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FDA PAPERS

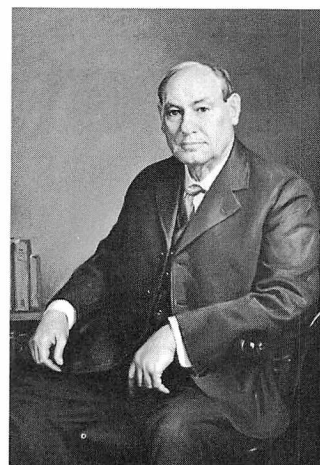
**MEETING
SENIOR CITIZENS**
Dialogues for Action

**RAISING ANIMALS FOR
RESEARCH**

Upton Sinclair

**DRUG
ACCOUNTABILITY**
Under the
Drug Abuse Control Amendments





"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

Food and Drug historians cite three cases of the past repeating itself. In each instance, they observe, growing public concern was largely ignored until an incident demanded action on the public's behalf.

In 1906 it was passage of the original Pure Food Act following Upton Sinclair's expose of the meat packers (see page 16).

In 1938, after 5 years of congressional consideration, the Food, Drug, and Cosmetic Act was passed. It happened after more than 100 persons died from the toxic effects of a wonder drug ingredient.

Again, in 1962, the law was strengthened after the thalidomide episode.

To historians, and many others, the past is prologue. They say that food and drug business practices have developed without due regard for the public interest; that, on at least three occasions, the only solution was tighter regulation; therefore, present and developing practices not in accord with the public interest will have to be curbed by governmental regulation.

Others take the view that history's lessons can provide both the reason and the impetus to prevent repetition. They say that businessmen can be sensitive of and responsive to the public interest; that they can correct business practices without legislative intervention. In the American system that's the way it should work.

quotes

“We would like to see the day when . . . voluntary programs can be substituted for our regulatory activities. This is not possible now and probably will not be within the next several years. But there is every reason to believe that wholehearted participation by industry in voluntary compliance programs will bring about a very significant improvement in the output and quality of drug products. This we all seek.”

Winton B. Rankin, Deputy Commissioner, to The Proprietary Association's Third Manufacturing Controls Seminar, Saddle Brook, N. J., October 25, 1967.

“It is our view that the modern law enforcer must be a man of many talents. Accordingly, we have provided up-to-date training in the sociological and psychological aspects of criminal behavior; the pharmacology of depressant, stimulant, and hallucinogenic drugs; as well as such strictly law enforcement matters as the review of current Supreme Court cases on searches and seizures, arrests, and confessions

“The social sciences have a tremendous contribution to make. But for too long, law enforcers and social scientists have been content to remain suspicious of each other, each preferring their own methods instead of looking at the problem itself and then devising complementary approaches to it. The real question before us is: how long will it take law enforcement and the social sciences to learn this lesson? We do not have long to wait.

“In BDAC we are experimenting with such a diffusion of disciplines, and we feel—we know—we can do a better job of enforcing the Drug Abuse Control Amendments to the food and drug law—better, in the sense that we can develop data which will benefit us and society in understanding the phenomenon of drug abuse in America, its root causes, and its social, physical, and psychological implications. In so doing, we hope to make a scientific contribution to each of these disciplines.

John Finlator, Director, Bureau of Drug Abuse Control, to the International Narcotic Enforcement Officer's Association Convention, Louisville, Ky., October 25, 1967.

John W. Gardner
Secretary, U.S. Department of
Health, Education, and Welfare

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

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

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

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pharmacological considerations in the evaluation of IND's and NDA's

by Merle L. Gibson, M.D.

Studies of new drugs in man are divided into the clinical pharmacology studies, designated as phase 1 and phase 2, and the clinical trial, referred to as phase 3. Phase 1 is the first trial in normal man; phase 2 deals with more detailed observations of drug effects in normals and initial trials in disease states; phase 3 consists of broad clinical trials designed to ascertain whether the drug is of clinical benefit in the various disease states for which effectiveness is to be claimed. There may be considerable overlap in the conduct of the three phases of clinical trials of a new drug in man.

The phase 1 study is usually done in a comparatively small number of normal human volunteers and is primarily concerned with the determination of biologic activity in man and effects on such target organ systems as the liver, kidney, the hemopoietic system, and the heart. Observations of the metabolism of the drug may also be made during phase 1. These are performed to ascertain the manner in which the drug is handled metabolically by human subjects, as well as the amount and kind of excretion products produced as a consequence of this metabolism.

Metabolism studies in humans are encouraged so that this information can be utilized in the intelligent selection of proper animal species for the chronic toxicity studies which may be needed in the future. Dosage range studies are also initiated in phase 1, but the determination of safe dosage range may continue over into the phase 2 part of the clinical trial.

The fact that a great deal of information had been obtained about the activity of the drug in animals at times permits reliable predictions of the dose tolerance of man. This is especially true for those new drugs which are related chemically and biologically to drugs of known activity in man. Completely new entities may require longer periods of observation.

In phase 2, studies would be extended to include the initial therapeutic trials on a limited number of

patients suffering from the disease entity or syndrome for which the drug is expected to be useful. Clinical protocols are constructed setting forth the duration of the administration of the drug and the clinical observations and laboratory determinations which are to be made.

Considerable leeway during phase 1 and phase 2 would be permitted in regard to the plan of investigation and such details as the route of administration and the physical form in which the drug is administered. Thus, although a drug might be intended primarily for oral use, during this period an investigator could undertake studies with a parenteral form of a drug, provided preliminary animal experimentation had been done to indicate the safety of this route, and information was available concerning the nature of the solvent, etc. A plan of investigation may be revised during the course of the study and the IND may be amended to include the revised protocol. We agree that a reasonable degree of freedom for the investigator is essential if the full potentialities of a drug are to be developed.

The requirement that the sponsor of an investigational drug submit the qualifications of the investigator has emphasized the present scarcity of well-trained clinical pharmacologists and the need to train more individuals to undertake the work of drug evaluation.

The FDA recognizes this need and has entered into a rather substantial contract with Georgetown University for the establishment and operation of a laboratory of clinical pharmacology. Ideally, it is felt studies on the new drug should be undertaken primarily by an individual with a broad training in pharmacology, irrespective of his field of medical specialization, who carries out his studies in drugs in human beings rather than animals.

We believe that such individuals would presumably be best qualified to observe subtle pharmacologic effects during initial trials. We further believe that early clinical studies should be carried out by investigators trained in the field for which the

drug is used and familiar with the effect of related drugs. However, it is also recognized that some of the problems attendant upon the use of a new drug may not be fully appreciated until the use of the drug passes to less experienced hands than these initial users.

On the basis of data obtained in phase 1 and phase 2, a decision must be made as to the desirability of more extensive clinical trials, known as phase 3. By this time a final dosage form in all its particulars should be selected, and plans should be made to carry out a broadly based clinical trial. The construction of the clinical protocol, the selection of patients, the treatment regimen to be followed, and the measurements to be made should be designed to satisfy the two judgments to be made on the basis of the data obtained in the clinical trial: (1) Is the drug safe? and (2) Is the drug effective?

The word "safe" in this connotation cannot mean absolutely safe. Otherwise there would be few if any new drugs marketed. The adverse effects must be weighed against the therapeutic benefits. If it is a lifesaving agent or is palliative in a serious condition for which there is no effective remedy, a definite hazard is tolerable, certainly much beyond the degree which would be acceptable for a drug useful only for controlling a symptom amenable to other measures. All gradations of safety and therapeutic necessity are encountered. It is not possible, in our opinion, to set forth detailed criteria generally applicable as a basis for decisions. Each drug presents an individual problem involving a variety of factors.

Since safety and efficacy are not fixed quantities, it is necessary to define them in relation to the specific clinical situation under consideration in the clinical trial of a drug. For example, a drug such as methotrexate proposed for the treatment of certain neoplastic diseases might be acceptable if it showed fewer clinical benefits and a higher incidence of adverse reactions while the same drug proposed for the treatment of psoriasis would not. On the other hand, the trial of a drug such as an analgesic or a minor tranquilizer proposed for the treatment of a self-limited, uncomplicated, and nonfatal illness would demand that clinical benefits be demonstrated in a high proportion of patients and adverse reactions in a very low proportion of patients.

It is also important at the outset of a clinical trial to define what response would be indicative of safety and efficacy—that is, clinically meaningful. These decisions are made by the physician involved in the drug trial, based on his knowledge and understanding of the natural history of the disease states in which the drug is being tested, and a knowledge of the currently available drugs for the treatment of these disease states. In situations where the pharmacological action of the drug is amenable to objective measurement, these determinations might be fairly

easily made. For example, in the case of a drug with antimicrobial activity to be tested as an anti-infective agent, the clinical and laboratory response would not be difficult to measure. It is a much more difficult task to demonstrate drug efficacy in the evaluation of a test drug where there are little or no objective measures of patient response available. In these cases it is extremely important to have careful planning of the study, together with systematic observations and the accurate recording of events in the patient's course while receiving the test drug. Also, a decision must be made regarding what difference between the proportion of patients who are benefited by the test drug, as compared to a placebo, would be considered to demonstrate drug efficacy.

Adequate and well-controlled clinical investigations are not necessarily confined to the double-blind placebo comparison. At times these would not be feasible, nor would it be ethical or wise to withhold or deny treatment to a patient. It may be necessary in some instances to compare the response to a test drug with that of a drug known to be safe and effective in the treatment of the disease state being investigated. However, there is no requirement that a test drug be found more effective than other drugs for the same purpose.

The phase 3 studies must be conducted as controlled clinical trials by a sufficient number of qualified investigators with a large enough sample of patients to yield data upon which a judgment can be made concerning the safety and efficacy of the drug. We like to have reports from several investigators rather than from one or two. It is our experience that the results and impressions of one investigator may differ from those of another. A more accurate evaluation can be made on the basis of reasonably widespread investigations. The studies should be conducted by experts in the field applicable to the drug and with an intimate knowledge of the condition to be treated. It cannot be expected that each one will investigate all phases of interest. There may be individual limitations of facilities and time with respect to special studies which may be required. Investigations can be complimentary to one another as parts of a general plan of study.

Careful planning of the total investigation and of the individual studies is important to obtain decisive answers to all essential questions. The nature and extent of the required studies naturally depend on the drug and the purpose for which it is used. Results obtained in the course of such studies may necessitate investigations not originally conceived or may suggest emphasis on a particular aspect of the planned investigation. Even in phase 3 investigations, however, the regulations permit reasonable

variations and alternatives in the proposed protocol.

Experts in the field of pediatrics have pointed out that infants and children may react to drugs differently than adults. Incompletely developed enzyme systems may result in impaired metabolism of drugs, or conversely, drugs may have a greater effect on the incompletely developed enzymatic processes of the infant than on those of the adult. It is no longer considered safe to derive children's doses from safe adult doses by an age or weight formula. Safety and effectiveness of new drugs for infants and children must be shown by actual use in the various age groups.

It is impossible to predict in advance how many clinical case reports may be necessary to demonstrate that the test drug is safe and effective for the proposed indications. This will depend on the caliber of the investigations, the quality of the reporting, and the proportion of patients who demonstrate a clinical benefit.

In our experience these have varied widely—from comparatively few detailed case reports to as many as 12,000 individual case reports submitted to support a recently approved nonnarcotic analgesic. One can readily see the expenditure of time and energy required in the review of many of these submissions which may run to over 100 2-inch volumes of material.

As a result of the three phases of the clinical pharmacology and the clinical studies, the manufacturer must make a determination as to whether he has satisfactorily demonstrated safety and efficacy of the test drug if used under the recommended conditions. He then submits to the Food and Drug Administration a New Drug Application, known as an NDA.

The safety and effectiveness of the drug is evaluated by the FDA staff, and action is taken on the application in view of the recommendations with respect to indications for use and dosage and disclosure of other pertinent information. Based on this submission, a decision must be reached as to whether the drug is safe and effective if it is used as directed, and provided that the physician has all the informa-

tion furnished in the labeling.

If the investigational new drug studies previously described were well-conducted and well-reported, the FDA should have in its hands at the end of phase 3 investigations all the necessary information for prompt approval of the NDA.

Unfortunately, in practice this is rarely the case. Too often the submission consists of uncontrolled studies, testimonials as to the drug's effectiveness, and individual patient records containing much irrelevant information and omitting much pertinent data to the extent that scientific evaluation relative to safety and efficacy is precluded. In some cases the clinical reports are illegible, or indications for use are proposed in the labeling which are supported by few if any clinical studies. In other cases, too few patients receive the final dosage form proposed for marketing.

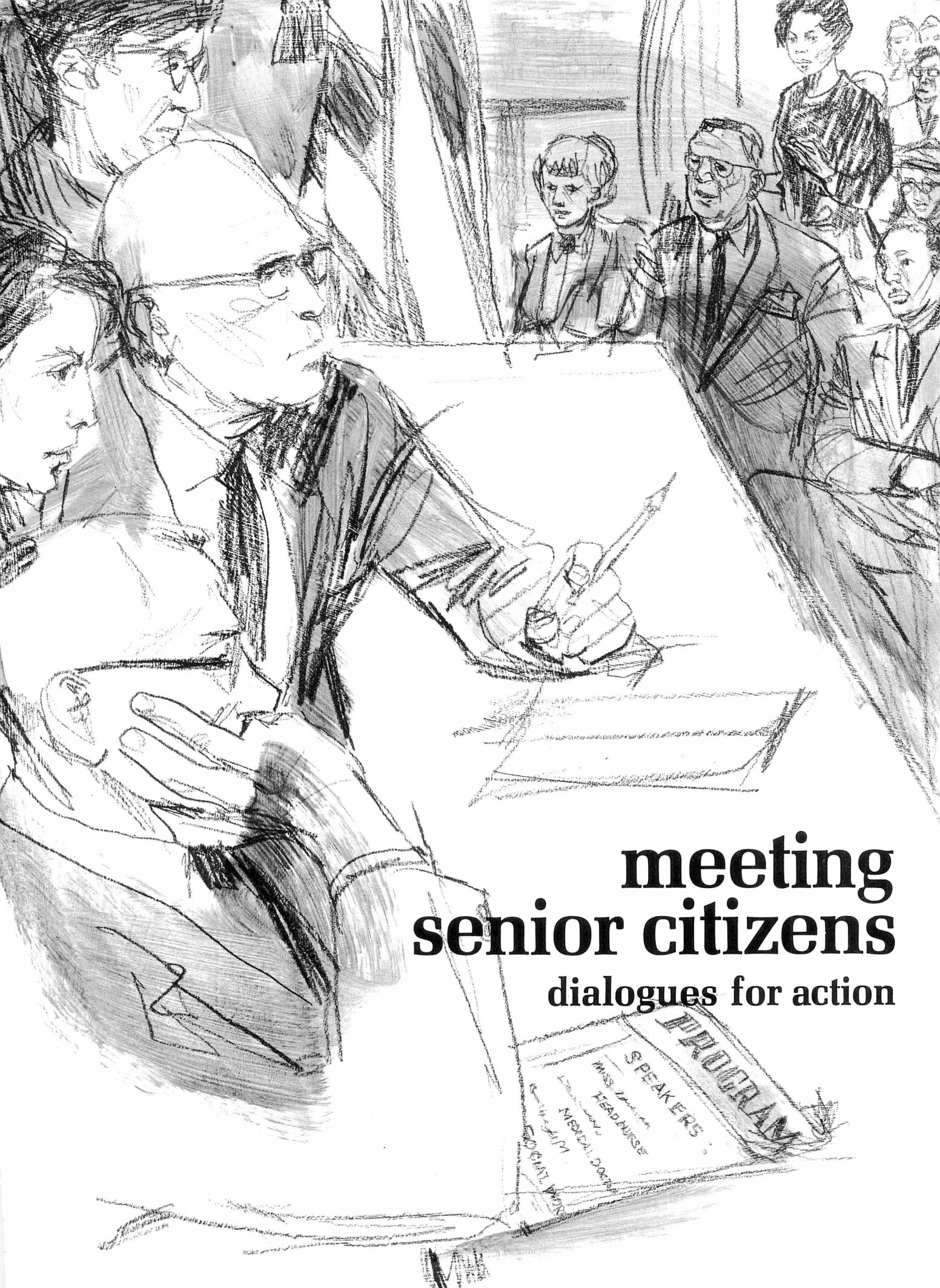
It is recognized that in true double-blind placebo studies it is often necessary to alter the final dosage form to compare with a placebo capsule. In these cases it is felt that therapeutic equivalency should be demonstrated—in other words, it should be shown that the altered form is absorbed, excreted, or otherwise handled by the body in a way similar to the final dosage form. Of course, there may be honest differences of opinion as to whether safety and efficacy have been demonstrated. The professional staff of the Bureau of Medicine is always willing to meet with the scientific representatives of the manufacturer to discuss these differences, or to discuss additional studies needed to correct the deficiencies.

Another problem of some magnitude occurs in the review of NDA's which rely on clinical data contained in applications approved prior to the 1962 Kefauver-Harris Amendments. These amendments include the provision that all drugs released between 1938 and 1962, previously reviewed only for safety, were to be reviewed retroactively for efficacy. The National Academy of Sciences—National Research Council has been given a contract to review these pre-1962 drugs and to advise the Administration whether they should be classified as effective, probably effective, or ineffective. Until the results of these reviews are forthcoming, NDA's for drugs identical to or very similar to those under consideration must be supported by their own evidence of safety and effectiveness.

Finally, two of the major factors limiting the evaluation of new drugs are: (1) the availability of patients with diseases for which the new drug may be appropriately tested, and (2) the availability of scientific investigators skilled in the procedures used in clinical trials who are willing to test them. Since several thousands of new drugs are tested in man each year, methods must be employed so that this shortage will be minimized and the release of safe and effective drugs will be assured.

Merle L. Gibson, M.D., Acting Director, Division of Neuropharmacological Drugs, Office of New Drugs, Bureau of Medicine, presented this paper at the meeting of the American Society for Pharmacology and Experimental Therapeutics, Washington, D.C., August 31, 1967.





meeting senior citizens

dialogues for action

PROGRAM
SPEAKERS:
MRS. J. J. J.
HEADNURSE
MEDICAL DOCTOR
SOCIAL WORKER



by Catharine Stahl

Another milestone on the road to consumer protection is the consumer education conference, tailored to bring FDA's "Life Protection" message to our older citizens.

