

NOVEMBER 1970

FDA PAPERS

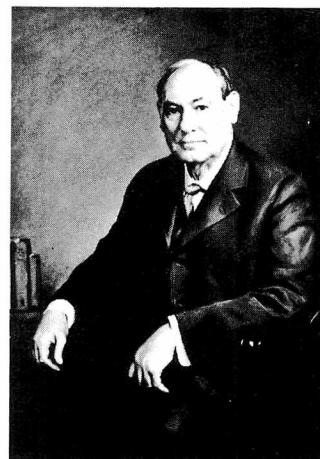
**INVESTIGATIONAL
AND NEW DRUGS**

**Single System,
Multiple Benefits**

MERCURY IN FISH

MINNEAPOLIS DISTRICT





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

Harvey W. Wiley, 1844-1930

Father of the Federal Food and Drugs Act of 1906

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

We need all the help we can get.

In the case of the United States, the State of New Jersey, et al., versus unsafe, impure, and unwholesome food, and unsafe and ineffective drugs, we've just about got it.

Such a conclusion may be reasonably inferred from a look at the essentials of a Single System concept that forms the backbone of an unprecedented State-Federal consumer protection partnership in New Jersey (see page 13).

If we seem to keep harping on the advantages of cooperation between State and Federal government and between government and industry, we can only refer to our opening statement: We need all the help we can get—from State and local governments, from the regulated industries and their trade associations, from the scientific and medical professions, from consumers and consumer protection organizations, from all with a stake in or an interest in protecting the public health and welfare. A regulatory agency, without support from those who created it, is from nowhere.

We feel that under the Single System in New Jersey—where all the participants work as one and where the results so far have pleased the FDA, the State of New Jersey, and the industries concerned—the consumers of food and drugs are getting the most and the best protection government can provide.

Elliot L. Richardson
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and Scientific Affairs

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

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

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

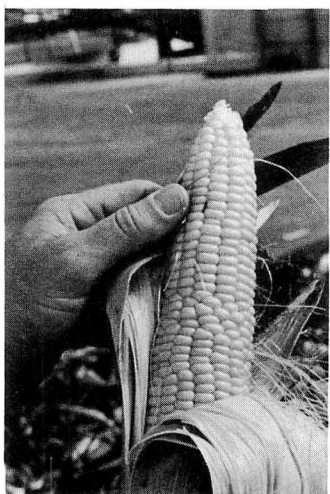
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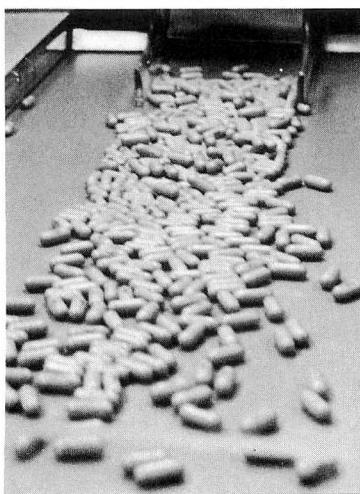
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Minneapolis District: Variety and Contrast

by Joe P. Durham



Variety is the spice of life and variety is the key word for food and drug work in FDA's Minneapolis District. It best describes the composition of the territory and the regulated industries here. The District includes some of the country's most productive agricultural and manufacturing establishments who make use of the major natural resources of abundant water, fertile prairies, and extensive forests.

Food as a general class is our primary workload, much of it requiring District staff people with strong bacteriological backgrounds. From the snapbeans of southern Wisconsin to the sugar beets and potatoes grown in northwestern Minnesota, we are concerned with all kinds of foodstuffs in production. The Minnesota District includes one of the Nation's major production areas for all kinds of dairy products and vegetables. The growing and harvesting seasons may be restricted somewhat by the short, warm summers, but the manufacturing industries and the area residents are active during winter too. A small but viable drug, pharmaceutical, and therapeutic devices industry, including manufacturers, repackers, and distributors, is active in both human and veterinary products. Some of the products made here are either nationally dominant or unique in their field. Rounding out District variety are smoked and fresh fish from the Great Lakes and other local waters, an impressive number of hazardous substance manufacturers, and now several makers of toys and consumer commodities.

The District's basic resources of soil, water, and people have been happily integrated to make it a land of abundant food production. The industry and progressive-mindedness of its people have resulted in an amazing diversity and magnitude of food products.

Early settlers quickly recognized the soil's lush fertility in providing the simple commodities they needed to exist. From these modest beginnings have come other products, almost unlimited in variety, and nearly all falling within FDA's jurisdiction. The District produces many kinds of vegetables for canning, freezing, and food fabrication; grains for prepared cereals; seeds and beans for oil extraction; and field corn for livestock feeding. Its animals yield meat, eggs, and dairy products. Its manufactured goods include such products from its forest areas as pitch, resins, dried yeast, maple syrup, vanillin, and even the paper so essential to modern life.

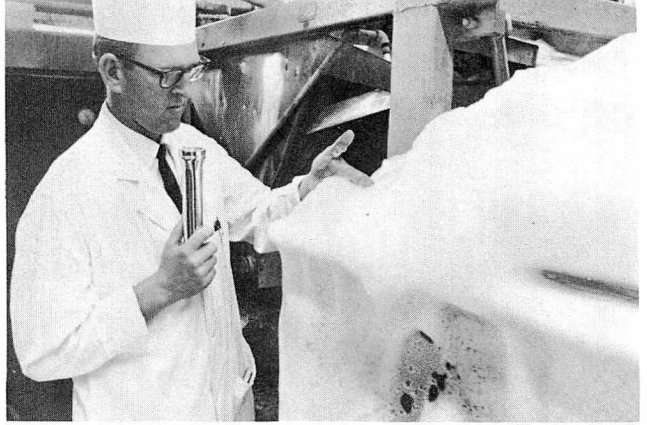
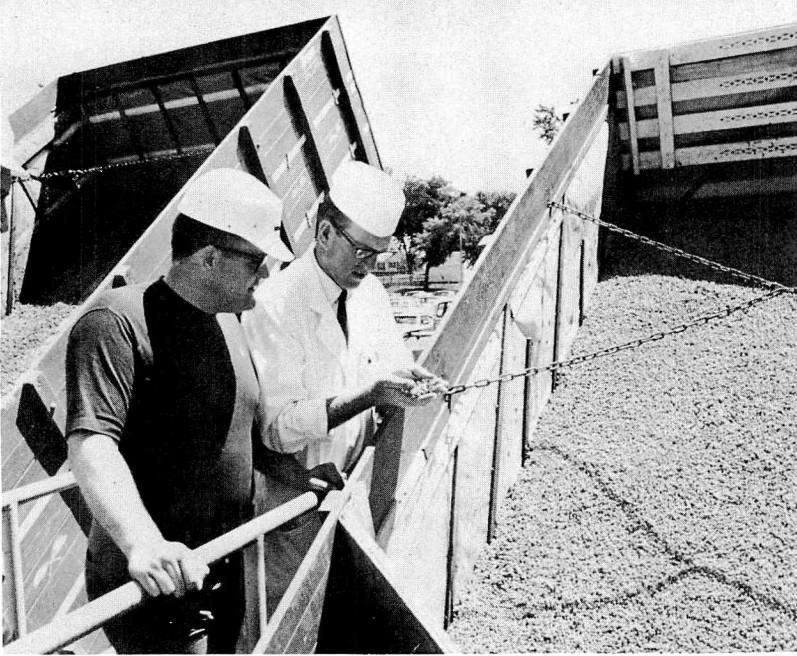
The importance of water to life and commerce was recognized by the Indians as the District's first inhabitants. Water has been increasingly important in the

lives of later residents and those outside the area too. The District's two Great Lakes (Superior and Michigan) have always been important from the time the first Ottawa Indians crossed Lake Superior in their birchbark canoes until today, when both domestic and oceangoing freighters dock at the District's three major lake ports. These water highways, combined with the barge traffic of the upper Mississippi River and other navigable streams, form an important link in the distribution of foods and manufactured products from the District as well as in the receipt of raw materials. Imports entered through these facilities constitute an important workload for Minneapolis District.

Although land and water are valuable assets, they are no more so than the dynamic character of the people who live and work in the area. One instance of this enterprising character was the creation by a small town pharmacist of an important multiproduct drug manufacturing establishment in northern Minnesota, which began with the use of oil from a local fish that previously had been considered worthless in commerce. Another has been the erection of a modern liquid oxygen plant at the end of a primitive gravel road some 50 miles into virgin timber and at least a hundred miles from the nearest smokestack. Still another is a sunflower oil extraction processor on the northern prairie far from any industrial center. Perhaps the most colorful example involves a poor youth of Italian descent who settled in one of our Scandinavian communities and became a millionaire manufacturing Chinese food.

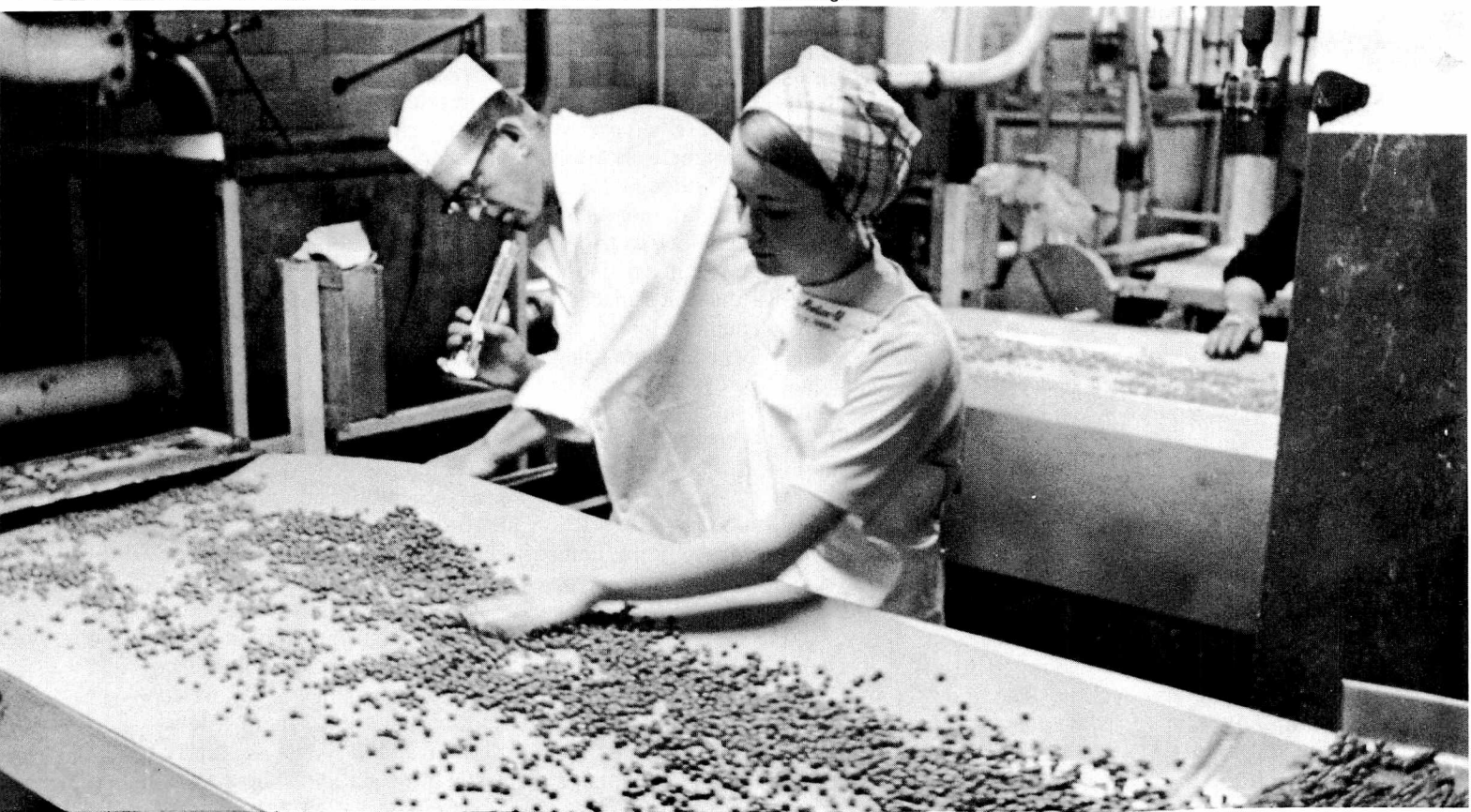
Perhaps the most unusual industry located in the District is the harvesting and processing of wild rice. Growing readily in the clear waters of northern Minnesota lakes, the plant *Zizania aquatica* has so far resisted attempts at domestic propagation. The harvest season is set by the State Conservation Department, which also closely regulates the way harvesting is done. Only licensed residents may harvest wild rice and they must follow prescribed methods.

Only canoes, of limited length and width and propelled by hand, may be used. Sticks used to knock the grain from the plant are limited in size. These precautions are taken to prevent unnecessary damage to the rice beds and to insure a continuing supply of this unusual food. The initial product, harvested before ripening, resembles green grass clippings. After drying and curing, it is parched in a technique that does not differ greatly from that used by the early Chippewa inhabitants. Parched wild rice commands a price of about \$9 a pound. Although not approaching the value of



Inspector checks for slime buildup, which would tend to increase bacterial growth, in froth-washing step that removes extraneous matter from peas before canning.

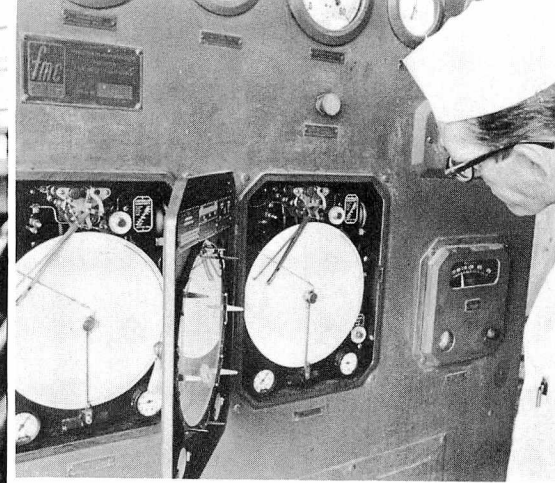
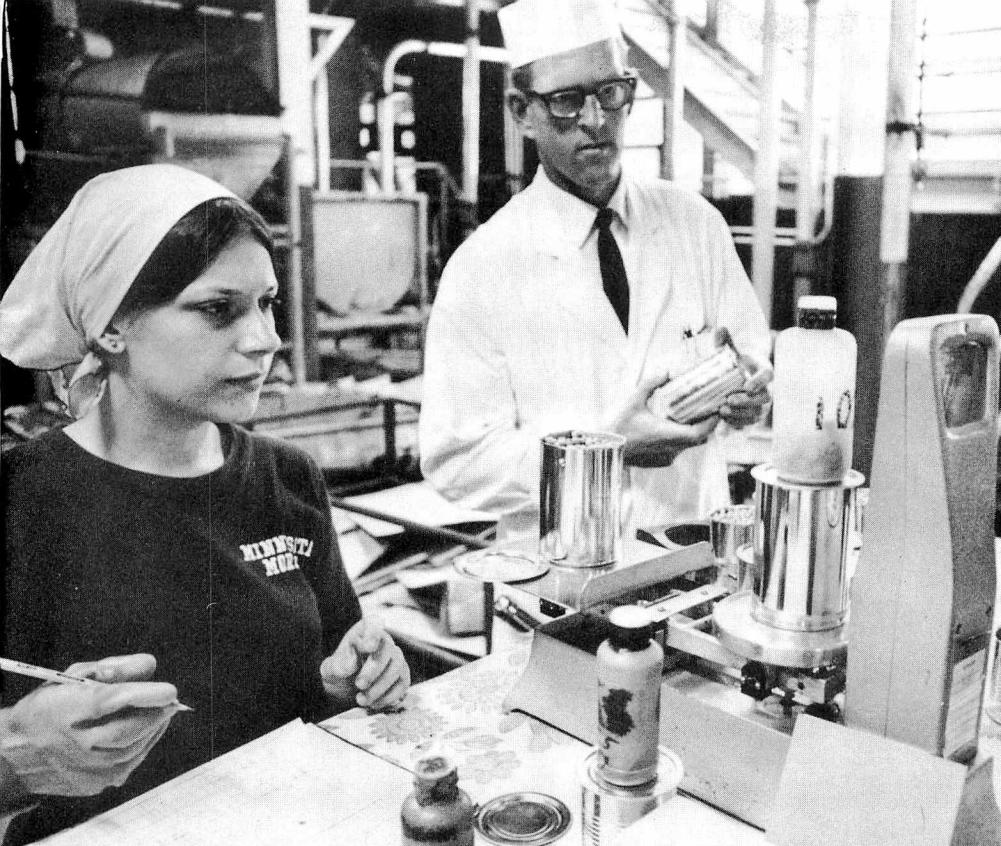
At a pea canning-freezing plant in Minnesota, inspector (right) and plant's quality control manager examine a load of incoming machine-shelled peas for insect or machine damage.



Plant worker (right) makes final inspection of peas to remove defective vegetable and foreign matter before canning while inspector lifts conveyor belt to look for evidence of insanitary conditions.

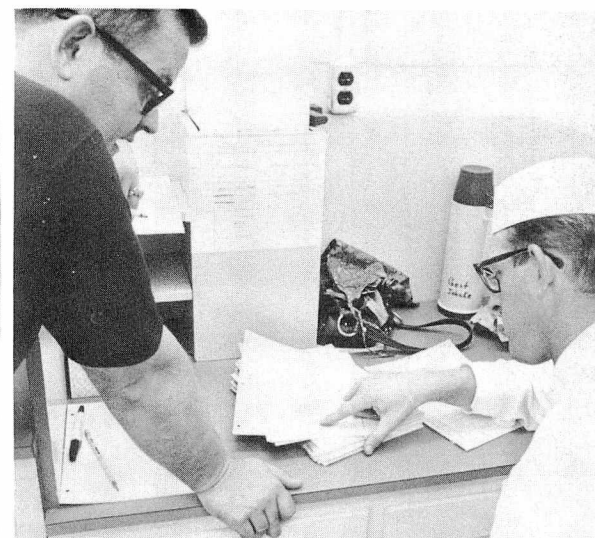


Inspector checks cleanliness of a liquid Freon freezer, a new method of quick-freezing food products by immersion in liquid Freon at -29° F., before the day's operation begins.



At console control panel of cooker, inspector checks time-temperature recording instruments that indicate whether cooking was adequate.

At check weight station, worker (left) weighs canned samples of peas taken by the inspector.

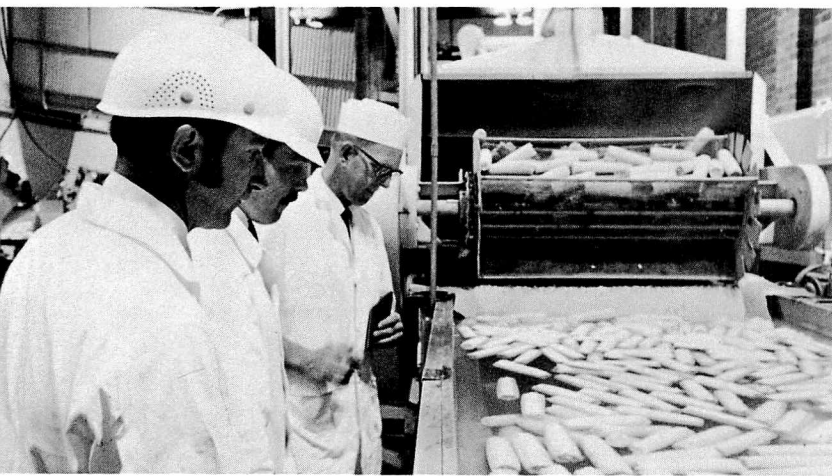


Inspector (right) examines plant's production record of bacteriological survey and analysis with quality control manager (left).

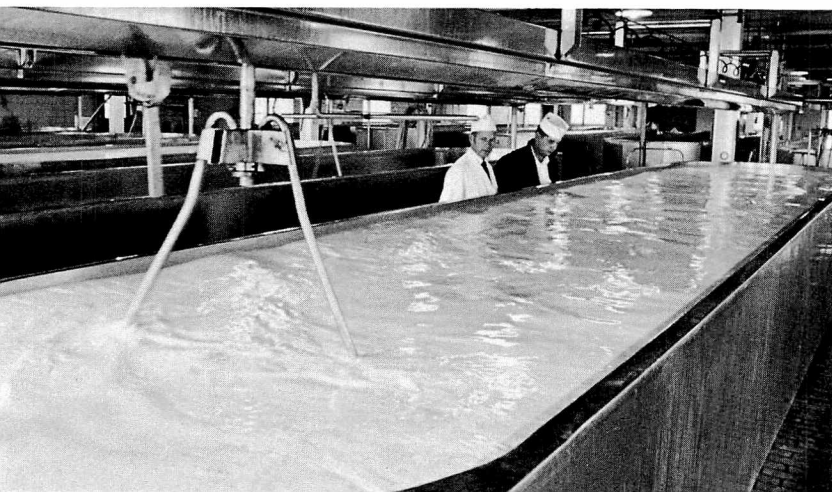
At plant's bacteriological laboratory, quality control manager (left) and inspector (right) examine petri dish held by technician who makes bacteriological counts of in-process samples of peas.



