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FDA PAPERS

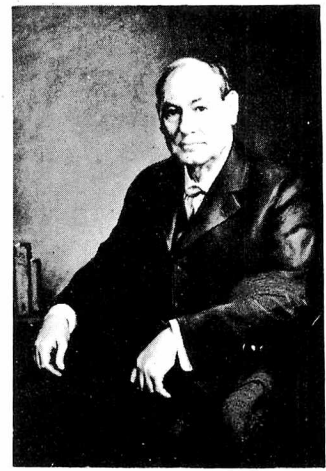
**TOXIC METALS
IN EARTHENWARE**

**FDA-FTC Liaison:
Teamwork That Pays Off**

SAN JUAN SECTION

**DRUG INFORMATION
FOR PHYSICIANS**





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

Harvey W. Wiley, 1844-1930

Father of the Federal Food and Drugs Act of 1906

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

The task of protecting the consumer on all fronts is so complex and formidable that no single government entity could hope to marshal and exercise the expertise needed to provide absolute protection everywhere that it may be needed. Thus, Congress has created a number of agencies, each with its own administrators and the appropriate kinds of experts needed to oversee major areas of responsibility. Over the years, amendments or other supporting legislation have refined each agency's responsibilities in the light of hindsight, experience, new philosophies, and new developments. In theory this forms a wall of protection for the consumer in all areas.

Since these agencies are somewhat different from each other in nature and purpose, their statutory responsibilities may sometimes either overlap slightly or there may be little gray areas in between that, if no one is watching, can amount to a sort of no-man's land of responsibility. Occasionally the difficulty of interpreting the laws involved has resulted in two agencies leaning over backward to avoid stepping on each other's toes. When this happens, the consumer sometimes suffers.

Some of these problems, not all, can be solved by legislation, but that takes time. The simplest, most sensible, and most timely way of protecting the consumer's interest is for officials of the two agencies to get together at a policy-determining level and decide who should do what, and just how one's action will support the other in terms of the desired end.

The Food and Drug Administration and the Federal Trade Commission are doing just that on a number of mutual concerns (see page 4) and are ready to deal with others as they crop up. This adds up to a stronger wall for the consumer and fewer abuses that slip through the cracks.

quotes

"In the near future, FDA will publish the first set of guidelines dealing with formulated main dishes such as frozen dinners, totally canned dinners, etc. In addition, we are attempting to make a more conscious effort to introduce nutritional quality in the setting of food standards. Another initiative of vital concern on the consumer input side is our present effort on nutrient labeling. We are attempting to experiment to find ways of identifying calories, carbohydrates, proteins, fats, type of fat, and vitamins and minerals on the label in a system which won't be so complex that it will not be used, but will not be so simplified that labeling information would be meaningless."

James D. Grant, deputy commissioner of food and drugs, to the Association of Margarine Manufacturers, Maui Island, Hawaii, March 5, 1971.

"Despite the judgment of disinterested and expert committees of professionals—judgments soundly based and documented—industry has challenged the requirement that all drug claims be supported by data derived from adequate and well-controlled clinical investigations. The challenge has been taken to the courts, in pressures for re-review, and in some instances has been in the form of highly charged emotional attack. This requirement means that drugs may not be kept on the market on the basis of proof of marketing success and acceptance of the drug by prescribers, which some manufacturers wanted. It is essential that we have in this country but one class of drugs; established drugs, which meet the same standard as entirely new products."

John J. Jennings, M.D., associate commissioner for medical affairs, FDA, to Chicago Drug and Chemical Association, Chicago, Illinois, February 25, 1971.

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

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

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

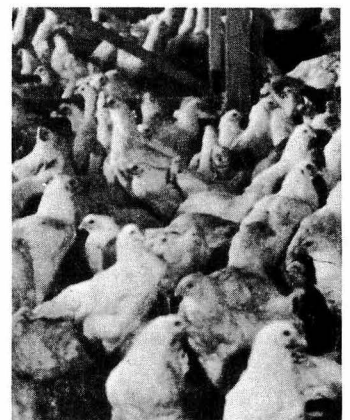
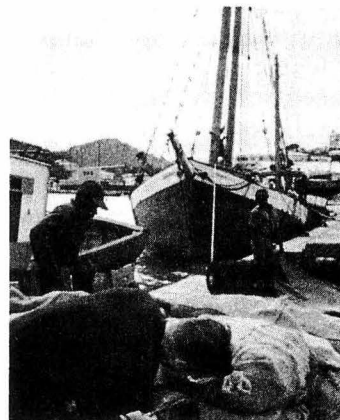
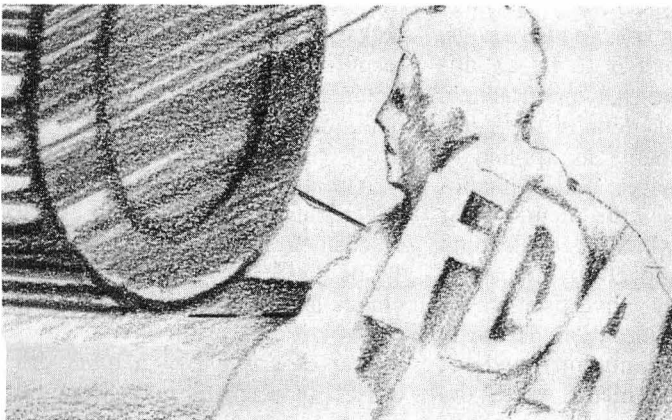
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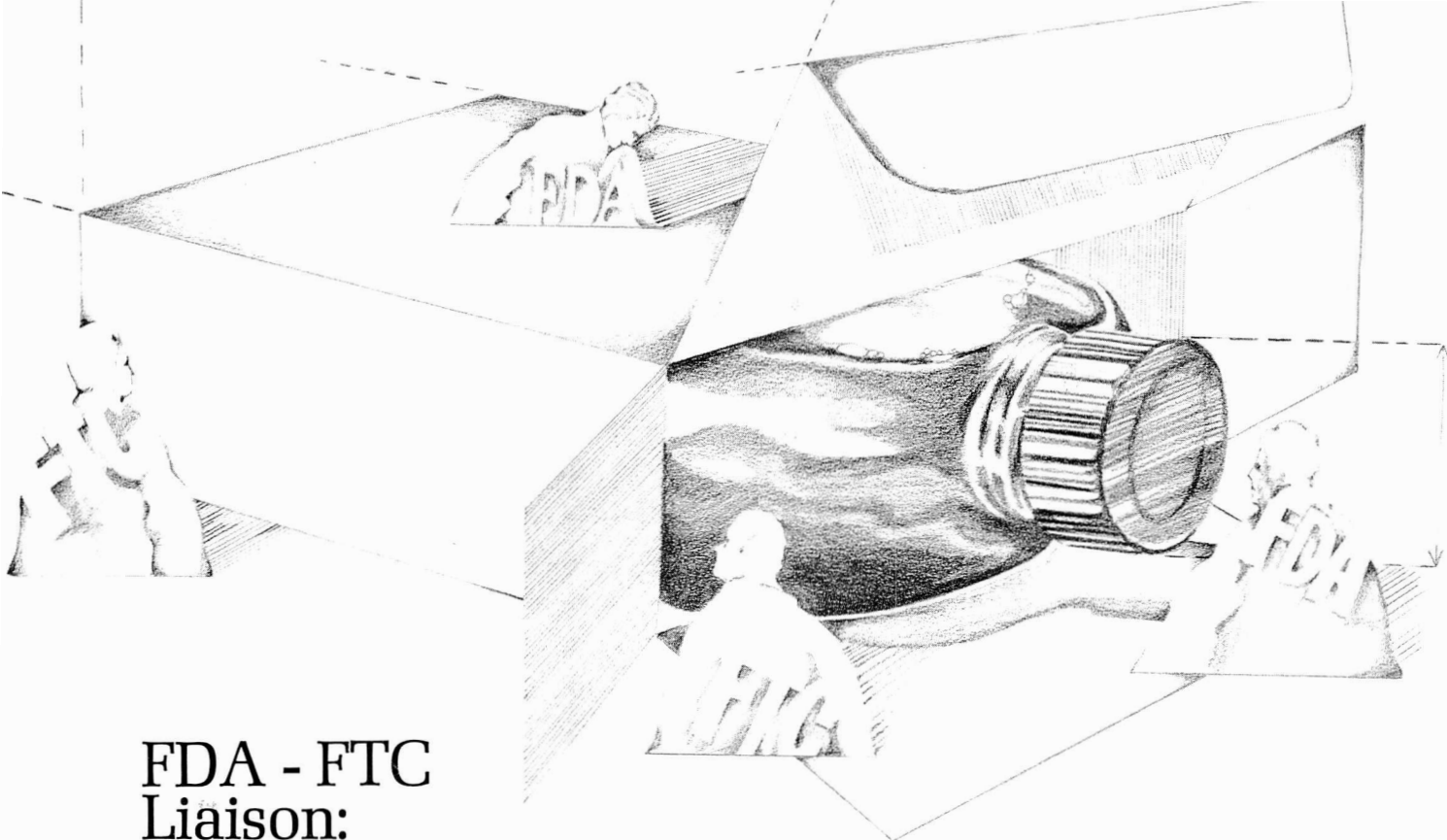
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FDA - FTC Liaison: Teamwork That Pays Off

by R. Joel Slomoff
and Robert E. Freer, Jr.