A year ago FDA asked the Consumer Specialists in its 17 District Offices to direct special attention to health education of the elderly. They were to develop, as part of an overall national program, effective local and State programs. The FDA would sponsor such projects on its own, or with the help of other Federal and local agencies.

Included in this new program to bring senior citizens up-to-date on foods, drugs, cosmetics, medical devices, and certain hazardous

substances was the sponsoring of regional conferences directed at professional groups and organizations concerned with the problems of the elderly.

The audience is 19 million Americans, 65 years and over—with 4,000 swelling their ranks daily. This represents one in every 10 people—10 percent of what FDA considers the Nation's richest resource—people. These Americans also represent a total buying power of \$40 billion. And this, according to the hearings held by the Senate Subcommittee on Consumer Interests of the Elderly, "makes them an alluring target for pitchmen inside or outside the law."

The target is not only alluring but also ample. For these older people, exposed by susceptibility and shibboleths, have an Achilles heel larger than that of the rest of the population. What makes them more vulnerable is the high incidence of chronic illness, low income, and loneliness. Add to these factors, human credulity, distaste of growing old, visual impairments, and faulty judgment—and the chance increases that they may become the major victims of fraudulent practices.

To protect them—through awareness of the medical care they receive, of the drugs prescribed for them, of the foods they eat, and of the devices that are used for their health—was one of the FDA's incentives for launching its program. Awareness, it was felt, would not only protect them from abuse in the marketplace, but would also buy their independence and self-esteem, and spark their will to continue to grow.

This is what the FDA set out to do, and the conference technique was the tool enlisted to carry out its mission.

Conferences are not convened full-blown. They evolve from meticulous, long-range planning and careful coordination among the sponsoring agencies.

Consider the "Health Frauds and Quackery Leadership Conference" presented in Boise, Idaho, earlier this year. It grew from suggestions offered by the FDA's Denver and Seattle Consumer Specialists at the Administration on Aging-sponsored Conference held in Salt Lake City in the fall of 1966. Impressed with their idea that a program on health frauds and quackery would be valuable if offered at the State level, the AOA representative contacted the

Boise Council on Aging.

The result—a leadership conference to increase knowledge of health frauds and to encourage educational programs on wise selection of health products.

Attending were 75 leaders representing the professions, community organizations, voluntary health agencies, and Government. Sponsoring were the Idaho State Nurses Association, the Boise Council on Aging, the Idaho Dietetic Association, the Idaho Cooperative Extension Service, and the FDA.

Steered by competent conference leaders, and garnished with kits of educational materials, a new FDA

film, "The Health Fraud Racket," and a chamber-of-horrors exhibit, prepared by the Post Office Department and the FDA, the suggestion planted 6 months earlier had developed into a full-fledged leadership conference.

While each conference displays a different "mix" of sponsors, the general mosaic is an integrated effort by individuals, private groups, industry, and representatives of all levels of government.

The Los Angeles meeting was under the sponsorship of the FDA, the Los Angeles County Department of Senior Citizens Affairs, and the University of Southern Cali-

fornia Rossmoor-Cortese Institute for the Study of Retirement and Aging.

This program attracted 164 professionals in positions concentrating on assistance to the aging. Among them were medical doctors, architects, registered nurses, social workers, recreation directors, teachers, consultants from the fields of sociology and psychology, administrators from voluntary organizations, and resource people from county, State, and Federal offices.

After a morning session of exploring nutritional and medical quackery, the professionals were instructed to select and attend two of



the four workshops offered. An evaluation card, filled in by the participants and tabulated by IBM computers, gauged the conference evaluation.

At the Governor's Annual Aging Conference in Austin, Tex., the sponsors included the AOA, the FDA, the Governor's Committee on Aging, and the Texas Agricultural Extension Service.

The Tampa Conference for 170 Community Leaders, also under FDA/AOA sponsorship, with the help of the Florida Commission on Aging, zeroed in on today's marketplace in an effort to help older citizens sidestep fraudulent products and appeals. Again, in Boston, the FDA and AOA teamed up to play conference hosts to 75 par-

ticipants representing the aging.

Before the year is over, each of the 17 FDA Districts will have held at least one such conference.

From the outset, it was abundantly clear that the conference leaders shared President Johnson's confidence in the integrity of industry and the role private enterprise should assume in attacking social problems. "The consumer," said the President in his February 17 Consumer Message, "must be protected against unsafe products, against misleading information, and against the deceitful practices of a few businessmen that can undermine confidence in the vast majority of diligent and reputable firms."

"It is our conviction," voiced the

representative of the National Better Business Bureau, and the other speakers echoed his belief, "that the majority of American businessmen are honest Unfortunately, a small but strident minority has cast a large, gray shadow over the marketplace."

Following are excerpts from conference proceedings:

- Noting that many older people are often stranded in the marketplace instead of being supported by it, it was observed that the health professions have not been as effective as the ad agencies and their clients in reaching the elderly. "Because the aged tend to place faith in advertising, the tendency is for them to seek self-medication rather than professional help. False



or misleading advertising is twisting the art of healing into the art of stealing."

- This art is refined and extensive. "It contains illegally promoted therapeutic and pseudo-therapeutic devices, food supplements, and so-called health foods. In its most sophisticated form it involves deliberately falsified scientific studies and false promotional claims for potent drugs or drugs that are not efficacious where serious illness is involved."

- In the area of food the participants were briefed on the proposed regulations that substitute for "Minimum Daily Requirements" the more accurate phrase "Recommended Dietary Allowances."

- "If the older person suspects that he is not eating right, he is ready prey for the nutritional quack who says 'take my pills and don't worry.' Yet he may not be able to intelligently read the label on that food supplement to know what he is buying, and may spend money for 50 times his maximum daily need of vitamins—which he could have had with his food."

- Since older people often lack the incentive to prepare well-balanced meals for themselves, "they should be encouraged to take a fresh look at some of the convenience foods that are on the market. The unit cost may be a little higher than the same quantity of food prepared in the traditional manner, but lack of waste and better nutrition resulting from a greater variety of food could easily make up the difference."

- "Malnutrition among the aging is not solely the result of low income; it is also due to loneliness, to poor cooking facilities, to shopping problems, to poor teeth, and to careless eating habits."



- "Drugs have changed even more than foods during the past 20 years. More of our elderly citizens are taking advantage of new medical care than ever before. Yet, many of them are still generally unaware of the need for their *intelligent* choice of medicines and medical services. They do not understand *why* they cannot diagnose and treat all 'minor' ailments safely. They do not realize the importance of following their doctor's directions *exactly* when they take the drugs he prescribes."

- "Since the elderly frequently do not consult physicians for regular checkups because of economic reasons, they rely heavily on drugs

which may be purchased over-the-counter."

"In this connection, it should be remembered that any drugs which produce temporary relief of a symptom, whatever that symptom may be, may be masking a more serious condition if that symptom persists when the medication is discontinued. It is important, therefore, that on any over-the-counter drug, the directions on the label be read carefully, the limitations as to temporary relief be taken literally, and the instructions against continued use be observed.

- "It is important to compare the statement on the label and in the package with what has been

the package with what has been said in the advertisement. There is a good reason for this. The FDA, when a new drug is introduced into the market, has jurisdiction over the labeling and will carefully study this labeling and restrict it to those conditions for which the drug has been shown to be safe and effective in the dosage and in the duration specified—and in these only.”

- The category of drugs available only on prescription are really the “big guns” in the drug world. “These drugs are for Mrs. Jones to take in a certain way for a certain period of time, and for her specifically—for her symptoms or disease.”

- And after Mrs. Jones is well, and there are still a few tablets or capsules left in the prescription bottle, the instruction she should follow is to flush them down the toilet. One of the most dangerous things she can do is to share her prescription drug with someone else.

- Industry and Government try hard to be sure that the food and



Catharine Stahl is Coordinator of Consumer Services. She came to FDA in May 1966 after 18 years as a consumer information specialist with private industry in New York.

drugs on today's market are pure and safe. “*Wise selection* and use of these items are the responsibility of the consumer.”

To assure this wisdom of selection and use, the conference leaders recommended “more, better, and specific information and education.”

- “I would like to suggest that those professionals who have significant contact with the elderly should help educate them directly. Physicians, ministers, lawyers, social workers, could make it their business to aid the elderly The doctor could play a much more important part in bringing to the attention of the patients some of the dangers of fake arthritic remedies, the pointlessness of unnecessary vitamins and the like. One of our leading geriatric physicians has commented that the older person is better off getting his vitamins from the grocery store than from the drugstore. Older persons themselves could and should organize to protect themselves through administering educational programs and pressuring for legislation. Control of advertising, via self-policing by periodicals and by enforcement, is necessary”

But it was obvious to both the conference leaders and the participants that a working partnership among the professions, Government, and private enterprise was essential to meet the overwhelming challenge that confronts us in dealing with the health problems of the Nation's elderly. Only through this harmonious partnership, with each group contributing new solutions to common problems, would the goal of assuring optimum health protection for every American be reached.

With this goal in mind, the Consumer Specialists headed for the grass roots. Their reports, full of promise and activity, show that

they have been speaking to retired groups, conducting workshops and seminars, answering tough questions, manning exhibits, and publishing articles. They also show that business, local government, private organizations, the professions, and—most rewarding of all—senior citizens themselves are responding favorably and keenly:

. . . In Chattanooga, 50 firms were invited to attend a capsule conference where they were presented with an informal review of FDA's concern for the older citizen.

. . . In Boston, the Consumer Specialist talked to a Senior Citizens Group; found them appreciative and alert—asking such questions as “What about prescriptions ordered by a doctor—are they cheaper by generic names?”

. . . In Chicago, an individual contact with an official of the Amalgamated Clothing Workers of America yielded six “mini-workshops,” featuring a “short and snappy” series on “How to Get the Most for Your Money.” Such workshops, say the Consumer Specialists, provide an opportunity to try new teaching ideas, to observe the learning patterns of older people, and to become more experienced in how to work with them.

. . . In Detroit, the Consumer Specialist arranged exhibits for the United Automobile Workers Older and Retired Workers Department, and conducted workshops with leaders of older citizens clubs to encourage a wise use of medicines, devices, and health services.

So it goes—across the country.

FDA, with the help of sister agencies in Government and similarly oriented private or commercial groups, will continue to penetrate the world of our elderly citizens and bring to their doorsteps awareness of the new medicine, the new foods, and the new hazards of the marketplace.

raising animals for research



Who would know what to do with all these animals—cows, dogs, donkeys, goats, sheep, pigs, rats, gerbils, chickens, turkeys, and quail? FDA scientists at the Division of Veterinary Research in Beltsville (Md.) do. They raise these animals and more, primarily for research on veterinary products.

Some of the animals, notably beagles, go to other FDA research units. Raising beagles is an important task of the Division; the dogs go to the FDA's Special Pharmacological Animal Laboratory (SPAL) for its work with pesticides and drugs for humans. Standardized procedures for breeding and raising the animals are used to eliminate any errors in experimental evaluation. The Division now has about 70 breeding females and raises around 400 puppies a year. Beagles make good laboratory animals because they are small and gentle, yet gregarious enough to be housed in groups or accommodate readily to individual housing.

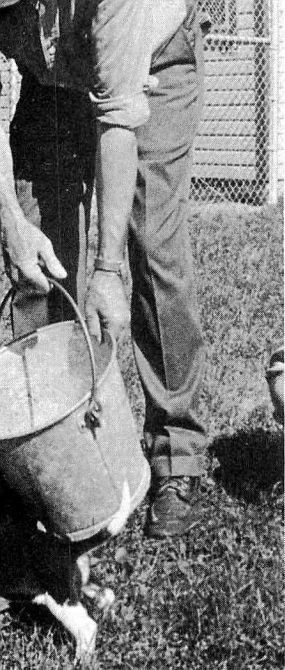
The Division's function is twofold: To determine the effect on a specific animal of a given food product or drug; and to determine the effect on the tissue or residue (meat, milk, eggs) of a food product or drug in an animal's system.

The facility has its own laboratory and can do its own work in microbiology, pathology, pharmacology, etc. The staff of 27, including five animal caretakers, can carry out an entire project.

Both research workers and caretakers, by adhering to the highest standards of humane treatment, find their work of added significance and more favorable to the animals.

The unit's work includes research on pesticide residues in feeds, parasites in all food-producing animals, aflatoxin in feeds, preparations for treatment of mastitis, and the effect of food and drugs on breeding, etc. Some of the work on veterinary products is initiated by complaints from consumers.

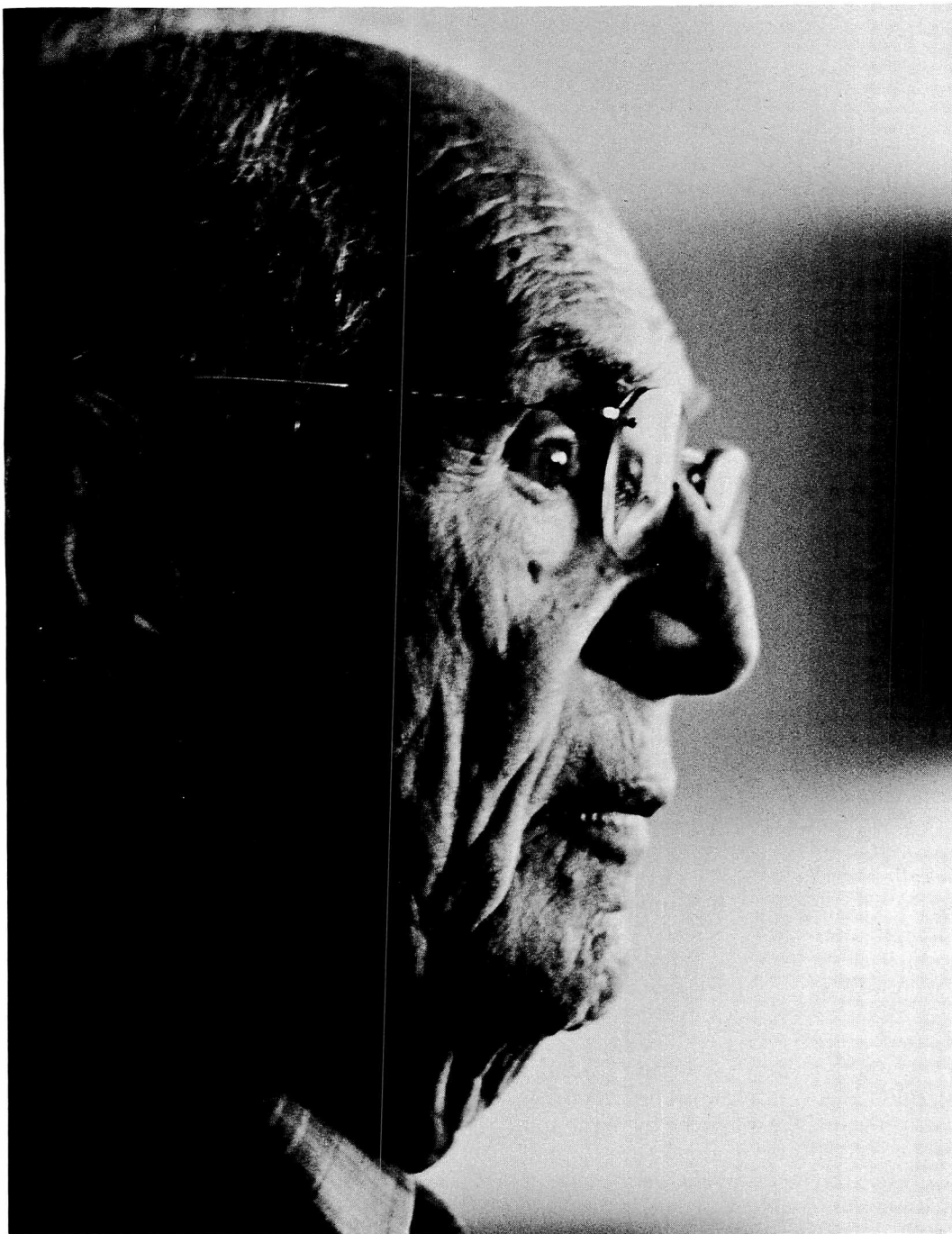




The Division of Veterinary Research is the only FDA facility that works with larger animals, such as horses, cows, swine, and sheep. SPAL works with dogs and miniature pigs, while other Divisions of the Bureau of Science work with the smaller laboratory animals — dogs, rabbits, guinea pigs, hamsters, rats, mice, and the like.

Now about 35 years old, the Division originally belonged to the Department of Agriculture. When FDA was separated from Agriculture, part of the facilities was transferred to FDA.

Although the Division's animal population is large and diverse, the doors of its cages and pens are always open to whatever other living creatures of land, sea, and air may be found useful in research and testing to achieve the aims and purposes of FDA's mission.



Upton Sinclair recently photographed at his home in Rockville, Maryland.

It is appropriate in this the 60th year of the Federal Food and Drugs Act to bring to the attention of the American public an event which led to the enactment of the 1906 law.

*The best account of the event, in our opinion, is described in Mark Sullivan's book "Our Times **America Finding Herself," published by Charles Scribner's Sons*

in 1927. In chapter 27, "The Crusade for Pure Food," Mr. Sullivan tells how Upton Sinclair's novel "The Jungle," published in 1906, influenced enactment of pure-food legislation.

With permission from Mark Sullivan, Jr., we quote from that chapter in his father's book which portrays industrial life as Sinclair saw it. Copyright © Mark Sullivan, Jr. 1927

Upton Sinclair

by Mark Sullivan

In 1906, Upton Sinclair, a young man devoted to romantic philosophy, realistic literature, and experimental socialism, finished a novel, named it "The Jungle," carried the manuscript to five different publishers who rejected it, decided to print it as he could, and asked his friend, fellow Socialist, and fellow author, Jack London, to write the announcement. London, seeing the novel as what the author meant it to be, described it as an appeal for socialism, a protest against "wage slavery," . . .

