecting methods. Many methods have been published.

Flasks containing media and test sample are incubated for 24 hours at 35 degrees C. to promote bacterial growth. Portions of incubated sample are put into selective broths before separating *Salmonella* from other bacteria.
Materials produced by bacteria during growth change the color of the separation plates according to the kind of organism present. (Right) Colonies that look most typical of Salmonella are transferred from separation plates to culture media in which Salmonella produce characteristic color changes. At this point Salmonella is presumed present pending biochemical and serological confirmation.

FDA microbiologists prepare plates for separating Salmonella. Plates are streaked with selective broths that separate Salmonella from other bacteria.

In confirmation, a sample from the color-change test is placed in each sera on a plate containing different sera (a component of blood). Clouding proves Salmonella is present. Part of the culture is also added to biochemicals (right) to produce a reaction by color change, and by clouding of samples of standard prepared sera (far right). Confirming tests identify Salmonella as one of 1200 types.
Ecologic effects

By
Laverne C. Harold D.V.M.
Robert A. Baldwin D.V.M.
of antibiotics

Ecology is the science of organisms as affected by the factors of their environment. Man is the organism which concerns us most, and antibiotics in the environment are the factors as we address the question: Has man adversely affected his environment with his varied and multiple use of antibiotics?

An antibiotic is a chemical substance which is produced by a micro-organism and which has the capacity, in dilute solution, to inhibit or destroy micro-organisms.

Without question, the discovery of antibiotics was one of the greatest of this generation. They have saved lives and helped to control one of the historic ravages of mankind—that of infectious diseases. They have also been used to treat and prevent diseases in livestock and food crops.

After twenty years of use, however, it is time to examine objectively all of the methods of use. This examination must be made so that antibiotics may continue to play the primary role which man has assigned them—that of treating and controlling infectious diseases.

The genesis of antibiotics is the world of the bacteria, fungi, and plant products. They were not concocted in the laboratories of our vast drug industry by men in white coats. Instead, they are to be found everywhere in nature.

Some of the antibiotics are called drugs because they are useful in the treatment of diseases of man and animal. Indeed, there is a continuous search in nature for new antibiotics.

There are now approximately 20 antibiotics that are used for the treatment and prevention of infectious diseases, both in man and animal. In man, antibiotics are used for a relatively short duration. In livestock, antibiotics may be used for the lifetime of the animal.

While they have been called "wonder drugs" by the public, certain inconsistencies in the action of antibiotics have puzzled human and veterinary clinicians from the beginning. Many times they had to greatly increase the dosage to see any effect against an infection. In other instances, they got no discernible response at all.

Various reasons have been given for the irregularities. At first, it was thought that under-dosing was the common cause. Later, it was found that certain strains of bacteria developed against which the antibiotic was ineffective. In more recent times, investigators have discovered a number of viruses associated with infectious disease, against which no antibiotic is normally effective. This discovery may have led us to overlook all the possibilities of drug resistance.

The R-Factor is said to be the mechanism of transferable drug resistance. It has two components: Resistance Transfer Factor (RTF), and Resistance Determinant (R-d). RTF may be likened to a radio system. It is capable of receiving and transmitting drug resistance information, but is not activated until it contacts the R-d. When this happens in one cell it starts a chain reaction.
Bacterial resistance to antibiotics has been known to develop in a number of ways. The resistance may be by mutation; by enzymes that destroy the antibiotic; by transduction; and by conjugation.

The real concern today is the resistance of bacteria to antibiotics by a method known as conjugation. By this process, two bacterial cells come together (e.g., in the intestinal tract) and connect. During the connection, a "signal" to resist antibiotics and sulfa drugs is transferred from one cell to the other. In the language of the scientists, this passing of genetic information between bacteria is known as infectious drug resistance, multiple drug resistance, or transferable drug resistance.

Exactly how this genetic information is passed on by conjugation is still being debated. Investigators agree, however, that resistance to antibiotics by conjugation does occur, both in the test tube and in the intestinal tract of man and animal.

The theory of drug resistance by conjugation currently in scientific favor is called the R-Factor. It is postulated that the R-Factor has two components. One is the Resistance Transfer Factor (RTF) which may be extra-chromosomal and contains DNA, the genetic material that specifies the design and construction of future generations. The other component of the R-Factor is called the Resistance Determinant (R-d). This is the genetic fragment that determines the specific drug resistance.

The RTF may be likened to a radio system tuned to handle at least one kind of genetic information: drug resistance. It is capable of receiving and transmitting this information, but is not activated for drug resistance until it comes in contact with the R-d.

How the R-d occurs in a bacterial cell is academic when we consider that one such cell will activate the RTF in any cell it contacts and start a chain reaction. As cell contacts cell, the "signal" is passed to resist the drug, until many organisms are resistant.

Experiences in man, animal, and test tube have demonstrated this. And it has been discovered that the R-d causes resistance not only to one specific drug, but to several. Further, the RTF is capable of receiving and transmitting simultaneous "signals" to resist a number of antibiotics.

This means that a micro-organism can become resistant to a number of the presently known effective antibiotics; that this infectious drug resistance can be passed from one species of bacteria to another; and that continued use of the antibiotics keeps the process going.

The specific drugs now known to be involved in infectious drug resistance are: penicillin, ampicillin, streptomycin, chloramphenicol, sulfadiazine, tetracyclines, neomycin, kanamycin, and furazolidone.

In the United States, the first report of bacteria carrying transferable antibiotic drug resistance was in August 1966. A second report was published by Dr. David H. Smith in the September 1966 New England Medical Journal. Both of these reports were based on isolations of Salmonella, E. coli, and Shigella bacteria from humans. An exhaustive search for similar reports in animals in the United States has been unavailing. This does not mean it might not occur in our animal population, but that no studies have been conducted to confirm or refute this point.

In Japan, in 1959, scientists first advanced the R-Factor theory to account for the increasing numbers of antibiotic-resistant bacteria they were observing. They proved the theory with studies which showed that dysentery-causing bacteria which were resistant could pass this resistance to E. coli, another type of common bacteria. In turn, the E. coli could pass the resistance to Salmonella, still another type of bacteria.

As early as 1957, workers in Britain were becoming concerned over the increasing numbers of bacteria they were finding resistant to antibiotics. Since that time, the British have definitely established that infectious drug resistance does exist in both their human and animal population.

Other countries and areas are now beginning to report incidents of this condition. These include
Germany, the Netherlands, the Middle East, Southeast Asia, and South America.

The implications of these studies, and evidence of infectious drug resistance in the United States, necessitates modification of our former thinking regarding infectious diseases transmissible between animal and man. Formerly, when bacteria common to animals were isolated in humans, it was considered evident that transfer from animal to man had occurred. If the bacteria happened to be a pathogen, it was viewed with concern.

Now, the credibility of categorizing bacteria as either human or animal may be meaningless, because the RTF has also been shown to transfer other genetic information: i.e., classification information. This is exemplified by a study that showed that a bacterial type usually associated with chickens was changed to a type closely approximating that found in cattle when the RTF component was introduced.

It must be emphasized that:

1. Infectious drug resistance is known only to occur, so far, among gram-negative enterobacteria; e.g., Salmonella, Shigella, E. coli. These are bacteria which may be in the lower intestine of both man and animals. The first two can cause salmonellosis, including typhoid fever and bacillary dysentery, to name a few diseases.

2. Investigators are prone to believe that the resistance continues only under constant antibiotic exposure; they call it "antibiotic pressure."

3. How often antibiotic resistance is transferred from one bacterium to another in nature is not definitely known.

4. How long the resistance remains after antibiotics are withdrawn is not known, either.

However, one study with pigs showed bacteria resistant to one of the antibiotics as long as 7 months after the pigs no longer had access to the drug, although the resistance was decreasing.

4. How widespread these resistant bacteria are among humans and animals in the United States has yet to be studied. Also, the number of these bacteria with which an individual or animal must come in contact before there is danger of a given antibiotic becoming ineffective remains to be investigated.

The Food and Drug Administration views the problem of infectious drug resistance in two parts:
1. As a regulatory agency, what steps must be taken on the basis of present evidence to protect the public health?
2. As a scientific agency, what FDA studies are required to obtain scientific evidence for future regulatory decisions?