The Federal Food, Drug, and Cosmetic Act makes illegal any food, drug, device, or cosmetic product that is adulterated or misbranded when introduced into or while in interstate commerce or when held for sale after shipment in interstate commerce. When the surveillance and investigative work of the Food and Drug Administration discloses a serious violation, the facts are reported to the Department of Justice with a recommendation for seizure, criminal prosecution, or injunction actions in the Federal courts. Under the statute each of the four commodities covered is deemed to be misbranded "if its labeling is false or misleading in any particular."

In addition to this general misbranding provision, the FDC Act defines a number of other circumstances under which a food, drug, device, or cosmetic shall be deemed to be misbranded—some of these definitions of misbranding applying specifically to foods, drugs, devices,

or cosmetics as the case may be. Among the definitions of misbranding specific to drugs or devices is failure of the labeling to bear (1) adequate directions for use, (2) adequate warnings against use in certain pathological conditions or by children where use may be dangerous to health, and (3) adequate warnings against unsafe dosage or methods or duration of administration or application to the extent necessary for the protection of users.

The Federal Trade Commission enforces the Federal Trade Commission Act, which prohibits unfair competition and unfair or deceptive acts and practices in commerce. The Wheeler-Lea Amendment to the FTC Act specifically declares false advertising of foods, drugs, devices, or cosmetics to be an unfair or deceptive act or practice. This amendment defines the term "false advertisement" as applied to foods, drugs, devices, and cosmetics to mean an advertisement, other than labeling, which is misleading in a material respect. In determining whether any advertisement is misleading, consideration is given not only to representations made or suggested by statement, word, de-

sign, device, sound, or any combination of these, but also to the extent the advertisement fails to reveal material facts, or consequences that may result from the use of the commodity.

Preventing deception of the public in the marketplace by misrepresentations of foods, drugs, devices, or cosmetics is the common objective of both agencies. The Food and Drug Administration strives to prevent misrepresentations that may occur as a result of false or misleading statements made in *labeling* or by the omission of certain information required in the labeling. Other than prescription drugs, which are entirely the province of the Food and Drug Administration, the Federal Trade Commission seeks to prevent misrepresentation resulting from false or misleading statements in *advertisements* or the omission of certain necessary statements from advertising.

Although the definition of false advertising of a food, drug, device, or cosmetic, as contained in Section 15 of the FTC Act, specifically excludes labeling, it is well established that written, printed, or graphic matter descriptive of a food, drug, device, or cosmetic may at one time

be used as advertising, and at another time may accompany the article and thereby become labeling. Concurrent jurisdiction by both agencies is not uncommon.

The FDC Act's requirement that drugs or devices bear adequate directions for use has been judicially interpreted as including directions for the use of the drug or device for those purposes for which it is prescribed, recommended, or suggested in advertising.

Although the responsibilities of the two agencies thus are closely related in many respects, significant differences in procedure and in the nature and effect of sanctions are inherent in the statutes and regulations governing the two agencies. The close relationship of the objectives of the two agencies as outlined in the foregoing, however, is now recognized as requiring a more effective liaison to eliminate any duplication of effort.

To provide for the exchange of complete information so that both agencies can most effectively serve the public interest, each agency has designated a liaison officer responsible directly to the chief operating official of his own agency to serve as a primary source of contact with the other agency. Since 1954 the existence of these liaison officers has been a point of formal agreement between the two agencies. But it was not until recently that full value has been realized from the liaison agreement.

Although in prior years the liaison meetings had been taking place on a frequent basis, they had not been at the high level anticipated by the original agreement. In the 1970's, through direct contact between former FTC Chairman Caspar W. Weinberger and his successor Chairman Miles W. Kirkpatrick with Commissioner of Food and Drugs Charles C. Edwards, M.D., the full intent of the liaison agreement has been achieved. Representing the Food and Drug Administration is Sam D. Fine, associate commissioner for compliance, and his special assistant. To represent the Federal Trade Commission,

Chairman Kirkpatrick has designated the Commission's liaison officer, who is also assistant to the general counsel. The three meet formally at least once a month, in turn at the Food and Drug Administration or the Federal Trade Commission. To fully inform each other on matters of current interest, they invite the appropriate senior officials of the two agencies, insuring that discussions will take place at a policy-determining level.

During the year that the liaison arrangement between the Federal Trade Commission and the Food and Drug Administration has been conducted in this fashion, marked progress in the coordination of joint activity has been noted within government and by key officials in the private sector. Among the subjects of greatest current interest to both agencies have been enzyme detergents with their appurtenant safety and efficacy issues, the current controversy over mouthwash efficacy, polyunsaturated fat labeling, toy safety, nutritional labeling, cents-off regulations, and the advertising of drugs which were reviewed for efficacy by the National Academy of Sciences/National Research Council.

Possibly the most outstanding example of interagency cooperation during the past year has been the joint effort in the enzyme safety area. A series of meetings between the agencies and on occasion with industry and representatives of the Soap and Detergent Association has not only utilized the medical knowledge of the Food and Drug Administration and the advertising regulatory and market expertise of the

Federal Trade Commission, but also has fostered a better understanding of the issues by industry. In the employment of new methods to serve the public interest, this stands out as an example of agency innovation through the liaison procedure.

The cooperation that has existed between the agencies on the question of enzyme safety has been exhibited as well in the other, previously mentioned areas. Interagency briefing sessions at the highest levels have assured consistency in regulating affairs and in formulating constructive responses by informed Federal officials.

Commissioner Edwards, making known his support of the FDA-FTC Liaison arrangement, said recently:

"Meeting the consumer protection issues which face this agency is truly a management challenge. I strongly believe that sound communication through our liaison agreement with other government agencies contributes not only to our effectiveness but enhances the scientific and regulatory capabilities of our system. The FDA-FTC Liaison is providing this communication."

FTC Chairman Kirkpatrick, in commenting on the new liaison procedures, has commended the good working arrangement that now prevails, and has said that he personally has found the briefing conferences and his meetings with Dr. Edwards to be most fruitful. Both Dr. Edwards and Chairman Kirkpatrick concluded their comments by expressing hope that the current profitable relations between these two agencies may serve as a model for liaison of a similar nature between other Federal agencies.



R. Joel Slomoff, special assistant to the associate commissioner for compliance, joined FDA in February 1970.



Robert E. Freer, Jr., assistant to the general counsel and liaison officer, FTC, joined that agency in June 1966.

Region IV Food Microbiology Seminars

Back in 1967 a problem situation had arisen in FDA's Atlanta District concerning consumer protection from microbiological contamination of food in the District's geographical area of four States. The various Federal, State, and local laboratories responsible for microbiological assay of foods for law enforcement and improved sanitation were operating largely independently of each other from State to State and city to city.

The Atlanta District director, Leslie O. McMillin, now regional food and drug director, Region IV, Atlanta, believed there was a need for increased communication among the official laboratories in the District that were responsible for microbiological examination of foods. He began work to meet this problem by planning a regional seminar for representatives of administrative, inspectional, and laboratory people in the departments of health and agriculture of Florida, Georgia, South Carolina, and North Carolina, the States then comprising the Atlanta District, and representatives of the Department of the Interior, the Public Health Service's National Communicable Disease Center in Atlanta, and FDA's Atlanta District, as well as specialists from FDA headquarters in Washington.