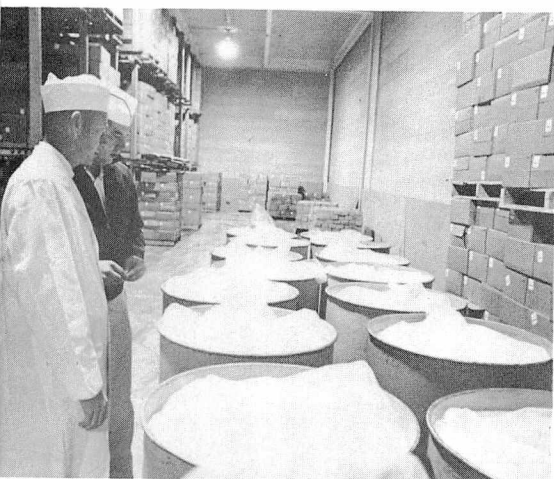
This view of production lines at a corn canning-freezing plant shows husked corn on way to cutters for removal of kernels from ears.



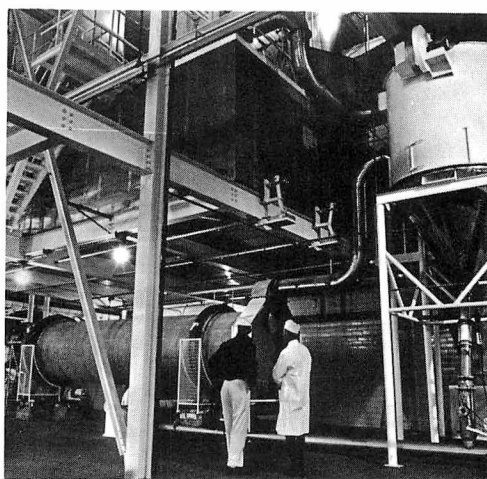
During a joint State-Federal inspection, two State inspectors and FDA inspector check ears of corn on way to quick freezer.



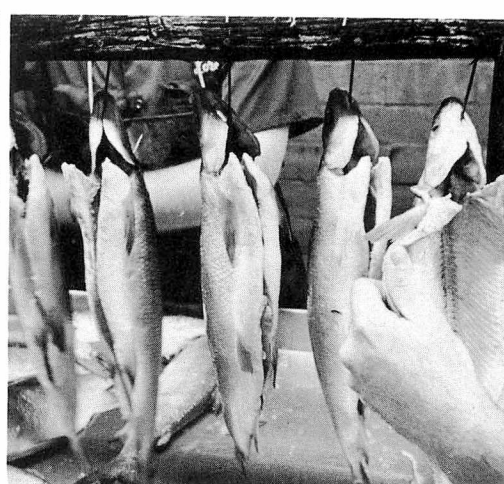
In a large modern cheese factory, inspector (left) and plant manager look at one of 10 cheese vats, each holding 32,500 pounds of milk.



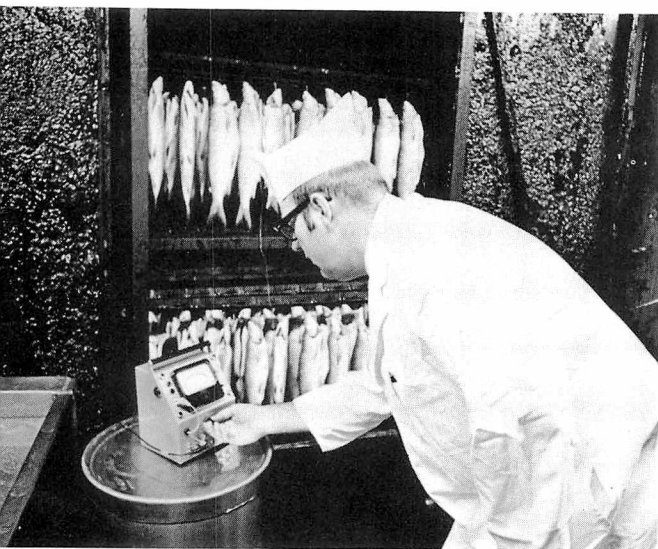
Cheese curd is packed in drums for manufacturing processed cheese foods.



In an operation for production of dried milk, the inspector (right) and a plant representative look at some of the specialized conveying and drying equipment.



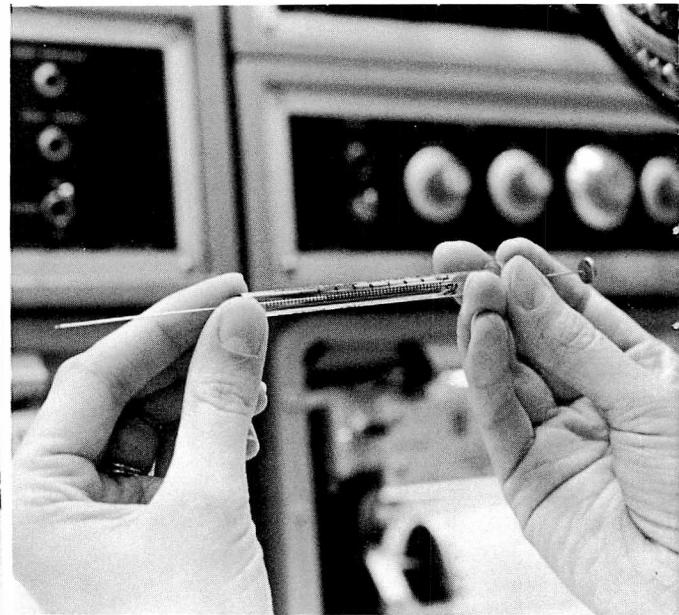
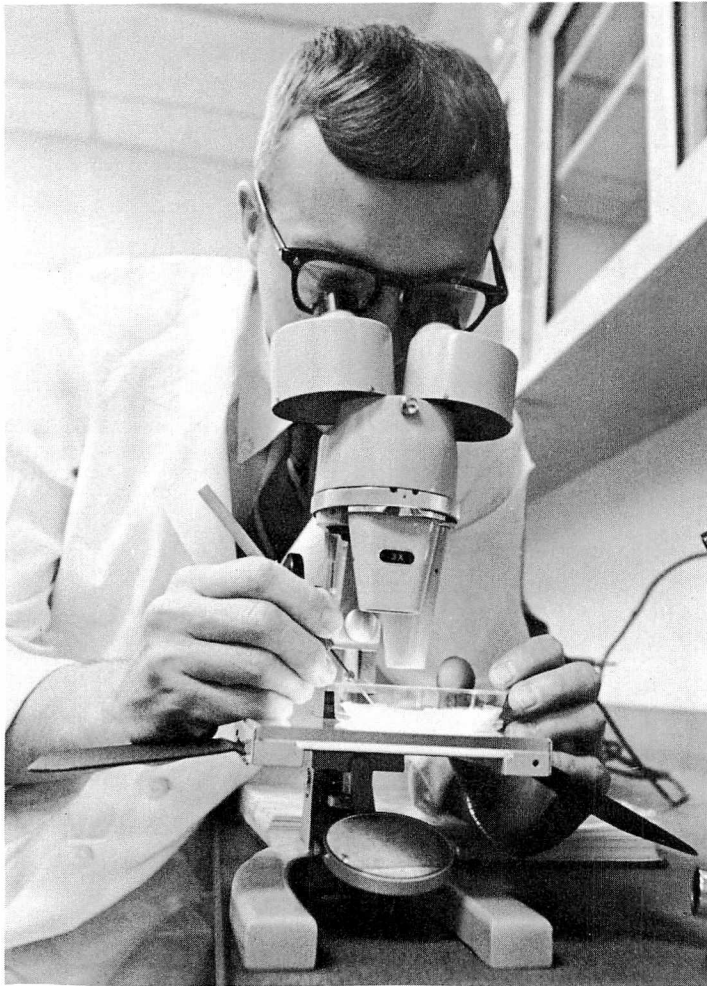
In a smoked fish processing plant, the inspector examines a lot of whitefish prior to the smoking operation.



The inspector checks electronic equipment used to monitor internal temperatures of several fish during the smoking process.

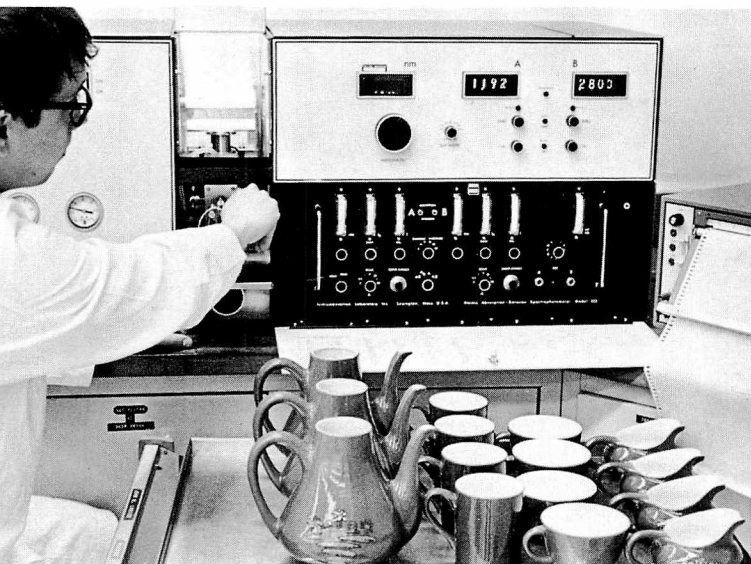


A workman shows a valuable store of processed wild rice at a plant near Aitkin, Minnesota.



In a process for detecting, identifying, and measuring pesticide residues, an analyst prepares to inject an extract from a food sample into a gas chromatograph.

In the District laboratory, an analyst "reads" a sample of food for filth, using a wide-field microscope.



Atomic absorption is used here to determine amounts of leachable lead, a toxic metal, in samples of pottery.



At a staff meeting of District supervisory people are (left to right) Ronald W. Sell, chief chemist; Robert F. Houk, administrative officer; Joe P. Durham, deputy regional food and drug director, FDA Region V, and District director; George R. Goers, chief inspector; and Horace A. Allen, deputy District director.

gold, it is not unusual to find the product stored under armed guard. In one instance, a supply of wild rice was stored in the vault of a local bank.

Just as impressive are the numbers of the District's better known industries. The hundreds of cheese and butter plants scattered across the District rival the numerous country elevators on the prairie. The cheese and butter makers are devoted to their trade, and proudly preserve the art brought over from the old countries. Other industries are vegetable oil processing, complete to the finished product; extensive cranberry bogs; sugar processing from raw beets to the table product; cereal processing from wheat to finished baked goods; and chocolate product processing. Barley is grown and processed into barley malt and its ultimate use in brewing continues to make Milwaukee famous as the beer-producing center of the Nation. The precise machining of metals and electrical composites into therapeutic medical devices such as heart pacemakers is one of the industries of Minneapolis District.

Our activities cover this wide range of FDA responsibilities and our inspectional branch is well equipped to handle them. Through growing and harvesting seasons, inspectors conduct surveillance and investigational activities in the vegetable processing industries. Particular emphasis is placed on pesticide application practices and bacteriological conditions as well as processing and quality control. The expanding convenience food industry with its use of local crops requires inspectional expertise in many novel processing techniques and application of bacteriological inspectional knowledge.

Because of its immense expanses of water, Minneapolis District is water oriented. Sometimes there is too much and flooding occurs, usually beginning about the first week in April. When flooding is imminent, Minneapolis District goes into action to cover emergency flood control work over the wide area involved. Staffers well remember the flood of 1965, when the District's three major river systems—the Red River of the North, the Minnesota, and the Mississippi with its five tributary rivers—ran wild. Early spring rains, melting heavy snow, brought flooding across the entire District. Work was progressing well with the passing of the flood until the evening of May 6, when within four hours the Twin Cities (Minneapolis-St. Paul) area was rocked by nine tornadoes that inflicted millions of dollars in damage and killed 14 people. District inspectors did not slow down. They just changed direction. Last year when there was a call for inspectors to help

clean up after Hurricane Camille in Mississippi, Minneapolis District answered.

The growing and harvesting seasons end early in the fall with the advancing low temperatures, but not FDA's inspectional activities. The five-month winter season creates a landscape of striking beauty, with Christmas card appeal—and bone-chilling temperatures. But it's business as usual, as the temperature drops to as low as 20, 30, even 40 degrees below zero. Winter is a time of production—manufacture and processing of products stored from the previous harvest. It's a time of deep snow, icy roads, frostbite, uncooperative automobiles, long underwear, and emergency equipment for the inspectors who travel the area. Some have been stranded in heavy blizzards for days until the weather cleared. Minneapolis District's record of service is excellent despite the severe weather. In winters sometimes totaling eight feet of snow, the District office has been closed only once in the last ten years because of the weather. Even then somebody was on hand to answer the telephone.

Minneapolis District's laboratory branch on the second floor of the modern District office building is a force of dedicated men and women. The team includes 20 analysts and two laboratory supervisors to conduct the wide variety of analyses required for up-to-date enforcement of FDA regulations. The laboratory is divided into two nearly equal sections, one handling food problems and the other human and animal drugs, medicated feeds, and hazardous substances.

The foods section is responsible for examining food products for sanitation, natural poisons such as aflatoxins, chemical contamination such as unauthorized or excessive food additives, and most important, pesticides. Over the years the District has accumulated an extensive background of analytical experience in detection of pesticide residues. The largest single designation of District laboratory manpower for this fiscal year is for examination of foods for pesticide residues. Last year more than 400 samples were completed, including raw crops, dairy products, animal feeds, and some processed foods. The pesticide group has an excellent reputation for high quality analytical work. This reputation was enhanced recently with the measurement of DDT and analog levels in coho salmon from Lake Michigan, and the PCB, DDT, and analog levels in chubs from Lake Michigan. The most recent example of quality pesticide work concerns the examination of carrots for dieldrin residues. This analysis resulted in voluntary destruction of a carload of carrots.

Besides pesticide analyses, food section personnel have been much involved recently with the problem of mercury residue in fish. Nearly 200 samples of fish and water have been examined to determine whether waters in the District were contaminated. Many fish examined showed some mercury contamination; the District continues to monitor the area for this problem. The Minneapolis laboratory has also been asked to participate in a Cold Smoked Salmon Survey in which 48 samples are examined for pH, nitrites, salt content, and moisture. This effort is expected to require about 1½ man-years. With these problems and the added ones of sanitation work, a few standards samples, and a number of samples for heavy metals, the food section has considerable variety in its work.

The same is true of the drug section, which examined nearly 400 District drug samples last year and expended about seven man-years on drug samples from outside the District. Samples range from simple single component drugs to complex multicomponent preparations and in many cases present a challenge to research the literature and talk to Bureau of Drugs people to devise new analytical schemes. The section is also responsible for examining veterinary drugs, including medicated feeds. Many times the methodology is inadequate and methods projects must be developed to analyze a sample. The District laboratory has considerable expertise in this area and is frequently called when collaborators for methods studies are needed and when problems arise in other Districts. The section also examines hazardous substances products, where major problems involve imported earthenware containing lead and products without proper flammability label warnings.

These two sections with their attendant aides, technicians, helpers, and clerks make up a highly trained and dedicated unit of analytical support for regulatory enforcement.

In meeting its varied consumer protection responsibilities, Minneapolis District has long recognized both the necessity and the value of a strong program of State-Federal cooperation. Although the District and the States of Minnesota and Wisconsin have always benefited from a free exchange of inspectional, analytical, and administrative assistance, their efforts in recent years have focused on a more formal approach to joint program planning and coordination. The basic objective is to use the combined resources and capabilities of the District and its State counterparts effectively and efficiently, within legal limitations. The

States have extended this philosophy to the city and local level.

Current District programs involve joint planning and workload sharing in the medicated animal feeds industry and several categories of the food industry. Currently 21 State inspectors in Wisconsin and Minnesota are conducting feed mill inspections and related investigations under FDA commissions. Over 700 mill inspections have been conducted by State people in the past two years. This cooperative surveillance of the food industry has resulted in more complete coverage and has significantly reduced duplication. Assumption of responsibility by the States for most of the large dairy industries in the District has allowed FDA inspectors to concentrate on other industries.

Since initiation of the District's first industry self-certification project in 1968, Minnesota's Department of Agriculture has been included as a full participating partner (see FDA PAPERS, April 1969, "What's Happening at Blue Earth?"). This voluntary quality assurance program in Minneapolis District has now been expanded to include seven of Green Giant's plants in Minnesota and Wisconsin. Both States are cooperating fully with the District in the entire program.

All these efforts to foster closer cooperation of District and State programs are beginning to bear fruit. Interstate versus intrastate considerations are becoming less important and the surveillance arms of both the District and the States are made longer through a cooperative approach to mutual responsibilities. The real benefactors, however, are the taxpayers and consumers throughout Minnesota, Wisconsin, and the rest of the Nation.

The National Center for Microbiological Analysis shares the District building, with its bacteriological laboratories on the second floor. The Center's main purpose is to develop new information and techniques in the field of bacteriology and apply them to the Agency's work. It also contributes to the District's effort by providing microbiological analysis of samples. Results provided by NCMA have been used in a number of instances for compliance purposes.

Minneapolis District's dedication to public safety and the consumer's interests has been the subject of objective appraisal throughout its entire history and it has never been found wanting. District staff people are proud of their achievements in promoting the common good of all who use the commodities produced and manufactured here.

Single System, Multiple Benefits

by Alex Labonski

A new era in the field of State-Federal relations has emerged from a triad of cooperative programs between the New Jersey State Departments of Health and Agriculture and FDA's New York District that eliminates duplication of effort and makes maximum use of manpower and resources available for consumer protection. Under this Single System concept, primary responsibility for specific inspectional and analytical work is assigned either to a State agency or FDA, not both. The program currently covers human drugs, medicated feed mills, and pesticide residues.

All concerned, the State, FDA, and the regulated industries, are pleased with the Single System's accomplishments to date. New Jersey, besides being known as the "Garden State" because of its agricultural output, is sometimes called "The Nation's Medicine Chest" because of its high pharmaceutical production.

The largest of these Single System programs is in the field of drugs for humans. In September 1967, representatives of the New Jersey State Department of Health requested a meeting with former Commissioner of Food and Drugs James L. Goddard, M.D., to seek a more active partnership arrangement with FDA. At this meeting the Single System was conceived as a way of eliminating duplication of effort and making the maximum use of manpower and resources of Federal and State agencies in the interest of consumer protection. The concept was further developed at a meeting in January 1968, attended by management from FDA's New York District and the State Department of Health, at which an evaluation was made of the State's capabilities for functioning in this type of program. An outline was de-

veloped establishing such goals as FDA commissioning of State personnel and the interchange of personnel in key positions on temporary assignments.

The State Department of Health selected Francis Timko, chief of the State Health Department's Bureau of Food and Drugs, and Donald Foley, coordinator of its Drug, Device, and Cosmetic Program, along with eight of their operating pharmaceutical field representatives, all holders of degrees in pharmacy, to undergo intensive training by FDA's New York District with the ultimate goal of commissioning these persons as FDA agents in the area of human drugs. These officials went through the following training:

- A series of joint drug manufacturer inspections with experienced FDA inspectors, during which the trainee acted primarily as observer in the first inspection, assumed the role of partner in the second inspection (including write-up of the report), and actively assumed the leader role in the third and subsequent inspections, the FDA trainer acting primarily as an observer in this last phase.

- Attendance at an FDA seminar on the techniques of collecting drug monitoring samples and performing recall effectiveness checks (investigations made at the consignees of drug manufacturers to determine if they are complying with instructions to return drugs not meeting specifications).

- Joint field training with experienced food and drug inspectors in the collection of drug monitoring samples. These are samples collected from the active stocks of New Jersey pharmaceutical manufacturers to monitor their products' compliance with standards.

- Performance by each of the eight operational New Jersey men

of a number of independent drug inspections and monitoring sample collections at FDA's direction.

- Performance by each of the New Jersey men of several joint recall effectiveness checks with an FDA trainer.

- Attendance by the State men at a comprehensive FDA drug seminar in which they spent considerable time studying the portions of the Federal law covering drugs, the Current Good Manufacturing Practice regulations, and the mechanics of performing and reporting control drug inspections.

- Attendance at the District's two-week laboratory instrumentation course that provides instruction on evaluating the sophisticated laboratory equipment used in a modern drug manufacturer's quality control department.

In August 1968, after being trained in the New Jersey food and drug laws and their enforcement, all FDA inspectors in Newark Section at or above journeyman level were commissioned as special agents of the New Jersey Department of Health and given the full authority of that position. In May 1969, eight operational New Jersey field representatives and their first and second line supervisors were commissioned by the Food and Drug Administration to perform FDA operations in the area of human drugs. Thus all of this training culminated in cross-commissioning between the Bureau of Food and Drugs of the New Jersey State Department of Health and the FDA New York District's Newark Section, the inspection arm that covers all of New Jersey.

As the first step in this training program which led to FDA's commissioning of New Jersey State Department of Health personnel, a Memorandum of Understanding was signed between the New York Dis-



At a machine that chills and solidifies an ointment prior to blending, State's Louis Lordi (left) and FDA's Lester Mathis (right) confirm the posted identification of the batch.

In a drug plant during training of New Jersey drug inspection personnel, FDA's Stanley Fenichel (left) and State's Benjamin Greengold (right) check accuracy of plant's weighing and recording of ingredients for a batch of a drug.