Immediately following publication of the Report of the Committee on the Veterinary Medical and Non-Medical Uses of Antibiotics, in August 1966, FDA asked sponsors of drugs containing antibiotics intended for use in food-producing animals to submit data showing whether such antibiotics are present as residues in the meat, milk, and eggs from the treated animals. This Federal Register policy statement put a 180-day time limit on submission of the data. Firms not responding are subject to FDA action to withdraw approval for marketing of the products. Generally, no residues are permitted, and FDA intends to exclude from the market those products on which tissue residue data are lacking.

In another FDA move based upon a recommendation by the Committee, action was taken, in September 1966, to disallow the use of antibiotics to preserve fish and poultry. FDA proposed to rescind tolerances of chlortetracycline and oxytetracycline in poultry, fish, and shellfish treated with these antibiotics for preservative purposes.

Because the Committee recognized a potential hazard to man through exposure to antibiotic sprays and dusts, FDA forwarded the report to the U.S. Department of Agriculture, which registers these products under the Federal Insecticide, Fungicide, and Rodenticide Act.

Other regulatory actions are under consideration.

At the same time, FDA initiated interagency conferences to explore the need for scientific studies of the long-term effects from antibiotics, as recommended by the Committee.

On September 9, 1966, FDA scientists met with their colleagues from the Departments of the Army, Air Force, Interior, State, Agriculture; the National Science Foundation, Naval Medical Research Institutes, Public Health Service.
Veterans Administration, National Aeronautics and Space Administration, Agency for International Development, and the Executive Office of Science and Technology. This group met again on December 9, 1966.

Meanwhile, FDA has contracted with the National Academy of Sciences for a symposium on the Scientific Aspects of Medicated Feeds, to be conducted by the National Research Council, on June 5-7, 1967. Some 25 authorities in the field of medicated feeds have been invited to present reports dealing with: (1) the value and safety of growth-promoting agents in livestock and poultry feeds; (2) the therapeutic value and safety of various combinations of drugs used in feed for disease prevention, treatment, and control; (3) the significance and potential danger of developing reservoirs of pathogens resistant to the chemotherapeutic agents used in feeds; and (4) the significance of drug residues in food consumed by man.

As these actions indicate, FDA shares the concern of the medical community about multiple antibiotic resistance and infectious drug resistance in bacteria. The agency recognizes its responsibility to protect the public health through control of veterinary and nonmedical uses of antibiotics so that these life-saving drugs can continue to have that effect. At the same time, FDA recognizes that the evidence of infectious drug resistance in the United States is meager; that studies of its influences in animals must be expanded; that epidemiological studies are necessary for understanding its effects on man.

Has man adversely affected his environment with his varied and multiple uses of antibiotics? Perhaps, but we must arrive soon at a clear "yes" or "no" answer.

Highlights of FDA's consumer protection activities are illustrated in this new pamphlet. Single copies are available from FDA headquarters and field offices.
ATLANTA DISTRICT

FDA had more than one good reason for ordering seizure of nine cases of frozen deviled crabs at Seafood Enterprises, Tampa, Fla., on November 4. The crab product was manufactured under insanitary conditions; contained cod instead of crabmeat; bore false and misleading labeling; and lacked adequate ingredient declarations. The product is manufactured by Bayou Foods, Inc., Mobile, Ala.

ATLANTA BDAC

In the first terminated jury trial involving LSD sales, Richard C. Bird, Miami, Fla., was found guilty on November 9. The judge ordered a presentence investigation by the probation officer. A religious freedom defense was stopped at the hearing, and the Neo-American Church did not assist in Bird's defense. Bird is an official of the local Neo-American Church.

BALTIMORE DISTRICT

After being convicted by State authorities on drug charges, a Virginia truck stop owner continued his illegal operations and was subsequently convicted on Federal charges. Lacy F. Dudley, Rocky Mount, had been fined $350 and sentenced to 60 days in jail on State charges of unlawful possession of dangerous drugs. He then illegally dispensed prescription drugs to an FDA inspector, which led to Federal prosecution. He was fined $1,000 on November 14, given a 1-year suspended sentence, and placed on probation for 3 years.

BOSTON DISTRICT

A distributor of fake cancer cures has been sentenced for violating the regulations enforced by the Division of Biologics Standards of the U.S. Public Health Service. FDA had earlier made numerous seizures of George S. Zuccala's products. In the current action, Zuccala, Hartford, Conn., was sentenced to 9 months in prison for shipping an unlicensed cancer vaccine.

BOSTON BDAC

Alice C. (Lisa) Bieberman, Boston, Mass., was found guilty on November 17 of illegal sales of LSD. She was sentenced December 6 to 6 months in jail on each count, to run concurrently. The sentences were suspended and she was placed on probation for 1 year.

BUFFALO DISTRICT

The District held its first Workshop on Good Manufacturing Practices for Feed Mixers, November 30, at Syracuse, N. Y. Talks on Salmonella, antibiotics in feeds, cooperative Federal-State inspections, and other topics, were given to 31 feed industry representatives. Speakers included Cornell University professors, and representatives from The Eastern Federation of Feed Merchants, New York State Department of Agriculture and Markets, FDA headquarters, and Buffalo District.

CHICAGO DISTRICT

The first of a series of four FDA workshops on Salmonella in dried milk products was held in Oshkosh, Wis., on December 6. Bacteriology professors at the University of Wisconsin, and other speakers, described the nature of the organisms, and its prevention and control, to 180 participants.

CHICAGO BDAC

Anthony Di Donato was finally arrested on November 4. Also known as Tony Donato, Michael Donato, and Tony Calvise, Di Donato was originally fined $5,000 in January 1966, for the illegal sale of approximately 385,000 amphetamines. He was given 30 days to pay the fine but did not comply. An arrest warrant was issued, and the U. S. Attorney's office asked FDA's help in locating him. Two BDAC agents established contact with him, and Di Donato said he would surrender. On the appointed date he called the agents and said that he would not surrender, since he did not have the $5,000. Through an informant the agents were able to locate him about 75 miles from Chicago. The Illinois State Police finally arrested Di Donato and delivered him to the U. S. Marshal.

CINCINNATI DISTRICT

Two physicians were fined for dispensing drugs without a doctor-patient relationship. William Graham Fisher, M.D., Columbus, Ohio, was fined $5,000 in December and placed on probation for 5 years for illegally dispensing amphetamines. Augustus D. Slone, M.D., Paintsville, Ky., was fined $635 in December for causing drugs to be dispensed from his clinic without a prescription and without a doctor-patient relationship. His employees actually dispensed the drugs with his sanction.

DALLAS DISTRICT

A Texas crabmeat packer has been permanently enjoined from shipping microbiologically contaminated crabmeat in interstate commerce. Ruby R. Lowe, trading as Star Crab Co., Palacios, Tex., and her principal employee, Bernie J. Langston, consented to the injunction on November 9. Mrs. Lowe and her late husband have a long record of FDA violations in various parts of the country. In 1961, a food poisoning incident in Houston, Tex., was traced to contaminated crabmeat produced by the Lowe's company. A $1,000 fine was imposed on the
company, and Mr. Lowe was sentenced to 3 months in jail. The Division of Food and Drugs, Texas State Department of Health, prosecuted the Lowes in 1962, and fined the firm $115.

DENVER DISTRICT
Because it contained flammable ammonium nitrate pellets, a boxcar of wheat was seized recently in Denver, Colo. A Colorado Milling and Elevator employee noticed the white pellets adhering to the sides of the rail car, and the firm reported this to FDA. The shipper was Potter Co-op Grain Co., Potter, Nebr.

The W. H. Grew Manufacturing Co., Salt Lake City, Utah, destroyed more than $9,000 in drugs manufactured from raw material suspected of Salmonella contamination.

DETOUR DISTRICT
The District helped sponsor a 1-day workshop for medicated feed mixers at Michigan State University, East Lansing, Mich., on November 16. Other participants were: The Michigan Department of Agriculture, Laboratory Division; Michigan State University Cooperative Extension Service; and Michigan Grain and Agricultural Dealers Association. The industry workshop was conducted to acquaint feed mixers with the principles of good manufacturing practices for medicated feeds, preparation of new drug and antibiotic applications, drug residues in animal by-products, and the Salmonella problem in animal feeds.