"The Jungle" was one of the earliest examples of Tolstoyan pessimism and other Russian influences on American fiction, and, as a novel, was measurably comparable to the best of its Slavic models. It told the epic tragedy of Jurgis, a Lithuanian peasant who saw in his native village one of the posters with which American industrial corporations and steamship companies lured immigrants to America. Jurgis came to Chicago, and got a job in the stock-yards—which Sinclair called "Packingtown," a name that had been used locally, and which "The Jungle" caused to become familiar nationally and to endure for several years. In Packingtown, the immigrant came into contact with about every evil that American industry and politics contained. He had to pay graft to get his job, and more to keep it; he lived in a lodging-house where the keeper "would rent the same bed to double shifts of men, one working every day and using it at night, the other working by night and using it by day"; he was cheated by the real-estate man who sold him a house on the instalment plan under a contract the Lithuanian could not read; he and his family were infected by hideous diseases, and by moral ulcers as well, from the conditions under which they toiled; he was "speeded up" beyond his strength by "pace-makers"; he found the company he worked for had secret mains through which they stole water from the city; he saw his neighbors used as pawns and victims of the worst practices of municipal politics; he was blackmailed into paying high prices for adulterated beer because "the saloonkeeper 'stood in' with all the big politicians in the district"; he went through the familiar experiences of being "laid off,"

of striking, and of being "black-listed"; he was persecuted by "spotters"; he lost his savings through a bank failure; when an intolerable grievance led him to "beat up" the foreman over him, he found the company "stood in" with the courts, and he was sent to jail unjustly. Hardly a solitary American influence, institution, or individual that this immigrant-laborer met, failed to cheat him, exploit him, brutalize him.

Not only was Jurgis the victim of constant tragedy. Every human being that had any important part in the book was a tragedy. And not only the human beings. The animals were portrayed by Sinclair as tragedies. As one result, the workmanship of the book was like the picture it aimed to convey of the stock-yards, a welter of the terribly grim, together with some other things that Sinclair meant to be terribly grim, but which to the average American reader were almost comically trivial.

But let no one think "The Jungle" was a book to smile at. As a picture of America taking peasants from the fields of Europe and throwing them into the crucible of American industry, like ore or any other raw material; as the reality of what idealism called the "melting-pot," "The Jungle" was a not too greatly exaggerated bit of truth about American industrial life as it was at that time — a "Jungle" could have been written about the coal mines, the steel-mills, and many other industries.

Sinclair's vagarious excitability always left the reader of his books uncertain how far the author's intention was art, and how far propaganda. So far as Sinclair had in mind propaganda for reform, he meant his book to show the process by which workers became, and in Sinclair's judgment ought to become, Socialists.

But all this passed over the public's head. The public ignored the tragedy of Jurgis the man, neglected the sociological jeremiad, was unmoved by the plea and propaganda for socialism. Sinclair's picture of the sausage-making machines, for example, was meant by him to make readers feel sad about the number of hand-workers displaced. But what most

impressed the public was something unappetizing about the stuffing process: "There was a sort of spout, a stream of sausage-meat would be shot out . . . a wriggling snake of sausage of incredible length."

What the public took hold of avidly and excitedly were some adventitious allusions to the food they were buying and eating; casual passages which Sinclair intended as mere bits of local color, as minor in the whole picture as the squeals of the pigs; off-hand details which vivified the impression made upon some of the more sensitive senses by the modern mass manufacture of food. One was the stock-yards smell, which Sinclair described quite mildly:

a strange pungent odor, that you caught in whiffs; you could literally taste it as well as smell it—you could take hold of it, almost, and examine it at your leisure . . . an elemental odor, raw and crude; it was rich, almost rancid, sensual and strong.

That was the most innocuous of Sinclair's bits of description. It, alone, would have made no commotion. The stock-yards smell was an old story; newspapers had made jokes about it for years. But Sinclair went farther.

He pictured a meat inspector, a government official, so agreeably engaged in chatting with a visitor about the deadliness of the dangers inherent in eating tubercular pork, that he let a dozen carcasses pass him without testing them. Another inspector, more meticulously conscientious, had proposed, as a means of saving frugal packers from temptation, that tubercular carcasses be treated with an injection of kerosene — and had been dropped from the government's inspection service, quickly and mysteriously — an incident not only raising disagreeable doubts about the wholesomeness of the meat every one was eating, but implying that the packers had a political pull which enabled them to get rid of overconscientious inspectors.

"There was said to be two thousand dollars a week hush-money from hogs that had died of cholera on the trains," and which "were . . . hauled away to a place in Indiana where they made a fancy grade of lard." Old cattle, and diseased ones, made into canned beef. "Potted chicken" made of "tripe, the fat of pork, beef suet, hearts of beef, and waste-ends of veal."

Devilled ham . . . made out of the waste-ends of smoked beef that were too small to be sliced by the machines; and also tripe dyed with chemicals so that it would not show white.

Old rancid butter "oxidized" by a forced-air process, to take away the odor, re churned with skim-milk, and sold in the cities. A good part of what the public buys for lamb and mutton is really goat's flesh! . . . The rats were nuisances; the packers would put poisoned bread out for them; they would die, and then rats, bread, and meat would go into the hoppers together. . . . Men worked in the tank-rooms, full of steam, in some of which there were open vats near the level of the floor . . . [when] they fell into the vats, sometimes they would

be overlooked for days, till all but the bones of them had gone out to the world as Durham's Pure Leaf Lard.

The passages giving these bits of local color in the *Odyssey* of Jurgis, as he worked his tragic way through Packingtown, were not more than eight pages in the 308 of "The Jungle"; but it was those eight pages the public seized upon.

For appreciation of his larger purpose, his artistic and social objective, Sinclair had to accept what came to him from a few high-brow critics and radicals in America, and some abroad, such as Winston Churchill, then prominent as an English writer, later as a cabinet member, who wrote:

This terrible book . . . pierces the thickest skull and most leathery heart. It enables those who sometimes think, to understand. It is possible this far-reaching book may come to be a factor in far-reaching events. The issue between capital and labor is far more clearly cut to-day [in America] than in other communities or in any other age.

Sinclair, seeing no increase in the Socialist vote in America, seeing the social revolution no nearer, seeing only an immense commotion about pork and beef, showed a flaw in his gratitude for the enormous fame the book brought him. In editions subsequent to the first, he inserted a foreword, in which he accepted the judgment of those literary critics who had compared "The Jungle" with several classics of social reform; and naively confirmed it as his own. Sinclair's foreword to the latest edition of "The Jungle" avers:

"The Jungle" belongs with books like Harriet Beecher Stowe's "Uncle Tom's Cabin," Charles Dickens' "Oliver Twist," which have influenced legislation and helped to improve the conditions of the lowly."

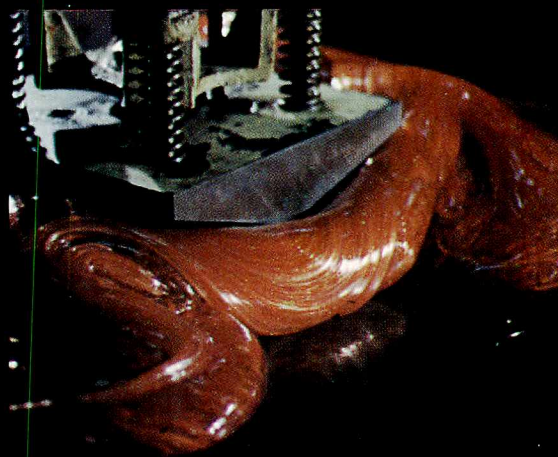
But Sinclair, speaking of himself, complained that he had wished to appeal to the hearts of the people, but had only succeeded in reaching their stomachs:

I had not been nearly so interested in the "condemned meat" as in something else, the inferno of exploitation. I realized with bitterness that I had been made a "celebrity," not because the public cared anything about the workers, but simply because the public did not want to eat tubercular beef.

But much more than the effects of "The Jungle" entered into the storm that arose throughout the country. The things Sinclair suggested with his bits of impressionistic painting about beef were paralleled by conditions known with exactness about the large-scale preparation of other foods. "The Jungle," indeed, was merely the final, spectacular, fictionistic climax to a long agitation that had been carried on in solid and convincing ways by patient investigators, food chemists in the employ of the State and Federal Governments, journalists of the exact-minded "Muck-raker" type, leaders of women's clubs, and other reformers and altruists.

FDA takes a look at candy

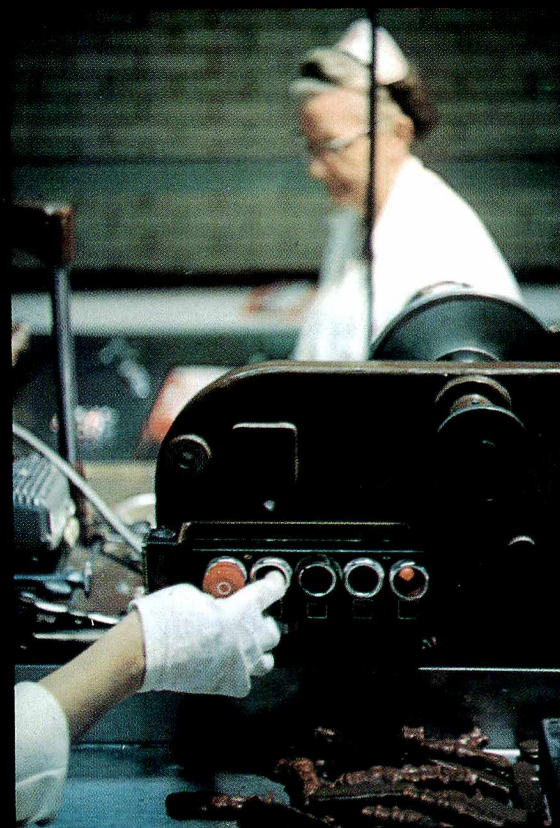
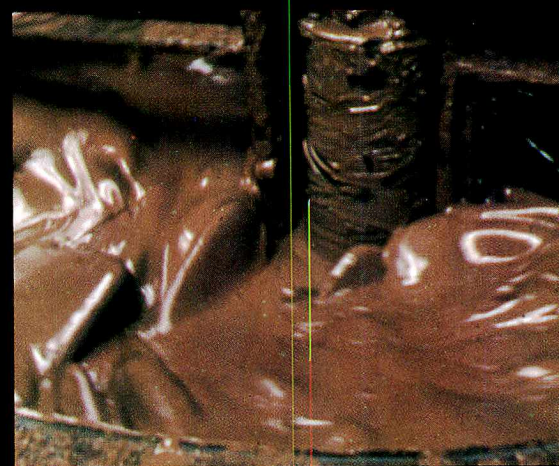
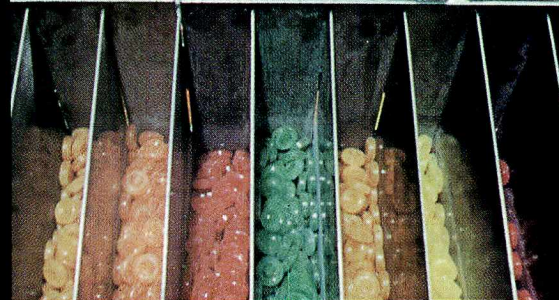
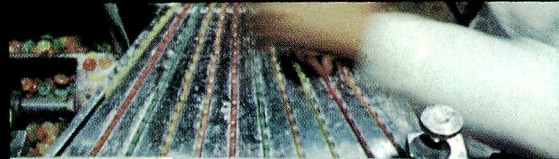


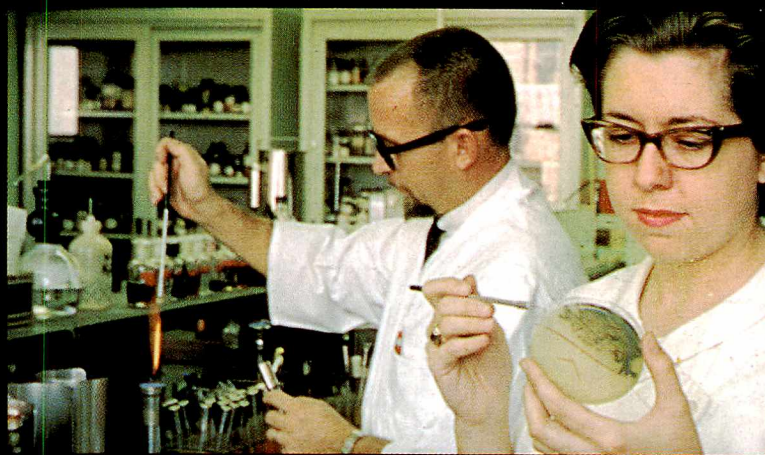


Christmas would never be the same without candy, nor would a score of other festive and ordinary days. No one need fear that the supply will run out, however, for candymakers are producing more every year. They sold 3.73 billion pounds in 1966, enough to provide about 19 pounds per American. Families with annual incomes of less than \$7,000 eat more candy than more affluent households according to an advertising survey. The industry has made impressive progress in food technology and manufacturing processes re-

cently. Like other food producers, however, candymakers have been concerned with *Salmonella*. In fiscal year 1968 there have been three major recalls of candy contaminated by *Salmonella*.

Aside from bacterial problems, FDA has been troubled by candies for children which look like pills and cigarettes. "For the sake of those small, inquisitive, innocent victims of accidental poisoning, let's bid farewell to the candy pill," Dr. Goddard said last year.





Both FDA and the candy manufacturers check candy and equipment for cleanliness: FDA Inspector examines candy-mixing equipment for batch contamination (left top); industry and FDA Microbiologists check for *Salmonella* contamination (next four pictures); FDA Inspector examines chocolate-melting equipment for sanitation (right bottom). Candy ingredients which must be checked for wholesomeness include coatings, nonfat dry milk, chocolate, nuts, and coconut.



drug accountability

under the Drug Abuse Control Amendments

by K.A. Durrin

The concept of "controlled drugs"—that is to say, barbiturates, amphetamines, and other drugs which represent a potential for abuse unless they are strictly controlled—became embodied in law with passage of the 1965 Drug Abuse Control Amendments to the Food, Drug, and Cosmetic Act.

Simply stated, the law requires those who are engaged in the production and distribution of controlled drugs to account strictly for the manufacture, storage, and movement of bulk materials and finished products through legitimate channels of commerce, and to prevent any of them from getting into illegal trade.

Testimony presented before Congress while the amendments were under consideration indicated that half of the stimulant and depressant drugs then produced in this country were being diverted into illegitimate channels; that some producers of these drugs were either unable or unwilling to account for their production and distribution; and that there was considerable irresponsibility on the part of some drug manufacturers and handlers which had a direct causal relationship to the spread of the national drug abuse problem.

Many still assume that illegal drugs are manufactured in bath-tubs, basements, or abandoned factories. While in some cases this is true, the experience of FDA's Bureau of Drug Abuse Control indicates that over 95 percent of

illegally traded dangerous drugs are siphoned off from the legitimate drug manufacturers and traders.

The public image of the Bureau may well be that of an organization whose work consists entirely of undercover criminal investigation designed to ferret out and apprehend illegal traffickers in dangerous drugs. Essential as this kind of police work is, it is just as important to stem the tide of drug abuse by drying up the sources of illegal supplies. If, with the cooperation of the legitimate pharmaceutical industry, the flow of illegal drugs can be cut off at its source, we will have taken a far more effective step toward the reduction and eventual elimination of the drug abuse problem.

Since the overwhelming percentage of illegal drug supplies originates in the diversion of legal drugs into illegal channels, the answer to the problem must lie substantially in tight accounting and physical control practices of legitimate manufacturers and handlers of these drugs.

The law is explicit enough on who must keep records, and what kind of information these records must contain.

The basic manufacturer who synthesizes controlled drugs; dosage form processors; jobbers; repackers; wholesalers; retailers; private and public clinics; hospitals; research institutions; dispensing physicians—in short, all who handle, dispense, or sell controlled drugs must main-

tain a detailed accounting of their purchases and dispositions and must make these records available for inspection.

All companies, institutions, and individuals handling controlled drugs must maintain records of initial inventories, production, purchases, and sales or other disposition. Since records of bulk material as well as dosage forms must be kept, it seems obvious that a close relationship must be established between the quantities of bulk material and products manufactured from them. Such documentation would include statistical and physical evidence of the degree and nature of loss of bulk material in the manufacturing process. Given customary manufacturing practices, the percentage of losses in one plant will closely resemble those in another.

All companies that manufacture, sell, or distribute controlled drugs to anyone but the ultimate consumer must register annually with the Food and Drug Administration.

Those who prescribe controlled drugs for the individual patient are limited by the rule that the retail pharmacist cannot refill a prescription more than five times, nor later than 6 months after it was written. The physician is thus limited as to the number of refills he can order on a prescription; the druggist is restricted on the number of refills he can make, and the time during which such a prescription can be filled.

Of direct concern to manufac-

turers, wholesalers, and retailers is the fact that BDAC Agents have authority, under the law, to inspect the records of the manufacture and sale of controlled drugs. This is often the only personal contact that handlers of these drugs have with the Bureau.

BDAC accountability investigations follow a well-established pattern—yet they vary according to the particular requirements of the company or organization to be inspected. The agent who is charged with an accountability investigation will always identify himself to an officer responsible for the company's operations, and furnish him with a Notice of Inspection.

Investigations cover a wide range of manufacturing and accounting procedures: The date of initial inventories; identification and location of bulk materials and manufactured stock; methods of record-keeping for drugs stored or in transit; frequency of physical inventories and comparison with the inventories carried on the books; theoretical and actual yield as recorded in batch control records; date, kind, quantity, and control number of drugs received, in addition to the registration number of suppliers; records of rejects and returns, and professional samples—all these play a major part in the balance which must be established between initial inventory, receipt, and production of controlled drugs on the one hand, and disposal and

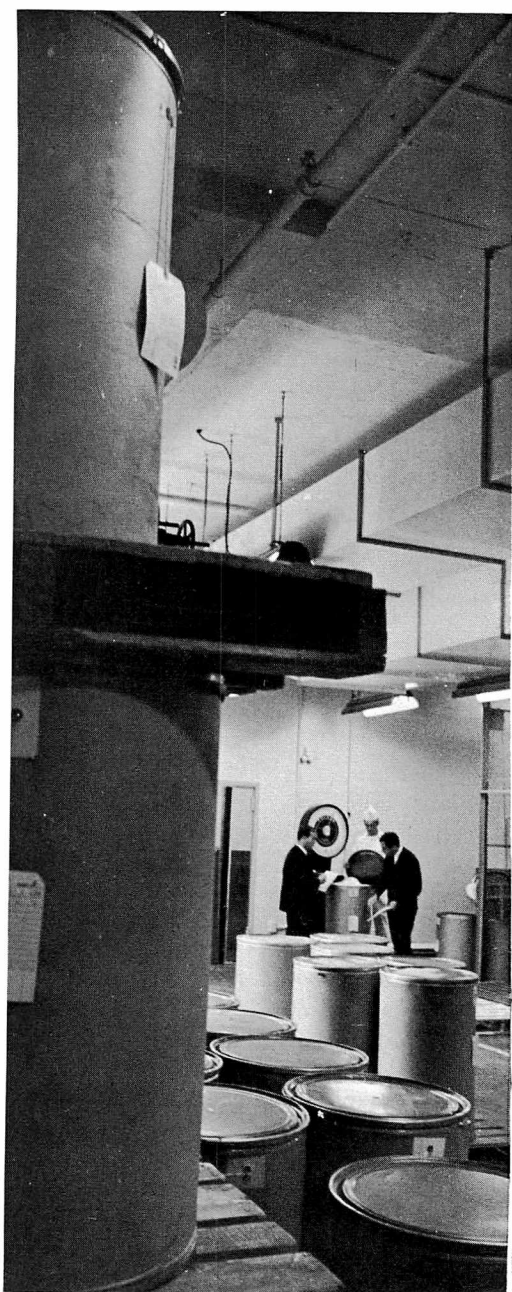
current stock on the other.

