APRIL 1968

FDA PAPERS

INTERNATIONAL PHARMACOPEIA
Global Experts Study Advantages

CUSTOMS AND FDA
A Seasoned Partnership That Works

Food and Drug Imports
New Ways to Better Protection

THE SCIENTIFIC WORLD OF FOOD AND DRUGS

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

Harvey W. Wiley
From his commencement address
"Life and the Coming Time"
Hanover College, 1867

Of the $27 billion in annual U.S. imports, nearly a sixth—over $4 billion—is foods, drugs, and cosmetics. FDA is responsible for the same safety, wholesomeness, and purity of these imports as for domestic products traded in interstate commerce (see page 16). A list of imported products would be long and diverse, and the number and diversity seem likely to increase with the rise in world trading expected as a result of the tariff reduction agreements reached in the Kennedy Round of trade negotiations.

FDA stands ready to allocate its manpower and facilities to those import areas where maximum protection to health will result. To meet modern trends in industrialization and transportation and the expanding awareness overseas of U.S. requirements, the Agency is constantly reassessing its mission and is developing new programs and techniques which will smooth the flow of imports, yet maintain the high quality to which the U.S. consumer is entitled by law.

In this "international" issue an attempt is made to show something of the changing import picture and how FDA works with other Government agencies, other nations, and groups of nations in the interest of assuring better foods, drugs, and cosmetics to consumers, not only in the United States, but everywhere.

quotes

"We believe that the drug situation can be brought under control by a strong enforcement effort; by the close supervision of the manufacture and trade of dangerous drugs; by a detached examination of all its causative and contributory factors; by a proper approach to youth, untainted by paternalism and condescension; and by a nationwide educational effort in grade, high school, college, and the entire adult world. Perhaps most important of all, it can be done by a rededication of the adult world to the proposition that the drug syndrome *does* exist in our affluent society; that it is, in fact, an insidious cancer eating into that society; that we must garner all of our mental, physical, and material forces in an effort to reach a respectable understanding of that problem, and a solution that may be respected by all.

"The abuse of drugs in our society may never be eliminated, but it can be diminished through a better understanding of what we are talking about and through a better education of and communication with each other."

John Finlator, Director, Bureau of Drug Abuse Control, at the 20th Annual Meeting of the American Academy of Forensic Sciences in Chicago, Ill., February 22, 1968.

"In spite of what you might have heard, under the new standard for vitamin and mineral supplements, individuals can obtain, without a prescription, supplements providing vitamins and minerals at levels recognized by nutrition experts to be adequate for good nutrition. Because a certain segment of the population apparently prefers to obtain its nutrients from pills rather than from a variety of commonly available foods, that segment will continue to have its freedom of choice in this regard. The marketplace will still contain vitamins, minerals, and other nutrients determined to be essential in human nutrition by the Food and Nutrition Board-National Research Council."

Eugene H. Stevenson, Assistant Director, Division of Nutrition, Bureau of Science, to the Seventh Food Update Seminar of the Food and Drug Law Institute, Inc., Atlanta, Ga., February 19, 1968.

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FDA PAPERS
VOL.2, NO.3/APRIL 1968

Customs and FDA Two Federal agencies work together to assure safe and wholesome imported food and drugs. 4

International Pharmacopeia Nations discuss benefits of pharmacopeias and drug standardization on an international basis. 10

Food and Drug Imports New ways are being devised to meet changing conditions in imports to protect the consumer. 16

A Look at Imports The day-to-day activities of FDA Districts in surveillance over incoming food and drugs. 19

Scientific World of Food and Drugs How FDA works with other countries to raise levels of safety and wholesomeness. 27

Field Reports 33

State Actions 36

Seizures and Post Office Cases 37

Notices of Judgment 41

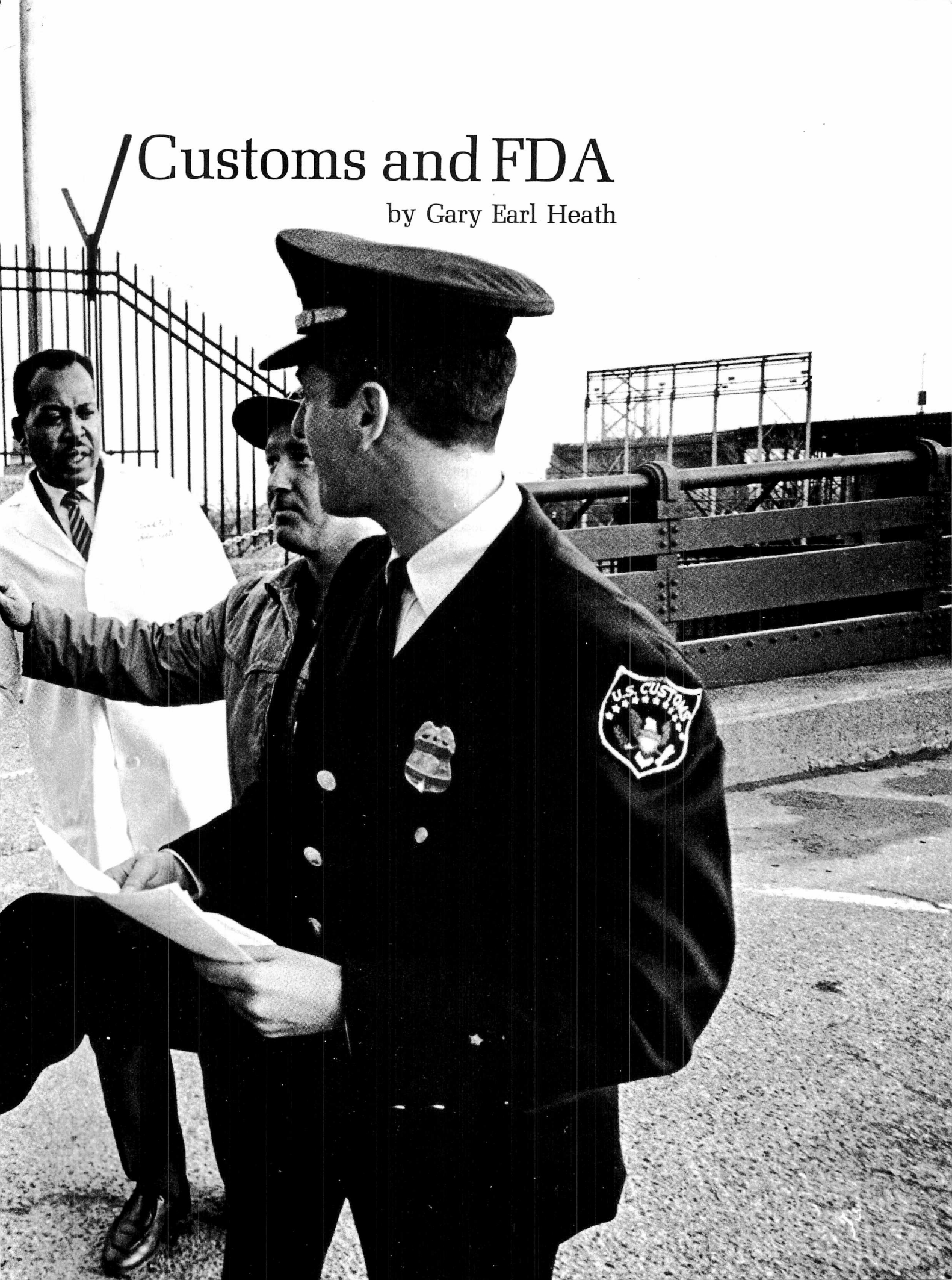
Section 705 [375] of the Food, Drug, and Cosmetic Act.

(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.

Customs and FDA

by Gary Earl Heath



A U.S. Customs officer in a mail division sees a package from abroad with an identifying and evaluating declaration reading "Cosmetics $15.00." He opens it and finds two small bottles of what appears to be lotion. A folder of instructions is enclosed, and the inspector reads enough of it to determine that claims are made for the product as a bust "developer."

He reports his findings to the nearest Food and Drug Administration office, enclosing the folder. The package is carefully laid aside to await FDA's reply. The product is subsequently refused admission to the United States by FDA, and the Customs officer has been the first to discover a product that may or may not be actually harmful, but which is certainly mislabeled under provisions of the FDC Act and fraudulent under U. S. Postal regulations. Later, other shipments of the product are stopped at ports throughout the United States, a fraud order is issued by the Post Office Department, and another racket is nipped in the bud.

An entry document is received at a large Customs port. Upon reviewing it, a Bureau Commodity Specialist sees that it lists food products, and sends a notice to the local FDA Inspector, who decides whether FDA needs samples of the food when it arrives or whether his own examination will be sufficient.

In each of the foregoing cases, the Bureau of Customs takes the first step in the process of deciding whether a product that comes under FDA jurisdiction is to be admitted to the United States or refused entry.

Cancer and arthritis "cures," drug products that fail to meet exacting U. S. standards, untested drugs and medicinal preparations, as well as such food products as cookies, tea, coffee, bread, and spices all are subject to FDA regulations, sampling, examination, and testing. And more often than not the first U. S. Government organization to see or know about these items is the Customs Service.

Perhaps there is a tanker truck entering from Canada with a load of maple sirup destined for a processing plant south of the border. Customs takes its own samples, sends a notice to FDA, and allows the load to proceed. But the processing plant must hold the sirup separately from other supplies until it has received clearance from FDA. This may require a relatively simple straining process, or may necessitate a more complicated cleaning or purifying process before the product can be used in the United States. FDA makes that decision, but Customs is the agency which first handles the product offered for entry.

The Code of Federal Regulations, Title 21, Part 1, sets forth the Federal Food, Drug, and Cosmetic Act and General Regulations, and under Sec. 801 (381),(a), says:

"The Secretary of the Treasury shall deliver to the Secretary of Health, Education, and Welfare, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health, Education, and Welfare, and have the right to introduce testimony."

The Secretary of the Treasury delegates this authority to the Commissioner of Customs, who in turn redelegates it to the Customs officials at the various field levels.

FDA has its own imports inspectors. The FDA Districts which examine imports are located at Baltimore, Boston, Buffalo, Chicago, Dallas, Detroit, Los Angeles, New Orleans, New York, Philadelphia, San Francisco, and Seattle.

FDA maintains its own laboratories for testing foods and drugs and cosmetics. It exchanges information with Customs on imports, but each agency usually does its own testing. Customs is interested in the percentage of certain ingredients, by which it determines the rate of duty under the U. S. tariffs; FDA is interested in the cleanliness or adulteration, the quality, and the possible dangers of the imported product.

When merchandise is detained by Customs at FDA's request, it can be reconditioned under FDA supervision and then released by Customs. If entry is refused, the product must be returned to the country of origin or destroyed under Customs supervision.

For assurance of compliance, merchandise may be stored in a bonded warehouse or even in the importer's facilities until it has been cleared by FDA. But fundamentally, Customs is responsible for the care of the merchandise until it has been released or refused entry. Accordingly, whenever bonds are required for any purpose in connection with imports, they are Customs bonds. If a shipment is forwarded from the port of first arrival to an interior port, it is forwarded under a Customs bond.

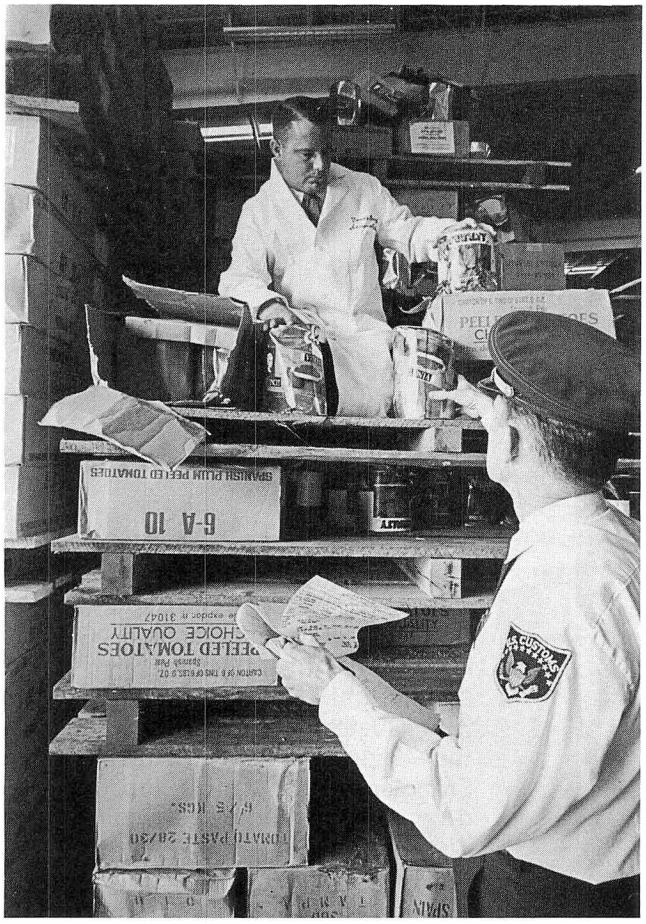
As an example of the way FDA and Customs work together, consider the case of a shipment of 12,000 pounds of whitefish from Canada. FDA in Chicago detained the shipment, which was infested by the parasitic worm *Triaenophorus crassus,* and ordered it either exported or destroyed.

The shipment went from Chicago to Detroit and then to Windsor, Ontario. Canadian Customs refused entry to that country, since the shipment had not cleared U. S. Customs. When the shipment was returned to Detroit and inspected, only 9,000 pounds of fish was found on the truck.

Further inspection by both FDA and Customs indicated that it was not the shipment that had been previously refused because of infestation, but another shipment of badly decomposed fish.

The truck was seized and the fish destroyed. Two of the men responsible for the substitution were indicted on charges of falsifying and conspiring to falsify Customs records. One received two sentences of imprisonment for 2 years each, which were suspended, and was fined $1,000. The other received identical sentences without the fine. Customs also collected $15,000 from the truck owner as a penalty for misuse of the truck and trailer.

On previous pages, Customs Bureau officer and FDA Import Inspector are ready to join in inspection of truckload of fresh produce just arrived in Detroit from Windsor, Ontario, and inspector will take sample for pesticide analysis.



After report by Customs to FDA of damage to lot of canned tomatoes from Spain during unloading of ship in Tampa, inspector and Customs officer check damage in pier warehouse.

Merchandise that may be perfectly acceptable when shipped can arrive in a damaged condition. Damage can be caused by water, by contamination with spilled chemicals, or even by the careless unloading of a ship. As Customs officers inspect arriving merchandise, any damaged conditions are routinely brought to the attention of the FDA Inspector or the nearest FDA office.

At New York alone during the last 6 months of 1967, Customs people referred damaged shipments of the following items to FDA: beer, bulk drugs, candy and confectionery, packaged and bulk cheese, wines and liquors, bakery items, spices, botanicals, and frozen and canned seafood.

Unlabeled canned goods and canned goods with no English labeling likewise are referred promptly to FDA Inspectors.

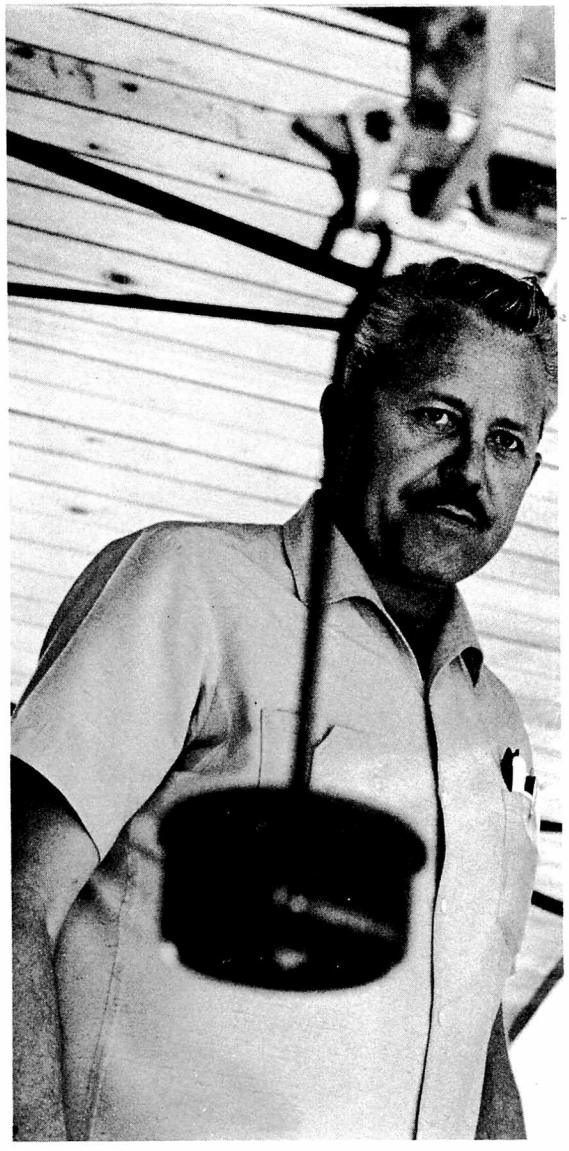
In one case, a Customs Inspector became suspicious of activities in an enclosure at the far end of a pier and reported this to an FDA Inspector. Investigation disclosed that floor sweepings of coffee beans were being picked up and packed there for sale. The sweepings were contaminated by assorted dock filth, and FDA halted the illegal enterprise.

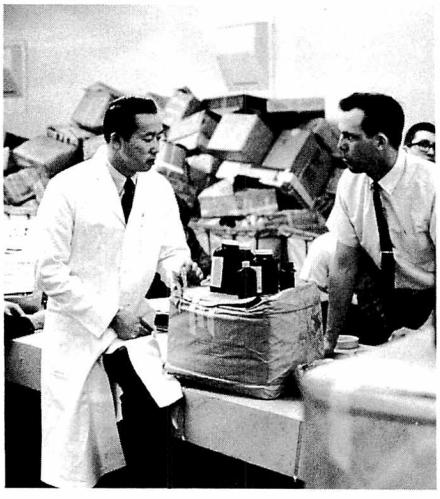
At Customs areas in the Customhouse and the Appraiser's Stores in New York, space is allotted to FDA people. The flow of Customs paperwork has been arranged to suit FDA needs, so that pertinent entry documents can be reviewed promptly by both services. A Customs clerk in the entry division carries out a preliminary sorting of entry documents and passes any along to the FDA which concern that Agency. Since as many as 5,000 invoices are received each week, this has proven to be an important cooperative venture.

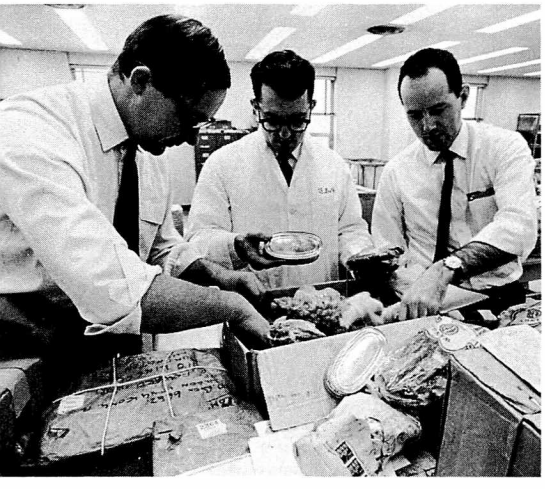
At times, information on an invoice does not denote that an item being shipped is one of concern to FDA. Customs, in examining samples of the merchandise, causes any such items found to be referred promptly to FDA.

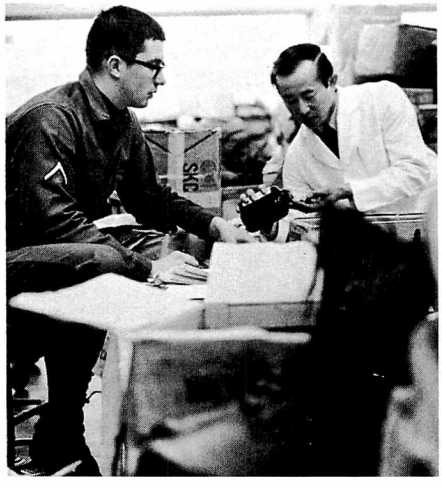
Of vital concern to Customs and FDA is the relatively new Customs Bureau procedure known as Immediate Delivery under which an importer can receive his shipment immediately on arrival, filing the customs entry within 6 days. The procedure is used at airports, seaports, and border ports, and is a boon to international traders, especially dealers in perishable commodities. Without some way that Customs can let FDA know about the merchandise, the goods may be in the hands of the importer before FDA receives the necessary information.

At Kennedy International Airport in New York and at other airports where international flights land, a routine has been set up under which any items that would be of interest to FDA are called to the Agency's attention before the merchandise is delivered. In this way, there is little likelihood that foods, drugs, or cosmetics will be released unless they have been cleared by FDA. Thus, the Immediate Delivery procedure can still function normally, but complete control is maintained over items









Photos at left show Customs officials with Import Inspector (in smock) at Detroit Post Office examining Chinese food items mailed from Hong Kong, and at right, Import Inspector is shown with Customs official (top) and military representative (below) in San Francisco Post Office looking over drug items mailed by servicemen from Viet Nam. Above, inspector and Customs officer at Nogales, Ariz., watch weighing of fruits and vegetables from Mexico.

which could affect the health of the American public.

Small shipments of items under the purview of the FDC Act and FDA regulations arrive daily by mail from abroad. During fiscal year 1967 about 52 million packages were handled by the various Customs Mail Divisions. Included in these shipments are many medicines, drugs, cosmetics, and foods, which are subject to FDA regulations.

The Customs officers at the various Mail Division points are given instructions from FDA about what to look for, what to report, and what to pass. The instructions include copies of FDA regulations. There is no compilation of the quantity of foreign parcels called to the attention of FDA, but records show that Customs officers have ever been alert to prevent the entrance of fraudulent articles that clearly do not meet the requirements of U. S. statutes.

Customs holds and notifies FDA of foods, drugs, cosmetics, and other articles suspected of not being in compliance with the FDC Act and other statutes administered by that Agency. Prompt reporting by Customs not only stops a particular shipment but also alerts FDA that some new product is being shipped in what may be an attempt to violate the law.

Persons attempting to smuggle such merchandise across the U. S. borders from Canada and Mexico are constantly being stopped by Customs officers who have been alerted by FDA warning notices forwarded from Customs headquarters.

Customs officers maintain working familiarity with FDA rules and regulations and both changes and notices of violations are distributed so Customs men will know what to watch for.

The rapid, continuing increase in containerization—the practice of shipping huge packages with many different items in each—concerns both FDA and Customs. Shall these containers be opened at the port of first arrival or be shipped to an inland port near the ultimate destination?