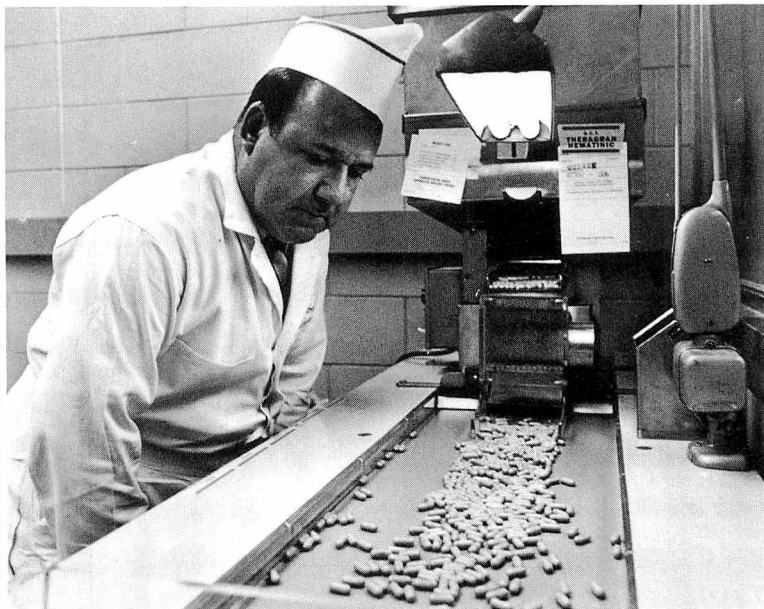


Drawing a sample of vitamin tablets from a tablet compressor are State's Louis Lordi (left) and FDA's Stanley Fenichel (right).

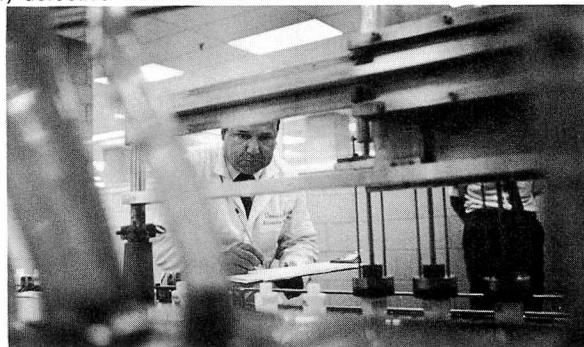
At drug plant's ointment blender readied for use, State's Lucius Bowser (left) and FDA's Michael Williams (right) inspect machine for cleanliness and sanitation condition.



A sample of coated drug tablets is withdrawn from a tablet-coating machine by State's Lucius Bowser (left) and FDA's Lester Mathis (right).

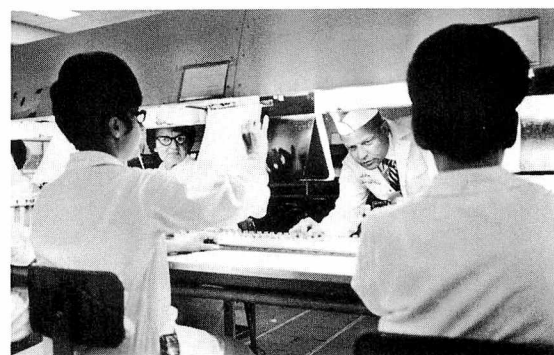


After training by the New York District, New Jersey personnel conduct inspections unassisted. Here State's Benjamin Greengold, at visual inspection table, watches capsule-shaped tablets passing on conveyor belt for visually defective tablets or tablets of another kind.



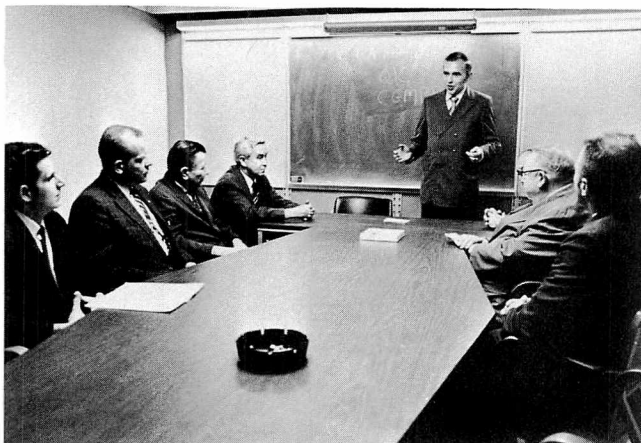
On a line that fills bottles with liquid drug and labels them, State's Benjamin Greengold checks to see if bottles are labeled and if the labeling is correct.

In plant's quality control department, State's Louis Lordi (left) observes employee as she checks filled ointment tubes for proper weight.



State's Lucius Bowser checks operations at a line where employees examine vials of an injectable drug under strong light for particulate matter.

At a machine that fills bottles with tablets, State's Lucius Bowser observes the accuracy of the filling operation.



FDA supervisory inspector lectures New Jersey personnel. Lectures and briefings are a part of the training and follow-through. Here the supervisory inspector discusses the Food, Drug, and Cosmetic Act and FDA inspection techniques.



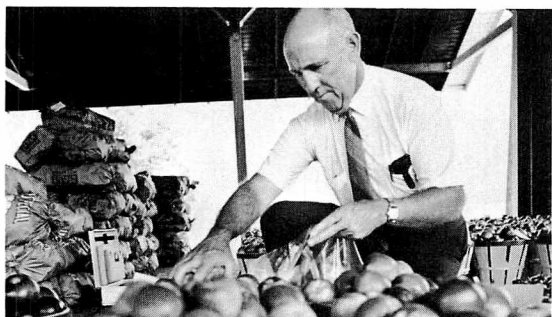
A State inspector's credentials under the cross-commissioning aspect of the Single System Program include card (left) that gives him FDA authority in the area of human drugs and card (right) issued by the Drug Program of the Bureau of Food and Drugs, New Jersey Department of Health.



In the medicated feeds inspection program carried out by the New Jersey Department of Agriculture, the State's William Huggins, in a medicated feed plant, checks the weight of a drug raw material to which an amount of carrier has been added.




In medicated feed plant storage area, State's Robert MacCloud checks plant's drug inventory to determine if it has the required new drug authorizations.



An inspector of the Division of Markets, State Department of Agriculture, collects samples of produce for pesticide residues analysis.



At the ceremonies in which an FDA commission was presented to James R. Cowan, commissioner, New Jersey Department of Health, are (left to right) Ralph Bernstein, chief, Special Programs Branch, FDA Region II; Luther Stringham, representing the director, DHEW Region II; former New Jersey Governor Alfred E. Driscoll; Governor William T. Cahill; Mr. Cowan; Weems Clevenger, food and drug director, FDA Region II; Francis E. Timko, chief, Bureau of Food and Drugs, State Department of Health; and Donald E. Foley, drug program coordinator, Bureau of Food and Drugs, State Department of Health.



trict and the Department on June 25, 1968. The agreement placed major responsibility for the collection of drug surveillance samples and the performance of drug recall effectiveness checks on the State Bureau of Food and Drugs and the responsibility for analyses of such samples on FDA's New York District. The parties subsequently expanded the terms of the memorandum considerably by verbal agreement. An updated Memorandum of Understanding was signed between the two agencies last July 23 in the office of Governor William T. Cahill when the recently appointed State commissioner of health, Dr. James R. Cowan, received his FDA commission.

The major points of the updated memorandum (in all of which both participants have been active since July 1, 1970):

- The individual drug establishment inventories of the State and the Newark Section of FDA's New York District have been merged and divided. Primary responsibility for surveillance and compliance inspectional coverage of each individual drug firm in New Jersey is borne by either the State or FDA. Any drug assignment received or originated by an agency not primarily responsible for that firm is referred to the agency with primary responsibility, which can and does receive assistance from the other agency if requested.

- The State and New York District routinely furnish each other with all their respective surveillance/compliance work schedules.

- Each FDA-commissioned State officer performs a minimum of four FDA-assigned drug plant inspections annually. These inspections follow all FDA guidelines and procedures, including complete reports, which are reviewed by a New York

District supervisory inspector for follow-up, if required.

- All other drug inspections performed by New Jersey personnel under their own State authority are reported as required by the State, but also include complete FDA data reporting forms that are entered into New York District's data system.

- The New Jersey State Department of Health independently collects drug surveillance samples for analyses by FDA's New York District and performs drug recall effectiveness checks as requested by the New York District.

- FDA provides State personnel with regular refresher training by seminar and joint field work at least biannually.

Major accomplishments of the Single System concept drug program from the date of the Memorandum of Understanding in 1968 to the present:

- Approximately a thousand drug surveillance samples have been collected from New Jersey manufacturers by State personnel for New York District analyses. About 30 of the analyses have revealed products that deviated from specifications. Actions against these violations have resulted in a number of drug recalls. FDA saved many man-hours in sample collection time and the State participated in a wide-scale drug analytical monitoring program of State manufacturers—a totally new endeavor. Most important, the consumer received greater protection.

- Many of the recall effectiveness checks that the District's Newark Section would have been required to perform alone are now shared by State personnel, thus spreading the workload.

- FDA's New York District, after clearing its impending actions with the State, has placed a total

of 27 embargoes on foods and drugs suspected of being adulterated or misbranded or both. In every one of these actions the New York District would have requested the State to place the embargo itself if the District had not held the State-commissioned power, since FDA in each case had good reason to believe the suspected merchandise would not be voluntarily held by the dealer until confirmatory analyses or legal actions were complete.

- After inspections by New Jersey or New York District, the licenses of four drug manufacturers were withdrawn and their inventories were embargoed until their operations and products were brought into compliance. Three of the firms were operating in gross violation of FDA's Current Good Manufacturing Practice regulations for finished pharmaceuticals. The fourth, a manufacturer of both drugs and pesticides, was found to be contaminating its over-the-counter drugs with pesticides because of inadequate cleaning procedures between production runs.

- Based on inspectional and analytical evidence developed solely by New York District, the State closed a yeast manufacturing firm because of *Salmonella* contamination.

- Since May 1969 when the State personnel were first commissioned by FDA, the State has performed an average of three complete inspections a month covering compliance assignments as issued by New York District, using FDA authority and FDA procedures and techniques.

- All State drug inspections performed, under either State or FDA credentials, are recorded into FDA's data system.

New Jersey today is the only State whose inspectors are commissioned by FDA to conduct work in

the field of human drugs and is the only State that has granted FDA inspectors the authority of State officials. Today the State and Federal agencies carry out drug plant inspections, collect samples, and make special investigations based on joint planning and a complete exchange of investigational information. The Single System in New Jersey does away with the practice that exists in most other States in which each pharmaceutical plant is visited periodically by both State and Federal inspectors. Thus the public, under the Single System concept, receives a greater degree of protection for its tax dollar through more efficient use of personnel and more frequent and more extensive inspections.

The second part of the Single System program with New Jersey involves the Division of Agricultural Chemistry of the New Jersey State Department of Agriculture and FDA's New York District and covers the medicated feeds industry. After undergoing formal and field training supplied by FDA's Philadelphia District, two operating State inspectors and their division director, Delmar K. Myers, were commissioned by FDA to perform inspections of medicated feed mills.

The division's management staff and field inspectors commissioned by FDA have assumed inspectional responsibilities for all medicated feed produced in New Jersey. Samples of feed are analyzed primarily by State chemists.

During the past two years the State has performed all the medicated feed inspections in New Jersey and has covered each of the approximately 50 mills at least once. The State feed mill reports follow all FDA guidelines and procedures and are reviewed by a New York District supervisory inspector before entry into the FDA data sys-

tem. Biannual planning conferences between the Division of Agricultural Chemistry and FDA's New York District are held and FDA refresher field and formal training is given as needed.

The third Single System program involves the Division of Markets of New Jersey State Department of Agriculture in the pesticide residue area. After New York District held a seminar for the Division's representatives, at which FDA sampling techniques were described and demonstrated and joint field training was completed, a Memorandum of Understanding was signed on June 4, 1968, under which the State committed, at food distribution points, the manpower necessary to collect pesticide surveillance samples requested by FDA for analyses by New York District.

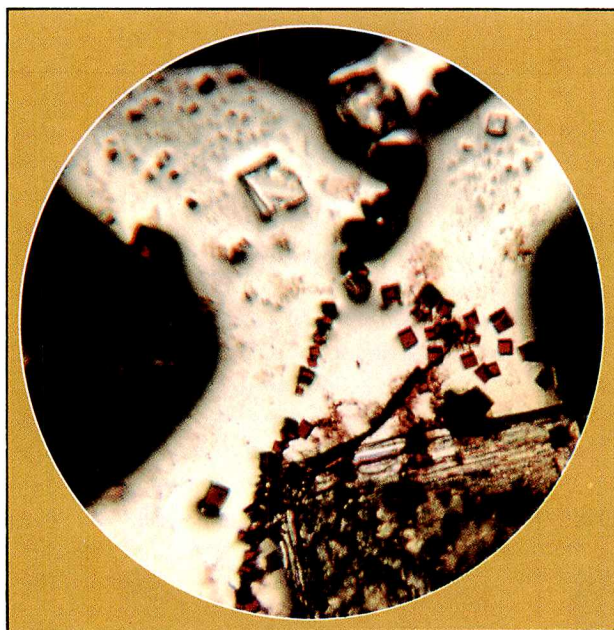
The State currently is collecting 10 samples each month of produce grown in New Jersey for pesticide residue analyses by New York District. FDA receives the obvious benefit of sizable manpower savings in sample collection time, and the State has the opportunity for active participation in a pesticide residue surveillance program (which it didn't have before). Here again the consumer benefits from the greater protection under the system.

All samples collected by the division follow FDA procedures and the resulting sample records are reviewed by a New York District supervisory inspector prior to entry into FDA's data system.

The Single System results in increased consumer protection through maximum use of State and Federal resources. Because of this program's success, New Jersey and FDA's New York District are working actively to extend it to cover food products and hazardous substances, where both have responsibilities.



Alex Labonski, supervisory inspector of the New York District who coordinates the Single System Program in New Jersey, joined FDA in Philadelphia District as an inspector in 1962.



microchemical crystallography

by Charles C. Clark, Chemist, Baltimore District

Microchemical crystallography, the process of reacting a chemical compound with another chemical to produce an identifiable crystal, has gained wide acceptance among chemists in the identification of drugs. These tests require only small amounts of sample. Many microchemical tests are capable of detecting and identifying less than one milligram (approximately 1/30,000 ounce) of a drug. These tests require only a relatively inexpensive microscope. Most other chemical identification procedures require expensive instrumentation or considerable time.

The Food and Drug Administration performs identity tests as well as assays on thousands of drug samples yearly. Drug manufacturers also must perform identity checks on their finished products to assure that they are complying with required procedures for current good manufacturing practice. Often microchemical tests meet these needs.

Often the crystals that are formed in these tests almost defy verbal description and make communication between chemists difficult. A picture of the crystal with the color produced by the reagent is truly worth a thousand words and provides ground for discussion among chemists.

The photographs on the following pages were taken by the author. They show crystals obtained from some of the most common drugs FDA chemists encounter in their work. Most of the tests used are from the book, *Official Methods of Analysis*, by the Association of Official Analytical Chemists. Captions under the pictures indicate, first, the drug; second, the reagent used; and last, the magnification power used.

The AOAC procedures for the antihistamines tests on the next two pages are—gold chloride, AOAC 10th ed., 32.286(b); platinum chloride, AOAC 10th ed., 32.286(c); and gold bromide, AOAC 10th ed., 32.293(b). The procedure: Dissolve 0.1-0.5 mg. of the amine (salt or free base) in 1 drop of 0.1N HCl. Add 1 drop reagent, placing cover so as to cause the 2 drops to come together. Examine after 30 minutes.