The extent and depth of such an accountability investigation depends on the size of the processor or handler, and may take anywhere from a day to 2 weeks or more.

There is a strong implication in this kind of examination that BDAC Agents are not merely interested in accounting aspects and procedures. A substantial part of the investigation is concerned with the physical aspects of storage and safekeeping of controlled drugs. Thus, an agent will want to know whether these drugs are processed, stored, and shipped under conditions which constitute a safeguard against pilferage; whether finished goods are kept under lock and key, or under guard; whether employees are periodically checked when they leave the plant; and whether any drugs have been unaccounted for since the law went into effect on February 1, 1966.

Such detailed investigations may appear onerous to the manufacturer who has to meet production and delivery schedules. However, BDAC Agents attempt to conduct their accountability investigations with the greatest possible consideration for plant requirements and with the least possible disturbance of normal plant operations.

An accountability investigation, at any rate, is of considerable benefit to the manufacturer who seriously and conscientiously attempts to comply with the spirit and letter of the law. It can, in many cases,



BDAC Agents make an accountability check at a major drug company: they compare actual weights and identities of raw materials with firm's records (left) and go over records on controlled drugs with company officials (middle). Records are of initial inventories, production, purchases, and sales, etc. Plants which have established good security measures for controlled drugs usually keep bulk materials under lock and key and restrict the access of personnel of these areas (right and bottom).



make him aware of a variety of loopholes through which his stocks—and with them, considerable sums of money—are diverted into illegal channels.

BDAC files contain a considerable number of cases which indicate that only the tightest record-keeping and inventory control can protect the manufacturer or dealer from pilferage, which can make him violative of the law, and, at the very least, may cost him money. A few months ago, the receiving clerk of a west coast wholesaler was arrested when he attempted to sell 180,000 dosage units of barbiturates stolen from his employer. BDAC's investigation determined a shortage of nearly 1,000,000 dosage units valued at almost \$17,000. Tighter security measures and accounting procedures could have avoided this sort of loss.



Kenneth Durrin is Chief, Branch of Accountability Investigations, Bureau of Drug Abuse Control.

The cost of purloined drugs, of course, is not the only price the manufacturer or dealer has to bear. Those who manufacture or handle controlled drugs bear a special responsibility to society. Their products are of vital importance to the health of the Nation; they can, by the same token, also be a destructive force in the lives of many of our people.

Implicit in the Drug Abuse Control Amendments is the responsibility of all controlled drug handlers to police themselves. This means that care must not only be taken on proper accounting and storage methods but also on the problem of sales to illegitimate purchasers. Buyers should be screened through State licensing authorities and credit sources. An FDA registration number by itself is no assurance of a buyer's legitimacy.

There have been a number of instances where illicit traffickers in controlled drugs have assumed the guise of authorized handlers. In one case, a west coast manufacturer received an order for 12 pounds of amphetamine powder, written on the engraved stationery of a Midwestern veterinary hospital and accompanied by a \$50 cash payment. When a cursory investigation indicated some doubt of the legitimacy of the hospital, the manufacturer notified the BDAC Field Office whose agents discovered that the "veterinary hospital" was a ruse of a convict ring operating out of a Midwestern

State penitentiary. The convicts had printed the imposing stationery in the prison print shop and had induced a prison guard to act as their courier to the outside world.

In another case, BDAC accountability investigators found that an east coast pharmaceutical house had made abnormally large shipments of controlled drugs to a retail pharmacy in the Southwest. Investigation revealed this pharmacy to be a "drop" for a gang of traffickers in controlled drugs.

The diversion of professional samples to the illegal market can also become a serious problem. Unwanted samples should be destroyed by physicians, while manufacturers should regularly check their distribution lists to make certain that samples do not end up in the wrong hands.

The basic premise of accountability investigations is that manufacturers and handlers of controlled drugs are obligated, under the law, to account for the drugs they process or trade, and to prevent their illegal dissemination. Any company, institution, or individual making a conscientious effort to comply with the law will have no problem with BDAC accountability investigations. But where infractions occur as the result of wilful or negligent disregard of the law, action can be taken, including seizure of controlled drugs, citation and hearing, and criminal prosecution.

field reports

ATLANTA DISTRICT A health food distributor was found guilty September 22 of maintaining poor sanitation and storage for his products. Sentencing is pending for Akins Distributors, Inc., Jacksonville, Fla., which stores and distributes a variety of "natural foods" and vitamins and minerals. The foods, including flour, dried vegetables, bran flakes, and cracked wheat and rice, all packaged in cloth or paper containers, were infested with insects and contaminated by rodent filth. Although FDA issued several warnings, the firm did not correct the violative conditions.

BALTIMORE DISTRICT Frozen strawberries with no lids or markings were seized September 27 at Wilmington, Del. The 530 tins, valued at \$3,000, were delivered in a damaged condition to Diamond Cold Storage Co., where further damage took place due to improper handling of goods while stored. The strawberries were adulterated while held for sale because they contained wood chips, insects, and miscellaneous debris, and misbranded because they bore no labeling.

Three lots of adulterated molasses, valued at \$2,050, were seized at Princeton, W. Va., on September 20. Manufactured by Norris Bros. Syrup Co., W. Monroe, La., the molasses contained a sweetening substance other than sorghum and sugarcane molasses, and was misbranded since two lots were unlabeled and labeling on the third lot was false and misleading.

BOSTON DISTRICT After learning of a canning problem through routine factory inspections, the District then inspected all sardine canneries in Maine. Based on the results of these factory inspections, a conference was held in August between representatives of the canneries, the Division of Inspections of the State of Maine, and the FDA. Voluntary agreement was reached that will lead, hopefully, to a satisfactory solution to the problem.

BUFFALO DISTRICT To help prevent poisonings in the home, the District is cooperating with the Bureau of Emergency Medical Services of the New York State Department of Health in a yearlong poison prevention campaign. They are both assisting the New York State Federation of Home Bureaus with chapter education projects, community education projects, and chapter county cooperative projects.

A Pennsylvania cheese firm and its manager were fined September 18 because the swiss cheese manufactured by the firm was deficient in milk fat and was misbranded since it failed to comply with the standards. Fairview Swiss Cheese Cooperative Association, Fredonia, was fined \$400, and John Koller was fined

\$1,000 and placed on probation for 2 years. The firm has a history of failing to comply with standards.

CHICAGO DISTRICT Four representatives of the Borden Co. visited the District Office recently to discuss procedures for establishing the firm's quality control bacteriological laboratories to cover all products produced by them in the Chicago area.

"Focus on Health" was the title of an aging conference held in Chicago, Ill., October 30. Sponsored by the District, Chicago Commission for Senior Citizens, and the University of Illinois Cooperative Extension Service, the conference drew 200 directors of Senior Centers and other professionals concerned with the health problems of aging.

CINCINNATI DISTRICT An \$18,000 fine against an Ohio drug firm was reduced to \$400 in Federal court on September 14 because the firm had made needed improvements. C.M. Bundy Co., Cincinnati, had been fined for shipping adulterated and misbranded drugs and failing to maintain good manufacturing practices. The judge said he would lower the fine if the firm took positive steps to correct the violations. On October 1 the firm moved to new quarters which will provide more space and better facilities.

DALLAS DISTRICT A \$2,000 fine was imposed on Mountain Pass Canning Co., Anthony, Tex., on September 5 for shipping tomato sauce manufactured from decomposed raw material. Responsible officials of the firm visited the District in late September and reported that they had taken corrective steps to prevent future violations of this type. They are using a different variety of tomato which permits machine harvesting, installed new equipment, and adopted a program to prevent production of tomato products from decomposed tomatoes.

DALLAS BDAC A father and son were arrested on drug charges recently. First the son was arrested in Dallas, Tex., by BDAC Agents for negotiating a sale of methamphetamine. In his pocket agents found a letter from his father indicating that the father was supplying the drug. The Los Angeles Police then arrested the father for illegal possession of methamphetamine.

DENVER DISTRICT Approximately 1,800 pounds of Monterey Jack cheese were seized in Salt Lake City, Utah, on September 15 due to adulteration with rodent and insect hairs and because the product was prepared under insanitary conditions. The shipper was Nelson-Ricks Creamery Co., Rexburg, Idaho.

DETROIT DISTRICT "The Elderly as Consumers" was the theme of a workshop in which the District participated at Indiana University, Bloomington, on Octo-

ber 3 and 4. Approximately 400 professionals who work with senior citizens attended the conference, sponsored by the Indiana Commission on Aging and the Aged. The purpose of the meeting was to promote health and economic protection for the elderly by informing them how to use drugs safely and effectively and how to select health services and products wisely.

More than 900 cases of canned mushrooms were seized during September and October because the product was inadequately labeled, contained short drained weight, or consisted of decomposed mushrooms. Processed and shipped by United Canning Co., East Palestine, Ohio, the mushrooms were valued at \$5,500.

KANSAS CITY DISTRICT Due to insanitary storage conditions, the Better Foods Wholesale Grocery Co., Kansas City, Mo., was fined \$1,000 on one count on August 30. Foods products stored in the warehouse had become adulterated with insect and rodent filth. The court placed the remaining seven counts in abeyance, and told the defendant to appear again in 90 days. If sanitary conditions at that time are not satisfactory, the court will consider stronger action.

LOS ANGELES DISTRICT DDE pesticide residues were found in butter shipped by United Dairymen of Arizona, Phoenix, to a Los Angeles dealer in September. Some 16,000 pounds of the butter, valued at \$11,000, were seized on a charge that the butter contained an unsafe amount of food additive. This seizure reflects a problem with Arizona dairy feeds which contain plant materials bearing residues of DDT and related pesticides.

Cutitone Acne Cream, considered a new drug because of a new active ingredient, was seized in Los Angeles, Calif., in September on grounds that there was no approved New Drug Application. The seizure involved 153 tubes, valued at \$88. The preparation was originally formulated with bithionol as an active ingredient, and was covered by a New Drug Application. In early 1967, the application was canceled when adverse reactions to the drug were reported. The manufacturer, Campana Corp., Div. of Purex Corp., Batavia, Ill., then substituted a compound similar to bithionol in the formula, but did not file a New Drug Application.

LOS ANGELES BDAC Two clandestine drug laboratories in the Los Angeles area were halted recently. A young couple were arrested in a suburb for running an illegal DMT laboratory, and the laboratory chemicals and equipment were seized. Another laboratory was stopped by agents before it even started. A local chemist complained to the Los Angeles Police that he had been threatened and instructed to manufacture LSD. The police contacted BDAC, which introduced an agent into the operation. When the suspects ob-

tained the last chemicals needed for the laboratory, they were arrested and the laboratory equipment and chemicals seized.

MINNEAPOLIS DISTRICT Forty Dynatone Facial Exerciser devices, valued at \$2,000, were seized in September at a Minneapolis department store because of false health claims contained in accompanying literature and newspaper advertisements. Claims were made for problems including double chins, crow's-feet, and wrinkles. Oral claims were also made for restoring youthful resiliency and tone of neck and facial muscles by inducing muscle contraction through electrical impulses.

Analytical Methodology for Pesticide Residues, Medicated Feeds, and Microbiology was the topic of a State and Federal Workshop Program conducted by the District on September 6-8. More than 40 scientists from regulatory agencies in Minnesota, North Dakota, South Dakota, and Wisconsin attended. The program covered all phases of analytical methodology in pesticide residue and medicated feed analysis, and microbiology. The purpose of the conference was to provide an interchange of ideas, giving all participants new perspectives on their problems.

NEW ORLEANS DISTRICT The District participated in a food warehouse sanitation workshop September 13 and 14 in Birmingham and Montgomery, Ala. The receptiveness of the audience was graphically illustrated during a September 19 inspection. A wholesale grocer at Florence, Ala., had sent his management to the Birmingham workshop, and they demonstrated to the FDA Inspector a number of ground, building, and housekeeping improvements they had made after attending the workshop.

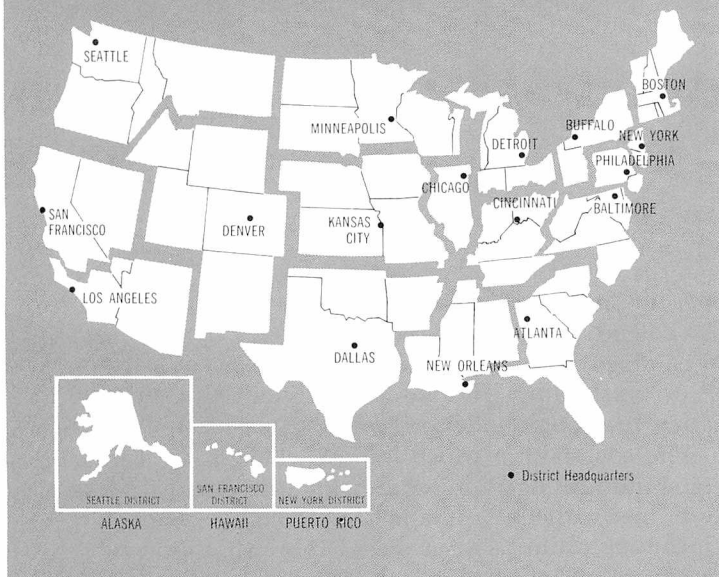
For processing and storing macaroni products in an establishment infested with insects, a New Orleans, La., firm was fined \$500 on October 18. Taormina Brothers also stipulated that it would cease all manufacture of macaroni products.

NEW YORK DISTRICT As a result of two recent Supreme Court decisions involving consent for inspections, FDA is now required to obtain warrants from the courts when met with a refusal to allow inspection.

Recently the District was faced with two such refusals. It then obtained warrants to inspect R & N Drug, Inc., Secaucus, N.J., and L'Fortune Co., New York, N.Y. Both firms subsequently allowed inspection.

When FDA found that some of 8,300 bags of cocoa beans sampled recently were insect and rodent defiled, the brokers voluntarily agreed to have the affected lots reconditioned in line with FDA guidelines.

FOOD AND DRUG ADMINISTRATION DISTRICTS



PHILADELPHIA DISTRICT Mysterious Myst-All, a Japanese novelty item alleged to determine executive power potential, was voluntarily recalled in September because it is a hazardous toy. The dumbbell-shaped glass product contains methanol, which is flammable and toxic. The importer and distributor, Chadwick-Miller, Inc., Boston, Mass., recalled approximately 48,000 of the items from national distribution.

As part of a current program on *Salmonella* contamination of animal byproducts for feed, the District collected a sample of processed poultry byproducts on September 22 manufactured by the College Hill Poultry Co., Fredericksburg, Pa. Laboratory examination detected *Salmonella* in a 20-ton lot destined

for shipment to Maryland. FDA is investigating the problem further.

SAN FRANCISCO DISTRICT Due to bacterial contamination, two shrimp products were seized in September. "Peacock Brand" canned shrimp meat, valued at \$10,300, was seized at San Francisco, Calif., on September 1. The product, manufactured by Point Adams Packing Co., Newport, Oreg., contained excessive coliforms and had been packed under insanitary conditions. Frozen shrimp meat, valued at \$4,365, was seized at Crescent City, Calif., on September 16. The contaminated product was packed by Astoria Seafood Co., Astoria, Oreg.

SEATTLE DISTRICT Inspection of a Seattle canner on September 14 uncovered a lot of 30,000 pounds of salmon, 30 percent of which was decomposed. The firm voluntarily removed the entire lot from the plant for sale as fish bait or for rendering under supervision of the National Canners Association.

A Good Manufacturing Practice Medicated Feed Workshop was cosponsored by the District in Bellevue, Wash., on September 12. Other cosponsors were the Oregon Department of Agriculture; Oregon Feed, Seed and Suppliers Association; Washington State Department of Agriculture; Washington State Feed Association; and Washington State University. More than 100 persons represented all the northwestern States and Canada. *Salmonella* contamination in animal feeds and salmonellosis in humans were featured topics.

FDA DISTRICT OFFICES

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

BALTIMORE 900 Madison Avenue
Baltimore, Maryland 21201

BOSTON 585 Commercial Street
Boston, Massachusetts 02109

BUFFALO 599 Delaware Avenue
Buffalo, New York 14202

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

CINCINNATI 1141 Central Parkway
Cincinnati, Ohio 45202

DALLAS 3032 Bryan Street
Dallas, Texas 75204

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

DETROIT 1560 E. Jefferson Avenue
Detroit, Michigan 48207

KANSAS CITY 1009 Cherry Street
Kansas City, Missouri 64106

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

MINNEAPOLIS 240 Hennepin Avenue
Minneapolis, Minnesota 55401

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

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

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

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

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

FDA BUREAU OF DRUG ABUSE CONTROL FIELD OFFICES

ATLANTA 1831 Peachtree Road, N.E.
Atlanta, Georgia 30309

BALTIMORE 401 Water Street
Baltimore, Maryland 21202

BOSTON J. F. Kennedy Federal Bldg.
Rm. E-311/Boston, Massachusetts 02203

CHICAGO Engineer Bldg.
Rm. 1700/205 West Wacker Drive
Chicago, Illinois 60606

DALLAS 1114 Commerce Street
Rm. 723/Dallas, Texas 75202

DENVER New Customhouse Bldg.
Rm. 228/721 19th Street
Denver, Colorado 80202

KANSAS CITY U.S. Courthouse
Rm. 225/811 Grand Avenue
Kansas City, Missouri 64106

LOS ANGELES 714 West Olympic Boulevard
Rm. 1010/Los Angeles, California 90015

NEW YORK 201 Varick Street
Rm. 1051-A/New York, New York 10014

state actions

Consumer Services Office Established The Office of Consumer Services was permanently established and the Florida Consumers Council authorized by the Florida legislature on July 10. The Office, within the Department of Agriculture, had been opened on March 1. The Council consists of 20 top officials of State organizations. The purposes of the Office and Council are to: alert the public to the activities of unscrupulous operators, study and recommend ways of combating such activities, and serve as a clearing house for consumer complaints.

