

# **FDA** PAPERS

**FDA'S DALLAS DISTRICT**  
An Incident in Laredo

Extemporaneous Mixing of  
**PARENTERAL MEDICATIONS**

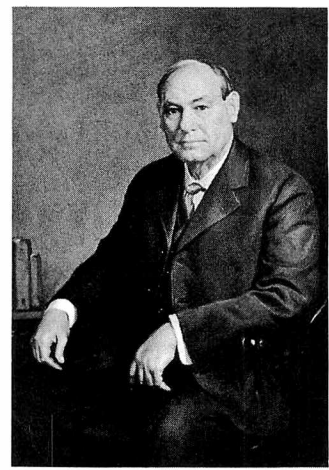
**Pesticides**

A Report on Residues in Food

**FDA SCIENCE ADVISORS**  
How They Help Field Scientists







*"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

**P**ublic concern about pesticide residues in food has decreased in recent years. At least this is the indication to be drawn from the decreasing number of letters on this subject by worried consumers to the FDA.

There is, however, a noticeable current of concern which was set in motion as a residual of public alarm, and which shows no sign of meandering. It is another of the undercurrents in our society which requires technological control and regulatory vigilance. So long as these factors work, it appears, the public is reassured.

The evidence plainly shows no need for concern (see page 4). There is every reason to believe the American food supply is free of harmful pesticide residues, and has been for some time. It is reassuring evidence. It is so reassuring that some may conclude that pesticides no longer present a risk in the form of unsafe residues. Anyone reaching such a conclusion could go so far as to suggest that the resources devoted to control and surveillance could be diverted to problems of greater public concern.

That would be a mistake.

We must maintain, and in some respects increase, control of pesticide technology. We must maintain and improve surveillance of the food supply. For, if we don't, the risk becomes a hazard with predictable outcome; a new explosion of public alarm.



# quotes

**T**he employment of simple arithmetic will emphasize the far-flung effect from the misuse of a potent drug by one individual at one of the larger beef cattle feeding establishments. Forty thousand animals on feed simultaneously at a single feed lot is not uncommon today. The average market weight of each animal may be taken as 1,000 pounds. These animals dress out conservatively at 50 percent. The total edible products represent 20 million pounds. If we use one-half pound as the average meat consumption per day, this represents the intake of meat for approximately one-fourth to one-fifth of our U. S. population. An error in the use of a potent drug or chemical in this single feed lot—resulting in residues in edible tissues—could affect from 20 to 25 percent of the people in the United States. Such a possibility did not exist a few short years ago. Everything now points to the fact that such a possibility may be even greater in the immediate future as the emphasis on large integrated establishments increases.”

*Fred J. Kingma, D.V.M., Deputy Director, Bureau of Veterinary Medicine, at the Clinical Pharmacology Session of the 4th Annual Conference for Veterinarians, University of Georgia, Athens, April 15, 1967.*

**A**lthough it hasn't received the publicity that the *Salmonella* and botulism outbreaks have received, probably our most frequent cause of food poisoning is still coagulase positive *Staphylococcus*. This organism is present on the skin, in the throat and nasal areas, as well as in festering wounds. Many foods, once seeded, will allow these organisms to grow and produce toxins unless the food is refrigerated. Even if the organism itself has been killed by heat, if sufficient toxin has been produced, it is still capable of causing the symptoms of *Staph.* poisoning. As you know, the toxin is heat resistant. Here again the solution is: Prevent the product from being seeded with the organisms.”

*Weems Clevenger, Director, New York District, to New York Institute of Food Technologists, Inc., March 22, 1967.*

**John W. Gardner**  
Secretary, U.S. Department of  
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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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# pesticides

## A REPORT ON RESIDUES IN FOOD

by R. E. Duggan  
and  
Keith Dawson

Civilization advances proportionate to man's ability to overcome the problems associated with securing the essentials of survival: food, water, and shelter. He competes with other forms of life for these essentials, and he has developed complex and inter-related scientific mechanisms resulting in the most bountiful supply of food and fiber ever known.

By contrast with past ages, today's average man has little direct knowledge of the sophisticated means employed to obtain food. Modern society has had to provide a control mechanism to protect his interests.

In the United States the Food and Drug Administration has a unique responsibility to act in the individual's interest. The Agency has no conflicting interests or responsibilities in the production or marketing of foods and allied products. There is an equally im-

portant responsibility to recognize and accept technological advances resulting in more and better foods.

To this end the use of chemicals is not new. It probably began when a cave dweller first observed that food left in the smoke of the fire or the salty residue of sea water did not disappear into a mass of insects before he could eat it.

If we were to correlate chemical discoveries with the resulting effects on food production, especially when accompanied by similar advances in other sciences, we would most likely find that our bountiful supply of food and fiber was made possible by such advances.

There are many uses for pesticide chemicals for purposes other than food production. Large quantities of these chemicals are used in disease prevention, such as mosquito control; in fiber production, such as cotton dusting; in forest conservation; in highway weed control. Pesticides do not stay put. They drift through the air and are contained in the dust and dissolved or suspended in the water systems of the world. The possibilities for potentiation and interaction are innumerable. When drugs, food additives, air pollutants, and other similar factors influencing man's total environment are added to the list of pesticides, there is reason to exercise caution and to maintain control. It becomes imperative when the individual cannot exercise a choice concerning exposure to these factors.

The comparatively simple chemicals, lead, arsenic, mercury, bromides, sulfur, of a quarter century ago have been augmented by several hundred complex, synthetic, organic, chemical compounds. They come in a wide variety of basic chemical structures: chlorinated ring compounds, organic phosphorus, Carbamates, and some whose chemical identity is not fully known. They are recommended for a multitude of uses, ranging from highly specific to broad spectrum applications. Some decompose or dissipate rather rapidly. Others are remarkably persistent.

There is a wide variation in the acute toxicity levels and in the "no effect" levels of various pesticide chemicals as measured by test animals. The interpretation of data obtained on laboratory animals to humans is not a precise mathematical exercise, although it is generally acceptable. By nature, however, pesticides are toxic and, quite naturally, there is a substantial and growing public interest in toxic residues from all sources in man's environment and, more specifically, in food.



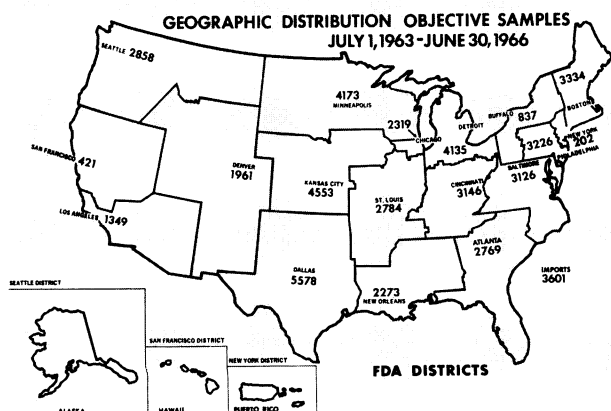
Historically, the Food and Drug Administration has exercised control of such residues in foods. The almost explosive use of toxic chemicals in agriculture, beginning in the 1940's, led Congress to pass an amendment to the Food, Drug, and Cosmetic Act in 1954. This amendment directed that FDA establish safe and legal tolerances for pesticide chemicals on raw agricultural products, after USDA approved the usefulness of such chemicals. Tolerances have been, and are being, established on the basis of raw foods as shipped in interstate commerce.

A tolerance is granted only on the showing that the residues on the food are safe by pharmacological tests at levels greatly exceeding those remaining on the food. Furthermore, a tolerance will not be granted for levels exceeding those necessary in the production of the food even though the pharmacological data shows that a higher level is safe.

Tolerances are not additive. For example, if two similar chemicals each have a tolerance of 1 ppm on a food, this means that both chemicals combined may not exceed 1 ppm. Specific regulations have been promulgated for those instances where more than one pesticide chemical is present. Section 408 of the FDC Act is applicable only to raw agricultural products. Residues remaining in foods after processing are subject to Section 409 which concerns food additives. Regulations provide that processed foods will be legal if prepared from raw foods containing legal residues and if the residue in the ready-to-eat food does not exceed the tolerance on the raw product. One of the factors given consideration in establishing tolerances is the total amount of pesticide chemicals and combinations which might be consumed over extended periods of time.

Every year, the FDA determines the amount of pesticide chemicals in thousands of samples of food in the enforcement of the tolerances. These analyses are made on foods as shipped in interstate commerce. Shipments containing excessive residues may be removed from the market by seizure and the shipper may face legal proceedings.

Figure 1



In the surveillance program, samples are collected throughout the year at producing, shipping, and destination points. Figure 1 shows the geographic representation of the 49,044 objective samples obtained during the period July 1, 1963—June 30, 1966.

Objective samples are surveillance-type samples; there is no reason to suspect that residues will be found. FDA differentiates between objective samples and those selected for examination because of information or other causes indicating the presence of excessive residues. Figure 1 shows that general nationwide coverage was obtained. For all practical purposes, these can be considered as "random" samples. The total number of samples provides a high degree of reliability in the results.

Modern pest control often requires use of more than one chemical to achieve the desired result. The FDA has been instrumental in developing and perfecting multiresidue methods, which permit the examination of a sample for many residues by a single test. The analytical procedure used on all samples will detect the presence of the following 54 pesticide chemicals:

- |                             |                             |
|-----------------------------|-----------------------------|
| 1. Aldrin                   | 28. Isobutyl ester 2,4,D    |
| 2. BHC                      | 29. Iso-octyl ester 2,4,5,T |
| 3. Bulan                    | 30. Iso-octyl ester 2,4,D   |
| 4. Butyl ether esters 2,4,D | 31. Isopropyl ester 2,4,5,T |
| 5. n-butyl ester 2,4,D      | 32. Isopropyl ester 2,4,D   |
| 6. n-butyl ester 2,4,5,T    | 33. Kelthane                |
| 7. Chlorbenside             | 34. Lindane                 |
| 8. Chlorbenzilate           | 35. Malathion               |
| 9. Chlordane                | 36. Methoxychlor            |
| 10. Chlorothion             | 37. Methyl parathion        |
| 11. CIPC                    | 38. Ovex                    |
| 12. Dacthal                 | 39. Parathion               |
| 13. DDE                     | 40. PCNB                    |
| 14. DDT (o,p+p,p; Op; pp)   | 41. Perthane & olefin       |
| 15. Diazinon                | 42. Prolan                  |
| 16. Dichloran               | 43. Ronnel                  |
| 17. Dieldrin                | 44. Strobane                |
| 18. Dilan                   | 45. TCNB                    |
| 19. Dyrene                  | 46. TDE                     |
| 20. Endrin                  | 47. Tedion                  |
| 21. Ethion                  | 48. Telodrin                |
| 22. Ethyl hexyl ester 2,4D  | 49. Tetraiodoethylene       |
| 23. EPN                     | 50. Thimet                  |
| 24. Folpet                  | 51. Thiodan I               |
| 25. Heptachlor              | 52. Toxaphene               |
| 26. Heptachlor Epoxide      | 53. Trithion                |
| 27. Hexachlorobenzene       | 54. Vegadex                 |

Any one, or combination of chemicals, present in the sample will be detected and measured.

A selected portion of the samples are examined for residues of Carbamates, chlorophenoxy compounds, and carbaryl. Although these are important pesticide chemicals, analytical resources are not equal to examining all samples for these compounds. The number of objective samples examined for these chemicals, plus the knowledge gained through inspections in the growing areas, provides assurance that no serious problem will develop without recognition and followup for control purposes.

During this 3-year period almost half (49.5 percent) of the objective samples contained residues and 29 percent contained more than one pesticide residue. See Figure 2. The picture is approximately the same

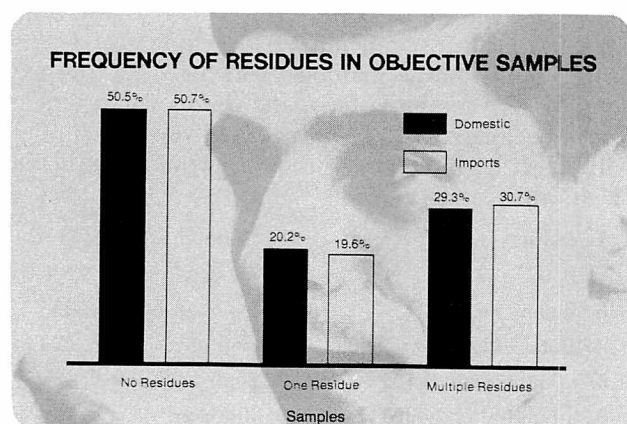


Figure 2

when these rates are computed on an annual basis from fiscal year 1964 through fiscal year 1966.

The 10 most commonly found pesticide chemicals in domestic samples and the 10 most commonly found in import samples follow in order:

#### Domestic Samples

DDT  
DDE  
Dieldrin  
TDE  
Heptachlor Epoxide  
Lindane  
BHC  
Endrin  
Aldrin  
Toxaphene

#### Import Samples

DDT  
DDE  
Dieldrin  
TDE  
BHC  
Lindane  
Aldrin  
Kelthane  
Heptachlor Epoxide  
Endrin

Frequency of residues of these chemicals in terms of percent of samples examined is shown in Figure 3. These percentages will add to more than 100 percent of the samples because about 30 percent contain more than one residue.

Tolerances have been established for a number of specific chemicals on various foods. The relative

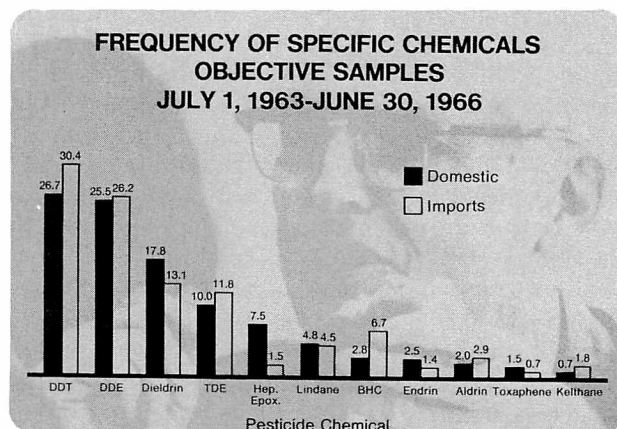


Figure 3

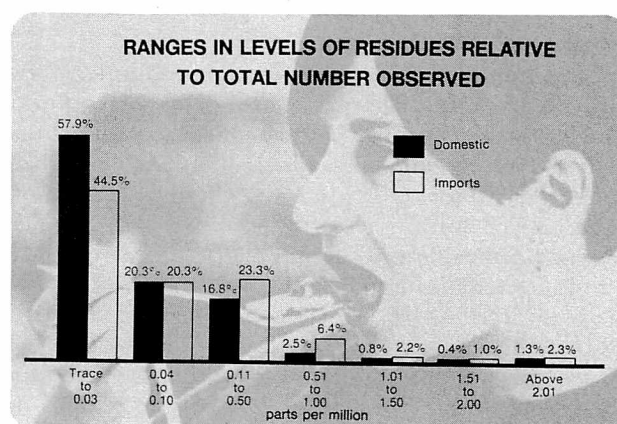


Figure 4

toxicity of the residues is quite important as is the relative consumption of the food item.

Although a detailed report and analysis of amounts of specific chemicals found on specific foods is beyond the scope of this paper, some general observations are pertinent. A total of 81 different chemicals were found in domestic samples during the 3-year period. Thirty-three chemicals were common to all years.

Irrespective of tolerance levels, it can be seen from Figure 4 that about 42 percent of the residues on domestic samples and about 55 percent of the residues on import samples exceeded 0.03 ppm. About 22 percent of the domestic samples and about 35 percent of import samples contained residues exceeding 0.1 ppm. Also, it can be seen that total residue levels on imported foods are higher than those on domestic foods, and that similar chemicals are found at about the same frequency.

These general findings show that a relatively high frequency of many different pesticide chemicals are in foods as shipped in interstate commerce.

In contrast to the finding that imported foods generally contain higher levels of residues, approximately 3 percent of domestic objective samples and 1.5 percent of import samples contained residues in



excess of the tolerances or analytical guidelines. The total percentage is somewhat misleading, since this percentage varies substantially within broad food categories, such as fruits, vegetables, cereals, fish, and dairy products. For example, only 1.5 percent of the domestic raw fruits, vegetables, and cereals, and 0.9 percent of the import samples of similar products, have contained excessive residues. Many tolerances are in effect for these products. On the other hand, excessive residues are found more frequently in products for which there are no tolerances, such as shell eggs and fish, and particularly those where indirect sources affect residue levels.

The primary objective of FDA is to protect the consumer from eating foods containing significant amounts of these poisonous substances. The tolerance procedure and the surveillance program with accompanying regulatory control provides information only on the foods as shipped. Foods are washed, trimmed, cooked, and prepared in many different ways which affect the remaining residues. For this reason, tolerances are established on the food as shipped in interstate commerce, because it is not practical to establish tolerances at other points in the food processing procedure.

As an additional precaution and as final assurance that the primary objective is being reached, it is necessary that information be obtained on food as it is actually consumed. The tolerance concept does not anticipate, as a practical matter, that all foods will contain residues at the tolerance level for all chemicals for which a tolerance has been established, or even that all of a single food will always contain a residue at the tolerance level. Actual experience throughout the years proves this to be a valid concept. The safety factor included in establishing tolerances does take care of isolated situations of this nature.

Several investigators have stated that foods are the major sources of pesticide chemicals in man. There has been relatively little information concerning the kind and amounts of residues in foods as they are eaten. The "market basket" or "total diet" studies by the Food and Drug Administration provide the most reliable index of the residues being consumed in the diet in the United States.

Briefly, these studies consist of purchasing in retail food stores, as would any consumer, a diet list of 82 foods in a quantity sufficient to satisfy the Nation's largest appetite, a 17- to 19-year-old male, for 2 weeks. The diet list was developed by the Household Economic Research Division of the USDA.

The food is prepared for the table by dietitians. It is separated into 12 similar kinds or classes of foods to avoid problems in analysis and, more important, to minimize the dilution factor. A composite consists of all food items within a class mixed together for analysis. Each class composite of food is examined at

a much lower sensitivity level than that used for the samples described earlier. This lower sensitivity requires much more care during the analysis.

Each year a total of 30 diet samples are examined in 5 geographic regions, and 30 different cities are represented. This level of sampling was not achieved during the first year of the study. A detailed evaluation report of data obtained through April 1966 is in manuscript for future publication.

The data indicates that a well-balanced diet in the United States contains pesticide chemicals as follows:

chlorinated organic chemicals—0.02 ppm  
organic phosphate chemicals—0.003 ppm  
chlorophenoxy chemicals —0.003 ppm  
Carbamate chemicals —0.05 ppm

Statistically, there was no difference in the findings when each year of the study was considered separately.

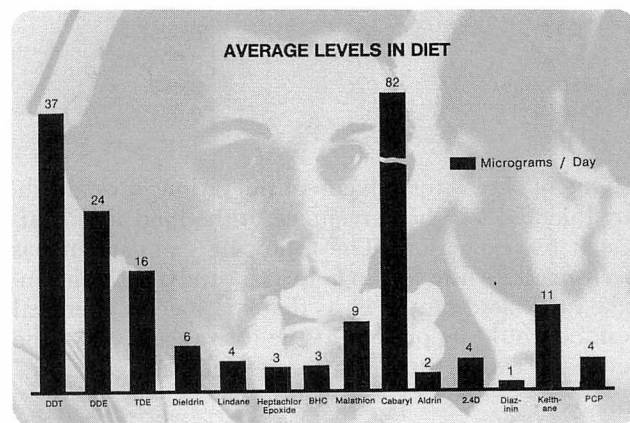


Figure 5

The chlorinated organic chemicals are the most widely used and persistent pesticides. Irrespective of the statistical interpretation, there was a finite increase from 0.08 mg/day to 0.12 mg/day in the total amount of chlorinated pesticides found in the second year of the study, indicating a need for continued surveillance. The average frequency of the 14 most commonly found chemicals is shown in Figure 5. This percentage is calculated from the total number of food composites examined. Organic phosphate compounds were not found until the second year of the study. In our opinion, this is due to improved methodology, and does not represent a change in the residues present.