FDA is willing in most instances to examine the merchandise at its final destination, if manpower and time are available. Customs makes its examinations at a regular Customs port of entry, for examination at other than a Customs port would require considerable extra expense to the importer.

This problem, like many others created by an age of ever faster transportation, is one that importers, Customs, and FDA are determined to solve by cooperative efforts.

The Bureau of Customs receives no reimbursement from FDA for its work. It is just another of the variety of tasks performed regularly by the Bureau as a part of its mission to enforce all laws regulating both exports and imports from and to the United States.

About 40 Government agencies have rules and regulations applicable to some aspect of foreign commerce. The Customs officer on the line coordinates his work with all these agencies where necessary.

The Customs man takes pride in his work as a protector of the American public. He is aware that what he does in line of duty is for the very real benefit of his fellow citizens, and knows that his work in assisting the Food and Drug Administration actually helps to protect his own family as well as others.

Gary Earl Heath is an Information Specialist in the Office of Public Information and Publications, Bureau of Customs.

International Drug Pharmacopeia

by
Daniel Banes, Ph.D.

Every nation, to safeguard public health and refine medical practice within its borders, needs assurance of the identity and purity of its commercial drug products, whether these are made domestically or abroad. It was toward this end that an International Drug Symposium on Pharmacopeias and International Cooperation on Drug Standardization, in which officials of FDA participated, was held recently in Washington during the 81st annual meeting of the Association of Official Analytical Chemists. The symposium * looked at the situation emerging in Western Europe, Japan, the United States and the World Health Organization concerning multination pharmacopeias.

Pharmacopeias—sets of monographs which name the essential physicochemical characteristics of drugs and the means of verifying identity and purity—have been compiled nation by nation as a guide to medical practice and drug control.

At the beginning of the 19th century, Europe had around a hundred "official" pharmacopeias. Upon the unification of various smaller states into larger nations, the number dropped. Nonetheless, the two dozen or so that remained often presented conflicting or incomplete profiles of important drugs.

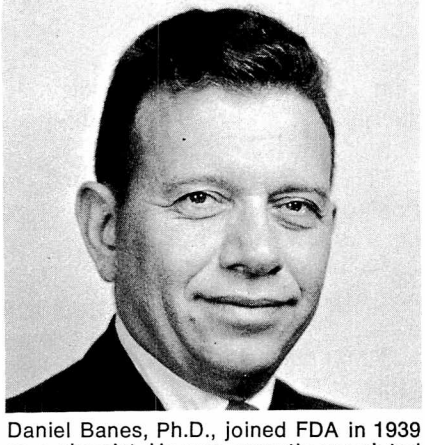
Only recently have nations collaborated on pharmacopeias. The logic favoring this collaboration is not hard to see. Nations make common use of many drug preparations. The effort required to compile pharmacopeias on a periodic basis in an age of rapid introduction and distribution of drugs consumes a significant part of any nation's scientific energies, often in unfruitful duplication of efforts made elsewhere.

The growing "internationalization" of the pharmacopeia cannot be ignored by the United States. Because of its own status as importer and exporter of drugs, because it is a center of the development, testing, and manufacture of drugs, and because it is the possessor of a fund of governmental experience in drug regulations, the United States affects and is affected by international pharmacopeial efforts.

** The papers comprising this symposium have been published in the Journal of the Association of Official Analytical Chemists, Vol. 51, pp. 81-113, January 1968.*

The experience of four North European nations may serve as an introduction to the legal, administrative, cultural, and policy-making aspects of pharmacopeial collaboration. Sweden, Denmark, Norway, and Finland subscribe to a Nordic Pharmacopeia in lieu of separate national compendiums.

Dr. Hans Hellberg of the National Pharmaceutical Laboratory, Stockholm, described the successes of the venture, the similarities and differences among these countries in control processes, their current problems and their hopes for further "internationalization." These countries are similar in many ways, unalike in others. The languages of Denmark, Norway, and Sweden are mutually understandable, with some attentive effort; and although Finnish is entirely different from the other languages, Swedish is spoken to some extent in Finland. The Nordic countries have abolished passport checks among themselves, have established a common labor market for certain workers in the medical field, have almost eliminated customs duties among themselves, and are on the way to adopting common patent legislation.



Daniel Banes, Ph.D., joined FDA in 1939 as a chemist. He was recently appointed Acting Associate Commissioner for Science.

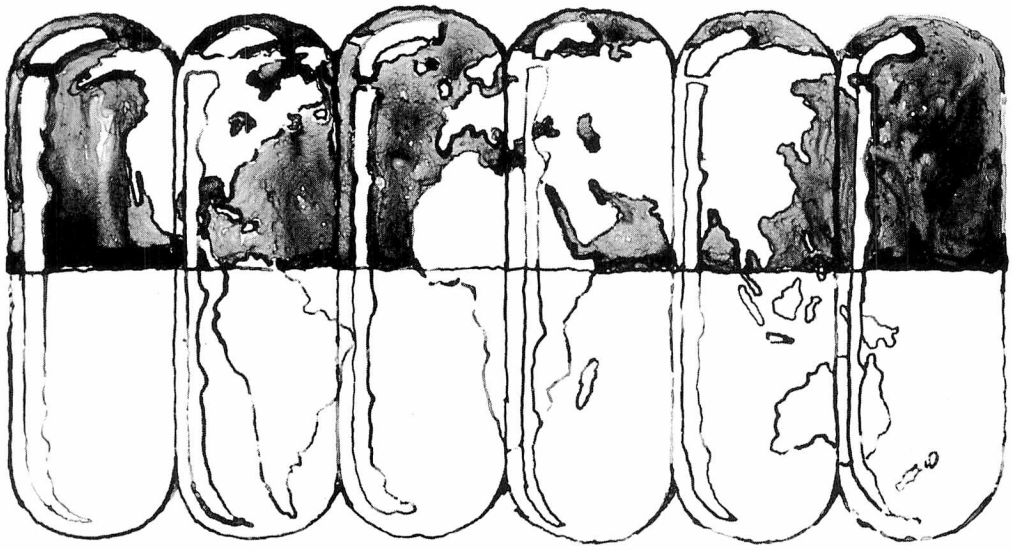
The Nordic Pharmacopeia Commission was formed in 1948, and the first edition of its work appeared in 1963 in all four languages. It has been official for all four countries since 1964. Annual looseleaf supplements are published. A wholly new edition, to be forthcoming, will remedy a number of shortcomings, as the supplements have already begun to do. The makers of the Nordic Pharmacopeia, although they plan the new edition, are watching with some interest the activities of the European Pharmacopeia Commission, a subject to which I shall return.

Although each of the countries concerned has its own legislation regarding drugs and its own control organization, they do cooperate in several ways, for instance, in active control of manufactured drugs. There are limitations in this field. For example, although information is exchanged about deficiencies that may be found through random tests of specialties held in stock, such evidence from one country cannot be used as a reason for administrative action by another. The information is used by the country receiving it to carry out an investigation of its own.

There are some, Dr. Hellberg said, who believe this cooperation could be extended even further, for example, to a common Nordic registration system. But there are difficulties. Each country has its own traditions in drug legislation and such a registration system would get into legal problems. Moreover, "in some countries there are regulations of a more politico-economic nature which are rather difficult to change."

The Swedish official, after considering future lines of possible international cooperation, including compendiums of prescribing information and data on the safety and efficacy of drugs as well as their identity and purity, summed up his views this way:

"Finally, it is highly desirable that the number of bodies publishing pharmacopeias and pharmacopeia-like monographs should be reduced. Few countries have such resources of their own that they can ignore the pharmacopeias of other countries. In a country like mine where we import almost half of our drugs and, in addition, a lot of substances from which home-produced drugs are prepared, we need to use the phar-



macopeias of other countries. This means that we—like industry—have to check the same goods according to several different monographs.

"It is therefore highly desirable from the point of view of both the controlling bodies and the industry, in small countries, that the number of pharmacopeias diminishes. The contribution to this reduction which the Nordic countries rendered by combining their four pharmacopeias now appears to be insufficient. The present hopes are directed toward what the coming so-called European Pharmacopeia will achieve."

The history and current status of that pharmacopeia were outlined by G. B. Marini-Bettòlo, Director of the Instituto Superiore di Sanita, Rome. The work is being carried out under the auspices of the Council of Europe. Although the six countries of the Common Market, or European Economic Community (EEC), are members of the Council, it includes other nations. The Common Market countries are France, Italy, West Germany, Belgium, the Netherlands, and Luxembourg. Two non-EEC countries participating in the European Pharmacopeia are Great Britain and Switzerland. Great Britain also is a member of the European Free Trade Area (EFTA) bloc, to which the four Nordic countries belong. Hence, references by European speakers at the symposium to "bridge building" in the pharmacopeia and drug standardization area were hardly exercises in rhetoric.

Although the Common Market countries had expected to embark on their own pharmacopeia, they decided to work through the geographically broader Council of Europe. In fact, Prof. Marini-Bettòlo noted, the six have agreed to move to ensure that the standards, methods, and monographs of the European Pharmacopeia shall become the official standards applicable in their respective countries. This is the most striking aspect of the European Pharmacopeia effort; it will create common standards binding on participating nations. Other published international pharmacopeias have not been obligatory.

Because the pharmacopeia will affect the legislation of eight countries, decisions on the choice of its monographs must be unanimous, Prof. Marini-Bettòlo noted.

In 3 years, the Commission charged with preparing the European Pharmacopeia has covered considerable ground. It agreed on the general criteria for drafting the text as well as on the general notices concerning nomenclature, atomic weights, percentages of an element in a molecule, solubility, concentration of solutions, methods of assay and tests, storage, units of measurement, and so on. It has agreed on the lists of general methods, both chemical and biological, to be adopted in the pharmacopeia; on the first list of monographs to be prepared; and on a system of following the work itself and of final approval of the texts. Over 700 draft documents have been produced—some representing original work. The general methods of analysis and about 50 monographs have been approved and will form the first volume of the European Pharmacopeia. Work on the second volume is "already well advanced." The Commission has collaborated with the Nordic Pharmacopeia and has corresponded with the U.S. Pharmacopeia.

The European Pharmacopeia, the Italian official said, "will not only be the fulfillment of the obligation undertaken by the Council of Europe with the European Economic Community, but we hope, the beginning of the use of common standards for drugs for the whole of Europe." After ratification of the Pharmacopeia Commission's work by all the signatory countries, participation will be open to all the countries of the Council of Europe. Since there is widespread use in other parts of the world of the standards of the European countries, the European Pharmacopeia "is bound to have worldwide significance," as Prof. Marini-Bettòlo put it. What kind of common drug regulation if any might result from adoption of common pharmacopeial standards? Dr.

P. Siderius of the Netherlands noted that all the Common Market countries but West Germany have premarketing clearance systems for efficacy, safety, and conformity with labeling. But there are considerable differences among them in ways of enforcing legislative prerequisites for marketing of drugs. The goal for coordinating Common Market legislation aims at allowing a drug which receives premarketing clearance in one country to qualify automatically for marketing in the others.

Dr. Siderius had some doubt that this goal could be achieved "because it has become apparent . . . that criteria used in member-states of the EEC for admission to the market of new drugs were and are extremely divergent. . . ." His recommendation: establishment of "a joint competent agency in which all six members of the EEC are represented. Manufacturers should be allowed to submit drug applications directly to this agency, which should be equipped and staffed adequately to fully examine the applications and be given responsibility to deliver or refuse permits for putting the drug concerned on the Common Market.

"On the national level, existing official organizations and facilities for drug control should be kept intact in order to evaluate the safety and efficacy of drugs that are of national significance. This will permit member-states to continue their own policy of screening the drugs on their national market."

A report on the International Pharmacopeia, which contains "recommended" rather than mandatory standards, was given to the Symposium by Teodor Canbäck, of the World Health Organization. The first edition of the International Pharmacopeia, consisting of two volumes and an addendum, was completed in 1959. Some newer nations preferred it to adopting the standards of any single country, and many have recognized it in their legislation.

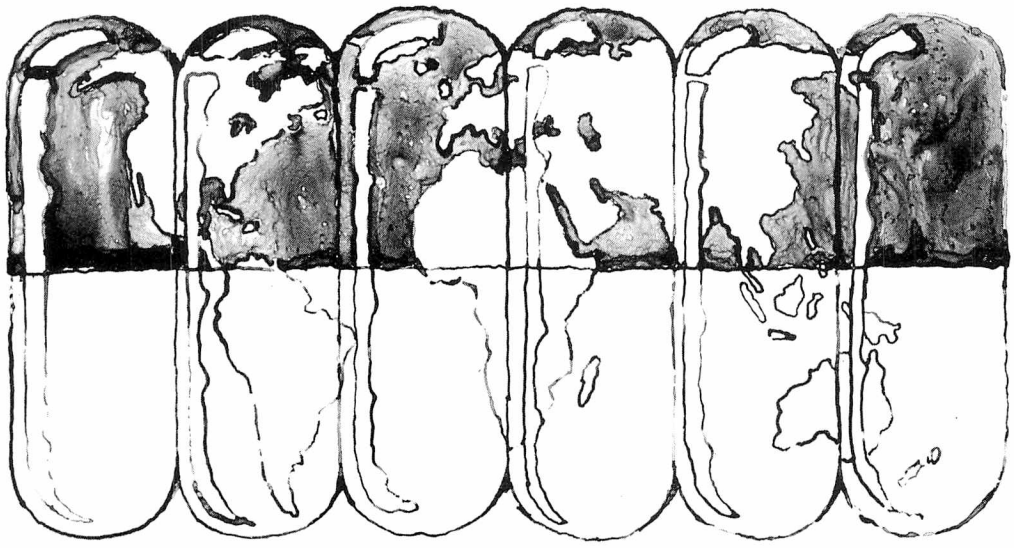
Although Dr. Canbäck described the second edition, soon to be published, as still a "traditional book," he felt the need for upgrading information contained in official compendiums. The four problems, more or less interconnected, are (1) to raise the technical standard of the tests chosen; (2) to select parameters of real importance in describing the drug and its purity and efficacy; (3) to include evaluated data on blood levels, etc., required to get a desired clinical response with the drug; and (4) to speed up the publication of the data.

The trend of the work within WHO is developing along three lines: (1) producing a recommendation for an inspection system similar to that used in the United States ("good manufacturing practices"); (2) establishing reference chemicals to be used in pharmacopeial tests; and (3) issuing data sheets on old and new drugs.

British and Japanese speakers also urged greater international cooperation.

Dr. H. Davis, pharmaceutical consultant in the United Kingdom, listed among several recommendations the establishment of coordinated standards and methods for pharmacopeial drugs. He advocated cooperation between expert committees of national or regional pharmacopeial authorities of the major drug-producing countries at the draft stages of monograph production. "For pharmaceutical specialities which now constitute a high proportion of dispensed medicines, international data sheets are suggested. The setting up of an international clearinghouse under the auspices of WHO or another appropriate international body is recommended," he said.

Kakuma Nagasawa of the National Institute of Hygienic Sciences, Tokyo, asked for international cooperation in adopting reference standards for drug assay. He said in Japan 72 reference standards have been prepared and distributed by his Institute. Many reference standards or working standards for antibiotics and biological products also are distributed by Japan's National Institute of Health.



"It is not easy to establish these standard preparations," he said, and in an era of increasing international interchange of drugs, "it is very inconvenient for clinical purposes if standards with the same name but different natures are established in different countries.

"I hope common reference standards will be used by many countries in the near future. The matter might be settled by relying chiefly on the work of the Committee on Authentic Chemical Substances of the International Pharmacopeia. However, it is an urgent problem to establish such standards promptly on an international basis. I think that sooner or later the international exchange of information relative to specifications and test methods of the reference standard preparations will be essential."

Except in the United States and Great Britain, all major national pharmacopeias have been produced by Government-supported groups. The advantages of those written by non-Government bodies were enumerated by the respective representatives of the U.S. Pharmacopeia and the National Formulary, Drs. Lloyd C. Miller and Edward G. Feldmann. Despite their independent origins, both U.S.P. and N.F. are official Federal compendiums.

U.S.P. has had the "official" designation since 1906 and has worked, in Dr. Miller's words, "with an awareness that, for all practical purposes, the Federal Government has been watching over its shoulder." Yet U.S.P. and N.F. are not solely responsible for setting U.S. drug standards. In 1940, Federal law was passed requiring FDA to set standards of purity and potency for insulin if U.S.P. or N.F. did not. A further step in Federal sharing in standards setting came in 1946 when Congress designated FDA to establish antibiotics standards. Whether there will be a further trend in this direction—and, indeed, whether "internationalization" of pharmacopeias may encourage or impede such a trend—remains to be seen. Dr. Miller, discussing what may be transferred from the national experience to the international level, stressed the value of continuity of effort, a quality he thought likely to be greater in an independent organization. Such independence, however, rests on the organization's ability to gain and retain volunteers for editorial work and on its ability to meet financing problems. Smallness may be another advantage, along with the ability to maintain direct lines of communication with experts, Dr. Miller said.

Dr. Feldmann also spoke for advantages of independence and close cooperation of individuals in Government agencies, the pharmaceutical industry, and academic institutions.

"The compendia have maintained a unique independence of viewpoint and freedom of movement which by nature cannot be duplicated either in Government agencies or in private industry. While the N.F. and U.S.P. are recognized by law as, 'official' compendia, the completely independent and unfettered position which they enjoy has permitted an unusual degree of voluntary cooperation in working toward the common goals."

As Dr. Miller noted, "It has been said that drafting drug standards is often an exercise in the fine art of plagiary." In this light, perhaps I will be forgiven for borrowing some remarks from Dr. Canbäck for a closing paragraph. In his talk, the WHO representative said:

"In all these fields we need close international cooperation. It is necessary to convince people that the time is gone when it was possible for a group of pharmacists to sit down and produce a handbook of drug standards. Too much copying from sources lacking in basic materials has gone on for too long. Many of the criteria which we are asking for today can only be collected by people specializing in narrow fields. We have to find them, get their cooperation, and start working. It is a big task, but as practically every country is interested, it would be rational to do this on an international level." ■

Food and Drug imports

by LeRoy M. Gomez

The Food and Drug Administration is charged with assuring that all imported products meet the same requirements of the Food, Drug, and Cosmetic Act as products manufactured domestically and shipped from one State to another.

Imported foods, drugs, and cosmetics worth approximately $4 billion enter the United States annually through the 293 ports of entry and 71 customs stations.

During a given week any one of the major ports in the United States may receive whisky from Scotland, shrimp from Ecuador, cookies or cosmetics from England, coffee from Colombia, cocoa from Africa, cheese from the Scandinavian countries, vitamins from Denmark, or quinine from West Germany.

Tea, milk, and cream are not only subject to the requirements of the Food, Drug, and Cosmetic Act, but also to the Tea Importation Act and the Import Milk Act, respectively, both administered by FDA.

FDA examines every lot of tea offered for import to determine whether it meets the standards of purity, quality, and fitness for consumption prescribed under the Tea Importation Act.

Milk and cream may be imported into the continental United States only by permit, under the Import Milk Act, after certain sanitary and other prerequisites are fulfilled. At present, three firms in Canada, one in New Zealand, and one in Denmark hold effective permits to ship milk and cream to the United States.

FDA inspections of foreign manufacturers are restricted to inspections conducted as a prerequisite for approval for antibiotic certification or New Drug Applications. For all other products, the Agency relies on a program of surveillance sampling of imports to determine problem areas or trends, as a guide in overall planning for import coverage.

All foods, drugs, devices, and cosmetics are subject to examination by FDA at the time of entry to determine their admissibility. These examinations are usually made while the goods are being cleared through Customs. Imports examined by FDA are not released for distribution until a final decision is made as to their suitability for consumption.

The Bureau of Customs, Department of the Treasury, assists FDA in maintaining surveillance over food and drug imports and denying admission to those which do not meet the requirements of the Act.

Since Bureau of Customs personnel are assigned to each port of entry, they advise FDA of any imports under that Agency's jurisdiction. On occasion, at FDA's request, Bureau of Customs personnel will collect samples for laboratory examination and forward them to the nearest FDA District laboratory.

Those imports which are found, upon examination, not in compliance with the Act are not entitled to admission into the United States. Any import refused admission is subject to reexportation or destruction under the supervision of Bureau of Customs.

FDA's policy concerning imported foods and drugs is consistent with the Agency's mission of providing maximum consumer protection through a combination of alternative approaches, intended to minimize risk to the American consumer. The Agency's goal: to provide that coverage for imports consistent with their impact on the consumer.

The Agency has provided additional guidance, in the form of Compliance Programs, for greater uniformity of coverage among the 17 Districts. These programs allow the Districts latitude in allocating their efforts to the various problem categories designated by Headquarters.

With improved technology among industries everywhere, there has been a proportionate increase in imports of foods which are ready for consumption and require minimum processing by the consumer. The Districts are placing emphasis on sampling of those foods which are ready for consumption when entered instead of those which will receive further processing by domestic manufacturers and are subject to FDA domestic programs.

For example, FDA gives sampling priority to imported chocolate candy over cocoa beans, the latter used in domestic manufacture of chocolate candy.

In the food area, FDA's major import program is directed at detecting contamination considered to be a health hazard. Thus, greater attention is being given to heat-and-serve foods and neutral or alkaline canned foods, which have either a history of or a potential for bacterial contamination.

Surveillance of imported foods for pesticide residues is directed at preventing foods carrying excessive residues from entering the American marketplace.

In the summer of 1967, FDA's Dallas District encountered excessive endrin contamination in cucumbers and cantaloupes imported from Mexico. See "FDA's Dallas District—an Incident in Laredo," FDA PAPERS, June 1967.

These products never reached consumer channels, due largely to prompt District action and the cooperation of the Bureau of Customs, the U.S. Department of Agriculture, the Mexican Government, and several groups of American importers and Mexican growers.

In keeping with its overall approach, FDA places greater responsibility on the consignee of imported foods for assuring that the imported goods he distributes or uses in the manufacture of other products are in compliance with the law.

Historically, some kinds of foods have had a high rate of detention. Some of these have been permitted to be brought into compliance with the law before being admitted into the United States.

Where reconditioning of these foods, in the past, has been adequate to bring them into compliance, FDA is now permitting the consignee to recondition them before they are sampled and examined for final determination of admissibility.

Spices, for example, can be cleaned by air-blowing and screening. Previously, FDA detained the spices and supervised their cleaning. Now an importer may choose to clean the spices before they are examined to insure that they are admissible. As a means of control, FDA samples and examines those spices the importer or consignee claims need no cleaning prior to import.