KANSAS CITY DISTRICT
A Japanese wrinkle remover was seized in October as a new drug without an approved application. The 87 vials of "Elicon Young" (silicone injection) were seized at the office of Howard Dolyak, D.O., Stuart, Iowa. Manufactured and shipped by the Koken Kogyo Co., Ltd., Tokyo, Japan, the product was valued at $187.

KANSAS CITY BDAC
R. T. McCreight, D.O., was arrested in Ness City, Kans., for selling 5,000 amphetamines to undercover agents. On six different occasions, agents purchased a total of 5,000 amphetamine tablets and 80 capsules. Based on these buys, agents arranged to buy 12,000 amphetamines from McCreight. When he delivered the drugs on December 1 at the Ness City Airport, a small community airfield which he formerly owned, he was arrested. He later posted a $2,000 bond.

LOS ANGELES DISTRICT
Due to Salmonella contamination, 22 pounds of imported beef pituitary powder were seized at Leo Linden Laboratories, Inc., Culver City, Calif. The product, valued at $440, was manufactured by Laboratorio Opoterapico of Argentina and shipped to the California firm by Van Gilder-Faute Corp., New York, N.Y.

MINNEAPOLIS DISTRICT
Minneapolis District and the Wisconsin Department of Agriculture are planning parallel work on bacteriological inspections of Wisconsin nonfat dry milk plants for Salmonella contamination. An initial work-planning session was held at LaCrosse, Wis., on September 29. Three joint bacteriological establishment inspections have been made already, and results of inspections and sample analysis will be shared.

NEW ORLEANS DISTRICT
New Orleans Shrimp Co., Inc., New Orleans, La., spent more than $100,000 for improvements, including a larger production area, new flaked ice storage bin, deveining units, storage equipment, stainless steel working surfaces, and breading line equipment.

NEW YORK DISTRICT
A fine of $8,000 was imposed on G. Santoro & Sons, Inc., Brooklyn, N.Y., for holding macaroni products under insanitary conditions. Joseph Signorelli received a suspended sentence of 18 months and was placed on probation on November 23. In his presentencing remarks, the judge characterized the conditions involved in the violation as "disgusting" and "outrageous."

Chas. Pfizer & Co., Inc., Clifton, N. J., voluntarily destroyed $159,000 worth of Terramycin Solution on November 18. The firm recalled the solution after discovering it contained a precipitate of sodium and magnesium citrate. The firm stated it did not consider the precipitate a health hazard.
NEW YORK BDAC

Both counterfeiting and illegal sales tripped up John Sywilok, New York, N. Y. He was first arrested by Secret Service agents for selling counterfeit bills. BDAC agents furnished information leading to this arrest, and then on November 23 arrested Sywilok for selling controlled drugs.

PHILADELPHIA DISTRICT

Two Philadelphia FDA inspectors were too close to a recent food poisoning case for comfort. Wayne Stafford and Kenneth Martin developed severe symptoms of food poisoning after eating at a diner in Allentown, Pa., in October. Inspector Stafford required hospital treatment. Investigation showed that the diner used drinking water from a contaminated well, and stored and handled food in an insanitary manner. Bacteriological findings in sausage and butter samples taken at the diner were reported to the State of Pennsylvania Department of Health.

ST. LOUIS DISTRICT

A convicted Louisiana drug peddler has lost his chance to appeal his case. Harry Zarafonetis, Springhill, had been found guilty in April 1966 of selling amphetamines and barbiturate drugs without a prescription. He was then sentenced to 2 years in prison, given a 1-year suspended sentence, and placed on probation for 3 years. The defendant posted $5,000 bond and indicated he would appeal the judgment. In November, the U. S. Attorney indicated that Zarafonetis' time for perfecting his appeal had expired and issued a mandate granting Zarafonetis 30 days in which to surrender himself.

SAN FRANCISCO DISTRICT

A joint effort on egg pasteurization in California has failed to achieve the desired results. A new California State law (effective June 1966) requires that all frozen and liquid eggs be pasteurized. To reduce the high cost of pasteurizing equipment, several small egg breakers organized under the name of Nulaid Foods Division of Pacific Growers Association. Liquid eggs were broken out at each participating ranch, and the magma held in refrigerated holding tanks. The magma was picked up two or three times a week in a tank truck and taken to Sonoma Valley Cheese Factory, Sonoma, Calif., where it was pasteurized. FDA inspection of the pasteurizer in October 1966 revealed the excessive time lags and holding temperatures in the process. Several samples collected from lots shipped throughout the country were found to be decomposed.

SEATTLE DISTRICT

As a result of a recent salmonellosis outbreak at Seattle Pacific College, Western Farmers Association, Seattle, Wash., has voluntarily discontinued making cooked, deboned chicken for the institutional trade. The outbreak was allegedly caused by the firm's chicken product. Stocks of the suspect product at the plant will be processed further. The U. S. Department of Agriculture is supervising reconditioning of stocks returned from distribution channels.
In a Decatur pharmacy, Georgia State Board of Pharmacy Inspector, Jack West, audits DACA prescriptions.

States to Check Pharmacies FDA works with State drug control officials to curb illegal traffic in prescription drugs in community pharmacies. The new program places major responsibility on participating State Boards of Pharmacy and State Health Department drug enforcement units to control illegal sales or diversion of drugs, particularly those drugs subject to the Drug Abuse Control Amendments of 1965.

Drug enforcement officials in six States—Florida, Georgia, Indiana, New York, Texas, and Washington—are investigating complaints concerning illegal sale or diversion of controlled drugs by community pharmacies. State offices work closely with field offices of FDA's Bureau of Drug Abuse Control (BDAC). Under State laws they are instituting punitive legal and administrative action against violators.

The States' drug accountability coverage of community pharmacies will greatly extend BDAC's ability to cope with major drug abuse problems of an interstate or underworld nature. BDAC will, however, watch the community pharmacy found to be making major interstate, illicit drug sales or counterfeiting.

The cooperative program started in August 1966 with a 4-day training course in retail drug investigation for 25 drug enforcement officials representing the six pilot States and New York City. Three courses are scheduled for early this year in Baltimore, Md., Kansas City, Mo., and San Francisco, Calif., for the States which will soon be added to the program.

Informal agreements have been established with each participating State and local drug control agency to avoid duplication of effort. Periodic work-planning conferences will be held between the regional BDAC Field Offices and State and local participating agencies.

FDA first proposed a cooperative Federal-State drug control pilot program at the 1965 annual meeting of the Association of Food and Drug Officials of the United States (AFDOUS) in New York City. Conferences were held shortly thereafter with the officers and Executive Committee of the National Association of Boards of Pharmacy (NABP) and the Executive Board of AFDOUS. These meetings affirmed State officials' interest in working closely with FDA in curbing illicit drug traffic.

City, State Officials Reject Salvage Plan Juice ran out on the floor of a railroad car of "frozen" spinach in Baltimore recently. A & P Stores rejected the thawed California spinach, and the B & O Railroad then sent the spinach to a cold storage company where it was refrozen. The railroad wanted to salvage and relabel the product. But after the Baltimore City and Maryland State Health Departments inspected the spinach, the entire shipment of 101,268 pounds was condemned and destroyed.

New Utah Facility Opened The Utah Department of Agriculture held an open house on November 9 to celebrate the opening of its new building in Salt Lake City. The facility houses the State Chemist, Seed Laboratory, Weights and Measures Division, and the Federal-State Animal Division.

Michigan Investigates Feeds The Michigan Department of Agriculture's Laboratory Division recently reported that Martin's Feed Mill, New Paris, Ind., had shipped two questionable animal feeds to a Michigan feed company. The labels were incomplete and the drug levels and combinations appeared unusual. The Division collected samples and made a factory inspection. Investigation showed that one feed was a new drug without an approved New Drug Application, and the other violated the firm's approved antibiotic Form 10. Both feeds were seized and later destroyed.