Except for carbaryl, the levels of residue are closely related to the frequency with which the residues are found.

The kinds of specific chemicals and the relative amounts present are important because of wide variations in toxicity. DDT and its analogs, DDE and TDE, account for about three-fourths of the daily intake of chlorinated organic compounds at a total intake of 0.077 mg/day in the diet used in this study. Residues of dieldrin, lindane, and heptachlor epoxide

follow in order of frequency. The six most commonly found residues account for 90 percent of the total intake. However, consumption of 4 kilograms (8.8 lbs.) of food a day is almost twice the consumption of 2.2 kilograms (4.8 lbs.) of food by the "average" individual. Therefore, the actual intake of pesticides in a well-balanced diet will be substantially lower than those reported.

Acceptable daily intakes of specific pesticide chemicals in foods have been jointly proposed by the FAO of the United Nations and by the WHO Expert Committee. The following compares these levels with the findings calculated from the total diet samples:

	Acceptable Daily Intake (mg/kg body weight)	Calculated from Total Diet Samples
DDT	0.01	0.0005
Lindane	0.0125	0.00006
Malathion	0.02	0.009
Carbaryl	0.02	0.0012

One of the factors given consideration in establishing tolerances is the percentage of the food supply affected by the action. The following comparison has been made of the findings in this study with the intake calculated on the basis that the specific chemical residue would be present at the tolerance level in the foods for which there is a legal tolerance:

	Calculated from Tolerance (mg/kg body weight)	Calculated from Total Diet Samples
Dieldrin	0.006	0.0009
Heptachlor Epoxide	0.0006	0.0004
2,4-D	0.017	0.00005

These figures show a substantial margin still remains before residues in ready-to-eat foods even reach the currently acceptable levels.

Major components of the diet will affect the consumption of pesticide chemicals. For example, meat, fish, and poultry composites and dairy products composites, when combined, account for more than half of the intake of chlorinated pesticides. Most of the residues in these foods result from indirect additions through animal food, water, or other environmental factors.

Recently, a tolerance has been established for DDT and its analogs in dairy products, not because of direct application but because DDT is so widely distributed in the environment that it is impractical to prevent exposure of dairy animals to this chemical.

It is well recognized that continuing use of other persistent pesticides will aggravate this situation. The uses of such chemicals are being critically examined to minimize or avoid such situations.

From the above, we can conclude in general terms that currently the incidence and levels of pesticide residues in the Nation's food supply are not approaching dangerous or even alarming levels. The frequency and levels of residues in the Nation's food supply must not be permitted to increase unnecessarily. Additional measures are needed to avoid increases in specific food items where indirect sources result in residues; specifically, dairy products, eggs, and fish. Surveillance and control must continue at current levels to detect and eliminate problems arising from unexpected, unanticipated, and unavoidable sources, as well as from misuse. There are instances where residues remaining in the soil from previous crop treatment have migrated into subsequent crops. The usual degradation or disappearance of a chemical due to weathering may be delayed because of climatic conditions.

Improved analytical procedures may demonstrate conclusively the presence of a residue where, earlier, less sensitive procedures had failed. There are no "marker" foods that can be used as common denominators from which to judge the food supply as a whole.

The information on ready-to-eat foods obtained from the market survey is most reassuring, and supplements the interpretation of the data obtained on samples examined for compliance with tolerances. This kind of surveillance serves as a final check on the effectiveness of controls being exercised throughout the food production and distribution system.

In summary, there should not be alarm or complacency concerning pesticide residues in food. Continued responsible judgment and caution are required of those who use pesticide chemicals for whatever purpose. Additional research will provide better information concerning the total effect on man of environmental exposure to pesticide chemicals. Continued vigilance is required of those having the responsibility for the public's interest.

Keith Dawson is a Program Analyst with the Bureau of Regulatory Compliance.



Reo E. Duggan is Acting Deputy Associate Commissioner for Compliance.



# FDA's Dallas District

*An Incident  
in Laredo*

by Sam Fine

**T**exas and Oklahoma make up the Dallas District—an area covering more than 336,000 square miles. From the Gulf coastal plains in the east to the high, rolling plateaus of the west, enormous quantities and many varieties of agricultural products are grown. From the Gulf of Mexico come shrimp and oysters, while the ranches produce cattle, sheep, turkeys, and dairy products. Canned, frozen, or fresh, these products are shipped from the Dallas District throughout the United States.



To make sure that this food is pure and properly labeled, 47 inspectors check shipments, inspect plants, and collect samples. A staff of 40 bacteriologists and chemists conduct thousands of tests a year, mostly in the laboratory. The more important testing programs include sampling for microbiological contamination in breaded shrimp, shelled pecans, peanuts, and animal feeds, and for pesticide residue contamination in fruits and vegetables.

Early this year, we learned that some vegetables imported from Mexico were likely to be contaminated with a pesticide residue—a problem that was to involve three Federal agencies, the Mexican Government, and several groups of American and Mexican importers and growers.

Early in January, FDA analysts in Dallas discovered that there were

Following cucumbers were cantaloupes, one of Mexico's largest export crops, and one of the few melons particularly susceptible to pesticide contamination. This fact became clear to local growers and importers when, on February 26, three carloads of cantaloupes were detained in Laredo because of endrin contamination.

After checking with FDA headquarters in Washington, D. C., Dallas District chemists were directed to examine only the edible portion of the cantaloupe, since the rind or peel would not be used for food. The laboratory was set up on a 16-hour-day schedule to check all samples as quickly as possible.

On March 10, Laredo Customs officials, FDA Inspectors, food brokers, growers, and railroad people met for the first of three important meetings in Laredo. More FDA In-

From shipments imported either by railroad or by truck, some 1,200 samples were selected for analysis in FDA laboratories in Laredo, Dallas, New Orleans, and Denver. Working on a round-the-clock schedule, FDA and U. S. Customs officials inspected 454 carloads of cantaloupes. During a 6-week period, more than 100 carloads from the Apatzingan area of Mexico had to be destroyed because of pesticide contamination.



Foster explains FDA's role to insure that all foods are free of excessive pesticides.

significant amounts of endrin, a pesticide, found in imported cucumbers. FDA regulation does not permit a residue of endrin in raw agricultural products when shipped interstate. Several carloads, routinely inspected at Hidalgo, a point-of-entry on the Mexican-U.S. border, were detained. During the next six weeks, FDA and/or Customs Inspectors supervised destruction of 6 out of 240 shipments.

spectors were assigned to handle carload sampling which, as the season progressed, increased from 5 to 50 carloads a day.

On March 14, the Dallas District had refused entry of 22 out of 77 carloads of cantaloupes.

By March 20, the testing of samples climbed to 134. To meet this increased workload, the District personnel began a 24-hour, 7-days-

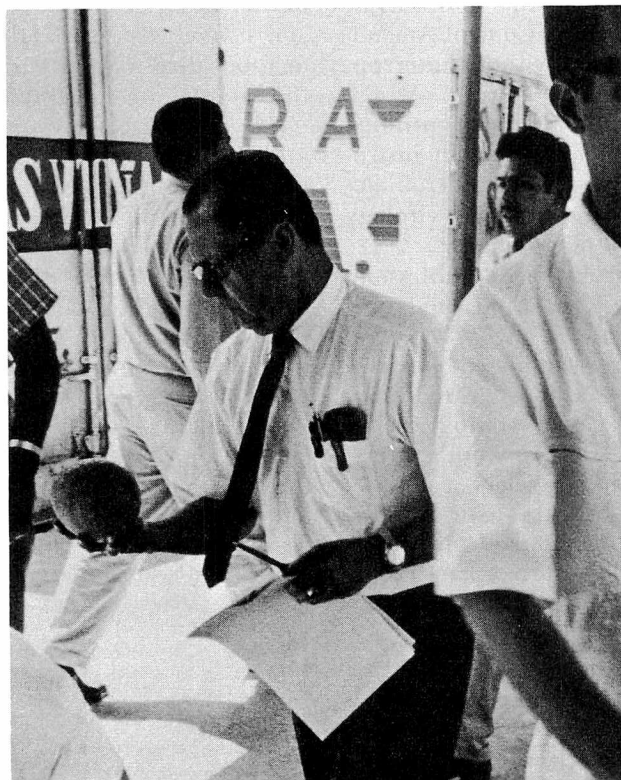
a-week schedule. In the meantime, a new \$38,000 mobile laboratory was being rushed to Laredo from Detroit.

One of the most difficult problems was transportation of samples from Laredo to the Dallas laboratory, a distance of 450 miles. Some 32 samples were delayed by flight cancellations, and a few samples had actually been lost. When this became known to the brokers, concern quickly spread among those whose shipments from the Apatzingan area were being held longer than the normal waiting period.

The brokers were entitled to post bond which permitted them to move their cantaloupes into the United States. Few, however, could afford this gamble. For instance, one shipment of 223 crates had moved as far north as Ypsilanti, Mich., where it had to be removed from a railway car, dumped, and buried.

In Dallas, a new transportation and sampling procedure was launched. To expedite analysis, the Dallas laboratory examined only the samples from Laredo, while the FDA labs in New Orleans and Denver handled sampling from Hidal-





go and El Paso. With a coordinated air and express-bus transportation system, the Laredo samples began to move overnight from Laredo to Dallas, on schedule.

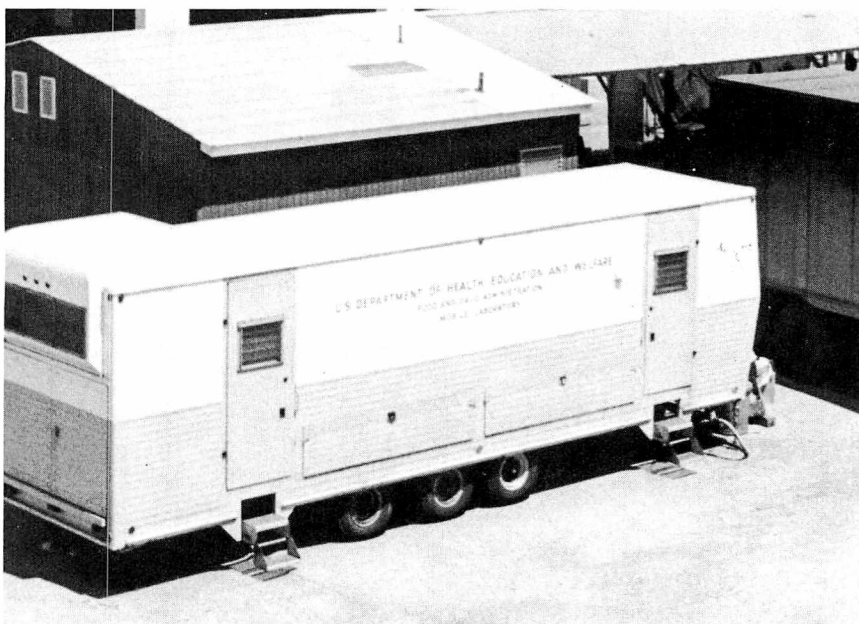
On March 20, the Mexican Government contacted the State Department in Washington, D. C., about the Laredo problem. Through the FDA's Office of International Affairs, an invitation was extended to the Mexican Government to send a representative to meet with FDA, Custom, and USDA officials.

The mobile laboratory arrived in Laredo on March 25. H. E. Outlaw, Director of the Laredo Customs District, provided space and utilities for the laboratory as well as an office for the additional FDA Inspectors and analysts who were brought in to accelerate the movement of truck and railroad car inspections. Within four days, the mobile laboratory was operating.

FDA Inspectors and Customs officials in Laredo learned that several Mexican growers believed that their detained cantaloupes had not been destroyed as ordered but diverted in the United States. The growers were invited to visit the Laredo city dump where tons of the contaminated melons were buried. As they watched, two trucks loaded with more than 500 crates of cantaloupes were dumped to be covered by a bulldozer.



Sam D. Fine has been Director of the Dallas District since 1960, and directed Kansas City District from 1957-60. He joined FDA in 1939 as a Junior Chemist.



With the arrival of the mobile laboratory in Laredo, imported cantaloupes were tested on-the-spot by FDA inspectors for possible endrin residue contamination.

Meanwhile, the day-by-day work of the Dallas District continued:

Samples of dietary foods showed undeclared sulfa drugs and preservatives, and contained inert glandular ingredients . . .

Inspections of candy, refrigerated doughs, and specialty flours revealed heavy rodent infestations, and a sanitation workshop was set up for food warehousemen . . .

The bacteriologist-inspector team concept was applied to the pecan industry . . .

Analysis and identification of drugs collected in the enforcement of the Drug Abuse Control Amendments continued without interruption . . .

Twenty FDA analysts continued their university training in instrumental analysis. Four microbiologists attended courses in virology and advanced microbiology . . .

A seminar for FDA professionals in inspectional and analytical work was planned . . .

Plans were completed for two industry workshops: Medicated Feeds, and Good Manufacturing Practice for drug manufacturers, repackers, and relabelers . . .

The meeting with Mexican growers convened in Laredo on March 29. Chief Chemist Norman Foster

represented FDA. Gathered around the table were two brokers, the president of the local growers association, and six growers from a 4,000-acre area of cantaloupe-producing farms near Apatzingan, Michoacan, in southwest Mexico. An FDA analyst, Humberto Guerrero, was the interpreter for the bilingual group.

Mr. Foster told the Mexican growers and importers that the enforcement of Federal law applied both to products in interstate commerce and to imports. He described to the group how pesticide tolerances were established; the present methods used for analysis; and how the samples were selected.

The endrin residue problem, he said, first came to the attention of the Dallas Inspectors in 1963. Lettuce and carrots to be shipped interstate from the Hereford area of Texas were found contaminated with endrin residue. Contamination also was discovered the following year on carrots grown in the Rio Grande Valley.

The high pesticide residue contamination found in Hereford was the result of drift or wind contamination. Some fields, said Mr. Foster, were contaminated as far as five miles from where the pesticide was

originally applied. In the Rio Grande Valley, he said, contamination was believed to have been caused by overapplication of the pesticide to cotton which subsequently contaminated the soil.

Mr. Foster told the group that the persistence of endrin varied for different types of soils and that the growers would have to determine this in their own fields, under their climatic conditions. The growers then requested that FDA Inspectors be sent into Michoacan to test some 1,500 fields for soil contamination. The meeting ended with Mr. Foster extending an invitation to visit the mobile laboratory.

The next morning, Mr. Foster was notified that the Mexican Government's Assistant Director General of Sanidad Vegetal would attend the final conference. Other officials included representatives from the U.S. Department of Agriculture, U.S. Customs, and the brokers and growers who had attended the previous meetings.

The Assistant Director General said his government was grateful to

the FDA and the Customs people for their interest and help in the clarification of the pesticide problem. He was particularly pleased that the mobile laboratory had been brought to Laredo to expedite sample examination. After the USDA representative announced the Notice of Withdrawal of Registration for endrin on melons, a Customs official assured the group that attention was also being directed to imports at other U.S. ports-of-entry as well as in Laredo.

Mr. Foster told the Assistant Director General, who had observed that there was a need for an expanded pesticide research program in his country, that the Dallas District was prepared to train his people in soil and food examination. The length of the training period, he said, would depend on the scientific background and experience of the trainees.

Later, in his report, Mr. Foster said that relations throughout the Laredo meetings were cordial and sincere. "To sum up the whole mat-

ter," he said, "I think a great deal was accomplished."

On March 30, the Dallas District was notified that the Mexican Government had begun analysis of soil samples from the growing areas of Michoacan.

By March 31, a total of 454 carloads had been examined by the FDA—94 had been detained. In Apatzingan, Michoacan, four FDA Inspectors arrived on April 3 at the invitation of the Mexican Government. The inspectors, with the assistance of Mexican officials, sampled cantaloupes in the fields, and the Mexican Government had the samples flown to Dallas for examination. Inspector Ted Rotto phoned the District office each day and received a report on the samples examined. Where the samples indicated the cantaloupes still in a field were contaminated, Rotto made arrangements with the Mexican officials for destruction of the melons in the field. The Mexican Government issued certificates, based on the analyses in Dallas District, on shipments from the satisfactory fields, and those shipments were released at the border without further examination.

During the second week in April, Mexican and U.S. authorities noted that there was a significant decrease in detentions—out of a total of 1,200 samples examined, 106 carloads had been detained.

March 1967 will be long remembered by Dallas District personnel as the month of the melon incident in Laredo. It was an experience illustrating how an FDA District can mobilize its resources to eliminate a hazard to the public health.

The incident in Laredo received little attention outside the area because the District was able to take the situation in hand immediately. There was no cause to alert the public to the problem; we knew that the melons entering the American marketplace were free of endrin residues. It was a big incident, but really no different from a thousand other actions taken in this District every year.

U.S. Customs official supervises dumping of contaminated cantaloupes near Laredo.





One of the basic principles of modern medicine is that each particular drug must have a definite composition so that its administration will produce a uniform and predictable response. Drugs for parenteral administration are tailored so that they meet specific medical needs. Because of this "tailoring" these drugs require special safeguards. The mixing of two or more of these highly potent and especially tailored drugs for administration to a patient may bring about a serious imbalance in one or more of the drugs in the admixture, resulting in the administration of an ineffectual or hazardous solution to the patient.

form. Since more than one component is involved, there is an increased potential for incompatibilities to occur. Predictions as to how these components will react when used as a combined form have been found sorely deficient in the light of actual trial. Any change in viscosity, pH, particle size, light exposure, storage conditions, solvents, and oxidation-reduction conditions can easily upset the system, causing loss of activity, inertness, or toxicity.

It is an unfortunate fact that an ill person does not always have a single symptom which can be relieved with a single drug. There are complicating influences, so it is

this solution, chemical reactions that cannot be readily predetermined do occur. The problem of parenteral incompatibilities is of growing concern to the pharmaceutical firms, hospital pharmacists, and FDA because parenteral admixtures are often prescribed, compounded, and dispensed without sufficient knowledge of their possible physical or chemical interactions.

A medical news item in the *Journal of the American Medical Association* of October 31, 1966, concerning adverse effects produced by mixing local anesthetics, points up this recurring problem. In offering our comments on this problem, we replied as follows:

"From time to time we received inquiries as to why the Food and Drug Administration does not require the manufacturers of injectables to indicate in their brochures the various other parenterals with which they can be mixed and, conversely, those with which they are incompatible.

"As your item points out, mixtures of drugs may have effects which are quite different from those which would be anticipated from the actions of the individual ingredients.

"Drug products are tailored specifically to provide definite chemical and biological effects. Admixture of two or more of these drug products may cause physical, chemical, and biological changes, resulting in drug incompatibilities with the possibility of toxic or inert substances being administered to the patient. For these reasons, such admixtures may frequently come within the legal definition of new drugs and require the submission of extensive laboratory, animal and clinical studies in order for them to be legally mentioned in the product brochure.

"To require each manufacturer to carry out such studies for every possible combination of his particular preparation with other injectables (including those manu-

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# extemporaneous mixing of parenteral medication

by

Earl L. Meyers, Ph.D,

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A parenteral drug is administered to a patient during a critical period of his treatment. The identity, strength, quality, and purity of this drug are of paramount importance to the health and welfare of the patient, and of significant concern to the attending physician.

It is generally acknowledged that formulations of manufactured products are complex and their compatibility characteristics are not the same as those of the active component alone. The interactions of active component and excipients are complex to the point that large research projects have stemmed from attempts by pharmaceutical firms to combine a well-known chemical into a more useful dosage

not surprising that the attending physician will attempt to mix two or more drugs in order to more effectively control the several symptoms which the patient presents. Extemporaneous mixtures such as this invariably bring with them the risk of drug incompatibility.