At the time there were specialized laboratory standardization programs in the Atlanta District for the Grade A milk and potable water programs and in examination of shellfish growing waters and market oysters and clams, but no similar program or standardized examinations for other foods.

Official microbiological examination of foods is conducted primarily as scientific support in regulatory efforts to assure that proper sanitary and protective procedures for the production, treatment, and handling of foods are being followed. Naturally occurring viable but harmless micro-organisms in food must be adequately separated from harmful organisms for significant detection and assessment of the latter.

The number of organisms, particularly toxin-producing organisms, may have a significant interpretation, but it's sometimes difficult to determine the number of organisms that have been present in the food sample because they may go through a growth cycle and produce their toxins, then die off and not be detected in the food when it is examined.

The microbiological laboratory is expected to report the condition of food in the marketplace, but unless a sample is carefully handled, obtaining and transmitting it to the laboratory may invalidate it.

Foods sometimes may have growths of several types of bacteria, some relatively innocuous, and the presence of these may obscure the presence of other micro-organisms of greater significance. Often there are a variety of microbiological examinations available and thus different laboratories may make findings that are not comparable.

All of these problems may make practical regulatory

application more difficult. The lack of uniform laboratory procedures between laboratories and the resulting variations in findings obviously raise questions concerning the competence of one or more of the laboratories involved.

It was these kinds of difficulties that Atlanta District believed could be overcome by the seminars, where information of mutual benefit could be exchanged and working level procedures compared.

The Atlanta District office was host to the first meeting, in November 1968. Among the topics treated were administrative and enforcement problems; coordination between State, local, and Federal activities; the relationship of inspectional findings to laboratory results; and methodology involving such organisms as *Salmonella*, staphylococci, clostridia, and *Shigella*, with laboratory demonstrations and roundtable discussions. Those attending were so impressed with accomplishments that they proposed annual seminars in the future.

The State of South Carolina was the host for the 1969 seminar, in October at Columbia, where the Board of Health laboratories were made available for demonstrations. The areas of chief interest included examination of meat and marine products and other microbiological problems of food handling establishments, virological examinations, and enforcement problems at the State and local levels.

The Florida Division of Health laboratories at Jacksonville was the site for the third seminar, in November 1970. The sessions covered new advances in methodology, such as fluorescent antibody techniques and enrichment serology procedures. Other subjects included legal and regulatory problems, establishment of suitable guidelines on the significance of bacteriological findings in food, laboratory personnel problems, and proposed improvements in standardization of procedures.

Since the first seminar, the Atlanta District and FDA's Region IV have been expanded to include the eight southeastern States, adding Kentucky, Tennessee, Alabama, and Mississippi. Participation has increased to include representatives from agencies of all these States as well as other Federal installations in the expanded area and from some universities. A committee is now being formed to make the annual meetings permanent and possibly to form a functioning organization.

The exchange of information and ideas at the seminars has served to improve the capabilities of all the participants, and the personal interrelationships developed have facilitated the prompt exchange of relevant information and handling of mutual problems as they arise. Although the coordination among laboratories has improved significantly, there is much to be done. We believe these seminars will contribute much to the improvement of sanitary conditions of food service in restaurants and institutions and in food production and processing.

Providing Drug Information to Physicians

by Edwin M. Ortiz, M.D.

Communicating up-to-date drug information promptly and accurately to physicians and other health professionals is a major function of the Food and Drug Administration's Bureau of Drugs.

This responsibility has assumed added importance in recent years in the light of increasing professional and public interest in drug use. Moreover, it provides a single, authoritative source of information from the agency charged by law with the duty of reviewing the safety and effectiveness of the Nation's drug supply.

The problems facing the physician both in training and in practice are staggering. First of all, he must become familiar with a multitude of drugs to be used for several indications as drugs of first and second choice. Later in his career he will find himself changing his prescribing patterns because more effective medications or medications with fewer adverse reactions have become available to him.

As our population becomes exposed to more concomitant medications, the problem of drug interaction becomes more serious. Many times the physician must decide whether an abnormal laboratory result stems from the effect of a medication on a certain organ or is caused by alteration in the laboratory test without impairment of organ function.

First, I would like to discuss labeling, since this is the most commonly used mechanism by the FDA to transmit information to the physician. Then I shall briefly discuss other available methods to inform the physician, and certain special problems in the area of communications.

The basic purpose of prescription drug labeling is to provide the physician with adequate information for safe and effective use of a particular drug. The package insert, the prime example of labeling, is the document that is in most prescription drug packages, including trade containers and special purpose packages such as those used for promotional mailing. The package insert includes required information such as indications, warnings, and other information relating to the drug's safety and efficacy. It usually contains other material relating to the basic pharmacology in the mode of action and the conditions for which the drug is indicated.

The package insert is not intended to instruct the physician in diagnosing diseases or in recognizing pathological conditions, nor is it intended to replace the physician's basic medical education in pharmacology or drug therapy. In this limited sense, the package insert represents the best source of established information available to the practicing physician regarding the conditions of use under which a drug is considered safe and effective. The conditions of use listed in the package

insert are those for which the manufacturer of the drug has submitted data that satisfies the criteria expressed in the Federal Food, Drug, and Cosmetic Act.

Although the package insert is the prime example of Rx labeling, this term, as defined by the Federal Food, Drug, and Cosmetic Act, includes all written, printed, or graphic material that accompanies the drug while it is in interstate commerce. Brochures, mailing pieces, catalogs, and similar material distributed by or on behalf of drug manufacturers that contain drug information are considered as promotional labeling. The material contained in the approved package insert serves as a basis for and sets the limits of this promotional labeling as well as journal advertising.

The package insert originates as a part of the manufacturer's original New Drug Application (NDA). A draft of the insert based on data from animal testing and premarketing clinical trials is submitted with the NDA. The package insert, as finally approved, represents a distillation of the data establishing the drug's safety and efficacy.

For an indication to be listed in the package insert, it must be proved that the drug is safe and effective for this purpose. The proof must be in the form of adequate, well-controlled studies conducted by investigators who have the training and experience to enable them to interpret such studies. This information is usually submitted to the FDA in a form similar to that of a medical journal article. The investigator outlines his objectives, selection of patients, safety, and efficacy criteria, and the various parameters to be measured. Unlike a journal article, however, the submission to the FDA also contains the patients' work sheets. From these it is possible to reconstruct a study and to draw an independent and perhaps different interpretation. As a rule, studies by more than one well-qualified investigator are required to substantiate the efficacy of a drug for a particular indication.

Adverse effects believed to be caused by the drug must be reported to the FDA and to other investigators working with the drug during the premarketing testing. This information is included in the package insert under such headings as "Contraindications," "Warnings," "Precautions," and "Adverse Reactions."

Pregnancy Statement. Because new therapeutic entities are rarely tested on large numbers of pregnant women, it is difficult to establish unequivocally the safety of the drug for use during pregnancy. To gather as much information as possible and to provide maximum safety, the FDA has established guidelines for animal reproduction studies. Divided into three segments, the guidelines provide for a general study of

fertility and reproductive performance, teratologic and embryopathic potential, and prenatal and postnatal effects. Data derived from these studies is considered in labeling, although it is recognized that animal experience cannot be used with certainty to predict human safety.

If the animal data contains nothing significantly unfavorable, the package insert will usually bear a statement that the safety of the drug in pregnancy has not been established and its use in pregnancy is not recommended. The manufacturer is given the opportunity to cite acceptable animal data containing no adverse information. He may also include any information obtained, during premarketing trials, on use of the drug in pregnant women.

If the animal data contains unfavorable results and there is no human experience to contradict this, or if there is insufficient information on human use to make a safety determination, the drug is usually labeled as contraindicated in pregnancy.

Pediatric Dose. Another area that receives close attention is the pediatric dosage schedule. Such a schedule is not permitted under the package insert "Dosage and Administration" heading unless enough data has been presented to show that the schedule would provide for safe and effective use of the drug in the various age ranges listed.

When there is evidence that a drug might cause severe adverse effects in children, it is usually contraindicated in the pediatric age group. Prescription drugs now carry a package insert statement that the drug is not recommended for use in children unless adequate studies have been submitted to support such use.