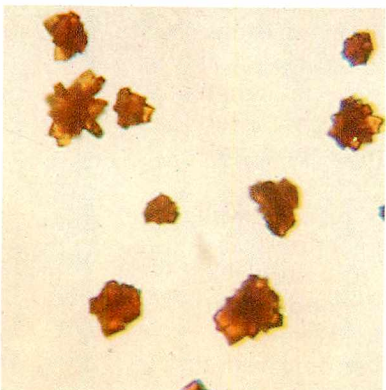
antihistamines



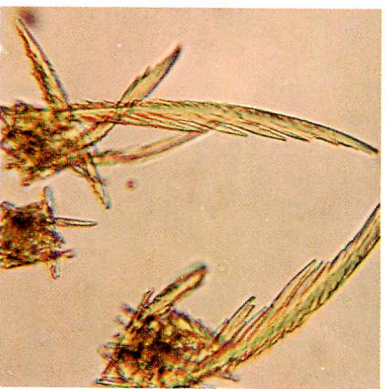
Brompheniramine – gold chloride 100X



Brompheniramine – gold chloride 430X



Brompheniramine – gold bromide 430X



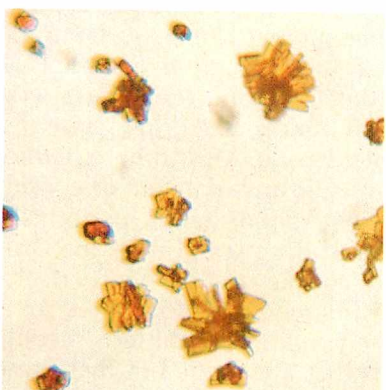
Chlorcyclizine – gold chloride 430X



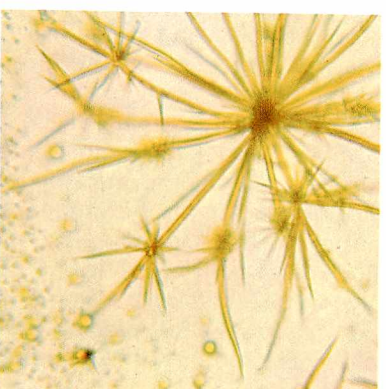
Chlorcyclizine – platinic chloride 200X



Chlorothén – gold chloride 100X



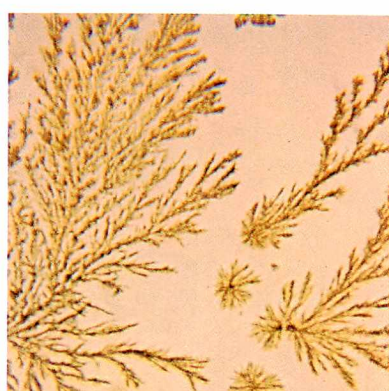
Chlorpheniramine – gold bromide 430X



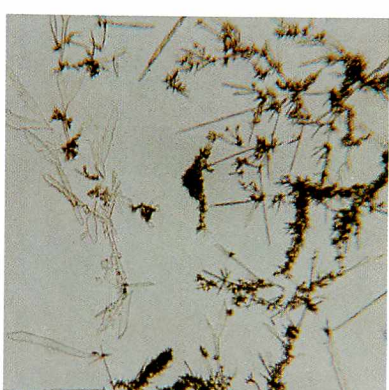
Cyclopentylate – gold bromide 430X



Cyclopentylate – gold chloride 430X



D-Methorphan – platinic chloride 100X

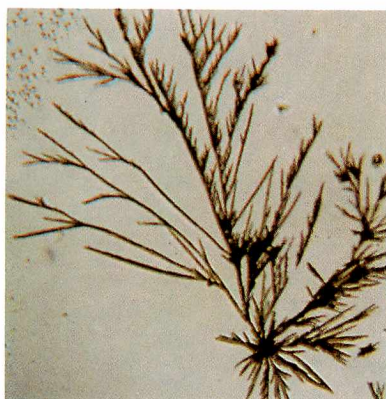


Diphenhydramine – platinic chloride 100X

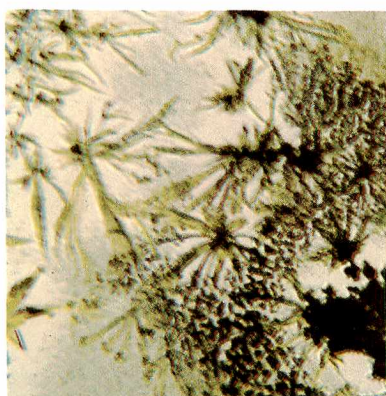


Diphenhydramine – gold chloride 100X

antihistamines



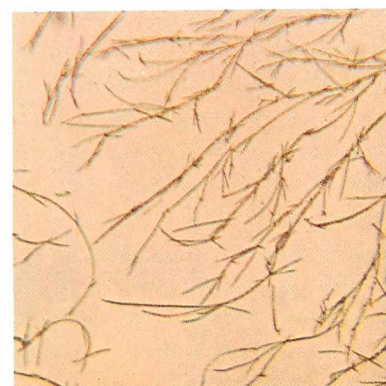
Methapyrilene – platonic chloride 100X



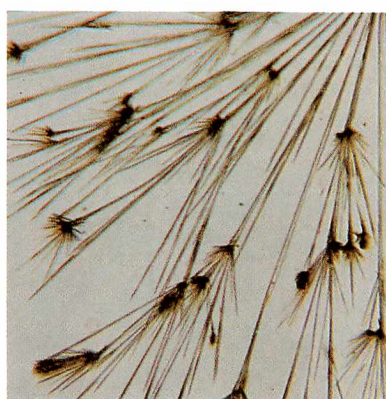
Methapyrilene – gold chloride 100X



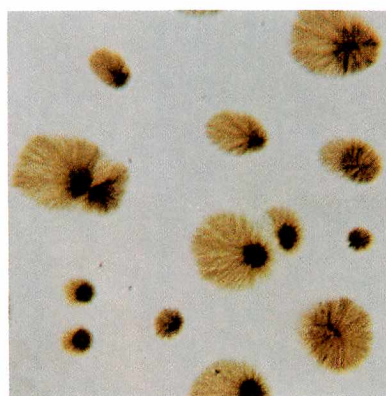
Pheniramine – gold chloride 100X



Phenyltoloxamine – platonic chloride 100X



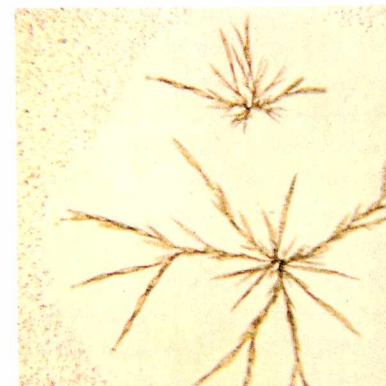
Pyrilamine – platonic chloride 100X



Pyrilamine – gold chloride 100X



Thenyldiamine – gold chloride 100X



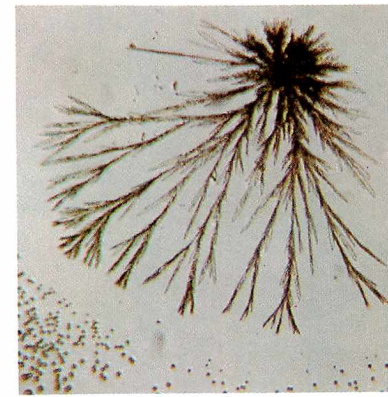
Thenyldiamine – platonic chloride 100X



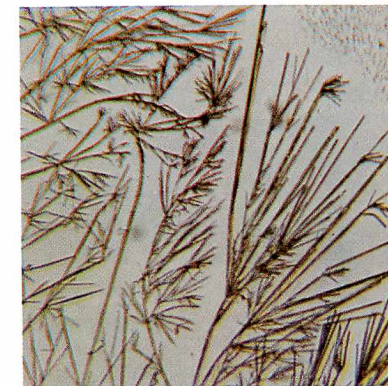
Thonzylamine – platonic chloride 100X



Thonzylamine – gold chloride 100X

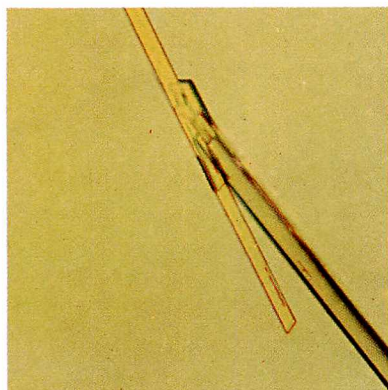


Tripelennamine – platonic chloride 100X

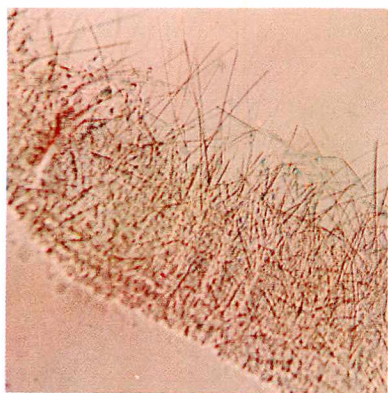


Tripelennamine – gold chloride 100X

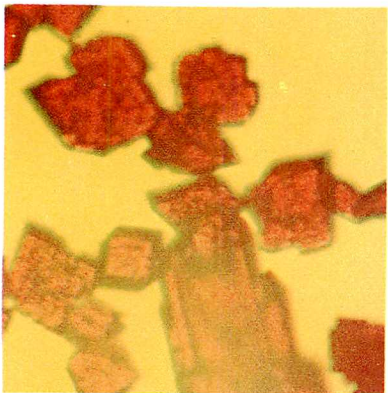
central nervous system stimulants



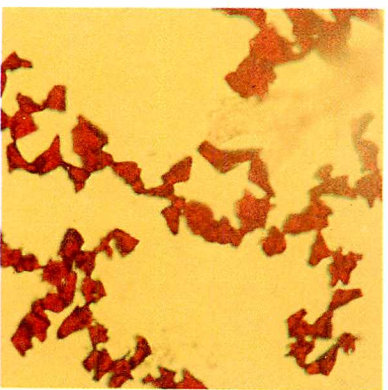
d-amphetamine – gold chloride 100X



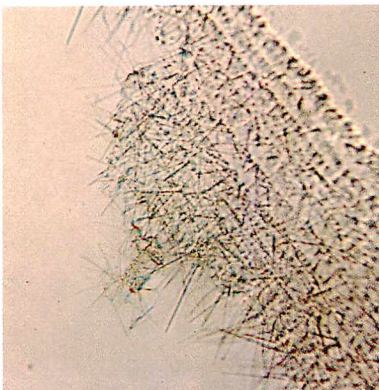
d-amphetamine – platinic chloride 100X



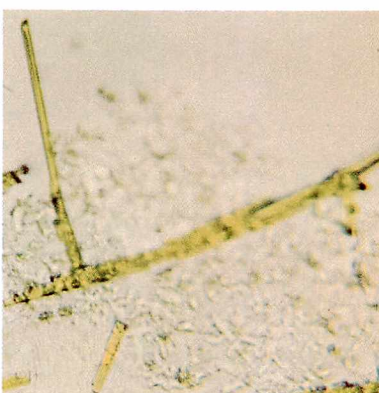
d-amphetamine – bismuth iodide 100X



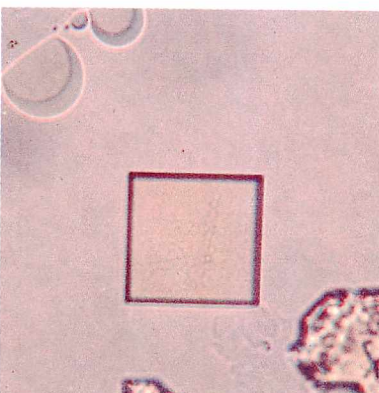
l-amphetamine – bismuth iodide 100X



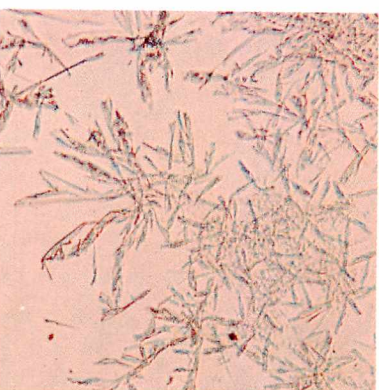
l-amphetamine – platinic chloride 200X



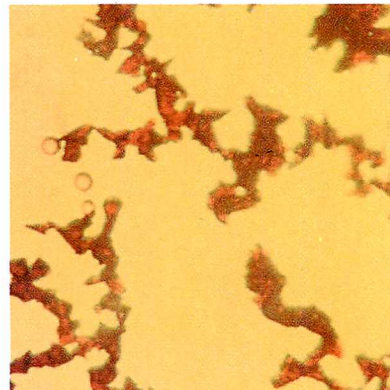
l-amphetamine – gold chloride 100X



dl-amphetamine – gold chloride 430X



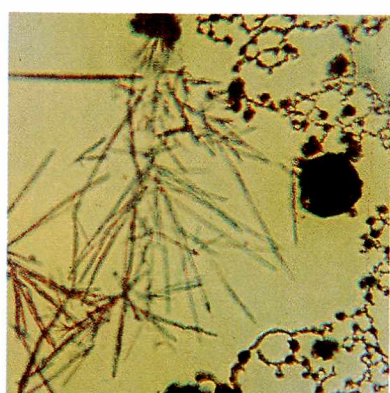
dl-amphetamine – platinic chloride 200X



dl-amphetamine – bismuth iodide 200X



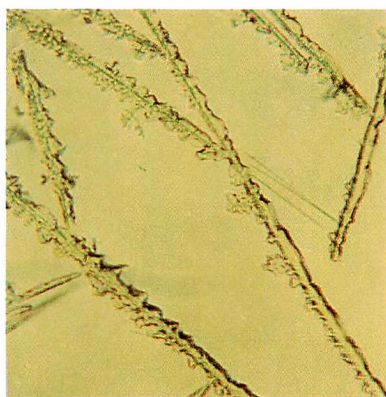
l-ephedrine – gold chloride 200X



l-ephedrine – bismuth iodide 200X

For procedures and reagents, these two pages, see AOAC 10th ed., 32.286-288.

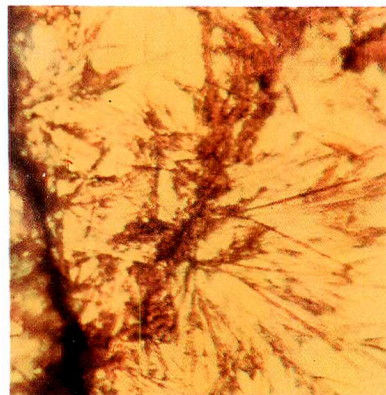
central nervous system stimulants



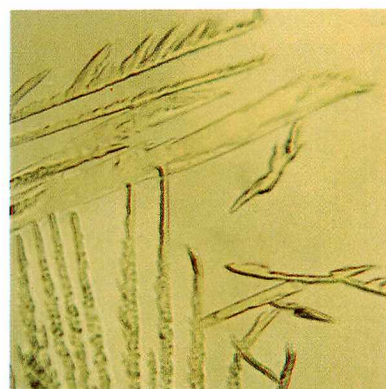
d-methamphetamine – gold chloride
100X



d-methamphetamine – platinic
chloride 200X



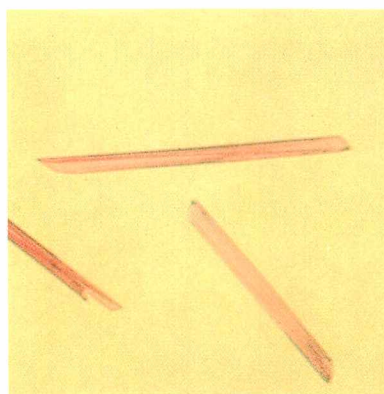
d-methamphetamine – bismuth iodide
100X



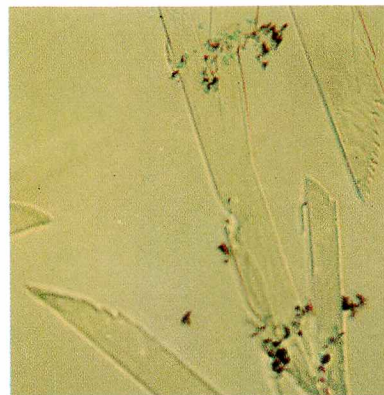
l-methamphetamine – gold chloride
100X



l-methamphetamine – platinic
chloride 100X



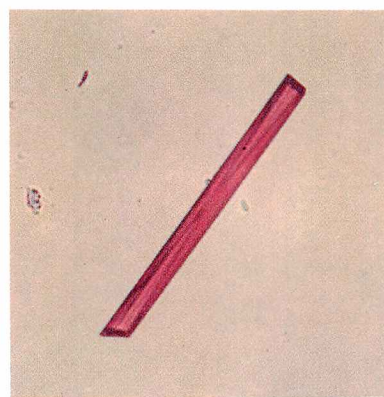
l-methamphetamine – bismuth iodide
200X



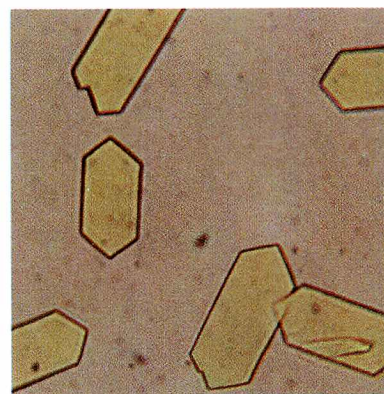
dl-methamphetamine – gold chloride
100X



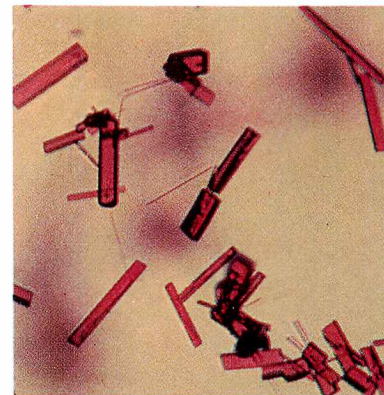
dl-methamphetamine – platinic
chloride 200X



dl-methamphetamine – bismuth
iodide 430X



Phenylpropanolamine – gold chloride
430X

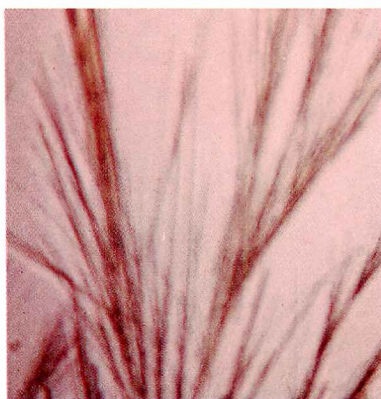


Phenylpropanolamine – bismuth
iodide 200X

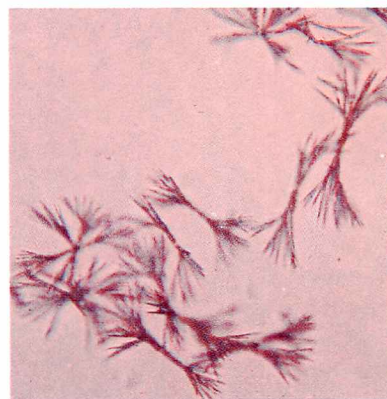
alkaloids and related amines



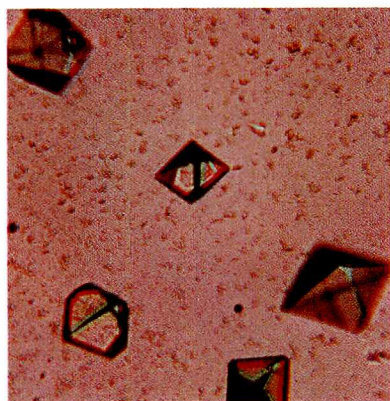
Apomorphine – gold chloride 200X



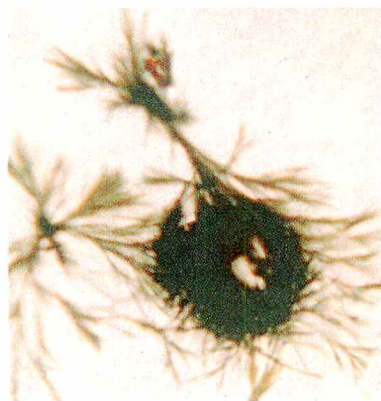
Codeine – platinic chloride 100X



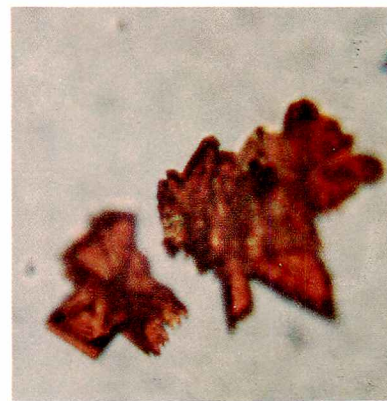
Ethylmorphine – IKI 200X



Apomorphine – KI 200X

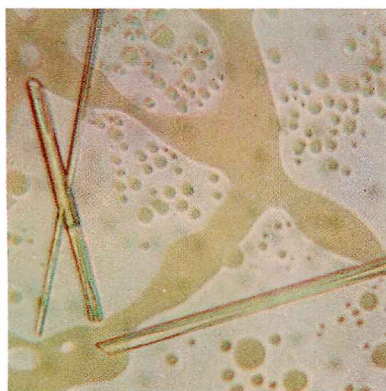


Codeine – IKI 430X

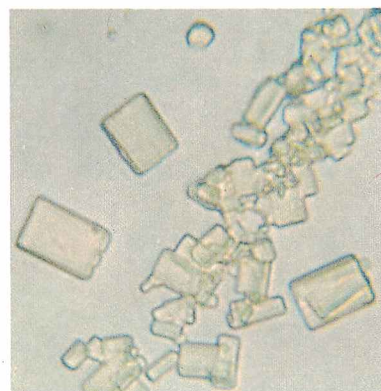


Morphine – IKI 430X

quinine



Quinidine – KI 430X



Quinine – KI 970X

Dissolve a small amount of the powdered sample in one drop of 1N HCl. Add a few crystals of KI, stir, leave uncovered and examine after one hour.

Mercury in Fish

by Anthony C. Celeste and Clifford G. Shane

In 1969 Norvald Fimreite, a graduate student at the University of Western Ontario, concerned at the increasing industrial use of mercury in Canada, determined to investigate his suspicions that much of this toxic metal was being released into the environment and was contaminating freshwater fish. In March 1970 he collected 42 samples of fish from the Lake St. Clair area of Ontario and sent them to a California laboratory for analysis. The analysis showed that the fish contained alarming amounts of mercury residues.

A serious hazard to humans from mercury contamination of the environment had already been shown several years earlier. In the 1950's reports from Japan confirmed that people were being poisoned by methyl mercury. A plastics manufacturing plant at Minamata, Japan, discharged waste containing mercury into the nearby bay. Families of fishermen in the area ate from the daily catch as a part of their normal diets. A total of 111 people died or suffered severe injuries from eating mercury-contaminated fish caught in the polluted waters. In 1956 Japan banned fishing in Minamata Bay. Scientists who examined fish from the bay found as much as 40 parts per million (ppm) mercury residues.

In 1965 at Niigata, Japan, 120 persons were poisoned. The mercury content of fish samples from that area ranged from 9 to 24 ppm. Again the poisonings resulted from the wastes of a plastics plant discharged into the waters of the nearby bay and river. The mercury residues were traced from the source to the fish and shellfish inhabiting the polluted water and to people who ate the fish. Some mothers who had otherwise shown few or no symptoms gave birth to infants with congenital defects that were ascribed to mercury poisoning.

Mercury contamination of the environment has also been reported in Sweden, where the sources were traced to agricultural and industrial uses.

The United States is one of the world's principal users of mercury and used 5.7 million pounds in 1968. The major uses of mercury in the United States are in chlorine-alkali manufacturing, electrical fluorescent lights, electrical switches and batteries, paint mildew proofing, various instruments, agricultural fungicides, catalysts for making plastics, pharmaceuticals for skin diseases, dental preparations, and general laboratory work.

There are many sources of direct and indirect mercury pollution of the environment. The sources with the greatest potential for contamination of food and water must first be identified before action can be taken to minimize or eliminate it. Mr. Fimreite's findings pre-

cipitated activity in Canada and investigations by FDA District offices and other Federal and State agencies in this country. The result is that additional safeguards have been instituted to strengthen consumer protection and possibly prevent another Minamata or Niigata.

Prior to Mr. Fimreite's activity, the United States had already established, in May 1969, an action guideline level of 0.5 ppm mercury in the raw edible parts of fish and shellfish. This level is based on present toxicological information and the analytical methodology available to science. Levels of mercury found in fish from Lake St. Clair as a result of Mr. Fimreite's action exceeded this 0.5 ppm guideline and the report of contamination thus became of immediate and extreme concern. Canadian officials also had established a guideline and began seizing fish taken from Lake St. Clair.

The FDA, after being advised by Canadian officials of the mercury contamination in Lake St. Clair in March 1970, notified the Detroit District of the potential problem. On March 23 Detroit District began an investigation to determine the seriousness and extent of pollution and sources of mercury contamination, coordinating its activities with Canadian officials and State and other Federal agencies.

Two chlorine-alkali plants were soon identified as the primary sources of release of mercury into the lakes and rivers mentioned. Canadian officials informed the District that a chlor-alkali plant in Sarnia, Ontario, owned by Dow Chemical Company, was discharging mercury into the St. Clair River from its plant situated at the river's mouth near Lake Huron. The Detroit office of the Federal Water Quality Administration of the U.S. Department of the Interior informed the FDA's Detroit District that Wyandotte Chemical Corporation, Wyandotte, Michigan, was using a mercury process at its plant on the Detroit River, south of the city. FDA investigation of these plants confirmed that mercury was being used and indicated probable discharge into the rivers.

Later investigations of three other chlor-alkali plants in Michigan indicated that two did not use mercury and the third had ceased operation and, in any case, had dumped its wastes into a depleted salt well. A survey of paper pulp mills in Michigan by the State's Department of Natural Resources and FDA's Detroit District showed these mills had discontinued use of mercury as a slimicide about five years earlier.

Following the discovery of pollution of the St. Clair River, Canada embargoed all commercial catches of walleye pike from Lake St. Clair and the St. Clair River and stopped domestic sale of and export of these

Anthony C. Celeste, chief chemist of the Detroit District, joined FDA's New York District as a chemist in 1960.



fish to the United States. The Canadian government announced a ban of commercial fishing in the lake and in the river. The announcement said fish in Lake Erie also were contaminated. The ban was later extended to all fishing—sport and commercial—in Lake St. Clair, the St. Clair River, and the Detroit River.

Detroit District, coordinating its efforts with the Bureau of Commercial Fisheries of the Department of the Interior and the Michigan Department of Natural Resources, obtained samples of fish from these waters. There was no commercial fishing in the U.S. waters of Lake St. Clair and the St. Clair River. Inspectors also collected samples of fish taken from Lakes Erie, Huron, and Michigan by commercial fishermen. All District fish wholesalers and cold storage plants were surveyed to locate fish taken from Lake Erie and Lake St. Clair. The Ohio Fish and Wildlife Service supplied the first samples of Lake Erie fish to Detroit District.

Analysts at Detroit District worked around the clock seven days a week. They completed the first analysis on March 29. The Denver and Chicago Districts assisted in the analyses. Cincinnati and Buffalo Districts covered their portions of Lake Erie.