The scientific literature is vast in drug incompatibilities. It covers a large variety of data dealing with immediate and latent chemical, physical, and therapeutic incompatibilities. The use of a single component parenteral solution presents little difficulty. However, when one or more injectables, each of which may contain preservatives, buffers, antioxidants, and acidic or basic components, are added to

factured by other companies) would be an impossible burden.

"Mixtures prepared by a physician for use on his own patients in the normal course of his practice are exempt from the new drug requirements, but the physician is responsible for their safety and effectiveness, including any adverse effects that may occur.

"In summary, parenteral preparations are meant to be given alone and we would recommend against mixing injections since the minor inconvenience in taking multiple injections is more than compensated for by the assurance of safety and effectiveness obtained when the product is used as the manufacturer intended."

Probably the chief cause of incompatibility is an alteration in pH. But there are many causes of incompatibilities when two or more injectables are mixed. Among these are vehicles, preservatives, antioxidants, stabilizers, buffers, containers, closures, and complexing.

In order to avoid chemical and physical incompatibilities, an intimate, detailed knowledge of the composition of the solutions is essential. An extemporaneous procedure is risky since it precludes the broad knowledge of the nature of the components and their characteristics, which is generally regarded in scientific pharmacy as a "must."

The therapeutic effects of the components may be considerably altered as a result of chemical interactions. The rate of reaction is dependent on many factors, including the chemical nature of the drugs, the order in which they are mixed, their relative concentrations, the pH of the solution, and the temperature. A warning signal may appear in the form of heat liberation, or the chemical change may take place without obvious evidence in the absence of formation of a precipitate, gas, color change, etc. The resultant changes in therapeutic action are difficult to predict.

Gross chemical instability of mixed drugs may result from a change in pH, buffering capacity, salt formation, complexing, or other forms of chemical denaturation. These effects, as well as others, are likely to result in extreme changes in reaction kinetics with the result that unanticipated changes in the actual chemical identity may progress at a highly accelerated rate.

During recent years there has been an increase in the number of drugs with limited stability after reconstitution. It is important that the stability period of the reconstituted drug be known. It may be dangerous to use these drugs beyond the stability period because their therapeutic effectiveness will have diminished. Usually injectable solutions are not prepared just before they are used. Often they contain two or more therapeutic agents. The elapsed time between preparation and starting of administration sometimes exceeds the point of assured stability. This can be complicated by failure to give appropriate protection to the prepared solution, thereby hastening decomposition.

**T**he extemporaneous mixing of parenterals has been a common practice in many hospitals. The physician's primary interest lies in the therapeutic value of the drugs in the treatment of the patient's illness. He obviously does not want to give a harmful combination of drugs. However, information on the physical and chemical incompatibility of a new combination is not always available, and that available is not always complete. Most of the data available on incompatibilities deal with physical changes visible to the human eye. This leaves a large gap in the information on chemical and biological incompatibilities.

The combination of drugs extemporaneously tailor-made at the direction of the physician is extensive. There has developed a relatively wide choice of prepared

carbohydrate, protein, vitamin, plasma expander, and multiple component electrolyte solutions. The physician may combine additional drugs with these solutions to better meet the individual needs of his patients. The number of possible combinations is virtually unlimited. We must be sure that the physician has all the necessary information available so that the patient receives only a safe and effective drug or combination of drugs.

Many hoped that the age of polypharmaceuticals was over soon after the advent of sulfanilamide and chemotherapy. However, a great deal of polypharmacy is still practiced in hospitals by nurses. The preparations she compounds on the heavily congested nursing unit are often complex mixtures for intravenous or intramuscular injection.

Because of the complexity of modern drugs, the hospital pharmacist is the one in the best position to compound such admixtures and to consult with and advise the physician in regard to incompatibilities in mixing injectables. However, it is readily appreciated that the limitation of personnel, time, space, facilities, and equipment prevent the hospital pharmacist from manufacturing and compounding the range of drugs produced by the pharmaceutical industry. While this is not the scope of hospital pharmacy, the pharmacist should accept his professional responsibility for the compounding of parenteral admixtures, since he is best equipped to meet the challenge of extemporaneous mixing and preparation of sterile products. He faces a significant problem in assuring that the products compounded in the hospital pharmacy do, in fact, comply with the highest professional standards necessary to produce a safe and effective drug that can be dispensed with confidence.

The hospital pharmacist possesses a great deal of knowledge of the physical, chemical, biological,

and pharmacological properties of drugs so he can furnish the physician a great variety of information which will assist him to prescribe more selectively for his patient. In pharmacology the physician and pharmacist meet on common ground. To be an effective consultant the pharmacist must be thoroughly aware of the educational background of today's physician in the area of pharmacology and therapeutics.

A clear-cut policy should be established in every hospital with respect to the procedure for admixing of parenteral solutions. If an admixture of intravenous solutions is needed, the pharmacist should prepare it. Sometimes circumstances make it difficult for the pharmacist to be involved in extemporaneous mixing of intravenous solutions, but it can be done through cooperation of the hospital staff. The pharmacist is then in a position to determine what constitutes a safe and effective admixture and what drugs may be incompatible when extemporaneously mixed.

The hospital pharmacist obviously must bear full responsibility for the quality of the preparations issued by his department. He may manufacture many of these himself. If so, he should maintain a quality control system in conformity with good manufacturing practice, with rationally organized and systematic procedures. He should employ personnel who are adequately trained and experienced and will operate under strict rules at all times.

In the preparation of drug products, he is constantly aware of the intricacies in manufacturing techniques, formulation incompatibilities, operational factors, tests and standards, packaging, and stability of the finished product. His control program must be tailored to the needs of his hospital and the effects upon the health and welfare of the patients.

There is a need for a comprehensive study of incompatibilities in parenteral admixtures. A few groups of persons interested in extemporaneous mixing problems, such as the hospital pharmacists, have prepared charts and tables showing the compatibility and incompatibility of some of the more commonly used drugs. Only a small amount of information is available depicting the incompatibilities of two drugs in intravenous solutions. Charts describing incompatibilities to be expected when various combinations of three or four drugs are administered in an intravenous solution are apparently nonexistent. There is very little information published indicating the effect of preservatives, antioxidants, stabilizers, buffers, solvents, pH, salt formation, concentration, and inactive components on the drugs added to large volume injectable solutions.

A thorough chemical and pharmacological testing of all possible intravenous drug combinations to reveal incompatibilities is a project of staggering proportions. For example, Misgen noted that 500 drugs will make 124,775 different combinations, and 100 drugs, cross-matching three at a time, will make 161,741 different combinations. In another study Dunworth and Kenna found, upon reviewing inpatient charts, that 24 medications were commonly added to in-

travenous solutions, and, programming this on a computer, that over 11,000 unique combinations in pairs, threes, and fours were possible with the 24 basic drug products.

Most of the existing information is limited to the reporting of physical incompatibilities only. Chemical and pharmacological incompatibilities of such combinations must also be considered. Published information about drug compatibilities have these additional weaknesses:

1. *Many formulas actually tested have subsequently been altered.*
2. *Many combinations tested in advance by pharmaceutical manufacturers have never been prescribed and, more important, should never be prescribed.*
3. *Compatibility testing programs are, for the most part, superficial in nature.*

When tables or charts are prepared without a thorough investigation of all of these possibilities, the information in itself is a possible hazard to the patient who will receive the extemporaneous mixed injectable.

The evaluation of compatibility problems is now being based in part on applicable principles of physical chemistry. However, many factors can be fully evaluated only by following biological response with time. A considerable volume of work is required to ensure that parenteral admixtures have led to the desired response on actual administration. This, obviously, could never be carried out by the individual pharmacist; it requires facilities and investment on too great a scale. Instead, the major advances in knowledge with respect to the extemporaneous mixing of injectables will probably be the results of efforts by the pharmaceutical industry and the hospital pharmacist.

In the meantime, it is advisable to limit the practice of extemporaneous mixing of injectables to those cases where a background of information exists to justify it.



Earl L. Meyers, Ph.D., is Acting Director, Division of Oncology and Radiopharmaceuticals, Bureau of Medicine. This article is a digest of a paper delivered to the Annual Pharmacy Congress, St. John's University, New York, March 17, 1967.



# analysis of pesticide residues

*American consumers of all ages may be confident that their foods are free from harmful amounts of pesticide residues, due to*



*FDA's tolerance-setting and enforcement procedures. Analyses of raw agricultural products as well as total diet surveys show that pesticide residues are much lower than the amounts judged to be safe by FDA and the World Health Organization.*



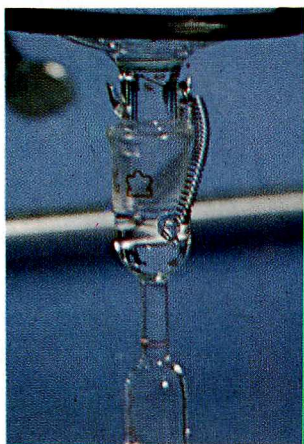
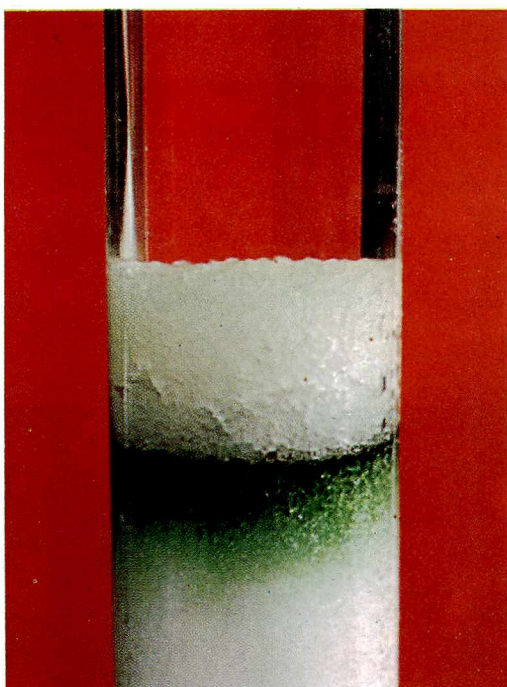


Examination begins with representative sample of the product, in this case melons.

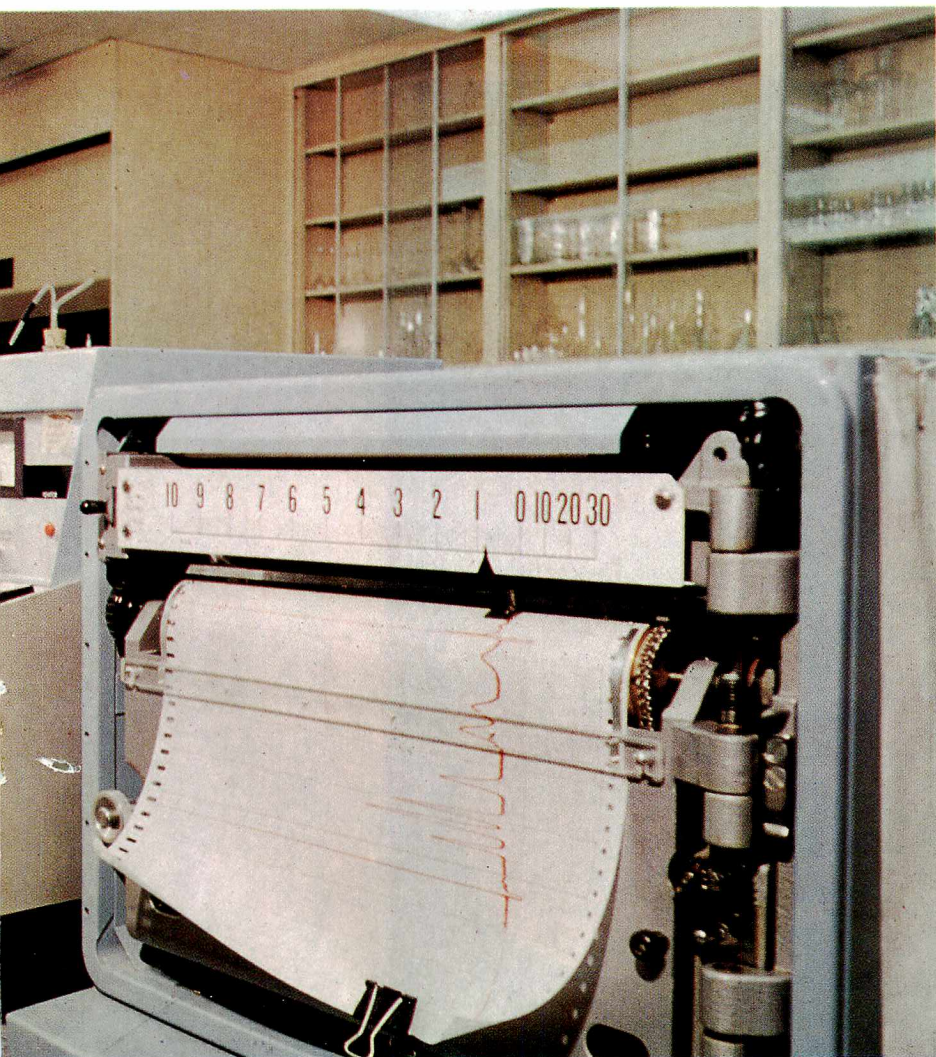
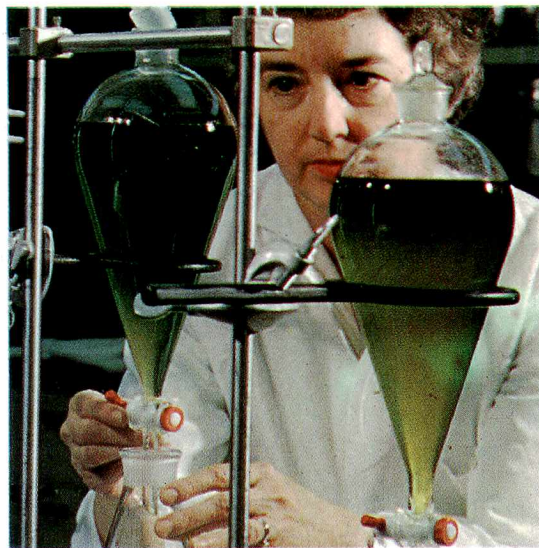
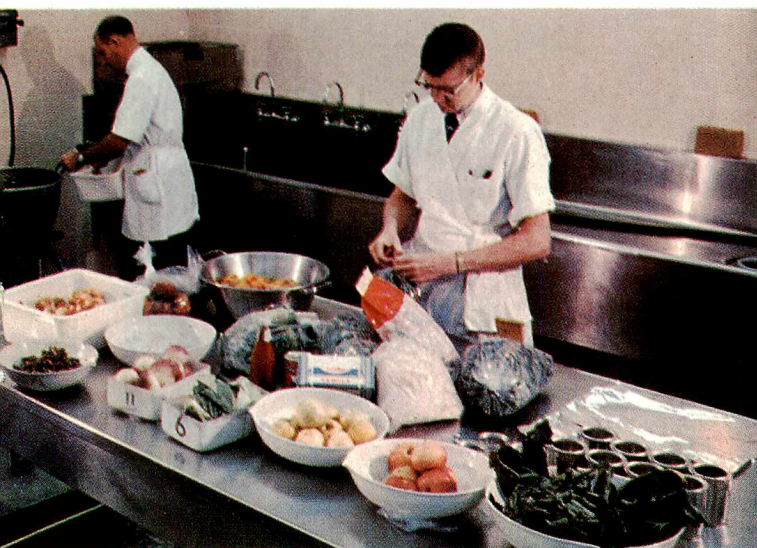
Laboratory scientists select portions of inspector's sample for analysis. Pesticides are extracted by blending sample with a solvent. (Top left).

In "market basket" or "total diet" studies FDA analyses 82 items in 2-week diet of a 19-year-old boy. Scientists cook or prepare food for table, but use a small, homogeneous sample for analysis. (Top center).

After extraction, pesticides are separated from nonpesticide material

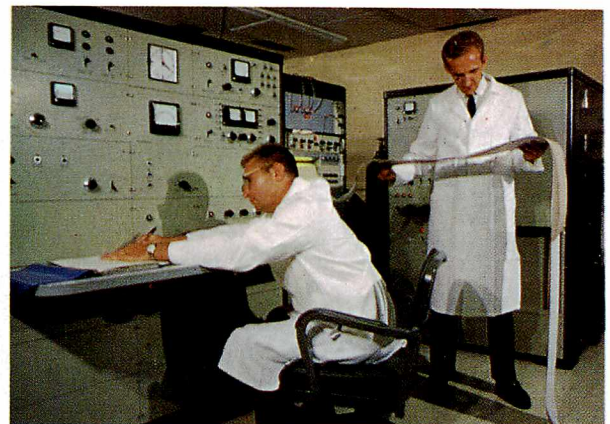






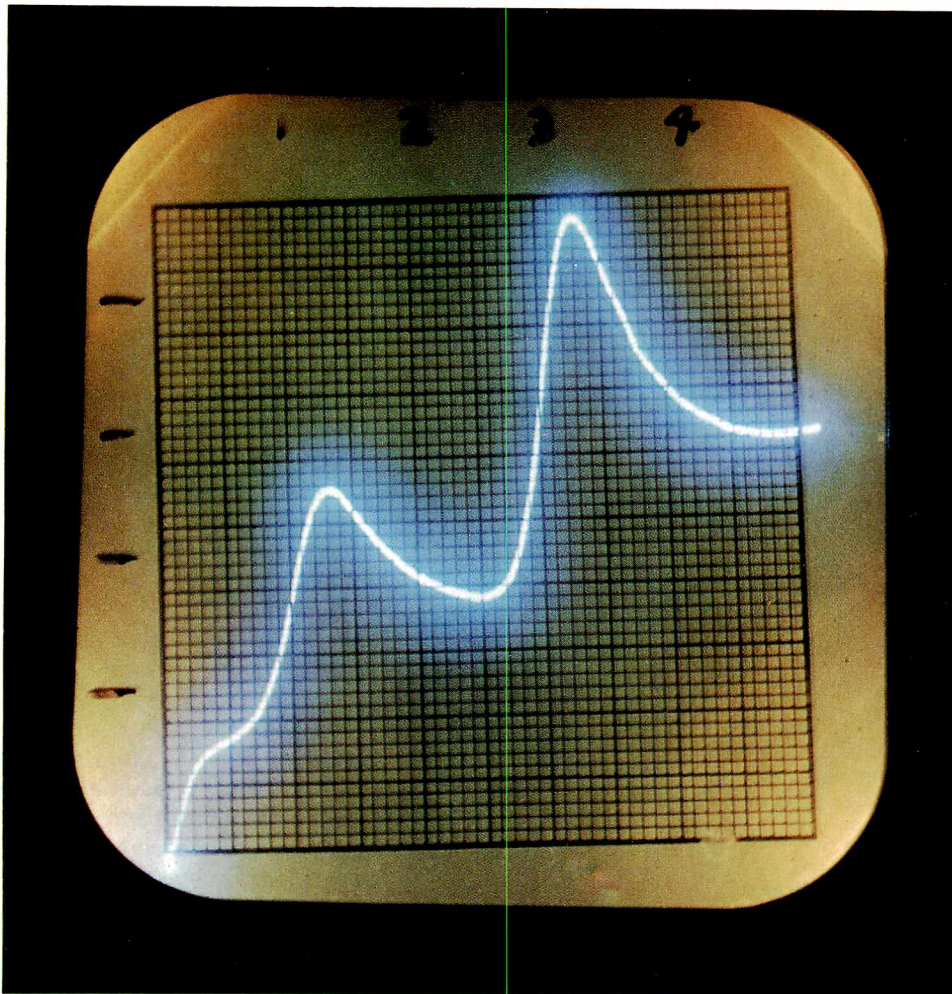
by solvent partitioning. (Top right) Column chromatography isolates pesticide chemicals from remaining biological material. Green band holds back impurities, such as color and fats, while pesticides pass through. (far left) Pesticides collect in evaporative concentrator below column. This solution is reduced to a definite volume, measured in the volumetric collection flask. (Bottom left) A measured portion of the concentrated solution is injected into column of a gas chromatograph, the primary instrument utilized in pesticide residue analysis. Pesticide chemicals distribute between a moving gas and a stationary liquid; differences in distribution characteristics of the pesticides cause them to separate. A pesticide passes from the column into a highly sensitive detector, causing an electronic signal which is recorded (chromatogram is shown on right). From the chromatogram the chemist can determine the pesticides and quantities present. (Bottom center)





Other instrumental techniques are used to add certainty to identification. Thin layer chromatography (upper left) and oscillographic polarography (lower) provide substantiating information.