The recommended format for labeling was published in the *Federal Register* on February 6, 1970. It should ordinarily contain information in substantially the format and order and with the section headings as follows:

- Description
- Actions
- Indications
- Contraindications
- Warnings
- Precautions
- Adverse reactions
- Dosage and administration
- Overdosage (where applicable)
- How supplied

Inclusion of the sections on Animal Pharmacology and Toxicology, Clinical Studies, and References are optional and are not required. These sections are more desirable in labeling brand-new drug entities than in labeling older drugs for which information can be found in standard textbooks.

The FDA concern with the package insert does not end with its approval of the NDA. Each time a manufacturer makes a major change in the production of a drug or a change in the mode of the drug's presentation to the medical community, he must submit a *supple-*

mental application to the original NDA. For example, after FDA's approval, a manufacturer often continues investigational research for indications other than those approved in the package insert. When the manufacturer feels he has sufficient data to support *new* claims, he submits it as a Supplemental New Drug Application. This material is subjected to the same scrutiny as the original NDA, and requires "adequate, well-controlled studies" for approval of efficacy. If the data meets FDA criteria, the supplemental application is approved, then the package insert is revised.

The FDA may also require labeling changes based on adverse information received about a new drug. These changes may add contraindications, warnings, precautions, or adverse reactions to the package insert, or may restrict the drug's use.

When a drug is first marketed, it is often accompanied by a promotional campaign that results in its widespread use by the medical community. This may uncover adverse effects that were not discovered in the premarketing clinical trials because of the relatively narrow range of patients tested. A serious adverse reaction that occurred in one patient in 1,000 might not be detected in premarketing trials unless there were perhaps 10,000 patients tested. In addition, patients in adequate, well-controlled clinical trials are carefully selected and usually receive only the drug being tested. After marketing begins the patients may not be as carefully screened, or they may be treated with several additional drugs at the same time which could result in drug interreactions.

Package insert changes that include new indications, new dosage forms, or other modifications intended mainly to improve the drug's marketing are generally brought to the attention of the practicing physician by the firm's promotional efforts. However, when more serious changes are made in the warning or adverse reaction sections of the package insert, such as the possibility of aplastic anemia or thromboembolism, FDA usually requests the company to bring this information directly to the attention of physicians by a letter sent first-class mail in a distinctly marked envelope. These have become known as "Dear Doctor" letters.

The FDA realizes that the package insert may not be the best possible method for reaching the physician with information on a drug's safety and effectiveness. The latest approved package insert is not always readily available to the physician. Also, some inserts contain information that, while factual, is purely promotional.

The future of the package insert is a subject of serious discussion throughout the medical community. Within the FDA we believe the basic purposes of the package insert might be divided into three categories: (1) Adequate information to the physician for safe and effective use of the drug, (2) Education of the physician regarding a specific drug, and (3) Factual basis and limitations for promotion of the drug to the medical profession.



Edwin M. Ortiz, M.D., director, Division of Metabolic and Endocrine Drug Products, Office of Scientific Evaluation, Bureau of Drugs, joined FDA in August 1963.

I would like also to mention briefly other communications. The first is direct mailing to physicians, either by a Drug Information Bulletin issued by the FDA or by a "Dear Doctor" letter issued by the firms. The FDA Bulletin is a single sheet of paper containing pertinent recently available drug information of interest to the physician. It has a simple format that makes it technically easy to assemble and mail. Drug Information Bulletins have been issued recently on oral contraceptives, lithium carbonate, levodopa, and oral hypoglycemic agents. These Bulletins may be issued monthly or every two months in the near future to keep a constant flow of information going to physicians. Currently the FDA is exploring ways of evaluating the impact of such bulletins on the practicing physician. We also are meeting with medical society representatives in various sections of the country to obtain the benefit of their opinions and suggestions on medical communications.

The second method consists of articles in the medical literature or in semimedical publications. It is common knowledge that there is a considerable time lag between submission of an article to a reputable medical journal and its publication. Therefore, drug information may reach the physicians sooner through other types of publications, such as the *American Medical News*. Unfortunately, some articles published in the medical literature lack adequate scientific validity. It would even be hard for the physician reading such an article to determine whether it is scientifically valid without having available to him the raw data on which the tabulations and conclusions are based.

Advertising and promotional labeling constitutes a major source of information for many physicians. As noted in the foregoing, the drug manufacturers usually relay information about new drug entities and about new indications for previously marketed drugs promptly to the practicing physicians, once they are approved by the FDA. Since the advertisement and the promotional labeling are based on the approved labeling for the drug, it is essential that the approved labeling be updated frequently and that it include all the necessary precautionary information. The *Physician's Desk Reference* (PDR), widely used by many physicians, constitutes promotional labeling.

Many physicians obtain drug information, especially that related to new indications and new drug entities, from the company representative, or detail man. I am

not aware that the detail man has been used effectively to transmit information on adverse reactions or precautionary information on drugs. The detail man, incidentally, could constitute an excellent source of information on adverse reactions to drugs, if manufacturers would take the initiative in this area.

Finally, a few words about a compendium. This is a comprehensive compilation of information on marketed drugs. The American Medical Association is about to publish such a listing. It also will compare the effectiveness of drugs.

Concerning the difficulties of transmitting information to the physicians, there are two major problems involved with this type of communication. One is transmitting information on widely used drugs pertaining to serious adverse reactions. We are all aware of major announcements of this nature concerning oral contraceptives and oral hypoglycemic agents. Information of this type should be released to the physicians with adequate lead time and should contain scientifically sound statements. Premature release to the lay press of any statement about such information or actions should be avoided, since this can lead to marked emotional reaction or even panic among the consuming public.

We also have the problem of disseminating the information on efficacy for drugs marketed between 1938-1962. When approved, these drugs were evaluated for safety, and evaluation for efficacy was referred more recently to the National Academy of Sciences-National Research Council. The FDA, in acting on the NAS/NRC recommendations, is not only making judgments that are affecting more than 80 percent of all drugs on the market, but is questioning some aspect of the effectiveness claimed for a majority of these products.

Of the total number of indications reviewed by the NAS/NRC, only 19 percent were given a straight "effective" rating. A certain number of indications classified as "effective, but . . ." by the Academy have been reclassified as "effective" prior to publication by the FDA. Recently, we published a proposal in the *Federal Register* to the effect that if indications other than those called "effective" are to be used in the labeling, it be so indicated on the label.

The problem of informing the physicians about drugs is huge and complex. To help us solve it requires close cooperation among the academic community, organized medical groups, and the drug manufacturers, as well as the public.

San Juan Section: the Uncommon Commonwealth

by Harry P. Lynch

In *La Fortaleza*, the 437-year-old governor's mansion at San Juan, Puerto Rico, stands a venerated grandfather clock whose hands have been stopped at the hour of 4:30 for over 70 years. It was on October 23, 1898, that General Francisco Ortega, the Spanish Governor of Puerto Rico, surrendered the island to Admiral William Sampson of the U.S. Navy and dramatically thrust his sword into the clock's machinery, stopping it forever.

The time marked the end of 400 years of Spanish discovery, conquest, and rule in the New World and the beginning of Puerto Rico's association with the United States, itself freed of foreign rule only four generations. That association has seen the green tropical island, called *Borinquen* by the original Indian inhabitants, emerge from U.S. territorial to full and free commonwealth status.

If Mexico is the United States' Good Neighbor to the South, Puerto Rico is its blood kin. More than that, Puerto Rico is this country's gateway to and its window on the entire Latin American vista. Puerto Rico, through its own energies and those of the Federal Government, has become a showplace for the U.S. brand of democracy, with its blemishes and blessings, and the center of an unusual cultural homogeneity of the two Americas on full view to Latin America and the world.

In Puerto Rico and the three U.S. Virgin Islands nearby the Food and Drug Administration discharges its responsibilities for consumer protection and assurance of food and drug industry compliance with the law in exactly the same way it does in the 50 States. Only the scenery is different, and some of the problems.

FDA's San Juan Section is 1,600 miles as the jet flies from the Agency's Region II headquarters in New York, of which it is a part. A thousand miles of ocean separate the island from Florida, the nearest point in continental North America and the contiguous States. Puerto Rico is the fourth largest island in the West Indies and the smallest and easternmost of the Greater Antilles group (Cuba, Jamaica, Hispaniola). It lies immediately west of the Virgin Islands, westernmost of the Lesser Antilles. The two Antilles groups together form a sprawling, but closely linked chain, no more than a hundred miles separating any two adjacent islands, extending from the foot of Florida eastward, then southward to the northeast tip of Venezuela, and embracing the Caribbean Sea on the north and east. The other islands of the West Indies are either independent republics or they are owned by or associated with the United Kingdom, France, or the Netherlands.