FDA is considering whether to extend this principle by permitting imported raw materials intended for further domestic processing to be entered without examination. This would be restricted to those imports which are due to receive a processing during the normal course of commercial operations that would bring them into compliance. For example, imported raw sugar is intended for recrystallization. The normal recrystallization process eliminates impurities.

The Districts have been encouraged to solicit industry cooperation by asking national trade associations, industry groups, and importers associations to set up systems of reporting importations which did not undergo FDA examination but nevertheless are rejected by the consignee because they failed to meet the requirements of the Act.

FDA, through its educational programs, is encouraging corrective measures in the country of origin by individual producers and their associations and by governmental agencies. Such measures have eradicated many causes of deterioration and contamination in a number of commodities in various parts of the world. The result has been an upgrading in the quality of imports.

The detention rate for dates from Iraq and Iran, for example, has decreased from 10 percent to less than 1 percent, attributable in part to the efforts of FDA officials and U.S. industry representatives in helping educate foreign date producers in proper sanitary and production control procedures.

Moreover, individuals, associations, and various foreign governmental agencies have started systems of sampling and examinations of specific lots of goods intended for shipment to the United States to determine before shipment whether they comply with FDC Act requirements.

All these advances are intended to achieve the most effective use of FDA's available manpower and to provide optimum consumer protection.

For greatest effectiveness, the FDA will assign inspectors in the field to look at those products which are amenable to visual examination. When an import is examined by a properly trained and qualified inspector who can determine by a look that it does not meet the requirements of the Act, there is no need for laboratory analysis to confirm gross visible contamination or obvious misbranding. Detention of the importation may be based on the inspector's findings.

Analytical manpower will be reserved for analysis of (1) products not conducive to wharf examination, (2) foods ready for consumption and not amenable to wharf examination, and (3) selected samples to confirm suspected adulteration or misbranding encountered during wharf examination.

Drug importations valued at approximately $150 million enter the United States annually. Few enter in dosage form. Most are entered in bulk form to be used in the formulation of dosage form drugs by domestic manufacturers.

FDA's Import Program for drugs and vitamins has been established to complement the Agency's programs for domestic drug producers. Under this program, primary attention is directed to drug importations in dosage form.

The Current Good Manufacturing Practices Regulations for drugs place the responsibility for analysis of drug raw materials on domestic manufacturers. They are obliged to control components used in manufacture and processing to assure that the raw materials conform to the appropriate standards of identity, strength, quality, and purity, and that they are free of contaminants at the time of use.

FDA, however, still maintains surveillance over all bulk drug components to determine if they meet the requirements of the Act, and to determine which should receive program emphasis.

Since it is important to examine those drugs with the biggest impact on the consumer, greater emphasis is put on examination of (1) drugs considered the most therapeutically significant by FDA's Bureau of Medicine, (2) drugs for investigational use or new drugs, (3) drugs produced by foreign firms whose production histories indicate noncompliance with the requirements of the Act, and (4) drugs which receive little or no processing by domestic manufacturers.

Innovations in foreign commerce, primarily the increased use of air freight and containerization, have caused FDA to modify operations for coverage of imported products.

The Agency has found the need to assign full-time import inspectors to the John F. Kennedy Airport at New York and O'Hare Airport at Chicago. Districts elsewhere have been required to increase manpower assigned to air freight shipments.

Additional staffing will be required at international airports when "Jumbo Jets" begin to appear in 1970, since these planes are expected to carry three times the loads of the present generation of large jet aircraft.

Containerization—the practice of stowing large amounts of cargo into strongly constructed standard-sized boxes or vans at the manufacturer's plant inland and shipping the vanload as a unit to its destination—poses a need for modification of FDA examination procedures.

Since the shipment is removed from its protective box either at the consignee's door or at a customs inspection station, FDA must provide manpower at either location to examine the contents.

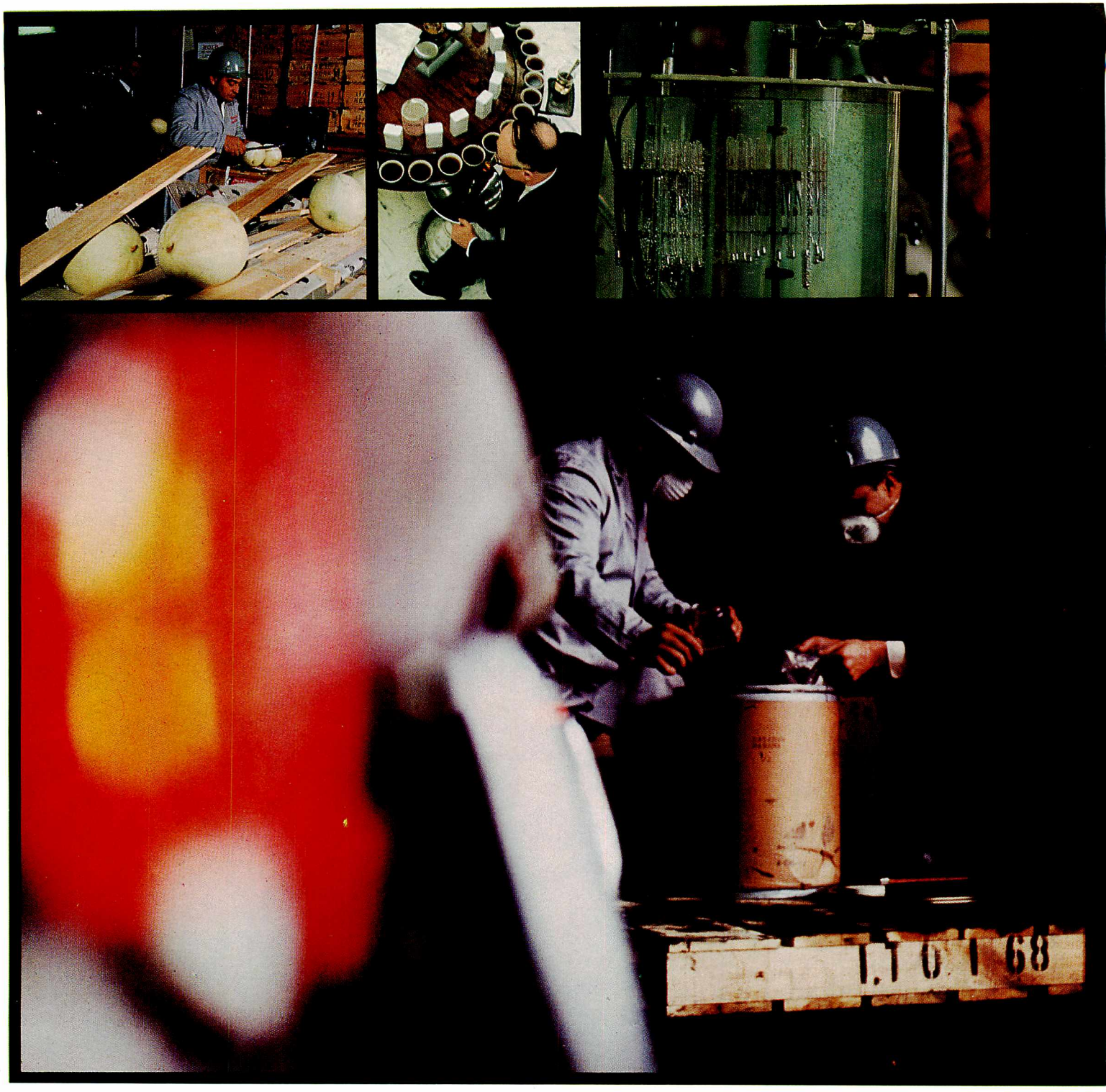
Delivery of the container intact at an inland city could result in redistribution of the volume of imports. If the containerization trend continues, FDA inland Districts can reasonably expect an increase in import workload requiring staffing changes at inland Districts and Resident stations. It follows that any extensive use of this procedure will require transfer of FDA personnel from import docks where examinations are now made to the metropolitan areas where the consignees are located.

FDA is ready to meet the challenges of the changing world to assure the Nation that its supply of foods and drugs will meet high standards of quality and purity, regardless of origin.

LeRoy M. Gomez, Program Analyst, is in the Executive Development Program in the Office of the Commissioner. He joined FDA in 1960.

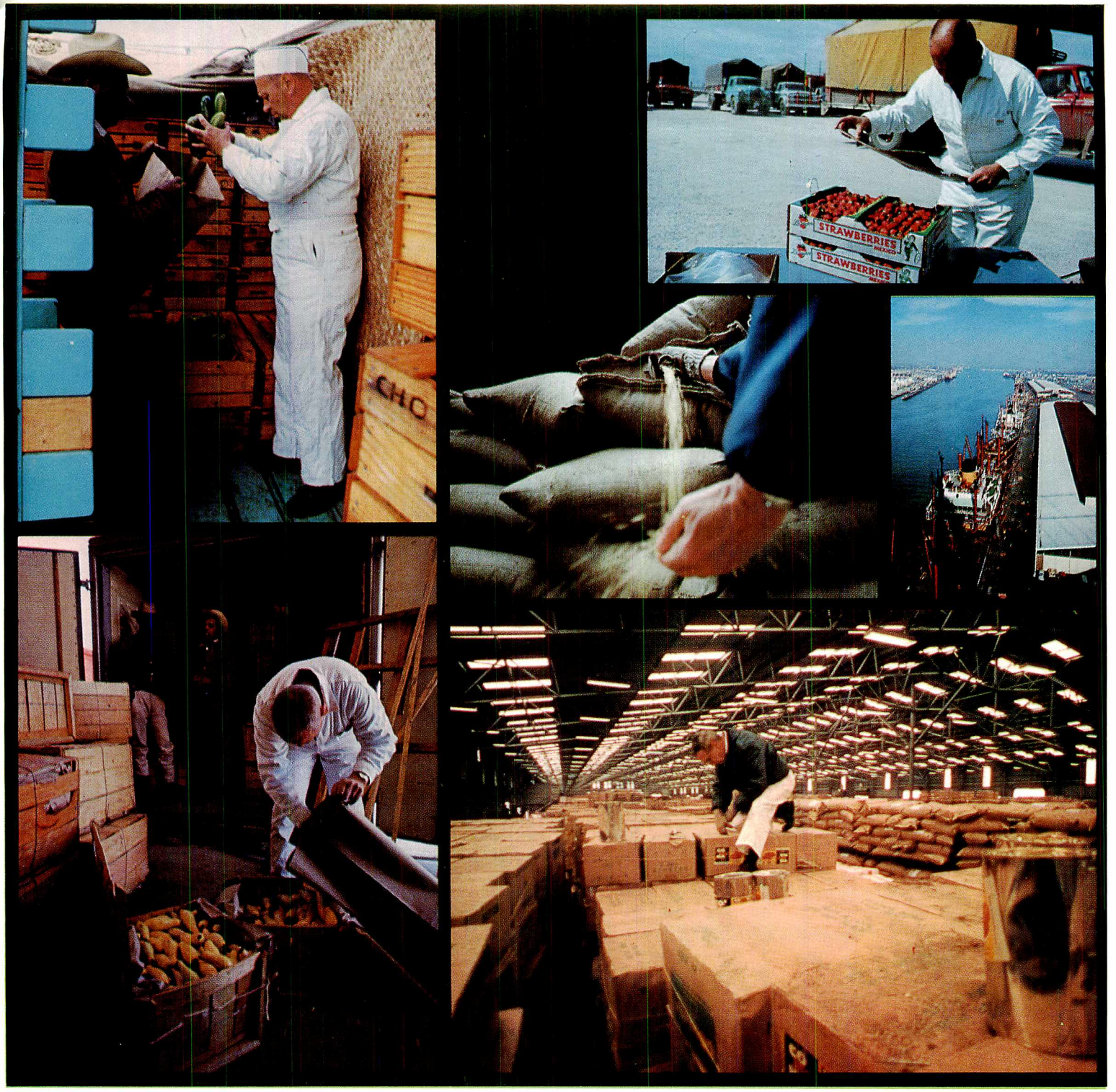
A Look at Imports

At ports, border stations, and international air terminals, FDA men keep watch over a daily flow of foods, drugs, and cosmetics from other countries to protect the U.S. consumer.



New York district

In cold storage in ship's hold at dockside in Brooklyn (top left), Import Inspectors have ordered that unloading of honeydew melons from Chile be halted after report that shipment of pesticide chemicals stored nearby had spilled and melons may have become contaminated. They are shown scraping samples from melons. Laboratory tests confirmed contamination, and District required that melons be washed to remove chemical and recrated before entry to the United States. Bottom, masked and gloved inspectors obtain antiseptic samples of bulk drugs from Denmark for microbiological tests. Top center, chief tea tester at District puts out samples of imported tea for purity and taste tests under Tea Importation Act. Right, scientist checks accuracy of Japanese fever thermometers.



Dallas district

At Hidalgo, Tex., on Mexican border (photos at left and at top), inspector takes samples of yellow squash, cucumbers, and strawberries to be analyzed at Dallas District laboratories for pesticide residues. Hidalgo is busy entrance point for truckloads of fresh produce from Mexico. At pier warehouse in Houston, inspector (bottom right) removes samples of 10-pound, commercial-size cans of tomato paste from Portugal to be analyzed in labs. Center, he takes sample of sesame seed from Nicaragua, using tubular instrument called trier, which forces open weave of bag to allow stream of grain to pour forth. Center right, bird's-eye view shows ships lined up alongside pier in Houston Channel, which runs 50 miles inland from Gulf of Mexico.

San Francisco district

In Chinatown, inspector (top, left and center) makes random check of retail food stores, tasting, smelling, and taking samples. He checks invoice records of air freight official at International Airport (top right). Center left, inspector talks to Customs Bureau officer at Post Office. Customs declaration on parcel post package in small center photo says it contains cosmetics. It will be examined by FDA men. Inspector in photo at bottom left is looking at a package which contains a 7-foot live snake, one of hundreds of items, legal and illegal, mailed home daily by servicemen in Viet Nam. Other illegal items intercepted here include drugs and explosives. At bottom right, inspector is looking at contents of large cargo containers on city pier.

Boston district

In District labs (top left), chemist strains macaroni from Italy through sieve in procedure to isolate insect and filth fragments. Top center, chemist sterilizes spoon before using it to remove quantity of walnuts from Iran from sample for bacterial contamination test. Bottom left, scientist uses refractometer to isolate solids in canned tomatoes from Italy. Bottom center, District's tea tester sniffs imported tea sample as part of enforcement of taste and purity standards under Tea Importation Act. Bottom right, biologist siphons herring meal from British Columbia onto smear plate for *Salmonella* test. Top right, Import Inspector in pier warehouse obtains sample of cocoa beans from Nigeria to be examined for mold and insect infestation.

Seattle district

Import Inspector boards ship carrying consignment of Japanese fireworks, to check labeling. He talks (two photos, top left) to port official, then to crane operator standing on oceangoing cargo container against backdrop of opened hatch. Bottom, left and right, in pier warehouse, he makes visual check and takes samples of corn from Peru for analysis of insect and rodent infestation. Bottom center, he uses ultraviolet "blacklight" for visual test of rodent urine on bags. Center, he tastes a preserved duck egg from Taiwan at Chinese delicacy shop in Seattle. Top right, he bores into frozen Canadian salmon and halibut with electric drill in cold storage warehouse. Heat from drilling warms up fish enough for quick smell to test for decomposition.

Atlanta district

At Tampa, photos left to right in top row show inspector in cold storage warehouse at pier collecting sample of frozen shrimp from Venezuela, walking alongside pier in company of Customs Bureau officer with whom he works, and examining damaged lots of canned tomatoes from Spain in warehouse. Damage was brought to his attention by Customs men. About half of lot was unsalvageable and ordered destroyed. In second row and bottom center, inspector removes samples of Danish cheese from pier warehouse in Miami. Photo, center right, shows crane operator on Danish ship. Bottom, left and right, inspector takes samples of frozen shrimp from Honduras off vessel in Miami. Center, inspector at Atlanta lab applies smell test to thawed shrimp from Iran in check for decomposition.

Los Angeles district

Frozen tuna (photos at left) is hoisted in boxes from ship's hold to pier, as inspector checks for decomposition. Chemist in mobile FDA lab at Nogales, Ariz. (photos at top), grinds Mexican peppers for pesticide residue test in gas chromatograph. Center, inspector takes sample of oranges at truck dock for pesticide residue check. Inspector is taking samples of Philippine copra for insect tests in oleomargarine plant in Los Angeles (right center, and bottom, second from left). Bottom center, inspectors at Los Angeles take samples of celery seed from India and are shown leaving ship where they took tea samples. Bottom right, chemists check weight of contents against labels for dried French pea soup mix and canned oysters from Japan. Soup mixes are also tested for possible infestation by insects.

The Scientific World of Food and Drugs

by Kenneth E. Taylor, D.V.M., and Clem O. Miller, Ph.D.

There is increasing concern among the nations of the world about the quality of their foods and medical supplies. The United States, as an exporter and importer of both, takes an active hand in international undertakings and nation-to-nation agreements and exchanges of scientific information on the qualities, standards, cleanliness and wholesomeness, and safety of these necessities of life. The Food and Drug Administration works with other U.S. Government agencies and departments concerned with health and trade and represents this country in its work with international organizations dedicated to improving the world of food and drugs.

Office of International Affairs

FDA established the Office of International Affairs (OIA) in October 1966 in recognition of the Agency's growing involvement in international activities. It provides multilateral leadership and assistance in FDA's efforts to assure quality in imports of foods, drugs, and cosmetics. Besides serving as a focal point for improving FDA's relationship with foreign governments and industries and international organizations, the Office of International Affairs coordinates those FDA activities which have international dimensions with the Department of Health, Education, and Welfare Office of International Affairs and the Department of State.

OIA coordinates and assists international operations within FDA, makes necessary contacts outside FDA, and looks for ways the Agency can improve those functions involving regulated items in international trade.

Many day-to-day operations require FDA liaison with the Department of State. The Agency has

Many day to day operations require liaison between the

FDA & THE STATE DEPARTMENT & THE U.S. EMBASSIES

The Agency has established a working relationship which provides direct communication between the Food and Drug Administration

established a working relationship here which provides direct communication with United States Embassies overseas. Food and drug information is transmitted to and received from U.S. commercial, agricultural, and scientific attachés in the world's capitals. These communiques furnish rapid and pertinent answers to questions from FDA and the international community. At home the desk officers in the Department of State bring FDA activities to the attention of foreign government diplomats who represent their countries in Washington. FDA tries to develop close liaison with foreign embassies so that both the Agency and countries exporting food and drugs to the United States may keep abreast of scientific and technical developments of international significance. This system also permits the interchange of medical and health information and conversation about regulatory compliance problems in general.

The OIA, with assistance from many specialists, also works with the various operating bureaus and offices in FDA to carry out a variety of additional international activities. These include the following:

Training and orientation of foreign scientists, inspectors, and visitors: For several years FDA has made available, to foreign scientists and inspectors, the opportunity for training in its laboratories and field offices. Referrals for food and drug orientation come from international organizations (WHO and FAO), schools of public health, the Agency for International Development, and other Government agencies. These visits to U.S. Government offices are coordinated with the Department of State, and requests should be arranged in advance so FDA can serve the needs of applicants better.

Interchange of information: FDA, in response to requests from the international community, has prepared several publications for distribution to help foreign interests understand FDA requirements. One publication, "Requirements of the United States Food, Drug, and Cosmetic Act" (Publication No. 2 Revised September 1967), has been particularly popular. FDA in this publication emphasizes aspects of special interest to foreign manufacturers and importers. Other publications frequently requested include: Food, Drug, and Cosmetic Act and Regulations, Fair Packaging and Labeling Act, Federal Milk Import Act, Federal Hazardous Substances Act, Pesticide Analytical Manual, and Food Additives Manual. The Agency has available a complete list of FDA publications and procedures for obtaining desired publications.

Antibiotic Certification: FDA is required by law to certify all antibiotics used in the United States and must inspect the manufacturing firm, whether domestic or foreign. The inspection and certification procedures include a number of instructions on quality control methods and standards. The Agency today inspects over 70 firms in 25 countries. Foreign manufacturers include those participating in the AID program, those supplying the U.S. Armed Forces, and those exporting bulk or finished antibiotics to the United States.

International Organizations: OIA coordinates and develops FDA participation in food and drug seminars held by the World Health and Pan American Health Organizations.

FDA recently developed an adverse drug reaction reporting system which covers several thousand civilian hospitals and Government medical installations. The Agency reached an agreement with the World Health Organization to establish an international reporting center operated by the Bureau of Medicine. It will provide a worldwide early warning and intelligence system on adverse reactions of drugs.

FDA has taken part in a growing interchange of information concerning food standards and food processing and distribution through the United Nations Codex Alimentarius and its subcommittees. The Agency invites further development and interchange of this type of information.

Committee Management Office

The Committee Management Office has responsibilities for maintaining the central FDA file on membership and representation of FDA personnel on international commissions, councils, panels, working groups, and the like, and coordinates the appointment of members and representatives to these international groups.

FDA participates with international organizations in related interests and missions through appointment of staff members to membership on commissions, councils, committees, panels, and working groups of these organizations. FDA representatives are appointed because of their expertise in the respective areas of interest of the working groups. FDA shares its technological expertise and data with counterpart agencies of other nations who are members of the international organization. Membership of FDA staff people on these subsidiary bodies makes communication of this important function easier.

The U.S. Government requires that food and drugs offered for import into the United States meet the standards established by FDA. As an exporter of food and drugs, the United States is interested in the development of standards and methodology for production of these commodities so that the country will import products of high quality.

The commissions, panels, and the like provide a convenient way to establish a common nomenclature, language, standard, and methodology.

The international organizations in which FDA staff members participate can be grouped as follows:

1. International organizations: Food and Agriculture Organization (FAO), World Health Organization (WHO), and the Joint FAO/WHO Codex Alimentarius Commission.

2. International scientific unions: International Union of Pure and Applied Chemistry (IUPAC).

3. Various other organizations.

FDA's greatest effect on international affairs comes through the work of its representatives on subsidiary bodies of the Joint FAO/WHO Codex Alimentarius Commission. This Commission is an international body operating under the auspices of the FAO and WHO. It develops and establishes international standards for foods to protect the consumer's health and promote world trade. The Codex Alimentarius, or food code, is the Commission's official publication. The Commission's food standards provide sellers and buyers uniform criteria for identifying sound, wholesome foods. It includes standards for both processed and raw foods which are distributed to consumers. Any member nation of WHO or FAO may send delegates to Commission meetings. In November 1966 the Commission had 39 members.

The Codex food standard describes and identifies food by many factors, including ingredients and, when applicable, residues and additives. The standards include specifications for labeling, sampling, and testing procedures; requirements for hygiene; and procedures and safeguards for producing sound, wholesome, and marketable products. Acceptance of the Codex standards by a member nation is voluntary.