The mass spectrometer (upper right) also helps identify unknown compounds. FDA's analytical system can detect at least 54 pesticide chemicals.



# FDA Science Advisors

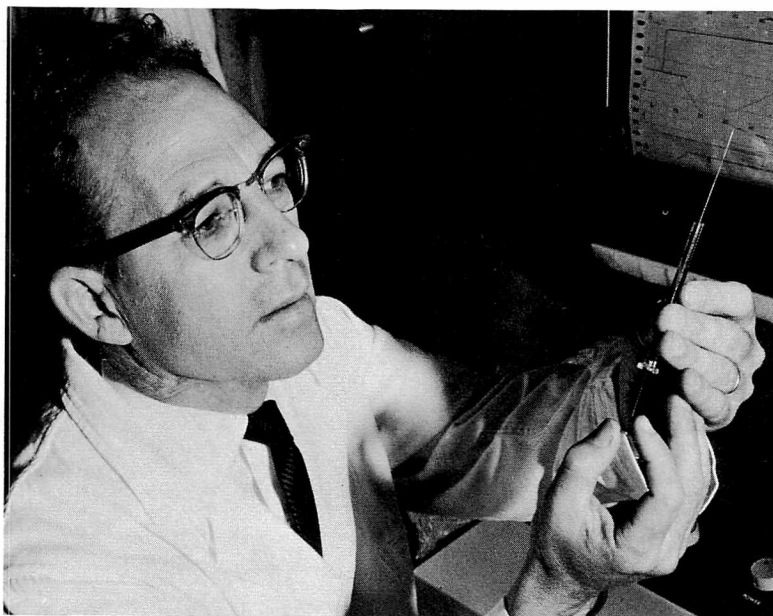
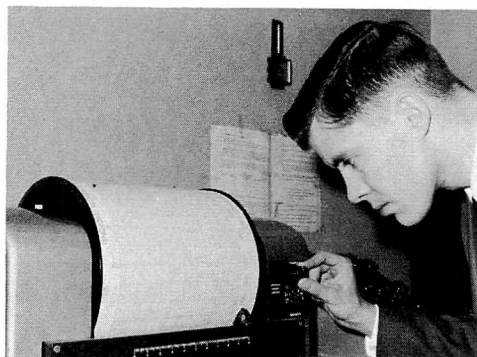
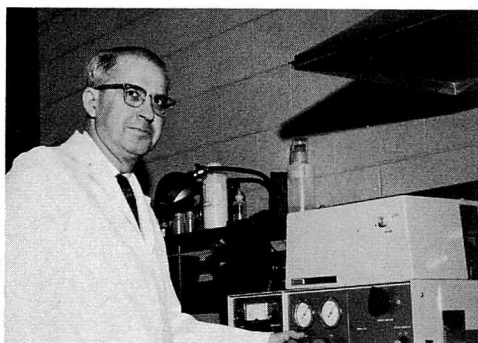


**how they help  
field scientists**

*by H. P. Eiduson  
and J. R. Weatherwax*







**DENVER DISTRICT** Dr. Paul Urone  
Professor of Chemistry, University of Colorado  
Boulder, Colorado (TOP RIGHT)

**ATLANTA DISTRICT** Dr. Hermenegild A. Flaschka  
Professor of Chemistry, Georgia Institute of  
Technology, Atlanta, Georgia (TOP LEFT)

**DETROIT DISTRICT** Dr. David F. Boltz  
Professor of Chemistry, Wayne State University  
Detroit, Michigan (MIDDLE LEFT)

**CHICAGO DISTRICT** Dr. Donald E. Smith  
Professor of Chemistry, Northwestern University  
Evanston, Illinois (BOTTOM LEFT)

**T**he specter of scientific obsolescence hangs over all present-day scientists. With the explosion of knowledge in all branches of science, the individual scientist has great difficulty in keeping abreast with the latest developments in his own field, to say nothing of closely related fields. Some professional societies, such as The American Institute of Chemists, are developing an Accreditation Program which will allow members to be certified as to their continuing chemical competence. Such certification would be good for three or five years, at which time new proof—additional

formal training, attendance at scientific meetings, published papers, active membership in scientific and related societies, etc.—would be needed for the certification to be continued. Thought is being given by some States and local communities to the licensing of certain chemical specialties in order to certify to chemical competency.

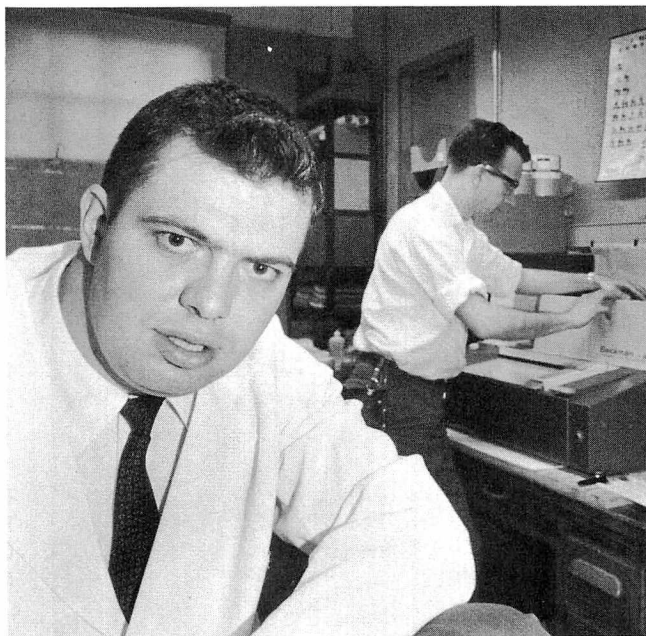
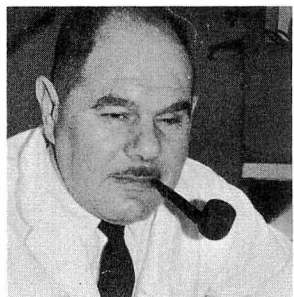
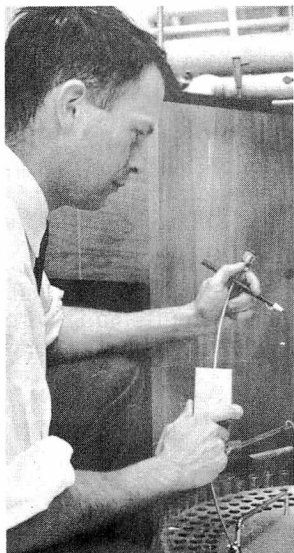
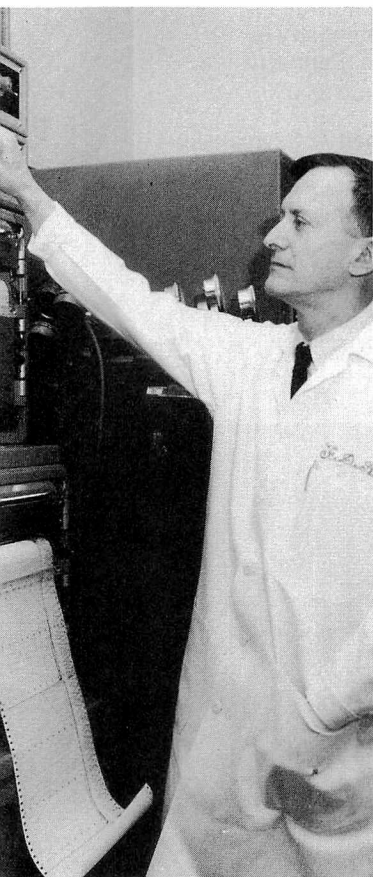
The need to counter this specter of scientific obsolescence is not only important to the individual scientists, but also to his employees. In order to carry out its responsibility of protecting the health of the American consumer, scientific com-

petency is essential to the Food and Drug Administration. Scientists at headquarters and in the field must use every resource to improve their competency. And FDA must make use of the most advanced analytical techniques and instrumentation.

To help field scientists, FDA turned to the academic community and established its Science Advisors Program.

The program was initiated in May 1966 with the appointment of an outstanding chemistry professor for eight District laboratories. All seventeen Districts, plus the National Drug Testing Center at St.





**BALTIMORE DISTRICT** Dr. William C. Purdy  
Professor of Chemistry, University of Maryland  
College Park, Maryland (TOP RIGHT)

**SEATTLE DISTRICT** Dr. William S. Chilton  
Assistant Professor of Chemistry  
University of Washington, Seattle, Washington  
(TOP MIDDLE)

**NEW YORK DISTRICT** Dr. Robert Ginell  
Professor of Chemistry, Chairman of Graduate  
Studies Program, Brooklyn College  
Brooklyn, New York (BOTTOM MIDDLE)

**BOSTON DISTRICT** Dr. Arno H. A. Heyn  
Professor of Chemistry, Boston University  
Boston, Massachusetts (BOTTOM LEFT)

Louis, now have a Science Advisor. All of the Science Advisors are on the chemistry faculty of a university within ready commuting distance of the District and are actively engaged in teaching and research. They are also involved in the direction of graduate study in the field of analytical chemistry or studies where analytical chemistry is a principal part of the investigation. After a year's experience, specific instances of benefit can be identified: Dr. Meloan, Science Advisor to Kansas City District, introduced a new technique of determining fluorine by colorimetric "de-

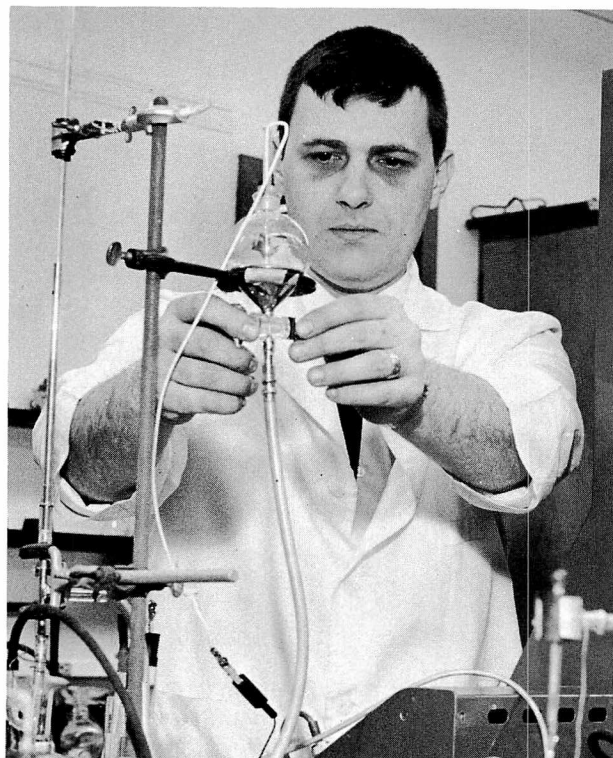
complexing" of cobalt.

Dr. Bruckenstein of Minneapolis District contributed materially to the solution of a longstanding, difficult analytical problem: the determination of cyclamate in fruit products.

**D**r. Szymanski of Buffalo District assisted in the development of an assay procedure for polyamines by means of nuclear magnetic resonance (NMR), a procedure having importance in the area of drug analysis.

Dr. Pecsok, Science Advisor to Los Angeles District, instituted the use of a simpler digestion procedure in place of the Schöniger combustion flask technique in a research project on the pesticide, Systox, in foods.

However, the great advantage of the Science Advisor Program is not the specifics which can be enumerated, but rather the overall influence which Advisors bring to bear on the professional development of field scientists, on general upgrading of the scientific climate of District laboratories, and on the stimulus for good research.



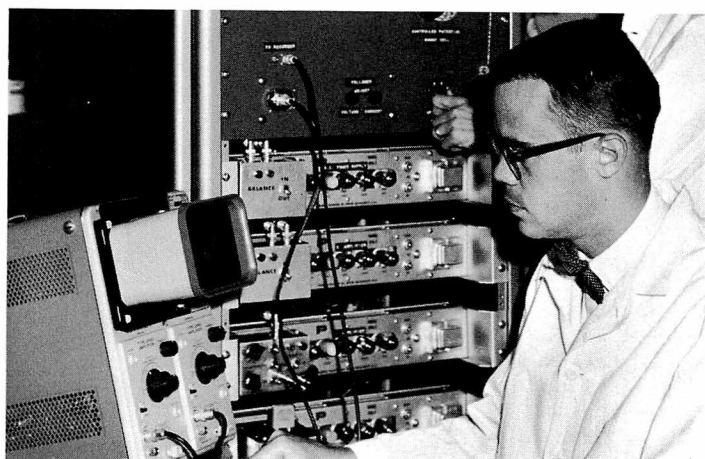
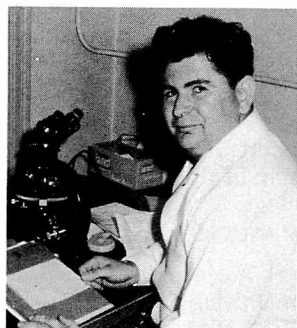
**LOS ANGELES DISTRICT** Dr. Robert L. Pecsok  
Professor of Chemistry, Vice Chairman of Dept.  
of Chemistry, University of California at  
Los Angeles — Los Angeles, California (RIGHT)

**ST. LOUIS DISTRICT** Dr. Thomas P. Layloff  
Assistant Professor, St. Louis University  
St. Louis, Missouri (TOP LEFT)

**PHILADELPHIA DISTRICT** Dr. Murray M.  
Tuckerman — Head, Dept. of Chemistry  
Temple University, Philadelphia, Pennsylvania  
(BOTTOM LEFT)

**BUFFALO DISTRICT** Dr. Herman A. Szymanski  
Director of Division of Natural Sciences and  
Mathematics, Chairman of Dept. of Chemistry  
Canisius College, Buffalo, New York (BOTTOM MIDDLE)

**NEW ORLEANS DISTRICT** Dr. Donald G. Davis  
Professor of Chemistry, Chairman of Dept. of  
Chemistry, Louisiana State University  
New Orleans, Louisiana (BOTTOM)



In the area of professional development, the Science Advisors have given technical seminars to field chemists and have been instrumental in having local universities provide courses specifically tailored for FDA scientists. For instance, Dr. Davis of New Orleans District arranged for Louisiana State University at New Orleans to provide a lecture series on physiological chemistry for District personnel. Dr. Davis had studied the analytical problems that the chemists were facing and judged that the outstanding difficulties were in the ex-

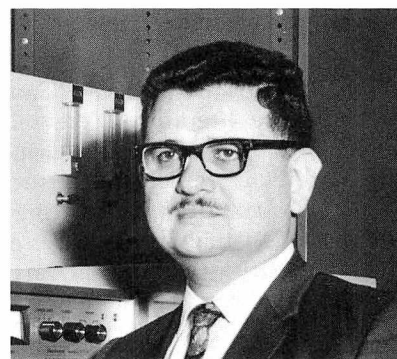
traction and isolation of materials. He felt that a knowledge of cell structure and metabolism, and the methods and techniques of the biochemist, would provide background to help analysts solve problems—whether these problems are in foods, drugs, pesticides, or microbiology.

Dr. Urone of Denver District has helped organize a series of lectures covering "Modern Aspects of Organic Chemistry" to be given by a member of the faculty of the University of Colorado to Denver District chemists. Several other Science Advisors have made similar ar-

rangements with local universities for their District's personnel.

Denver District recently conducted a Conference on Pesticide Residue Analysis which was attended by scientists from a wide assortment of Government and industry laboratories engaged in this work. Dr. Urone took a prominent part in the conference, and his presentations on the theoretical and practical aspects of his specialty, gas chromatography, were regarded as a highlight of the meeting.

The Science Advisor visits the District laboratory approximately one day a week. During these visits he



**CINCINNATI DISTRICT** Dr. Joseph J. Klingenberg  
Professor of Chemistry, Xavier University  
Cincinnati, Ohio (TOP MIDDLE)

**KANSAS CITY DISTRICT** Dr. Clifton E. Meloan  
Associate Professor of Chemistry, Kansas State  
University, Manhattan, Kansas (TOP RIGHT)

**DALLAS DISTRICT** Dr. Charles T. Kenner  
Professor of Chemistry, Southern Methodist  
University, Dallas, Texas (MIDDLE RIGHT)

**MINNEAPOLIS DISTRICT** Dr. Stanley Bruckenstein  
Professor and Chief of Analytical Chemistry  
Institute of Technology, University of Minnesota  
Minneapolis, Minnesota (BOTTOM RIGHT)

**SAN FRANCISCO DISTRICT** Dr. Frederick R. Jensen  
Associate Professor of Chemistry  
University of California, Berkeley, California (LEFT)

consults with the chemists who are engaged in research work. He discusses the problems encountered, the direction of the work, and offers suggestions. All Districts report that interest in research work has been stimulated by the regular visits. One District reports that they believe the greatest influence of the Science Advisor has been in improving the scientific climate and morale simply by being available for consultation. The Advisors have been helpful in opening the doors to local universities so that answers to many problems are more readily available.

In December 1966, a conference of the original eight Science Advisors was held at FDA headquarters in Washington, D. C. The conference was attended by headquarters scientists and several of the field Chief Chemists. The conference was designed to serve two basic purposes: first, to acquaint the Advisors with each other and headquarters personnel; second, to provide the opportunity for an interchange of thought and ideas concerning the District and headquarters scientific efforts and goals. Several constructive suggestions

were made, including recommended improvements in various research operations and career development activities. The conference discussions were incorporated into proceedings sent to all concerned.

**T**he Science Advisor Program to date can readily be summarized by the words of one of the District Chief Chemists—"The Science Advisor is a true member of our staff. He helps us with small problems as well as big ones."



# field reports

**ATLANTA DISTRICT** Some 6,000 capsules of seaweed for human use were detained at the port of Jacksonville, Fla., in March. The seaweed was detained since it is a food for which no standard of identity has been promulgated, and the article was misbranded. The three mail entries were shipped by Chase Organics, Ltd., Shepperton, England. The label failed to bear the common or usual name of the food and of each ingredient. An application to relabel was submitted and denied.

**ATLANTA BDAC** Four University of Florida students were given heavy sentences April 12 in Gainesville, Fla., for sales and possession of LSD. Robert K. Davis, 22, was sentenced to 4 years in prison, to be served consecutively. Sergio L. Abreu, 22, was sentenced to 2 years in prison, to be served consecutively, and placed on probation for 2 years. Lawrence Yoeman, 20, and Kerry W. Mulford, 21, were sentenced to 1 year and 6 months in prison, respectively.

**BALTIMORE DISTRICT** Eleven "Sauna Beauty" steam baths and some literature were seized March 27 at Dixie Rentals, Inc., Virginia Beach, Va. The devices, valued at \$1,826, were manufactured by Hydro-Massage Co., Chicago, Ill. The labeling and promotional literature suggest that the device is effective as a treatment for bursitis, rheumatism, arthritis, circulatory problems, and excess weight.

**BOSTON DISTRICT** A Diapulse device was found to be misbranded by a Federal Court in Hartford, Conn., on March 17. The Government charged that the labeling for the device, a pulsed electromagnetic generator, was false and misleading in suggesting that it was adequate and effective for more than 100 diseases and therapeutic purposes.