Wisconsin Acts Against Rutabagas Because of excess chlordane, 6,000 pounds of rutabagas were seized in St. Paul, Minn., recently. They were shipped by Windfall Farms, Exeland, Wis. Chlordane had been placed directly in the drill with the seed. The State of Wisconsin Department of Agriculture examined the remaining seven fields and two bins of rutabagas that had been harvested and found all but one small lot contained excessive amounts of chlordane. The State is supervising the plowing under of more than $35,000 worth of the rutabagas.
Americans waste over one billion dollars a year on worthless health products and practices. FDA's new motion picture, "THE HEALTH FRAUD RACKET," exposes the cunning traps and trappings of the fraud, the quack, and the charlatan. This 28-minute, full color motion picture tells how to distinguish between legitimate and fraudulent products, how to spot quackery, and what to do about it.

Arrange free showings in your plant, office, and community. Write: Films, Office of the Assistant Commissioner for Education and Information, Food and Drug Administration, Washington, D.C. 20204
seizures and prosecutions

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

A total of 119 seizure actions to remove adulterated, misbranded, and unsafe product from the consumer market were reported in November. These included 80 seizures of foods: 9 because of poisonous and deleterious substances, 54 because of contamination, and 17 because of economic violations. Other seizures included 5 of vitamins and dietary foods, 18 of drugs, 11 of medical devices, 4 of hazardous substances, and 1 of colors.

<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FOOD / Poisonous and Deleterious Substances</strong></td>
<td>Newman Grocery &amp; Produce Co. / Hillsville, Va. (S)</td>
<td>Contains toxaphene, a pesticide chemical not in conformity with regulations.</td>
</tr>
<tr>
<td></td>
<td>James E. Crouse/Rural Retreat, Va. (S)</td>
<td>Contains chlordane, a pesticide chemical not in conformity with regulations.</td>
</tr>
<tr>
<td></td>
<td>F. H. Vahsing, Inc./Hereford, Tex. (M,S)</td>
<td>Contains paraquat and methyl paraquat in excess of established tolerance.</td>
</tr>
<tr>
<td></td>
<td>West Coast Farms/Watsonville, Calif. (S)</td>
<td>Contains poisonous Salmonella micro-organisms.</td>
</tr>
<tr>
<td></td>
<td>Monark Egg Products, Inc. / Kansas City, Mo. (M,S)</td>
<td>Contains poisonous Salmonella micro-organisms.</td>
</tr>
<tr>
<td></td>
<td>Producers Produce Co./Springfield, Mo. (P,S)</td>
<td>Contain chlordane, a pesticide chemical not in conformity with regulations.</td>
</tr>
<tr>
<td></td>
<td>Windfall Farm, Claude and Betty Bartlett Exeland, Wis. (S)</td>
<td>Contain chlordane, a pesticide chemical not in conformity with regulations.</td>
</tr>
<tr>
<td><strong>Contamination, Spoilage, Insanitary Handling</strong></td>
<td>Bien Trading Co., Inc./New York, N.Y. (S)</td>
<td>Partly decomposed.</td>
</tr>
<tr>
<td></td>
<td>Gottfried Baking Co./New York, N.Y. (M,S)</td>
<td>Insect-contaminated.</td>
</tr>
<tr>
<td></td>
<td>State Wholes., Grocers/Detroit, Mich. (D)</td>
<td>Held under insanitary conditions; insect-contaminated.</td>
</tr>
<tr>
<td></td>
<td>Wyoming Dairy Foods, Inc./Torrington, Wyo. (M,S)</td>
<td>Prepared under insanitary conditions; insect-contaminated.</td>
</tr>
<tr>
<td></td>
<td>Hernandez/Las Cruces, N. Mex. (M,S)</td>
<td>Insect-contaminated.</td>
</tr>
<tr>
<td></td>
<td>Wilfred Karlsen, Ltd./Yarmouth, Nova Scotia, Canada (S)</td>
<td>Insect-contaminated.</td>
</tr>
<tr>
<td></td>
<td>Cain Coffee Co., Inc./Corpus Christi, Tex. (D)</td>
<td>Held under insanitary conditions; rodent-contaminated.</td>
</tr>
<tr>
<td></td>
<td>Weston Biscuit Co./Waco, Tex. (M,S)</td>
<td>Prepared and packed under insanitary conditions; insect- and rodent-contaminated.</td>
</tr>
<tr>
<td></td>
<td>Texas Broom Factory/San Antonio, Tex. (S)</td>
<td>Insect-contaminated.</td>
</tr>
<tr>
<td></td>
<td>California Corn Husk Co./Norwalk, Calif. (S)</td>
<td>Prepared and packed under insanitary conditions; E. coli.</td>
</tr>
<tr>
<td></td>
<td>Alaskan Glacier Seafoods/Petersburg, Alaska (P,S)</td>
<td>Held under insanitary conditions; insect-contaminated.</td>
</tr>
<tr>
<td></td>
<td>Dart Warehouse Corp./Los Angeles, Calif. (D)</td>
<td>Insect-contaminated.</td>
</tr>
<tr>
<td></td>
<td>Educator Biscuit Co./Lowell, Mass. (M,S)</td>
<td>Held under insanitary conditions; insect-contaminated.</td>
</tr>
<tr>
<td></td>
<td>Yavner Bros., Inc./Norfolk, Va. (D)</td>
<td>Held under insanitary conditions; insect-contaminated.</td>
</tr>
<tr>
<td></td>
<td>Ancona Brothers Wholesale Grocery/Omaha, Nebr. (D)</td>
<td>Held under insanitary conditions; rodent-contaminated.</td>
</tr>
<tr>
<td></td>
<td>Canton Wholesale Co./Canton, Ga. (D)</td>
<td>&quot;</td>
</tr>
<tr>
<td></td>
<td>Alexander Grocery Co./Savannah, Ga. (D)</td>
<td>&quot;</td>
</tr>
<tr>
<td></td>
<td>Gateway Milling Co./Peoria, Ill. (D)</td>
<td>&quot;</td>
</tr>
<tr>
<td></td>
<td>Nebraska Consolid. Mills/Omaha, Nebr. (M,S)</td>
<td>Insect-contaminated.</td>
</tr>
<tr>
<td>PRODUCT &amp; PLACE</td>
<td>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</td>
<td>CHARGES</td>
</tr>
<tr>
<td>----------------</td>
<td>-----------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Herring Roe &amp; Whale Tailbone Meat</td>
<td>Canadian Seafood Co./Vancouver, British Columbia, Canada (P,S) Affiliated Food Stores/Dallas, Tex. (D)</td>
<td>Excessive E. coli.</td>
</tr>
<tr>
<td>Los Angeles, Calif. 10/13/66</td>
<td></td>
<td>Insect-contaminated.</td>
</tr>
<tr>
<td>Dallas, Tex. 11/18/66</td>
<td>Kitty’s Kandy Kitchen / Oklahoma City, Okla. (M,S)</td>
<td>Prepared and packed under insanitary conditions; insect-contaminated.</td>
</tr>
<tr>
<td>Paprika, ground/Oxnard, Calif. 9/9/66</td>
<td>Dixie Peanut Co./Fitzgerald, Ga. (P,S)</td>
<td></td>
</tr>
<tr>
<td>Pecan Pralines/Lawrence, Kans. Ft. Scott, Kans. 10/18/66</td>
<td>Texas Laboratories/Dallas, Tex. (D)</td>
<td></td>
</tr>
<tr>
<td>Peanuts, raw, shelled/Chicago, Ill. 8/9/66</td>
<td>HLH Products/Dallas, Tex. (D)</td>
<td>Held under insanitary conditions; insect-contaminated.</td>
</tr>
<tr>
<td>Pepper, whole, white/Dallas, Tex. 10/19/66</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pepper, ground, black/Dallas, Tex. 11/18/66</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pickles/Houston, Tex. 9/19/66</td>
<td>Manhattan Pickle Co./Chicago, Ill. (M,S)</td>
<td>Insect-contaminated and moldy.</td>
</tr>
<tr>
<td>Pineapple, sliced/Hayward, Calif. 10/27/66</td>
<td>Treasure Island Food Prod. / Hayward, Calif. (D)</td>
<td>Held under insanitary conditions; fly-contaminated.</td>
</tr>
<tr>
<td>Pinto Beans/Rosemead, Calif. 10/11/66</td>
<td>La Victoria Foods, Inc./Rosemead, Calif. (D)</td>
<td>Held under insanitary conditions; insect-contaminated. Rodent-contaminated.</td>
</tr>
<tr>
<td>San Francisco, Calif. 10/31/66</td>
<td>C. H. Barth Co., Inc./Twin Falls, Idaho (S)</td>
<td></td>
</tr>
<tr>
<td>Popcorn/Minneapolis, Minn. 11/2/66</td>
<td>Colonial-Great Western Warehouse Minneapolis, Minn. (D)</td>
<td></td>
</tr>
<tr>
<td>Decatur, Ala. 10/27/66</td>
<td>Brock &amp; Spriect Co., Inc./Decatur, Ala. (D)</td>
<td></td>
</tr>
<tr>
<td>Popy Seed/New York, N.Y. 10/13/66</td>
<td>Port Warehouse, Inc./New York, N.Y. (D)</td>
<td></td>
</tr>
<tr>
<td>Potatoes, dried/New York, N.Y. 9/2/66</td>
<td>Baker &amp; Williams/New York, N.Y. (D)</td>
<td>Held under insanitary conditions; rodent-contaminated.</td>
</tr>
<tr>
<td>Potatoes, frozen/Grand Rapids, Mich. 8/22/66</td>
<td>Western Idaho Potato Processors / Nampa, Idaho (M,S)</td>
<td>Prepared and packed under insanitary conditions; excessive coliforms.</td>
</tr>
<tr>
<td>Potatoes, Flakes/Dallas, Tex. 11/17/66</td>
<td>Contract Packaging Assn./Dallas, Tex. (D)</td>
<td>Held under insanitary conditions; insect- and rodent-contaminated.</td>
</tr>
<tr>
<td>Norfolk, Va. 11/10/66</td>
<td>Southgate Terminal Whse./Norfolk, Va. (D)</td>
<td></td>
</tr>
<tr>
<td>Roswell, N. Mex. 10/26/66</td>
<td>Pecos Valley Sesame Seed/Roswell, N. Mex. (D)</td>
<td></td>
</tr>
<tr>
<td>Shrimp, breaded/Atlanta, Ga. 11/14/66</td>
<td>Singleton Packing Corp./Tampa, Fla. (P,S)</td>
<td>Prepared and packed under insanitary conditions; staphylococci.</td>
</tr>
<tr>
<td>Shrimp, breaded/Gehring, Nebr. 11/3/66</td>
<td>Booth Fisheries Corp./Brownsville, Tex. (P,S)</td>
<td>Prepared and packed under insanitary conditions; staphylococci.</td>
</tr>
<tr>
<td>Denver, Colo. 11/4/66</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Des Moines, Iowa 9/30/66</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albuquerque, N. Mex. 10/11/66</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carnegie, Pa. 10/14/66</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shrimp, breaded/Phoenix, Ariz. 9/24/66</td>
<td>Crossman Trucking Co./Los Angeles, Calif. (S)</td>
<td>Decomposed; bacterial contamination.</td>
</tr>
<tr>
<td>Shrimp, dried/9/21/66</td>
<td>Thos. P. Gonzalez Corp. / Los Angeles, Calif. (D)</td>
<td>Contaminated by birds.</td>
</tr>
<tr>
<td>Augusta, Ga. 11/19/66</td>
<td>Delmonico Foods Inc. of Florida/Tampa, Fla. (M,S)</td>
<td>Prepared and held under insanitary conditions; insect-contaminated. Decomposed.</td>
</tr>
<tr>
<td>Tomato Juice/Tulsa, Okla. 10/17/66</td>
<td>Texsun Corp./Weslaco, Tex. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Tomato Sauce/St. Thomas, V.I. 10/20/66</td>
<td>Pueblo Wholesale, Inc./Baymon, P.R.</td>
<td></td>
</tr>
</tbody>
</table>