FDA moved to prevent importation of contaminated fish from Canada, informing the U.S. Customs Service that all Canadian fish were to be held for FDA examination before release. On April 10 a lot of white bass from Canada, reportedly taken from Lake Erie, was detained when the mercury level was found to be over 0.5 ppm. Canada exports about 80 million pounds of Great Lakes fish annually to the United States. At the same time the Canadian government banned the distribution of perch and walleye from Lake Erie.

Food and Drug Administration officials at meetings with officials from Michigan, Ohio, the Ontario government, and the Canadian federal government began an attack on the problem. Agreements were reached to work to eliminate contamination of the lakes and to accelerate testing to better define the problem.

Canada agreed to impound and test all perch and walleye from Lake Erie and issue a formal release on each entry assuring that the fish had been tested. The agreement later was extended to bass and sheepshead. No fish would be entered from Lake St. Clair. Canada would not allow export of fish from other lakes found to be contaminated with mercury. FDA would test all entries of fish from Lake Erie not certified by the Canadian government and spot check all entries.

State governments also began taking action as information was developed implicating bodies of water within their borders.

Clifford G. Shane, chief inspector of the Detroit District, joined FDA's Kansas City District as an inspector in 1955.



In an expanding investigation all other FDA Districts became involved on April 10 upon FDA's announcement of a nationwide program to:

1. Determine which bodies of water—rivers, lakes, etc.—over the Nation had the potential for being contaminated with mercury from pollution by chlor-alkali plants, vinyl chlorine plants, and other operations in which mercury compounds are used or misused.
2. Determine the levels of mercury residues in sport and commercial fish from these waters.
3. Determine the levels of mercury residues in imported fish.

These objectives were to be accomplished in cooperative activities with State and local governments and other Federal agencies through the inspectional and laboratory branches of FDA Districts. Analytical findings, communications, reports of inspectional activities, and developments were to be referred to the Bureau of Foods and Pesticides for information coordination and compilation.

The program anticipated that all major sources of stream pollution would be identified by September. However, it appears that FDA cannot be certain of the completeness of this assessment, since there have been findings of high residues in situations where there is no concrete determination of mercury sources. Further, the migratory habits of fish add to the complexity of the problem. These and other factors preclude at this time a determination that all areas of stream pollution have been identified or that all areas where fish are likely to have high residues have been pinpointed.

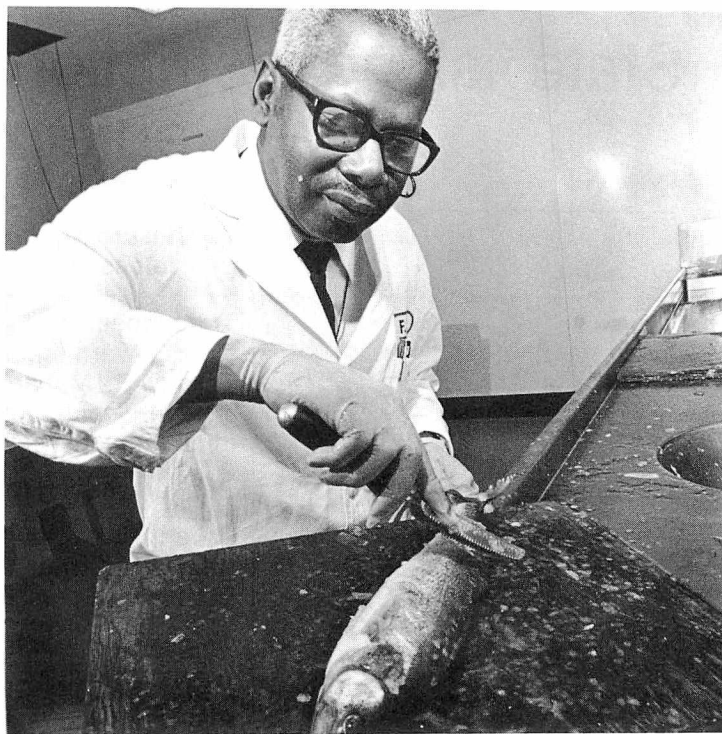
By selectively sampling and analyzing fish from areas with known or suspected pollution, FDA has been able to isolate areas that needed further attention from the respective States. More than 900 samples representing 37 species of fish from 28 bodies of water had been analyzed through mid-September. About 25 percent of the samples were found to contain mercury at or above the 0.5 parts per million guideline level.

The FDA program and the activities of other Federal and State agencies have resulted in 18 States issuing limitations, warnings, or bans on fishing. The following table identifies those States that have taken action to limit consumer consumption of fish high in mercury residues: see page 30.

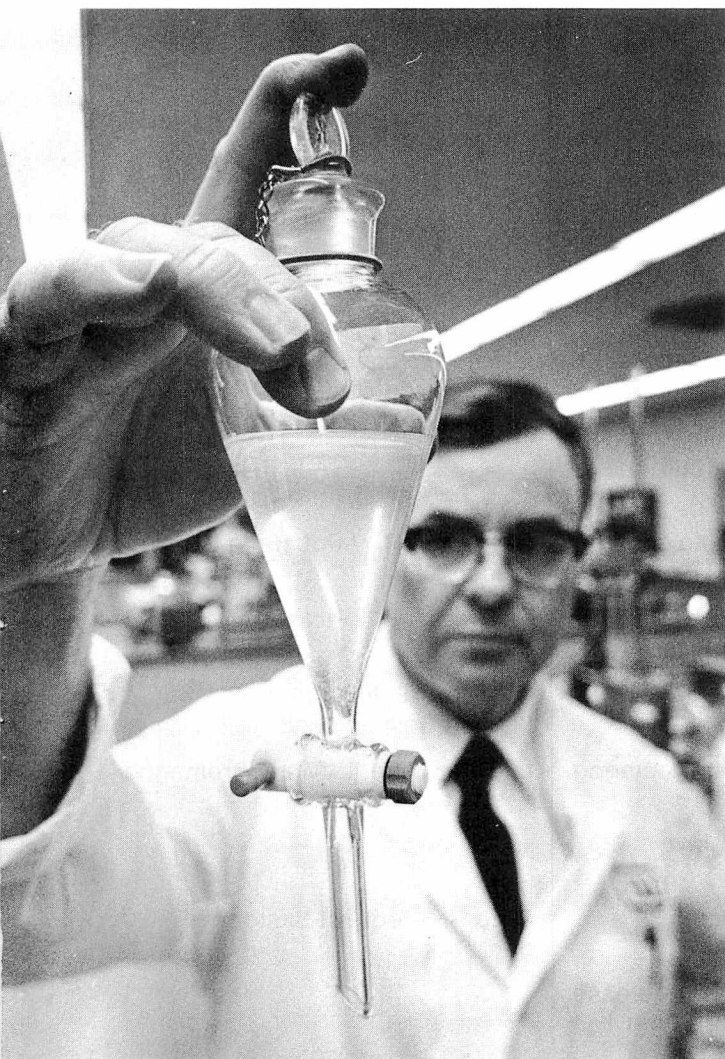
In its continuing activities, FDA hopes to identify and eliminate any remaining problems of mercury contamination of freshwater fish. The Agency will take regulatory action against any fish product, either imported or in interstate commerce, found to contain 0.5 parts per million or more of mercury.



Norvald Fimreite, the graduate student whose investigations precipitated a series of actions by both the Canadian and U.S. Governments to protect consumers from mercury residues in freshwater fish, is shown with some samples used in his research.



At the Detroit FDA District laboratories, a physical science aide prepares fish for analysis for mercury.



A chemist in the Detroit District laboratory shakes a separatory funnel in a sample purification step of analysis prior to determination on a spectrophotometer.



A Detroit District chemist observes an apparatus that chemically digests a fish sample into liquid form for analysis.

State fishing restrictions because of mercury —September 1970

State	Closure, warning, or catch release for sport fishery	Closure, embargo, or warning to commercial fishery
Alabama	Tombigbee R. up to Jackson Dams—warning; Mobile R., Tensaw R., Mobile-Tensaw system, Tennessee R. and impoundments—warning	Tombigbee R.—closed; Mobile R., Tensaw R., Mobile-Tensaw system, Tennessee R. and impoundments—closed
California	Danger warning (general)	
Georgia	Savannah R., New Savannah Dam to Highway 12—closed; Brunswick Estuary—closed	Brunswick Estuary—closed
Louisiana	Calcasieu R.—warning	
Michigan	Detroit R., L. St. Clair, St. Clair R.—catch and release only; So. L. Huron, West L. Erie—take no walleye, drum, or white bass.	Detroit R., L. St. Clair, St. Clair R.—closed; So. L. Huron, West L. Erie—closed to walleye, drum, white bass. Embargo on species other than walleye, drum, white bass.
Mississippi	Pickwick L.—warning	Pickwick L.—closed
New Hampshire	Merrimac R., Connecticut R.—danger warnings for pickerel, yellow perch, smallmouth bass	
New York	L. Champlain, Erie, Ontario, Oswego R., Niagara R., St. Lawrence R.—danger warnings; L. Onondaga—closed	
North Carolina	Danger warning (general)	
Ohio	L. Erie—warning released via news	L. Erie—closed to walleye, embargo on white bass
Pennsylvania	L. Erie—danger warning for walleye, drum, smallmouth bass, white bass	
South Carolina	Savannah R., Augusta to coast—closed	Savannah R., Augusta to coast—closed
Tennessee	Tennessee R., Pickwick L.—warning, catch and release	Tennessee R., Pickwick L.—closed
Texas		Oysters, 19,900 acres Lavaca Bay—closed
Vermont	L. Champlain, L. Memphremagog—danger warning	L. Champlain, L. Memphremagog—embargo on sales
Virginia	N. Fork Holston R., below Saltsville—warning	
West Virginia	Ohio R.—danger warning	Ohio R.—request to stop operations
Wisconsin	Wisconsin R.—catch and release recommended, no more than 1 meal per week	

Investigational and New Drugs

By Marion J. Finkel, M.D., and Joshua Zatman

To the millions of consumers throughout the country our procedures and requirements at the Bureau of Drugs in processing Investigational and New Drug Applications are more than a matter of academic interest. They see our expectations as their guarantee of the safety and efficacy of the drugs they use. This is why we are constantly seeking new ways of both strengthening and streamlining our review methods, of providing added safeguards for those on whom drugs are tested, and of improving investigative reports.

Just recently we proposed to amend our regulations to provide a 30-day waiting period for the initiation of human drug tests after we receive the Investigational New Drug Application. And we have proposed to set up special institutional review committees to assure that clinical testing of persons in hospitals, prisons, research facilities, or other institutions is carefully supervised. At the same time, we are trying to speed up our actions so drugs can be marketed and made available to the physician and the patient without unnecessary bureaucratic delays.

We demonstrated our desire and our ability to achieve this purpose by approving New Drug Applications for L-dopa last May in half the time the law gives us to act on New Drug Applications. Our approval, for the first time, carried a requirement that the pharmaceutical firm maintain structured, prolonged clinical trials to provide information on the drug's long-term studies, not only to ascertain prolonged safety but also ultimate efficacy. Examples of the latter could include antihyperglycemic and antilepticemic agents.

Our primary concern in all of our actions is the protection of the consumer. This responsibility is spelled out clearly in the first Food and Drugs Act in 1906 and in sub-

sequent additions and amendments all the way up to the 1962 Kefauver-Harris Amendments. These amendments, among other things, increased the FDA's regulatory authority over the clinical testing of new drugs and required substantial evidence of a drug's efficacy, in addition to its safety, before it could be marketed.

Crucial to the marketing is the kind and extent of investigational drug testing. It is in the three testing phases that we expect the Investigational New Drug sponsor to carry on the adequate and well-controlled investigations that are basic to compiling and presenting to us the substantial evidence needed under the law to validate the New Drug Application. Before explaining what we mean by the phrase, "adequate and well controlled investigations," let us outline briefly the three phases and the information required in IND Forms 1571, 1572, and 1573.

In Phase I, pharmacology studies are used to determine toxicity, metabolism absorption and elimination, and other pharmacological action; preferred route of administration; and safe dosage range. These studies involve a small number of persons and are conducted under carefully controlled circumstances by persons trained in clinical pharmacology.

When Phase I demonstrates satisfactory results, the sponsor may proceed to Phase II—initial trials on a limited number of patients for specific disease treatment or prevention. Additional pharmacological studies performed concurrently on animals may be necessary to indicate safety. If the information obtained in Phases I and II demonstrates reasonable assurance of safety and effectiveness or suggests that the drug may have a potential value outweighing possible hazards, proposals for Phase III, involving extensive clinical trials, are in or-

der. These studies are intended to assess the drug's safety, effectiveness, and most desirable dosage in treating a specific disease in a large group of subjects.

The information in the IND Forms must include: 1. Chemical and manufacturing data. 2. Results of all preclinical studies, including animal investigations. 3. A statement of the investigators' training and experience. 4. Copies of all informational material supplied to each investigator. 5. The sponsor's agreement to notify the FDA and all investigators of any adverse effects resulting from the drug's use in either animal or human tests. 6. The investigator's agreement to obtain the consent of the person before the drug is tested on him. 7. Agreement to submit annual progress reports and commitments regarding disposal of the drug when studies are discontinued. 8. A detailed outline of the planned investigation.

It is on this last requirement that the IND usually stands or falls. The outline or protocol must set forth a clear-cut, comprehensive description of the procedures, measurements, controls, and analysis methods to be followed to obtain objective, unbiased, therapeutic information. Too frequently, however, the protocol has been unclear, insufficiently detailed, and poorly designed.

Perhaps we have been at least partly responsible because we failed to make absolutely clear just what we expected. We held workshops independently and at the invitation of the pharmaceutical industry to explain what we meant by adequate and well-controlled investigations and the kind of evidence to be elicited from those studies to justify an NDA approval. And we talked with individual drug manufacturers.

It became evident from these discussions that written clarifica-

tion was needed. Accordingly, last May, the FDA published the final version of regulations outlining the principles constituting the essential elements of controlled clinical drug testing (see FDA PAPERS, June 1970). They form the ground rules for determining the substantial evidence the law requires for us to approve drugs for marketing.

And in June of this year, we proposed to the Pharmaceutical Manufacturers Association that we each develop written clinical guidelines for specific classes of drugs, that we meet in the fall to discuss our respective protocols and decide upon jointly approved guidelines, and that these then be submitted to advisory panels of academic experts for their review. It should be emphasized that these guidelines are suggestions and recommendations for desirable clinical studies. They are in no way intended to mitigate against the introduction of additional well-planned clinical trials or substitution of these trials for certain of the guidelines when circumstances or newer information so dictate.

The true function of the controlled trial is twofold: to separate the valid advances in drug therapy from a host of false leads and unverifiable clinical impressions, and to delineate scientifically and objectively the extent of and limitations surrounding the drug's safety and effectiveness.

As Dr. D. R. Laurence says in his book, *Clinical Pharmacology*, "Progress is delayed when convinced opinions are offered in place of convincing facts. The former, though not necessarily wrong, are unreliable, despite the great assurance with which they are often advanced."

A confirming opinion is voiced by the New York Academy of Medicine's Committee on Public Health in a 1962 report: "It is the judgment of competent authorities

that the relative effectiveness of specific therapeutic measures can be reliably established only in well-controlled comparative clinical investigations."

What should the protocol include? Certainly, as in any other plan, it must state its objective—the question or questions to be answered by the clinical trial.

Next, the protocol must contain criteria for accurately diagnosing and defining the disease involved, along with appropriate confirming laboratory tests. The initial diagnosis, therefore, must be correct and based on uniform and fully described methods so other clinicians may use them with the same result.

The third factor to be included is a method of selecting patients and allocating them to treatment groups in such a way as to minimize the risk of bias. In the words of Dr. Louis Lasagna, "It is difficult to conceive of a rule more important for the clinical investigator than that of avoiding bias in the allocation of cases to different treatment groups." Experience has shown that the best way to avoid bias and eliminate influencing variables, both known and unknown, is deliberate randomization.

Dr. A. B. Hill, in a 1952 article, "The Clinical Trial," in the *New England Journal of Medicine*, explains that this method of allocation accomplishes two aims: "It insures that neither our personal idiosyncrasies (consciously or unwittingly applied) nor our lack of balanced judgment has entered into the construction of the different treatment groups . . .; it removes the danger . . . that believing we may be biased in our judgments we endeavor to allow for that bias and that in so doing we may overcompensate and introduce a lack of balance from the other direction. . . ."

To obtain valid data, the clinical

trial must be conducted on a valid, unbiased basis. No analysis, however high-powered, can compensate for data of dubious validity.

The fourth protocol requirement also involves the elimination of bias—this time, bias by both patient and observer in reporting results of the clinical tests. It should explain the methods of observation, the recording of results, and a description of the scoring system. In sum, the protocol must detail what measurements will be taken, how they will be taken, and precisely when.

Fifth, we expect the protocol to include a description of the steps to be taken to compare variables such as age, sex, duration of disease, and use of drugs other than those under study. If the groups of patients in the study are similar in observable characteristics at the outset, it would be logical to assume that, in a rigidly designed protocol, changes that take place in the groups subsequently may be attributable to the only known difference between them—the treatment.

An extension of this requirement is the next step—that of describing the methods to be used in analyzing the patient responses. This involves use of standard record forms, uniformity in completing them, and appropriate methods for storing and retrieving the information easily and promptly.

Not only is it important in a controlled trial to avoid bias in setting up the treatment groups to be compared; it is equally important to minimize the introduction of bias that may arise during the experiment because of the preconceptions and expectations of the investigator and patient. The protocol, therefore, should list the methods to be followed to avoid that kind of bias. In general, the double-blind control should be incorporated into the experiment whenever it is feasible, although the single-blind tech-

nique is sometimes used, particularly in early stages of investigation or where the results to be measured are truly of the objective type.

The use of a patient as his own control seldom provides a valid study. Some exceptions include powerful diuretics, drugs for the treatment of malignancy, and oral contraceptives, namely, situations where the effect of a drug is so marked that its efficacy is obvious or where facts on historical controls are well established.

The double-blind technique refers to a treatment, the specific nature of which is unknown to both subject and observer. Single-blind refers to a trial in which one participant, usually the patient, is unaware of the treatment being received at any specific time. To be a valid control, of course, the placebo should closely imitate the test drug in shape, taste, smell, and any other action perceivable by the patient and physician.

Another vital factor in a protocol is a precise statement of the nature of the control group against which the effects of the new treatment can be compared. In a controlled experiment, comparison is obviously implicit. To use personal experience as a basis of comparison, personal experience that was obtained under different circumstances, certainly at another time, and perhaps at another place, would frequently and usually lead inevitably to erroneous conclusions because it fails to provide comparable bases for examinations of control and experimental groups.

Finally, the protocol must include a summary of statistical methods to be used in analyzing the data derived from the subjects. There may be times when results of a clinical trial are so clear-cut that a test of statistical significance is unnecessary. But medications are seldom so startlingly effective. For that reason, the sponsor of an ex-

Marion J. Finkel, M.D., deputy director, Bureau of Drugs, since last April, joined FDA as a medical officer in May 1963.

perimental drug would be wise to seek the advice of a competent statistical consultant in preparing his protocol.

We at the Bureau of Drugs feel that the standards and requirements outlined in the foregoing are essential to a valid conclusion of a drug's safety and efficacy. Without them, the testing procedure can neither be considered adequate nor well controlled.

There is another consideration that can be opportunely mentioned. The Food and Drug Administration has for some time deplored the "therapeutic orphan" aspect of the labeling of many drugs. Too many package inserts contain a statement such as "Contraindicated in children because studies have been inadequate to demonstrate safety in this age group." We, like Dr. Harry Shirkey, feel that this situation requires correction when feasible. Accordingly, we are adopting the policy that it is possible that a New Drug Application for a drug that would have considerable therapeutic utility in children and/or will be used by the practicing physician in the absence of adequate investigational studies in children will not be approved unless the necessary studies are performed.

It would be logical to assume that after the pharmacological and clinical studies have been carried out as well and as comprehensively as we expect, the New Drug Application would sail through our offices with little difficulty. Unfortunately, many NDA's founder on the rock of inadequate data with regard to the manufacturing processes to be used in producing the new drug. Some of the major deficiencies include:

1. Failure to name all the components of the drug, including inert substances and those used in the synthesis of the new drug.
2. Failure to state the quantities of inactive ingredients per dosage form unit—that is, per tablet or per mil-



Joshua Zatman, assistant for medical communication to the director, Bureau of Drugs, joined FDA in April 1969.

- liliter.
3. Failure to list the components of the batch formula in the finished product.
4. With regard to facilities and personnel, reference is sometimes made to a master file or another New Drug Application which has become outdated. Such information is useless unless it is on a current basis.
5. Inadequate information on the sterilization, sampling, and labeling procedures.
6. Inadequate information on the characteristics and testing of containers to demonstrate their suitability for the intended use, especially for plastics, metal tubes, and aerosols.

To remove many of the often observed manufacturing controls deficiencies in both IND's and NDA's, we have set up joint FDA-PMA committees to establish written guidelines for the use of all manufacturers. These committees are in the final stages of agreement on the detailed guidelines.

To those who would dismiss all of these requirements as so much unnecessary paperwork, we can only say that long experience has demonstrated conclusively that they are, indeed, vital components of procedures designed to protect the public.

Adapted from an address by Dr. Finkel to the University of Wisconsin IND-NDA Conference at Milwaukee on October 4.