The device was originally seized in December 1965. Twenty-one witnesses testified for the Government during the 4-week trial, largely in medical and scientific fields. The jury returned a general verdict for the Government in less than 5 hours. In responding to the special interrogatories, they found 49 of the claims made for the device by its labeling to be false or misleading, including infections, stimulation of tissue response, stimulating the RES, otitis media, systemic disease, tuberculosis, typhoid fever, osteoarthritis, staph infections, gangrene, increasing leukocytes and steroids in the blood for the stimulation of the liver and spleen, and giving results where all else has failed. No finding was made as to the other claims charged

by the Government. The device is distributed by the Diapulse Corp. of America, New York, N. Y. The company said that it has sold approximately 3,000 of the machines throughout the Nation, at a cost of \$2,300 each. The company indicated that it plans to appeal.

**BUFFALO DISTRICT** The owner of a Pennsylvania pharmacy and his pharmacist were fined March 29 for dispensing drugs on unauthorized refills and selling prescription drugs without prescriptions. Eugene Swanson, Swanson's Pharmacy, Penn Hills, Pa., was fined \$500 plus court costs, given a suspended sentence, and placed on probation for a year. The pharmacist, Samuel O. Stilley, was fined \$300 plus court costs, given a suspended sentence, and placed on probation for a year.

A joint Salmonella Workshop for Dry Milk Manufacturers was held in Syracuse, N. Y., on March 21. Sponsored by Baltimore, Boston, Buffalo, and Philadelphia Districts, the workshop drew 184 industry representatives and State officials from Connecticut, Delaware, Maryland, Massachusetts, New York, Pennsylvania, Vermont, and Virginia. Speakers were drawn from Cornell University, The American Dried Milk Institute, New York State Department of Agriculture and Markets, USDA, and FDA.

**CINCINNATI DISTRICT** The Sixth Circuit Court of Appeals at Cincinnati recently affirmed the trial court's decision in a drug sales case. The trial court had found that Siler Drug Store Co., Inc., Perry H. Siler, president, and James Sutton, an employee, guilty of selling prescription drugs without a prescription. The firm was fined \$5,000, Siler was sentenced to 10 years in jail and Sutton to 5. The terms are to be served concurrently. Appeal was based on the trial court's refusal to grant a continuance, alleged improper cross-examination, and the contention that it was improper to hold both the corporation and its officers liable for the acts of the employee.

More than 38,000 envelopes of chocolate topping and Freeze Queen Mix were seized recently at Kenner Product, Inc., Cincinnati, Ohio, a toy manufacturer. The items are distributed with toys and are intended for preparation of frozen desserts. Both items are short weight. The Freeze Queen Mix is an "imitation," but is not so labeled.

**DALLAS DISTRICT** The Novelty Peanut Co., Dallas, Tex., and its president Charles Bennett, were each fined \$1,500 on March 24 for shipping adulterated candy in interstate commerce. Bennett was given a 3-year suspended sentence and placed on probation for 3 years.

**DENVER DISTRICT** Bottles of Enfamil baby formula were seized in March because of contamination with manure fragments. The manufacturer, Mead Johnson & Co., Evansville, Ind., is voluntarily recalling 8-ounce containers of the formula. The Colorado State Environmental Health Unit dispatched investigators to remove as much of the product from the retail market as possible.

**KANSAS CITY DISTRICT** Because they were contaminated with *E. coli*, excessive coliforms, and high total bacterial count, 35 cases of "McCormick's" pecans were seized March 23 at Omaha, Nebr. The shipper was Azar Brothers, Inc., El Paso, Tex. The nuts were packed under insanitary conditions.

Some 120,000 pounds of wheat were seized at Wolcott & Lincoln, Inc., Kansas City, Kans., on February 27, because they were adulterated with rodent excreta and dead mice. The wheat, valued at \$3,200, was shipped by Upland Grain Co., Upland, Nebr.

Disposable 15-cc. syringes to be used for mastitis treatment were seized on March 7 from Dr. G. E. Brandt, Garnavillo, Iowa. The product contained an antibiotic for which the certification of the specific lots had been revoked. Manufacturer of the 9¼ cartons was Masti-Kure Products Co., North Franklin, Conn.

**LOS ANGELES DISTRICT** A consumer complaint about a dead mouse in a can of refried beans led to inspection of the Rosarita Mexican Foods Co., Mesa, Ariz. Inspectors found insanitary storage conditions and rodent damage. A lot of 1,083 bags of rodent-contaminated pinto beans, valued at \$8,000, was seized.

**MINNEAPOLIS DISTRICT** The District helped sponsor its first training course for food inspectors April 10-14. Fifty FDA Inspectors attended the short in-service training course on dairy processing. The course was sponsored by FDA in cooperation with the Department of Food Science of the University of Minnesota and the Minnesota Department of Health.

**NEW ORLEANS DISTRICT** A case involving seizure of candy on the basis of interstate movement of ingredients is being terminated. The U. S. Marshal seized the entire factory stock of candy suckers at Blackburn Candy Co. of Louisiana, Alexandria, La., on March 17. Some suckers contained imbedded pennies and nickels as prizes. The action was based on a charge of adulteration of an article held for sale after shipment in interstate commerce. The Government proved that the principal ingredient, corn sirup, had moved in interstate commerce. The firm has now ceased operations.

**NEW YORK DISTRICT** A smoked fish processor was enjoined March 8 from receiving and shipping into interstate commerce smoked fish which were prepared and packed under insanitary conditions. Acme Smoked Fish Corp., Arcee Sales Co., Brooklyn, N. Y.; Rubin Caslow, Harry Morton, and Joseph Brownstein consented to a decree of permanent injunction.

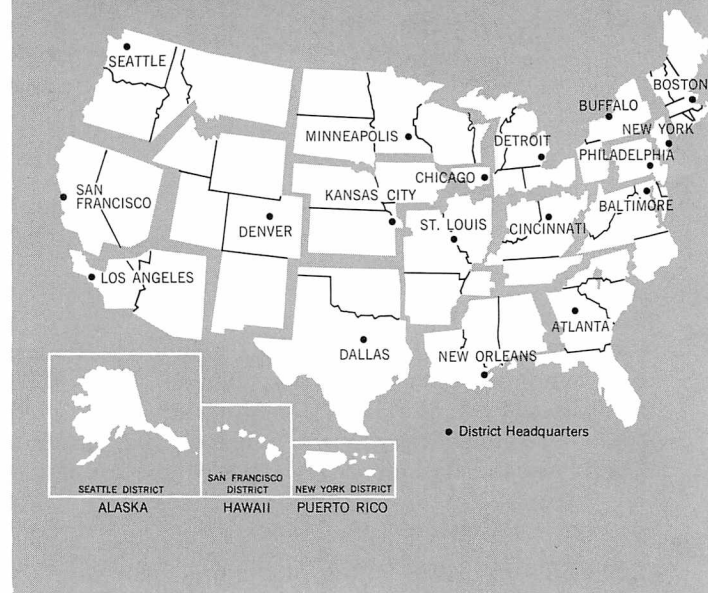
Over the Memorial Day weekend in 1966, a *Salmonella* outbreak involving some 500 people in the New York metropolitan area was directly attributed to this smoked fish processor.

As part of the terms of the injunction, the firm had to destroy 50,000 pounds of smoked fish, valued at approximately \$50,000, because of the possibility that they may have become contaminated with *Salmonella*. The firm hired a special commercial cleaning firm for \$11,000 to help it clean up its plant. The firm took approximately 2 weeks, under District supervision, to bring its facilities up to an acceptable level of sanitation. Operations were resumed on March 23.

Five defendants involved in a large-scale distribution of counterfeit drugs have been sentenced. They were charged with shipping some 700,000 counterfeit Smith Kline & French amphetamines in interstate commerce and intending to defraud the public. On March 3, a New Jersey judge sentenced Howard A. Press to 3 years in prison, Abraham H. Klein to 2 years, and Daniel Traina and James Taylor each to a 2-year suspended sentence. On March 9, he sentenced Morris Furer to 3 years.

The indictment followed a Federal raid at Morris Furer's home in Union, N. J., 2 years ago, in which some 1 million counterfeit tablets and capsules were found behind a movable staircase. Klein has filed a notice of appeal.

**NEW YORK BDAC** Before he could come to trial on charges of selling LSD and assaulting BDAC Agents, Raymond Hutzler burned to death in an apartment fire. Hutzler offered a large quantity of LSD to two BDAC Agents at his apartment in Brooklyn, N. Y., on January 26. When the agents identified themselves and attempted to arrest Hutzler, he became violent. In the fight that followed, one agent severed several tendons in his arm on broken window glass, and had to be hospitalized. The other agent was also treated in a hospital for cuts and bruises and was then released. Hutzler was finally subdued when other agents came to the scene. Reportedly a student of karate, Hutzler was released on bail. He died in a fire in another apartment in Brooklyn on April 1.



**PHILADELPHIA DISTRICT** The District held a workshop program on good manufacturing practice for 170 drug manufacturers, repackers, and relabelers on April 5 and 6 in Philadelphia. Representatives from about 38 percent of the drug firms in the District were present. Talks by FDA personnel were followed by question and answer sessions.

**SAN FRANCISCO DISTRICT** Two San Francisco men convicted of smuggling and selling LSD have disappeared. Bernard Roseman and Bernard Copley were arrested by U. S. Customs Agents in April 1963 while they were selling LSD to an FDA Inspector for \$15,000. Based on Roseman's statement that the LSD had been manufactured in Israel, the pair were indicted on two counts of violation of the Smuggling Statute. In addition, the indictment charged six counts of violation of

the FDC Act and one count of conspiracy. When they were found guilty by a trial judge, they appealed to the Ninth Circuit Court of Appeals, which upheld the judge's ruling. They then applied to the U. S. Supreme Court for a Writ of Certiorari, which was also denied. On March 9, the defendants were notified to report for service of the sentences (5 years each). They did not surrender and a bench warrant was issued for their arrest.

**SEATTLE DISTRICT** Due to the presence of *E. coli*, staphylococci, and a high total bacterial count, 14,934 pounds of frozen breaded shrimp steaks were seized March 8 at the Naval Supply Depot, Seattle, Wash. The lot, valued at \$10,155, was shipped by Ocean Products, Inc., Dover, Fla.

#### 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 Bldg.  
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

**ST. LOUIS** U.S. Courthouse & Customhouse  
Bldg., Rm. 1002/1114 Market Street  
St. Louis, Missouri 63101

**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 02110

**CHICAGO** 205 West Wacker Drive  
Engineering Building, Rm. 1700  
Chicago, Illinois 60606

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

**DENVER** 1814 California Street  
Denver, Colorado 80202

**KANSAS CITY** U.S. Courthouse  
Rm. 803/811 Grand Avenue  
Kansas City, Missouri 64106

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

**NEW YORK** 346 Broadway, 12th Floor  
New York, New York 10013



# state actions

**Iowa Attacks Salmonella** Iowa is attacking *Salmonella* in nonfat dried milk in a systematic manner. The Milk Sanitation Division, Iowa Department of Agriculture, picks up samples of dry milk powder weekly from every processor in the State. The producers voluntarily hold the sampled lots until the State laboratory returns the report of analysis. The State laboratory does not type its findings but merely reports results on a positive or negative basis. When positive samples are encountered, the firm is offered the choice of reprocessing or destroying as they see fit. The Department then works with the firms to correct the problem.

**Chinese Dinners Seized** Prompt identification of *Salmonella* by the Colorado Department of Health in a food poisoning case resulted in a nationwide recall of frozen dinners manufactured by Chun-King Foods, Minneapolis, Minn.

**Contaminated Dog Candy Recalled** The Orleans Dog Candy Co., Chicago, Ill., voluntarily recalled all stocks of its Lolli-Pup dog candy in March because the State of Connecticut found *Salmonella* micro-organisms in the candy. The firm began tests to determine the cause of the contamination.

**Pesticide Residue Problem** Florida officials stopped sale on 918 half-bushel crates of imported acorn squash at the port of Pompano Beach in March due to high residue, and embargoed 70 acres of acorn squash, 40 acres of zucchini squash, 70 acres of yellow crook-neck squash, and 270 acres of cucumbers produced by Champion Growers, West Palm Beach.

The analytical work was done on the spot in a trailer laboratory at the Farmer's Market in Miami. An

FDA chemist was also assigned to the Florida Department of Agriculture laboratory, and one inspector worked full time in Pompano Beach. At one time, three Florida Inspectors, one FDA Inspector, three Florida chemists, and one FDA chemist were working full time on the pesticide problem.

Champion Growers destroyed their pickings and broke under 90 acres of squash and 20 acres of cucumbers. The situation is now under control, and Champion Growers are back at full production.

## **Parsley With Pesticides Destroyed**

After pesticide residues were found in factory samples of dried parsley flakes and stalks, the California Bureau of Food and Drug Inspections supervised destruction of 18,000 pounds of the products. The processing firm was California Vegetable Concentrates, Saticoy, Calif.

## **Pennsylvania Embargoes Doctor's Drugs**

The Pennsylvania Department of Health has embargoed several lots of drugs, including tablets, injectables, liquids, and ointments, manufactured and labeled by Dr. Stuart Kabnick, Philadelphia, Pa. The drugs lack mandatory labeling and were accompanied by literature containing false and misleading claims.

## **Merchandise Salvaged**

The Indiana State Board of Health supervised salvage operations on human and veterinary drugs, and cosmetics, involved in a train wreck in March. Approximately \$90,000 worth of the merchandise was destroyed by burying and another \$90,000 worth was salvaged.

**GMP Workshop Held** A Good Manufacturing Practices Workshop was held at Purdue University in April, cosponsored by the Colleges of

Pharmacy of Butler and Purdue Universities, the Indiana State Board of Health, and the Detroit and Cincinnati Districts. Over 90 drug manufacturers, repackagers, relabelers, and distributors attended.

## **Evaporated Milk Destroyed**

Thousands of cans of evaporated milk damaged in a fire were finally destroyed in January and February. A salvage dealer in Boston, Mass., Buy-Rite Co., received nearly 40,000 cases (48 cans each) of the milk from a warehouse fire in Marion, Ind., in November 1966. The fire damage was not serious, but the cases and labels were wet. Cleanup and relabeling were delayed so long that rusting and pinholing set in.

When redistribution started, complaints began to come in about swells, leaking cans, etc. The District examined samples and advised the States concerned that salvage was not possible. The Food Division of the Connecticut Department of Consumer Protection directed the roundup and destruction of more than 1,500 cases of the milk. The Maine Department of Agriculture supervised the recall and destruction of approximately 1,000 cases, and the Division of Food and Drugs of the Massachusetts Department of Health recovered and destroyed some 25,000 cases. The Division destroyed the cans by puncturing them and running over them with a bulldozer at the city dump.

**Mayonnaise Diverted** After the California Bureau of Food and Drug Inspections quarantined 37,596 pounds of mayonnaise because decomposed eggs had been used to make it, the product was diverted to nonfood use in April.

# 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 re reported by the FDA District Office.

A total of 79 seizure actions to remove adulterated, misbranded, and unsafe products from the consumer market were repted in March. These included 46 seizures of foods; 2 because of poisonous and deleterious substances, 36 be-

cause of contamination, and 8 because of economic violations. Other seizures included 11 of human drugs, 6 of veterinary drugs, 5 of medical devices, 3 of prophylactics, 1 of cosmetics, and 7 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>FOOD / Poisonous and Deleterious Substances</b>		
Eggs, frozen/Newport, R.I. 2/21/67 Providence, R.I. 2/16/67	J. Fleishman & Co., Inc./Roxbury, Mass. (S) "	Contain poisonous Salmonella micro-organisms. "
<b>Contamination, Spoilage, Insanitary Handling</b>		
Apples, diced, dehydr./Dunkirk, N.Y. 2/15/67	Petri Baking Products Co., Inc./Dunkirk, N.Y. (D)	Moldy.
Atmul 500 shortening/Kansas City, Kans. 3/9/67	Crissey Co./Kansas City, Kans. (D)	Held under insanitary conditions; insect contaminated.
Butter/Toledo, Ohio 12/30/66	Oscar Joseph Stores, Inc./Toledo, Ohio (D)	Moldy.
Cake Mixes/Springfield, Mass. 12/28/66	Hartford Dispatch & Warehouse Co., Inc. (D)	Held under insanitary conditions; rodent contaminated.
Che-Zing, grated Amer. cheese/Dallas, Tex. 2/27/67	Norris Dairy Products, Inc./Dallas, Tex. (D)	"
Eggs, frozen/Sparks, Nev. 12/7/66 Brooklyn, N.Y. 1/10/67	Nulaid Farmers Assn./San Leandro, Calif. (S) "	Decomposed. Decomposed.
Flour/Waynetown, Ind. 2/24/67	Boldt Milling Co., Inc./Waynetown, Ind. (D)	Held under insanitary conditions; rodent contaminated.
Tupelo, Miss. 2/13/67	J. J. Rogers & Sons/Tupelo, Miss. (D)	"
Wynne, Ark. 2/27/67	Wynne Wholesale Grocer Co./Wynne, Ark. (D)	"
Irvington, N.J. 2/20/67	Court Industrial Co./Irvington, N.J. (D)	"
Lewiston, Maine 2/28/67	Lewiston Auburn United Groceries/ Lewiston, Maine (D)	"
Mustard, ground/Mesa, Ariz. 1/5/67	Kadison Laboratories, Inc./San Francisco, Calif. (M, S)	Prepared and packed under insanitary conditions; ro- dent contaminated.
Oleomargarine/Bowling Green, Ky. 3/2/67	The Mar-Gold Corp./Atlanta, Ga. (M, S)	"
Peanut(s), shelled/Hopkins, Minn. 3/8/67	Johnson Nut Co./Hopkins, Minn. (D)	Held under insanitary conditions; rodent contaminated.
candy crunch/Portland, Maine 3/1/67	Matthews Candy Co./Dallas, Tex. (M, S)	Prepared and packed under insanitary conditions.
Peas and lima beans/Bowdon, Ga. 1/17/67	Roop Wholesale Grocery/Bowdon, Ga. (D)	Insect contaminated.
Pecan(s)/Norman, Okla. 2/20/67	Azar & Solomon/San Antonio, Tex. (P, S)	Prepared and packed under insanitary conditions.
shelled/Jackson, Tenn. 2/21/67	Roper Pecans Co./Hickman, Ky. (P, S)	" ; E. coli present.
St. Paul, Minn. 3/7/67	Wynnewood Pecan Co./Wynnewood, Okla. (P, S)	" "
pieces/Huntingdon, W. Va. 2/21/67	Roper Pecan Co./Hickman, Ky. (P, S)	" "
Apache, Okla. 2/15/67	Azar & Solomon/San Antonio, Tex. (P, S)	" "
Chicago, Ill. 2/15/67	Wynnewood Pecan Co./Wynnewood, Okla. (P, S)	" "
Chicago, Ill. 2/17/67	"	" "
Pinto beans, dried/Mesa, Ariz. 3/3/67	Rosarita Mexican Foods Co./Mesa, Ariz. (D)	Held under insanitary conditions; rodent contaminated.
Potatoes, fresh/Alexandria, La. 2/14/67	Noah's Potato Chip Co./Alexandria, La. (D)	" "
Sesame seed/Brooklyn, N.Y. 3/15/67	American Transportation Co./Brooklyn, N.Y. (D)	" ; insect contaminated.
Shrimp, frozen, breaded/Seattle, Wash. 1/18/67	Oceans of The World Western, Inc./South Pasadena, Calif. (P, S)	Prepared and packed under insanitary conditions; high bacterial count.
Columbus, Ohio 2/14/67	Ocean Products, Inc./Dover, Fla. (P, S)	"
Birmingham, Ala. 2/16/67	"	"
Seattle, Wash. 3/8/67	"	"
Manhattan, Kans. 2/2/67	Springdale Farms Service Co., Inc./ Springdale, Ark. (P, S)	"
frozen, blocks/Monroe, Wash. 2/20/67	East Point Seafood Co./Kodiak, Alaska (P, S)	"
Squash seeds, chestnuts/New York, N.Y. 2/24/67	A. L. Bazzini Co./New York, N.Y. (D)	Held under insanitary conditions; rodent contaminated.
Strawberries, frozen/Buffalo, N.Y. 3/6/67	Kelley Farquhar & Co./Puyallup, Wash. (P, S)	Decomposed.