Contamination, Spoilage, Insanitary Handling (cont'd)

Insect-contaminated.
Prepared and packed under insanitary conditions; insect-contaminated.
Moldy.
Held under insanitary conditions; insect-contaminated.
Insect-contaminated and moldy.
Held under insanitary conditions; fly-contaminated.
Held under insanitary conditions; insect-contaminated.
Rodent-contaminated.
Insect-contaminated.
Held under insanitary conditions; insect-contaminated.
Prepared and packed under insanitary conditions; insect-contaminated.
Rodent-contaminated.
Insect-contaminated.
Held under insanitary conditions; insect-contaminated.
Decomposed.
Decomposed.
Insect-contaminated.
Prepared and held under insanitary conditions; insect-contaminated.
Decomposed.
Decomposed.
Decomposed.

FDA Papers / February 1967 / 31
<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheddar Cheese/Denver, Colo. 10/13/66</td>
<td>Bert F. Allen/Hastings, Nebr. (S)</td>
<td>Economic Violations</td>
</tr>
<tr>
<td>Cherries, canned/Austin, Tex. 11/9/66</td>
<td>Perry Canning Co./Perry, Utah (P,S)</td>
<td>Label &quot;pasteurized&quot; is false and misleading; product does not conform to definition and standard of identity for cheddar cheese. Below standard quality; more than 15 percent of blemished cherries. Short weight.</td>
</tr>
<tr>
<td>Dips Barbecue, Garlic, Martini, Blue Cheese Cincinnati, Ohio 10/14/66</td>
<td>Oscar Ewing, Inc., t/a Food Specialties of Ky. Louisville, Ky. (M,S)</td>
<td>Artificial sweeteners substituted for natural fruit sweetness; ingredients cyclamate and saccharin not labeled.</td>
</tr>
<tr>
<td>Fruit Punch/Portland, Oreg. 9/29/66</td>
<td>Gem Canning Co./Emmett, Idaho (M,S)</td>
<td></td>
</tr>
<tr>
<td>Oleomargarine/Shiremanstown, Pa. 11/4/66</td>
<td>Old Dutch Foods, Inc./Blasdell, N.Y. (M,S)</td>
<td>Fails to conform to definition and standard for oleomargarine; contains less than 80 percent fat.</td>
</tr>
<tr>
<td>Hayesville, La. 10/14/66</td>
<td>Crossroads Canning Co. / Campobello, S.C. (P,S)</td>
<td></td>
</tr>
<tr>
<td>Cincinnati, Ohio 11/18/66</td>
<td>Old Dutch Foods, Inc./Blasdell, N.Y. (M,S)</td>
<td>Fail to bear packing medium as required by standards for canned peaches.</td>
</tr>
<tr>
<td>Peanut Butter/Beaver Heights, Md. 11/1/66</td>
<td>Morgan Packing Co., Inc./Austin, Ind. (P,S)</td>
<td>Below quality standard for canned tomatoes; excess peel.</td>
</tr>
<tr>
<td>Tomatoes, canned/Lexington, Ky. 10/16/66</td>
<td>H. E. Kelly &amp; Co., Inc./New Church, Va. (P,S)</td>
<td></td>
</tr>
<tr>
<td>Baltimore, Md. 10/13/66</td>
<td>McCall Farms/Effingham, S.C. (P,S)</td>
<td></td>
</tr>
<tr>
<td>Lincoln, N.C. 8/26/66</td>
<td>Milroy Canning Co., Milroy, Ind. (P,S)</td>
<td></td>
</tr>
<tr>
<td>Cincinnati, Ohio 10/12/66</td>
<td>A. W. Sisk &amp; Son, Inc./Preston, Md. (S)</td>
<td></td>
</tr>
<tr>
<td>Milford, Del. 11/1/66</td>
<td>Vanco Food Products/San Pedro, Calif. (P,S)</td>
<td>Below labeled strength; deficient in vitamins Bt and B6.</td>
</tr>
<tr>
<td>Tuna, grated/Spokane, Wash. 9/26/66</td>
<td>Geratrix Tablets/St. Louis, Mo. 10/25/66</td>
<td>Below labeled strength; deficient in vitamins Bt and B6.</td>
</tr>
<tr>
<td>Nutri-Bio/Oxon Hill, Md. 9/6/66</td>
<td>W. T. Thompson Co./Los Angeles, Calif. (M,S)</td>
<td>Below labeled strength; deficient in vitamins Bt and B6.</td>
</tr>
<tr>
<td>Gardena, Calif. 8/24/66</td>
<td>John E. Riley/Oxon Hill, Md. (D)</td>
<td>Below labeled strength; deficient in vitamins Bt and B6.</td>
</tr>
<tr>
<td>Pruitt’s Kelp Plus/Kingsport, Tenn. 10/7/66</td>
<td>Nutri-Bio Rudnat Corp./Gardena, Calif. (D)</td>
<td>Below labeled strength; deficient in vitamin C.</td>
</tr>
<tr>
<td>Thera “18” (vitamins w/minerals) Pikeville, N.C. 10/20/66</td>
<td>T. D. Pruitt/Kingsport, Tenn.(D) and Barrow’s Chemical Co., Inc./inwood, L.I., N.Y. (M,S)</td>
<td>Below labeled strength; deficient in vitamin A.</td>
</tr>
<tr>
<td>Vitamins—Dietary Food</td>
<td>Wayne Medical Co./Pikeville, N.C. (D)</td>
<td>Contains iodine, a food additive not in conformity with regulations.</td>
</tr>
<tr>
<td>Geratrix Tablets/St. Louis, Mo. 10/25/66</td>
<td>W. T. Thompson Co./Los Angeles, Calif. (M,S)</td>
<td>Below labeled strength; deficient in vitamin A.</td>
</tr>
<tr>
<td>Nutri-Bio/Oxon Hill, Md. 9/6/66</td>
<td>John E. Riley/Oxon Hill, Md. (D)</td>
<td>Below labeled strength; deficient in vitamin A.</td>
</tr>
<tr>
<td>Gardena, Calif. 8/24/66</td>
<td>Nutri-Bio Rudnat Corp./Gardena, Calif. (D)</td>
<td>Below labeled strength; deficient in vitamin A.</td>
</tr>
<tr>
<td>Pruitt’s Kelp Plus/Kingsport, Tenn. 10/7/66</td>
<td>T. D. Pruitt/Kingsport, Tenn.(D) and Barrow’s Chemical Co., Inc./inwood, L.I., N.Y. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Thera “18” (vitamins w/minerals) Pikeville, N.C. 10/20/66</td>