BALTIMORE DISTRICT The District held two training courses recently—one for industry personnel and the other for FDA'ers. With the assistance of the Department of Justice Bureau of Narcotics and Dangerous Drugs, District personnel set up a training course for employees of Barre Drug Co., Baltimore, dealing with responsibilities of those who work with narcotics and control drugs. The principal speaker was Vincent Lozowicki, compliance officer with the BNDD Baltimore office. FDA people from the Baltimore, Philadelphia, and Boston Districts attended a training course in the operation of the Technicon Autoanalyzer, with instruction by Harvey Miller, supervisory chemist from the Chicago District. Beverly McCarthy from FDA's Training Institute attended in conjunction with a visit to the Baltimore District.

BOSTON DISTRICT When District inspectors found during an investigation of a local firm that it was re-packing one type of fish into cartons labeled as other types, seizures were ordered. Blocks of frozen cod were found in cartons labeled as flounder, and the inspectors took samples which, when examined electrophoretically, confirmed that the blocks were indeed codfish. Massachusetts' State inspectors embargoed the 38,000-pound lot until a U.S. marshal received orders to seize it. The lot was valued at approximately \$11,000 as codfish and would have been valued at \$15,000 as flounder. Electrophoretic examination of another lot of frozen fish blocks labeled as sole showed that the fish was Greenland turbot. This 2,500-pound lot was also seized.

BUFFALO DISTRICT A New York firm recently voluntarily destroyed 3,000 pounds of egg noodle products which it had recalled from the market because of *Salmonella* contamination. The firm estimates that the amount destroyed represents about 12,000 to 15,000 individual servings.

CHICAGO DISTRICT FDA's message of concern for the consumer and how the Agency implements its programs in relation to this concern are brought to the public's attention in various ways by the District's consumer specialists, Marguerite Robinson and Marie Ekvall. Miss Robinson developed and coordinated the third annual Consumer Problems Conference held recently at Southern Illinois University, Carbondale, which zeroed in on food and nutrition and introduced a new consumer problem relating to housing. Miss Robinson's presentation was titled, "How Safe Is Your Food?" The conference, cosponsored by FDA, Illinois Home Economics Association, Illinois Public Aid, and the University of Illinois Cooperative Extension Service,

is an areawide meeting attended by over 400 people, including educators, public aid employees, and the consuming public.

Both Miss Robinson and Mrs. Ekvall have made plans to work with the Health and Welfare Section of the Illinois Home Economics Association. They have developed their programs to include a workshop at the District and to implement the White House Conference on Food, Nutrition, and Health. This section of the association includes over 100 home economists who represent Cook County and the Illinois Departments of Public Aid, as well as hospital dietitians, nutritionists, and home economists from voluntary agencies throughout the State. The purpose of this program is to provide a greater impact for FDA's work with low-income people.

The consumer specialists are also planning to conduct ten regional workshops in consumer education at the request of the State of Illinois Department of Public Instruction. Over 2,000 teachers attending from throughout the State will hear the message, "FDA Looks at Consumer Education."

Using the radio as another medium, the consumer specialists have carried on an extensive program with radio stations throughout the State, ranging from three-hour live broadcasts to taped 30-second public service announcements. Among these was their participation in the series sponsored by WMBI in Chicago called "One Step Forward," which was designed especially for low-income areas of the city.

CINCINNATI DISTRICT T. C. Maraviglia, deputy regional food and drug director, and Carl R. Baeuerlen, District chief inspector, met at Columbus, Ohio, with John M. Stackhouse, director of the Ohio Department of Agriculture; Dr. David A. Hill, chief, Division of Foods, Dairies, and Drugs, also of the Department; and Max Weimer, his assistant. The meeting was held to discuss the feasibility of establishing specific, formal work-sharing agreements between Cincinnati District and the Department in certain food areas. The State officials have taken the matter under consideration.

Informal working agreements with Ohio in the medicated feed area and in sharing pesticides sampling and analytical results are already in effect.

DALLAS DISTRICT Hendrich Deelstra, Ph.D., professor of organic chemistry at the University Officielle, Republic of Burundi (Central Africa), visited the District laboratory to discuss FDA's methodology for determining pesticide residues in fish. Dr. Deelstra said

that cotton is a large crop in Burundi and that the fields are being sprayed aerially with pesticides. He is concerned about the runoff that may drift into nearby rivers and streams and possibly contaminate the fish.

DENVER DISTRICT New Improved W.M.C. Baking Specialty, a bright yellow powder used in bakery products and manufactured by Wheat Product Co., Colorado Springs, was ordered seized in Kansas City, Missouri, because of the presence of nitrites and nitrates, food additive compounds that are not permitted in such products.

KANSAS CITY DISTRICT On-the-job training started in late August for those State feed inspectors from several States who attended a basic training school earlier in the summer at Keokuk, Iowa. Omaha resident inspectors worked with an inspector from Nebraska and one from Iowa. Similar training was expected to get under way in Missouri during the latter part of September.

Kansas City and Chicago Districts and FDA's State Services office in Washington held the medicated feed training school at Keokuk for the State inspectors. Attendees were from Idaho, Illinois, Iowa, Kentucky, Missouri, Nebraska, and Tennessee. The training course agenda included FDA inspection techniques, discussion of State and Federal laws and regulations, report writing, and training inspections.

Both District offices made plans at that time to give on-the-job training to participants in the Keokuk school as the final step toward obtaining FDA commissions.

As a result of what the District calls "forty well-spent weeks" of training with its personnel, Lorraine Burns can now preside at exhibits and can present slides, films, and other visuals to small neighborhood groups not otherwise reached in the Kansas City area.

Mrs. Burns, a local elderly citizen, was assigned to the Kansas City District for a period of 40 weeks as a consumer education aide. The assignment came through the Senior Community Services Aides Project of the American Association of Retired Persons and the National Retired Teachers Association for her to assist the District's consumer specialist in reaching a greater number of consumers, particularly senior citizens.

Mrs. Burns' tenure with the project contributed a valuable service to FDA's consumer education program, and she plans to continue her interest in consumer education on a volunteer basis with the Scouts, and church and other small groups.

LOS ANGELES DISTRICT The presence of live insects resulted in the seizure of a 26-ton carload of soy grits and soy flour shipped from Decatur, Illinois, to a milling firm at Los Angeles. The cause of the infestation has not been determined.

A consumer complaint that a can of beef and rice product purchased at a Los Angeles food market was swollen was followed by District investigation of the dealer's stocks. Other swollen cans were found, and the firm decided to recall all stocks of the article from its branch stores. Although it was not determined what caused the swelling, examination of samples by the District laboratory were negative for food poisoning bacteria.

MINNEAPOLIS DISTRICT A local drug wholesaler asked the District to witness destruction by burning of over 900,000 special formula amphetamine-vitamin tablets. The firm had been warehousing and repacking the tablets for a doctor who discontinued his weight-reducing clinic, thus creating a large surplus of an unusable drug. The tablets were valued at \$3,258, and when the firm decided to destroy them, the doctor agreed to share the loss on a 50-50 basis.

NEW ORLEANS DISTRICT An entire shipment of imported sardines has been recalled because of problems found after the District's import officials had released the shipment into domestic commerce. The problems involving the 300,000-can lot of Danish "Clupea Canning" brand sild sardines went unnoticed and the lot escaped detention because it had been under refrigeration. Removed from refrigeration, the cans remained intact on the wharf long enough to pass examination and to be shipped. Then as temperatures rose, they began to explode. When the manufacturer was informed of the problem, which appeared to be faulty can seams and possible underprocessing, he came to the District office accompanied by the consignee, Emmanuel Stecker of the Maine Cannery Sales Corp., who voluntarily recalled the shipment for return to Denmark.

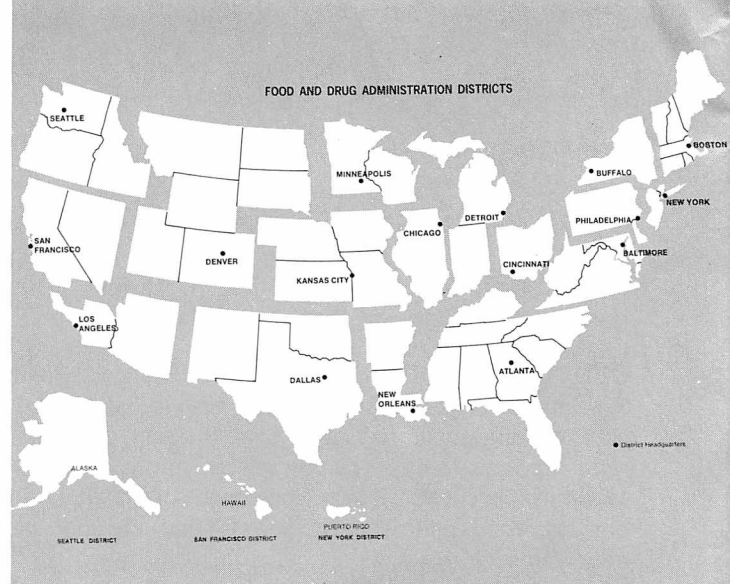
NEW YORK DISTRICT To help combat a serious problem of food spoilage due to insect infestation and rodent contamination in Puerto Rico, FDA has offered training to those who might be involved in trying to correct the problem. The San Juan Section (commonly called SanSec) of the New York District conducted a warehouse inspection and sanitary maintenance training for Puerto Rico Health Department officials and other government representatives during the week of August 17-21. Along with the New York District, SanSec is planning a two-day seminar-workshop for sanitation in the food manufacturing and storage industries in Puerto Rico. The program, tentatively set for November 5-6, will cover insect, rodent, and bacteriological problems, and controls for achieving and maintaining a safe and clean food supply.

Plans for offering such training were made following a recent request for help from Sylvia Lopez de Perez, Director of the School Lunch Program, Puerto Rico Department of Education, in solving what appeared to

be a very serious problem. The School Lunch Program feeds children on a daily basis in 2,500 public schools throughout Puerto Rico. Staples used include rice, flour, cornmeal, and beans, which are stored in 14 warehouses. From July 1968 to July 1969 warehouse food spoilage amounted to \$50,000. By October 1969 the spoilage rate was threefold.

Along with Puerto Rico Department of Health authorities, SanSec inspected three of the food warehouses located in the San Juan area and found that storage conditions in two were extremely poor. Considerable quantities of food stocks were found to be insect infested and rodent defiled. In the third warehouse, storage and sanitary conditions were satisfactory; however, insects were found in two lots of rice. SanSec collected samples representing several lots from the first two warehouses inspected, and referred results of the analyses to the Department of Health authorities for further action. The Department ordered the 146,000 pounds of foodstuffs destroyed. Local authorities ordered destruction of an additional 83,000 pounds not sampled by SanSec.

PHILADELPHIA DISTRICT A new Philadelphia Consumer Protection Committee has been formed by major Federal, State, and city consumer law enforcement agencies to combat fraud and deceptive selling practices. The principal goal of this committee is to establish a one-stop reporting system for consumer complaints, which will then be filed with the appropriate agency to bring about prompt response. Participating in the formation of the new committee were representatives of Philadelphia's office of the mayor, Federal Trade Commission, offices of the District Attorney, the State's Attorney General, the U.S.



Attorney, Commissioner of Police, and this District.

SAN FRANCISCO DISTRICT Two imported products came under the District's jurisdiction recently for different reasons. Four lots of frozen frog legs from India with a total value of more than \$11,000 were detained because of *Salmonella* contamination. A 25-case lot of canned sliced pineapple of Malaysian origin was seized in Stockton, California, after District analysis determined it had been excessively trimmed and therefore did not conform to FDA's standard of quality for canned pineapple.

SEATTLE DISTRICT Inspectors from the District and from the State of Washington jointly supervised disposition of food products damaged in a recent fire that destroyed a juice producing firm in the area. The products destroyed totaled approximately 60,000 gallons of bulk apple juice concentrate and 200,000 cases of canned apple juice.

FDA DISTRICT OFFICES

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

BALTIMORE 900 Madison Ave.
Baltimore, Md. 21201

BOSTON 585 Commercial St.
Boston, Mass. 02109

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

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

CINCINNATI 1141 Central Pkwy.
Cincinnati, Ohio 45202

DALLAS 3032 Bryan St.
Dallas, Tex. 75204

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

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

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

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

MINNEAPOLIS 240 Hennepin Ave.
Minneapolis, Minn. 55401

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

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

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

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

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

HEW REGIONAL OFFICES I-X

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

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

PHILADELPHIA Post Office Box 12900
Philadelphia, Pa. 19108

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

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

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

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

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

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

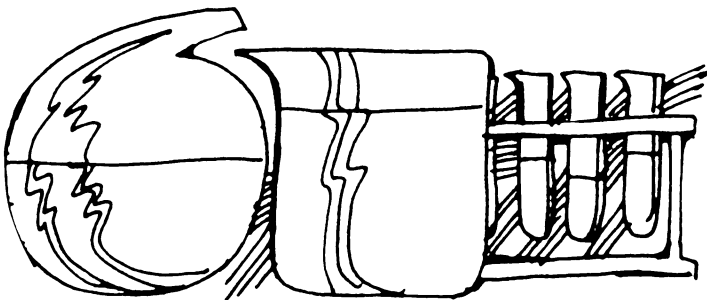
SEATTLE Arcade Bldg. Mezzanine
1319 2nd Ave., Seattle, Wash. 98101

product safety report

HAZARDOUS SUBSTANCES

The accompanying chart compares data for 1969 with that for 1968 and 1967 on accidental ingestions of products subject to the Federal Hazardous Substances Act.

The statistics indicate that one of the leading causes of hospitalization of children under five years of age is ingestion of products classified as caustic and corrosive cleaners. These generally contain strong acid or alkaline substances.



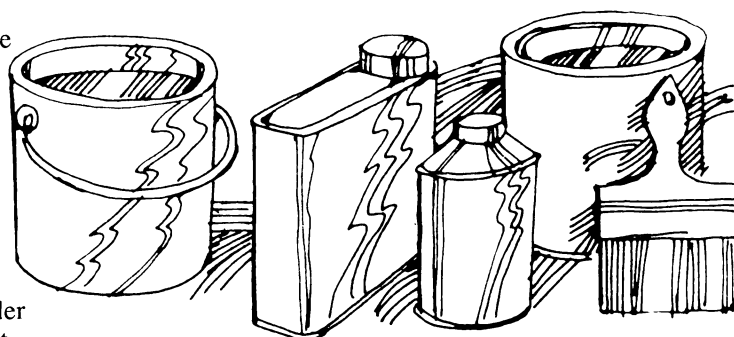
by establishment of adequate labeling for potentially hazardous household products. The purpose of the labeling requirements of this law is to alert the purchaser or user to hazards that may be encountered, to prescribe precautionary measures for handling and storage, to provide first aid information when necessary, to inform the physician and others of the hazardous ingredients, and to alert the public, especially parents, that they should keep the item out of the reach of children.

A means of dealing with products that are so hazardous that they are unsafe for household use, regardless of cautionary labeling, was provided by the "banning" provisions of the 1966 amendments to this statute.

Injuries by acids and alkalis are usually severe and rapid in their effects. The effects are evident whenever these substances come in contact with a body area—skin, eyes, mucous membrane, tongue, pharynx, stomach, and small intestines. The severity of the injury depends on the concentration of the chemical and the duration of exposure.

Ingestion of corrosive substances such as strong acids and alkalis frequently produces injuries of the esophagus which form strictures in healing and make that organ inadequate for maintaining nutrition. The management of a patient with a strictured esophagus requires long periods of hospitalization, months or years of dilations, or extensive surgical procedures to reconstruct an adequate swallowing tube. Treatment is difficult for the patient and is taxing on the family's finances.

Measures of prevention are of primary importance. One of these, we feel, is authorized under provisions of the Federal Hazardous Substances Act. A primary purpose of this statute is to protect the public health, particularly that of young children,



ACCIDENTAL INGESTION OF HOUSEHOLD PRODUCTS SUBJECT TO THE HAZARDOUS SUBSTANCES ACT

	1969 Incid. All Ages	Incid. Under 5 Yrs.	Hosp. Under 5 Yrs.	1968 Incid. All Ages	Incid. Under 5 Yrs.	Hosp. Under 5 Yrs.	1967 Incid. All Ages	Incid. Under 5 Yrs.	Hosp. Under 5 Yrs.
Household products containing petroleum distillates									
Cigarette and charcoal lighter fluids	1000	952	118	1111	1071	142	924	873	131
Oil paints, lacquers, and varnish	110	92	5	397	381	14	510	461	23
Solvents, paint and lacquer thinners, mineral spirits	882	718	83	596	552	91	564	504	74
Gasoline	1248	744	117	1136	842	132	875	627	93
Kerosene, fuel oil, petroleum distillates	1013	846	242	1159	1094	314	1007	947	257
Turpentine	813	691	79	953	879	95	312	300	85
TOTAL	5066	4043	644	5352	4819	788	4192	3712	663
Household polishes and waxes	797	696	134*	1019	975	178*	863	832	162*
Cleaners and detergents									
Bleaches (unspecified)	455	371	7	424	375	13	394	348	20
Bleaches (specified)	204	178	15	273	239	29	284	262	18
Cleaners and detergents	1512	1224	51	1741	1647	79	1237	1144	66
Solvents (nonpetroleum distillates)	59	41	17	135	123	22	156	143	19
Fabric cleaners	99	74	11	77	67	11	105	77	13
Caustic and corrosive cleaners	1174	790	154	831	679	126	652	496	87
TOTAL	3503	2679	255	3481	3130	280	2828	2470	223
Hobby and do-it-yourself kits									
Adhesives, cement glues, and glue (unspecified)	1109	930	14	643	599	13	438	297	13
Dyes	246	199	5	81	79	4	113	100	3
Ink	321	193	2	1	1	1	7	7	2
Gun bluers and cleaners	69	62	9	35	33	4	21	19	4
Artist and children paint sets	23	13	3	18	17	2	12	12	3
Miscellaneous	111	87	13	167	161	9	70	59	12
TOTAL	1879	1484	46	945	890	33	661	494	37
Yard and garden									
Fertilizers	531	392	4	109	96	4	105	81	4
Plants	1302	1033	29	1303	1172	35	881	768	33
TOTAL	1833	1425	33	1412	1268	39	986	849	37
Toys	22	17	3	180	174	4	32	28	2
Miscellaneous									
Automotive products	302	199	22	224	195	25	37	34	14
Chemicals	155	82	15	221	164	16	256	174	34
Household deodorizers and deodorants	669	587	19	151	146	15	348	344	8
Paint	1162	932	25	229	222	30	(Category breakdown not available for 1967)		
Miscellaneous	12	11	7	326	319	5			
TOTAL	2300	1811	88	1151	1046	91	641	552	56

Source—Abstracted from Poison Control Center Reports submitted to the National Clearing House for Poison Control Centers
 *Hospitalized cases are due to products containing petroleum distillates

state actions

Emergency Appointment John C. Schilling, chief of the milk control section of the St. Louis Health Department, has been appointed acting deputy health commissioner for environmental sanitation, in addition to his regular duties. Mr. Schilling replaces John L. Sadowski who died in an auto accident August 19, along with five members of his family. Mr. Sadowski had been deputy health commissioner with the St. Louis Environmental Sanitation Service since 1964, and had served the city health commission for about 20 years.

Cooperative Action Through a cooperative investigation started late last spring by the Alabama and Mississippi Departments of Agriculture and the FDA, the source of a contamination problem has been found and the problem has now been corrected. After residues of dieldrin were found in milk distributed in the Alabama State area, the investigation was initiated by the State of Alabama and FDA. One of the producers supplying milk to the dairy was found to be feeding his cows cottonseed meal that was determined to be the source of the dieldrin contamination. Because the meal was supplied by a Mississippi firm, that State's Department of Agriculture and FDA continued the investigation. They found that the meal itself had not been contaminated at the time it was produced, but it became contaminated when it was placed in used bags that had contained seed treated with pesticides.

The Mississippi Department embargoed 40 tons of cottonseed meal at the mill, and when the firm recalled all of the meal that had been distributed in bags, the State embargoed this also. After considering various methods of salvaging 9,500 used bags still on hand, the firm decided to destroy them. The bags were buried in a trench and covered

over with three feet of earth in the presence of a Mississippi Department of Agriculture representative. In the meantime the cottonseed meal had been relabeled as being fit only for fertilizer and had been sold to a fertilizer manufacturer.

Testing Requirements Based on its most recent tests for mercury residue in fish taken from Lake Erie, the Ohio Department of Agriculture in September lifted presale testing requirements for sheepshead, catfish, carp, and mullet. At that time, presale testing of white bass was still required. The testing requirements for perch had been lifted several weeks before.

Quackery Exhibit An exhibit of devices and medicines used in quackery promotions in California was on display in September at the Los Angeles County Museum of Science and Technology, sponsored by the California Department of Public Health and the Los Angeles branch of the American Cancer Society. Displayed were various devices and preparations that had been subject to legal actions under California consumer protection laws through the past years. Some had also been subject to FDA investigations and action.

Quarantine California State inspectors from the Bureau of Food and Drugs quarantined 2,000,000 pounds of black-eyed beans and pinto beans of California origin in a bean storage warehouse in Turlock, after finding live rodent infestation. The State is allowing the quarantined articles to be released with the provision that each bag be first checked for evidence of rodents by use of the ultraviolet light.

