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
If 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.
"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."


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

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

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*The Food and Drug Administration is solely responsible for the contents of FDA PAPERS. The Advisors to the Editor are consultants on matters relating to the functions of the Federal Departments and Agencies listed.
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 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 Trienophorus 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.
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, unlike 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.

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 pharmacopoeias and pharmacopeia-like monographs should be reduced. Few countries have such resources of their own that they can ignore the pharmacopoeias 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-
macopoeias 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-Bettolo, 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-Bettolo 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-Bettolo 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-Bettolo 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 plagiarism." 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."

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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 Ap-

lications. 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.
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.
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.
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.
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.
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.
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.
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.
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

The Scientific World of Food and Drugs

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


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

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:

FDA
&
FAO
&
WHO
&
IUPAC

Food and Agriculture Organization

World Health Organization

International Union of Pure and Applied Chemistry
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. Di Lorenzo, 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 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.
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.

DETOIT 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, Ore. 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, Ore., has voluntarily destroyed 2,054 cartons of cookies, valued at $10,130. The District supervised the destruction.
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, patterned 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.

<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milo/Seattle, Wash. 1/9/68</td>
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<tr>
<td>Beans, Great Northern/Cairo, Ill. 1/10/68</td>
<td>Bartlett Grain Co./Sioux City, Iowa (S)</td>
<td>Contains silicon carbide (carborundum), which may render it injurious to health.</td>
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<tr>
<td>Beef Cheeks/Canton, Ohio 1/24/68</td>
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<tr>
<td>Chocolate Drink/Cincinnati, Ohio 1/30/68</td>
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<tr>
<td>Cocoa Powder U.S. and B &amp; L/Doraville, Ga. 1/22/68</td>
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<tr>
<td>Corn Husks/New Orleans, La. 1/5/68</td>
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<tr>
<td>Garlic/San Juan, P.R. 12/7/67</td>
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<tr>
<td>Dry Milk, spray process nonfat/Mendota, Ill. 1/4/68</td>
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<tr>
<td>Nuts, Cashew, shelled/Denver, Colo. 1/30/68</td>
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<tr>
<td>Paprika, Victory Brand and Odix Brand/New Orleans, La. 1/26/68</td>
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<tr>
<td>Pecan(s)/Odessa, Tex. 1/13/68</td>
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<tr>
<td>pieces/Philadelphia, Pa. 1/26/68</td>
<td></td>
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<tr>
<td>shelled/Birmingham, Ala. 1/16/68</td>
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<tr>
<td>Perch fillets/Rockland, Maine 11/28/67</td>
<td></td>
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<tr>
<td>Potatoes, French fried, frozen/Laramie, Wyo. 1/12/68</td>
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<tr>
<td>Rice, Patna and long grain, brown/Emeryville, Calif. 1/19/68</td>
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<tr>
<td>Texas, extra long/Los Angeles, Calif. 10/19/67</td>
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<tr>
<td>Shrimp/Brownsville, Tex. 1/2/68</td>
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<tr>
<td>canned, frozen/Covellis, Ore. 11/6/67</td>
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<tr>
<td>stuffed Jumbo/Cleveland, Ohio 11/1/68</td>
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<tr>
<td>Walnut(s), shelled/Seattle, Wash. 2/1/68</td>
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<tr>
<td>black kernels/ Omaha, Nebr. 1/10/68</td>
<td></td>
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<tr>
<td>shelled/Vancouver, Wash. 2/2/68</td>
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<tr>
<td>Wheat/Kansas City, Kans. 1/11/68</td>
<td></td>
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<tr>
<td>Banana Catsup and Rice Crackers/Los Angeles, Calif. 11/30/67</td>
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<tr>
<td>Hawaiian Ices/Jacksonville, Fla. 1/8/68</td>
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<td></td>
</tr>
<tr>
<td>Liquor Flavored Lollypops/New York, N.Y. 12/28/67</td>
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<tr>
<td>Margarine, corn oil/Woodville, Miss. 12/28/67</td>
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<tr>
<td>Economic Violations</td>
<td>Imported from Japan and the Philippines.</td>
<td>Label fails to bear quantity of content statement in English units, no artificial coloring statement.</td>
</tr>
<tr>
<td></td>
<td>Circus Ices, Inc./Anaheim, Calif. (M,S)</td>
<td>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. Articles are not flavored with liquor.</td>
</tr>
<tr>
<td></td>
<td>Four Star Candy Co., Inc./Newark, N.J. (M)</td>
<td>Vitamin D in part omitted.</td>
</tr>
<tr>
<td></td>
<td>Fort Worth Poultry &amp; Egg Co./Fort Worth, Tex. (S)</td>
<td></td>
</tr>
</tbody>
</table>
PRODUCT, PLACE & DATE SEIZED | MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D) | CHARGES
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Taco Sauce/Little Rock, Ark. 1/15/68 | Valley Canning Co./Anthony, Tex. (M,S) | Fail to conform to definition and standard for canned tomatoes; not sealed and processed as to prevent spoilage.