A statewide consumers conference will be held in Miami on December 1-2, when Miss Betty Furness, President Johnson's Advisor on Consumer Affairs, will speak.

Cosmetic Firm Fined \$35,000 For making false and misleading representations to induce the public to purchase its products, a cosmetic firm was fined \$35,000 on September 8. Investigations by the California Department of Public Health's Bureau of Food and Drug Inspections led to the fine and a permanent injunction. Holiday Magic, Inc., San Rafael, Calif., had invited the public to attend "opportunity meetings" through newspaper advertisements. The ads contained false representations about the possible income that could be made, and did not disclose that those recruited had to make a substantial investment in the firm. When the corporation consented to the entering of the Final Judgment without any proof, trial, or adjudication of any fact or law, the Superior Court of the State of California permanently enjoined it from making any false or misleading representations in recruiting distributors.

In December 1965, the firm and another company, Zolene, Inc., were permanently enjoined from making any false or misleading representations relating to the sale of their cosmetics. The complaint alleged that false and misleading claims were made in newspapers and on television, including claims that the cosmetics were completely organic; were made from fruits, nuts, herbs, and vegetables; contained no chemicals, preservatives, alcohol, or mineral oil; had therapeutic effect on certain skin conditions, such as acne, psoriasis, diaper rash, and eczema.

Minnesota Adopts Sanitary Regulations The Minnesota State Department of Agriculture has recently adopted regulations prescribing sanitary requirements for manufacturers of bakery products and for bottlers of nonalcoholic beverages. Minnesota Department of Agriculture officials believe this to be the first time a State regulatory agency has attempted to develop comprehensive regulations specifically designed to promote an acceptable sanitary environment for the baking industry. At the same time, the Department established Standards of Identity for soda waters and bakery products comparable to those established under the Federal Food, Drug, and Cosmetic Act. The regulations will be administered by the Department's Division of Food Inspection.

Kansas Embargoes Contaminated Wheat The Kansas State Board of Health placed an embargo against contaminated wheat in September. More than 2.7 million pounds of crotalaria-contaminated wheat were embargoed in nine counties in Kansas and four in Missouri. The contaminated wheat is being

cleaned and processed under State supervision to bring it into compliance. Wet weather in parts of Kansas and Missouri this year had delayed wheat harvest until August, which caused changes in harvest procedures, and the threshed wheat contained an excessive amount of weed seeds. The wheat was originally sampled by the Kansas City FDA District; county agents and industry grain associations familiar with the problem acted immediately to correct it.

Salmonella Ordinance Passed Seizure of contaminated egg whites in Iowa recently led to passage of a *Salmonella* ordinance in Minnesota. Frozen egg whites shipped by the Lonsdale Egg Co., Lonsdale, Minn., were seized at the Des Moines Cold Storage Co., Des Moines, Iowa. A local competitor of the egg company noticed an article in a Des Moines paper reporting the seizure and notified the local Minnesota news media. The Community Health Departments of three Minneapolis suburbs then sampled lots of Lonsdale eggs at local bakeries and embargoed several. One suburb, Bloomington, subsequently passed an ordinance on November 7 requiring that all frozen eggs sold there be pasteurized or treated to destroy all live *Salmonella* organisms.

Mexican Children Poisoned Seventeen children died and many more became ill in Tijuana, Mexico, in late September from eating sweet baked goods containing the pesticide parathion. The poisonings were first attributed to fresh milk from local dairies, and Mexican health authorities closed the dairies. Further examination showed the parathion in pastry made in a

Tijuana bakery. Mexican officials learned that a warehouse in Mexicali, Mexico, had supplied sugar to the bakery, and that parathion had been stored next to the sugar. However, the way the baked goods became contaminated has not been determined definitely.

None of the baked goods entered the United States in commercial quantities. The San Diego County Health Department, the California Department of Agriculture, and FDA's Los Angeles District assisted the Mexican government.

Pharmacy Board Rules As a result of work done by FDA's Boston District, the Massachusetts Board of Registration in Pharmacy took action against two pharmacists and a pharmacy employee on September 12. Since Lawrence R. Kadis, Walnut Drug Corp., Newtonville, Mass., and his employee, Irwin Speare, had been fined and imprisoned for an FDA O-T-C offense, the Board placed both men on probation for 2 years. Because he was convicted of conspiracy to violate the Massachusetts Narcotic Drug Law, John L. Tarlow, Tarlow Rexall Pharmacy, Boston, Mass., was denied a request for return of his license to practice pharmacy. Work by the Boston District had resulted in his imprisonment on the conspiracy charge.

Oklahoma Sets Precedent A precedent was set by the Oklahoma State Board of Pharmacy in September when it ruled that drugs which had been involved in a fire were subjected to enough heat to destroy their potency. When an FDA Resident Inspector and two officials from the Board first inspected the Oklahoma City pharmacy, they concluded that the stocks of prescription drugs were



Texas State and Dallas officials have supervised reconditioning of \$60,000 worth of damaged foods brought to Dallas from the area battered by Hurricane Beulah. Their work is not yet finished. Examining seams on canned goods are (from left): City of Dallas Inspector David Pinkston; Texas State Inspector W. A. Nance, Jr.; and FDA Inspector Leonard J. Farr.

unfit to use. When the Underwriters Salvage Company refused to destroy the lot voluntarily, the matter was referred to the State Board of Pharmacy, which agreed with the officials' opinion. Then the Division of Food and Drugs, Oklahoma Health Department, issued a letter to the Attorney General of Oklahoma, concurring in the conclusion of the Board and requesting that a court order be sought for condemnation and destruction of the drugs. When the insurance company was informed of the Board's findings, it decided to destroy the drugs voluntarily. The Board's action is expected to result in more expeditious handling of damaged drugs in the future.

Kansas Officials Meet The Metropolitan Kansas City Conference of Food and Drug Officials, an affiliate of the Mid-Continent Division of AFDOUS, held its fall meeting at the Kansas City District on September 20. The all-day training session drew 40 persons from local, county, State, and Federal health agencies. Officers elected for 1968 were: James Grohusky, Kansas-Wyandotte County Health Department, President; Don Rice, Kansas City (Mo.) Health Department, Vice President; George L. Vinz, Kansas

City District Supervisory Inspector, Secretary.

State Officials Commissioned

FDA commissioned six State officials in September as officers of the Food and Drug Administration: Stanley I. Trenhaile, Commissioner, Idaho Department of Agriculture; John P. Orcutt, Commissioner, Colorado Department of Agriculture; Joseph H. Francis, Chairman, Board of Commissioners, Utah Department of Agriculture; B. Dale Ball, Director of the Michigan Department of Agriculture; Gus R. Douglass, W. Virginia Commissioner of Agriculture; and Albert B. Heagy, State Chemist, Maryland State Board of Agriculture.

Food Labeling Law Passed Labels for foods shipped interstate and intrastate will be required to show the percentage of an ingredient in those foods where it is of material interest to a consumer, or to state that none of a certain ingredient is present, according to a bill passed by the 1967 session of the Florida legislature. In the latter provision, the bill requires more information than do the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act.

seizures and Post Office cases

SEIZURE ACTIONS

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

A total of 97 seizure actions to remove adulterated, misbranded, and unsafe products from the consumer market were reported in September/October. These included 54 seizures of foods: 4 because of poisonous and deleterious substances, 39 because of contamination, and 11 because of

economic violations. Other seizures included 1 of color additives, 30 of drugs (including 8 of veterinary and medicated feeds), 9 of medical devices (including 1 prophylactic), and 3 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD / Poisonous and Deleterious Substances		
Butter/Los Angeles, Calif. 9/14/67	United Dairymen of Arizona/Tempe, Ariz. (M,S)	Contains excessive food additive, DDE.
Egg whites, frozen/Des Moines, Iowa 9/6/67	Lonsdale Egg Co./Lonsdale, Minn. (M,S)	Contain poisonous Salmonella micro-organisms.
Wheat/Duluth, Minn. 8/29/67	Minto Farmers Elevator/Minto, N. Dak. (S)	Contains a mercurial pesticide chemical.
Buffalo, N.Y. 9/12/67	J. E. Wells Co./Sidney, Ohio (S)	Contains pink wheat.
Contamination, Spoilage, Insanitary Handling		
Apricots, canned/Dayton, Ohio 8/25/67	Richmond Foods, Inc./Dayton, Ohio (D)	Contain partly decomposed substance.
Beans, pinto, navy, lima, black-eyed peas/Dallas, Tex. 10/4/67	Jay Freeman Co., Inc./Dallas, Tex. (D)	Held under insanitary conditions in an insect-infested warehouse.
lima, Great Northern/Winston-Salem, N.C. 9/1/67	Clyde L. Foy Co./Winston-Salem, N.C. (D)	Held under insanitary conditions; insect contaminated.
Breeder 1171/Boston, Mass. 9/25/67	Channel Fish Co./Boston, Mass. (D)	Rodent infested.
Butter/Pana, Ill. 9/8/67	Farmington Coop. Creamery Association/Farmington, Iowa (M,S)	Prepared under insanitary conditions; insects.
Fort Wayne, Ind. 9/27/67	Benson Produce Co./Benson, Minn. (M,S)	"
Cheese, Monterey Jack/Salt Lake City, Utah 9/15/67	Nelson-Ricks Creamery Co./Rexburg, Idaho (M,S)	Prepared under insanitary conditions.
Cocoa Beans/Philadelphia, Pa. 9/1/67	Atlantic Terminal & Warehouse Co., Inc./Philadelphia, Pa. (D)	Held under insanitary conditions; bird excreta and insect contaminated.
Philadelphia, Pa. 10/10/67	General Marine Terminals/Philadelphia, Pa. (D)	"
Jersey City, N.J. 10/2/67	The General Cocoa Co./New York, N.Y. (S)	Insect contaminated.
Cod blocks/Rankin County, Miss. 9/28/67	Shamrock Fisheries Corp./St. Louis, Mo. (S)	Decomposed.
Coffee Beans/Fort Worth, Tex. 9/28/67	Johnson Van & Storage/Fort Worth, Tex. (D)	Insect contaminated.
Ginger Ale/Middletown, R.I. 10/10/67	Cliquot Club Co./Millis, Mass. (M,S)	Moldy.
Meat, potted/San Francisco, Calif. 9/5/67	United Packers, Inc./Opelousas, La. (M,S)	Decomposed.
Los Angeles, Calif. 10/6/67	"	"
Metrecal Cookies/Jackson, Miss. 10/2/67	Jerry L. Maxey/Jackson, Miss. (D)	Insect contaminated.
Mushrooms, canned/East Palestine, Ohio 9/13/67	United Canning Co./East Palestine, Ohio (M,S) Return shipment from Beaver Falls, Pa.	Partly decomposed; fail to bear accurate statement of quantity of contents.
Syracuse, N.Y. 9/20/67	United Canning Co./East Palestine, Ohio	Contain decomposed mushrooms.
Pancake and Waffle mix, Buttermilk and Pancake mix, Breeding mix/Detroit, Mich. 9/25/67	Karr-Stevens, Inc./Detroit, Mich. (D)	Held under insanitary conditions; insect contaminated.
flour/Pueblo, Colo. 10/3/67	Robb Ross Corp./Sioux City, Iowa (M,S)	Insect contaminated when shipped.
Poppyseed/Boston, Mass. 9/12/67	J. Sklar & Co., Inc./Boston, Mass. (D)	Held under insanitary conditions; insects.
Port Wine, white and dark, Sherry Wine/Atlanta, Ga. 9/13/67	General Wholesale Co., Inc./Atlanta, Ga. (D)	Held under insanitary conditions.
Potatoes, hash brown/Detroit, Mich. 8/31/67	Potato Service, Inc./Presque Isle, Maine (M, S)	Prepared and packed under insanitary conditions; excessive coliforms and bacteria.
Raisin Bran/Dallas, Tex. 9/12/67	Binyon O'Keefe Warehouse Co., Inc./Dallas, Tex. (D)	Held in insect-chewed packages.
Rice/Miami, Fla. 9/13/67	Robbins Warehousing & Distributing Co./Miami, Fla. (D)	Insect contaminated.
Cleveland, Ohio 10/2/67	Gust Gallucci Co., Inc./Cleveland, Ohio (D)	"

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Contamination, Spoilage, Insanitary Handling (cont'd)		
Sausages, canned "Chorizos en Manteca"/ Port Newark, N.J. 9/14/67	F & J. M. Carrera, Inc./San Juan, P.R. (S)	Contain decomposed sausages.
Scallops, cubed, Sole wedges/Los Angeles, Calif. 9/15/67	Anchor Sea Food Corp./Los Angeles, Calif. (D)	Contain bacteriological contamination.
Shrimp, frozen, breaded/New Orleans, La. 9/19/67	New Orleans Shrimp Co./New Orleans, La. (P, S) Return shipment from Pensacola, Fla.,	Prepared and packed under insanitary conditions; contain staphylococci.
Jacksonville, Fla. 9/21/67	New Orleans Shrimp Co./New Orleans, La. (P, S)	"
Memphis, Tenn. 8/25/67	"	"
Shrimp meat, canned/San Francisco, Calif. 9/1/67	Point Adams Packing Co./Newport, Oreg. (P, S)	"
Crescent City, Calif. 9/16/67	Astoria Seafood Co./Astoria, Oreg. (P)	"
Strawberries, frozen/Wilmington, Del. 9/27/67	Diamond Cold Storage Co./Wilmington, Del.	Contain wood chips, insects, and miscellaneous debris; insufficient labeling information.
Tomato Catsup/New Orleans, La. 9/15/67	Naas Foods, Inc./Sunman, Ind. (M, S)	Contains decomposed tomatoes.
Juice/Wichita, Kans. 9/12/67	Texsun Corp./Weslaco, Tex. (M, S)	"
Puree/Fullerton, Calif. 9/12/67	Productos Kern's S.A. de C.V./Mexicali, Mex. (M, S)	Contains fly eggs and maggots.
Wheat/Spokane, Wash. 9/1/67	Pickert Grain Co./Finley, N. Dak. (S)	Rodent contaminated.
Kalama, Wash. 9/15/67	Farmers Union Grain Terminal Association/ Ulm, Mont. (S)	"
Economic Violations		
Bubble Gum Shake/Los Angeles, Calif. 8/9/67	Topps Chewing Gum, Inc./Duryea, Pa. (M, S)	Inconspicuously labeled.
Butter/Dubuque, Iowa 8/18/67	Oak Brand Ice Cream Co./Freeport, Ill. (M, S)	Contains less than 80 percent of milk fat.
Mackerel, Sultana/Terminal Island, Calif. 8/31/67	Star-Kist Foods, Inc./Terminal Island, Calif. (P, S)	Jack mackerel have been substituted.
Mint Sticks/Vernon, Calif. 9/6/67	Atkinson Candy Co./Lufkin, Tex. (M, S)	Short weight.
Molasses/Princeton, W. Va. 9/20/67	Norris Bros. Syrup Co./West Monroe, La. (M, S)	A sweetening substance other than sorghum and sugar- cane molasses has been substituted; insufficient labeling.
Noodles/Kansas City, Kans. 7/31/67	Country Kitchen Food Products/Carthage, Mo. (M, S)	Not in conformity with standard of identity of egg noodles.
Salt Lake City, Utah 8/17/67	Golden Grain Macaroni Co./San Leandro, Calif. (M, S)	Deficient in egg solids.
Nuts, mixed/Lewiston, Maine 9/14/67	Superior Nut Co., Inc./Boston, Mass. (M, S)	Vignette shows approx. 18 percent peanuts, but mixture contains almost 80 percent peanuts.
Peaches, sliced, Seline/Kansas City, Mo. 9/18/67	California Cannery & Growers/Stockton, Calif. (P, S)	Not in conformity with definition and standard of quality for canned sliced peaches.
Peanuts, salted, Virginia Slims/Phoenix, Ariz. 8/28/67	Bell Brand Foods, Ltd./Santa Fe Springs, Calif. (M, S)	Labeling suggests that peanuts will cut down calories, thin out fat, reduce weight.
Potato Chips/Lawton, Okla. 10/11/67	Mead-Co., Inc./Lubbock, Tex. (M, S)	Short weight.
COLOR ADDITIVE		
Vegetable Butter/Detroit, Mich. 8/2/67	American Shortening & Oil Co./Detroit, Mich. (D)	Contains artificial coloring, and its label fails to state that fact.
DRUGS / Human Use		
Aknemed/Norfolk, Va. 9/19/67	The Aknell Corp./Birmingham, Ala. (S)	New drug not approved for safety and efficacy.
Baltimore, Md. 10/6/67	"	"
A.T.A. Tablets, Cholinase Aromatic Solution/Fresno, Calif. 7/27/67	H.R. Cenci Pharmaceutical Co./Fresno, Calif. (M, S)	Inadequate directions for use; insufficient mandatory labeling information.
Bariatric Formula #B-1, B-2, 205, 213, 214, 221/Coral Gables, Fla. 9/15/67	Bariatric Corp./Coral Gables, Fla. (D)	False and misleading claims for nutritional and iron deficiency anemias with an aid against constipating factors.
Chlorpheniramine Maleate Capsules and Triple Sulfa Tablets/Plymouth, Mich. 9/14/67	Plymouth Laboratories, Inc./Plymouth, Mich. (D)	Below USP standard quality and labeled strength; fail to disintegrate within 30 minutes.