<td>Wayne Medical Co./Pikeville, N.C. (D)</td>
<td></td>
</tr>
<tr>
<td>AK Cream/Richmond, Va. 11/3/66</td>
<td>S. E. Massengill Co./Bristol, Tenn. (M,S)</td>
<td>DRUGS / Human Use</td>
</tr>
<tr>
<td>Alergimist Solution</td>
<td>Brunson Corp./Miami, Fla. (M,S)</td>
<td>New drug not approved for safety and effectiveness.</td>
</tr>
<tr>
<td>Union City, N.J. 11/22/66</td>
<td>S. E. Massengill Co./Bristol, Tenn. (M,S)</td>
<td>New drug not approved for safety and effectiveness.</td>
</tr>
<tr>
<td>Altus, Okla. and Oklahoma City, Okla. 7/27/66</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Florence, S.C. 10/21/66</td>
<td>Wallich Laboratories / Los Angeles, Calif. (D)</td>
<td></td>
</tr>
<tr>
<td>APC Tablets/Los Angeles, Calif. 9/19/66</td>
<td>(Repacker)</td>
<td>New drug not approved for safety and effectiveness.</td>
</tr>
<tr>
<td>Elion Young (silicone inj.) Stuart, Iowa 10/5/66</td>
<td>Koken Kogyo Co., Ltd./Tokyo, Japan (M,S)</td>
<td>Inadequate warnings against use; contains belladonna.</td>
</tr>
<tr>
<td>Mackenzie Regulators/Seattle, Wash. 9/27/66</td>
<td>G. O. Guy Drugs/Seattle, Wash. (D)</td>
<td>Contains iodine, a food additive not in conformity with regulations.</td>
</tr>
<tr>
<td>Organic Sea Plant Minerals Sheboygan, Wis. 10/20/66</td>
<td>Kett’s Health Food Center / Sheboygan, Wis. (D)</td>
<td>New drugs not approved for safety and effectiveness.</td>
</tr>
<tr>
<td>Prednisolone Acetate Liver Injection Massillon, Ohio 11/3/66</td>
<td>Safety Syringe Corp./Massillon, Ohio (S) (Return shipment)</td>
<td>False and misleading claims to control appetite and cause weight loss.</td>
</tr>
<tr>
<td>Prednisolone Capsules/New York, N.Y. 10/20/66</td>
<td>Proline Co./New York, N.Y. (D)</td>
<td></td>
</tr>
</tbody>
</table>

32 / February 1967 / FDA Papers
PRODUCT, PLACE & DATE SEIZED

<table>
<thead>
<tr>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
</table>
| At Last (heart worm treatment) Pensacola, Fla. 10/13/66 | Veterinary / Medicated Feed
At Last Laboratories/Theodore, Ala. (M,S) | New drug not approved for safety and effectiveness. |
| Biloxi, Miss. 10/12/66 | International Mineral & Chemical Corp. Carlsbad, N. Mex. (M,S) |
| Dyna-K (potassium chloride) Des Moines, Iowa 11/4/66 | J. R. Clark Co./Salt Lake City, Utah (S) |
| New Age Complete Fish Feed Spokane, Wash. 11/4/66 | Anthony Products Co./El Monte, Calif. (M,S) |
| Pepto-Live Inj./Omaha, Nebr. 10/24/66 | Sodium Sulfamethazine/Winchester, Ill. 9/22/66 |
| Sodium Sulfamethazine/Winchester, Ill. 9/22/66 | Super Speed Anemia Ban/Omaha, Nebr. 9/6/66 |
| Super Speed Anemia Ban/Omaha, Nebr. 9/6/66 | Body Energizer/Redmond, Wash. 10/7/66 |
| Body Energizer/Redmond, Wash. 10/7/66 | Catheterization Kits/Highland Park, Mich. 10/12/66 |
| Catheterization Kits/Highland Park, Mich. 10/12/66 | Electronic Massage/Kansas City, Kans. 10/20/66 |
| Electronic Massage/Kansas City, Kans. 10/20/66 | Niagara Recliner Chairs/Los Angeles, Calif. 9/14/66 |
| Niagara Recliner Chairs/Los Angeles, Calif. 9/14/66 | Shape-Maker/Kansas City, Mo. 9/28 and 9/30/66 |
| Shape-Maker/Kansas City, Mo. 9/28 and 9/30/66 | Undershorts/Atlanta, Ga. 10/27/66 |
| Undershorts/Atlanta, Ga. 10/27/66 | Water Conditioner/Colorado Springs, Colo. 10/20/66 |
| Medical Devices | |
| Aquarian Enterprises/Burbank, Calif. (M,S) | False and misleading claims to treat infections, many types of aches and pains, diseases of the heart, lung, and gallbladder. |
| Clinical Products, Inc./Pittsburgh, Pa. (M,S) | Below labeled quality; nonsterile. |
| Colran Method, Inc. (formely. Figure Control) Kansas City, Kans. (D) | False and misleading claims to improve figure, lose inches while relaxing, spot reducing; inadequate directions for alleviating arthritis, muscle cramps, wrinkles. |
| Niagara Therapy Mfg. / Los Angeles, Calif. (M,S) | Inadequate directions for use. |
| Shape Maker/Kansas City, Mo. (D) | False and misleading claims in sales spiel; inadequate directions for use. |
| Mandate Sales, Inc./St. Petersburg, Fla.(M,S) | False and misleading claims to be effective in reducing weight, and relieving heart and circulatory conditions; inadequate directions for use. |
| Prophylactics | |
| Nat'l. Hygienic Products/Dothan, Ala. (S) | Below labeled quality, defective. |
| M & M Rubber Co./Kansas City, Mo. (M,S) | |
| COLOR | |
| Antonio Perez Martin/Santa Cruz de Tenerife, Spain (M,S) |
| HAZARDOUS SUBSTANCES | |
| Montgomery Ward/Chicago, Ill. (S) |
| Aerosol Corp./New Kingston, Pa. (M,S) |
| Filtered Rosin Products/Baxley, Ga. (M,S) |
| Welco Alloys Corp./Detroit, Mich. (M,S) |

FDA Papers / February 1967 / 33
## Terminated Criminal Cases

Charging violation of the Federal Food, Drug, and Cosmetic Act when the court action has been reported by the FDA District Office.