The U.S. Government is a member of the Codex Alimentarius Commission. J. K. Kirk, FDA Associate Commissioner for Compliance, was a U.S. delegate in 1965 and 1966. Much of the Commission's work is done by committees, each headed by one of the participating countries. It is to the advantage of the United States that the standards reflect acceptable marketing and manufacturing practices and adequate legal regulations.

FDA is represented on 12 of the 17 Codex Committees. These, with the names of the FDA representatives at the most recent meetings:

Joint FAO/WHO Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products; Robert W. Weik (alternate), Division of Food Standards and Additives.

Codex Committee on Food Additives; Dr. Herbert Blumenthal, Division of Toxicological Evaluation.

Codex Committee on Food Hygiene; L. R. Shelton (chairman), Assistant to the Director, Division of Microbiology; William F. Eisenberg (alternate), Division of Microbiology.

Codex Committee on Food Labeling; J. K. Kirk, Associate Commissioner for Compliance.

Codex Committee on Methods of Analysis and Sampling; Dr. William Horwitz, Assistant Director, Bureau of Science.

Codex Committee on Pesticide Residues; Dr. O. G. Fitzhugh, Division of Toxicological Evaluation.

Codex Committee on Cocoa Products and Chocolate; L. M. Beacham, Director, Division of Food Standards and Additives.

Codex Committee on Processed Fruits and Vegetables; Mr. Beacham (alternate).

Codex Committee on Fish and Fishery Products; Mr. Beacham.

Codex Committee on Dietetic Foods; Sidney Weissenberg, Assistant for Special Dietary Foods, Office of Associate Commissioner for Compliance.

Economic Commission for Europe/Codex Alimentarius Group of Experts on Standardization of Fruit Juices; Mr. Beacham.

ECE/Codex Alimentarius Group of Experts on Standardization of Quick Frozen Foods; Mr. Beacham (alternate).

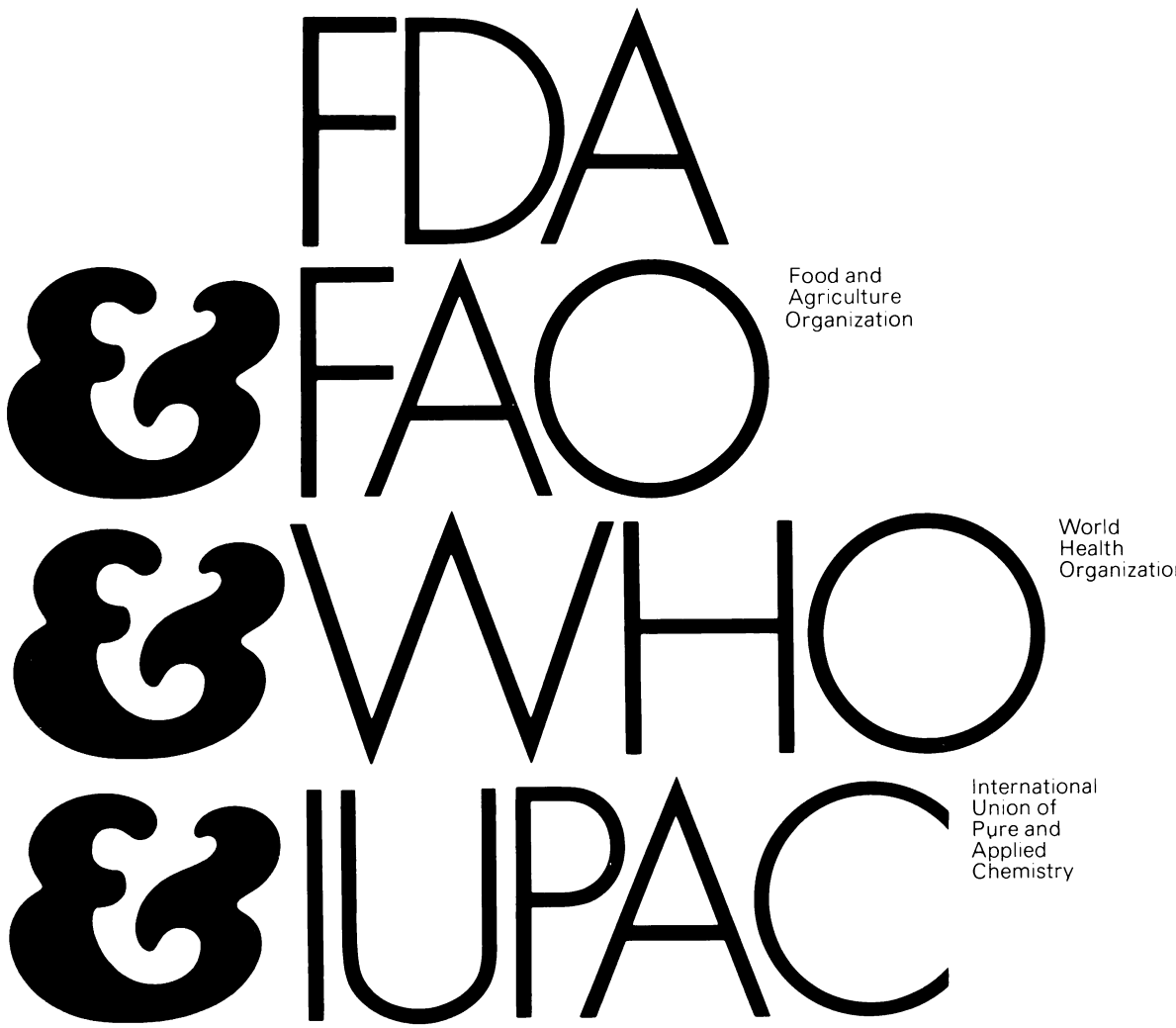
The Food and Agriculture Organization is an autonomous organization which by agreement also serves as a specialized agency of the United Nations. It has a close working relationship with other specialized agencies through the U.N. Economic and Social Council. FDA is represented on one working party:

FAO Working Party of Experts on Pesticide Residues; J. William Cook, Deputy Director, Division of Food Chemistry.

This working party works jointly with the WHO Expert Committee on Pesticide Residues on proposed pesticide tolerances in food and methods of analysis and the Codex Committee on Pesticide Residues of the Codex Alimentarius Commission. It cooperates with other international organizations by exchanging and collating data on pesticide chemicals.

The World Health Organization is an independent international agency with its own membership and financial resources. Its relationship with the United Nations is governed by the terms of the WHO Constitution, the U.N. Charter, and by agreements covering fields of mutual interest. Membership in WHO is open to all countries. Members of the United Nations may join by accepting the WHO Constitution. Others are admitted when their applications are approved by

Membership of FDA staff people on international organizations makes communication easier between



a majority vote of the WHO Health Assembly.

FDA is represented on two WHO Expert Panels and two Expert Committees:

WHO Expert Panel on Antibiotics; Dr. W. W. Wright, Acting Director of the National Center for Antibiotics and Insulin Analysis, Division of Pharmaceutical Sciences.

WHO Expert Panel on Food Additives; Dr. A. J. Lehman, Director, Division of Pharmacology.

WHO Expert Committee on Quality Control; Dr. Joseph J. DiLorenzo, Office of Associate Commissioner for Science.

WHO Expert Committee on Pesticide Residues; Dr. Fitzhugh.

The FAO and WHO have common interests in the use of food additives and they jointly sponsor a committee on these substances:

Joint FAO/WHO Expert Committee on Food Additives; Dr. Fitzhugh represents FDA.

The International Union of Pure and Applied Chemistry (IUPAC) is a voluntary nonprofit association of organizations, each representing the chemists of member countries. IUPAC's goals are: (1) to promote continuing cooperation among the chemists of the member countries; (2) to study topics of international importance to pure and applied chemistry that need regulation, standardization, or codification; (3) to cooperate with other international organizations that deal with topics of a chemical nature; and (4) to contribute to the advancement of pure and applied chemistry in all its aspects.

Scientists of FDA are on the following sections of this organization:

IUPAC Section on Pesticides—To develop, improve, and standardize methods of pesticide residue analysis, and determine the chemical nature of terminal residues; J. William Cook, Deputy Director, Division of Food Chemistry.

IUPAC Applied Chemistry Division, Food Section—To study methodology associated with food additives, mycotoxins, and smoke constituents; Dr. Henry Fischbach, Director, Division of Food Chemistry.

IUPAC Trace Substances Commission; Dr. Fischbach (chairman).

IUPAC Commission on Units and Quantities in Clinical Chemistry; Dr. B. H. Armbrecht, Division of Veterinary Research.

FDA is represented on these various other international independent organizations:

International Committee on Microbiological Specifications for Foods of the International Association of Microbiological Societies—To seek agreement on realistic limits for the bacteriological content of specific classes of foods as a preliminary step in appraising ways to improve microbiological safety, whether by processing procedures, improved sanitation, or laboratory testing; Dr. G. G. Slocum, now retired.

Joint United States-Japan Cooperation on Development and Utilization of Natural Resources—To promote the Government-to-Government exchange of technical personnel and research findings in human and natural resources. It was decided that the cooperation should begin with seven subjects, among them studies on botulinus and other toxic micro-organisms; Dr. Joseph C. Olson, Jr., Director, Division of Microbiology.

Joint United States-Japan Cooperation on the Development and Utilization of Natural Resources Panel on Mycoplasmosis of Domestic Animals—To exchange information on mycoplasmosis, a disease of domestic animals; Dr. Charles G. Durbin, Director, Division of Veterinary Research.

Pan American Medical Association, Vice President for North American Section on Toxicology—To exchange medical knowledge and research among countries of the Western Hemisphere; Dr. A. J. Lehman, Director, Division of Pharmacology.

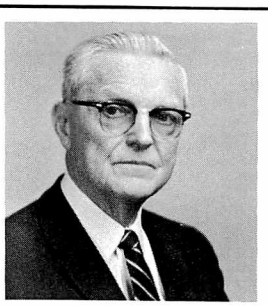
Federation Dentale Internationale Committee on Dental Materials, Instruments, and Therapeutics—To develop and recommend standards for dental materials; Dr. Joseph B. Davis, Office of Medical Review, and Dr. Alvin F. Gardner, Office of Marketed Drugs.

Joint United States-Canadian Food Resources Working Group—To arrange for emergency transborder shipment of food commodities; William Kittel, Emergency Preparedness Officer, Office of Associate Commissioner for Compliance.

The International Organization for Standardization-Technical Committee 76-Transfusion Equipment for Medical Use—To establish standardization of plastic materials used in transfusion equipment and containers made of plastic material between member countries; Dr. Earl L. Meyers, Director, Division of Oncology and Radiopharmaceuticals.

Kenneth E. Taylor, D.V.M. (left), is a Food and Drug Officer in the Office of International Affairs.

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



field reports

ATLANTA DISTRICT A Florida macaroni company and its president were fined a total of $12,000 on February 2 on insect adulteration charges. Vivi Manufacturing Co. (formerly Delmonico Foods, Inc.) was fined $7,500. Its president, Peter S. Viviano, was fined $4,500, given a 1-year suspended sentence, and placed on probation for 5 years with the condition that he not violate the FDC Act during that period. In 1959 the firm entered a plea on a filth adulteration charge, and in 1963 the firm and president were convicted on charges of deficient egg solids in egg noodle products.

BALTIMORE DISTRICT "Solfoton" capsules, valued at $17,093, were seized at Richmond, Va., on January 8 because of contaminated ingredients. Mallinckrodt Chemical Works, Jersey City, N.J., had shipped lactose contaminated with a viable mold to W. M. Poythress & Co., Inc., Richmond. The Virginia firm then used the lactose to make the "Solfoton" capsules.

BOSTON DISTRICT J. Fleishman & Co., Inc., Boston, was fined $4,000 on January 29 for shipping frozen egg products which were adulterated with *Salmonella* or decomposed. Saul, Arthur, and Howard Fleishman were each placed on probation for 2 years. The case was based on establishment inspections of June 1965 and January 1967 when numerous deviations from good manufacturing practices were noted. This case was brought by indictment as a second offense prosecution, since Saul Fleishman was prosecuted in 1965 for a similar offense.

A veterinary drug distributor was sentenced to 2 years' probation on January 22 for shipping an antibiotic mastitis preparation after he had received a recall letter from the manufacturer. The distributor is Dale E. Dudgeon, doing business as Vet-Pro, Ipswich, Mass.

BUFFALO DISTRICT "Da Costa" tablets, valued at $387, were seized February 1 at Buffalo, N.Y. Manufactured and shipped by Richlyn Laboratories, Inc., Philadelphia, Pa., the tablets are labeled for use in the management of angina pectoris. FDA alleged that the product was misbranded, since it failed to bear adequate directions for use and full disclosure information.

"Teat Dilators," valued at approximately $21,219, were seized January 29 at the manufacturer, H. W. Naylor Co., Inc., Morris, N.Y. FDA alleged that the active ingredient in the veterinary product was adulterated by a nonpermitted color additive, External D & C Orange No. 4. The certificate covering this color was cancelled in October 1966. FDA discovered the violation through a routine inspection of the firm.

CHICAGO DISTRICT Approximately 20,000 pounds of prepared cake mixes, valued at $3,000, was destroyed voluntarily because the products were contaminated with *E. coli.* The owner of the mixes, G. A. Goodrich Co., Chicago, Ill., is no longer in business.

The Kitchens of Sara Lee recalled $8,000 worth of pastries from the New Jersey area after consumer complaints of contamination. Analysis by the firm, located in Deerfield, Ill., showed less than 250 ppm hydrocarbons of the hexane group in the products tested. The District visited the firm after receiving information that a New Jersey woman had become ill after eating some of the firm's pastries. The company had also received complaints, and before the inspector's visit had sent 20 men to the New Jersey area to remove all the suspect goods from the market. The firm also had stopped distribution of warehouse stocks in Illinois and in two other locations in the country involved with the suspected production. No complaints had been received from those areas.

The history of the shipment showed that the firm loaded a refrigerator semitrailer, belonging to a private owner, with assorted frozen pastries for shipment to two warehouses in New Jersey. At the first New Jersey stop the driver reported a slight odor when he opened the door of the trailer, but since the odor disappeared quickly, he paid no further attention to it.

CINCINNATI DISTRICT When a court-ordered inspection found continued insanitation at M. P. Brothers Co., Inc., Nashville, Tenn., after the firm had entered guilty pleas to charges of insanitation, the judge fined the corporation and its president, Mack P. Brothers, $2,000 each (see October FDA PAPERS). The judge reserved final judgment in the case and requested another inspection in 6 months. He promised to consider additional fines if the warehouse were still not in acceptable condition. Recent reinspection showed improved conditions. The case was concluded without assessing any increase in fines.

DALLAS DISTRICT More than 23 million thyroid and thyroid-digitalis tablets promoted nationally for use in weight reduction were seized in late January because of false and misleading labeling claims and other violations. The drugs were seized at Lanpar Co., Dallas, Tex., and at National Western Laboratories, Inc., Abilene, Tex. The order for forfeiture included the charge that the drugs are dangerous to health when used as prescribed, recommended, or suggested in their labeling.

The president of Lanpar Co. testified on January 24 before the Senate Antitrust Subcommittee, which was investigating possible antitrust violations in the relationships of obesity specialists and drug firms.

DENVER DISTRICT Approximately 15 million "Thyrodig" tablets, valued at $190,000, were seized at Western Research Laboratories, Denver, Colo. FDA

charged that the combination thyroid-digitalis pills, used in weight reduction regimens, were misbranded.

DETROIT DISTRICT Two food industry workshops on warehouse operations were held in Michigan in February. The workshops, in Grand Rapids on February 6 and in Detroit on February 8, drew 130 people. Sponsored jointly by the District and the Food Inspection Division of the Michigan Department of Agriculture, the workshops included presentations by the Fish and Wildlife Service, U.S. Department of Interior; Michigan Pest Control Operators Association; Michigan State University Cooperative Extension Service; and the sponsors.

KANSAS CITY DISTRICT Bulk wheat, valued at $3,417, was seized at Wolcott & Lincoln CGW Elevator, Kansas City, Kans., on January 11. The wheat, shipped by Farmers Cooperative Association, Dallas, S. Dak., contained insect-damaged kernels and rodent pellets.

LOS ANGELES DISTRICT The working man's family as consumers was the focus of the first consumer conference in Los Angeles sponsored by a labor union. Mrs. Maurine Neuberger, FDA's Consultant on Consumer Relations, was the principal speaker at the conference, which drew 550 people. Topics included food economics, food safety, and nutrition. Cosponsors were the Food and Drug Council of the Teamster's Union, radio station KLAC in Los Angeles, and the District.

Investigation of illegal, clandestine manufacturing of dangerous drugs was discussed at a workshop held by the District in Los Angeles in January. Attending were 19 agents and detectives from the narcotics bureaus of the Los Angeles City Police and Los Angeles Sheriff's Department. They looked at chemicals and laboratory apparatus likely to be found in a clandestine drug plant and saw a demonstration of the methods an enforcement lab uses in identifying dangerous drugs.

For storing foods under insanitary conditions and causing them to be contaminated with rodent and insect filth, Lundsing & Co., Los Angeles, Calif., and its president, Frederick H. Nielsen, Jr., were each fined $150 in January. The firm deals in imported gourmet foods. The first inspection showed extensive rodent damage in candy and bakery products; a second inspection revealed insect filth in cereal and vegetable products.

MINNEAPOLIS DISTRICT Approximately 1,450 medicine droppers were seized at Lakeside Laboratories, Milwaukee, Wis., in January, because, although the labels stated they were sterilized, the packages had holes and openings at the seam closures. The shipper was Dougherty Brothers Co., Buena, N. J.

NEW ORLEANS DISTRICT Due to pesticide contamination, 2,000 bales of Arkansas alfalfa hay was destroyed by burning in Louisiana recently. Even though the bales were broken up and the hay spread out to accelerate burning, the task took 2 days.

The District will be the first to hire sample collectors at entrance grades lower than those of Food and Drug Inspectors. The District handles a relatively large volume of routine sample collections, many on request from other Districts. In the past, this work has been handled by inspectors, whose entrance grades require academic backgrounds beyond those necessary for routine sampling duties. After training, the new sample collectors will handle routine assignments to free the inspectors for more complex inspection work.

NEW YORK DISTRICT Newark District Court dismissed 8 of 14 counts of an Information against a drug repacker on January 22, holding that the alleged charges were based on information obtained during an inspection which violated the defendant's rights against illegal search and seizure. The judge found that the search of the defendant's records was not consented to and as a consequence the defendant's rights were violated. FDA had charged Kaybel, Inc., Englewood, N.J., with failing to include full disclosure information in labeling and with failing to have a supplemental NDA. Also charged were two individuals, Harry Bell and Abraham Kaye. The original inspection, in July 1965, was a routine one. The Newark decision is one of the first arising out of a 1967 Supreme Court decision regarding the constitutionality of regulatory inspections, and sets a new precedent with respect to the rights of firms inspected by FDA.

Secret caches of drugs and clandestine operations in secret rooms, in violation of an injunction, were uncovered in New York by inspectors in January, FDA has charged. Bronx Drug Co., Bronx, N.Y., has been operating under an injunction brought by FDA in 1963 for repacking and distributing prescription drugs in violation of the Food, Drug, and Cosmetic Act. FDA Inspectors with warrants made simultaneous inspections at six locations operated by Isaac Zonana, the proprietor. They uncovered secret caches of drugs at Bronx and Mount Vernon addresses. Clandestine repacking and storage operations were going on behind false walls and in secret rooms, the District charged. Large amounts of outdated and deteriorated drugs and physicians' samples were subsequently seized, the District said.

PHILADELPHIA DISTRICT As a result of FDA's cancellation of certification on chloramphenicol, Richlyn Laboratories, Inc., and Vitamix Pharmaceuticals, Inc., Philadelphia, Pa., voluntarily recalled all outstanding previously certified lots. The recall, to the physician level, affects nationwide distribution. Vitamix is recalling a distribution which includes 1,524 bottles of 100's; Richlyn is recalling more than 3 million capsules of 250-mg. strength and 480,000 capsules of 100-mg. strength.

SAN FRANCISCO DISTRICT Due to subpotency, Barnes-Hind Ophthalmic Products, Sunnyvale, Calif.,

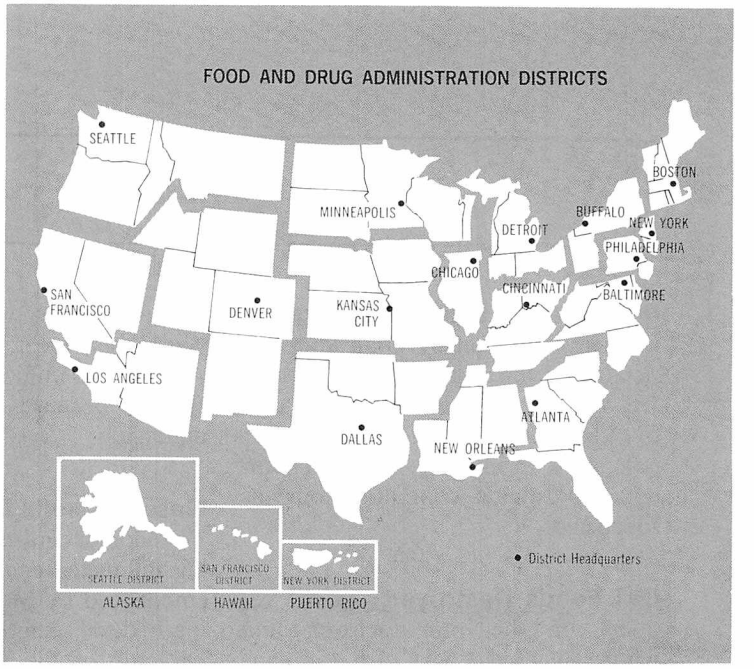
recalled all outstanding lots of tetracaine hydrochloride in plastic 0.5-cc. droppers. FDA analysis of one lot indicated that it was approximately 20 percent of the declared potency. The manufacturer then analyzed some of its reserve stock of the same lot number and found it satisfactory. Several subsequent analyses by FDA chemists using a variety of methods confirmed the original finding of subpotency. When informed of the results, the firm made additional analyses, using a method different from its ordinary procedure. It confirmed FDA's findings and initiated a voluntary recall of all outstanding lots. Apparently the drug deteriorated with age, possibly because of some reaction with the container.

The District detained 110,000 pounds of degelatinized bonemeal shipped from Hamburg, Germany, because of *Salmonella* contamination.

Rice, valued at $4,015, was seized at Saroni Sugar & Rice, Inc., Emeryville, Calif., on January 19 due to contamination with rodent urine.