Puerto Ricans are mindful of the history and culture and the stunning economic progress of their island commonwealth, proud of being U.S. citizens on terms they themselves have defined, and content to control

their own destiny while remaining part of a larger and wealthier American entity. Should Puerto Rico ever decide that statehood holds more for her future than commonwealth status, her citizens need only say the word at the polls. That may come someday.

The gentle Trade Winds of the Atlantic blow the year around against the northern and eastern sides of the island, creating a heavy rainfall and making this windward side a paradise of tropical greenery and balmy beaches. The south and west, or leeward, side, with considerably less rainfall, is more arid, ranging in some areas to desert terrain, where irrigation is required for agriculture. The climate is mild all the year, the temperatures ranging from 68 to 86 degrees F.

This island of mountains and coastal plains was discovered by Christopher Columbus on his second voyage to the New World in 1493 and it and the Virgin Islands are the only part of what is now the United States that he ever visited. Spain took possession and ruled the island for four centuries, ceding Puerto Rico to the United States in 1898 following the Spanish American War.

Puerto Ricans were granted U.S. citizenship in 1917 and the right to elect their own governor in 1947. They also elect a General Assembly and their resident commissioner, who represents them in the Congress, but has no vote. In 1952 the Congress approved a new constitution giving Puerto Rico home rule as a free commonwealth of the United States. In a 1967 referendum Puerto Ricans voted strongly in favor of continuing the commonwealth status, rejecting both independence and statehood. Puerto Ricans do not vote for President (unless they move to one of the States), and do not pay Federal income taxes.

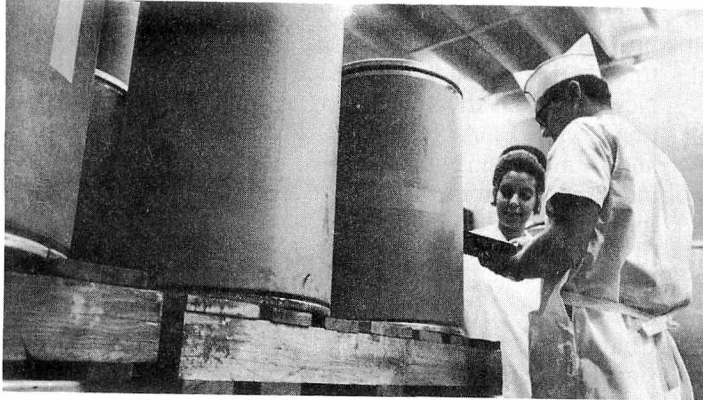
A Federal food and drug office was opened in San Juan shortly after the enactment of the Federal Food and Drugs Act of 1906, but was closed early in the Depression of the 1930's after reaching a peak of four or five people. In 1960 it was reopened as a one-man resident post of FDA's New York District. The author held that assignment until 1963, and returned two years ago to take over the San Juan Section, which is quartered in that part of the city now known as Old San Juan. In the meantime, under the leadership of Dennis B. Miracky, now a supervisory inspector in FDA's San Francisco District, the staff expanded from two people in 1965 to 14 in 1969, when the Section's laboratory began operation. The present staff numbers 16 and plans call for further expansion.

And not a moment too soon. With the phenomenal and continuing expansion of the industrial economy of Puerto Rico and the Virgin Islands, FDA's responsibilities have grown apace, particularly in the area of drug regulation.

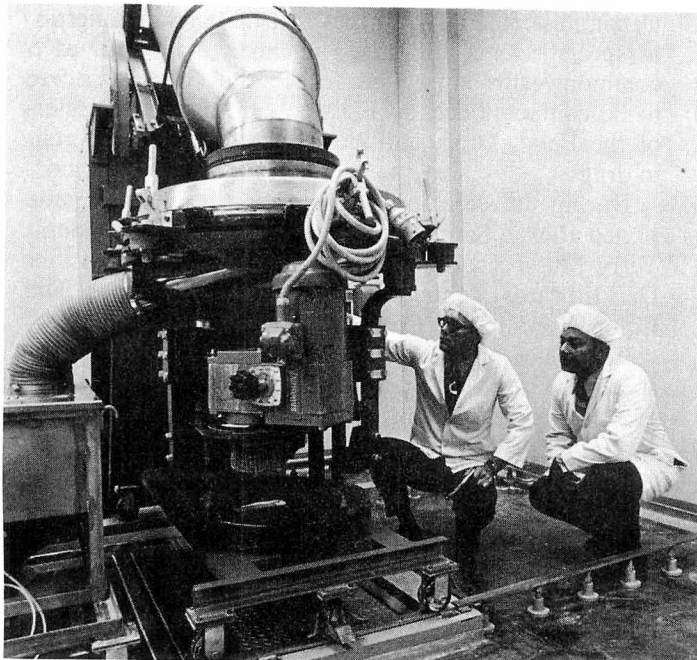
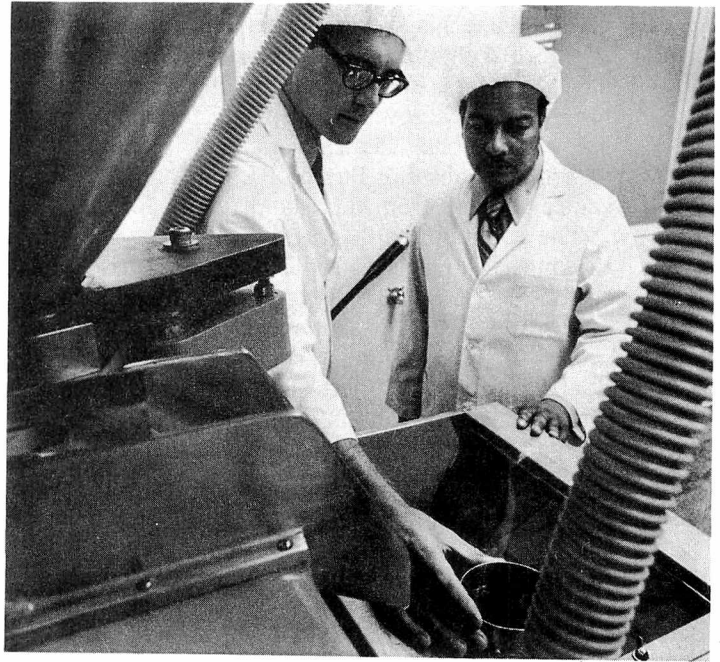
In a drug plant near San Juan that manufactures both prescription and over-the-counter drugs, FDA Inspector Edward R. Atkins (left) and Puerto Rico Inspector Carmen R. Buxo check the plant's average tablet weight figures against the weighing scale.



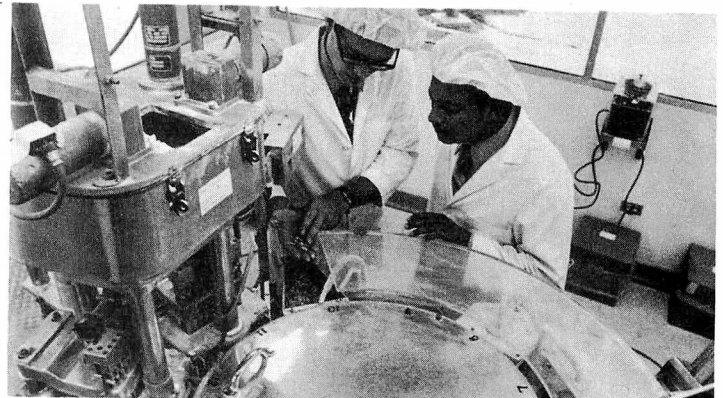
In the plant's raw materials storage area, Inspectors Atkins and Buxo examine sticker tags on containers for correct identification of contents.



FDA Inspector Edward R. Atkins (left) and Puerto Rico Inspector Anibal Lopez (right), in a plant that makes drug capsules and tablets, examine a slugging machine after cleanup. This machine compresses powdered drug ingredients for adherence of particles as a preliminary step to final compression into tablets. Cleanup prevents cross-contamination of different drugs processed by the same machine.



The two inspectors look at a closed system comminuting or grinding machine. Drug ingredient is shown being automatically dumped from barrel above into machine and vacuum tube at left carries ground material through a closed system to another processing point in the plant.