# seizure actions

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>Contamination, Spoilage, Insanitary Handling (cont'd)</b>		
Walnut(s)/Joplin, Mo. 1/5/67 meats/Chicago, Ill. 3/1/67	Interstate Grocery Co./Joplin, Mo. (D) Oregon Filbert Growers, Inc./Salem, Oreg. (S)	Held under insanitary conditions; rodent contaminated. Prepared under insanitary conditions; E. coli present.
Wheat/Detroit, Mich. 1/18/67	Forrester Grain Co./Toledo, Ohio (S)	Rodent contaminated.
<b>Economic Violations</b>		
Butter, whipped/Cincinnati, Ohio 3/9/67 Fruit Drink Mixes (grape-orange-lemon)/ Hazelton, Pa. 2/16/67	National Cheese Co./Chicago, Ill. (M, S) Crystal Foods, Inc./Toms River, N.J. (M, S)	Short weight. Label statements "Fruit Drink made with true fruit juices" and "pre-sweetened with Sweet'n Low granu- lated sugar substitute" are false and misleading. Products are imitations without accurate weight statements.
Ice Cream Mix and Topping/Cincinnati, Ohio 3/9/67	Kenner Products, Inc./Cincinnati, Ohio (D)	Labels fail to bear "imitation" and accurate statement of quantity of content.
Oleomargarine/Bridgeville, Pa. 2/16/67	Old Dutch Foods, Inc./Blasdel, N.Y. (M, S)	Not in conformity with standards of identity for oleo- margarine; contains less than 80 percent fat.
Shrimp, canned/Stockton, Calif. 1/19/67	Whitney Fedaligo Sea Foods, Inc./Seattle, Wash. (P, S)	Broken pieces of shrimp have been substituted for whole shrimp as depicted on label.
Stockton, Calif. 1/11/67	Safeway Stores, Inc./Seattle, Wash. (S)	"
Strawberry Preserves and Raspberry Preserves/Albany, N.Y. 2/7/67	Produits Daimant/Quebec, Canada (M, S)	Fails to conform to definition and standard of iden- tity for fruit preserves; less than 45 parts of fruit.
Tomatoes, canned/Norfolk, Va. 2/17/67	John N. Wright, Jr., Inc./Federalburg, Md. (P, S)	Below standard of quality for canned tomatoes due to excess peel.
<b>DRUGS / Human Use</b>		
Aminophylline, rectal/Memphis, Tenn. 1/13/67	Denver Chemical Manufacturing Co./ Stamford, Conn. (M, S)	Below U.S.P. standard for strength; not in conformity with good manufacturing practice; inadequate direc- tions.
Cough Syrup/Laurel, Miss. 2/17/67	The Althena Co., Inc./Laurel, Miss. (D)	False and misleading claims for croup; inadequate warnings against use by young children.
& Decongestant/Los Angeles, Calif. 3/3/67	California Institutional Supply Co., Inc./ Los Angeles, Calif. (D)	Inadequate antihistamine warning; label fails to indi- cate "Temporary Relief."
Coranga Dressing/Donelson, Tenn. 1/31/67	Mar-Tay, Inc./Orlando, Fla. (M, S)	New drug not approved for safety and efficacy.
Curban "P" Caps/Pasadena, Calif. 2/2/67	Pasadena Research Labs./Pasadena, Calif. 2/2/67	Below labeled potency; deficient in dextro-amphet- amine HCl.
Enzyme Tablets (Acne Remedy)/Los Angeles, Calif. 1/17/67	Northwestern Pharmaceuticals/Los Angeles, Calif. (D)	Inadequate warnings against use.
Esplen/New York, N.Y. 2/28/67	Phoenix Pharmacal Co./New York, N.Y. (D)	New drug not approved for safety and efficacy.
Lincocin/Cincinnati, Ohio 10/27/66	The Upjohn Co./Kalamazoo, Mich. (M, S)	Not in conformity with regulations; does not state effectiveness, side effects, and contraindications.
Livferrvim Tablets, Phenobarbital Tablets, and Thyroid Tablets/Cedar Rapids, Iowa 2/10/67	Pilco Laboratories/Cedar Rapids, Iowa (D)	Below U.S.P. standard for quality and strength.
Parkalergy Tablets, Amphetamine Tablets, Geriatric Tablets, and Acetylsal 10 w/phenobarb./Wilmington, Del. 2/17/67	H. B. Park Pharmacal Co./Wilmington, Del. (D)	Below labeled potency; inadequate directions for use; inadequate warnings against misuse.
Potassium Iodide Tablets and A.P.C. Half Strength Tablets/Carthage, N.Y. 3/1/67	Fox Drug Co./Carthage, N.Y. (D)	Below U.S.P. standards; inadequate directions for use; inadequate warnings against use.
<b>Veterinary / Medicated Feed</b>		
Chick Feed Fortifier/Cheraw, Colo. 2/7/67	Farmland Industries, Inc./Cheraw, Colo. (D)	Not from certified batch; deficient in amprolium.
Golden Formula 100/Ipswich, Mass. 12/27/66	Rhinecliff Labs., Inc./Los Angeles, Calif. (M, S)	Antibiotic not certified for treatment of mastitis.
Mastitis Treatment/Belvidere, N.J. 3/16/67	Masti-Kure Products, Inc./Norwich, Conn. (S)	"
Mineral Feed Supplement Cobalt and Mineral Feed Supplement Manganese/ Ephrata, Pa. 2/17/67	Key Minerals Corp./Salt Lake City, Utah (M, S)	New drugs not approved for safety and efficacy; food additives not in conformity with regulations.
Poultry Formula Concentrate Myconox/ Center, Tex. 5/26/66	Naremcro, Inc./Springfield, Mo. (M, S)	Contains food additives not in conformity with regula- tions.
Premix/Bluffton, Ohio 2/17/67	Dr. Mayfield Labs./Charles City, Iowa (M, S)	Contains reserpine which is unsafe for use in drinking water of poultry; reserpine ingredient not declared.



## seizure actions

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>MEDICAL DEVICES</b>		
Drain Tubes/Muskegon, Mich. 2/24/67	Davol Rubber Co./Providence, R.I. (M, S)	Below labeled quality.
Orbit Kitten/Salt Lake City, Utah 2/2/67	Healthcraft Corp./Emeryville, Calif. (M, S)	False and misleading claims to keep the midriff trimmed, reduce size without reducing weight, relax tension of lower back muscles.
Osborn Super Jet Water Massage/Los Angeles, Calif. 11/23/66	Osborn Engineering Sales Corp./Los Angeles, Calif. (D)	False and misleading claims to stimulate blood circulation, relieve muscular ailments, treat nervous fatigue.
Sauna/Milwaukee, Wis. 9/28/66	Sauna Buffalo/Buffalo, N.Y. (M, S)	False and misleading claims to treat aches, taut nerves and tension, to lose or gain weight, improve sleep.
Steam Cabinet/Gainesville, Ga. 2/16/67	National Health System/Plymouth, Ind. (M, S)	Inadequate directions for use; inadequate warnings against use by elderly persons or those suffering from high blood pressure or heart disease.
<b>Prophylactics</b>		
Gold Dollar; Ritz/Kansas City, Mo. 1/12/67	Allied Latex Sales Co./Dothan, Ala., and Morgantown, W. Va. (M, S)	Defective; holes.
Rubber/Dallas, Tex. 2/27/67	Dean Rubber Co./North Kansas City, Mo. (M, S)	"
Charlotte, N.C. 3/10/67	"	"
<b>COSMETICS</b>		
Cinnamon Toothpicks/Stockton, Calif. 2/21/67	Baden's/Independence, Kans. (M, S)	Contain poisonous oil of cinnamon.
<b>HAZARDOUS SUBSTANCES</b>		
Dura Seal Renovator/St. Louis, Mo. 2/23/67	Pines International Chemical Co./Chicago, Ill. (M, S)	Lacks consumer protection information required by the Fed. Hazardous Substances Act.
Gun Blue/Richmond, Va. 1/26/67	C. S. Van Gordon & Son/Eau Claire, Wis. (M, S)	"
Hardener for Polyester Resins/Linden, N.J. 2/20/67	Glass Plastics Corp./Linden, N.J. (D)	"
Rag Dolls/Pasadena, Calif. 2/10/67	Cepelia Corp./New York, N.Y. (S)	Highly flammable.
Moonachie, N.J. 3/14/67	A. D. Sutton & Sons/New York, N.Y. (S)	"
Brooklyn, N.Y. 3/21/67	Imported from Poland	"
Spot Remover/Madison, Wis. 3/7/67	Superior Carpet Products, Inc./Hyde Park, Mass. (M, S)	"

## POST OFFICE DEPARTMENT

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

### Complaints Docketed Under 39 U.S.C. 4005 (Fraud)

April 6, 1967 (POD Docket No. 2/259): Marie Chantal Corp., New York, N.Y.  
Sale of "Sauna Slimming Underwear" advertised as a new way to reduce body weight; permit reduction around the waist, hips, thighs, or all over; that use of the garment will effectively and permanently overcome or cure obesity.

April 11, 1967 (POD Docket No. 2/260): The Con-Trol Co., and L. J. P. Products, Inc., New York, N.Y.  
The concerns advertised that their product "Con-Trol Cocktail" was a sensational breakthrough in weight reduction and the obese could lose "10-25-50 lbs." in a short period of time and would effectively cause weight reduction without the need for special foods, plans, or methods to follow.

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

March 21, 1967: Fraud Order No. 67-23, against Vodon Industries, P. O. Box 3121, Grand Central Station, New York, N.Y.  
Sale of "Voodoo Dolls" advertised as possessing mystical powers

with which the remitter could project good or evil and enable the choice of accomplishment in the areas of love, money, health, happiness, or success.

# notices of judgment

## NOTICES OF JUDGMENT on Seizure Actions

### FOOD / Poisonous and Deleterious Substances

#### Egg whites, frozen, and eggs, frozen, at Phoenix, Dist. Ariz.

Charged 7-25-66: while held by W. A. Bruce & Co., Phoenix, Ariz., the articles, prepared and packed by the dealer from eggs shipped in part in interstate commerce, contained the added poisonous and deleterious substance, *Salmonella* micro-organisms; 402(a)(1). Consent decree ordered destruction. (1)

#### Egg yolk solids product, dried, at Ottawa, N. Dist. Ill.

Charged 9-14-66: when shipped by Wenk Produce Co., Madison, S. Dak., the article labeled in part "Bud Brand Dried Egg Products Yolk Solids—Standard . . . Distributed by Anheuser-Busch, Inc. St. Louis, Mo." contained the added poisonous and deleterious substance, *Salmonella* micro-organisms; 402(a)(1). Consent decree authorized release to Anheuser-Busch, Inc., for reprocessing. (2)

#### Yeast, dried, hickory-smoked, at Miami, S. Dist. Fla.

Charged 7-7-66: when shipped by Bakon-Yeast, Inc., 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

#### Anchovy fillets, canned, Empress Brand, at Birmingham, N. Dist. Ala.

Charged 10-27-66: when shipped by Bien Trading Co., Inc., New York, N.Y., the article contained decomposed anchovy fillets; 402(a)(3). Default decree ordered destruction. (4)

#### Chilies, dried, at Tucson, Dist. Ariz.

Charged 8-9-66: while held for sale, the article contained insect filth and moldy chilies; 402(a)(3). Consent decree ordered destruction. (5)

#### Beans, Great Northern, dried and dried black-eyed peas, at Richmond and Petersburg, E. Dist. Va.

Charged 1-4-66: while held for sale, the articles contained insect filth, and had been held by Wm. R. Hill & Co., Richmond, Va., under insanitary conditions; 402(a)(3), 402(a)(4). Default decree authorized donation to public/charitable institution for use as animal feed. (6)

#### mung, Azuki beans, and rice, at Los Angeles, S. Dist. Calif.

Charged 1-31-66: while held by American Warehouse, Los Angeles, Calif., the articles contained insect and rodent filth, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Golden Jade Corp., t/a Kwong Dack Wo Co. and Roy Kito, t/a Fugetsu Do Candy Co., Los Angeles, Calif.; and Frank D. Fong, t/a Quong Fat Co., of San Francisco, Calif., for salvaging. (7)

#### mung and rice, at Brooklyn, E. Dist. N.Y.

Charged 7-28-65: while held by Asiatic Enterprises, Inc., Brooklyn, N.Y., the articles contained rodent filth and mold, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (8)

#### pinto, at Alma, W. Dist. Ark.

Charged 5-26-66: when shipped by Southwest Bean, Inc., Ulysses, Kans., the article had been packed and held under insanitary conditions; 402(a)(4). Consent decree authorized release to shipper for processing for seed or feed use. (9)

#### pinto, at Laredo, S. Dist. Tex.

Charged 6-24-66: while held for sale, the article contained rodent filth, and had been held under insanitary conditions at David M. Slaughter & Son, Inc., Laredo, Tex.; 402(a)(3), 402(a)(4). Consent decree authorized release to James Moore & Co., Laredo, Tex., for reconditioning. (10)

#### Candy, peppermint stick, at Dallas, N. Dist. Tex.

Charged 12-20-66: 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 decree ordered destruction. (11)

#### Mustard, ground, at Mesa, Dist. Ariz.

Charged 12-27-66: when shipped by Kadison Labs., Inc., San Francisco, Calif., the article contained rodent filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (12)

#### Peanuts, shelled, at Albany, M. Dist. Ga.

Charged 2-11-66: when shipped by Gold Kist Peanut Growers (Div. of Cotton Producers Association), Graceville, Fla., the article contained insect filth; 402(a)(3). Consent decree authorized release to shipper for reconditioning. (13)

#### Pecans, unshelled, at Chicago, N. Dist. Ill.

Charged 4-25-66: when shipped by Troy Simms Pecan Co., Dothan, Ala., the article contained rancid and moldy nuts and empty shells; 402(a)(3). Consent decree authorized release to Abe Fowler & Sons, Inc., Vicksburg, Miss., for reconditioning. (14)

#### Pecans, unshelled, at East Peoria, S. Dist. Ill.

Charged 12-3-65: when shipped by Randall Nut Co., Nashville, Tenn., the article contained moldy, rancid, and decomposed nuts; 402(a)(3). Consent decree authorized release to shipper for salvaging. (15)

#### Soybeans, at San Francisco, N. Dist. Calif.

Charged 3-15-66: while held by Haslett Warehouse Co., San Francisco, Calif., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Wo Hop Co. of San Francisco, Calif., for salvaging. (16)

#### Whale meat and herring roe combination, frozen, Ajinomoto Iso-No-Kaori Brand, at Los Angeles, C. Dist. Calif.

Charged 10-7-66: when shipped by Canadian Seafood Co., Vancouver, Canada, the article contained *E. coli* and bacterial filth; 402(a)(3). Default decree ordered destruction. (17)

### FOOD / Economic Violations

#### Crabs, deviled, frozen, Frosty Brand, at Raleigh, E. Dist. N.C.

Charged on or about 7-8-66 and amended 7-29-66: when shipped by Mr. Frosty Seafoods, Inc., Newport News, Va., the article was short weight, and its labeling was false and misleading, since flounder fish had been substituted in part for crabmeat; 403(e)(2), 403(a), 402(b)(2). Default decree ordered destruction or donation to private/charitable institution. (18)

#### Milk, nonfat, dry, at Aurora, W. Dist. Mo.

Charged 4-11-66: when shipped by H. C. Christians Co., Chicago, Ill., another substance had been substituted for the article, and the labeling was false and misleading as to contents; 402(b)(2), 403(a). Consent decree authorized release to shipper for use as animal feed. (19)

#### Olives, ripe, canned, at New Rochelle, S. Dist. N.Y.

Charged 8-24-66: when shipped by Oberti Olive Co., Div. of Tri-Valley Growers, Madera, Calif., the article labeled in part "Black California Ripe Olives . . . Distributed by Sweet Life Brands, Inc., New York, N.Y. . . . contains approximately 46 olives" was short drained weight (approx. 4.67 percent) and was short in unit count (approx. 37.2 percent); 403(e)(2). Default decree authorized donation to public/charitable institution. (20)

#### Peach halves, canned, Miss Georgia, at Haynesville, W. Dist. La.

Charged 10-13-66: when shipped by Besco Products Co., Zebulon, Ga., the label lacked the name of the packing medium present, since the label stated "Packed in Heavy Syrup" and the article was packed in light syrup; 403(g)(2). Default decree ordered destruction or donation to public/charitable institution. (21)

#### Preserves, imitation strawberry, at Minneapolis, Dist. Minn.

Charged 11-15-65: when shipped by Paul Mark, Inc., Fargo, N.D., the article was short weight (approx. 3 percent); 403(e)(2). Default decree authorized release to shipper for relabeling. (22)

#### Tomatoes, canned, at Cincinnati, S. Dist. Ohio.

Charged 10-11-66: when shipped by Milroy Canning Co., Inc., Milroy, Ind., the article labeled in part "Canned tomatoes . . . Little Skipper . . . Distributed by Pilot Stores, Inc., Cincinnati 12, Ohio" contained excess peel; 403(h)(1). Default decree ordered donation to public/charitable institution. (23)

#### canned, American Beauty, at Lexington, E. Dist. Ky.

Charged 10-4-66: when shipped by Morgan Packing Co., Inc., Austin, Ind., the article contained excess peel; 403(h)(1). Default decree ordered donation to public/charitable institution. (24)

#### canned, Favorite Brand, at Tupelo, N. Dist. Miss.

Charged 11-16-63: when shipped by Manchester Canning Co., Inc., Nashville, Tenn., the article contained excess peel; 403(h)(1). After removal of the case to W. Dist. Tenn., consent decree authorized release to shipper for relabeling. (25)

### FOOD ADDITIVES

#### Eaton's vitamin and mineral products, phenobarbital tablets, and stilbestrol tablets, at Salem, Dist. Mass.

Charged 3-12-65: while held by Grosvenor Laboratories, Salem, Mass., the vitamin and mineral products, packed by the dealer after shipment in interstate commerce, lacked required information for special dietary uses; all of the vitamin and mineral products, except Konealed multivitamin tablets, contained a nonconforming food additive, folic acid; the labeling of the Konealed B-Plus vitamin and mineral capsules, and the Konealed B-Plus vitamin capsules contained false and misleading implications of nutritional value for certain ingredients; 403(j), 402(a)(2)(C), 403(a). The labeling of phenobarbital tablets and the stilbestrol tablets, packed by the dealer after shipment in interstate commerce, lacked adequate directions and information for use; the labels lacked the prescription legend; and the label of the phenobarbital tablets lacked the name and address of the manufacturer, packer, or distributor, and lacked "Warning—May be habit forming"; 502(f)(1), 503(b)(4), 502(b)(1), 502(d). Default decree ordered destruction. (26)

#### Hibexin vitamin B tablets, Isocap multivitamin tablets, Kontax athlete's foot liquid, Optorex eyedrops, and Spanorex appetite depressant capsules, at Paducah, W. Dist. Ky.