SEATTLE DISTRICT What and how to teach about drugs were the featured topics at the "Youth and Drug" workshop January 20 for the tri-cities area of Richland, Kennewick, and Pasco, Wash. Sponsored by the District and the Washington State Office of Public Instruction, the workshop will be presented in four other areas of the State.

The District was almost required to get an inspection warrant in January to see records of a drug firm in Portland, Oreg. During a controlled-drug inspection of Don Hall Laboratories, the firm refused ready access to its production records because they also contained pricing, shipping, and other data not subject to inspection. The firm indicated that it would make stripped files available and set certain other conditions, to which the District could not agree. The District then asked the U.S. Attorney in Portland to issue an inspection warrant. He agreed, but first informed the firm's attorney. After a meeting of the attorneys and the firm's president, the firm agreed to allow the inspection without the original conditions. The inspectors returned to the plant the same day to continue their work.



As a followup to the voluntary recall and destruction of chocolate coating contaminated with metal fragments (see March '68 FDA PAPERS) by Guittards Chocolate Co., San Francisco, Calif., the National Biscuit Co., Portland, Oreg., has voluntarily destroyed 2,054 cartons of cookies, valued at $10,130. The District supervised the destruction.

FDA DISTRICT OFFICES

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

BALTIMORE 900 Madison Avenue
Baltimore, Maryland 21201

BOSTON 585 Commercial Street
Boston, Massachusetts 02109

BUFFALO 599 Delaware Avenue
Buffalo, New York 14202

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

CINCINNATI 1141 Central Parkway
Cincinnati, Ohio 45202

DALLAS 3032 Bryan Street
Dallas, Texas 75204

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

DETROIT 1560 E. Jefferson Avenue
Detroit, Michigan 48207

KANSAS CITY 1009 Cherry Street
Kansas City, Missouri 64106

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

MINNEAPOLIS 240 Hennepin Avenue
Minneapolis, Minnesota 55401

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

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

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

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

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

FDA BUREAU OF DRUG ABUSE CONTROL FIELD OFFICES

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

BALTIMORE 401 Water Street
Baltimore, Maryland 21202

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

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

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

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

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

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

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

state actions

Investigation Brings Embargo A joint investigation by Utah State officials and the Salt Lake City Health Department resulted in an embargo of $16,000 worth of butter-sugar mix used primarily in ice cream mixes. Pesticide contamination was suspected.

Old Foods Destroyed At the request of the manufacturer and wholesaler, old stocks of 6,456 cans of yams and 200 cases of condensed milk were destroyed under the supervision of the Missouri Division of Health.

Insanitary Operation Halted A bakery operation was halted by joint action of FDA and New York State Department of Agriculture & Markets Inspectors. The Chautauqua County Health Department had first reported to FDA that A. J. Petri & Sons, Inc., was operating under questionable sanitary conditions. A followup inspection of the bakery by FDA and State Inspectors revealed that cookie-filling operations were indeed being carried out under primitive and insanitary conditions in a shack a short distance from the main plant. The main plant, its related buildings, and surroundings showed evidence of rodents, rodent contamination of stored food, and generally insanitary conditions. The State then seized all in-process and finished filled cookies in the main plant and all raw materials and cookie filling in the smaller building. The plant was shut down until it is cleaned up. In addition, a Federal seizure of rodent-contaminated shelled peanuts was made.

Unfit Foods Destroyed Illinois State Food and Drug Inspectors supervised voluntary destruction of more than 1.8 million pounds of unfit foods during 1967. The unfit foods included cereal products, fats and oils, sugar products, fruits and vegetables, meat, poultry, and fish. Almost 1.4 million pounds was destroyed because of fire and water damage.

Massachusetts Protects Children Toy doctor-and-nurse kits containing unlabeled candy pills have been embargoed by Massachusetts, pending Federal seizure. George Michael, Director of the Commonwealth of Massachusetts Food and Drug Division, told FDA about the pills, similar to those mentioned in the FDA PAPERS picture story in the December-January issue. Working with FDA, the State embargoed the kits.

Joint Inspection Held A joint inspection was held by Philadelphia District Inspectors and representatives of the Foods Section of the Pennsylvania Department of Health on January 29. They inspected American Home Food Products, Milton, Pa., in the first of several joint inspections being conducted. Joint inspections have already been made in the area of medicated feeds.

Measures Conference Set The Michigan Association of Weights and Measures officials will hold its annual conference May 22-24 in Jackson. Program topics will include the Fair Packaging and Labeling Act, aerosol packaging and design, and scale and meter repair and maintenance. The conference's purpose is to promote uniformity in legal requirements, specifications and tolerances, and methods of inspection and testing, and to keep officials informed about what is being done in jurisdictions other than their own. The Food Inspection Division of the Michigan Department of Agriculture coordinates all activities of the weights and measures officials in the State; the Chief of the Division is president of the association. Michigan updated its weights and measures law in 1964, patterning it closely after the Model State Law drafted by the National Conference on Weights and Measures.

Meat Sale Brings Action Diamond Meat Co., Philadelphia, Pa., was fined $100 on January 26 for selling decomposed meat to a Pennsylvania State hospital.

The action was brought by the Pennsylvania Department of Agriculture after the hospital expressed concern about the quality of ground beef it had received from the firm. The Department's analysis of beef samples indicated that the meat had been thawed and refrozen and was not fit for use. (The Department examines food products for institutions when they request the service.) The meat company is appealing the case.

Salmonella Program Progresses Federal and State veterinarians met in Lexington, Ky., on February 1 to discuss with Cincinnati and Detroit Districts the role of each in the FDA-USDA-State program for eradicating *Salmonella* in rendering plants. The veterinarians were from Indiana, Kentucky, Ohio, and Tennessee. The agreement reached provides for initial enforcement by Federal and State veterinarians, and for any necessary regulatory actions to be brought under the FDC Act.

Salvage Operations Hampered A fire caused by a train wreck at Dunreith, Ind., in early January destroyed most of the contents of a tomato cannery on the railroad siding. Indiana Division of Food and Drug Inspectors found no salvageable food items in the wreck but were investigating canned vegetables in the cannery warehouse to see if they could be saved. The salvage operations were hampered by chemical fumes, freezing weather, and snow and sleet.

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 68 seizure actions to remove adulterated, misbranded, and unsafe products from the consumer market were reported in January. These included 32 seizures of foods: 1 because of poisonous and deleterious substances, 24 because of contamination, and 7 because of economic violations. Other seizures included 23 of drugs (including 2 of veterinary and medicated feeds), 8 of medical devices (including 2 of prophylactics), and 5 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
	FOOD / Poisonous and Deleterious Substances	
Milo/Seattle, Wash. 1/9/68	Bartlett Grain Co./Sioux City, Iowa (S)	Contains silicon carbide (carborundum), which may render it injurious to health.
	Contamination, Spoilage, Insanitary Handling	
Beans, Great Northern/Cairo, Ill. 1/10/68	Greaney Brokerage Co./Cairo, Ill. (D)	Held under insanitary conditions.
Beef Cheeks/Canton, Ohio 1/24/68	Beacon Foods/Highland Park, Ill. (S-broker)	Contain decomposed meat.
Chocolate Drink/Cincinnati, Ohio 1/30/68	Chocolate Royale, Ltd./Cincinnati, Ohio (M,S)	Insect contaminated and moldy when shipped.
Cocoa Powder U.S. and B & L/Doraville, Ga. 1/22/68	Monarch Citrus Products Co./Doraville, Ga. (D)	Insect contaminated.
Corn Husks/New Orleans, La. 1/5/68	M-G., Inc., Farm Service, Feed Division/ Weimar, Tex. (M,S)	Insect contaminated and moldy when shipped.
Garlic/San Juan, P.R. 12/27/67	Andrea Marzario S.P.S./Genova, Italy (S)	Insect contaminated while held for sale.
Dry Milk, spray process nonfat/Mendota, Ill. 1/4/68	Mendota Creamery Co./Mendota, Ill. (D)	Held under insanitary conditions; rodent contaminated.
Nuts, Cashew, shelled/Denver, Colo. 1/30/68	Hollander Trading Corp./New York, N.Y. (S)	Packed under insanitary conditions.
Denver, Colo. 1/30/68	"	"
Paprika, Victory Brand and Odix Brand/ New Orleans, La. 1/26/68	Lykes Bros./New Orleans, La. (D)	Contaminated by pigeon excreta.
Pecan(s)/Odessa, Tex. 1/13/68	The Thompson Co., Inc./Searcy, Ark. (P,S)	Prepared and packed under insanitary conditions; E. coli.
pieces/Philadelphia, Pa. 1/26/68	Roper Pecan Co./Hickman, Ky. (P,S)	"
shelled/Birmingham, Ala. 1/16/68	H. J. Bergeron Pecan Shelling Plant/New Roads, La. (P,S)	"
Perch fillets/Rockland, Maine 11/28/67	F. J. O'Hara Co., Inc./Rockland, Maine (D)	To be reconditioned.
Potatoes, french fried, frozen/Laramie, Wyo. 1/12/68	Idaho Potato Growers, Inc./Aberdeen, Idaho (M,S)	Prepared and packed under insanitary conditions.
Rice, Patna and long grain, brown/Emeryville, Calif. 1/19/68	Saroni Sugar & Rice, Inc./Emeryville, Calif. (D)	Held under insanitary conditions; rodent contaminated.
Texas, extra long/Los Angeles, Calif. 10/19/67	Kwong On Lung/Los Angeles, Calif. (D)	Held under insanitary conditions; insect contaminated.
Shrimp/Brownsville, Tex. 1/2/68	Florida Seafood Canning Co., Inc./Apalachicola, Fla. (S)	Contain decomposed shrimp.
canned, frozen/Corvallis, Oreg. 11/6/67	Winchester Bay Seafoods, Inc./Winchester Bay, Oreg. (P,S)	Prepared and packed under insanitary conditions; staphylococci.
stuffed Jumbo/Cleveland, Ohio 1/11/68	Southern Shell Fish Co./Gretna, La. (S)	"
Walnut(s), shelled/Seattle, Wash. 2/1/68	Lindsey Nut Co./Concord, Calif. (P,S)	Prepared and packed under insanitary conditions; E. coli.
black kernels/Omaha, Nebr. 1/10/68	Barnes & Son Shelling Co./Bolivar, Mo. (S)	"
shelled/Vancouver, Wash. 2/2/68	Compton Nut Co./Dundee, Oreg. (S)	"
Wheat/Kansas City, Kans. 1/11/68	Farmers Cooperative Association/Dallas, S. Dak. (S)	Insect-damaged kernels and rodent pellets.
	Economic Violations	
Banana Catsup and Rice Crackers/Los Angeles, Calif. 11/30/67	Imported from Japan and the Philippines.	Label fails to bear quantity of content statement in English units, no artificial coloring statement.
Hawaiian Ices/Jacksonville, Fla. 1/8/68	Circus Ices, Inc./Anaheim, Calif. (M,S)	Label statements "Low in Calories," "No Butterfat," and "Real Fruit in Every Bite" are misleading; not in conformity with standard of identity for water ices.
Liquor Flavored Lolypops/New York, N.Y. 12/28/67	Four Star Candy Co., Inc./Newark, N.J. (M)	Articles are not flavored with liquor.
Margarine, corn oil/Woodville, Miss. 12/28/67	Fort Worth Poultry & Egg Co./Fort Worth, Tex. (S)	Vitamin D in part omitted.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
	Economic Violations (cont'd)	
Maraschino Cherries/Brooklyn, N.Y. 11/17/67	Robins Sales Co., Inc./New York, N.Y. (S)	Short weight.
Taco Sauce/Little Rock, Ark. 1/15/68	Valley Canning Co./Anthony, Tex. (M,S)	"
Tomatoes, Switzer Brand, crushed/E. St. Louis, Ill. 1/8/68	Naas Foods, Inc./Portland, Ind. (M,S)	Fail to conform to definition and standard for canned tomatoes; not sealed and processed as to prevent spoilage.
	DRUGS / Human Use	
Acid Acetylsalicylic tablets/Auburn, N.Y. 1/12/68	Jenkins Laboratories/Auburn, N.Y. (D)	Below quality standard; not in conformity with good manufacturing practice regulations.
Bath Salt Novopin/Los Angeles, Calif. 11/30/67	Imported from Japan.	Label fails to list active ingredients.
Bisflav-C/Glendale, Calif. 1/4/68	Lanpar Co./Dallas, Tex. (M,S)	False and misleading claims for treatment of poor tissue tone associated with weight loss, purpura, arthritis, spontaneous abortion.
C. C. Pills/Atlanta, Ga. 12/29/67	R. G. Dunwody & Sons/Atlanta, Ga. (D)	Label fails to indicate that article contains calomel and that calomel is a derivative or preparation of mercury.
Col-Trol Cold Tablets/Vancouver, Wash. 1/17/68	Boyle & Co./Bell Gardens, Calif. (M,S)	False and misleading statements that Flavihist P.A. (bulk) and Col-Trol (repackaged) will provide 12 hours of continuous relief of nasal secretion.
DaCosta, sugar coated, yellow Tablets/Buffalo, N.Y. 2/1/68	Richlyn Laboratories, Inc./Philadelphia, Pa. (M,S)	Inadequate directions for use.
Digitalis Tablets and Powder/Dallas, Tex. 1/22 & 1/23/68	Lanpar Co./Dallas, Tex. (M)	False and misleading claims for obesity; inadequate directions for use; dangerous to health when used in dosage, frequency, and duration recommended.
Femicin Tablets/Denver, Colo. 12/28/67	Thayer Laboratories, Inc./Metuchen, N.J. (M,S)	No warning statement of possible damage to kidneys.
G.S.I. Antiseptic/Minneapolis, Minn. 1/15/68	G.S.I. Laboratory, Inc./Milwaukee, Wis. (M,S)	False and misleading claims to be effective for athlete's foot, dandruff, boils, sprains, burns, cuts.
Gauze Pads/New Haven, Conn. 1/24/68	A. E. Halperin Co., Inc./Boston, Mass. (M,S)	Not in conformity with USP standards; nonsterile.
IC No. 39-Ionic Calcium/Oakland, Calif. 2/5/68	Ionic Calcium Products Co./Eugene, Oreg. (M,S)	False and misleading claims to be effective for colds, to gain weight, to increase stamina.
Kelp Tablets/Cincinnati, Ohio 1/8/68	Spatz Health Foods/Cincinnati, Ohio (D)	Not in conformity with regulations; contain iodine, an unsafe food additive; label fails to bear statement of special dietary properties.
Kem Non Toxic Zero/Tucker, Ga. 2/2/68	Hysan Products Co./Chicago, Ill. (M,S)	New drug not approved for safety and efficacy.
Lanazol/Hewlett, N.Y. 1/5/68	H. G. Knoll & Co., Inc./Hewlett, N.Y. (D)	False and misleading claims for minor burns and scalds, chafing, superficial cuts.
Medicine Droppers/Milwaukee, Wis. 1/9/68	Dougherty Bros. Co./Buena, N.J. (M,S)	Below standard quality and purity; nonsterile due to incomplete seals.
P.F. Timed Capsules, Test-Still Tabs., Pregnatest Indicator/Hollywood, Fla. 7/5/67	Pharmex, Inc./Hollywood, Fla. (D)	False and misleading claims for hangover treatment.
Pro-Anal/Tulsa, Okla. 12/20/67	Jayhawk Specialty Co., Inc./Pittsburg, Kans. (S)	New drug not approved for safety and efficacy.
Solfoton Caps./Richmond, Va. 1/8/68	Wm. P. Poythress & Co., Inc./Richmond, Va. (M,D) and Mallinckrodt Chemical Works/ Jersey City, N.J. (S) of raw material "Lactose"	Mold contaminated.
Super Absorption (Peptonized Iron)/ Oklahoma City, Okla. 12/8/67	Anthony Products Co./El Monte, Calif. (M,S)	New drug not approved for safety and efficacy.
Thyrodig Tablets/Denver, Colo. 1/5/68	Western Research Laboratories, Inc./Denver, Colo. (D)	Inadequate directions for use; no "Caution" statement; dangerous to health when used in dosage, frequency, and duration prescribed.
Thyroid-Digitalis/Abilene, Tex. 1/22/68	Leo Linden Labs./Culver City, Calif. (M)	False and misleading claims for obesity; inadequate directions for use; dangerous to health when used in dosage, frequency, and duration prescribed.
	Veterinary / Medicated Feed	
Dr. Naylor's Medicated Teat Dilators/Morris, N.Y. 1/29/68	H. W. Naylor Co., Inc./Morris, N.Y. (D)	Contain External D&C Orange No. 4, a decertified color.
Weysol Animal Feed/Rochester, Ind. 11/30/67	Tri Foods Co./Concordia, Mo. (M,S)	False and misleading claims to promote sharper appetites in turkeys, healthier poultry and hogs, prevent worms in hogs, lower death losses in turkeys, prevent excessive flushing in growing pullets.
	MEDICAL DEVICES	
Air-Way 88 Sanitizor/Minneapolis, Minn. 1/17/68	Air-Way Sanitizor, Inc./Toledo, Ohio (M,S)	False and misleading therapeutic claims.
Cristofv Anti-Fatigue/Columbus, Ohio 1/31/68	Electrogen Industries, Inc./Westbury, N.Y. (M,S)	False and misleading claims to create an ideal out-of-doors atmosphere, restore alertness, eliminate drowsiness, relieve bronchial asthma, rheumatism, tranquilize persons in severe pain.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
	MEDICAL DEVICES (cont'd)	
Electronic Exerciser/Tulsa, Okla. 1/24/68	Contrex of Tulsa/Tulsa, Okla. (D)	False and misleading claims to trim figure; inadequate directions for use.
Everslim Sleep-and-Slim Garment/New York, N.Y. 2/1/68	The Everslim Corp./New York, N.Y. (D)	False and misleading claims to induce weight loss while sleeping.
Exerciser U.S. Pat. No. 3,050,695/Sacramento, Calif. 1/29/68	International Contrex Corp./Dallas, Tex. (M,S)	False and misleading claims to significantly increase caloric expenditure, decrease size of hips, waist, tummy, and thighs.
Vibrating Device/Arlington, Tex. 11/29/67	Newbern Co./Arlington, Tex. (D)	False and misleading claims to relieve insomnia, fatigue, muscle soreness, make all tensions disappear.
	Prophylactics	
Prophylactics/Nashville, Tenn. 1/12/68	Killashun Sales Div. of Akwell Industries/ Dothan, Ala. (S)	Defective, holes.
Sultan/Nashville, Tenn. 1/12/68	Killashun Sales Div. of Akwell Industries/ Dothan, Ala. (S)	"
	HAZARDOUS SUBSTANCES	
Aerial Flash and Whistling Bombs, Globe Torpedos, Single Shot and Repeater Fireworks/Hamer, S.C. 1/16/68	Robardi, Inc., d/b/a The Arsenal South of the Border/Hamer, S.C. (D)	Intended for use by children, dangerously flammable, lack warning information required by the Fed. Hazardous Substances Act.
Chemicals and Leaflets/Cornwells Heights, Pa. 1/30/68	M & B Laboratories/Cornwells Heights, Pa. (Repacker)	"
Cherry Bomb Salutes/Silver Lake, Okla. 1/18/68	New Jersey Fireworks Manufacturing Co., Inc./ Elkton, Md., and Vineland, N.J. (M)	"
Columbia Duplicating Fluid/Seattle, Wash. 1/9/68	Columbia Ribbon & Carbon Pacific, Inc./ Portland, Oreg. (M,S)	Lacks consumer protection information required by the Fed. Hazardous Substances Act.

DACA ACTIONS

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

NAME, PLACE & DATE	PRODUCT	CHARGES & DISPOSITION
Central Pharmaceutical Santa Monica, Calif. 12/26/67	109,000 units of controlled drugs.	Inadequate records.
Fred O. Galler, M.D. Los Angeles, Calif. 12/7/67	800,000 units of controlled drugs.	Inadequate records.
Henry Herbert Smith Los Angeles, Calif. 1/18/68	Chemicals and illegal drug manufacturing equipment.	Failure to register; unlawful manufacture of methamphetamine.
Zemel's Rexall Drug Store Littleton, Colo. 12/28/67	15,000 units of controlled drugs.	Inadequate records.
T.K. Pharmacy Denver, Colo. 12/8/67	14,000 units of controlled drugs.	Inadequate records.
Commerce City Drug Commerce City, Colo. 10/31/67	80,000 units of controlled drugs.	Inadequate records. Drugs destroyed by default.
Moore Kirk Laboratories, Inc. East Woodstock, Conn. 12/21/67	4½ million units of controlled drugs and 46 pounds of raw materials.	Inadequate records.
Harry Needleman, M.D. Miami Beach, Fla. 1/9/68	118,000 units of controlled drugs and 17 pounds of pentobarbital powder.	Inadequate records.
Union Pacific Railroad Dispensary Pocatello, Idaho 12/29/67	1,700 units of controlled drugs.	Inadequate records.
Kenyon Drug Co. Mechanicsville, Iowa 1/18/68	2½ million units of controlled drugs.	Inadequate records.
Vern's Big Sky Pharmacy Kalispell, Mont. 11/27/67	2,000 units of controlled drugs.	Inadequate records.
Heritage Prescription & Supply Co. Oklahoma City, Okla. 1/10/68	110,000 units of controlled drugs.	Inadequate records.
Saye Drug Co. Fountain Inn, S.C. 6/16/67	10,000 units of controlled drugs.	Inadequate records. Consent decree of condemnation.
Aztec Medical Center Salt Lake City, Utah 12/5/67	8,000 units of controlled drugs.	Inadequate records.