Contaminated Feed A chain reaction that ended in deaths of farm animals started a cooperative investigation by the Michigan Department of Agriculture's Plant Industry Division, the FDA, and the U.S. Department of Agriculture's Con-

sumer and Marketing Service. The deaths on a Michigan farm were reported to be due to mercury-contaminated feed. During the ensuing investigation the mercury was traced to a fungicide leaking from a faulty seed-treater at a feed mill in Montrose, Michigan. The fungicide was soaking floor sweepings that were later incorporated into a feed sold locally, and use of the feed at the farm reportedly caused the animals' deaths. All feeds possibly contaminated have been removed from feed use under supervision of the Michigan Department of Agriculture, and the feed mill has volunteered to remove seed-treating operations to a separate building and to decontaminate the plant areas where the leakage occurred.

Because almost all materials involved were from Michigan, the State Department of Agriculture was the principal investigator, assisted by the FDA and the USDA.

Filth in Foods Because of extensive rodent infestation in and around the premises, the Pennsylvania Department of Agriculture seized \$120,000 worth of foodstuffs at the Pantry Pride Supermarket in Philadelphia. Department inspectors worked throughout the night and well into the next day before seizing the food. They collected 20 mice and two mouse nests while examining the store premises, and found rodent excreta heavily and widely spread on, under, and throughout food stocks. Rodent activity was noted particularly in the processing room where cold cuts and other ready-to-eat items were handled, and the inspectors found areas where dust, debris, spilled food, and excreta "evidently had been accumulating for several years."

Bernhard Larsen, director of the Department's Bureau of Foods and Chemistry, said that the manager of the store closed the establishment after the food was seized.

seizures and post office cases

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

A total of 56 seizure actions to remove from the consumer market products charged to be violative were reported in September. These included 31 seizures of foods: 9 involved charges concerning poisonous and deleterious substances, 9 involved charges concerning contamination, and 13 in-

involved charges concerning economic and labeling violations. Other seizures included 1 of food additives, 2 of vitamins and dietary food, 14 of drugs (including 1 of veterinary and medicated feed), 5 of medical devices, 1 of cosmetics, and 2 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD / Poisonous and Deleterious Substances		
Beet sugar, granulated/Penn, Pa. 7/13/70	The Chesapeake Operating Co./ Baltimore, Md. (S)	Contaminated by antimony ore dust; held under in- sanitary conditions.
Pittsburgh, Pa. 7/9/70	"	"
Baltimore, Md. 8/14/70	"	"
Diet Rite Cola, Nesbit Orange, Grape, Cherry, Ski Hi, Dr. Pepper, Upper-10, R.C. Twist/Morgantown, W.Va. 7/15/70	Beverages of West Virginia/Morgantown, W.Va. (D)	Sugar held in bags contaminated with antimony ore dust used to prepare the article.
Meat scraps (dried animal by-product)/ Memphis, Tenn. 8/6/70	SARS/Gulf Soap Corp./Baton Rouge, La. (M,S)	Contain Salmonella micro-organisms.
Pickle chips in sugar and vinegar, pickle halves, sweet pickles, relish chunks in syrup, pickle juice, salad cube pickles/Hurlock, Md. 7/29/70	Hurlock Pickling Co., Inc./Hurlock, Md. (D)	Prepared under insanitary conditions from sugar held in bags contaminated with antimony ore dust.
sweet pickle chips, relish/Hurlock, Md. 8/24/70	"	"
Treasure Isle shrimp, frozen, cooked/ Stevens Point, Wis. 7/23/70	Ocean Products, Inc./Dover, Fla. (P,S)	Contain Salmonella micro-organisms.
W.M.C. Baking Specialty (flour)/Kansas City, Mo. 8/10/70	Wheat Products Co., Inc./Colorado Springs, Colo. (M,S)	Contains nitrites and nitrates, unsafe food additives not in conformity with regulations.
Contamination, Spoilage, Insanitary Handling		
Beans, flour/Hialeah, Fla. 8/14/70	Hammond Milling Co., Inc./Hialeah, Fla. (D)	Contaminated by insects.
Butter/Louisville, Ky. 8/20/70	Sugar Creek Foods/Louisville, Ky. (M,S)	Partly decomposed.
/Guaynabo, P.R., Carolina, P.R. 8/19/70	Dairymen's League Co-op Association/ New York, N.Y. (M,S)	"
Grapefruit and orange sections/Norwood, Mass. 7/21/70	Florida Citrus Cannery Corp./Plant City, Fla. (S)	Insect contaminated.
Onion rings, frozen, breaded/Dallas, Tex. 7/27/70	Miller's Pre-prepared Potato Co., Inc./Blue Island, Ill. (M,S)	Contaminated by fruit flies; prepared and packed under insanitary conditions.
Rice, extra long grain/Tulsa, Okla. 7/23/70	Downtown Warehouse Co./Tulsa, Okla. (D)	Held under insanitary conditions; contaminated by rodents.
Shrimp pieces, breaded/Elkins Park, Pa. 6/30/70	Gulf City Fisheries, Inc./Pascagoula, Miss. (M,S)	Prepared and packed under insanitary conditions; excessive coliforms.
Sno Top stems and mushroom pieces/ East Palestine, Ohio 8/4/70	United Canning Corp./East Palestine, Ohio (P,S)	Contain decomposed mushrooms.
Soy flour and grits/Los Angeles, Calif. 8/6/70	California Milling Co./Los Angeles, Calif. (D)	Insect contaminated while held for sale.
Economic and Labeling Violations		
Cod blocks, frozen, labeled as flounder/ Gloucester, Mass. 8/13/70	Quincy Market Cold Storage & Whse./ Gloucester, Mass. (D)	Codfish has been substituted for flounder which it was represented to be.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Economic and Labeling Violations (cont'd)		
Daisy cut sweet potatoes/East Point, Ga. 8/10/70	King Pharr Foods, Inc./Cullman, Ala. (P,S)	Not in conformity with the Fair Packaging and Labeling Act.
Drake's fry mix/Fort Wayne, Ind. 7/13/70	Drake's Batter Mix Co./Grass Lake, Mich. (M,S)	"
Fish blocks/Gloucester, Mass. 8/28/70	Pocasset Food Sales/Cranston, R.I. (S)	Labeled as sole but was Greenland turbot.
Fruit, mixed, canned/Fargo, N. Dak. 8/5/70	Allied Cannery & Packers, Inc./San Francisco, Calif. (S)	Not in conformity with the Fair Packaging and Labeling Act.
Instant nonfat dry milk/Hopkins, Minn. 7/23/70	Land O'Lakes Creameries, Inc./Eau Claire, Wis. (M,S)	Label declaration of net contents not in conformity with the Fair Packaging and Labeling Act; does not express weight in ounces and does not contain letters and numerals in a type size established by regulations.
Mexican cheese dip, frozen/Denver, Colo. 8/12/70	Ashley's Frozen Foods/El Paso, Tex. (M,S)	Net quantity of contents statement not in conformity with the Fair Packaging and Labeling Act.
Pineapple, canned, sliced/Stockton, Calif. 8/10/70	Imported from Malaysia.	Fails to conform to quality standard for canned pineapple because of excessive trimming.
Rice/Philadelphia, Pa. 8/20/70	Riviana Foods, Inc./Houston, Tex. (M,S)	Net quantity of contents statement not in conformity with the Fair Packaging and Labeling Act.
Shrimp, canned/Los Angeles, Calif. 8/6/70	E. M. Hashim & Bros./Cochin, China (P,S)	Not in conformity with the Fair Packaging and Labeling Act.
Belle O'Sea/Milwaukee, Wis. 7/9/70	Palacios Freezer, Inc./Palacios, Tex. (P,S)	"
meat, frozen, raw/Boston, Mass. 8/26/70	Central Wharf Fisheries, Inc./Portland, Maine (P,S)	"
Super-Cereal/Tulsa, Okla. 8/6/70	The Grist Mill/Los Angeles, Calif. (M,S)	"
Food Additives		
Instant Lime mix, Perma Fresh concentrate/Auburn, Mass. 8/19/70	Atlas Distributing Corp./Auburn, Mass. (D)	Contain cyclamate, an unsafe additive not in conformity with regulation.
Vitamins—Dietary Food		
Hi-Protein vegetable amino broth, organic seasoning, organic mineral salt, organic mineral bouillon/Detroit, Mich. 8/14/70	Dr. E. Bronner & Associates/Escondido, Calif. (M,S)	False and misleading label representations to be effective for special dietary use, but label fails to bear information concerning dietary properties (all articles).
"Nutri-Vac Chu-Weez" multivitamin tablets/Wauwautosa, Wis. 7/22/70	Nutri-Vac Co./Wauwautosa, Wis. (D)	Below labeled strength in vitamins A, B-12, and pantothenic acid.
DRUGS / Human Use		
Aldonall capsules/Fort Lauderdale, Fla. 4/29/70	Barrows Chemical Co./Inwood, L.I., N.Y. (M,S)	Below labeled strength.
Alidase "100" and "25" ampuls No. 14/ Highland Park, Mich. 8/28/70	G. D. Searle & Co./Chicago, Ill. (M,S)	Below NF standard quality for hyaluronidase, of which Alidase is a brand.
Amphetcaps/Detroit, Mich. 8/10/70	Cord Laboratories/Detroit, Mich. (M)	New drug not approved for safety and efficacy.
Bacitracin ointment/Atlanta, Ga. 5/28/70	Abbott Laboratories/North Chicago, Ill. (M,S)	Below USP standard for strength.
Bardase liquid/Atlanta, Ga. 5/25/70	Parke Davis & Co./Detroit, Mich. (M,S)	Below labeled strength in ingredients atropine sulfate, hyoscyamine sulfate, and hyoscine hydrobromide.
Calstron ampuls/Mableton, Ga. 7/2/70	Farnsworth Laboratories, Inc./South Chicago Heights, Ill. (M,S)	False and misleading claims for treatment of skin disorders, eczema, psoriasis, occupational dermatitis.
Frenquel/Vinita, Okla. 8/4/70	Wm. S. Merrell Co./Cincinnati, Ohio (M,S)	New drug not approved for safety and efficacy.
Le Conte hormones/Atlanta, Ga. 5/25/70	Le Conte Cosmetics/Los Angeles, Calif. (M,S)	"
Lysivit Jarabe/Hato Rey, P.R. 6/30/70	Adolfo Gomez/Hato Rey, P.R. (D)	False and misleading claims for treatment of anorexia, mental fatigue in school children, short memory, loss of weight.
Mallard scalp treatment/Pensacola, Fla. 5/25/70	Mallard Beauty Products/Mobile, Ala. (M)	False and misleading claims for treatment of dandruff, itchy scalp, bald spots, growing hair; new drug not approved for safety and efficacy; fails to bear established name of active ingredient.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
DRUGS / Human Use (cont'd)		
Obestat Ty-Med tablets/Sellersville, Pa. 8/7/70	Lemmon Pharmacal Co./Sellersville, Pa. (D)	New drug not approved for safety and efficacy; false and misleading claims for appetite control, metabolic stimulation of thyroid function; inadequate directions for use.
Proto Jec/Detroit, Mich. 8/14/70	Taylor Pharmacal Co./Decatur, Ill. (M,S)	False and misleading claims that the foreign protein content of the drug causes leukocytosis and a mobilization of immune bodies; inadequate directions for use; new drug not approved for safety and efficacy.
Shala-Min water filter and literature/ Amarillo, Tex. 7/20/70	Shala-Min of New Mexico, Inc./ Albuquerque, N. Mex. (M,S)	False and misleading claims.
Veterinary / Medicated Feed		
Honey Bloom compound/Ashland, Ohio 8/4/70	Hess & Clark/Ashland, Ohio (D)	New animal drug not approved for safety and efficacy; false and misleading claims to build up red blood cell count in horses, promote peak horsepower and breeding ability.
MEDICAL DEVICES		
Breath of Life emergency oxygen device/San Francisco, Calif. 2/17/70	Safety Laboratories, Inc./Miami, Fla. (M,S)	False and misleading claims to provide an hour or longer supply of oxygen for emergency first aid; inadequate directions for use for cardiac, asthmatic, exhaustion, or other attacks.
Copper bracelets/Fort Lauderdale, Fla. 7/23/70	British Imports, Ltd./Fort Lauderdale, Fla. (D)	False and misleading claims for relief from rheumatism, acidity, cramps, and stiffness in various joints.
KuF Diatherapuncteur, D'Acupuncture/ Denver, Colo. 8/14/70	Dr. Franio K. Bellokossy/Denver, Colo. (D)	Inadequate directions for use by laymen.
Theramatic Diathermy/Seminole, Tex. 7/24/70	Dynapower Systems Corp./Los Angeles, Calif. (M,S)	"
Dallas, Tex. 7/27/70	"	"
Cosmetic		
"Tween Kleen" tooth cleaner/Pipestone, Minn. 7/30/70	The White Co./Pipestone, Minn. (D)	Contains pumice, a deleterious substance, which may render it injurious to the user.
HAZARDOUS SUBSTANCES		
Lime-Elm/St. Paul, Minn. 6/12/70	Winn-Sol Products, Inc./Oshkosh, Wis. (M,S)	Label fails to state conspicuously the principal hazard of the irritant and instructions for first aid.
Whittemore Heel and Sole Enamel/ Philadelphia, Pa. 6/30/70	Whittemore Polish Co., Harri Hoffman Co., Inc./Milwaukee, Wis. (M,S)	Lacks consumer protection information required by the Fed. Hazardous Substances Act.

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

False Representation Orders Issued by Judicial Officer Under 39 U.S.C. 4005

August 18, 1970: False Representation Order issued against **Bel-Doxin, Inc.**, and **P.O. Box 135**, Peck Slip Station, New York, N.Y. Advertising and sale by mail of "Bel-Doxin" method promising dramatic weight losses.

Complaint Filed by the General Counsel Under 39 U.S.C. 4005 (False Representations)

August 20, 1970: **Arthritic**, P.O. Box 25745, Seattle, Wash. 98125. Advertising and sale by mail of a formula represented as a permanent cure for arthritis.

notices of judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

Corn, shelled, at Divernon, S. Dist. Ill.

Charged 4-15-70: when shipped by Divernon Grain Co., Divernon, Ill., to East St. Louis, Ill., reshipped to Mississippi, and returned to Illinois, the article contained a pesticide chemical, captan, for which there was no tolerance or exemption; and pesticide-treated seed corn had been substituted in part for shelled corn; 402(a)(2)(B), 402(b)(2). Default decree ordered destruction. (1)

FOOD / Contamination, Spoilage, Insanitary Handling

Coffee beans, 2 seizure actions at New Orleans, E. Dist. La.

Charged 3-11-70: while held by Lykes Bros. Steamship Co., New Orleans, La., the article contained bird excrement and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to E. A. Johnson Co., San Francisco, Calif., and Folger Coffee Co., Kansas City, Mo., for salvaging. (2)

Flour, at Catano, Dist. P.R.

Charged on or about 12-9-69: while held by Molinos de Puerto Rico, Inc., Catano, P.R., the article contained insects and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for conversion into stock feed. (3)

Guar gum and paprika, at Port Newark, Dist. N.J.

Charged on or about 2-19-70: while held for sale after being involved in a fire and subjected to water damage, the articles contained mold and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (4)

Pecan pieces, at Round Lake, Dist. Minn.

Charged 1-2-70: when shipped by SNA Nut Co., Chicago, Ill., the article contained *E. coli*; 402(a)(3). Default decree ordered destruction. (5)

Pecans, shelled, at Columbus, M. Dist. Ga.

Charged 1-6-70: when shipped by Eufaula Pecan Co., Eufaula, Ala., the article contained *E. coli* and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for salvaging. (6)

Potatoes, hash brown, frozen, Flav-R-Pack, at Hayward, N. Dist. Calif.

Charged 12-11-69: when shipped by North Pacific Cannery & Packers, Inc., Portland, Oreg., the article contained coagulase positive staphylococci and bacterial filth and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (7)

FOOD / Economic and Labeling Violations

Salad dressing, at Sioux City, N. Dist. Iowa.

Charged 5-11-70: when shipped by Zestee Foods, Inc., Oklahoma City, Okla., the article, labeled in part "Contents 1 Quart Swanson's Salad Dressing Distributed by Swanson's Stores, Inc. . . . Cherokee, Iowa," had had the valuable constituent, vegetable oil, in part omitted or abstracted, and the article failed to conform to the definition and standard of identity for salad dressing, since the article contained less than 30 percent by weight of vegetable oil—402(b)(1), 403(g)(1); and the article was in violation of the Fair Packaging and Labeling Act in that the quantity of contents declaration was not separately stated in the required location upon the principal display panel, since the declaration was not placed within the bottom 30 percent of that display panel; the article was labeled in terms of fluid measure and the net quantity of contents statement was not expressed in fluid ounces; and the net quantity of contents statement did not contain letters and numerals in an established type size, since the display panel had an area of more than 25 but not more than 100 square inches and the net quantity of contents declaration contained letters and numerals in a type size of less than 3/16 inch in height—15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(3)(C)(i). Default decree authorized donation to charitable institutions for consumption only. (8)

Syrup, Brand O, at Billings, Dist. Mont.

Charged 5-6-70: when shipped by Vincent Bar-None Co., Inc., Denver, Colo., the article was in violation of the Fair Packaging and Labeling Act in that its net quantity of contents declaration was not separately stated in a uniform location upon the principal display panel and alternate principal display panel, as required, since the declaration was not placed within the bottom 30 percent of such display panels; the net quantity of contents statement did not contain letters and numerals in an established type size, since each of such display panels had an area of more than 25 but not more than 100 square inches and the net quantity of contents statement contained letters and numerals in a type size of less than 3/16 inch in height; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Default decree authorized donation to charitable institution. (9)

FOOD AND COLOR ADDITIVES

Beverage, carbonated, at Opelika, M. Dist. Ala.

Charged 2-2-70: while held for sale, the article contained the nonconforming food additive, sodium cyclamate; 402(a)(2)(C). Default decree ordered destruction. (10)

Chubs, smoked, at Feasterville, E. Dist. Pa.

Charged 10-8-69: when shipped by City Smoked Fish Co., Detroit, Mich., the article contained the nonconforming food additives, DDT and DDE; 402(a)(2)(C). Default decree ordered destruction. (11)

Jam, yam, at San Diego, S. Dist. Calif.

Charged 4-30-70: when imported by Asian Trading Enterprises, Los Angeles, Calif., the article, labeled in part "Newton Halaya ube (Yam Jam) . . . Made in the Philippines by Newton Food Products Mfg. Malabon, Rizal," contained a nonconforming color additive; 402(c). Default decree ordered destruction. (12)

VITAMINS / DIETARY FOODS

Golden-50 Tablet vitamin and mineral tablets, at Chicago, N. Dist. Ill.

Charged 5-2-68: while held by Golden-50 Pharmaceutical Co., Inc. (distributor), Chicago, Ill., Evron Pharmaceutical Co., Inc. (packager), Chi-

cago, Ill.; after manufacture locally from ingredients shipped in interstate commerce, the name of the article, "Golden-50," the name of the firm, "Golden-50 Pharmaceutical Co., Inc.," the label statement, "High Potency," and certain statements in the article's labeling contained false and misleading claims that the article would prevent tiredness, lack of pep, worry, and weakness; that the nutritional value of the article was equivalent to that of large quantities of ordinary foods; that one tablet of the article provided all the nutrition anyone needed for good health; that in order to obtain adequate nutrition, a person over 50 years of age who does not take Golden-50 Tablets would have to consume large quantities daily of a large number of ordinary foods; that the article was of special value to persons over the age of 50; that taken daily the article would increase sexual interest, potency, and activity in persons over the age of 50; that the Golden-50 formula was exclusive; and that the vitamins in Golden-50 were better than vitamins available anywhere else—403(a), 502(a); and that the listing in the labeling of the ingredients, choline bitartrate, inositol, and dried yeast, falsely and misleadingly represented and suggested that the nutritional value of the article was enhanced by the presence of such ingredients; that the label statement "manganese . . . biotin . . . need in human nutrition is not yet established" was false and misleading, since the need for manganese and biotin had been established; that the label statement "choline . . . inositol . . . need in human nutrition is not yet established" was false and misleading, since it had been established that choline and inositol were not required in human nutrition—403(a). Golden-50 Pharmaceutical Co., Inc., moved to quash the warrant of seizure and to vacate the complaint, asserting: "(a) That Complaint for Forfeiture and Warrant of Seizure and Monition involves multiple seizures [seizure at two locations] of article impermissible under 21 U.S.C. §334; (b) The Complaint for Forfeiture and the Warrant of Seizure and Monition extend to items [envelopes, shipping boxes, "Free-Gift" checks, "Free-Bible-Offer" IBM invoice cards, promotional material stored in claimant's warehouse, etc.] which may not be seized under 21 U.S.C. §334; and (c) This Court does not have jurisdiction over the article of food and drug specified in this Complaint for Forfeiture and Warrant of Seizure and Monition, since the articles described and seized were not misbranded while in interstate commerce as defined in 21 U.S.C. §334 [only the raw materials that were used in the manufacture of the article were shipped in interstate commerce]". The Government served written interrogatories on Golden-50 Pharmaceutical Co., Inc. Thereafter, the court denied the motion to quash to the warrant and to dismiss the complaint.

Evron Pharmaceutical Co., Inc., also intervened, as a claimant of bulk quantities of the article seized in its premises, and alleged that such bulk quantities were repacked into bottles or were delivered to Golden-50 Pharmaceutical Co., Inc., that, at the time of seizure, such bulk quantities were being held in contemplation of future purchase orders from Golden-50 and others, and were undesignated and unlabeled (except generically).