Tomatoes, Switzer Brand, crushed/E. St. Louis, Ill. 1/8/68 | Naas Foods, Inc./Portland, Ind. (M,S) | Below quality standard; not in conformity with good manufacturing practice regulations.

Acid Acetyl salicylic tablets/Auburn, N.Y. 1/12/68 | Jenkins Laboratories/Auburn, N.Y. (D) | Label fails to list active ingredients.

Bath Salt Novopin/Los Angeles, Calif. 11/30/67 | Imported from Japan. | False and misleading claims to promote treatment of poor tissue tone associated with weight loss, purpura, arthritis, spontaneous abortion.

Biaslav-C/Glendale, Calif. 1/4/68 | Lapar Co./Dallas, Tex. (M,S) | Label fails to indicate that article contains calomel and that calomel is a derivative or preparation of mercury.

C. C. Pills/Atlanta, Ga. 12/29/67 | R. G. Dunwody & Sons/Atlanta, Ga. (D) | False and misleading statements that Flavilhist 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. 2/13/68 | Richlyn Laboratories, Inc./Philadelphia, Pa. (M,S) | False and misleading claims for obesity; inadequate directions for use; dangerous to health when used in dosage, frequency, and duration recommended.

Digitalis Tablets and Powder/Dallas, Tex. 1/22 & 1/23/68 | Lapar Co./Dallas, Tex. (M) | No warning statement of possible damage to kidneys.

Femicin Tablets/Denver, Colo. 12/28/67 | Thayer Laboratories, Inc./Metuchen, N.J. (M,S) | False and misleading claims to be effective for athlete’s foot, dandruff, boils, sprains, burns, cuts.

G.S.I. Antiseptic/Minneapolis, Minn. 1/15/68 | G.S.I. Laboratory, Inc./Milwaukee, Wis. (M,S) | Not in conformity with USP standards: nonsterile.

Gauze Pads/New Haven, Conn. 1/24/68 | A. E. Halperin Co., Inc./Boston, Mass. (M,S) | False and misleading claims to be effective for colds, to gain weight, to increase stamina.

IC No. 39-Ionic Calcium/Oakland, Calif. 2/5/68 | Ionic Calcium Products Co./Eugene, Oreg. (M,S) | Not in conformity with regulations; contain iodine, an unsafe food additive; label fails to bear statement of special dietary properties.

Kelp Tablets/Cincinnati, Ohio 1/8/68 | Spatz Health Foods/Cincinnati, Ohio (D) | New drug not approved for safety and efficacy.

Kem Non Toxic Zero/Tucker, Ga. 2/2/68 | Hysan Products Co./Chicago, Ill. (M,S) | False and misleading claims for minor burns and scalds, chafing, superficial cuts.