Charged 11-4-64: while held by W. G. Lamb Wholesale, Inc., Paducah, Ky., the Hibexin and Isocap tablets contained the nonconforming food additive folic acid; the valuable constituent ascorbic acid had been in part omitted or abstracted from the Hibexin tablets (22 percent deficiency); the label of the Spanorex capsules contained false and misleading weight-reduction claims; the labeling of the Kontax liquid lacked adequate directions for use; and the labeling of the eyedrops lacked adequate warnings; 402(a)(2)(C), 409, 402(b)(1), 502(a), 502(f)(1), 502(f)(2). Default decree ordered destruction. (27)

#### Ice balls and ice elephants, plastic, at Los Angeles, S. Dist. Calif.

Charged 8-16-66: when shipped by Hiraoka & Co., Ltd., Tokyo, Japan, and by an unknown shipper, Hong Kong, China, the articles were nonconforming food additives, since the plastic was easily punctured or cracked and the fluid within contained viable micro-organisms and miscellaneous debris; 402(a)(2)(C), 409. Default decree ordered destruction. (28)

#### Ice balls, plastic, Frosty Drink, at Chicago, N. Dist. Ill.

Charged 6-9-66: when shipped by South Sea Trading Co., Ltd., Hong Kong, China, the article labeled in part "Frosty Drink Coolers . . . water is inside . . . Unique Products, Chicago, Ill." was a nonconforming food additive (the article was a thin, leaking in part, easily punctured, hollow plastic ball containing a fluid of miscellaneous debris and viable micro-organisms); 402(a)(2)(C). Default decree ordered destruction. (29)

#### Par-Li-Cin liver and vitamin tablets, at Glendale, S. Dist. Calif.

Charged 10-26-64: when shipped by Lanpar Co., Dallas, Tex., the article contained the nonconforming food additive, folic acid; the labeling contained a false and misleading nutritional claim; and the label lacked required spe-



cial dietary use information; 402(a)(2)(C), 409, 403(a), 403(j). Consent decree authorized release to shipper for reconditioning. (30)

#### VITAMINS / DIETARY FOODS

**Bio-Sal Trace Mineral Salt tablets and mineral salts**, at Watertown, W. Dist. Wis. Charged 2-11-65: while held for sale by G. G. Schneider & Son, Watertown, Wis., the labeling of the mineral salts which had been shipped in interstate commerce and the tablets manufactured by the dealer from such mineral salts, was false and misleading in claiming that the articles were of special nutritive value for providing trace mineral salts to the human diet; and the labeling lacked adequate directions for use for such diseases as cancer, arthritis, ulcers, etc., for which the articles were represented by the dealer; 403(a), 502(f)(1). Default decree ordered destruction. (31)

**Dietary supplement tablets, Ferrolip OB**, at Morton Grove, N. Dist. Ill. Charged 1-3-66: when shipped by Baxter Laboratories, Inc., Mountain Home, Ark., the labeling was false and misleading as to the proportion of calcium for pregnant or lactating women supplied by the article, and the labeling lacked required information concerning the minimum daily requirements of vitamins and minerals; 403(a), 403(j). Default decree authorized donation to private/charitable institution. (32)

**Energy Plus multivitamin and mineral tablets**, at Tempe, Dist. Ariz. Charged 4-16-65: when shipped by Pharmaceutical Research Corp., Buena Park, Calif., the labeling contained false and misleading claims for certain ingredients, false and misleading statements of nutritional fact, and false and misleading therapeutic claims; and, while held for sale, vitamin B<sub>12</sub> had been in part omitted or abstracted and the label was false and misleading as to strength, since the article lacked vitamin B<sub>12</sub> (approx. 21 percent); 403(a), 502(a), 402(b)(1), 403(a). Default decree ordered delivery of tablets to public/charitable institution and destruction of the accompanying labeling. (33)

**La Tonic tonic, Lanatal tablets, Repaheme tablets, and La Vite tablets**, at Shreveport, W. Dist. La. Charged 4-22-66: while held for sale, the La Tonic tonic and Lanatal tablets were deficient and the labels false and misleading as to strength, since the La Tonic tonic lacked vitamin B<sub>1</sub> (approx. 50 percent) and vitamin B<sub>2</sub> (approx. 58 percent), and the Lanatal tablets lacked ascorbic acid (approx. 79 percent) and vitamin B<sub>1</sub> (approx. 80 percent); the Repaheme tablets were prescription drugs due to their folic acid content and lacked the prescription legend; and the La Vite tablets had had vitamin B<sub>1</sub> omitted or abstracted and the label was false and misleading as to vitamin B<sub>1</sub> content, since the article was deficient (approx. 87 percent); 501(c), 502(a), 503(b)(4), 402(b)(1), 403(a). Default decree ordered destruction. (34)

**Vitamin-mineral tablets**, at Pikeville, E. Dist. N.C. Charged 8-19-66: while held for sale, the valuable constituent, vitamin B<sub>1</sub> had been omitted or abstracted, and the labeling was false and misleading as to vitamin B<sub>1</sub> content (approx. 33 percent deficiency) and was false and misleading in denying that the needs for certain specified minerals in human nutrition had been established; 402(b)(1), 403(a). Default decree ordered destruction. (35)

**Wate-On liquid and Super Wate-On liquid**, at Stamford, Dist. Conn. Charged 11-3-62 and amended 3-15-65: when shipped by the Fleetwood Co., Chicago, Ill., the articles lacked required special dietary information, and the labeling contained false and misleading therapeutic claims including weight-gaining claims; 403(j), 502(a). After contest by the shipper and removal to E. Dist. Mo., for trial, the label was amended upon motion of the Government. Upon consent, the court ordered condemnation and destruction of the articles. (36)

#### ANIMAL FEEDS

**Medicated feed**, at Waterloo, N. Dist. Iowa. Charged 11-15-65: while held by Geerlings Feed Mills, Inc., Waterloo, Iowa, the article, manufactured by the dealer from diethylstilbestrol shipped in interstate commerce, was deficient in strength and the article's label was false and misleading as to strength, since the article lacked diethylstilbestrol (approx. 35 percent); 501(c), 502(a). Consent decree authorized release to the dealer for relabeling. (37)

**Medicated feed, Nishna-Valley Brand**, at Harlan, S. Dist. Iowa. Charged 1-21-66: while held by Farm Service Cooperative, Harlan, Iowa, the strength of the article, which had been manufactured by the dealer from a premix drug shipped in interstate commerce, was deficient and its labeling false and misleading as to amount and efficacy, since the article was deficient (approx. 30 percent) in diethylstilbestrol; 501(c), 502(a). Default decree ordered destruction. (38)

**Medicated feed mix**, at Chappell, Dist. Nebr. Charged 4-12-66: when shipped by Feed Products, Inc., Denver, Colo., the article contained the food additive oxytetracycline in combination with sulfamethazine and penicillin, intended for mixing with swine feed, and its intended use was nonconforming; and oxytetracycline had been substituted wholly or in part for sulfamethazine; 402(a)(2)(C), 409, 501(d)(2). Default decree ordered destruction. (39)

#### DRUGS / Human Use

**Acnevol vitamin A-combination capsules**, at Cleveland, N. Dist. Ohio. Charged 8-7-64: while held by Ro-Mar Products Co., Cleveland, Ohio, the name "Acnevol" and the article's labeling contained false and misleading claims concerning treatment of acne; 502(a). Consent decree authorized release to Ro-Mar Products Co., for relabeling. (40)

**Allergimist solutions A and B**, at Atlanta, N. Dist. Ga. Charged 4-18-66: when shipped by the Brunson Corp., Miami Springs, Fla., the articles were new drugs without effective New Drug Applications; 505(a). Default decree ordered destruction. (41)

**A. T. A. amphetamine-combination tablets**, at Fresno, S. Dist. Calif.

Charged 4-1-66: while held by H. R. Cenci Pharmacal Co., Fresno, Calif., the article, which had been manufactured by the dealer from ingredients shipped in interstate commerce, was overstrength and its labeling false and misleading, since it contained more than the declared 1 gr. thyroid; and the article lacked adequate directions and information for its use; 501(c), 502(a), 502(f)(1). Default decree ordered destruction. (42)

**Amphetamine and barbiturate tablets and capsules**, at Fort Worth, N. Dist. Tex. Charged 10-1-66: while held by Dorothy V. Moody, t/a Staggs Pharmacy, Fort Worth, Tex., a prohibited act had occurred with respect to the articles, since they were in the dealer's possession for sale, without a prescription, outside the ordinary and authorized course of her business; 301(a)(3). Default decree ordered destruction. (43)

**Amphetamine sulfate tablets**, at Philadelphia, E. Dist. Pa. Charged 9-14-65: while held by Richard L. Nelson, Philadelphia, Pa., the labeling lacked adequate directions for use and the articles were not exempt therefrom since they were not possessed by a regular and lawful dealer in prescription drugs, and were not to be dispensed upon prescription; 502(f)(1). Default decree authorized release to FDA. (44)

**Antibiotics, insulin, barbiturates, and other prescription and nonprescription drugs**, at Minneapolis, Dist. Minn. Charged 6-4-65: while held by Western Salvage & Appraisal, Minneapolis, Minn., after being damaged in a tornado at Fridley, Minn., the articles had, thereby, been held under insanitary conditions; some articles were unlabeled, since the labels were washed free; and some labels were rendered inconspicuous, due to rain damage; 501(a)(2)(A), 502(b)(1&2), 502(e)(1)(A)(i), 502(f)(1), 502(c). Consent decree authorized destruction. (45)

**Bio-Gen 8 Beauty Masque liquid**, at Milwaukee, E. Dist. Wis. Charged 5-27-65: when shipped by Face Up, Inc., Chicago, Ill., the article was a new drug without an effective New Drug Application; its accompanying labeling contained false and misleading therapeutic claims; and its label lacked the established name of each active ingredient; 505(a), 502(a), 502(e)(1)(A)(ii). Default decree ordered destruction. (46)

**Biohydron antihistamine-analgesic-compound tablets**, at Landover, Dist. Md. Charged 7-14-65: when shipped by Hance Bros. & White Co., Philadelphia, Pa., the quality of the article labeled in part "Biohydron . . . Prepared Expressly for Kent Pharmacal Co., Wilmington, Del." was deficient, since the article would not disintegrate rapidly enough to afford relief within 3 hours, as implied and suggested by its dosage recommendation; 501(c). Default decree ordered destruction. (47)

**Col-Pac 12 antihistamine timed-disintegration capsules**, at Rochester, W. Dist. N.Y. Charged 8-13-64 and amended 8-26-64: while held for sale, the labeling of the article, packed by Approved Pharmaceutical Corp., Syracuse, N.Y., after shipment in interstate commerce, contained false and misleading representations of 12 hours of continuous relief per capsule; 502(a). Default decree ordered destruction. (48)

**Diethylstilbestrol tablets, enteric-coated, U.S.P.**, at Fairfield, Dist. Conn. Charged on or about 7-1-66: while held by McKesson Laboratories, Fairfield, Conn., who had packed the article from bulk, the article's quality was deficient, since it failed the U.S.P. disintegration test; and the article lacked the required name of manufacturer, packer, or distributor, since the label bore the unqualified name "McKesson Laboratories"; 501(b), 502(b)(1). Consent decree ordered destruction. (49)

**Herb tablets, herb teas, and bulk herb mixes**, at Quincy, Dist. Mass. Charged 11-23-64: while held by Puregrade Health Products, Quincy, Mass., the labeling of the herb mixes, which had been shipped in interstate commerce, and the tablets and teas repacked and labeled from such herb mixes, contained false and misleading therapeutic claims, and lacked adequate directions for the articles' intended uses; 502(a), 502(f)(1). Default decree ordered destruction. (50)

**Khorion chorionic gonadotropin and Khorion diluent**, at Houston, S. Dist. Tex. Charged 5-10-66: when shipped by Maizel Laboratories, Inc., Chicago, Ill., and while held by Dow B. Hickman, Inc., Houston, Tex., the accompanying carton inserts supplied by the shipper and inserted into the cartons by the dealer contained false and misleading therapeutic claims; and the labeling lacked adequate directions or information for such claimed therapeutic uses; 502(a), 502(f)(1). Default decree ordered destruction. (51)

**Manning's calomel cathartics, Whoa liniment, herbal remedies, and bulk ingredients**, at Bessemer, N. Dist. Ala. Charged 11-23-64: while held by Donald R. Manning, t/a Manning Botanical Physical Therapy Clinic, Bessemer, Ala., the labeling of some of the articles (some of which were manufactured and packaged by the dealer from the bulk ingredients shipped in interstate commerce) lacked adequate directions for use for their intended uses, and the labeling of some of the articles lacked adequate warnings against dangerous and unsafe uses; Humming Bee cascara sagrada herbal-combination drops lacked a label containing the name and place of business of the manufacturer, packer, or distributor; and the labels of Bi-Lax calomel-combination capsules and Humco calomel cathartic lacked the established name of each active ingredient, and lacked the quantity of the mercury derivative therein; 502(f)(1), 502(f)(2), 502(b)(1), 502(e)(1)(A)(ii). Default decree ordered destruction. (52)

**Medical Fluid 360**, at Dallas, N. Dist. Tex. Charged 5-10-65: when shipped by Dow Corning Corp., Midland, Mich., the article lacked an effective New Drug Application and was not exempt therefrom, and the labeling of the article lacked adequate directions for its intended use (injection into female patients for breast augmentation); 505(a), 502(f)(1). After claim and contest by Keene Pharmacal Co., Dallas, Tex., the court entered a decree of summary judgment in favor of the Government and ordered the article destroyed. (53)

**Niapon dipyrone tablets**, at El Paso, W. Dist. Tex.

Charged 9-22-66: when shipped by Private Formulae, Inc., St. Louis, Mo., the article labeled in part "Niapon . . . Dipyrone . . . Distributed by Mercury Pharmaceutical Co., El Paso, Texas" was a new drug without an effective New Drug Application; and lacked adequate directions and information for use for all its intended purposes; and was dangerous to health, when used as directed; 505(a), 502(f)(1), 502(j). Default decree ordered destruction. (54)

**Papavatrul L-A pentaerythritol tetranitrate capsules**, at Van Nuys, Rosemead, and Anaheim, S. Dist. Calif.

Charged 2-9-66: when shipped by Kenwood Laboratories, Inc., New Rochelle, N.Y., the article was a new drug without an effective New Drug Application; 505(a). Default decree ordered destruction. (55)

**Surgical sutures, absorbable and unabsorbable, U.S.P.**, at Columbus, S. Dist. Ohio.

Charged 7-19-63 and amended 11-6-63: while held by Underwriters Salvage Co., Columbus, Ohio, after salvage from a local, fire-damaged drug store, the articles lacked the prescribed labels, since the labels had been unrecognizably burned and charred; 502(g). Default decree ordered destruction. (56)

#### MEDICAL DEVICES

**Diabetest urine-sugar test paper**, at New York, S. Dist. N.Y.

Charged 10-14-65: when shipped by The Diabetest Co., Webster, Mass., the quality of the article was deficient (approx. 30 percent failed to indicate presence of 0.1 percent sugar); 501(c). Default decree ordered destruction. (57)

**urine-sugar test paper**, at Providence, Dist. R.I.

Charged on or about 10-20-65: when shipped by Moore Kirk Laboratories, Inc., Worcester, Mass., the quality of the article labeled in part "Diabetest A Self-Test Method for Urine Sugar . . . The Diabetest Co. . . . Webster, Mass." was deficient (approx. 40 percent failed to indicate presence of 0.1 percent sugar); 501(c). Default decree ordered destruction. (58)

**Gloves, surgical**, at Riverside, Dist. N.J.

Charged 11-1-65: while held for sale, the quality of the article was deficient, and the labeling was false and misleading as to sterility, since the article contained mold; 501(c), 502(a). Consent decree authorized release to B. F. Goodrich Co., Riverside, N.J., for relabeling. (59)

**surgical, sterile, disposable**, at Willard, N. Dist. Ohio.

Charged 11-12-65: when shipped by Electronized Chemical Corp., Burlington, Mass., the article was deficient in quality, and its label was false and misleading as to sterility, since the article contained viable microorganisms; 501(c), 502(a). Consent decree authorized release to Pioneer Rubber Co., Willard, Ohio, for sterilizing and repackaging. (60)

**Olympus Whirlpool Bath aerator and circulator**, at Denver, Dist. Colo.

Charged 1-12-66: when shipped by Sales Research Development Co., Bountiful, Utah, the accompanying sales manuals and booklets contained false and misleading therapeutic claims; 502(a). Default decree authorized release to FDA. (61)

**Saratoga Hydro-Air Massage**, at Omaha, Dist. Nebr.

Charged 2-28-64: while held by True Value Productions, Inc., Omaha, Nebr., the labeling used by the dealer contained false and misleading therapeutic claims; 502(a). Consent decree authorized release to Cascade Products Co., McHenry, Ill., for relabeling. (62)

**Vapozone steam, ozone, and ion generator**, at Detroit, E. Dist. Mich.

Charged 9-15-64: when shipped by Carl Ronzi, Zurich, Switzerland, and while held by Vapozone Corp., Detroit, Mich., the labeling supplied by the shipper and reprinted by the dealer contained false and misleading therapeutic claims, and lacked adequate directions for use; 502(a), 502(f)(1). Consent decree authorized release to dealer for relabeling. (63)

#### HAZARDOUS SUBSTANCES

**Cracker Ball ball-type explosive caps**, 9 seizure actions at Seagoville, N. Dist. Tex., Enid, W. Dist. Okla., Norfolk, E. Dist. Va., Kansas City, Dist. Kans., Lincoln, Dist. Nebr., St. Joseph, W. Dist. Mo., and Denver, Dist. Colo.

Charged between 6-15-66 and 6-24-66: when shipped by Marutamaya Ogatsu Fireworks Co., Ltd., Onda Enterprises, Ltd., S. Mantsuna & Co., Ltd., Yaguchi Trading Co., Ltd., Yokohama and Tokyo, Japan, and unknown shippers in Taiwan and Japan, the articles were extremely flammable solid substances that generated pressure through explosion when subjected to friction or to percussion; and their containers lacked required conspicuous label statements; 2(p)(1)(A,C,E,F,I&J). Consent decree in action in W. Dist. Mo., ordered destruction. Default decrees in other actions ordered destruction. (64)

**Etching cream, Etchall Miracle**, at Baltimore, Dist. Md.

Charged on or about 6-28-65: when shipped by Etchall, Inc., Columbia, Mo., the article was a corrosive substance containing ammonium bifluoride (approx. 28 percent) and tubes containing it lacked required conspicuous label statements; the placement of label information was not at the dispensing end of the tube as required; and the outside cartons and accompanying literature lacked required information; 2(p)(1)(B,F&J), 2(p)(2), 2(n), 2(p)(1)(B,C,E,F,G&J). Default decree ordered destruction. (65)

**Floor wax, Dura Sheen**, at West Lawn, E. Dist. Pa.

Charged 7-28-66: when shipped by Pines International Chemical Co., Chicago, Ill., the article was a toxic substance presenting a special hazard because of its petroleum distillate content (approx. 22 percent), and its containers lacked a number of the required conspicuous label statements; 2(p)(1)(B,F&J), 3(b). Default decree ordered destruction. (66)

**Liquid locomotive smoke and electric train sets**, at Girard, W. Dist. Pa.

Charged 5-26-66 and amended 6-15-66: while held by Girard Manufacturing Co., Girard, Pa., the liquid smoke which was bottled by the dealer after shipment in interstate commerce and labeled in part "Marx Locomotive

Smoke . . . Louis Marx & Co., Inc. . . . New York" and "Electric Train Set by Marx . . . A Complete Set . . . Heavy duty Steam-Type Smoking Locomotive . . . Louis Marx & Co., Inc., Girard, Pa." was a toxic substance presenting a special hazard because of its petroleum distillate content, and its containers lacked a number of the required conspicuous label statements; 2(p)(1)(B,F&J), 3(b). Consent decree authorized release to the dealer of the electric train sets after dealer's segregation of the liquid smoke. A default decree ordered destruction of the liquid smoke. (67)

**Paint thinner, C & H**, at Atlanta, N. Dist. Ga.

Charged 8-22-66: while held by Cheatham Chemical Co., Inc., Atlanta, Ga., the article, packed by the dealer after shipment in interstate commerce, was a toxic substance presenting a special hazard because of its petroleum distillate content, and its containers lacked a number of the required conspicuous label statements; 3(b). Consent decree authorized release to dealer for relabeling. (68)

**Roof coating, Ultra-Bright**, at Atlanta, N. Dist. Ga.

Charged on or about 7-7-66: when shipped by Gardner Asphalt Products, Tampa, Fla., the article was a toxic substance presenting a special hazard because of its petroleum distillate content, and its containers lacked a number of the required conspicuous label statements; 2(p)(1)(B,F&J), 3(b). Default decree ordered destruction. (69)

**Rug spray**, at East Point, N. Dist. Ga.

Charged 7-7-66: when shipped by Lenox Chemicals, Ltd., New Hyde Park, N.Y., the article, labeled in part "Spray For Step-Off Rugs . . . Selling Agent Iselin Jefferson Co., Inc., New York, N.Y." was a flammable substance, and its containers lacked a number of the required conspicuous label statements; 2(p)(1)(E&F). Default decree ordered destruction. (70)

**Solder flux, Sal-Met**, at Los Angeles, S. Dist. Calif.

Charged 8-2-66: when shipped by Hascol Enterprises, Sharon, Pa., the article was a toxic and corrosive substance, and its containers lacked a number of the required conspicuous label statements; 2(p)(1)(B,C,E,F&G). Default decree ordered destruction. (71)

**Water repellent, X-33**, 18 seizure actions at Galesville, W. Dist. Wis., Cohasset, Dist. Mass., North Little Rock, E. Dist. Ark., Leola, Aberdeen, and Vermilion, Dist. S. Dak., Silver City, Dist. N. Mex., Kellerton and Shannon City, S. Dist. Iowa, Alta, Dedham, Cherokee, Truesdale, Rockwell City, Sutherland, Laurens, and Larchwood, N. Dist. Iowa, and Winona, N. Dist. Miss.