SEIZURE ACTIONS

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
DRUGS / Human Use (cont'd)		
Cough and Cold Remedy/Los Angeles, Calif. 9/13/67	Imported from Osaka, Japan.	New drug not approved for safety and efficacy.
Cuticura Cutitone Acne Cream/Los Angeles, Calif. 8/29/67	Campana Corp./Batavia, Ill. (M, S)	"
Cyanocobalamin USP Injectable/Roswell, N. Mex. 8/31/67	Interstate Pharmaceuticals/San Gabriel, Calif. (S)	Strength differs from USP standard.
Dex Amo #2 capsules/Farmingdale, N.Y. 9/26/67	Garden Laboratories, Inc./Hackensack, N.J. (M, S)	Below declared strength; not in conformity with good manufacturing practices.
Distilled Water/Akron, Ohio 8/3/67	Absopure Water Co./Detroit, Mich. (M, S)	Not in conformity with USP standard because of total bacteria and faulty packaging.
Ferrous Sulfate/Plymouth, Mich. 9/14/67	Plymouth Laboratories/Plymouth, Mich. (D)	Not in conformity with USP requirements for tablet disintegration.
Hesperidin Plus Vitamin C, Stress Vitamin, Lipotropic Capsules, Garlic-Parsley Tablets, Therapeutic Tablets, Vitamin A and B ₂ tablets/Chicago, Ill. 6/12/67	Frederick Herrschner Pharmaceutical Co./Chicago, Ill. (D)	False and misleading claims to raise resistance of capillaries against virus invasion; relieve stress and tension; help digestion; as a gas repellant; to treat multivitamin deficiencies; restore healthy skin, treat acne; prevent lesions of skin and eyes, cracking lips.
Hydrogen Peroxide/Detroit, Mich. 8/15/67	Berke Chemical Co./Detroit, Mich. (D)	Below USP standard in quality and purity.
Iron Hy-Dex Capsules/Carolina, P.R. 9/7/67	Nessen Laboratories, Inc./Carolina, P.R. (D)	New drug not approved for safety and efficacy; below labeled strength.
Lipo-K Capsules and Tablets, Normo-tension Tablets and Injection/Philadelphia, Pa. 8/9/67	Quaker City Pharmacal Co./Philadelphia, Pa. (D)	New drugs not approved for safety and efficacy.
Meprobamate Tablets/Emeryville, Calif. 8/29/67	Interstate Laboratories/Emeryville, Calif. (D)	" ; inadequate labeling information.
Pantho Nail/St. Louis, Mo. 9/6/67	Wm. T. Thompson Co./Los Angeles, Calif. (S)	False and misleading claims to promote stronger, healthier finger and toe nails and be effective for growth and normal maintenance of skin, hair, and nails.
Penicillin G Powder/Indianapolis, Ind. 9/13/67	Vet-A-Mix, Inc./Shenandoah, Iowa (M, S)	Strength differs from that stated on label.
Polybor 3/Lubbock, Tex. 7/18/67	Armstrong Warehouse & Transfer Co./Lubbock, Tex. (D)	Contains boron, a food additive not in compliance with regulations.
Pro-Lon Tablets/New York, N.Y. 8/4/67	Male Health Clinic/New York, N.Y. (D)	False and misleading claims to be effective as a treatment for premature ejaculation.
Reserpine Tablets/Detroit, Mich. 5/6/67	Mallard, Inc./Detroit, Mich. (D)	Strength differs from official USP standard.
Veen Dragees/Montebello, Calif. 8/31/67	W. Affeman/Frankfurt, Germany (S)	New drug not approved for safety and efficacy.
Veterinary / Medicated Feed		
Arizona Star Lactation Ration w/NF-180/Phoenix, Ariz. 8/22/67	Arizona Milling Co., Inc./Phoenix, Ariz. (D)	Below labeled strength in furazolidone.
Diethylstilbestrol Pellets/Vineland, N.J. 9/18/67	Milan Pharmaceuticals, Inc./Morgantown, W. Va. (M, S)	New drug not approved for safety and efficacy.
Horse Worm Pellets/Griiffin, Ga. 8/25/67	Bingman Laboratories, Inc./Caldwell, Ohio (M, S)	Below labeled strength in piperazine dihydrochloride.
Birmingham, Ala. 8/21/67	"	"
Norco Milk Replacer/Norfolk, Nebr. 9/25/67	Tri Foods, Inc./Concordia, Mo. (M, S)	False and misleading claims for the prevention of bacterial calf diarrhea; contains uncertified antibiotic.
Pig Pre-Starter Pellets, medicated/Hugo, Colo. 9/8/67	Snell Grain Co./Hugo, Colo. (D)	Premix is an illegal combination of antibiotics.
Poultry Lift/Kansas City, Mo. 8/18/67	I.D. Russell Co. Laboratories/Kansas City, Mo. (D)	Deficient in penicillin; contains uncertified antibiotic.
Sulfa-Trol Pellets/Birmingham, Ala. 8/15/67	Bingman Laboratories, Inc./Caldwell, Ohio (M, S)	Not in conformity with good manufacturing practice regulations; differs from declared standard.
MEDICAL DEVICES		
Bed Wedge "Foam Incliner #1239" and Bed Wedge "The Relaxer"/Hanover, Pa. 8/28/67	Popular Products Manufacturing Co./Chicago, Ill. (M, S), Cadie Products Corp./Paterson, N.J. (M. S.), and Hanover House/Hanover, Pa. (D)	False and misleading claims as a treatment of respiratory and circulatory conditions, to relieve aches due to varicose veins, heart conditions, asthma.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
MEDICAL DEVICES (cont'd)		
Body Massager "Dial"/Los Angeles, Calif. 8/23/67	Dial Manufacturing Co./Phoenix, Ariz. (M, S)	False and misleading claims to tone facial muscles, stimulate circulation, smooth tension lines, induce sleep.
Dynatone facial exerciser/Minneapolis, Minn. 9/27/67	Dynatone, Inc./Wichita, Kans. (M, S)	False and misleading claims to firm and tone age-revealing areas of face and neck, strengthen sagging muscles, firm chin and front of neck.
Endura-Dent/Detroit, Mich. 8/24/67	Endura Appliance Corp./Freeport, N.Y. (M, S)	False and misleading claims as a family appliance to prevent tooth decay and gum problems.
Ionator Air Purifier/Phoenix, Ariz. 9/20/67	Emerson Radio & Phonograph Corp./Jersey City, N.J. (M)	False and misleading claims to control and relieve respiratory ailments, asthma, hay fever, dust and pollen allergies, produce cleaner, healthier atmosphere.
Massage-A-Belt, Samson Formette Belt/New Orleans, La. 9/14/67	Frank M. Katz, Inc./New York, N.Y. (S) and Morris Kirschman & Co./New Orleans, La. (D)	Inadequate directions for use and inadequate warnings.
Muscle Stimulator/Setauket, N.Y. 6/14/67	Exertronics of Long Island/Setauket, Long Island, N.Y. (D)	False and misleading claims to tone and tune muscles of the hips, thighs, and abdomen, disperse fatty tissue, reduce size.
Rucken Roll/Pacific Palisades, Calif. 8/25/67	H. Eissmann/Urach, Germany (S)	False and misleading claims to release muscle tensions, roll out bulges on hips, thighs, abdomen, legs.
Saniway Mark IV Air Washing/Eau Claire, Wis. 7/31/67	Va-U-Way, Inc./Toledo, Ohio (M, S)	False and misleading claims to prevent colds, flu, pneumonia, scarlet fever, tuberculosis, diphtheria, smallpox, pleurisy, meningitis.

Prophylactics

Rubber/New Orleans, La. 9/18/67	Allied Latex Sales Co./Dothan, Ala. (M, S)	Defective; holes.
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HAZARDOUS SUBSTANCES

Acriglas Kit/Montezuma, Iowa 8/7/67	Schramm Fiberglass Products/Chicago, Ill. (M, S)	Lacks consumer protection information required by the Fed. Hazardous Substances Act.
Electrasol/Richmond, Va. 9/12/67	Economics Laboratory, Inc./Baltimore, Md.	"
Spring dishwasher detergent/Towson, Md. 10/4/67	North American Chemical Corp./Paterson, N.J. (M, S)	"

DACA ACTIONS

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

NAME, PLACE & DATE	PRODUCT	CHARGES & DISPOSITION	NAME, PLACE & DATE	PRODUCT	CHARGES & DISPOSITION
Piedmont Drug Co. Gainesville, Ga. 8/28/67	82,797 units controlled drugs.	Failure to keep adequate records. Seized.	George Gasser, D.O. Potosi, Mo. 8/14/67	16,000 units controlled drugs.	Failure to keep adequate records. Seized.
Rock-Mor Drugs, Inc. Stone Mountain, Ga. 8/11/67	11,121 units controlled drugs.	Failure to keep adequate records. Seized.	Park & Lock Drugs, Inc., t/a Pastor's Pharmacy Philadelphia, Pa. 6/1/67	700,000 units controlled drugs.	Inadequate records and illegal sales. Seized.
Max G. Goldsmith Indianapolis, Ind. 8/23/67	60,000 units amphetamines and barbiturates. Approximately 300,000 units of various drugs.	Illegal sales. Seized.			
John R. Kauffmann, t/a Fixaco Co. Imperial, Mo. 5/16/67	Controlled drugs.	Illegal sales. Executive seizure. Disposition by default.			

POST OFFICE DEPARTMENT

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

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

September 29, 1967: Fraud Order against **Bijou, Bijou Hollywood Studios**, Hollywood, Calif. Advertisements published in various newspapers and magazines offered a "Blitz Diet" for reducing 5 pounds overnight. Mail impounded pending decision by Judicial Officer on operator's motion for reconsideration.

October 5, 1967: Fraud Order against **Robert H. Glick, Robert Glick, Glick, Western, So.** Pasadena, Calif. Mail-order promotion involving the advertising and sale of product alleged to treat and/or cure obesity.

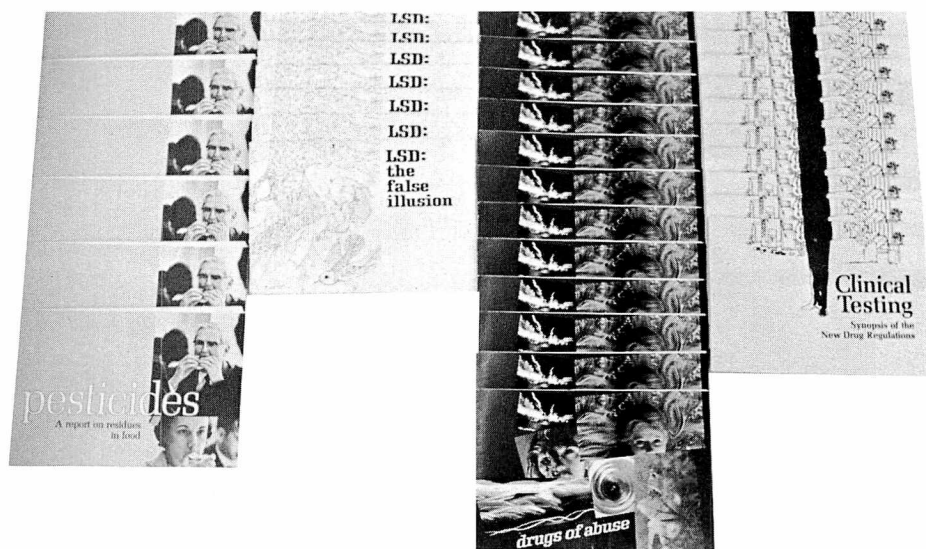
Complaints Filed by the General Counsel Under 39 U.S.C. 4005 (Fraud)

September 27, 1967: **Bountiful Method**, New York, N. Y. Solicitations of orders and sale through the mails of a leaflet containing instructions as to development of the female bustline.

September 27, 1967: **Glamorous**, New York, N. Y. Solicitations of orders and sale through the mails of a leaflet containing exercise instructions to reduce the female waistline.

September 27, 1967: **Heavenly Hips**, New York, N. Y. Solicitations of orders and sale through the mails of a leaflet containing exercise instructions to reduce female hips.

REPRINTS



Want to hang on to your copy of FDA PAPERS, yet pass certain articles along? You can have your magazine and give it away too. Single reprints of some articles from FDA PAPERS are available free. Send all requests to: Publications Services Staff, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204.

notices of judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

Alfalfa seed screenings, at Harrisburg, Dist. Oreg.

Charged 4-7-67: when shipped by W. R. Grace Co., Sunnyside, Wash., the article contained a quantity of the added pesticide chemical toxaphene for which there was no tolerance or exemption; 402(a)(2)(B). Default decree ordered destruction. (1)

Wheat, at Kansas City, Dist. Kans.

Charged 9-6-66: when shipped by Frieling Grain Co., Gaylord, Kans., to Kansas City, Mo., the article contained a pesticide chemical, namely, a mercurial compound, for which there was no tolerance or exemption; 402(a)(2)(B). Default decree ordered destruction. (2)

Yeast, Torula, dried, at Loma Linda, C. Dist. Calif.

Charged 2-27-67: when shipped by Lake States Div., St. Regis Paper Co., Rhinelander, Wis., the article contained the added poisonous and deleterious substance *Salmonella* micro-organisms; 402(a)(1). Default decree ordered destruction. (3)

FOOD / Contamination, Spoilage, Insanitary Handling

Beans, pinto, at Deming, Dist. N. Mex.

Charged 2-16-67: while held by Mimbres Valley Farmers Association, Inc., Deming, N. Mex., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Thomas P. Gonzalez Corp., Los Angeles, Calif., for salvaging. (4)

Beans, pinto, at Mesa, Dist. Ariz.

Charged 1-25-67: while held by Rosarita Mexican Foods Co., Mesa, Ariz., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (5)

Candy, peppermint sticks, 2 seizure actions, at Rosenberg, S. Dist. Tex., and McKinney, E. Dist. Tex.

Charged 12-15-66 and 12-19-66: when shipped by Earl's Candy Co., Macon, Ga., the article contained rodent filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decrees ordered destruction. (6)

Cheese, cheddar, at Clinton, W. Dist. Mo.

Charged 9-20-65: when shipped by Aldrich Milk Products Co., Aldrich, Minn., the article contained manure fragments, and rodent and insect filth, and was prepared, packed, and held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for salvaging. (7)

Cheese, cheddar, at Neosho, W. Dist. Mo.

Charged 11-4-66: when shipped by Wyoming Dairy Foods, Inc., Torrington, Wyo., the article contained insect filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (8)

Flour, at Big Spring, N. Dist. Tex.

Charged 2-10-67: while held by Stripling Supply Co., Big Spring, Tex., the article contained rodent filth, and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized destruction. (9)

Flour, at Woburn, Dist. Mass.

Charged 2-3-67: while held by Jaquith & Co., Inc., Woburn, Mass., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (10)

Fruit mix, glazed, at Bogart, M. Dist. Ga.

Charged 11-16-66: when shipped by Paradise Fruit Co., Plant City, Fla., the article contained insect filth, and had been held [prepared and packed] under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (11)

Macaroni, egg noodles, and spaghetti, at Augusta, S. Dist. Ga.

Charged on or about 10-31-66: when shipped by Delmonico Foods, Inc. of Florida, Tampa, Fla., the articles contained insect filth, and were prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (12)

Mushrooms, dried, at Los Angeles, S. Dist. Calif.

Charged 10-19-65: while held for sale, the article contained insect filth; 402(a)(3). Consent decree authorized release to Service Foods, Los Angeles, Calif., for salvaging. Attempts to salvage were abandoned and amended consent decree ordered destruction. (13)

Noodles, egg, at Norfolk, E. Dist. Va.

Charged 11-1-66: while held by Yavner Bros., Inc., Norfolk, Va., the article contained insect filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered delivery to public/charitable institution for use as animal feed. (14)

Peanuts, Spanish, shelled, and popcorn, at Olympia, W. Dist. Wash.

Charged 12-2-66: while held by Matthews Candy Co., Olympia, Wash., the peanuts contained rodent filth, and both articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (15)

Peanuts, unshelled, at Berkeley, N. Dist. Calif.

Charged 1-17-67: when shipped by Ellis L. Ganey Peanut Co., Abilene, Tex., the article contained insect filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (16)

Peas, black-eyed, canned, at St. Louis, E. Dist. Mo.

Charged on or about 12-15-66: while held for sale, the article contained decomposed black-eyed peas; 402(a)(3). Decree authorized donation to public/charitable institution for use as animal feed. (17)

Pecans, shelled, at Tulsa, N. Dist. Okla.

Charged 2-14-67: when shipped by Azar & Solomon, San Antonio, Tex., the article contained *E. coli*, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (18)

Pepper, black, ground, at Dallas, N. Dist. Tex.

Charged 11-17-66: while held by HLH Products, Dallas, Tex., the article contained insect filth, and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (19)

Popcorn, at Pulaski, M. Dist. Tenn.

Charged 2-1-67: while held by M. Cohen & Sons, Inc., Pulaski, Tenn., the article contained insect filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (20)

Prunes, frozen, at Chicago, N. Dist. Ill.

Charged 11-1-66: while held for sale, the article contained moldy prunes; 402(a)(3). Default decree ordered destruction. (21)

Rice, at Norfolk, E. Dist. Va.

Charged 11-9-66: while held for sale, the article contained insect filth; 402(a)(3). Consent decree authorized release of a portion of the article to Producers Rice Mills, Inc., Stuttgart, Ark., for salvaging. Default decree authorized delivery of remainder of article to public/charitable institution for use as wildlife feed. (22)

Rice, at River Grove, N. Dist. Ill.

Charged 12-1-66: while held by Consolidated Foods Corp., River Grove, Ill., the article contained insect and rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (23)

Shrimp, breaded, at Los Angeles, C. Dist. Calif.

Charged 12-6-66: when shipped by Grasso & Son Freezing & Processing Corp., McAllen, Tex., the article, labeled in part "Breaded Fantail Shrimp", contained *E. coli*, staphylococci, and bacterial filth; and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Joe Grasso & Son, Inc., Galveston, Tex., for salvaging. (24)

Shrimp, breaded, frozen, at Denver, Dist. Colo.

Charged on or about 11-23-66: when shipped by Booth Fisheries, Brownsville, Tex., the article contained *E. coli*, coagulase positive staphylococci, and bacterial filth, and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (25)

Shrimp, breaded, frozen, at Gehring, Dist. Nebr.

Charged on or about 11-3-66: when shipped by Booth Fisheries, Brownsville, Tex., the article contained *E. coli* and coagulase positive staphylococci, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (26)

Shrimp, breaded, frozen, at Phoenix, Dist. Ariz.