Inspectors Atkins and Lopez check capsules at a high speed encapsulating operation.



On an examination line where workers visually inspect empty capsules for defectives before they are filled with drugs, Inspectors Atkins and Lopez observe the operation.

In Puerto Rico, during the past 20 years, there has been a deliberate, intensive, and successful effort by the commonwealth's government and responsible economic interests to move the island from the sugar-rum-coffee economy that existed up to the 1940's to one based on industry and tourism, providing more employment for the island's vast labor reserve and generally upgrading the standard of living of her citizens. Under the aegis of an agency known as "Fomento" (Spanish for "promotion"), Puerto Rico exploited its advantages: tax-free movement of Puerto Rican goods to the States, a government policy formed to insure an inflow of money, machinery, and managerial talent to provide jobs for Puerto Ricans; and a rising consumer demand from the island's work force.

The commonwealth government's role was probably the most significant. Industry and tourism facilities established in Puerto Rico are exempted from major taxes for 10 years if they meet certain conditions; and under other conditions, such as locating in underdeveloped areas of Puerto Rico, may receive additional credits extending the tax exemption for up to 17 years.

Puerto Rico's use of these inducements, plus willing hands, a stable political situation, a salubrious climate, and outdoor life the year around, has succeeded almost beyond anyone's imagination, and the end is not nearly in sight. From a gross national product of \$287 million in 1940 and a per-capita income rate of \$120 a year, the GNP in 1969 reached \$4 billion, with a per-capita income of \$1,250. Industry, which formerly contributed half as much as agriculture, now contributes 2½ times as much, with only three-fourths the number of people employed by agriculture. Industrial plants rose to 82 by 1950, to 1,161 by 1965, and to 1,800 by mid-1969.

The rise in Puerto Rican industry is particularly marked in drug manufacturing. In 1960 there was only one U.S. drug company with a manufacturing plant in Puerto Rico. Today there are 25 drug plants owned by companies in the States and producing drugs for U.S. foreign, or Puerto Rican use. An additional 26 locally owned plants produce drugs used only in Puerto Rico, many of these being produced under contract for use in the extensive health programs of the commonwealth's Department of Health. An additional 20 plants are under construction or expected to be completed in the next two years under ownership of companies in the States. The products of drug plants in Puerto Rico, like those in the States, range from the simplest over-the-counter drugs to antibiotics and complex steroids.

As Puerto Rico's expanding drug production reached and passed that of some of the top drug producing States, there arose the question of whether FDA would have adequate manpower and facilities to assure that the drugs produced are safe and effective as required by the law. Since New York District's Newark Section and the State of New Jersey had already established a joint drug regulatory program known as the Single

System Concept (see FDA PAPERS, November 1970), the answer for the San Juan Section and the Puerto Rico Department of Health seemed obvious: Why not a Puerto Rico-FDA Single System of drug regulation?

Last November 3 the Puerto Rico Department of Health and FDA signed two memorandums of understanding to inaugurate a Single System Concept. Under the first agreement, signed by Angel Alberto Colon, M.D., then assistant secretary of environmental health in the Puerto Rico Department of Health, and Weems L. Clevenger, director of food and drugs, FDA Region II, New York, it was agreed that inspectors of the department's Drug Inspection Group would undergo on-the-job training, performing joint inspections of drug plants in Puerto Rico with inspectors from FDA's San Juan Section.

This first-phase training, now completed, lasted for up to two months for each of the Puerto Rico inspectors. In the second phase each will spend a month at New York District headquarters, making joint inspections with FDA inspectors throughout that District and familiarizing themselves with new drug instrumentation equipment they are likely to find being used in Puerto Rico drug plants.

The November 3 signing ceremonies in the Governor's Office were attended by Governor Luis A. Ferre of Puerto Rico and Commissioner of Food and Drugs Charles C. Edwards, M.D. The second agreement, signed by Secretary of Health Ernesto Colon Yordan, M.D., and Mr. Clevenger, provided for the department to commission FDA inspectors in the San Juan Section as special agents authorized to impose embargo under commonwealth laws, and for Puerto Rico inspectors to be commissioned by FDA to enforce the provisions of the Food, Drug, and Cosmetic Act as they pertain to drugs.

During the ceremonies Dr. Colon Yordan commissioned FDA's San Juan Section Inspectors Ira Colton, Terry Musson, Edmund Fry, and Edward Atkins, and Dr. Edwards conferred FDA commissions on Drs. Colon Yordan and Colon.

The chief of the Department of Health's Drug Inspection Group is Brigman Diaz. Mr. Diaz and four of his inspectors, Margarita Rodriguez, Margarita Velasquez, Miguel Cruz, and Isabel Falcon were scheduled to receive FDA commissions this April. Others to be commissioned at later ceremonies are Anibal Lopez, Juan Ortiz, and Carmen Buxo.

The Drug Inspection Group is responsible for regulating some 1,500 drug establishments, including 800 retail pharmacies as well as drug manufacturers and distributors. All the Puerto Rico inspectors hold degrees in pharmacy. Ultimately, the commonwealth's plans call for dividing the drug inspection force, some inspectors being primarily responsible for drug retailers and distributors and the others for manufacturing.

Dr. Colon Yordan, who before his appointment as Secretary of Health two years ago directed a hospital in Ponce, feels the Single System program will provide



At a ceremony in San Juan last November in which FDA and the Puerto Rico Department of Health signed memorandums of understanding to inaugurate the Single System Concept, Puerto Rico Governor Luis A. Ferre (right) looks at papers just presented to Dr. Ernesto Colon Yordan (center), Puerto Rico Secretary of Health, by Commissioner of Food and Drugs Charles C. Edwards, M.D. (left), commissioning the secretary with authority to enforce the Federal Food, Drug, and Cosmetic Act as it pertains to drugs.



Left photo, chief inspector of the Drug Programs Drug Inspection Group is Brigman Diaz (left), and right photo, supervisory chemist of the Drug Program's Drug Section is Marta Fernandez (right), both shown conferring with Harry P. Lynch, FDA's San Juan Section chief.



At the Puerto Rico Department of Health laboratories, Milagros Santos (left), chemist in the Drug Section of the department's Drug Program, demonstrates the operation of a Baird atomic spectrograph to Sonia Rivera (right), FDA chemist in the San Juan Section. Miss Santos was trained to operate this instrument at the University of Arizona.



On a parapet of San Juan's ancient Spanish fort, El Morro, now a tourist attraction, are Harry P. Lynch (right), chief of the FDA's San Juan Section; Billy G. Miles (center), laboratory supervisor; and Edward R. Atkins (left), inspector.



Checking rock lobster tails from the Dominican Republic for composition are Billy G. Miles (left), San Juan Section laboratory supervisor; Sonia Rivera (center), a chemist; and Marta DeArce, chemist with the Puerto Rico Department of Health, who is receiving training in food analysis.



Microbiological analysis of imported oysters is being carried out in the San Juan Section laboratory by David L. Stephens, microbiologist, who streaks Petri dishes with culture from test tubes at right.



Conducting a quantitative analysis of heroin confiscated by the U.S. Customs Service at the San Juan airport, using an ultraviolet visible spectrophotometer in the Customs laboratory, is Jose Martinez (left), Customs chemist, with Billy G. Miles (right), FDA laboratory supervisor at San Juan.

advantages both in assuring safe and effective drugs and in improving health care for Puerto Rican citizens.

Although the commonwealth government welcomes the establishment in Puerto Rico of drug manufacturing plants owned by companies in the States, the Secretary said, there will be no relaxation in the commonwealth and Federal insistence on production of drugs that are safe and effective. "We don't want these companies to feel that Puerto Rico is an inspection haven, or that they can expect less regulation than in the States," he said.

He said he is pleased at the progress of food and drug programs on the island and that the commonwealth will provide FDA all means at its disposal to obtain regulatory compliance. As for the Single System, its effect will apply with equal force to those firms that produce drugs only for intrastate use. Under the Single System program each of the two inspection entities provides the other with copies of its plant inspection reports, so that both will have a historical record of the regulatory picture involving all drug plants.

The groundwork was laid for implementing the Single System Concept early last year when the Department of Health asked assistance from FDA in setting up a drug regulatory program in Puerto Rico. FDA's Region II responded by selecting Robert J. Martin, then Chicago District's laboratory director, who has since been appointed deputy director of food and drugs in charge of the New York District, to serve under a commonwealth appointment as director of the Food and Drug Program in the Department of Health. Mr. Martin spent eight months on loan to the department, helping to train the drug inspectors and to set up food and drug analytical equipment and procedures in the department's Institute of Health Laboratories in San Juan.