Thereafter, Golden-50 Pharmaceutical Co., Inc., served interrogatories on the Government. After answers to the interrogatories were filed, consent decrees were entered that authorized destruction of certain specified labeling and the release to the claimants of the tablets and remaining labeling for bringing into compliance with the law. (13)

DRUGS / Human Use

Ahead hair restorer cream, at Pittsburgh, W. Dist. Pa.

Charged 3-28-67: when shipped by Kelly Products, Inc., Royal Oak, Mich., the label lacked the established name of each active ingredient; the article had been manufactured in an unregistered establishment; and the article was a new drug without an effective approved New Drug Application; 502(e)(1)(A)(ii), 502(o), 502(a). Default decree ordered destruction. (14)

Amphetamine-peptone injectable, at Turner, Dist. Kans.

Charged 8-12-68: when shipped by Myers Carter Laboratories, Glendale, Ariz., the article, labeled in part "P/G Forte . . . Dextro Amphetamine Sulfate . . . Peptones . . . intramuscular use only . . . Distributed by Arend-Miller Pharmacal, Inc. Shawnee Mission, Kansas," was a new drug without an effective approved New Drug Application; 505(a). Consent decree ordered destruction. (15)

Basorex methyltestosterone and yohimbine combination capsules, at St. Louis, E. Dist. Mo.

Charged 10-2-69: while held by Basic Pharmaceuticals, St. Louis, Mo., after being manufactured locally from an active ingredient shipped in interstate commerce, the labeling lacked adequate directions for use, and the article was not exempt from such requirement, since it was a drug subject to the new drug provisions of the law and its labeling was not authorized by an approved New Drug Application; 502(f)(1). Default decree ordered destruction. (16)

Brater's stramonium and salt petre powder, at Philadelphia, E. Dist. Pa.

Charged 12-29-69: when shipped by Cooper & Cooper, Inc., Brooklyn, N.Y., the article had been prepared and processed in an unregistered establishment and the article's label lacked the required prescription legend; 502(o), 503(b)(4). Default decree ordered destruction. (17)

Digoxin tablets U.S.P., at Miami, S. Dist. Fla.

Charged 3-12-70: when shipped by Davies Rose Hoyt, Needham, Mass., the circumstances of the article's manufacture, packing, and holding lacked conformity with current good manufacturing practice and the article's strength differed from and its quality fell below the U.S.P. standard, since the article failed to meet the U.S.P. test for content uniformity; 501(a)(2)(B), 501(b). Default decree ordered destruction. (18)

Hairseptic di-isobutylcresoxyethoxyethyl dimethyl benzyl ammonium chloride combination scalp conditioner, at Fort Wayne, N. Dist. Ind.

Charged 2-20-70: when shipped by Aristocrat Hairseptic Co., Columbus, Ohio, the article was a new drug without an effective approved New Drug Application; 505(a). Consent decree ordered destruction. (19)

Iodinated casein tablets, at Coral Gables, S. Dist. Fla.

Charged 11-6-67: when shipped by Milan Pharmaceuticals, Inc., Morgantown, W. Va., the article, labeled in part "SC Pink for 'Yellow,' 'SC Omega Blue,' 'SC White,' 'SC Pastel Green,' 'SC Tan,' or 'Gray'" . . . contains . . . Thyroactive Casein . . . Manufactured for Bariatric

Corporation Coral Gables, Florida," was a new drug without an effective approved New Drug Application; 505(a). Consent decree ordered destruction. (20)

Iodinated casein tablets, 5 seizure actions at San Francisco, N. Dist. Calif., Oneonta, N. Dist. N.Y., Louisville, W. Dist. Ky., Framingham, Dist. Mass., and Havre de Grace, Dist. Md. Charged between 9-2-69 and 10-1-69: when shipped by Beth Corp., Miami, Fla., the article was a new drug without an effective approved New Drug Application; 505(a). Consent and default decrees ordered destruction. (21)

Nettete aluminum chloride deodorant, at Philadelphia, E. Dist. Pa. Charged 1-22-69: when shipped by Effie M. Davis Co., Oneida, N.Y., the label of the article lacked a quantity of contents statement; the labeling lacked adequate directions for use, since the instructions to use 3 or 4 times a week were inadequate to insure effectiveness as an antiperspirant; and the labeling lacked a warning statement not to apply to broken skin and to discontinue use if rash developed; 502(b)(2), 502(f)(1), 502(f)(2). Released to shipper for relabeling under bond. (22)

Ni-Kur acetaminophen and vitamin combination liquid, at Barberton, N. Dist. Ohio. Charged 5-6-69: when shipped by Cord Labs., Detroit, Mich., and while held by Selador, Inc. (Ni-Kur, Inc.), the bottle label and the dealer's labeling of the article contained false and misleading claims for the treatment and cure of arthritis and the common cold; and the article was a new drug without an effective approved New Drug Application; 502(a), 505(a). Default decree ordered destruction. (23)

Provitamin B₁₂ pangamic acid capsules, at Madeira Beach, M. Dist. Fla. Charged on or about 11-18-69: when shipped by Krebs Laboratories, San Francisco, Calif., the article was a new drug without an effective approved New Drug Application; the labeling contained false and misleading claims about the article being the only nontoxic detoxicant, about it having a life-saving potential, and about it having a possible role in prevention and treatment of cancer; and other false and misleading claims for coronary artery insufficiency, angina, cyanosis, asthma, arthritis, abnormal bowel or kidney functions, allergies, rheumatic heart disease, alcoholism, atherosclerosis, premature aging, and other therapy; 502(a), 505(a). Default decree ordered destruction. (24)

DRUGS / Veterinary

K-M vitamin K combination solution, at Wisconsin Rapids, W. Dist. Wis. Charged 5-11-70: when shipped by Hilltop Labs., Inc., St. Paul, Minn., the article was a new animal drug without an effective approved New Animal Drug Application; and its label contained false and misleading claims for improving feed assimilation and conversion, promoting growth in chicks and growing birds, increasing egg production up to 17 percent, and increasing water and feed consumption; 501(a)(5), 502(a). Consent decree authorized release to shipper for compliance operations. (25)

Opticure methyl violet and furfural combination spray for pink eye, at Atlanta, N. Dist. Ga. Charged 3-30-70: when shipped by William Cooper & Nephews, Inc., Chicago, Ill., the circumstances of the article's manufacture, packing, and holding lacked conformity with current good manufacturing practice; the article was a new animal drug without an effective approved New Animal Drug Application; the purity and quality of the article was deficient, since it contained methoxychlor, a chlorinated pesticidal chemical; and the strength of a portion of the article was deficient and the labeling of such portion was false and misleading since it contained less than the declared amount of methyl violet; 501(a)(2)(B), 501(a)(5), 501(c), 502(a). Default decree ordered destruction. (26)

MEDICAL DEVICES

Eye cups, at Holland, W. Dist. Mich. Charged 5-20-70: when shipped by Griffith Labs., Inc., Union, N.J., the article's quality and purity was deficient and its labeling was false and misleading, since the article was not sterile as represented but was contaminated with viable micro-organisms; 501(c), 502(a). Default decree ordered destruction. (27)

Respirator, 2 seizure actions, at Little Rock, E. Dist. Ark., and Birmingham, N. Dist. Ala.

Charged 7-17-69: when shipped by Crown Products Co., Div. of Chilcote Co., Cleveland, Ohio, the article, labeled in part "Res-Q-Aire Emergency Respirator . . . Medically approved Machsa, Inc., Cleveland, Ohio," bore the name, Res-Q-Aire, and statements on the carton label and attached card which were false and misleading as to the adequacy and effectiveness of the article as a means of resuscitation; the labeling lacked adequate directions for use, and such could not be written, since the article was neither effective nor safe for its intended purpose; the labeling lacked warnings against use involving obstructions, aspirated objects and dentures, and involving infants or children where the volume of air would be excessive; and the article was dangerous to health when used as prescribed in the labeling; 502(a), 502(f)(1), 502(f)(2), 502(j). Default decree ordered destruction. (28)

Respirator, Res-Q-Aire, at Santa Ana, C. Dist. Calif.

Charged 11-4-69: when shipped by Res-Q-Aire, Inc., Canton, Ohio, Machsa, Inc., Cleveland Heights, Ohio, and Crown Products, Cleveland, Ohio, the article bore the name, Res-Q-Aire, and statements on the carton label and attached card which were false and misleading as to the adequacy and effectiveness of the article as a means of resuscitation; the labeling lacked adequate directions for use and such could not be written, since the article was neither effective nor safe for its intended purpose; the labeling lacked adequate warnings against use involving obstructions in the mouth or throat, aspirated objects and dentures, and involving infants and children where the volume of air would be excessive; and the article was dangerous to health when used as prescribed in the labeling; 502(a), 502(f)(1), 502(f)(2), 502(j). Default decree ordered destruction. (29)

Theramic model A-6DT40 electronic instrument, at Charlotte, W. Dist. N.C. Charged 3-30-70: when shipped by Dynapower Systems Corp., Los Angeles, Calif., the labeling of the article contained false and misleading claims for the treatment of infections, otitis media, fractures, bone and tissue healing, smooth muscle spasm, bursitis, arthritis, low back pain, sinusitis, urinary tract infections, prostatitis, and hepatitis; its labeling lacked adequate directions for such uses, and adequate directions could not be written, since the article was worthless for such uses; and the article was dangerous to health when used in the dosage and with the frequency and duration recommended in its labeling, since it was ineffective for the treatment of serious disease infections and, by reason of its ineffectiveness, it was unsafe for such use; 502(a), 502(f)(1), 502(j). Default decree ordered destruction. (30)

HAZARDOUS SUBSTANCES

Detergent for automatic dishwashers, at Superior, W. Dist. Wis.

Charged 5-11-70: when shipped by A & L Labs., Inc., Minneapolis, Minn., the article, labeled in part "Co-op Automatic Dishwasher Detergent . . . Packed for National Cooperatives, Inc., Albert Lea, Minn.," was a toxic and irritant substance and lacked a number of the required conspicuous label statements; 2(p)(1)(E&G). Default decree authorized donation to a charitable institution. (31)

Doctor Rust No. 2 rust remover, at Stuart, S. Dist. Fla.

Charged 11-18-69: while held by Stuart Chemical Co., Stuart, Fla., after being repacked, the article was a toxic and irritant substance and lacked a number of the required conspicuous label statements; and the label bore the statements "Non-toxic" and "Safe To Use" which negated and disclaimed the required label statements; 2(p)(1)(B, D, E, F, G, & J), 2(p)(1). Default decree ordered destruction. (32)

Flux for soldering, at Kearny, Dist. N.J.

Charged 11-19-69: when shipped by Burnley Battery & Manufacturing Co., North East, Pa., the article labeled in part "Blue Seal Solder Flux . . . Contains Zinc Chloride . . . Blue Seal Division Cloroben Chemical Corporation, Kearny, New Jersey" was a toxic and irritant substance and lacked a number of the required conspicuous label statements; and the main panel of the label lacked the signal word, the statement of principal hazard or hazards, and instructions to read the cautionary information elsewhere on the label; 2(p)(1)(E&G), 2(p)(2). Consent decree authorized release to Cloroben Chemical Corp. for relabeling. (33)

Speed Bond plastic resins with hardener, at Poughkeepsie, S. Dist. N.Y. Charged 2-27-70: when shipped by Atomized Materials Co., Inc., Cecil, Pa., the hardener contained the toxic and corrosive substance, methyl ethyl ketone peroxide in dimethyl phthalate, and the accompanying leaflet lacked required information; the label lacked a number of the required conspicuous label statements; and certain required information on the label failed to appear in at least 6 point type; 2(n), 2(p)(1)(B, C, E, G, J), 2(p)(2). Default decree ordered destruction. (34)

NOTICES OF JUDGMENT ON Criminal Actions

FOOD

Barrow Grocery Co., Inc., and Joseph L. Manson, Jr., president and treasurer, Blackstone, E. Dist. Va.

Charged 4-7-70: a pancake and waffle mix was held in a building that was accessible to insects and was contaminated with insect filth; 402(a)(3), 402(a)(4). Nolo contendere pleas; fines. (35)

Ramo, Inc., t/a Sunshine Pecan Co., Div. of Ramo, Inc., and t/a Guadalupe Valley Pecan Co., San Antonio, W. Dist. Tex.

Charged 5-28-70: when shipped, pecan pieces contained *E. coli* and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea; fine. (36)

M. Zukerman & Co., and Nathan Zukerman, Vineland, Dist. N.J.

Charged 2-25-70: doughnut flour was held in a building accessible to insects and rodents and was contaminated with rodent and insect filth; 402(a)(3), 402(a)(4). Guilty pleas; fines and probations. (37)

NOTICES OF JUDGMENT ON Injunction Actions

Ploeger Packing Co., Inc., Paul H. Ploeger, Jr., president, and Benjamin P. Greene, executive vice president, Darien, S. Dist. Ga.

Charged 9-26-69 in complaint for injunction: that the defendants were engaged in introducing into interstate commerce crabmeat which had been prepared, packed, and held at defendants' plant under insanitary conditions; 402(a)(4).

Following the entry of a temporary restraining order and a consent decree of preliminary injunction, a consent decree of permanent injunction was entered which enjoined the defendants against the violations complained of and which required the defendants, before making any further interstate shipments of crabmeat, to clean and make their plant suitable for the preparation and packing of crabmeat. (38)

Standard Products Co., Inc., and Hanna R. Humphreys, Jr., president, White Stone, E. Dist. Va.

Charged 2-14-69 in a complaint for injunction: that the defendants were engaged in distributing in interstate commerce, fish byproducts for animal consumption which contained an added poisonous and deleterious substance, *Salmonella* micro-organisms, and which had been prepared, packed, and held at the defendants' plant under insanitary conditions whereby such byproducts may have been rendered injurious to health; 402(a)(1), 402(a)(4).

A consent decree of preliminary injunction was entered which enjoined the defendants against the violations complained of and which required that the defendants, before making any further interstate shipments of fish byproducts, establish methods, facilities, and controls that would assure that such byproducts were not contaminated with *Salmonella* micro-organisms, and that the byproducts on hand be destroyed or reprocessed. Upon a subsequent showing that the defendants had complied with all requirements of the consent decree, an order was entered dissolving the injunction. (39)

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

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

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

Charles C. Edwards, M.D., Commissioner of Food and Drugs
Washington, D.C., November 1, 1970

FACT SHEETS
BUREAU OF NARCOTICS AND DANGEROUS DRUGS / U.S. DEPARTMENT OF JUSTICE

Keeping Up With the

DRUG



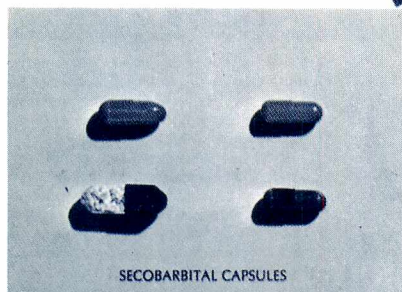
A FEDERAL SOURCE BOOK:

Answers to
the most frequently
asked questions
about drug abuse

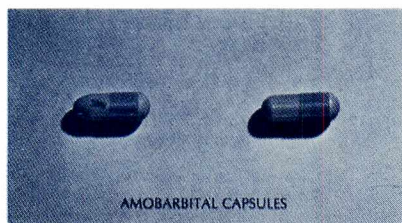
Is it possible...

...that someone you care about has
changed for no apparent reason?

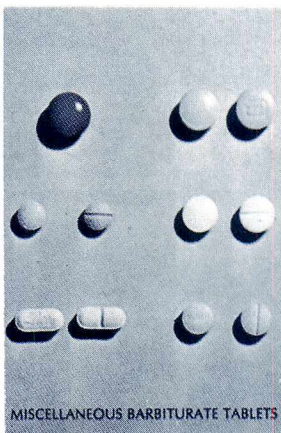
Drugs of Abuse



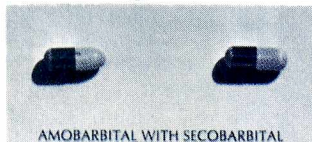
SECOBARBITAL CAPSULES



AMOBARBITAL CAPSULES



MISCELLANEOUS BARBITURATE TABLETS



AMOBARBITAL WITH SECOBARBITAL



This group of drugs depresses the central nervous system and relieves anxiety. They are valuable when used properly but extremely dangerous when abused.

Barbiturates are depressants. The first barbituric acid derivative was introduced to medicine shortly after the turn of the century. Since then, hundreds of barbiturates have been synthesized. They are prescribed as sedatives and to induce sleep, or in smaller doses, to provide a calming effect. Legally, people can buy and use these drugs only with a doctor's prescription, but they are extensively abused.

Barbiturate abusers often are involved in traffic accidents because their reactions tend to be sluggish. Accidental deaths from overdoses of barbiturates are common because abusers become confused as a result of the effects of the drug and forget how many they have already taken. The combination of alcohol and barbiturates can be lethal.

These drugs are addicting. Signs of physical dependence appear with doses well above therapeutic level. Withdrawal from barbiturates is especially dangerous and is characterized by accompanying convulsions and delirium. Depressants—they're real downers!

To cope with drug abuse the first things we need to know are what the drugs are and what they will do. A series of three booklets and one leaflet published or coordinated by the Bureau of Narcotics and Dangerous Drugs in the Department of Justice answers most questions. All are available from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.

"Answers to the Most Frequently Asked Questions About Drug Abuse" is a 29-page booklet produced jointly by the Departments of Defense; Health, Education, and Welfare; Justice; Labor; and the Office of Economic Opportunity. Price 25 cents or \$18.75 per 100 copies.

"Fact Sheets" contains 18 fact sheets on the various aspects of drug abuse, its control, the classes of drugs involved, bibliography on each drug class, and sources of more detailed information. Price 50 cents.

"Drugs of Abuse" is a 16-page booklet in full color showing the various drugs of abuse, their effects, their legal uses where appropriate, and their illegal uses. Price 40 cents.

"Has Anyone You Care About Changed for No Apparent Reason?" is a leaflet of signs of behavior to look for in determining whether a friend or a family member may be abusing drugs. Price 15 cents.

OFFICIAL BUSINESS



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Announcements

AOAC Publication—11th Edition The 11th edition of the *Official Methods of Analysis*, primary publication of the Association of Official Analytical Chemists, was scheduled to be off press in mid-October, the AOAC said. This edition contains all methods of analysis approved through the 1969 meeting. There are new methods of multiresidue pesticide determinations, drug residues in animal tissues, natural contaminants such as mycotoxins, examination of foods for bacterial contamination, and a greater emphasis on food additives. Some older methods no longer in general use have been omitted to make room for more rapid and sensitive assays, many of them utilizing advanced instrumentation. An entire chapter is devoted to the important topic of laboratory safety.

Considered a classic reference work, the AOAC publication contains analytical methods for agricultural products, foods, beverages, drugs, cosmetics, color additives, and other commodities important in public health. The methods have been validated by careful collaborative studies in laboratories throughout the world, and can be relied upon to be accurate, have convenient practical application, and give reproducible results in the hands of professional analysts. New editions are published every five years, and the book is updated after each annual meeting by supplements, which purchasers will receive automatically by returning the card enclosed with each book. Although not specifically prescribed by law, the methods of the AOAC have long enjoyed status in the courts and are relied upon by regulatory agencies of Federal, State, Provincial, and municipal governments, the regulated industries, and research workers in agriculture and public health.

The 11th Edition, priced at \$30 a copy, contains 964 pages plus index. It may be purchased from the Association of Official Analytical Chemists, Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

FDLI-FDA CONFERENCE The 14th Joint Educational Conference of the Food and Drug Law Institute and the Food and Drug Administration will be held December 10-11 at the Marriott Twin Bridges Motor Hotel, Washington, D. C. Commissioner of Food and Drugs Charles C. Edwards, M.D., will present a first session keynote address, "FDA—Today and Tomorrow"; Frank McLaughlin, director for industry relations, President's Committee on Consumer Interests, will speak on "What the Consumer Expects"; and John G. McClellan, administrator, General Laboratory Division, Wisconsin Department of Agriculture, will explain how "State Agencies Protect Consumers." Lawrence I. Wood, president-elect of the FDLI, will preside over the first session.

The second session will include three separate workshops—food, human drug, and veterinary drug—all scheduled for 2 p.m., December 10. Dr. Albert C. Kolbye, Jr., deputy director, Bureau of Foods and Pesticides, FDA, will be moderator for the food workshop, at which FDA's goals and progress, consumer expectations, and industry's role will be discussed. Henry E. Simmons, M.D., director, Bureau of Drugs, FDA, will moderate the human drug workshop, covering preclinical investigations, investigational clinical studies, FDA's program to improve quality of IND's and NDA's, research and development of a new drug product, the consumer's concern about drugs, and responsible drug reporting. Dr. C. D. Van Houweling, director, Bureau of Veterinary Medicine, FDA, will moderate the veterinary drug workshop, which will discuss New Animal Drug Amendments and implementing regulations—their effect on sponsors/FDA's view, their effect on producers/industry's view, and regulatory and compliance features. The workshop will also cover consumer protection as viewed by food producers in the beef, pork, and poultry fields. Following a general discussion on the above subjects, Howard R. Dentz, assistant commissioner for education and information, FDA, will speak on consumer education and information.

The third session will begin at 9 a.m., December 11, with Fred J. Delmore, industry relations coordinator, FDA, as moderator, and will cover FDA consumer programs, microbiology in FDA-new horizons, FPLA status report, and FDA's product safety program. Following closing remarks and summary by Franklin M. Depew, president of the FDLI, the conference will adjourn at noon.