Charged 9-23-66: when shipped by Crossman Trucking Co., Los Angeles, Calif., the article, labeled in part "Young's Choice Breaded Shrimp . . . Packed by Young's Market Company . . . Los Angeles," contained bacterial filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (27)

Shrimp, breaded, stuffed, Sea Pak, at Denver, Dist. Colo.

Charged on or about 11-22-66: when shipped by Sea Pak Corp., St. Simons Island, Ga., the article had a high total bacterial count, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (28)

Shrimp, frozen, at La Mesa, S. Dist. Calif.

Charged 12-2-66: while held for sale, the article contained decomposed shrimp; 402(a)(3). Consent decree authorized release to KFC Distributing Co., La Mesa, Calif., for salvaging. (29)

Squash seeds, and chestnuts, dried, at New York, S. Dist. N. Y.

Charged 2-14-67: while held by A. L. Bazzini Co., Inc., New York, N. Y., the squash seeds contained rodent filth and the chestnuts contained insect filth, and both articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (30)

Tomatoes, canned, 2 seizures at Salisbury and Greensboro, M. Dist. N.C.

Charged 4-12-67: when shipped by Homestead Canning Co. (Dade Farms, Inc., Div.), Homestead and Princeton, Fla., the article, labeled in part "Powhatan Brand . . . tomatoes . . . Distributed by Taylor and Sled, Inc., Food Brokers Richmond, Virginia," contained insect filth; 402(a)(3). Default decrees ordered destruction. (31)

Tomatoes, canned, and spinach, canned, at Iola, Dist. Kans.

Charged on or about 11-9-66: while held for sale, the spinach contained a decomposed substance, and when shipped by Allen Canning Co., Siloam Springs, Ark., the tomatoes were below standard of quality because of excess peel; 402(a)(3), 403(h)(1). Default decree ordered destruction. (32)

Tomato paste, canned, at Jamaica Plain and Roxbury, Dist. Mass.
Charged 11-15-66: while held for sale, the article contained a decomposed substance; 402(a)(3). Default decree ordered destruction. (33)

FOOD / Economic Violations

Mushrooms, canned, stems and pieces, at Canandaigua, W. Dist. N.Y.
Charged 1-13-67: when shipped by United Canning Corp., East Palestine, Ohio, the article labeled in part "Original Brand Pizza Style Mushrooms . . . Selected Pieces and Stems Packed By Original Crispy Pizza Company of Canandaigua, Inc." was labeled falsely as to the packer; the label lacked the place of business of manufacturer, packer, or distributor, and lacked an accurate statement of quantity of contents; the name "Pizza Style Mushrooms" and the position on the label of the name of the vegetable ingredient (pieces and stems) were not as specified in the standard of identity; and the weight of the drained mushrooms in their container was below the standard of fill; 403(a), 403(e)(1)&(2), 403(g)(2), 403(h)(2). Consent decree authorized release to shipper for relabeling. (34)

Oleomargarine, Old Dutch, at Bridgeville, W. Dist. Pa.
Charged 2-15-67: when shipped by Old Dutch Foods, Inc., Blasdell, N.Y., the article did not conform to standard of identity because of low fat; 403(g)(1). Default decree authorized donation to public/charitable institution. (35)

Preserves, strawberry, Vachon, and preserves, raspberry, Vachon, at Albany, N. Dist. N. Y.

Charged 2-27-67: when shipped by Produits Daimant, Ltd., Ville Ste. Marie, Canada, the articles did not conform to standard of identity because of deficiency of fruit; 403(g)(1). Consent decree authorized release to shipper for export to original supplier. (36)

Shrimp, frozen, Gulf Princess, at New York, S. Dist. N. Y.
Charged 1-7-66: when shipped by Isla Camorrohera, S. A., Ciudad Del Carmen, Mexico, the article was short weight (approx. 11 percent); 403(e)(2). Consent decree authorized release to Rubenstein Foods, Inc., Dallas, Tex., for repacking. (37)

Sorghum sirup, at Chattanooga, E. Dist. Tenn.
Charged 2-1-67: when shipped by Rayford Farmer, Section, Ala., corn sirup had been substituted in part for the article; corn sirup had been added to the article so as to reduce its quality and make it appear of more value than it was; the labeling was false and misleading as to contents; and the label failed to name each ingredient; 402(b)(2), 402(b)(4), 403(a), 403(i)(2). Default decree ordered donation to public/charitable institution. (38)

VITAMINS / DIETARY FOODS

Dietary supplement tablets, at Detroit, E. Dist. Mich.
Charged 12-27-65: while held for sale, the valuable constituent vitamin B₁ had been in part omitted or abstracted, and the label statement concerning vitamin B₁ content was false and misleading since the article was deficient in vitamin B₁ (approx. 21 percent); 402(b)(1), 403(a). Default decree ordered destruction. (39)

Juvsopan vitamin capsules, at Whittier, C. Dist. Calif.
Charged 2-27-67: while held for sale, the valuable constituents vitamin A and vitamin B₁ had been in part omitted or abstracted, and the labeling was false and misleading as to such vitamin content; 402(b)(1), 403(a). Default decree ordered destruction. (40)

Poly-Beta B-complex combination capsules, at Buffalo, W. Dist. N.Y.
Charged 9-17-64: while held by Leader Drug Stores, Inc., N. Y., the labeling of the article, which had been shipped in bulk and had at Syracuse, N. Y., for the dealer, been repacked and labeled in part "Poly-Beta Therapeutic B-Complex Now With 12 Amino Acids With 20 mcg. B-12," contained a number of claims about the article which were false and misleading since, among other things, (1) its B-vitamin content was such as to be insignificant in the treatment of vitamin B deficiency, (2) its amino acid content was so insignificant as to be of no value in human nutrition, and (3) the ordinary diet generally does not require vitamin B₁₂ supplementation; the labeling contained the false and misleading therapeutic claim that the article was "an aid to the hematopoietic system in nutritional anemia, as well as in many macrocytic and microcytic anemias"; and the labeling lacked adequate directions for its represented use as a lipotropic factor; 403(a), 502(a), 502(f)(1). Default decree ordered destruction. (41)

Vigortol capsules, at Saugus, C. Dist. Calif.
Charged 3-6-67: while held for sale, the article, which had been manufactured by Modern Drugs, Inc., Saugus, Calif., from ingredients shipped in interstate commerce and labeled in part "Vigortol vitamin, mineral and mixed gland capsules . . . Distributed by Windsor Drugs, Inc., Los Angeles, Calif." contained a nonconforming food additive, iodine, and the labeling contained false and misleading claims for rejuvenation of aging males; 402(a)(2)(C), 403(a). Default decree ordered destruction. (42)

Vim-Vite vitamin combination tablets, at Honolulu, Dist. Hawaii.
Charged 2-2-66: when shipped by California Vitamin Co., Los Angeles, Calif., the label reading in part "35 Elements All in One Hi-potency Tablet Vim-Vite Multivitamin Tablet 19 Vitamins Complete B-Complex 10 Minerals . . . Barney Inamoto . . . Honolulu" was false and misleading, since the article did not contain 19 vitamins and 10 minerals, and the nutritional value of the article was not enhanced by the inclusion of ingredients such as biotin, choline, alfalfa powder, prune powder, copper, and zinc; and the accompanying promotional leaflet contained false and misleading therapeutic claims including claims for conjunctivitis, edema of the legs, decayed teeth, sleeplessness, vomiting, and rickets; 403(a), 502(a). Default decree ordered destruction. (43)

Vitamin and mineral tablets, capsules, and liquid, protein tablets and safflower oil capsules, at Princeton, Dist. W. Va.

Charged 11-18-64: while held by Milan Pharmaceuticals, Inc., Princeton, W. Va., the promotional catalogue, printed locally on order of the dealer, contained false and misleading therapeutic and nutritional claims concerning all of the articles except the safflower oil capsules; the labeling of the Geriatric vitamin and mineral capsule-tabs and the safflower oil capsules lacked adequate directions for use as lipotropic agents, which they were represented to be; and some of the articles contained the food additives intrinsic factor (in the Vi-Min-Plus capsule-tabs and Geriatric vitamin and mineral capsule-tabs) and vitamin K (in the Vi-Teen tablets), and their use and intended use lacked conformity to law; 403(a), 402(a)(2)(C), 502(a), 502(f)(1). Consent decree ordered destruction of Vi-Min-Plus capsule-tabs and Geriatric vitamin and mineral capsule-tabs, and authorized release of the other articles to dealer for relabeling. The dealer failed to comply with the terms of the decree and the court ordered the released articles destroyed. (44)

DRUGS / Human Use

Allergimist intranasal solutions A and B, 2 seizure actions at Altus and Oklahoma City, W. Dist. Okla.

Charged 7-25-66 and 7-26-66: when shipped by Preston Dee Brewer, and B & J Store, Booker, Tex., the articles were new drugs without effective approved New Drug Applications; 505(a). Default decrees ordered destruction. (45)

Allergimist intranasal solutions A and B, 2 seizure actions at Amarillo, N. Dist. Tex., and San Antonio, W. Dist. Tex.

Charged on or about 5-5-66: when shipped by Brunson Corp., Miami Springs, Fla., the articles were new drugs without effective approved New Drug Applications; 505(a). Default decrees ordered destruction. (46)

Aqua-Film contact lens solution, 3 seizure actions at Bellaire, S. Dist. Tex., Dearborn, E. Dist. Mich., and Boston, W. Dist. Mass.

Charged 4-4-67, 4-25-67, and 4-26-67: when shipped by Mi-Con Laboratories, Inc., Wauconda, Ill., the article's purity and quality were deficient and its label false and misleading as to sterility, since the article contained viable micro-organisms, and in the Bellaire, Tex., seizure the package label contained false and misleading claims for the destruction of *Pseudomonas aeruginosa* bacteria; 501(c), 502(a). Default decrees ordered destruction. (47)

Aspir-B aspirin tablets, U.S.P., at Syracuse, N. Dist. N.Y.
Charged 4-14-67: while held by Walker Corp. & Co., Inc., Syracuse, N.Y., the article, manufactured by the dealer from aspirin shipped in interstate commerce, failed U.S.P. standards since it contained excess free salicylic acid; 501(b). Consent decree ordered destruction. (48)

Barbeloid tablets, at Pasadena, C. Dist. Calif.
Charged 2-20-67: while held by United Laboratories, Inc., Pasadena, Calif., after manufacture by International Pharmaceutical Manufacturing Co., San Pedro, Calif., from ingredients shipped in interstate commerce, the article was deficient in strength, and the labeling was false and misleading, because of a deficiency of pentobarbital sodium and phenobarbital; 501(c), 502(a). Default decree ordered destruction. (49)

Butabarbital sodium tablets, N. F., at Los Angeles, C. Dist. Calif.
Charged 3-1-67: when shipped by Davis Edwards Pharmacal Co., New York, N. Y., the butabarbital sodium strength of the article was deficient (approx. 15 percent); 501(b). Default decree ordered destruction. (50)

C-Tex vitamin C tablets, at Denver, Dist. Colo.
Charged 5-9-66: while held by C-Tex Carter Co., Denver, Colo., the accompanying leaflets, prepared on orders of the dealer, contained false and misleading therapeutic claims; 502(a). Consent decree authorized release to dealer for reconditioning. (51)

Desoxycorticosterone acetate tablets, at Pasadena, C. Dist. Calif.
Charged 3-3-67: while held by United Laboratories, Inc., Pasadena, Calif., who labeled the article, the article's label lacked the required name of manufacturer, packer, or distributor, and the labeling lacked adequate directions and was not exempt from such requirement; 502(b)(1), 502(f)(1). Default decree ordered destruction. (52)

Dimethylsulfoxide liquid, at Philadelphia, E. Dist. Pa.
Charged 11-26-65 and amended 1-28-66: while held by Main Drug Store, Philadelphia, Pa., the labeling lacked adequate directions for its intended uses; 502(f)(1). Default decree ordered destruction. (53)

Dr. Thatcher's nasal spray, at Chattanooga, E. Dist. Tenn.
Charged 2-28-67: when shipped by Table Rock Laboratories, Greenville, S. C., the article was short in volume (approx. 9 percent); 502(b)(2). Consent decree authorized destruction. (54)

Gray's ointment, at Cleveland, N. Dist. Ohio.
Charged 5-24-67: when shipped by W. F. Gray & Co., Nashville, Tenn., the article was short weight (approx. 8 percent); 502(b)(2). Default decree ordered destruction. (55)

Histop decongestant tablets, at Findlay, N. Dist. Ohio.
Charged 5-24-67: when shipped by Dewey Products Co., Grand Rapids, Mich., the article's labeling lacked a warning for the phenylephrine hydrochloride contained in the article; 502(f)(2). Consent decree authorized release to shipper for relabeling. (56)

Livferrvim iron gluconate tablets, enteric coated; phenobarbital tablets, U.S.P.; and thyroid tablets, U.S.P.; at Cedar Rapids, N. Dist. Iowa.
Charged 2-9-67: while held by Pilco Laboratories, Inc., Cedar Rapids, Iowa, after manufacture by the dealer from ingredients shipped in interstate commerce, the strength of the phenobarbital tablets was deficient; and the quality of the thyroid and Livferrvim tablets was deficient because of their failure to meet tablet disintegration tests; 501(b), 501(c). Consent decree ordered destruction. (57)

Medi-Stims medicated toothpick, at Los Angeles, C. Dist. Calif.

Charged 3-13-67: when shipped by Iodent Chemical Co., Detroit, Mich., the article's labeling contained false and misleading dental health claims; 502(a). Default decree ordered destruction. (58)

Meprobamate tablets, at Fort Lee, Dist. N. J.

Charged 5-26-65: when shipped from Manila, Philippine Islands, by Sarfati & Co., Inc., New York, N.Y., the article, labeled in part "Miltown Meprobamate . . . Wallace Laboratories . . . Cranbury, N.J. Package circular enclosed," was a new drug without an effective approved New Drug Application that had been manufactured in the Philippine Islands; the label was false and misleading since Wallace Laboratories was not the manufacturer, packer, or distributor of the article, and no package circular was enclosed; the label lacked the name and place of business of the [actual] manufacturer, packer, or distributor; and the labeling lacked adequate directions and was not exempt from such requirement; 505(a), 502(a), 502(b)(1), 502(f)(1). The article was claimed by City Wide Drug Wholesalers, Inc., Fort Lee, N. J. After the claimant's motion for summary judgment was denied, the court granted summary judgment to the Government and ordered the article destroyed. (59)

Penicillin topical ointment, at Santurce, Dist. P. R.

Charged 4-11-67: while held for sale, the article's strength was deficient (approx. 14.7 percent); 501(c). Default decree ordered destruction. (60)

Peritrate SA pentaerythritol tetranitrate tablets, at Glendale, E. Dist. N.Y.

Charged 2-28-66: when shipped by Warner-Chilcott Laboratories, Inc., Morris Plains, N.J., the article was a new drug without an effective approved New Drug Application for all the purposes in its labeling; the labeling contained false and misleading claims about medical studies concerning the article's effectiveness; the labeling lacked adequate directions for use and was not exempt therefrom, since the labeling was not the same, nor substantially the same, as the labeling authorized in the shipper's approved New Drug Application; and medical journal advertisements for the article lacked a true summary of the article's effectiveness, since they falsely represented that a purportedly well-controlled clinical investigation proved that, due to the article, 22 percent more of certain patients treated with the article remained alive after 2 years than patients treated with a placebo, and misleadingly represented that a referenced study supported claims concerning the drug's effectiveness, while not revealing that the research involved the use of young pigs in a manner which in no way approximates the human disease situation; 505(a), 502(a), 502(f)(1), 502(n). Consent decree ordered destruction. (61)

Potassium iodide tablets, N.F., and A.P.C. half-strength tablets, N.F., at Carthage, N. Dist. N.Y.

Charged 2-20-67: while held by Fox Drug Co., Carthage, N.Y., who had repacked the articles, the quality of the A.P.C. half-strength tablets fell below U.S.P. standards because of excess salicylic acid; the label of the potassium iodide tablets lacked adequate directions for use and was not exempt since it lacked the required warning concerning small-bowel lesions; and the label of the A.P.C. half-strength tablets lacked adequate directions for use, including the frequency or duration of administration, and kidney damage warnings; 501(b), 502(f)(1) & (2). Consent decree authorized release to dealer for relabeling. (62)

Provohist cough liquid, at Los Angeles, C. Dist. Calif.

Charged 3-1-67: while held by California Institutional Supply Co., Inc., Los Angeles, Calif., after manufacture by Modern Drugs, Inc., Saugus, Calif., from ingredients shipped in interstate commerce, the labeling of the article contained false and misleading therapeutic claims, and the labeling lacked adequate directions for use, and adequate warnings against use; 502(a), 502(f)(1) & (2). Default decree ordered destruction. (63)

Steri-Len storing solution and Aqua-Film contact lens soaking/wetting solution, at Oklahoma City, W. Dist. Okla.

Charged 4-24-67: when shipped by Mi-Con Laboratories, Inc., Wauconda, Ill., the articles' purity and quality were deficient and their labels false and misleading as to sterility, since the articles contained viable micro-organisms; 501(c), 502(a). Default decree ordered destruction. (64)

T. D. Curban "P" amphetamine combination capsules, at Pasadena, C. Dist. Calif.

Charged 2-1-67: while held by Pasadena Research Labs., Los Angeles, Calif., the article, which had been repacked by such firm after manufacture by International Pharmaceutical Manufacturing Co., San Pedro, Calif., from ingredients shipped in interstate commerce, had been manufactured, processed, packed, and held under conditions lacking good manufacturing practice; its strength was deficient in dextro-amphetamine hydrochloride (approx. 26 percent); and its labeling was false and misleading as to strength; 501(a)(2)(B), 501(c), 502(a). Default decree ordered destruction. (65)

Tri-Magna antacid tablets, at Phoenix, Dist. Ariz.

Charged 4-20-67: when shipped by Riders, Ltd. (Windsor Drugs, Inc.), Saugus, Calif., the article lacked adequate directions for management of peptic ulcers; 502(f)(1). Default decree ordered destruction. (66)

Venolax horsechestnut and herb combination tablets, at Miami, S. Dist. Fla.