POST OFFICE DEPARTMENT

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

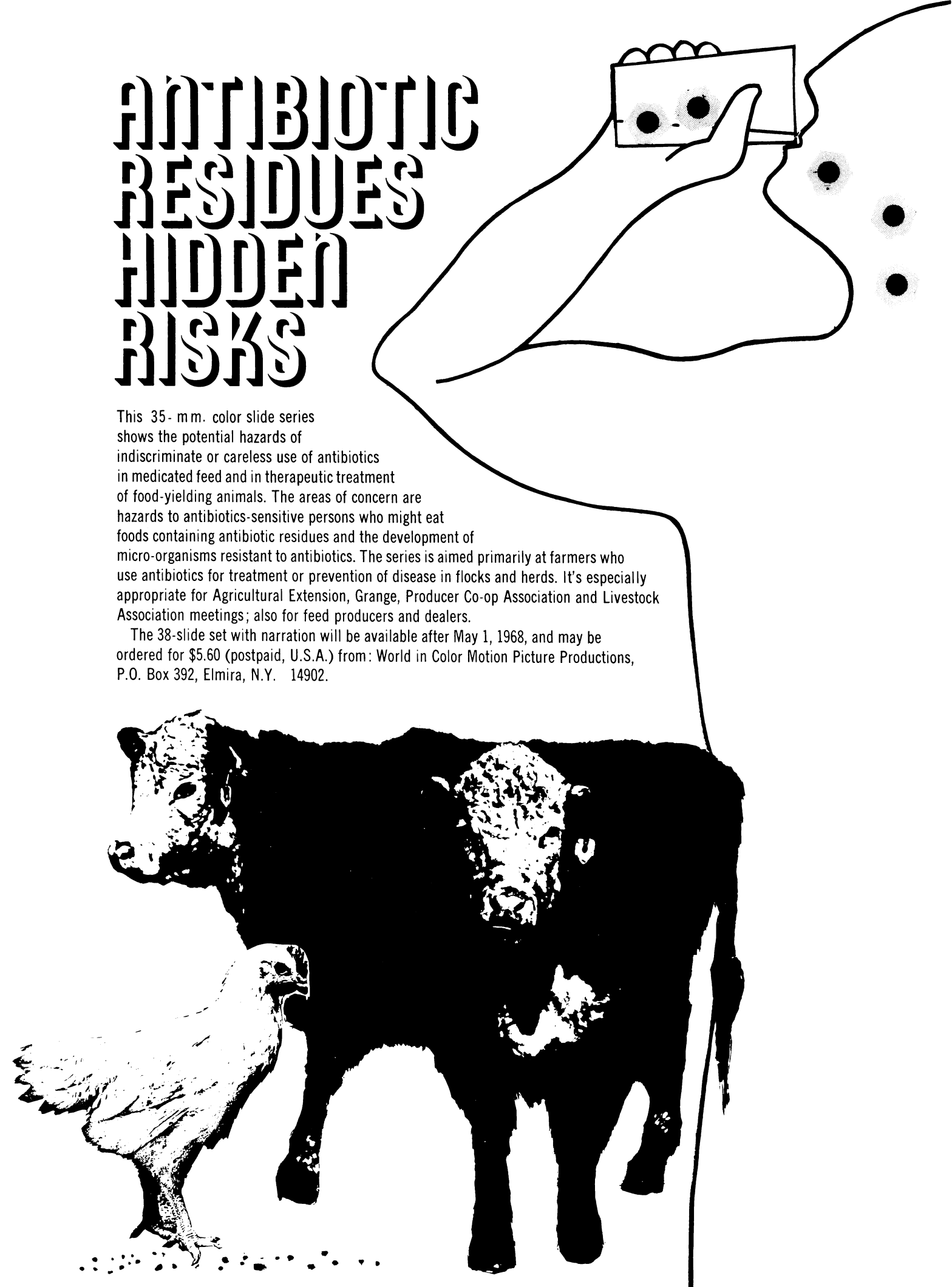
Fraud Orders Issued by Judicial Officer Under 39 U.S.C. 4005 (Fraud)

January 19, 1968: Fraud Order issued against **G. R. Sullinger,** Everett, Wash. This second Fraud Order covers the new mailing address used in an attempt to circumvent the initial Fraud Order issued against the operator for promoting mail-order sales of a device called "Marvel" represented as a scientifically sound and effective means of overcoming male impotence.

February 6, 1968: Fraud Order issued against **Human Factors,** Chico, Calif. Solicitations of orders and sale through the mails of instructions to public allegedly enabling purchaser to hypnotize others while they sleep.

February 8, 1968: Fraud Order issued against **Oyster Products Co.,** and **Oystamins,** Eureka, Calif., and Seattle, Wash. Cited breach of affidavit relating to previous complaint that product did not increase sexual abilities or powers of consumers.

ANTIBIOTIC RESIDUES HIDDEN RISKS



This 35-mm. color slide series shows the potential hazards of indiscriminate or careless use of antibiotics in medicated feed and in therapeutic treatment of food-yielding animals. The areas of concern are hazards to antibiotics-sensitive persons who might eat foods containing antibiotic residues and the development of micro-organisms resistant to antibiotics. The series is aimed primarily at farmers who use antibiotics for treatment or prevention of disease in flocks and herds. It's especially appropriate for Agricultural Extension, Grange, Producer Co-op Association and Livestock Association meetings; also for feed producers and dealers.

The 38-slide set with narration will be available after May 1, 1968, and may be ordered for $5.60 (postpaid, U.S.A.) from: World in Color Motion Picture Productions, P.O. Box 392, Elmira, N.Y. 14902.

notices of judgment

NOTICES OF JUDGEMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

Alfalfa hay, at Thermal, C. Dist. Calif.
Charged 11-18-66: when shipped by various growers in the State of Arizona, the article contained the pesticide chemicals DDT and toxaphene for which there was no tolerance or exemption; 402(a)(2)(B). Consent decree authorized release to Janss Cattle Industries, Thermal, Calif., for salvaging. **(1)**

Cabbage, fresh, at Wilmington, E. Dist. N.C.
Charged 10-6-66: when shipped by Horton's Produce, Hillsville, Va., the article contained a quantity of the pesticide chemical toxaphene in excess of the tolerance; 402(a)(2)(B). Default decree ordered destruction. **(2)**

Carrots, fresh, at Hialeah, S. Dist. Fla.
Charged 10-14-66: when shipped by F. H. Vahlsing, Inc., Hereford, Tex., the article contained the pesticide chemical chlordane in excess of the tolerance; 402(a)(2)(B). Default decree ordered destruction. **(3)**

Corn, shelled, at Kansas City, W. Dist. Mo.
Charged on or about 1-5-67: when shipped by Bingham Feed & Grain, Knoxville, Iowa, the article contained the pesticide chemical 2,4-D for which there was no tolerance or exemption; 402(a)(2)(B). Default decree ordered destruction. **(4)**

Egg product, dried, dehydrated, 2 seizure actions at Kansas City, Dist. Kans.
Charged 9-16-66 and 10-5-66: when shipped by Monark Egg Products, Inc., Kansas City, Mo., the article contained an added poisonous and deleterious substance, **Salmonella** micro-organisms; 402 (a)(1). Consent decree authorized release to shipper for reconditioning. **(5)**

Eggs, frozen, at Dallas, N. Dist. Tex.
Charged 8-20-65: when shipped by Harp's Green Valley Farms, Shawnee, Okla., the article contained the poisonous and deleterious substance **Salmonella** micro-organisms; 402(a)(1). Consent decree authorized release to shipper for reconditioning. **(6)**

Lettuce, fresh, at Forty Fort, M. Dist. Pa.
Charged 11-16-66: when shipped by J. R. Norton, Aguila, Ariz., the article contained a quantity of the pesticide chemical toxaphene in excess of the tolerance; 402(a)(2)(B). Consent decree ordered destruction. **(7)**

Rutabagas, fresh, at St. Paul, Dist. Minn.
Charged 10-13-66: when shipped by Windfall Farm, Exeland, Wis., the article, labeled in part "Rutabagas Packed for Don Brings, St. Paul," contained the pesticide chemical chlordane in a quantity in excess of the tolerance; 402(a)(2)(B). Default decree ordered destruction. **(8)**

Wheat, at Denver, Dist. Colo.
Charged 10-25-66 and amended on or about 1-10-67: when shipped by Potter Cooperative Grain Co., Potter, Nebr., the article contained the added poisonous and deleterious substance ammonium nitrate pellets; 402(a)(2)(A). Consent decree authorized release to Union Pacific Railroad Co., Denver, Colo., for reconditioning. **(9)**

Wheat, at Spokane, E. Dist. Wash.
Charged 11-5-65: when shipped by Teslow, Inc., Manhattan, Mont., the article contained a pesticide chemical, a mercurial compound, for which there was no tolerance or exemption; 402(a)(2)(B). Consent decree authorized release to shipper for salvaging. **(10)**

FOOD / Contamination, Spoilage, Insanitary Handling

Beans, pinto, dried, at McAllen, S. Dist. Tex.
Charged 4-12-66: while held by Sweeney & Co., McAllen, Tex., the article contained bird and rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for reconditioning. **(11)**

Beans, pinto, dried, at Rosemead, C. Dist. Calif.
Charged 9-27-66: while held by La Victoria Foods, Inc., Rosemead, Calif., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. **(12)**

Chestnuts, unshelled, at Richmond, E. Dist. Va.
Charged 1-3-66: when shipped by Antolini & Co., New York, N.Y., the article contained insect filth and moldy, decomposed chestnuts; 402(a)(3). Default decree ordered destruction. **(13)**

Chickpeas, at Bayamon, Dist. P.R.
Charged 9-20-65: while held for sale, the article contained rodent filth; 402(a)(3). Consent decree authorized release to Puerto Rico Food Products Corp., San Juan, P.R., for reconditioning. **(14)**

Eggs, frozen, at Brooklyn, E. Dist. N.Y.
Charged 12-20-65: when shipped by C. Kaitis, Chicago, Ill., the article contained decomposed eggs; 402(a)(3). Consent decree authorized release to L. Rudolf Co., Inc., New York, N.Y., for salvaging. **(15)**

Eggs, frozen, at Chicago, N. Dist. Ill.
Charged 6-30-65: while held for sale, the article contained decomposed eggs; 402(a)(3). Consent decree authorized release to Nichols Badger Brand Products, Inc., Chicago, Ill., for salvaging. **(16)**

Eggs, frozen, at Cincinnati, S. Dist. Ohio.
Charged 12-8-65: when shipped by Sol Rich Co., Chicago, Ill., the article, labeled in part "Whole Eggs . . . C. Kontis Co." and (some) "Distributed by Egg Company, Inc. New York, N.Y.," contained decomposed eggs; 402(a)(3). Default decree ordered destruction. **(17)**

Eggs, frozen, at Cleveland, N. Dist. Ohio.
Charged 9-24-64: when shipped by Suncrest Poultry Farm, Inc., Phoenix, Ariz., the article contained decomposed eggs; 402(a)(3). Consent decree authorized release to the Earl K. Riley Co., Chicago, Ill., for salvaging. **(18)**

Eggs, frozen, at San Francisco, N. Dist. Calif.
Charged 12-7-65: when shipped by Langendorf United Bakeries, Seattle, Wash., the article, labeled in part "Frozen Whole Eggs . . . Packed by Landsberger Gry. & Prod. Inc., Sisseton South Dakota," contained decomposed eggs; 402(a)(3). Consent decree authorized release to Joseph Buchwald & Sons, Inc., San Francisco, Calif., for salvaging. **(19)**

Filberts, shelled, at New York, S. Dist. N.Y.
Charged 10-27-65: while held for sale, the article contained insect filth and moldy nuts; 402(a)(3). Consent decree authorized release to the Near East Co., New York, N.Y., for export to original foreign shipper. **(20)**

Lentils, beans, and peas, dried, at Miami, S. Dist. Fla.
Charged 7-29-66: while held by Green Bros., Inc., Miami, Fla., the lentils contained rodent filth, the beans and peas contained insect filth, and the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. **(21)**

Popcorn and flour, at Decatur, N. Dist. Ala.
Charged 10-25-66: while held by Brock & Spright Co., Inc., Decatur, Ala., the articles contained insect filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered donation to public/charitable institution for use as animal feed. **(22)**

Prunes, dried, at Cupertino, N. Dist. Calif.
Charged 1-20-66: when shipped by Oregon Prune Exchange, Forest Grove, Oreg., the article contained insect filth and rodent filth and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for salvaging as animal food. **(23)**

Rice, at Orange, E. Dist. Tex.
Charged 6-15-66: while held by Orange Rice Milling Co., Inc., Orange, Tex., after milling, the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. **(24)**

Rice, at San Juan, Dist. P.R.
Charged 11-4-65: while held by Covadonga Warehouse, San Juan, P.R., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Commercial Development Co. of Puerto Rico for reconditioning. **(25)**

Sesame seed and poppyseed, at Los Angeles, S. Dist. Calif.
Charged 7-27-66: while held by Karp's Bakers Supplies, Inc., Los Angeles, Calif., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. **(26)**

Shrimp pieces, frozen, Golden Fleet, at Memphis, W. Dist. Tenn.
Charged 12-7-65: when shipped by Singleton Packing Corp., Tampa, Fla., the article contained decomposed shrimp; 402(a)(3). Consent decree authorized release to shipper for salvaging. **(27)**

Walnuts, shelled, at Chicago, N. Dist. Ill.
Charged 1-3-66: while held for sale, the article contained insect filth; 402(a)(3). Consent decree authorized release to Associated Nut Growers, Visalia, Calif., for salvaging. **(28)**

Wheat, at Spokane, E. Dist. Wash.
Charged 5-2-66: when shipped by Farmers Union Grain Terminal Association, Williams, Mont., the article contained rodent filth; 402(a)(3). Consent decree authorized release to shipper for conversion into animal feed. **(29)**

Whitefish, frozen, at Chicago, N. Dist. Ill.
Charged 5-9-66: when shipped by Northland Fisheries, Ltd., and Keystone Fisheries, Winnipeg, Canada, the article contained parasitic cysts; 402(a)(3). Consent decree authorized release to Walter's Union Market, Inc., Chicago, Ill., for exportation to the foreign supplier. **(30)**

FOOD / Economic and Labeling Violations

Broccoli, frozen, at Detroit, E. Dist. Mich.
Charged 1-9-67: when shipped by Stokely-Van Camp, Inc., Mount Vernon, Wash., the label reading in part "Farm Maid Fresh Frozen Broccoli Cuts . . . Packed for Borman Food Stores, Inc., Detroit" was false and misleading, since the article was chopped broccoli instead of broccoli cuts; 403(a). Consent decree authorized release to Stokely-Van Camp, Inc., Indianapolis, Ind., for relabeling. **(31)**

Butter, at Chicago, N. Dist. Ill.
Charged 4-27-66: when shipped by Meinerz Creamery, Fredericksburg, Iowa, a product containing less than 80 percent by weight of milk fat had been substituted for butter; 402(b)(2). Consent decree authorized release to Berkshire Foods, Inc., for reworking. **(32)**

Butter, at Dubuque, N. Dist. Iowa.
Charged 8-16-67: when shipped by Oak Brand Ice Cream Co., Freeport, Ill., an article containing less than 80 percent by weight of milk fat had been substituted for butter; 402(b)(2). Consent decree authorized release to shipper for salvaging. **(33)**

Butter, at Philadelphia, E. Dist. Pa.
Charged 2-10-66: when shipped by Meinerz Creamery, Fredericksburg, Iowa, and reshipped by Berkshire Foods, Inc., Chicago, Ill., a product containing less than 80 percent milk fat had been substituted for butter; 402(b)(2). Consent decree authorized release to Berkshire Foods, Inc., for reworking. **(34)**

Butter, at Sioux City, N. Dist. Iowa.
Charged 10-22-65: when shipped by Randolph Creamery Co., Randolph, Nebr., the article was deficient in butterfat; 402(b)(2). Consent decree authorized release to shipper for reworking. **(35)**

Candy, pecan carmel bars, at Peoria, S. Dist. Ill.
Charged 12-5-66: when shipped by Corll Candy Co., Houston, Tex., the article contained insect and rodent filth and had been prepared and packed under insanitary conditions; the article's labeling "Pecan Fudge Bars" was false and misleading as applied to pecan carmel bars; and the name and place of business of the manufacturer, packer, or distributor, the statement of quantity of contents, and the statement of the ingredients on the inset label were inconspicuous, since such label had been folded over so it could not be read; 402(a)(3), 402(a)(4), 403(a), 403(f). Default decree ordered destruction. **(36)**

Candy, pecanettes, at Fairless Hills, E. Dist. Pa.
Charged 11-16-66: when shipped by Hillside Enterprises, Inc., Cleveland, Ohio, the article was short weight (approx. 12.3 percent); 403(e)(2). The shipper claimed the articles, denied knowledge concerning the charge, and claimed that a Chicago, Ill., firm was responsible for the packaging of the article. Upon the Government's motion for summary judgment, the court condemned the article and authorized donation to public/charitable institution. **(37)**

Cheese, cheddar, at Eastman, S. Dist. Ga.
Charged 10-6-66: when shipped by Purity Cheese Co., Mayville, Wis., the name "Sharp Cheddar" was false and misleading, and the article lacked conformity to the standard of identity for cheddar cheese since it contained excess moisture, was deficient in milk fat, and contained ingredients not permitted by the standard; 403(a), 403(g)(1). Default decree ordered donation to charitable institution. **(38)**

Cherries, canned, red, sour, pitted, Rainbow, at Austin, W. Dist. Tex.
Charged 11-7-66: when shipped by Perry Canning Co., Perry, Utah, the article fell below the standard of quality because of excess blemished cherries; 403(h)(1). Consent decree authorized release to shipper for salvaging. **(39)**

Crabs, deviled, frozen, at Tampa, M. Dist. Fla.
Charged 11-2-66: when shipped by Bayou Foods, Inc., Mobile, Ala., the article labeled "Sail Brand Baked Deviled Crab . . . Product of Seafood Enterprises, Inc. Tampa,

Fla. . . ." contained codfish which had been substituted for deviled crab, the name "Deviled Crab" was false and misleading, and the label lacked the common or usual name of each ingredient; 402(b)(2), 403(a), 403(i)(2). Default decree ordered destruction. **(40)**

Fish fillets, frozen, Margo, at New Orleans, E. Dist. La.
Charged 5-4-61: when shipped by Mariscos del Golfo, Merida, Mexico, the article's label statement "Snapper" was false and misleading; and the article was offered for sale under the name of another food, snapper fillets, when the article consisted of grouper fish fillets; 403(a), 403(b). A consent decree, without prejudice to the litigation of the charges, authorized release to the shipper for relabeling of all but one carton of the article.
Charged 5-21-62 in a petition for injunction against Government officials by the shipper and Silver Sea Sales Co., Inc., New Orleans, La., a distributor of the shipper's Margo brand fish fillets: that subsequent shipments of such fillets were being proceeded against by the Government. The court temporarily restrained certain officials of FDA and U. S. Customs from further detention proceedings with respect to certain lots of fillets labeled as "Snapper" and "Mexican Snapper" that were under import detention. Subsequently the court dismissed the petition for injunction.
At the trial of the seizure action, the Government contended that the fish was epinephelus morio and that the common name for fish of the species epinephelus was "grouper." The claimants contended that through usage this particular fish had acquired the name "snapper" and that the common name "snapper" was not reserved exclusively for fish of the family lutjanidae. Thereafter the court rendered a verdict for the shipper. **(41)**

Fruit cocktail, canned, at Syosset, E. Dist. N.Y.
Charged 11-25-66: when shipped by Tillie Lewis Foods, Inc., Modesto, Calif., the article, labeled in part "Sweet Life . . . Fruit Cocktail . . . Distributed by Sweet Life Brands, Inc., New York, N.Y.," lacked conformity to the standard of identity, since it was deficient in pineapple ingredient; 403(g)(1). Consent decree authorized release to shipper for relabeling. **(42)**

Orange juice, at Tulsa, N. Dist. Okla.
Charged 12-20-66: when shipped by Vita-Fresh Sales, Inc., Houston, Tex., the labeling contained false and misleading flu and cold claims; 403(a). Default decree ordered destruction of the labeling. **(43)**

Orange juice, Real Thing, 2 seizures at Lexington, M. Dist. N. C., and Goldsboro, E. Dist. N. C.
Charged 11-16-66 and 11-22-66: when shipped by Coble Dairy Products Cooperative, Inc., Anderson, S. C., the article contained substances other than orange juice, which substances had been substituted for orange juice; and the article lacked conformity to the standard of identity, since it contained substances other than orange juice that are not permitted, including citric acid and beta-carotene; 402(b)(2), 403(g)(1). Default decrees authorized donation to public/charitable institution. **(44)**

Orange juice drink, True Crystals, at Los Angeles, S. Dist. Calif.
Charged 11-5-65: when shipped by Plant Industries, Inc., Plant City, Fla., the article was short weight (approx. 2 percent); 403(e)(2). Consent decree authorized release to shipper for salvaging. **(45)**

Peach halves, canned, Crossroads Pride, at Cincinnati, S. Dist. Ohio.
Charged 11-2-66: when shipped by Crossroads Canning Co., Campobello, S.C., the article fell below standard of quality because of excessively hard peach halves; 403(h)(1). Consent decree authorized release to shipper for relabeling. **(46)**

Peach halves, canned, Dixie Delite, at Jackson, S. Dist. Ohio.
Charged 12-1-65: when shipped by Hendricks Canning Co., Easley, S.C., the article fell below the standard of quality due to excessive hardness, excessive weight variation, and excessive trimming of the peach halves; 403(h)(1). Consent decree authorized release to shipper for relabeling. **(47)**

Rock lobster tails, frozen, at Los Angeles, S. Dist. Calif.
Charged 5-10-66: while held by Rupert Fish Co., Inc., Los Angeles, Calif., after repacking and relabeling, the article was short weight (approx. 2 to 3 percent); 403(e)(2). Consent decree authorized release to dealer for salvaging. **(48)**

Shrimp, canned, Sea Trader, 3 seizure actions at Richmond, N. Dist. Calif., and Stockton, 2 actions, E. Dist. Calif.
Charged 12-30-66, 1-9-67, and 1-12-67: when shipped by Whitney Fedaligo Sea Foods, Inc., and Safeway Stores, Inc., Seattle, Wash., the article contained broken pieces of shrimp which had been substituted for whole shrimp; and the label statement "Tiny Pacific Shrimp" and the label vignette of whole shrimp were false and misleading, since the article contained broken pieces of shrimp; 402(b)(2), 403(a). Consent decrees authorized release of the articles charged on 1-9-67 and 1-12-67 to East Point Seafood Co., South Bend, Wash., for relabeling. Default decree ordered destruction of article charged on 12-30-66. **(49)**

Shrimp, frozen, breaded, Qik Fry, at Salt Lake City, Dist. Utah.
Charged 12-12-66: when shipped by Rose Frozen Shrimp, Inc., Los Angeles, Calif., the article lacked conformity to the standard of identity, since it was deficient in shrimp material; 403(g)(1). Default decree ordered delivery to public institution. **(50)**

Sorghum sirup, at Knoxville, E. Dist. Tenn.
Charged 12-30-66: when shipped by Rayford Farmer, Section, Ala., the article contained corn sirup which had been substituted for sorghum, corn sirup had been added, mixed, or packed so as to give the article an appearance of greater value than it was and so as to reduce its quality; the label was false and misleading, since the article was a mixture of sorghum sirup and corn sirup; and the label lacked the common or usual name of each ingredient; 402(b)(2), 402(b)(4), 403(a), 403(i)(2). Default decree authorized donation to charitable institution. **(51)**