The department's food and drug laboratories, which also analyze milk and water supplies from throughout the commonwealth, now have facilities and analytical capabilities on a par with most FDA District laboratories. Drug samples taken by the Drug Inspection Group are forwarded to these laboratories and violative findings are reported back. Mr. Diaz, chief of the Drug Inspection Group, then inaugurates the necessary regulatory action through Rosa Silva, chief of the department's Legal Office. In certain situations food samples taken by FDA in inspections of food processing firms in interstate commerce are analyzed by the departmental laboratories.

Puerto Rico's chief agricultural commodities are bananas and plantains, coffee, dairy and livestock products, sugar, coconuts, yams, sweet potatoes, pineapples, mangoes, papayas, oranges and grapefruit, guavas, melons, and cassavas, taro, and other tuber-type products. But although many crops do well, the island is overcrowded, with a density of 755 persons per square mile for its 2.7 million population. This means that the commonwealth must depend for much of its food supply on shipments from the States and imports.

Much of the food processed in Puerto Rico consists of specialty products made from agricultural commodities grown on the island, and these are not generally shipped interstate, although more and more of these specialty food products are being shipped to large cities in the States where there are sizeable Latin American population segments. Inspection responsibilities for locally produced and used food products, including both food processing and food service establishments, are carried out by a force of around 500 departmental sanitary inspectors stationed throughout the commonwealth on a regional basis. FDA's San Juan Section remains responsible for foods processed for interstate shipment and for imports.

One of the largest interstate food processing industries is the canning of tuna for both human and animal food. At present there are four large tuna packing plants, one in Ponce, on the southern side of the island, and three in Mayaguez, on the western coast of Puerto Rico. These plants pack 40 to 45 percent of all tuna consumed in the United States, operating the year around, processing tuna from boats fishing both the Atlantic and Pacific, on an around-the-clock schedule. All the plants plan expansions and a fifth plant is under construction.

During FDA's recent check of tuna for mercury content San Juan Section inspectors collected samples, which were analyzed in the departmental laboratory facilities Mr. Martin helped to set up, since the Section's lab did not have the necessary analytical equipment. (This equipment has since been installed.)

Other foods or beverages shipped to the States or exported in significant quantities include sugar, rum, and candies. Since much of Puerto Rico's food supply comes not only from the States but also from foreign countries, a substantial part of the San Juan Section's inspectional and laboratory manpower is devoted to imported food products.

Ironically, one island delicacy, which most Puerto Ricans can't even obtain, has caused trouble to both FDA and the Department of Health in the past few years. It's the land crab, native to the island but almost depleted because of the demand. The result has been increased prices for land crab meat to the point that smuggling from elsewhere in the West Indies has become profitable. Shipments are entered illegally since FDA some years ago began detaining practically all lots of the meat because of bacterial contamination—a result of processing where sanitary standards are much lower than Puerto Rico's and where food regulation is practically nonexistent.

The San Juan Section's responsibilities in the Virgin Islands mainly involve imports, although there are four drug plants on St. Croix and one device plant on St. Thomas that inspectors visit periodically. The third of the Virgin Islands, St. John, has had little industrial development. The U.S. Virgin Islands, like Puerto Rico, depend largely on outside sources for their food supply.

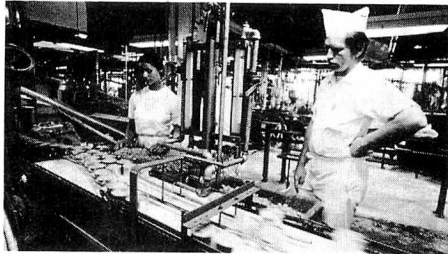
These islands, purchased from Denmark in 1917,



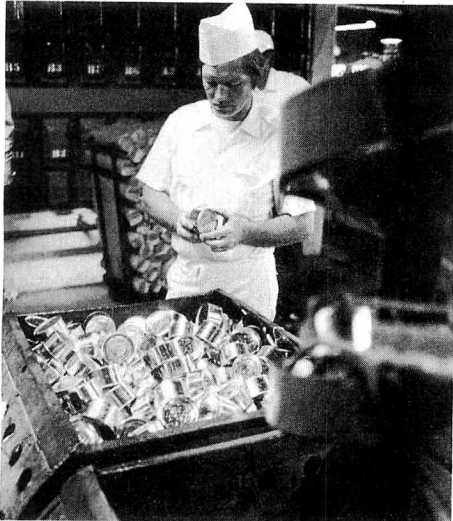
In a tuna cannery in Puerto Rico, FDA Inspector Terry Musson checks the temperature of fish thawing in tote bins.



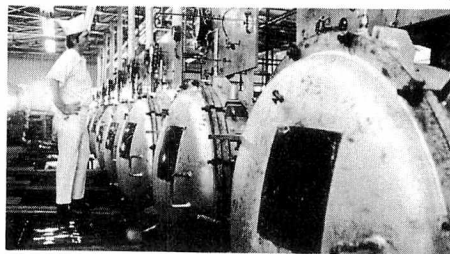
As tuna are being washed down before butchering, Mr. Musson smells a fish to check quality.



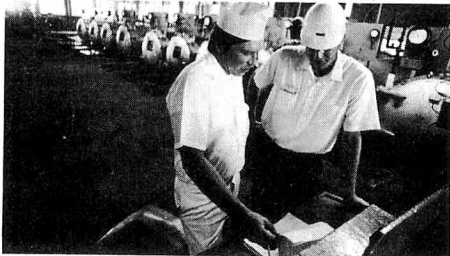
A production line employee who examines filled cans before sealing for quality of the pack, repacking where necessary, is observed by Mr. Musson (right) for adherence to sanitary practices.



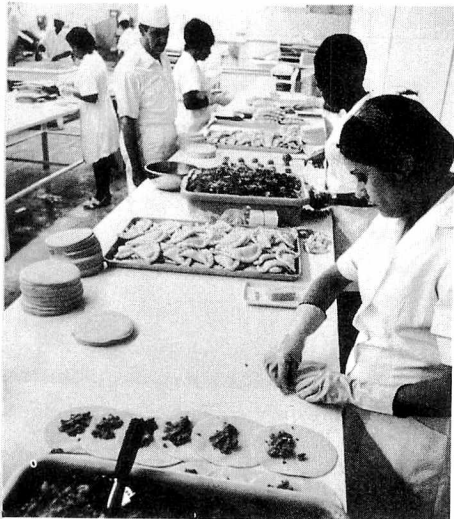
As cans of tuna come off the sealing line and go into baskets for retort sterilization, Inspector Musson makes visual examination of a can for quality of seams.



As canned fish undergo cooking in retorts, Mr. Musson checks the temperature on a recording thermometer, which keeps a record of the temperature used during the entire cooking process, against the mercury thermometer, which registers the cooking temperature at any given time.



Against a background of several sterilizing retorts, Mr. Musson (left) and the plant's quality assurance supervisor go over the retort control records permanently retained by the plant.



At a San Juan plant that prepares specialty food products (bottom left), FDA Inspector Victor M. Barreto (in hat) watches the preparation of pastelillos, a kind of cooked beef-vegetable tart that is shipped frozen to market and fried or baked by the housewife.

Here Mr. Barreto observes the packaging of rellenos (bottom right), another Puerto Rican specialty food, consisting of potato dumpling with beef.

retained status as free ports as a condition of the sale, so large amounts of food and beverages are imported duty free from Europe, other parts of the West Indies, and Latin America. Tourism and duty-free shopping facilities are major businesses, and FDA works closely with the U.S. Customs Service to protect both local consumers and tourists from unsafe and unwholesome food and drugs, banned hazardous substances, mislabeling, and other violations.

Since FDA has no resident post on the islands, the Custom Service furnishes the Section copies of consumption entries of FDA-regulated commodities offered for import. The Section examines these documents and may ask Customs to hold lots for inspection or sampling. Over the years of working with FDA, Customs officers have become trained to alert the Agency to shipments in which FDA is likely to be interested or which appear to be violative of the FDC Act or other statutes administered by the Agency.