Charged 4-29-67: when shipped by Barrows Chemical Co., Inc., Inwood, L.I., N.Y., and while held by Roger Pharmacal Co., Miami, Fla., the labeling, supplied by the dealer and applied by the shipper, lacked adequate directions for use and was not exempted as a prescription drug since it lacked required information for use by licensed practitioners; 502(f)(1). Default decree ordered destruction. (67)

Vita-Bio-Powr calcium polysulfide compound, at Portland, Dist. Oreg.

Charged 4-7-67: when shipped by Prune & Fruit Powder, Inc., Los Angeles, Calif., the accompanying leaflet contained false and misleading claims concerning the article's efficacy in exerting a detoxifying action combined with a nonspecific stimulation of the general defense mechanism of the body; 502(a). Default decree ordered destruction. (68)

DRUGS / Veterinary

Antibiotic mastitis treatment, at Columbus, S. Dist. Ohio.

Charged 2-28-67 and amended 3-31-67: while held for sale, the article was an antibiotic drug for which no certificate or release was in effect; 502(l). Default decree ordered destruction. (69)

Antibiotic mastitis treatment syringes, at Garnaville, N. Dist. Iowa.

Charged 3-2-67: while held for sale, the article lacked an effective antibiotic certificate or release; 502(l). Default decree ordered destruction. (70)

Chloramphenicol aquarium solution, at Nampa, Dist. Idaho.

Charged 5-29-67: when shipped by Northwest Veterinary Supply, Inc., the vial labeling lacked adequate directions for its intended uses, and the article lacked exemption from antibiotic certification since it had been orally represented and suggested for use for animals other than fish and had been so used; 502(f)(1), 502(l). Default decree ordered destruction. (71)

Electro Dex electrolytes fluid dextrose and other veterinary drugs, at Billings, Dist. Mont.

Charged 7-7-66: when shipped by Lyle A. Wittney & Co., Denver, Colo., Electro Dex electrolytes fluid dextrose lacked adequate directions for use—502(f)(1); Amino-Com 10 amino acid and vitamin combination contained viable micro-organisms—501(c); and Chloro-Histex and Chloro-Lac chlorpheniramine maleate combinations were new drugs lacking effective approved New Drug Applications—505(a). Default decree ordered destruction. (72)

Phenothiazine powder, at Chicago, N. Dist. Ill.

Charged 10-26-66: when shipped by Clover Chemical Co., Pittsburgh, Pa., the article labeled in part "Cooper Phenothiazine (Drench Grade) . . . Sold by William Cooper & Nephews, Inc. . . . Chicago" had labeling containing false and misleading claims for removal of ascarid worms from hogs; and its labeling lacked adequate directions for use; 502(a), 502(f)(1). Consent decree authorized release to William Cooper & Nephews, Inc., for relabeling. (73)

MEDICAL DEVICES

American vibrating and/or heating hand units, pads, cushions, and chairs, at Taylor, E. Dist. Mich.

Charged 8-5-66: when shipped by American Massage Sales & Manufacturing Corp., Silver Creek, N.Y., and while held by American Massage of Michigan, Taylor, Mich., the accompanying promotional material, including posters designed by the dealer, contained false and misleading gallstone, arthritis, muscle spasm, and other therapeutic claims; 502(a). Consent decree authorized release to shipper for relabeling. (74)

Figurecare electronic muscle stimulator, at Denver, Dist. Colo.

Charged 4-6-66: while held by Figure-Care Systems, Inc., Denver, Colo., the labeling used by the dealer in promoting sales of the article contained false and misleading claims for reducing, lacked the name and place of business of the manufacturer, packer, or distributor, and lacked adequate directions for use for muscle building and weight reduction, for which the device was represented by William G. Price, a sales representative for the dealer; 502(a), 502(b)(1), 502(f)(1). Upon withdrawal of the dealer's claim, default decree was entered authorizing release to FDA. (75)

Heating pad, chemical, Lightningpak, at Freeport, Dist. Maine.

Charged 4-19-67: when shipped by Edbert Co., Inc., Newton, Mass., the accompanying plastic bag label and the package insert contained false and misleading therapeutic claims; 502(a). Default decree authorized delivery to public/charitable institution. (76)

Selectronair air circulator, at Silver Spring, Dist. Md.

Charged 3-14-67: when shipped by the Shelton Metal Products Co., Inc., Shelton, Conn., the accompanying leaflet contained false and misleading asthma, sinus, and other therapeutic claims, and the false and misleading claim that the article provided clean, fresh air completely free of airborne germs to the corners of every room; 502(a). Default decree authorized release to FDA. (77)

Thermometers, oral, at Cleveland, N. Dist. Ohio.

Charged 5-5-67: when shipped by Philbern Thermometer Co., Inc., Bronx, N. Y., the article, which purported to comply with commercial standards, was deficient in quality, and the accompanying leaflet was false and misleading, since the article failed to meet the pigmentation retention test of such standards; 501(c), 502(a). Default decree ordered destruction. (78)

PROPHYLACTICS

Rubber prophylactics, Gentry and Royal Knight, at Hanover, M. Dist. Pa.

Charged 4-12-67: when shipped by Allied Latex Sales Co., Inc., Dothan, Ala., the articles were deficient and the labeling false and misleading, since the articles contained holes; 501(c), 502(a). Default decree ordered destruction. (79)

Rubber prophylactics, Peacocks, 2 seizure actions at North Kansas City, W. Dist. Mo.

Charged on or about 4-24-63 and 5-2-63: when shipped by Dean Rubber Co., Inc., Carolina, P. R., the quality of the article was deficient and the label false and misleading, since the article contained holes; 501(c), 502(a). The actions were consolidated and trial was had; after which the court ordered the article returned to the shipper in Puerto Rico for reprocessing and reinspection. Thereafter the court ordered that the article be destroyed if not reprocessed. The article was subsequently destroyed. (80)

Rubber prophylactics, Peacocks, 5 seizure actions, at Lexington, E. Dist. Ky.; Louisville, W. Dist. Ky.; Charlotte, W. Dist. N. C.; Milwaukee, E. Dist. Wis.; and South Euclid, N. Dist. Ohio.

Charged 2-27-67, 3-3-67, 3-7-67, 3-23-67, and 4-6-67: when shipped by Dean Rubber Manufacturing Co., North Kansas City, Mo., the quality of the articles was deficient, since they contained holes; 501(c). Default decrees ordered destruction. (81)

COSMETICS

Colognes, Russian Leather, and Stacy Gentlemens', at Providence, Dist. R. I. Charged 4-26-66: when shipped by Louangel Corp., Brooklyn, N. Y., the articles' labels lacked the place of business of the manufacturer, packer, or distributor; 602(b)(1). Consent decree authorized release to Weingeroff & Glick Enterprises, Inc., Providence, R. I., for relabeling. (82)

NOTICES OF JUDGMENT on Criminal Cases

FOOD

Alver Popcorn Co., a corporation; **Alver Bros. Co.,** a partnership; **Harold M. Alver,** president and partner; and **Oscar J. Alver,** vice president and partner, Milford, E. Dist. Ill. Charged 8-12-66: when shipped, popcorn contained bird and rodent filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea by corporation: fine. Nolo contendere pleas by partnership and individuals; fines. (83)

James R. Bray, t/a **Bray's Mill,** Mount Airy, M. Dist. N. C. Charged 4-3-67 by grand jury: when shipped, cornmeal mix, labeled in part "Mother's Self Rising Enriched Corn Meal Mix" and "Corn Meal," contained rodent filth and had been prepared and packed under insanitary conditions; and the valuable enrichment constituents, thiamine, riboflavin, and niacin, had been in part omitted from the cornmeal, and its labeling was false and misleading as to thiamine content (approx. 22 percent deficiency), riboflavin content (approx. 33 percent deficiency), and niacin content (approx. 62 percent deficiency), and the cornmeal also fell below the definition and standard of identity for enriched cornmeal because of the deficiencies of enrichment ingredients; 402(a)(3), 402(a)(4), 402(b)(1), 403(a), 403(g)(1). Guilty plea; imprisonment suspended, fine, and probation. (84)

Clinton Wholesale Co., Clinton, E. Dist. N. C. Charged 7-6-66: hominy grits were held in a building accessible to insects, and were contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (85)

Dickey-Crain Co., Inc., and **Charles C. Crain,** secretary-treasurer, Murphy, W. Dist. N. C. Charged 10-25-66: flour was held in a building accessible to rodents and insects, and was contaminated with rodent and insect filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (86)

Leonard J. Kessler, t/a **Loretto Milling Co.,** Loretto, M. Dist. Tenn. Charged 4-24-67: when shipped, white cornmeal contained insect filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea; fine and probation. (87)

Midway Wholesale Co., Inc., and **Harry M. Cherry,** general manager, Horse Cave, W. Dist. Ky. Charged 7-22-66: grits, spaghetti, macaroni, cake mix, and onions were held in a building accessible to rodents and insects and were contaminated with rodent and insect filth; 402(a)(3), 402(a)(4). Guilty pleas; fines, plus costs. (88)

Milford Packing Co., Inc., and **Leon Leibowitz,** president, Milford, Dist. Del. Charged 5-26-66: when shipped, relish, labeled in part "Shop-Rite Superior Quality Sweet Relish . . . Shop-Rite Supermarkets, Wakefern Food Corporation, Elizabeth, N. J.—Distributor," contained maggot and insect filth, and had been prepared under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine suspended. Guilty plea by individual; imprisonment suspended and probation. (89)

Oregon Prune Exchange, **Sam N. Peterson,** secretary-treasurer, and **Martin G. Herb,** plant superintendent, Forest Grove, Dist. Ore. Charged 4-24-67: dried prunes were held in a building accessible to rodents and insects, and were contaminated with rodent and insect filth; 402(a)(3), 402(a)(4). Guilty pleas; probations. (90)

Thomson Wholesale Grocery Co., Inc., and **Ben O. Howell,** president, Thomson, S. Dist. Ga. Charged 12-14-66: flour was held in a building accessible to rodents, birds, and insects, and was contaminated with rodent and bird filth; 402(a)(3), 402(a)(4). Nolo contendere pleas; probations. (91)

Whitson Food Products Co., and **Warren P. Whitson, Jr.,** vice president, Denton, E. Dist. Tex. Charged 12-13-66: navy beans, pinto beans, and starch were held in a building accessible to rodents, and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Nolo contendere plea by individual; the court found the individual not guilty. (92)

DRUGS

Richard Charles Bird, student, Coral Gables, S. Dist. Fla. Charged 6-16-66: sugar cubes containing LSD were unlawfully sold and delivered; 301(q)(2). After a plea of not guilty, the defendant moved for dismissal of the information, for election of counts, for discovery, and for a bill of particulars. The grounds alleged for dismissal included: excessive generality of the charges in the information, unconstitutionality of the information as a curtailment of religious freedom, entrapment, and violation of due process by the creation of impermissible and indefinite classifications as applied to drug users and research investigators. The defendant also moved for discovery and inspection of the drugs sold and of documents in possession of the Government. The defendant's motions were denied by the court, except that a bill of

particulars was to be supplied and defendant was authorized to inspect the confiscated drugs. After trial by jury, a verdict of guilty was returned; imprisonment suspended and probation. (93)

Harold L. Boudreau, Omaha, Dist. Nebr. Charged 1-24-67: amphetamine sulfate tablets were unlawfully sold and delivered and were possessed for the purpose of sale; 301(q)(2), 301(q)(3). Guilty plea; imprisonment and probation. (94)

C. M. Bundy Co., **Walter F. Wargell,** president, and **Robert S. Justice,** vice president, Cincinnati, S. Dist. Ohio. Charged 2-3-67 by grand jury: when shipped, cobalt chloride and ferrous sulfate combination enteric-coated tablets lacked an enteric coating that delayed the release of the medication until the tablets passed through the user's stomach—501(c); nitroglycerin-digitalis compound tablets were deficient in nitroglycerin—501(c); nitroglycerin tablets, U.S.P., fell below U.S.P. standards, since they failed the disintegration requirements—501(b); hydrocortisone ointment, U.S.P., differed from U.S.P. standards, since it was deficient in hydrocortisone—501(b); sodium nitrate and phenobarbital tablets were deficient in quality by reason of failure to disintegrate after being swallowed—501(c); and the circumstances of such articles' manufacture, processing, packing, or holding lacked conformity with current good manufacturing practice—501(a)(2)(B). Nolo contendere plea by the corporation; fine. Nolo contendere plea by Wargell; imprisonment suspended, fine, and probation. Nolo contendere plea by Justice; imprisonment suspended, fine suspended, and probation. (95)

Boyd F. Curtis, Hayti, E. Dist. Mo. Charged 10-26-66 by grand jury: amphetamine sulfate tablets were unlawfully sold and delivered and were unlawfully possessed; 301(q)(2), 301(q)(3). Guilty plea; imprisonment and probation. (96)

Orville D. Harris, pharmacist, St. Louis, E. Dist. Mo. Charged 7-29-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment and probation. (97)

Carl F. McCubbin, of Horse Cave, Ky., at Cape Girardeau, E. Dist. Mo. Charged 3-1-66 by grand jury: orange-pink, "heart"-shaped counterfeit Dexedrine tablets were unlawfully held for sale and sold with intent to defraud and mislead—301(i)(3); while held for sale, orange-pink, "heart"-shaped caffeine tablets, which were an imitation of Dexedrine tablets, were held, offered for sale, and sold in unlabeled bottles as Dexedrine tablets with intent to defraud and mislead—502(i)(2) & (3), 502(b)(1), 502(e)(1)(A)(i); and pink caffeine tablets, white caffeine tablets, and yellow caffeine tablets were offered for sale and sold in unlabeled bottles as amphetamine tablets with intent to defraud and mislead—502(i)(3), 502(b)(1), 502(e)(1)(A)(i). Not guilty plea. After trial by jury, guilty verdict; imprisonment. (98)

Hazel Morgan, truck-stop operator, and **Lloyd M. Cutshaw** and **Liza May James,** truck-stop employees, Norway, E. Dist. S.C. Charged 8-12-66: dextro-amphetamine sulfate tablets and amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea by Morgan; imprisonment and probation. Guilty pleas by Cutshaw and James; probations. (99)

INJUNCTION ACTION

Richlyn Laboratories, Inc., Best Pharmaceuticals, Inc., Medi-Pak, Inc., Sidney Weinberg, president of the corporations, and **Tasnim Mir,** director of research and development for the corporations, Philadelphia, E. Dist. Pa. Charged 9-30-64 in complaint for injunction: that the defendants were engaged in the business of manufacturing, packing, labeling, and distributing in interstate commerce (1) drugs which were manufactured, processed, packed, and held under conditions not in conformity with current good manufacturing practice; (2) U.S.P. drugs whose strength, quality, and purity differed from U.S.P. standards; (3) non-U.S.P. drugs whose strength, quality, and purity differed from that which they purported or were represented to possess; (4) drugs which had different substances substituted for the designated drugs; (5) drugs whose labeling contained false and misleading statements as to identity, purity, quality, and strength; (6) drugs whose labeling lacked adequate directions for use and warnings against misuse; and (7) new drugs without an approved New Drug Application; and that the defendants, as a result of factory inspections, seizure actions, and hearings under section 305 of the act, were well aware that their activities were violative; 501(a)(2)(B), 501(b), 501(c), 501(d), 502(a), 502(f)(1) & (2), 505(a). A temporary restraining order and a consent decree of preliminary injunction were entered, pursuant to which the defendants were enjoined from doing the violative acts complained of. (100)

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

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

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

James L. Goddard, *Commissioner of Food and Drugs*
Washington, D.C., December 1, 1967



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OFFICIAL BUSINESS

Announcements

REVISION OF FDA PUBLICATION NO. 2 AVAILABLE A new revision of the FDA publication "Requirements of the United States Food, Drug, and Cosmetic Act," Publication No. 2, is now available from the Superintendent of Documents, U. S. Government Printing Office, Washington, D. C. 20402, at a cost of 25 cents.

This publication contains a synopsis of the principal requirements of the Act. It emphasizes those aspects of interest to foreign manufacturers and importers of foods, drugs, devices, and cosmetics. It updates the 1964 revision by including a discussion of amendments and regulations issued since that time.

Some of the subjects emphasized in the booklet are the legal requirements for foods such as spices, canned fruits and vegetables, beverages, seafoods, meat, poultry, and dairy products. The provisions of the Act relating to pesticide residues on raw agricultural products, sanitation, and food standards are also discussed.

Drug manufacturers and distributors will be interested in sections of the booklet covering drug labeling, registration, advertising, good manufacturing practice, and the requirements of the Drug Abuse Control Amendments.

Although the main portion of the booklet deals with foods and drugs, manufacturers and distributors of devices and cosmetics will also find helpful material to assist them in complying with the law.

This booklet is not a substitute for the complete law and regulations (Title 21—Code of Federal Regulations, available from the Superintendent of Documents). FDA Publication No. 2 also contains references to other FDA publications and related Acts administered by FDA and other Federal agencies.

FDA INDUSTRY WORKSHOPS During December and January, 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 to attend should contact the nearest District or BDAC Field Office.

SCHEDULE OF FDA WORKSHOPS AND REGIONAL CONFERENCES DECEMBER 1967 & JANUARY 1968

FDA District or BDAC Field Office	Date	Location	Subject Area
New Orleans	December 12	Birmingham, Ala.	Pesticide and Drug Residues in Eggs and Egg Products
Detroit	January	Detroit, Mich.	GMP—Drugs
San Francisco	January	San Francisco, Calif.	Bacterial Contami- nation—Smoked Fish
Seattle	January 22-24	Seattle, Wash.	Pesticide Analytical Methods

TO ALL FDA-INDUSTRY WORKSHOP PARTICIPANTS— PAST AND FUTURE

The FDA-Industry Workshop program for the past year has been an impressive one. The scope of these cooperative educational activities is reflected in the record—10,700 industry personnel from nearly 3,000 firms attended a total of 106 FDA-Industry Workshops and Conferences.

The FDA Districts, BDAC Field Offices, and the Bureau of Education and Voluntary Compliance anticipate another fruitful year of two-way communication on important compliance problems through these workshops. We learn from each other, and this process can be effective only if there is a free flow of ideas and suggestions for improvement—and the sincere desire to implement them.

FDA assures you of complete support of your voluntary compliance programs during the coming year. We will continue our program, developing new tools and approaches to aid you in your programs for improving the quality of the Nation's food and drugs.

Fred J. Delmore, Director
Bureau of Education
and Voluntary Compliance