Sorghum sirup, Poor Boys Open Kettle, at Industry, C. Dist. Calif.
Charged 6-9-66: when shipped by Woody Herrin, Water Valley, Miss., glucose had been substituted in part for the article; the label statement "Sorghum" was false and misleading; and the label failed to bear the common or usual name of each ingredient; 402(b)(2), 403(a), 403(i)(2). Consent decree authorized release to Western Commerce Corp., Industry, Calif., for salvaging. **(52)**

Tea, Jasmine and **Darjeeling,** at Van Nuys, C. Dist. Calif.
Charged 12-9-66: while held by Sey-Co Products Co., Inc., Van Nuys, Calif., after repacking, the articles were short weight; 403(e)(2). Consent decree authorized release to Sey-Co Products Co., Inc., for reconditioning. **(53)**

Tomatoes, canned, at Baltimore, Dist. Md.
Charged 10-6-66: when shipped by H. E. Kelley & Co., Inc., New Church, Va., the article fell below standard of quality because of excess peel; 403(h)(1). Default decree ordered donation to public/charitable organizations. **(54)**

Tunafish chunks, canned, at Landover, Dist. Md.
Charged 11-18-66: when shipped by Ibec Packing Co., Inc., New York, N.Y., the article, labeled in part "Sea Trader Light Chunk Tuna . . . Safeway Stores Incorporated Distributor . . . Oakland, California," fell below standard of fill, since the average weight of pressed cakes of the solid pack tuna was approximately 6.6 percent less than that prescribed; 403(h)(2). Consent decree authorized release to shipper for repacking. **(55)**

DRUGS / Human Use

Afaco Original Homeopathic Formula tablets, at St. Joseph, W. Dist. Mo.
Charged 6-9-64: when shipped by International Afaco, Ltd., Chicago, Ill., the labeling was false and misleading as to ophthalmic therapy claims, and lacked adequate directions for use, and no such directions were feasible, since the article was medically worthless; 502(a), 502(f)(1). An answer denying the charges and signed by International Afaco, Ltd., Merle G. Farmsworth, president, and J. Kenneth Coles, D.O., was filed. In an amended answer, the respondents asked that the article be returned to Dr. Coles as the owner. After trial by the court, the article was condemned and ordered destroyed. The Government then moved to tax $982.49 as costs against Afaco, Farmsworth & Coles. The respondents urged that the court should exercise its discretion and refuse to tax costs against Farmsworth and Coles. The court said, "The statute seems to be mandatory in its requirements that costs be taxed against the respondents"; and the court distinguished **U.S. v. 353 cases, etc.,** 195 F. Supp. 685 (Ark.), as a case involving numerous counts where the Government had not sustained its burden of proof as to certain of the counts and was not entitled to have these costs concerning these counts assessed against the respondents. The court found that International Afaco, Ltd., was a corporation and that at no place in the pleadings was Farmsworth named as a party, but that International Afaco, Ltd., and Dr. Coles both signed the Answer as respondents. The court said, "Although Dr. Coles did not appear and contest the case, I see no way for him to escape the taxation of costs against him in view of the state of pleadings." The court ordered costs taxed against Afaco and Coles. **(56)**

Alergimist intranasal solutions A and B, at Florence, Dist. S.C.
Charged 10-21-66: when shipped by an unknown shipper, the articles were new drugs without effective approved New Drug Applications; 505(a). Default decree ordered destruction. **(57)**

Amphetamine, barbiturate, and **other depressant or stimulant drugs,** at Aurora, Dist. Colo.
Charged 2-3-67: while held by Ike Merkowitz, t/a Altura Drug, Aurora, Colo., the dealer operated an establishment for distributing such drugs and had failed to register such establishment as required by law, and complete and accurate inventory records of all such drugs were not prepared and kept; 301(p), 301(q)(4). Default decree ordered destruction. **(58)**

Amphetamine, barbiturate, and **other depressant or stimulant drugs,** at Chicago, N. Dist. Ill.
Charged 2-3-67: while held by Goldsmith Drug Co., Inc., Chicago, Ill., complete and accurate inventory records and receipt and disposition records of all such drugs were not prepared and kept; 301(q)(4). Default decree ordered destruction. **(59)**

Amphetamine, barbiturate, and **other depressant or stimulant drugs,** at East Point, N. Dist. Ga.
Charged 1-23-67: while held by City Pharmacy, East Point, Ga., the articles were possessed for sale outside the authorized course of the dealer's business since it was operating without a State permit, and complete and accurate inventory records of all such drugs were not prepared and kept; 301(q)(3), 301(q)(4). Default decree ordered destruction. **(60)**

Amphetamine, barbiturate, and **other depressant or stimulant drugs,** at Edgewater, Dist. N.J.
Charged 2-9-67: while held by Excel Pharmacal Co., Inc., Edgewater, N.J., the dealer operated an establishment for distributing such drugs and had failed to register such establishment as required by law and to prepare and keep complete and accurate inventory records of all such drugs; 301(p), 301(q)(4). Default decree ordered destruction. **(61)**

Amphetamine, barbiturate, and **other controlled-drug stocks,** at Kansas City, W. Dist. Mo.
Charged 2-14-67: while held by Interstate Wholesale Drug Co. (Kansas City Drug Co., Inc.), Kansas City, Mo., complete and accurate inventory records were not prepared; 301(q)(4). Consent decree authorized release to dealer for preparation of records. **(62)**

Amphetamine, barbiturate, and **other controlled-drug stocks,** at Marshall, Dist. N.C.
Charged 8-2-66: while held by Moore's Pharmacy, Marshall, N.C., the articles were held by a pharmacy whose license had been revoked by the State; 301(q)(3). Default decree ordered destruction. **(63)**

Amphetamine, barbiturate, and **other controlled tablets and capsules,** at New York, S. Dist. N.Y.
Charged 11-1-66: while held by Morris Gunner and Gay Pharmacy, New York, N.Y., the articles were possessed for sale outside the ordinary and authorized course of the dealers' business, without a prescription; 301(q)(3). Default decree ordered destruction. **(64)**

Amphetamine and barbiturate drug stocks, at Ottumwa, S. Dist. Iowa.
Charged 1-31-67: while held by J. W. Edgerly Co., Inc., Ottumwa, Iowa, complete and accurate inventory records and receipt and disposition records of all such drug stocks were not prepared and kept; 301(q)(4). Consent decree authorized release to dealer for preparation of records. **(65)**

Amphetamine and barbiturate drug stocks, at Dolton, N. Dist. Ill.
Charged 2-14-67: while held by Newman Drugs, Inc. (Newman Pharmacy, Inc.), Dolton, Ill., complete and accurate inventory records and receipt and disposition records of all such drugs were not prepared and kept; 301(q)(4). Default decree ordered destruction. **(66)**

Amphetamine and barbiturate drug stocks, at Kansas City, W. Dist. Mo.
Charged 2-2-67: while held by R. E. Adams Drug, Inc., Kansas City, Mo., complete and accurate inventory records and receipt and disposition records of all such drugs were not prepared and kept; 301(q)(4). Default decree ordered destruction. **(67)**

Chaulmoogra oil capsules, T.D., at Bell, C. Dist. Calif.
Charged 1-18-67: while held by Seal-Ins Labs., Inc., Bell, Calif., after manufacture from chaulmoogra oil, which had been shipped in interstate commerce, the labeling contained false and misleading arthritis claims, and the article failed to bear the required prescription legend; 502(a), 503(b)(4). Default decree ordered destruction. **(68)**

CPL 400 Digestive enzyme tablets, alpha-tocopheryl tablets, and **Papayazyme 800 Digestive tablets,** at Longview, E. Dist. Tex.
Charged 8-25-66: when shipped by Howard Products Co., Glendale, Calif., the articles were new drugs, since they were not generally recognized by qualified experts as safe and effective for phlebitis, belching, cancer, diabetes, influenza, slipped-disc pain, bruises, mental disease, pancreatitis, and other conditions described in the accompanying booklet "Howard Products Bulletin" and reprint of Reader's Digest article "Enzymes Medicines Bright Hope," and there were no effective New Drug Applications for the articles; 505(a). The above booklet and reprint accompanying the alpha-tocopheryl tablets contained false and misleading claims for protecting muscles from disintegration, disposal of cholesterol, problems affecting the heart, and other purposes; 502(a). Default decree ordered destruction. **(69)**

Diiodo nitrophenol solution, at Oklahoma City, W. Dist. Okla.
Charged 7-5-67: when shipped by Curts Laboratories, Inc., Kansas City, Mo., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. **(70)**

Erosol bath and massage oil, at New York, S. Dist. N.Y.
Charged 11-14-66: while held by Erosol, Inc., New York, N.Y., the labeling of the article, which had been manufactured by the dealer from drug ingredients which had been shipped in interstate commerce, contained false and misleading claims for increasing blood circulation, vaginal lubrication, solving frigidity and unresponsiveness in women, and creating tactile sensitivity and response; and the label lacked the established name of each active ingredient; 502(a), 502(e)(1)(A)(ii). Default decree ordered destruction. **(71)**

Geritag capsulettes, at Oklahoma City, W. Dist. Okla.
Charged 12-20-66: when shipped by S. J. Tutag & Co., Detroit, Mich., the labeling lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information; 502(f)(1). Default decree ordered destruction. **(72)**

Go-Pain analgesic cream, Blue ointment, Ichthammol ointment, and **boric acid ointment,** at Dallas, N. Dist. Tex.
Charged 10-14-66: when shipped by the DePree Co., Holland, Mich., the labels lacked an accurate quantity of contents statement, and the Go-Pain ointment labeling contained false and misleading therapeutic claims; 502(b)(2), 502(a). Default decree ordered destruction. **(73)**

Honey, at Dearborn, Harper Woods, and at 1494 Broadway and 22200 Grand River Avenue, Detroit, E. Dist. Mich.
Charged 11-8-61 and 5-31-62: while held by Detroit Vital Foods, Inc., certain literature accompanying the honey contained false and misleading therapeutic claims; 502(a). Following answers to interrogatories, a motion for dismissal by the claimant, Detroit Vital Foods, Inc., the court ordered that the honey, except for that at 22200 Grand River Avenue, be released to the claimant, that the honey seized at 22200 Grand River Avenue be held pending the filing of amended libel, and that the motion to dismiss be withdrawn. Following filing of amended libel, trial was had and opinion was rendered holding that the honey was intended to be used in the capacity of a drug and that the literature constituted accompanying labeling for the honey (218 F. Supp. 208). A decree for release of the honey for relabeling was entered, and upon appeal such judgment was affirmed (344 F. 2d 288). **(74)**

Kalton Extended Action Cold Capsules, at Paramus, Dist. N.J.
Charged on or about 7-15-64: when shipped by Manhattan Drug Co., Brooklyn, N.Y., the labeling contained false and misleading therapeutic claims; 502(a). Consent decree ordered destruction. **(75)**

Lironvit-12 liver-iron-vitamin injection and **Eritrogen vitamin B_{12} combination injection,** at Hato Rey, Dist. P. R.
Charged 10-11-66: while held by Terrier Laboratories, Inc., Hato Rey, P.R., the strength of the articles, which had been manufactured by the dealer from ingredients shipped in interstate commerce, was deficient; and the labeling was false and misleading, since the Lironvit-12 injection was approximately 70 percent deficient in riboflavin, and the Eritrogen injection was approximately 44.5 percent deficient in niacin; 501(c), 502(a). Default decree ordered destruction. **(76)**

Methamphetamine depressant or **stimulant drugs,** at Randolph, Dist. Nebr.
Charged on or about 10-26-66: while held by Glen E. Peters, M.D., Randolph, Nebr., the articles were possessed for sale outside the ordinary and authorized course of the dealer's business, without a prescription; 301(q)(3). Default decree ordered destruction. **(77)**

Miscellaneous drugs, at Newark, Dist. N.J.
Charged 6-3-66: when shipped by Pralex Corp., St. Thomas, Virgin Islands, the articles' label lacked the name and place of business of the manufacturer, packer, or distributor, and a quantity of contents statement; and their labeling lacked adequate directions for use; 502(b)(1), 502(b)(2), 502(f)(1). Consent decree authorized release to N.A.R. Corp., Newark, N.J., for relabeling. **(78)**

Patiton spruce oil combination ointment, at Council Bluffs, S. Dist. Iowa.
Charged 12-30-66: when shipped by Leneva Labs., Inc., Omaha, Nebr., the labeling contained false and misleading pain relief, sunburn, arthritis, and other therapeutic claims; and the label lacked the quantity, kind, and proportion of the alcohol ingredient; 502(a), 502(e)(1)(A)(ii). Consent decree ordered destruction. **(79)**

Phenylbutazone powder, at Gainesville, N. Dist. Fla.
Charged 12-8-64: when shipped by Rotex Pharma, Hamburg, Germany, the labeling of the bulk powder lacked adequate directions for use and was not exempted, since the article was for use as a new drug for which no application was effective, its label lacked the caution legend for a new drug for manufacturing, and the article was not for investigational use only; 502(f)(1). Consent decree authorized release to Zirin Laboratories International, Inc., Hialeah, Fla., for tableting, labeling, and investigational use pursuant to law by designated investigators. **(80)**

Prescription drugs, at Itta Bena, N. Dist. Miss.
Charged 9-28-66: while held by James G. Shankle, t/a Bena Drug Store, Itta Bena, Miss., the labeling of the articles lacked adequate direction for use, and they were not exempted, since the dealer was, at the time, not authorized to deal in prescription drugs; 502(f)(1). Default decree ordered destruction. **(81)**

Prescription drugs, at New York, S. Dist. N.Y.
Charged 6-28-61 and amended 7-31-62 for injunctive relief: while held for sale by Milshap Drug Sales Corp., New York, N.Y., the labeling of the articles which had not been repacked by the dealer (those labeled in part "physicians' samples," "professional sample," or "complimentary package," etc.) was false and misleading as applied to articles in possession of a repacker and intended for sale, and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(a).
The labeling of some of the repacked articles (those repacked from physicians' samples into stock bottles) was false and misleading because of the label statement "Clinical Trial Supply 12 Tablets" when the articles were in possession of a repacker and intended for sale, and not intended for use as "complimentary—not for sale" samples for physicians and other lawfully engaged in dispensing prescription drugs; some lacked adequate directions for use and were not exempt from such requirement, since they were prescription drugs, and their labels lacked an identifying lot number as required by regulations; some lacked an antibiotic certificate or release, since they were in a repackaged condition and had not been certified since repacking; some were new drugs without an effective New Drug Application, since applications filed were not effective with respect to such drugs; 502(a), 502(f)(1), 502(l), 505(a).
On 7-31-62, the court allowed the Government to amend the libel to include a prayer for an injunction prohibiting the claimant from repacking physicians' sample drugs. Also on that date, the claimant's motion to dismiss the libel was granted as to that portion which alleged that the seized articles bearing the legends "complimentary," "physicians' sample," etc., were misbranded under 502(a), solely because they were in the possession of a wholesaler and repacker who held them for sale to retail pharmacists. Consent decree dismissed the Prayer for Injunctive Relief and condemned and ordered destroyed each article which: **A.** Was a repacked drug; **B.** was a drug with respect to which the expiration date had expired; **C.** was a drug which manifested deterioration by organoleptic, chemical, or analytical examination; **D.** was an Investigational New Drug; **E.** was a drug which had for any reason been withdrawn from the market by the manufacturer; **F.** was a new drug with respect to which approval of the New Drug Application had been withdrawn; **G.** failed to bear or be accompanied by labeling containing the full disclosure information required by regulations; **I.** was a placebo; **J.** was in a package which contained two or more different drugs; **K.** was in a package bearing only a portion of the original physicians' sample label. Consent decree also authorized release of the remainder to the dealer. **(82)**

Quinidine sulfate tablets, at Hollywood, S. Dist. Calif.
Charged 8-8-66: while held for sale after being repacked and relabeled by an unknown firm, the article's purity and quality fell below the U.S.P. standard, the article contained niacin tablets which had been substituted in part for quinidine sulfate tablets, and the labeling representing the article to consist of quinidine sulfate tablets was false and misleading; 501(b), 501(d)(2), 502(a). Default decree ordered destruction. **(83)**

Red Heads cold capsules, at Royal Oak, E. Dist. Mich.
Charged 1-19-67: while held by Michigan First Aid, Inc., Royal Oak, Mich., the dealer's labeling lacked the required belladona, acetophenetidin, salicylate, and strychnine warnings; 502(f)(2). Default decree ordered destruction. **(84)**

Reserpine tablets, U.S.P., at Detroit, E. Dist. Mich.
Charged 5-15-67: while held by Mallard, Inc., Detroit, Mich., after manufacture from reserpine shipped in interstate commerce, the article's strength differed from U.S.P. standard, since it was deficient in reserpine (approx. 20 percent); 501(b). Default decree ordered destruction. **(85)**

Reserpine tablets, U.S.P., at Muskegon Heights, W. Dist. Mich.
Charged on or about 8-8-66: while held by Seaway Pharmacal Corp., Muskegon Heights, Mich., after manufacture from reserpine which had been shipped in interstate commerce, the circumstances of the article's manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice, and the article's strength and quality differed from U.S.P. standards, since the article was deficient in reserpine (approx. 14 percent); 501(a)(2)(B), 501(b). Default decree ordered destruction. **(86)**

Serax oxazepam capsules, at Secaucus, Dist. N.J.
Charged 5-23-66: when shipped by Wyeth Laboratories, Inc., Paoli, Pa., an advertisement for the article appearing in several medical journals lacked fair balance in its presentation and did not fairly show the effectiveness of the article in the conditions for which it was recommended; 502(n). Consent decree ordered donation to public/charitable institutions. **(87)**

Skin cream, at Richmond, E. Dist. Va.
Charged 11-1-66: when shipped by S. E. Massengill Co., Bristol, Tenn., the article, labeled in part "AK Cream Acne, Chapping, Psoriasis, Athlete's Foot, Insect bites . . . Urea Distributed by Donald G. Doeppe Co., . . . Kilmarnock, Va.," was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. **(88)**

Sodium dehydrocholate injection, at St. Louis, E. Dist. Mo.
Charged 1-9-67: when shipped by Maizel Labs., Inc., Chicago, Ill., the article labeled "Sodium Dehydrocholate . . . Distributed by Drake Laboratories, Inc., Chicago, Illinois" had been manufactured, processed, packed, and held under circumstances that lacked conformity with current good manufacturing practice; the labeling was false and misleading, since the article was deficient in the sodium dehydrocholate and was not in 5-cc. ampuls as represented, and the labeling lacked adequate directions and did not comply with the Rx drug exemption requirement for disclosure of information; 501(a)(2)(B), 502(a), 502(f)(1). Default decree ordered destruction. **(89)**

Thyroid powder, at Auburn, Dist. Miss.
Charged 12-1-66: while held for sale, the article's quality fell below U.S.P. standards, since the article contained **Salmonella** micro-organisms; 501(b). Default decree ordered destruction. **(90)**

DRUGS / Veterinary

Evergreen Egg Feed concentrate for laying hens, at Texarkana, W. Dist. Ark.
Charged 9-23-65: when shipped by Evergreen Mills, Ada, Okla., the article contained the food additive arsanilic acid, was intended for feeding to laying hens after diluting with grain, and its use was nonconforming since the label lacked adequate directions for use, and lacked a warning to withdraw from feeding 5 days before slaughtering; 402(a)(2)(C). Default decree ordered destruction. **(91)**

Piperazine wormer, at Des Moines, S. Dist. Iowa.
Charged 11-16-66: when shipped by Fleming Laboratories, Inc., Charlotte, N.C., the article labeled in part "Piperazine Wormer For Use in Drinking Water or Feed for . . . Poultry, Swine, Dogs, Cats and Horses . . . Manufactured by Cadco, Inc., . . . Des Moines" lacked the name and place of business of the manufacturer, packer, or distributor, since Cadco, Inc., was not the manufacturer; and the labeling lacked adequate directions for use in dogs, cats, and horses; 502(b)(1), 502(f)(1). Consent decree authorized release to Cadco, Inc., Des Moines, Iowa, for relabeling. **(92)**

Poultry drug for use in drinking water, at Bluffton, N. Dist. Ohio.
Charged 2-13-67: when shipped by Dr. Mayfield Labs., Charles City, Iowa, the article labeled in part "O.J. Mayfield, D.V.M. . . . Charles City, Iowa . . . for calming Flighty Laying Flocks" was a new drug without an effective approved New Drug Application for use in poultry drinking water; it contained reserpine, was a food additive, and its intended use was nonconforming; its label lacked an accurate statement of the quantity of the contents, and lacked the established name and quantity of each active ingredient since reserpine was not declared; 402(a)(2)(C), 502(e)(1)(A)(ii), 505(a). Default decree ordered destruction. **(93)**

MEDICAL DEVICES

Catheterization sets, at Highland Park, E. Dist. Mich.
Charged on or about 10-10-66: when shipped by Clinical Products, Inc., Pittsburgh, Pa., the article's quality was deficient, since the packages of the article contained holes and gaps, and the label statement "Sterile" was false and misleading; 501(c), 502(a). Default decree ordered destruction. **(94)**

Contour Control reducing device, at Jackson, S. Dist. Miss.
Charged 11-29-66: when shipped by Nameth & Hammond Enterprises, Dallas, Tex., and while held by Lou Fel Corp., t/a Poise 'N Ivy Shop, Jackson, Miss., the labeling contained false and misleading weight reduction and other therapeutic claims; 502(a). Default decree authorized delivery to FDA for exhibit and research purposes. **(95)**

Humidifier, portable, electric, at Buffalo, W. Dist. N.Y.
Charged 1-25-66: when shipped by Burgess Vibrocrafters, Inc., Grayslake, Ill., the labeling contained false and misleading cold, virus, and other therapeutic claims; 502(a). Consent decree authorized release to shipper for destruction of accompanying literature. **(96)**

Ionic Air Kleener, at Newark, Dist. N.J.
Charged 1-17-67: when shipped by Ionic Air Kleen, Inc., Montoursville, Pa., the labeling contained false and misleading asthma, hay fever, and other therapeutic claims; 502(a). Default decree authorized delivery to FDA. **(97)**

Kirby Sanitronic vacuum cleaner device, at Daly City, N. Dist. Calif.
Charged 6-8-65: when shipped by Scott & Fetzer Co., Cleveland, Ohio, the article's labeling contained false and misleading asthma and other therapeutic claims, and while held by Sanitronic Co., Daly City, Calif., the labeling lacked adequate directions for the treatment of tuberculosis and other diseases for which the article was orally represented by the dealer; 502(a), 502(f)(1). Consent decree authorized release to dealer for salvaging. **(98)**