Lanazol/Hewlett, N.Y. 1/5/68 | H. G. Knoll & Co., Inc./Hewlett, N.Y. (D) | Below standard quality and purity; nonsterile due to incomplete seals.


Solfoton Caps./Richmond, Va. 1/8/68 | Wm. P. Pohtress & Co., Inc./Richmond, Va. (M,D) and Mallinckrodt Chemical Works/Jersey City, N.J. (S) of raw material “Lactose” | New drug not approved for safety and efficacy.

Super Absorption (Peptonized Iron)/Oklahoma City, Okla. 12/8/67 | Anthony Products Co./El Monte, Calif. (M,S) | Inadequate directions for use; no “Caution” statement; dangerous to health when used in dosage, frequency, and duration prescribed.

Thyrodig Tablets/Denver, Colo. 1/5/68 | Western Research Laboratories, Inc./Denver, Colo. (D) | False and misleading claims for obesity; inadequate directions for use; dangerous to health when used in dosage, frequency, and duration prescribed.

Thyrodig Tablets/Denver, Colo. 1/5/68 | Leo Linden Labs./Culver City, Calif. (M) | Contain External D&C Orange No. 4, a decertified color.

Thyrodig Tablets/Denver, Colo. 1/5/68 | | 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.

Thyrodig Tablets/Denver, Colo. 1/5/68 | | False and misleading therapeutic claims.

Dr. Naylor’s Medicated T eat Dilators/Morris, N.Y. 1/29/68 | H. W. Naylor Co., Inc./Morris, N.Y. (D) | Veterinary / Medicated Feed

Weyso Animal Feed/Rochester, Ind. 11/30/67 | Tri Foods Co./Concordia, Mo. (M,S) |

Air-Way 88 Sanitizer/Minneapolis, Minn. 1/17/68 | Air-Way Sanitizer, Inc./Toledo, Ohio (M,S) | Medical Devices

Cristov Anti-Fatigue/Columbus, Ohio 1/31/68 | Electroten 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.
MEDICAL DEVICES (cont'd)

<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES &amp; DISPOSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic Exerciser/Tulsa, Okla. 1/24/68</td>
<td>Contrex of Tulsa/Tulsa, Okla. (D)</td>
<td>False and misleading claims to trim figure; inadequate directions for use.</td>
</tr>
<tr>
<td>Everslim Sleep-and-Slim Garment/New York, N.Y. 2/1/68</td>
<td>The Everslim Corp./New York, N.Y. (D)</td>
<td>False and misleading claims to induce weight loss while sleeping.</td>
</tr>
<tr>
<td>Exerciser U.S. Pat. No. 3,050,695/Sacramento, Calif. 1/29/68</td>
<td>International Contrex Corp./Dallas, Tex. (M,S)</td>
<td>False and misleading claims to significantly increase caloric expenditure, decrease size of hips, waist, tummy, and thighs.</td>
</tr>
<tr>
<td>Vibrating Device/Arlington, Tex. 11/29/67</td>
<td>Newbern Co./Arlington, Tex. (D)</td>
<td>False and misleading claims to relieve insomnia, fatigue, muscle soreness, make all tensions disappear.</td>
</tr>
</tbody>
</table>

Prophylactics

<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES &amp; DISPOSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prophylactics/Nashville, Tenn. 1/12/68</td>
<td>Killashun Sales Div. of Akwell Industries/Dothan, Ala. (S)</td>
<td>Defective, holes.</td>
</tr>
<tr>
<td>Sultan/Nashville, Tenn. 1/12/68</td>
<td>Killashun Sales Div. of Akwell Industries/Dothan, Ala. (S)</td>
<td></td>
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</tbody>
</table>

HAZARDOUS SUBSTANCES

<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES &amp; DISPOSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemicals and Leaflets/Cornwells Heights, Pa. 1/30/68</td>
<td>M &amp; B Laboratories/Cornwells Heights, Pa. (Repacker)</td>
<td></td>
</tr>
<tr>
<td>Columbia Duplicating Fluid/Seattle, Wash. 1/9/68</td>
<td>Columbia Ribbon &amp; Carbon Pacific, Inc./Portland, Oreg. (M,S)</td>
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</tr>
</tbody>
</table>

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.