### Defendant

<table>
<thead>
<tr>
<th>Name, Place, Date</th>
<th>Product</th>
<th>Charges &amp; Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>D. C. Renner Wholesale Co.</td>
<td>Storing food under insanitary conditions. Company and individual combined, fined $500. (E. Dist. of Tenn.-Chattanooga)</td>
<td></td>
</tr>
<tr>
<td>Mrs. Hazel R. Richards Cleveland, Tenn.</td>
<td>Storing food under insanitary conditions. Total fine $200. (E. Dist. of Tenn.-Greenville)</td>
<td></td>
</tr>
<tr>
<td>Taylor Grocery Co., and Hugh Taylor Newport, Tenn.</td>
<td>Food held under insanitary conditions. Corporation fined $2,500; individual, $1,000, suspended, and placed on 5-year probation. (S. Dist. of Tex.-Houston)</td>
<td></td>
</tr>
<tr>
<td>Julian M. Trevino, Jr., and Julian M. Trevino, Jr. Laredo, Tex.</td>
<td>Mustard seed, containing DDT, contaminated by rodents, and held under insanitary conditions. Defendants each fined $100. (N. Dist. of Tex-Dallas)</td>
<td></td>
</tr>
<tr>
<td>Charles C. Ducote, t/a De Coty Coffee Co. and Ceyork T. Ducote San Angelo, Tex.</td>
<td>Flour and lima beans held under insanitary conditions. Partnership fined $250; individuals each $250, suspended. (W. Dist. of Tex.-San Antonio)</td>
<td></td>
</tr>
<tr>
<td>Dawson Jones Bath County, Ky.</td>
<td>Selling penicillin and Enovid without prescription. Sentenced to 18 months in jail. (E. Dist. of Mich.-S. Div.)</td>
<td></td>
</tr>
<tr>
<td>James M. Mullins Cincinnati, Ohio</td>
<td>Selling amphetamine outside doctor-patient relationship. Fined $5,000 and placed on 5-year probation. (S. Dist. of Ohio-Columbus)</td>
<td></td>
</tr>
<tr>
<td>Wilbur Graham Fisher, M.D. Columbus, Ohio</td>
<td>Selling amphetamine, penicillin, and barbiturate without prescriptions, and unauthorized refilling of prescriptions. Defendants each fined $400. (Dist. of R.I.-Providence)</td>
<td></td>
</tr>
<tr>
<td>Antonio Trevino Brownsville, Tex.</td>
<td>Peddling amphetamine. Fined $100, sentenced to 6 months, suspended, and placed on 3-year probation. (S. Dist. of Tex.-Brownsville)</td>
<td></td>
</tr>
</tbody>
</table>

### Illegal Sales of Prescription Drugs

<table>
<thead>
<tr>
<th>Name, Place, Date</th>
<th>Product</th>
<th>Charges &amp; Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Middlesboro Milling Co., and Edward Lynn Bryant Middlesboro, Ky.</td>
<td>Cornmeal mix prepared under insanitary conditions. Defendants each fined $500; total fine $1,000, plus $35 costs. (E. Dist. of Ky.-London)</td>
<td></td>
</tr>
<tr>
<td>Mazzola Bros. Bakery Trust Newton, Mass.</td>
<td>Flour held under insanitary conditions. Fined $500. (Dist. of Mass.-Boston)</td>
<td></td>
</tr>
<tr>
<td>Greenpoint Terminal Wharf. Brooklyn, N.Y.</td>
<td>Beans and coffee held under insanitary conditions. Fined $2,000. (E. Dist. of N.Y.-Brooklyn)</td>
<td></td>
</tr>
<tr>
<td>Lewisville Roller Mills, Inc., Gwyn M. Jennings Lewisville, N.C.</td>
<td>Flour prepared under insanitary conditions. Defendants each fined $500. (M. Dist. of N.C.-Winston-Salem)</td>
<td></td>
</tr>
<tr>
<td>Athens Roller Mills, and David C. Collins Athens, Tenn.</td>
<td>Cornmeal prepared under insanitary conditions. Defendants each fined $200. (E. Dist. of Tenn-Chattanooga)</td>
<td></td>
</tr>
<tr>
<td>Leonard R. Calverley Dallas, Tex.</td>
<td>Peddling amphetamine and barbiturate. Fined $1,000, sentenced to 1 year, suspended, and placed on 1-year probation. (N. Dist. of Tex.-Dallas)</td>
<td></td>
</tr>
<tr>
<td>Clyde J. Chapman, D.O., t/a Chapman Clinic Sanger, Tex.</td>
<td>Selling amphetamine outside doctor-patient relationship. Fined $500; an additional fine of $500 was suspended, and defendant placed on 1-year probation. (E. Dist. of Tex.-Texarkana)</td>
<td></td>
</tr>
<tr>
<td>Robert S. Miles (employee Willett’s Service) Roanoke, Va.</td>
<td>Peddling amphetamine. Fined $500, sentenced to 1 year, suspended, and placed on 1-year probation. (W. Dist. of Va.-Roanoke)</td>
<td></td>
</tr>
<tr>
<td>Lacy F. Dudley, t/a Dudley’s Truck Stop Rocky Mountain, Va.</td>
<td>Peddling amphetamine. Fined $1,000 and sentenced to 1 year in jail; jail sentence suspended and placed on 3-year probation. (W. Dist. of Va.-Roanoke)</td>
<td></td>
</tr>
<tr>
<td>Frank E. Kipps (employee Glenvar T.S.) Salem, Va.</td>
<td>Peddling amphetamine. Sentenced to 1 year in jail, suspended, and placed on 3-year probation. (W. Dist. of Va.-Roanoke)</td>
<td></td>
</tr>
<tr>
<td>Brewer &amp; Co., Inc., and Howard D. Brewer Worcester, Mass.</td>
<td>Misbranding drugs, failing to conform with good manufacturing practices, false guarantees and false content labels. Corporation fined $1,000; charges against individual dismissed. Mr. Brewer died. (Dist. of Mass.-Boston)</td>
<td></td>
</tr>
</tbody>
</table>

### DACA Actions

Charging violation of the Drug Abuse Amendments of 1965 are published when they are reported by the Bureau of Drug Abuse Control Field Offices.