Charged between 3-31-64 and 7-23-65: when shipped by Wilmington Chemical Corp., Chicago, Ill., the article was an extremely flammable substance, and its containers lacked required conspicuous label statements; 2(p)(1)(E,F&I). Consent decrees authorized release of two lots for relabeling to Beaver Builders Supply, Inc., Galesville, Wis., and to John Dunaway, North Little Rock, Ark. A consent decree ordered destruction of one lot, and default decrees ordered destruction of remainder. (72)

#### NOTICES OF JUDGMENT on Criminal Cases

##### FOOD

**C. Economou Cheese Corp.**, and **Costas Economou**, president, Hinesburg, Dist. Vt.

Charged 3-12-64: when shipped, grated cheese labeled in part "Romanello Cheese Mfg By Economou Cheese Corp., Hinesburg, Vt." and "Capri Brand Grated Cheese Packed By International Cheese Co., Inc., Shelburne, Vt." contained rodent and insect filth, and had been prepared under insanitary conditions; 402(a)(3), 402(a)(4). Guilty pleas; fines. (73)

**Kroger Co.**, **Alois F. Moellenberg**, institutional manager, and **Herrin D. Hill**, warehousing manager, Houston, S. Dist. Tex.

Charged 11-17-66: egg noodles and flour were held and stored in a building accessible to insects whereby the article might become contaminated with insect filth; 402(a)(4). Nolo contendere pleas; fines. (74)

**Mazzola Bros. Bakery Trust**, Newton, Dist. Mass.

Charged 10-31-66: flour was held in a building accessible to insects and contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (75)

**R.G.B. Laboratories, Inc.**, **Presto Food Products, Inc.**, and **Richard G. Bourne**, president, Kansas City, W. Dist. Mo.

Charged 9-4-64: when shipped, a beverage labeled in part "Allerjoy . . . For Milk-Free Diets" had had the valuable constituent, vegetable protein, omitted or abstracted; the labeling contained false and misleading statements as to amount of vegetable protein content and false and misleading therapeutic and dietary claims, including replacement for milk in the diets of infants and others; and the article's labeling lacked required special dietary information; 402(b)(1), 403(a), 403(j). Not guilty pleas; verdict by jury of not guilty. (76)

**G. Santoro & Sons, Inc.**, and **Joseph Signorelli**, secretary-treasurer, Brooklyn, E. Dist. N.Y.

Charged 7-29-65 by grand jury: when shipped, elbow macaroni contained insect filth, and had been prepared under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Guilty plea by individual; probation. (77)

##### DRUGS

**Chester E. Ball**, musician, Akron, N. Dist. Ohio.

Charged 10-12-65: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; probation. (78)

**Alice C. Bieberman**, also known as **Lisa Bieberman**, graduate student, Boston Dist. Mass.

Charged 5-31-66: when shipped, sugar cubes containing LSD were a new drug without an effective New Drug Application; the label lacked the established name of the drug; and the labeling lacked adequate directions for use and adequate warnings against dangerous and unsafe use; 505(a), 502(e)(1)(A)(i), 502(f)(1&2). Not guilty pleas. After trial by court; imprisonment suspended, probation. (79)

**John L. Burkart**, t/a **Wilsey-Burkart Drug Store**, South Bend, N. Dist. Ind.

Charged 7-11-66: dextro-amphetamine sulfate tablets and penicillin tablets



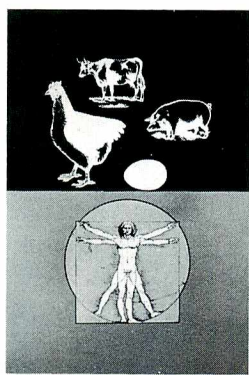
- were dispensed as unauthorized refills; 503(b)(1). Guilty plea; probation. (80)
- Eugene L. Cohen**, Philadelphia, E. Dist. Pa.  
Charged on or about 8-29-61 as violation of probation: assay reports were issued upon a number of types of caffeine-containing analgesic tablets, a codeine-type cough syrup, thyroid-containing tablets, a barbiturate elixir, and strychnine-containing tablets; and certain assay results were not obtained from any assay operations actually performed, contrary to the conditions of probation (D.O.N.J. 5972). After a hearing, the court imposed a fine, extended the term of defendant's probation, and extended the specified conditions of the probation to cover not only drugs, but foods, cosmetics, and hazardous substances. (81)
- Eddie Deno Collier**, Des Moines, S. Dist. Iowa.  
Charged 1-28-66 by grand jury: tablets containing amobarbital and dextro-amphetamine sulfate, methamphetamine hydrochloride tablets, dextro-amphetamine sulfate tablets, and amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment, plus costs. (82)
- John E. Cordova**, Fort Worth, N. Dist. Tex.  
Charged 10-12-65: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment. (83)
- Archie Goad**, truck-stop operator, Winslow, W. Dist. Ark.  
Charged 5-6-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; probation. (84)
- Josey-Miller Co., Inc.**, Beaumont, E. Dist. Tex.  
Charged 7-14-65: when shipped, Ideal Brand growing mash, a medicated feed, was deficient in sulfaquinoxaline; 501(c). Nolo contendere plea; fine and probation. (85)
- George Lee**, and **Booker T. Metcalf**, truck stop employees, Dallas, N. Dist. Tex.  
Charged 6-27-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea by Lee; imprisonment suspended, probation. Not guilty plea by Metcalf; after trial by court and jury, verdict of guilty; imprisonment suspended, probation. (86)
- William B. Mandell**, t/a Mandell Pharmaceuticals, Irvington, Dist. N.J.  
Charged 2-17-66: refusal to permit FDA inspection of all things relating to prescription drugs, as authorized by law, in a registered establishment in which prescription drugs were being held; 704(a). Not guilty plea. After presentation of Government's evidence before court and jury, the court entered a judgment of acquittal, based on failure of Government's evidence concerning whether the records, allegedly refused, had a bearing on a violation of the law. (87)
- June F. McFall**, Detroit, E. Dist. Mich.  
Charged 11-10-65: when shipped, amphetamine sulfate tablets were dispensed without a prescription and the labeling failed to bear adequate directions for their intended use; 502(f)(1), 503(b)(1). Guilty plea; imprisonment suspended, probation. (88)
- Raymond Mitchell**, truck-stop operator, Jane, W. Dist. Mo.  
Charged 5-17-66: dextro-amphetamine sulfate combination capsules were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment, fine, probation. (89)
- James M. Mullins**, service station employee, and **Robert Gulley**, truck driver, Cincinnati, S. Dist. Ohio.  
Charged 6-6-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea by Mullins; probation. Guilty plea by Gulley; imprisonment, probation. (90)
- John K. Newton**, Minneapolis, Dist. Minn.  
Charged 5-17-66: when shipped, amphetamine capsules and Biphetamine capsules were dispensed without a prescription; 503(b)(1). Not guilty plea. The defendant moved to suppress statements and admissions made at a hearing held pursuant to 21 U.S.C. 335, on the basis that the statements and admissions were involuntary because they were made as a result of a promise of immunity from prosecution or under the belief that they would not be used in evidence against him. The defendant relied upon the Notice of Hearing information sheet to support his contentions. In denying the motion, the court said: "There is, however, nothing in the information sheet which suggests that by giving information, immunity from prosecution would ensue," and the court distinguished the present case and *Shotwell Manufacturing Co. v. U.S.*, 371 U.S. 341 (1963). After trial by court and jury, a verdict of guilty was returned and the defendant was fined and placed on probation. (91)
- Nutritional Foods, Inc.**, and **Mrs. Pauline Toburen**, New Orleans, E. Dist. La.  
Charged 7-14-65: while held for sale, a colloidal bentonite liquid, an intestinal cleanser, dietary supplement liquid, beet juice, and dietary supplement tablets were offered for sale and sold as drugs for therapeutic use for various conditions, including arthritis, degenerative illnesses, and radioactive burns, and the labeling of such articles lacked adequate directions for such intended use; 502(f)(1). The defendants moved to suppress evidence of oral statements made by Mrs. Toburen and recorded at the store of Nutritional Foods, Inc. In denying the motion, the court said: "The motion to suppress is directed to a secret recording made by James R. McClellan, Inspector of the U. S. Food and Drug Administration, who entered the retail establishment of Nutritional Foods, Inc., at 1522 St. Charles Avenue, New Orleans, in the course of his duties, on March 18, 1964. This retail store sold certain vitamin and health food products to the general public. McClellan's testimony taken in connection with the present motion discloses that he made comments and general conversation with defendant about the health value of foods described by said defendant, and defendant's conversations and sales 'spiel' were secretly recorded by the Inspector. The defendant was at that time giving a lecture to about four to six people and McClellan relative to the claimed health properties of certain foods which she was offering for sale. The Inspector was investigating the essential facts concerning the defendant's sales 'spiel' in connection with possible criminal prosecution. No property of the defendant was seized by the Inspector and the recording was made at a time when she was not in police custody or under police interrogation. *Escobedo v. State of Illinois*, 378 U.S. 478 (1964) and *Massiah v. United States*, 377 U.S. 201 (1964) are clearly inapplicable. Neither case is remotely similar to the situation here. Defendant was, therefore, not entitled to counsel, for 'one is not entitled to counsel while committing his crime.' *Grier v. United States*, 9 Cir., 1965, 345 F. 2d 523. Obviously, *Griswold v. State of Connecticut*, 381 U.S. 479 (1965), the Connecticut birth control information case, is not apposite either on the facts or in principle. There would be no adequate reason for the Court to decline to receive the testimony of Inspector McClellan at the trial of this case. Therefore, the recording of the conversations and sales 'spiel' of defendant by Inspector McClellan is likewise admissible and could not properly be suppressed. *Lopez v. United States*, 373 U.S. 427 (1963). See also Rules 12 and 41, Federal Rules of Criminal Procedure." Thereafter, guilty pleas were entered by the defendants; probation. (92)
- Montie K. Price**, musician, Cleveland, N. Dist. Ohio.  
Charged 10-12-65: dextro-amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; probation. (93)
- Security Mills, Inc.**, Knoxville, E. Dist. Tenn.  
Charged 8-15-66: when shipped, Security Commercial Breeder Ration medicated feed contained the food additive, arsenic acid, at a level in excess of that authorized and its labeling was false and misleading as to amount of arsenic acid contained in the article; 402(a)(2)(C), 409, 502(a). When shipped, the labeling of Security Poultry Wormer was false and misleading as to the amount of piperazine and phenothiazine contained in the article, and false and misleading as to effectiveness against large roundworms and cecal worms, since the article was deficient in such drugs; 502(a). Guilty plea; fine. (94)
- Bernard I. Silverman**, t/a Columbus Clinic Pharmacy, East Chicago, N. Dist. Ind.  
Charged 8-3-64: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; fine, plus costs, and probation. (95)
- John C. Watts**, M.D., Detroit, E. Dist. Mich.  
Charged 5-18-66: when shipped, dextro-amphetamine sulfate tablets were dispensed without a prescription; and the labeling of such tablets lacked adequate directions for their intended use; and, while held for sale, dextro-amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1), 502(f)(1), 503(b)(1). Guilty plea; fine and probation. (96)
- Bruce K. Whitcomb**, Tarzana, S. Dist. Calif.  
Charged 5-19-66: when shipped, LSD was a new drug without an effective New Drug Application; it lacked a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; the label lacked the established name of the drug; and the labeling lacked adequate directions for use and adequate warnings against dangerous and unsafe use; 505(a), 502(b)(1) & (2), 502(e)(1)(A)(i), 502(f)(1) & (2). Not guilty plea. After trial and a verdict of guilty; probation. (97)
- Chauncina White Horse**, t/a Princess Yellow Robe, Shipshewana, N. Dist. Ind.  
Charged 10-11-66: while held for sale, oral representations were made for use of a cascara sagrada combination laxative, a liniment, and a methyl salicylate ointment, in the treatment of a number of conditions including uremic poison, bed-wetting, rheumatism, sinus, earache, hemorrhoids, athlete's foot, bad wire cuts on animals, and cows with sore udders; and the labeling of the articles lacked adequate direction for such intended uses; 502(f)(1). Guilty plea; sentencing suspended. (98)

#### DEVICES

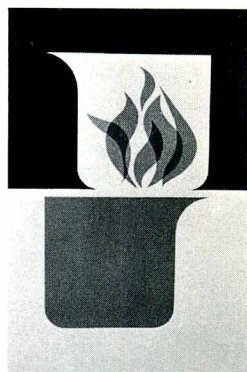
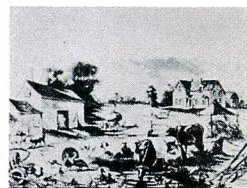
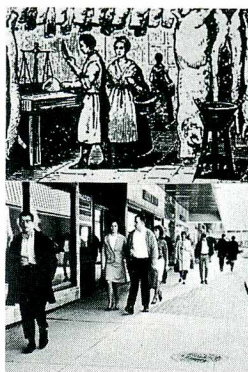
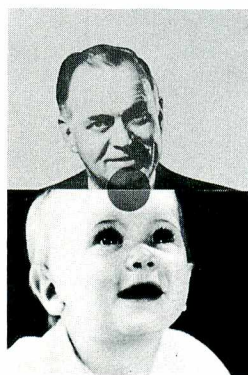
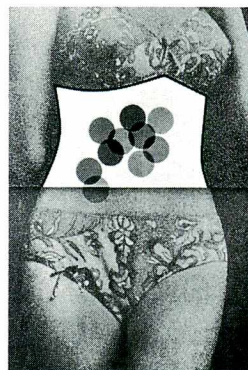
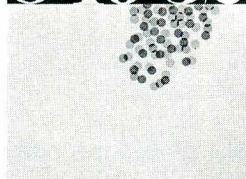
- David Aitchison**, Takoma Park, Dist. Md.  
Charged 7-6-64: when shipped, a piece of blotting paper for use in conjunction with the Drown Diagnosing Instrument and various drugs in liquid, tablet, and salve form comprising cancer treatments, had accompanying labeling that failed to reveal that the defendant was not at the time at Takoma Park, Md., registered or licensed to practice medicine; the labeling of the piece of blotting paper lacked adequate directions for use for its intended purpose; the booklet and letters accompanying the drugs contained false and misleading claims for cancer treatment and cure; the labels of the drugs lacked the name and place of business of the manufacturer, packer, or distributor, lacked an accurate statement of the quantity of contents, and lacked the common or usual name of each active ingredient; the labeling of the drugs lacked adequate directions for use for the cure and treatment of cancer; and the label of the salve lacked the name, quantity, kind, and proportion of arsenic contained in the salve, and the salve was dangerous to health when used as directed in the labeling; 502(a), 502(b)(1&2), 502(e)(2), 502(f)(1), 502(j). Not guilty plea. After trial before court and jury and a verdict of guilty, imprisonment under 18 U.S.C. 4208(b). (99)
- Circle Rubber Corp.**, and **Irving Lippman**, president, Newark, Dist. N.J.  
Charged 6-14-64: when shipped, the quality of Essex rubber prophylactics was deficient since they contained holes; 501(c). Guilty pleas; fines. (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 proceeds 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. Published by direction of the Secretary of Health, Education, and Welfare.

JAMES L. GODDARD, Commissioner of Food and Drugs.  
WASHINGTON, D. C., June 1, 1967



1x2=2x2=4  
8x2=16x2=32



# the ABC's of SALMONELLA

are illustrated in FDA's new multiple-use slide series. The color slides tell what *Salmonella* is, where it comes from, how it spreads, and how it can be eliminated from the processed food chain. The set is composed of an opening segment for food plant managers and employees, and a closing segment of FDA prevention guidelines. Individual food processors may insert their own slides, oriented to their specific industry problems, in the center segment. ■ The 42-slide set with narration may be ordered for \$5 (postpaid) from: World in Color Motion Picture Productions, P.O. Box 392, Elmira, N. Y. 14902.

OFFICIAL BUSINESS

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## Announcements

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### AFDOUS TO HOLD ANNUAL CONFERENCE

The Seventy-First Annual Conference of the Association of Food and Drug Officials of the United States will be held in St. Paul, Minn., June 18-22. This year's program will feature presentations by Federal, State, local, and industry officials and by members of the academic community. These will include a variety of subjects of importance to the Food and Drug Administration and comparable State and local organizations, to other consumer protection organizations, and to concerned industries.

According to the program chairman, Ralph Bernstein, the following subjects will be included on this year's agenda:

- Water Pollution Control
- Uniformity of State Laws
- The New FDA
- Fair Packaging
- The Consumer Movement
- Good Manufacturing Practices
- Food-Borne Viral Hepatitis
- International Food Standards
- Drug Abuse Control
- Important Committee Reports

Orlen J. Wiemann, Chief of the Milk, Food and Drug Section, Colorado State Department of Health, is President of this Association.

Business and membership inquiry correspondence with the Association should be directed to Evan Wright, Secretary, Association of Food and Drug Officials of the U. S., P. O. Box 1494, Topeka, Kans. 66612.

Inquiries concerning reservations and local arrangements should be directed to George Steele, Chairman, Local Arrangement Committee, Room 557, State Office Building, St. Paul, Minn. 55101.

**FDA INDUSTRY WORKSHOPS** During June and July, 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 CONFERENCES / JUNE & JULY 1967

FDA District or BDAC Field Office	Date	Location	Subject Area
Baltimore	June 7	Richmond, Va.	Sanitation & Standards in Canning
Chicago	June	Chicago, Ill.	Sanitation in Food Warehousing
Los Angeles	June 22	Los Angeles, Calif.	Medicated Feeds
Minneapolis	June 29	Minneapolis, Minn.	Medicated Feeds
New Orleans	June 14	Birmingham, Ala.	Medicated Feeds
San Francisco	June 15	Lake Tahoe area	Salmonella in Dried Milk
	June 20	Sacramento, Calif.	Medicated Feeds
Dallas	July 13	Oklahoma City, Okla.	Food Warehousing
	July 18	Houston, Tex.	Food Warehousing