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

POST OFFICE DEPARTMENT

Fraud Orders Issued by Judicial Officer Under 29 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 publicly 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.

FDA Papers / April 1698 / 39
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.
Porta-Sauna steam bath cabinet, at St. Paul Dist. Minn.

Charged 1-24-67: when shipped by Sherpi, Inc., Grand Rapids, Mich., the article's labeling contained false and misleading information regarding the weight and therapeutic claims; 502(a). Default decree authorized delivery to FDA. (101)

Samson Formette belt material and Prowm bicycle exerciser, at New Orleans, E. Dist. La.

Charged 12-22-66: when shipped by Halton Industries, Inc., New York, N.Y., the labeling contained false and misleading information regarding the therapeutic claims, and the labeling lacked adequate warnings for allergic individuals; 402(a)(2)(B), 402(a)(4). Nolo contendere plea by corporation; fine. (100)

Sauna heaters and controls, Tylco, at San Francisco, N. Dist. Calif.

Charged 9-26-66: when shipped by SCAPO (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 misleading material. (104)

Rubber prophylactics, at Chicago, N. Dist. Ill.

Charged 10-11-66: when shipped by National Hygienic Products Corp., Dothan, Ala., the labeling lacked adequate directions for use for the purposes and conditions for which it was intended; 501(f)(1). Default decree ordered destruction. (106)

Prophylactics, at Dallas, N. Dist. Tex.

Charged 11-18-67: when shipped by National Hygienic Products Corp., Dothan, Ala., the labeling lacked adequate directions for use for the purposes and conditions for which it was intended; 501(f)(1). Default decree ordered destruction. (107)

Rubber prophylactics, at Dallas, N. Dist. Tex.

Charged 9-28-66: when shipped by National Hygienic Products Corp., Dothan, Ala., the labeling lacked adequate directions for use and was false and misleading, since the article contained false and misleading claims; 501(c), 502(a). Default decree ordered destruction. (108)

Rubber prophylactics, at Chicago, N. Dist. Ill.

Charged 3-14-67: when shipped by Smith & Sargent Co., Brooklyn, N.Y., the labeling containing false and misleading therapeutic claims; 502(a). Consent decree authorized release to Smith & Sargent Co., Brooklyn, N.Y. (109)

Shake-Maker electronic stimulator device, at Kansas City, W. Dist. Mo.

Charged 9-27-66: while held by Shake-Maker, Kansas City, Mo., the labeling lacked adequate directions for use for the purposes and conditions for which it was intended; 501(f)(1). Default decree ordered destruction. (106)

NOTICES OF JUDGMENT on Criminal Cases


Charged 9-18-67: when shipped by Allied Latex Sales Co., Inc., Div. of Akwell Industries, Dothan, Ala., 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. (110)

Rubber prophylactics, Prime, at Akron, N. Dist. Ohio.

Charged 6-20-67: when shipped by Kilushan Sales Div. of Akwell Industries, Dothan, Ala., 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. (112)

Rubber prophylactics, Spartans, at Chicago, N. Dist. Ill.

Charged 11-18-67: 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. (113)

Rubber prophylactics, at Seattle, E. Dist. Wash.

Charged 7-17-67: 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)

Notice of Judgment issued by direction of the Secretary of Health, Education, and Welfare.

James L. Goddard, Commissioner of Food and Drugs

44 / April 1968 / FDA Papers
Good Drug Manufacturing Practices: No Margin for Error

**Title:** Good Drug Manufacturing Practices: No Margin For Error

**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.
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

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