<table>
<thead>
<tr>
<th>Name, Place, Date</th>
<th>Product</th>
<th>Charges &amp; Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clark-Grace, Inc. Chicago, III. Nov. 10, 1966</td>
<td>7,000 units of barbit. Lack of initial inventory required by law; refills not recorded. Destruction in presence of BDAC agents.</td>
<td></td>
</tr>
</tbody>
</table>
Alergimist solution A and solution B, at Charleston, S. Dist. 36 I February 1967
FDA Papers
Rubber prophylactics, at Chicago, N. Dist. III. Paint thinner, Morlux solvent, at Omaha, Dist. Nebr.
out an effective New Drug Application; 505(a). Default decree ordered destruction.
Charged 12-3-65. When shipped by the Brunson Corp., Miami Springs, Fla., the articles were new drugs with
area of the eye; 601(e). Default decree ordered destruction.
Charged 12-18-65. When shipped by the Brunson Corp., Saxonville, Mass., the labeling contained
required conspicuous label statements; 2(p)(l)(B,G & J). Consent decree authorized Chester
McKinley, Rich Hill, Mo., to relabel.
Charged 12-21-64. When shipped by Wilmington Chemical Co., Baltimore, Md., the quality of the article was
deficient and the labeling false and misleading since it contained mela
tin, which might be harmful to the consumer; 602(b)(2). Default decree ordered delivery to a public/
packer, or distributor; and failed to bear an accurate
statements; 2(p)(l)(B,G & J). Consent decree authorized authorizer Proven Products Co., San Jose, Calif., to
Charged 4-6-65. When shipped by Dr. Scat Chemical Co., Chicago, Ill., the article was a substance presenti
a special hazard because of its carbon tetrachloride content, and its containers lacked a number of
Type Cleaner, Dr. Scat, at Kansas City, Dist. Kans.
Charged 4-6-65. Charged 3-26-66. When shipped by Blue Magic Co. of N.C., Inc., the article was a toxic substance presenti
a special hazard because of its carbon tetrachloride content, and its labels lacked a number of the
Charged 3-22-65. Charged 3-26-66. When shipped by Wilmington Chemical Co., Chicago, Ill., the article was an extremely flammable substance, and its containers lacked a number of the required conspicuous label statements; 2(p)(l)(B,G & J). Consent decree authorized
"Charged 5-23-66. When shipped by the Brunson Corp., Miami Springs, Fla., the article was a new drug with
out an effective New Drug Application; 505(a). Default decree ordered destruction.
MEDICAL DEVICES
Derma Cold Ice Pack, at Piscataway, N. J.
Charged 2-25-65. When shipped by Harlemark Inter
national, Inc., San Antonio, Tex., the labeling of the article failed to bear adequate directions for use for the therapeutic
purposes for which the article was offered during a demonstration by John Graham, owner and
manager of the Health Crafters Sales and Service Co., 505(1)(l)(B).
Default decree ordered delivery to FDA.
PROPHYLACTICS
Charged 1-29-65. When shipped by American Hygenic Co., Baltimore, Md., the quality of the article was
deficient and the labeling false and misleading since it contained talc (94 percent), 505(1)(c), 505(2).
Default decree ordered destruction.
Rubber prophylactics, at Chicago, N. Dist. III.
Charged 2-15-65. When shipped by Crimp Rubber Corp., Newark, N. J., the quality of the article was deficient and the labeling false and misleading since it contained talc (94 percent); 505(1)(c), 505(2).
Default decree ordered destruction.
COSMETICS
Perfume, counterfeited Arpege, at Baltimore, Md.
Charged 12-3-65. When shipped by Nippy Manufacturing Co., Jamaica, N. Y., the article contained mold and viable bacteria; 301(1)(1). Default decree ordered destruction.
PROPHYLACTICS
Rubber prophylactics, at Chicago, N. Dist. III.
Charged 2-15-65. When shipped by Crimp Rubber Corp., Newark, N. J., the quality of the article was deficient and the labeling false and misleading since it contained talc (94 percent); 505(1)(c), 505(2).
Default decree ordered destruction.
Patches, sprays, Emch's Arthritis Drops, at Providence, R. I.
Charged 5-4-65. When shipped by Parfumerie Lido, Inc., New York, N. Y., the article contained a number of the required conspicuous label statements; 2(p)(l)(B,G & J). Consent decree authorized
authorized Proven Products Co., San Jose, Calif., to
PERIODICALS
rain are available online at: [FDA's official website](https://www.fda.gov).
DOCTOR report drug reactions!

FDA FOOD AND DRUG ADMINISTRATION • U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Announcements

FDA EDUCATIONAL FILMS are now being seen around the world.

"Bennies and Goofballs," a 20-minute black and white documentary narrated by Paul Newman with commentary by Commissioner Goddard, has been seen by audiences across the Nation and by the armed services overseas. Based on interviews with four actual victims of pep pill and sleeping pill abuse, the film dramatically details the dangerous psychological and physiological effects of "pill popping," and explains how the new Drug Abuse Control Amendments will help control this explosive sociological trend. The film is available free on short-term loan from: Public Health Service, Audiovisual Facility, Attn: Distribution Unit, Atlanta, Ga. 30333.

"A Reason for Confidence" takes you behind the scenes to see what FDA does to protect the health and safety of every American. During a busy day in the life of Nancy Taylor, homemaker and mother of three, she and her family use a variety of foods, drugs, cosmetics, and household chemicals. The 28-minute color film has been seen by an estimated 1.5 million people throughout the United States, and has been telecast 50 times. In October, it received the Cris Award for excellence from the Columbus Film Festival. The movie is available free from the nearest Association Films Regional Film Library: 600 Grand Avenue, Ridgefield, N. J. 07657; 561 Hillgrove Avenue, La Grange, Ill. 60525; 1621 Dragon Street, Dallas, Tex. 75207; 324 Delaware Avenue, Allegheny County, Oakmont, Pa. 15139; and 25358 Cypress Avenue, Hayward, Calif. 94544.

THE CANADIAN FOOD AND DRUG DIREC- TORATE is sponsoring a Symposium on Some Aspects of Drug Safety, in Ottawa, June 29-30. The first session will cover "Basic Principles Involved in Drug Safety," and the second session will deal with "Practical Applications." Space is limited, and advance registration fees of $10 should be sent to Mrs. C. Dazé, Food and Drug Directorate, Tunney's Pasture, Ottawa S, Canada.

FDA INDUSTRY WORKSHOPS During February and March, FDA Districts and BDAC Field Offices 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 drug abuse control) and foods (microbiological contamination, chemical residues, and sanitation). Anyone desiring further information should contact the nearest District of BDAC Field Office.

SCHEDULE OF FDA WORKSHOPS AND CONFERENCES / FEBRUARY & MARCH 1967

<table>
<thead>
<tr>
<th>FDA District or BDAC Field Office</th>
<th>Date</th>
<th>Location</th>
<th>Subject Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atlanta</td>
<td>February</td>
<td>North Carolina</td>
<td>Pesticide Residues</td>
</tr>
<tr>
<td></td>
<td>March</td>
<td>Atlanta, Ga.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>March 15</td>
<td>Atlanta, Ga.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>March 14</td>
<td>Albany, N.Y.</td>
<td>Drugs-GMP</td>
</tr>
<tr>
<td></td>
<td>March 16</td>
<td>Syracuse, N.Y.</td>
<td>Drugs-GMP</td>
</tr>
<tr>
<td></td>
<td>March 16</td>
<td>Buffalo, N.Y.</td>
<td>Drugs-GMP</td>
</tr>
<tr>
<td></td>
<td>March 16</td>
<td>Pittsburgh, Pa.</td>
<td>Drugs-GMP</td>
</tr>
<tr>
<td></td>
<td>February 16</td>
<td>Chicago, Ill.</td>
<td>Drug Abuse Control</td>
</tr>
<tr>
<td></td>
<td>February 16</td>
<td>Nashville, Tenn.</td>
<td>Sanitation in Food Warehousing</td>
</tr>
<tr>
<td></td>
<td>February 9-10</td>
<td>Oklahoma City, Okla,</td>
<td>Medicated Feeds</td>
</tr>
<tr>
<td></td>
<td>February 2</td>
<td>Austin, Tex.</td>
<td>Drugs-GMP</td>
</tr>
<tr>
<td></td>
<td>February 21-22</td>
<td>Los Angeles, Calif.</td>
<td>Drug Abuse Control</td>
</tr>
<tr>
<td></td>
<td>February 16</td>
<td>Detroit, Mich.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>March 14</td>
<td>Manhattan, Kans.</td>
<td>Drug Abuse Control</td>
</tr>
<tr>
<td></td>
<td>February 14</td>
<td>Los Angeles, Calif.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>February</td>
<td>Mississippi</td>
<td></td>
</tr>
<tr>
<td></td>
<td>New Orleans</td>
<td>Louisiana</td>
<td></td>
</tr>
<tr>
<td></td>
<td>February 14</td>
<td>Louisiana</td>
<td></td>
</tr>
<tr>
<td></td>
<td>February</td>
<td>Harrisburg, Pa.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>March 28</td>
<td>Little Rock, Ark.</td>
<td>Sanitation in Food Warehousing</td>
</tr>
<tr>
<td></td>
<td>March</td>
<td></td>
<td>Drugs-GMP</td>
</tr>
<tr>
<td></td>
<td>March 2</td>
<td>Corvallis, Oreg.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>March 20-21</td>
<td></td>
<td>Drug Abuse Control</td>
</tr>
</tbody>
</table>