Niagara heater/vibrator units, at Phoenix, Dist. Ariz.
Charged 4-15-66: while held for sale, the labeling lacked adequate directions for use for arthritis, ulcers, earache, broken bones, polio, face lifting, helping men keep their hair, and other such conditions for which the articles were offered by Mrs. Louise Snedden, sales representative for Niagara Therapy Manufacturing Co.; 502(f)(1). Consent decree authorized release to Aftab Ahmed, Phoenix, Ariz., for relabeling. **(99)**

Percuss-O-Whirl bath aerator, at Moline, S. Dist. Ill.
Charged 7-13-64: when shipped by Sholin Manufacturing Corp., Oconomowoc, Wis., and while held by Medox Equipment Co., Moline, Ill., the accompanying brochures of the shipper and leaflets of the dealer contained false and misleading claims for bursitis, injuries, circulatory disturbances, postpoliomyelitis spasm, and other medical conditions; 502(a). The article was claimed by the shipper and the charges contested. However, following claimant's failure to appear for a final pretrial conference and failure to comply with the court's orders, a default decree was entered ordering

destruction. (100)

Porta-Sauna steam bath cabinet, at St. Paul, Dist. Minn.
Charged 12-8-66: when shipped by Shepell, Inc., Grand Rapids, Mich., the article's labeling contained false and misleading weight reduction and therapeutic claims; 502(a). Default decree authorized delivery to FDA. (101)

Samson Formette belt massager and Proam bicycle exerciser, at New Orleans, E. Dist. La.
Charged 12-20-66: when shipped by Halton Industries, Inc., New York, N.Y., the labeling contained false and misleading weight reduction and other therapeutic claims, and the labeling lacked adequate warnings for swollen or inflamed areas or skin eruptions and calf pain; 502(a), 502(f)(2). Default decree ordered destruction. (102)

Sauna heater, Finn-Ette, at Madison, W. Dist. Wis.
Charged 12-20-66: when shipped by Heritage Sauna Co., Minneapolis, Minn., the article's accompanying promotional literature contained false and misleading claims for relaxing nerves and other therapeutic purposes; 502(a). Consent decree authorized release to Nord-Craft Specialties, Inc., Minneapolis, Minn., for relabeling. Upon default of such firm to repossess the article, an amended decree ordered the destruction of the article. (103)

Sauna heaters and control panels, TYLO, at San Francisco, N. Dist. Calif.
Charged 9-28-66: when shipped by SCAPRO (Scandinavian Produce Co. A.B.), Stockholm, Sweden, the labeling contained false and misleading therapeutic claims; 502(a). Consent decree authorized release to Nordic Sauna Co., San Francisco, Calif., and destruction of misbranding literature. (104)

Saunda facial sauna device, at Minneapolis, Dist. Minn.
Charged 1-10-67: when shipped by Health Products, Inc., Chicago, Ill., and while held by Northwestern Drug Co., Minneapolis, Minn., and its customer, the labeling contained false and misleading acne, sinus, and other therapeutic claims; 502(a). Consent decree authorized release to shipper for relabeling. (105)

Shape-Maker electronic stimulator device, at Kansas City, W. Dist. Mo.
Charged 9-27-66: while held by Shape Maker, Kansas City, Mo., the labeling lacked adequate directions for use for the purposes and conditions for which it was intended; 502(f)(1). Default decree ordered destruction. (106)

PROPHYLACTICS

Rubber prophylactics, at Chicago, N. Dist. Ill.
Charged 10-11-66: when shipped by National Hygienic Products Corp., Dothan, Ala., the quality of the article labeled in part "Prophylactics Derbies . . . Mfd. by National Hygienic Products Corp. . . . Distributed by Test Rite Products, Inc. Chicago" was deficient, and the labeling was false and misleading, since the article contained holes; 501(c), 502(a). Default decree ordered destruction. (107)

Rubber prophylactics, at Dallas, N. Dist. Tex.
Charged 10-19-66: when shipped by Allied Latex Sales Co., Inc., Div. of Akwell Industries, Dothan, Ala., the quality of the articles, labeled in part "Big Chief Lubricated Prophylactic Glenn Sales Co., Inc. . . . Dallas" and "Big Chief Translucent Prophylactics Manufactured for H. L. Blake Co., Inc. . . . Hot Springs, Arkansas," was deficient, since they contained holes; 501(c). Default decree ordered destruction. (108)

Rubber prophylactics, at San Francisco, N. Dist. Calif.
Charged 11-17-66: when shipped by National Hygienic Products Corp., Dothan, Ala., the quality of the article labeled in part "Romeos Mfg. by Aronab Products Company San Francisco" was deficient, since the article contained holes, and the label lacked the name and place of business of the manufacturer, packer, or distributor, since Aronab Products Co. was not the manufacturer; 501(c), 502(b)(1). Default decree ordered destruction. (109)

Rubber prophylactics, Bikinis, at Brooklyn, E. Dist. N.Y.
Charged 1-6-67: while held by S&S Distributing Co., Brooklyn, N.Y., after repacking, the article's quality was deficient, since the article contained holes; 501(c). Default decree ordered destruction. (110)

Rubber prophylactics, Gold Dollar and **Ritz,** at Kansas City, W. Dist. Mo.
Charged 1-6-67: when shipped by Allied Latex Sales Co., Inc., Dothan, Ala., and Morgantown, W. Va., the article's quality was deficient, and the labeling was false and misleading, since it contained holes; 501(c), 502(a). Default decree ordered destruction. (111)

Rubber prophylactics, Prime, at Akron, N. Dist. Ohio.
Charged 6-20-67: when shipped by Killashun Sales Div. of Akwell Industries, Inc., Dothan, Ala., the article's quality was deficient, and the labeling was false and misleading, since the article contained holes; 501(c), 502(a). Default decree ordered destruction. (112)

Rubber prophylactics, Spartans, at Chicago, N. Dist. Ill.
Charged 11-1-66: when shipped by M & M Rubber Co., Kansas City, Mo., the article's quality was deficient, and the labeling was false and misleading, since the article contained holes; 501(c), 502(a). Default decree ordered destruction. (113)

Rubber prophylactics, Viking, at Searcy, E. Dist. Ark.
Charged 7-11-67: when shipped by M & M Rubber Co., Kansas City, Mo., the article's quality was deficient, and the labeling was false and misleading, since the article contained holes; 501(c), 502(a). Default decree ordered destruction. (114)

NOTICES OF JUDGMENT on Criminal Cases

FOOD

Booth Fisheries Div., Consolidated Foods Corp., Brownsville, S. Dist. Tex.
Charged 9-1-67: when shipped, stuffed breaded shrimp contained insect filth and bacterial filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea; fine. (115)

Chico Farms, Inc., and **James M. Chikasawa,** president, Huntington Beach, S. Dist. Calif.
Charged 7-10-67: when shipped, White Chick fresh celery contained the pesticide chemicals parathion and methyl parathion in a quantity in excess of the tolerance; 402(a)(2)(B). Nolo contendere pleas; fines. (116)

Fairview Swiss Cheese Cooperative Association and **John Koller,** manager, Fredonia, W. Dist. Pa.
Charged 1-3-67: when shipped, swiss cheese had had the valuable constituent milk fat partly omitted, and it failed to conform to the standard of identity, since the article contained in its solids less than 43 percent milk fat; 402(b)(1), 403(g)(1). Nolo contendere plea by corporation; fine. Nolo contendere plea by individual; fine suspended and probation. (117)

Harry B. Kotzias, t/a Better Foods Wholesale Grocery Co., Kansas City, W. Dist. Mo.
Charged 3-14-67: macaroni was held in a building that was infested by insects and was contaminated with insect filth; 402(a)(3), 402(a)(4). Nolo contendere plea; fine. (118)

Olson Bros., Inc., La Habra, S. Dist. Calif.
Charged 5-18-67: when shipped, frozen eggs contained decomposed eggs; 402(a)(3). Guilty plea; fine. (119)

Original Crispy Pizza Crust Co., Jacksonville, M. Dist. Fla.
Charged 6-19-67: when shipped, pizza crusts, labeled in part "Baked by Original Pizza Crust Co. of Jacksonville, Inc. Division of Origena Pizza Crust Co., Inc. New York," contained rodent and insect filth and were prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Nolo contendere plea; fine. (120)

Rolling Mills, Inc., and **Richard C. Walden,** vice president, Indianapolis, S. Dist. Ind.
Charged 1-23-67: pinto beans and red beans were held in a building accessible to insects and rodents—402(a)(4); and dehydrated diced potatoes, soy flour, rice, and breader mix were held in a building accessible to insects and rodents and were contaminated with insect, rodent, and mammalian filth—402(a)(3), 402(a)(4). Nolo contendere plea by corporation; fine, plus costs. Nolo contendere plea by individual; fine suspended. (121)

Rose Frozen Shrimp, Inc., and **Joe Y. Nishimura,** vice president, Los Angeles, S. Dist. Calif.
Charged 5-4-67: when shipped, Qik Fry frozen breaded shrimp contained **E. coli** and coagulase positive staphylococci organisms and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). While held for sale, hake was packaged in the form of fish sticks and labeled "Rose . . . Fish Sticks . . . Ingredients: Cod" which label was false and misleading, since the article contained hake and not cod; 403(a). When shipped, Qik Fry frozen breaded shrimp failed to conform to the standard of identity, since the article tested less than 50 percent of shrimp material; 403(g). Nolo contendere pleas; fines. (122)

Supreme Dairy Products Co., t/a Aledo Cheese Co., and **Vern Luepke,** manager, Aledo, S. Dist. Ill.
Charged 7-5-67: when shipped, cheddar cheese contained insect filth and manure fragments; 402(a)(3). Guilty plea by corporation; fine. Guilty plea by individual; probation. (123)

Taormina Bros., a partnership, New Orleans, E. Dist. La.
Charged 3-20-67: when shipped, Little King macaroni shells and curls contained insects and insect parts and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea; fine. (124)

DRUGS

Edward Neal Bass, truck-stop operator, Chattahoochee, N. Dist. Fla.
Charged 9-10-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment and fine. (125)

Crookes-Barnes Laboratories, Inc., and **Arnold O. Jackson,** Quality Control Director, Wayne, Dist. N.J.
Charged 10-26-66: when shipped, Seconesin tablets did not contain the represented strength of secobarbital and mephenesin in each tablet, Sulfacidin ophthalmic solution lacked the represented stability to sustain neomycin sulfate until the given expiration date, and Iso-Sol dropperettes were deficient in tetracaine hydrochloride; and the conditions of such articles' manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice; 501(c), 501(a)(2)(B). Guilty plea by corporation; fine. Nolo contendere plea by individual; fine. (126)

Alan F. DeVore, D.O., and **Clarence A. Green, M.D.,** Elsa, S. Dist. Tex.
Charged 3-24-64 by the grand jury: conspiracy to ship, sell, and deliver with intent to defraud and mislead, a clear liquid drug identified as formic acid and performic acid, under the name Glyoxylide, whose labeling contained false and misleading claims for cancer, tuberculosis, and leprosy, and whose labeling lacked adequate directions for use and warnings against misuse, the common or usual name of the drug, the name and place of business of the manufacturer or distributor, and an accurate statement of quantity of contents; and conspiracy to sell and distribute a drug under the name of Glyoxylide which was falsely represented to be useful and helpful in treatment of cancer and other conditions; 502(a), 502(b), 502(e)(1), 502(f)(1) & (2), 18 U.S.C. 371. When shipped with intent to defraud and mislead, a clear liquid drug was accompanied by false and misleading labeling reading in part "Glyoxylide . . . is a medicinal 'catalyst' used as an adjunct in the therapy of cancer, tuberculosis, leprosy"; 502(a). Guilty plea by DeVore; fine and probation. Guilty plea by Green; imprisonment and probation. (127)

John S. Evans, Akron, N. Dist. Ohio.
Charged 3-15-67: methamphetamine hydrochloride tablets, phenobarbital tablets, and amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment. (128)

Richard C. Evans, Akron, N. Dist. Ohio.
Charged 3-15-67: amphetamine sulfate tablets and methamphetamine hydrochloride tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment. (129)

Kent F. Hager, Santa Monica, C. Dist. Calif.
Charged 11-23-66: LSD capsules were unlawfully sold and delivered and were unlawfully possessed; 301(q)(2), 301(q)(3). Guilty plea; probation. (130)

Oleum Products, Inc., and **Clyde E. Chatterton,** president, Chesapeake, S. Dist. Ohio.
Charged 6-9-67 by grand jury: Prohem rectal fluid, which was a new drug without an effective approved New Drug Application and whose labeling contained false and misleading rectal and prostate claims and lacked adequate warnings against unsafe use, was shipped to the holder of a guarantee; 502(a), 502(f)(2), 505. Guilty plea by corporation; fine. Guilty plea by individual; probation. (131)

Hugh Connie Phillips and **Jerry Dale Rogers,** service station employees, Texarkana, E. Dist. Tex.
Charged 9-8-66: amphetamine sulfate tablets, methamphetamine hydrochloride tablets, and phenobarbital tablets were dispensed without a prescription; 503(b)(1). Guilty pleas; imprisonments suspended, fines, and probations. (132)

Joseph Rabin, t/a Warrendale Pharmacy, Waltham, Dist. Mass.
Charged 5-15-67: penicillin tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment suspended, probation, and fine. (133)

Jacqueline J. Rich, hotel manager, St. Louis, E. Dist. Mo.
Charged 3-1-67: amphetamine sulfate tablets were unlawfully sold and delivered and were unlawfully possessed; 301(q)(2), 301(q)(3). Not guilty plea. After trial, guilty verdict; imprisonment. (134)

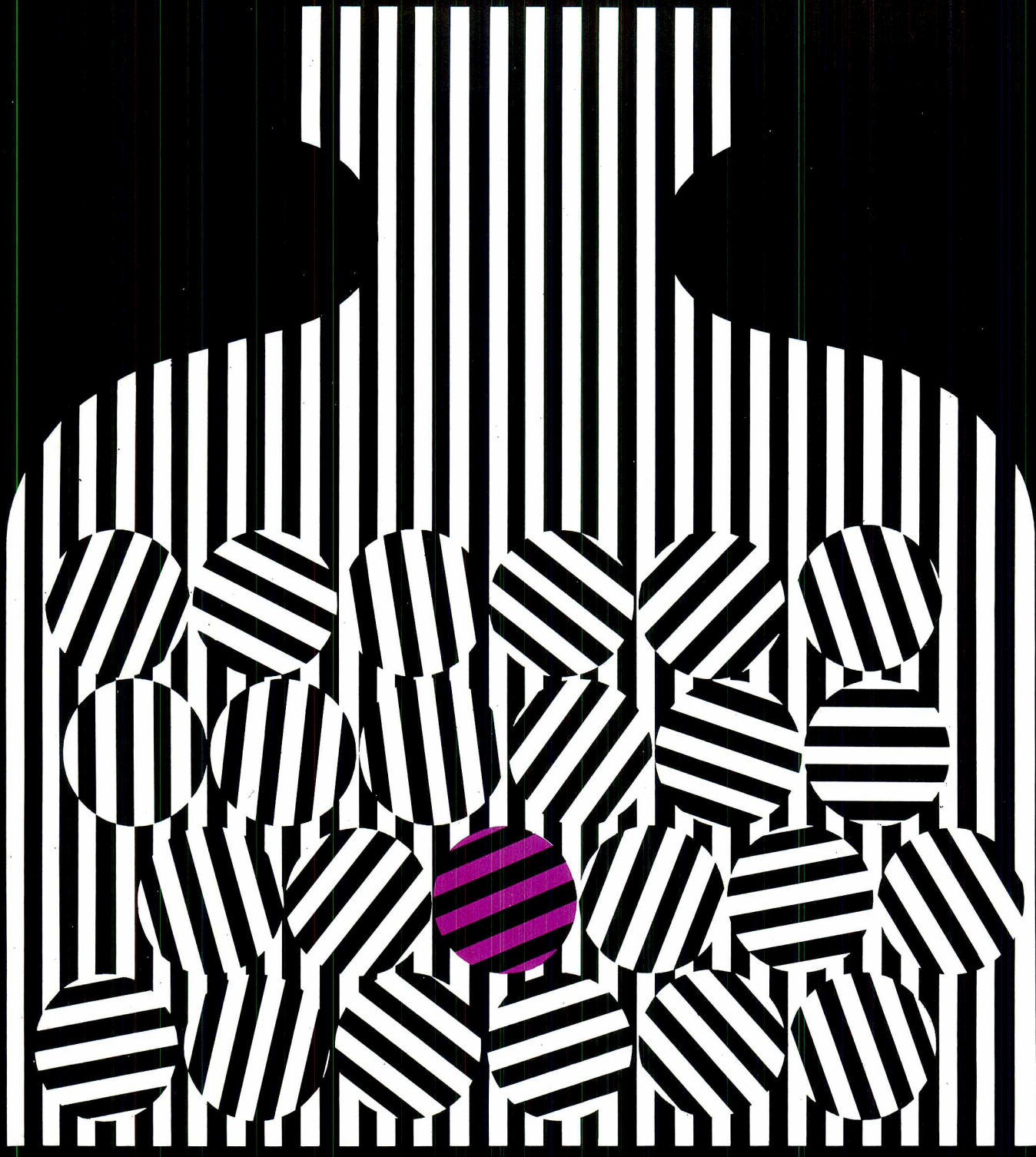
Francis Ray Robinson, truckdriver, Tulsa, N. Dist. Okla.
Charged 4-12-65 by grand jury: amobarbital sodium and secobarbital sodium capsules were dispensed without a prescription; 503(b)(1). After trial by jury, guilty verdict; imprisonment. Defendant then appealed, but the conviction was affirmed (366 F. 2d 575). (135)

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

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

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

James L. Goddard, *Commissioner of Food and Drugs*
Washington, D.C., April 1, 1968.



Good Drug Manufacturing Practices: No Margin for Error

TITLE: GOOD DRUG MANUFACTURING PRACTICES: NO MARGIN FOR ERROR
25 minute, 16 mm. color-sound film, 1968. For industry and professional use only. Not cleared for television.
PURPOSE: A motivational training film, designed to upgrade employee attitudes, and increase adherence to basic guidelines for error-free drug production.
CONTENT: A fictitious, life-sustaining drug is manufactured and released to meet an urgent deadline. Through the use of contemporary cinematography and a brief story line, GOOD DRUG MANUFACTURING PRACTICES: NO MARGIN FOR ERROR examines highlights of the production run under poor and good manufacturing practices.
AUDIENCE: Preview screenings indicate that this film is an important training tool for all drug industry personnel—from hourly employees to top management.

AVAILABILITY: FREE SHORT-TERM LOAN (up to two weeks) FROM: Bureau of Voluntary Compliance, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204 or your nearest FDA District Office.
PURCHASE INFORMATION FROM: Bureau of Voluntary Compliance, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204.
PRODUCED BY: Food and Drug Administration, U.S. Department of Health, Education, and Welfare

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Announcements

INDUSTRIAL MICROBIOLOGY SEMINAR A 3-day Government-industry seminar on the responsibilities of industrial microbiologists under Federal laws has been scheduled for May 27-29 by the Society for Industrial Microbiology, in cooperation with FDA and the U. S. Department of Agriculture. The seminar is part of the Society's series of educational "Summer Institutes." It will be held at the University of Maryland Adult Education Center, College Park, Md.

Titled "Federal Regulations and Practical Control Microbiology for Disinfectants, Drugs, and Cosmetics," the seminar will feature presentations by leading specialists from FDA, USDA, and industry. A representative of the Canadian Government also has been invited to discuss requirements of the Canadian laws.

Among the topics to be covered in formal presentations and roundtable discussions are:

Legal aspects of the Food, Drug, and Cosmetic and the Federal Insecticide, Fungicide, and Rodenticide Acts; petitions and registration procedures under the FDC Act; efficacy testing in support of applications for registration of sterilizing, disinfecting, and sanitizing chemicals; methods of industrial sterilizations; problems in sterility evaluation; common methods in sterility determinations; sterility testing environment, equipment, and facilities; quality control in the manufacture of sterile disposable devices; methods of evaluating efficacy of products sold as sterilizing agents; evaluation of sporicidal chemicals; evaluating hospital disinfectants; evaluation of germicidal and sanitizers for food contact surfaces in food processing plants, dairies, and eating and drinking establishments; problems in testing water-purifying chemicals and devices; quality control in cosmetic manufacture; and microbiology of cosmetics.

For further information, contact Morris R. Rogers, Applied Microbiology Group, Pioneering Research Laboratory, U. S. Army Natick Laboratories, Natick, Mass. 01760.

CANADIAN SYMPOSIUM SET The Food and Drug Directorate of the Department of National Health and Welfare will sponsor a Symposium on Current Views on Pesticides, in Ottawa, June 5-6.

For further information, contact H. B. Taylor, Symposium Secretary, Food and Drug Laboratories, Tunney's Pasture, Ottawa 3, Canada.

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

SCHEDULE OF FDA WORKSHOPS AND REGIONAL CONFERENCES MAY 1968

FDA District or BDAC Field Office	Date	Location	Subject Area
Baltimore	May 20	Richmond, Va.	GMP—Drugs
	May 22	Baltimore, Md.	GMP—Drugs
Kansas City	(April 30)	Pratt, Kans.	Medicated Feeds
	May 14	Omaha, Nebr.	Salmonella—Egg & Egg Products
Philadelphia	May 23	Philadelphia, Pa.	GMP—Drug Repackers, Relabelers & Distributors
San Francisco	May	San Francisco, Calif.	Medicated Feeds (Poultry
	May	San Francisco, Calif.	Medicated Feeds (Dairy)
FDA workshop in cooperation with Chemical Specialties Manufacturers Association & National Paint, Varnish & Lacquer Association	May 28	Washington, D.C. (Department of Commerce)	Hazardous Substances & Fair Packaging & Labeling

CONFERENCE, SEMINAR DATA AVAILABLE UPON REQUEST

Abstracts of presentations by Government and industry officials at the National Conference on Indirect Food Additives held in Washington, D.C., February 13-14 are available upon request without cost from: Bureau of Voluntary Compliance (VC-1), Food and Drug Administration, Washington, D.C. 20204. A complete transcript of the conference, including the discussion periods, can be purchased from: Ace-Federal Reporting, Inc., 415 Second Street, N.E., Washington, D.C. 20002, for $52.70, plus handling costs.

The Bureau of Voluntary Compliance also still has available for free distribution a limited number of copies of papers presented at the Seminar on Drug Stability as Affected by Environment and Containers, in Washington, D.C., November 6-7, 1967.