Both the Federal Government and the Puerto Rico commonwealth government are acutely aware that their activities are under the watchful eyes of Latin American countries, where food and drug and other programs involving public health are in some respects decades behind those which protect citizens of the United States. What Latin Americans may find puzzling in the States becomes more understandable in Puerto Rico because of the Spanish language and the common culture both share.

For that reason Governor Ferre and other forward-looking Puerto Ricans have caused to be established and are giving full support to a project that has been years in planning and which they hope will provide a meeting ground for cultural and technical exchanges between the Americas.

The North-South Center, located on the grounds of *El Morro*, San Juan's ancient fortress constructed by the Spaniards, began operation this year as an institution under the temporary sponsorship of the Caribbean Economic Development Corporation. Legislation is being introduced into the Puerto Rico Assembly for operation of the Center as an arm of the commonwealth government and as part of an Inter-American Institute of Social Technology, which would grant degrees and would be staffed by a faculty borrowed from universities throughout the Americas.

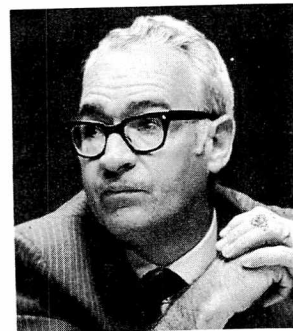
The purpose of the Center, as described by Governor Ferre, who first proposed the concept in 1949, is to "sponsor visits, exchanges, seminars, conferences, technical training, and other activities designed to bring persons from North America into contact with their opposite numbers from Latin America, and vice versa." The current sponsors believe Puerto Rico is a natural and fortuitous bridge between the Americas that offers the perfect setting for the Center. The Center's first project, a course in ophthalmology, was held in February and involved 22 physicians from 11 Latin American countries being given basic instruction in ophthalmology at the University of Puerto Rico Medical School by a

staff of 60 prominent ophthalmologists, mainly from the United States and Puerto Rico, but including one each from Mexico, Colombia, and Panama. Other typical projects have been scheduled on the LASH shipping system (a new method of shipping cargo), restoration of colonial architecture, and a course in public accounting. There are many more to follow.

Dr. Colon Yordan said he feels Puerto Ricans, most of whom speak both English and Spanish, have a certain obligation to Latin America and that the North-South Center provides an excellent opportunity for translating North American scientific and technical knowledge to Latin America. The Center will provide a place where Latin Americans can see the United States in action, particularly its organizations responsible for meeting health problems, he said.

He noted that although there are still 1.7 million poor people in Puerto Rico and that only \$40 for medical care is spent per year per patient (compared to \$354 in the States), the insular commonwealth has an outstanding health care system that is progressive and efficient. This system is organized by local areas and regions throughout the island, with medical centers in the larger communities. Of Puerto Rico's 3,200 physicians, 34 percent participate part time or full time in the department's public health programs. Although Puerto Rico is small, because of its relationship with the United States, the Secretary said, "We have stronger programs aimed at food and drug quality control than most of the Latin American countries." He believes that with the help of Federal grants and matching funds, along with private grants, the Department of Health can work with the North-South Center to develop modern health protection programs that will be of immeasurable benefit to Puerto Rico, Latin America, and the United States.

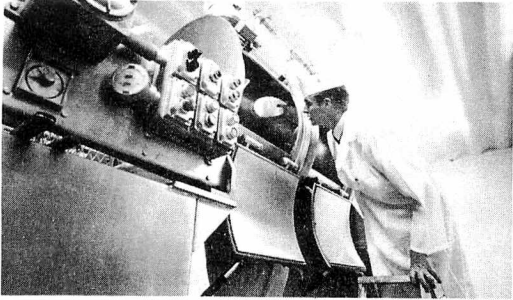
The Food and Drug Administration is ready and willing to do its part to help the Commonwealth of Puerto Rico to share with its Latin American neighbors the knowledge in food and drug protection it now enjoys. The Agency's present plans are to expand the San Juan Section staff to District size and capability. Several members of the present staff are Puerto Ricans and more will be added to make the Single System Concept a true and going partnership.



Harry P. Lynch, chief, San Juan Section, Region II, joined FDA at Philadelphia in 1955.



At a birthday reception for Puerto Rico Governor Luis A. Ferre (right) at La Fortaleza, the governor's mansion, Secretary of Health Ernesto Colon Yordan (center) and FDA's San Juan Section Chief Harry P. Lynch (left) talk with the chief executive about the new North-South Center at San Juan. The governor is the third man elected to that office and the 150th since Ponce de Leon became the first governor under Spanish rule.



In a drug plant that makes tablets and capsules on St. Croix in the Virgin Islands, FDA Inspector Richard E. Dent examines a machine that mixes drug ingredients.



Mr. Dent checks production technique and machine operation in the drug plant during an encapsulation process.



Mr. Dent (left), completing drug plant inspection on St. Croix, boards seaplane at Christiansted for hop to St. Thomas.



At Charlotte Amalie, St. Thomas, Inspector Dent looks over a shipping manifest with Joseph R. Banks (seated), District Director of Customs for the Virgin Islands.



At dockside in Charlotte Amalie, Mr. Dent takes a sample of yams offered for import from Tortola, one of the nearby British Virgin Islands.



The Animal Drug Certification Program

by S. L. McHenry, Ed.D.

Over the past several years, great advances have been made in the production of livestock and poultry. Without these advances, we would not have the bountiful supply of high quality meat, milk, and eggs that consumers enjoy today. This progress results from the application of new scientific knowledge in the agricultural industries: better management practices, improved breeding, new developments in nutrition, and the effective use of veterinary drugs for disease control and growth promotion.

Although the Food and Drug Administration realizes the economic value of animal drugs, it cannot permit illegal residues of these drugs in meat, milk, and eggs from food-producing animals. Producers and handlers of livestock are responsible for complying with the label instructions and for using the drugs as directed. The use of some drugs in meat animals must be discontinued

sufficiently in advance of slaughter to ensure the elimination of all residues in meat. Similar precautions must be taken to ensure the absence of residues from milk and eggs.

Obviously, it is impossible for the Government to check on every farmer to ensure his compliance with the law. It would be just as impractical, and a prohibitive expense, to take a sample of meat tissue from every animal slaughtered to determine if there are any illegal residues of drugs present at the time of slaughter. For these reasons, FDA is relying on a combination of producer education and vigorous enforcement to achieve 100 percent compliance with the Food, Drug, and Cosmetic Act.

Many producer associations cooperate with FDA in promoting voluntary compliance with the law. FDA's Bureau of Veterinary Medicine participates in educational meetings sponsored by agricultural organizations. The Bureau works closely with other governmental agencies, including those in the U. S. Department of Agriculture (USDA). The USDA's Federal Extension Service distributes our informational material to its counterparts at the State universities. We also send educational material to radio station



the trade press, industry associations, and supervisors of agricultural education.

FDA's efforts to educate producers were given additional impetus this year with the development of the voluntary Animal Drug Certification Program by industry groups. Reacting to the increasing concern by consumers about the safety of their food supply, these groups, with encouragement from FDA, developed a voluntary program asking all livestock and poultry producers to certify in writing, when marketing their animals, that they have followed manufacturers' directions concerning any drugs used. Coordinating the program is the National Animal Drug Certification Committee (NADCC), headed by C. W. McMillan, executive vice president of the American National Cattlemen's Association (ANCA). The NADCC is distributing certificates especially designed for the program, through its members, to producers of all species of animals that yield foods.

During the first month, the NADCC distributed one million of the certificates, 50,000 leaflets explaining the program, and a news release describing the program to 50 agricultural editors and farm broadcasters. Before the second issu-

ance, NADCC made some changes in their certificate to clarify certain points. The phrase "while in my possession" is included in the statements, and sheep is listed among the animal species. The withdrawal program is endorsed by the U.S. Department of Agriculture and the Food and Drug Administration.

In addition to ANCA, the committee members include (as of April 1) representatives of the Animal Health Institute, the American Feed Manufacturers' Association, American Meat Institute, National Broiler Council, National Livestock Feeders' Association, National Independent Meat Packers Association, National Pork Producers Council, River Markets Group, and Western States Meat Packers Association. All of these groups are informing their members about the certification program.

Animals enroute to slaughter plants are interpreted as food within the meaning of the Federal Food, Drug, and Cosmetic Act. Section 301(a) of that Act prohibits the introduction into interstate commerce of any food that is adulterated or misbranded. Processing plants that are inspected by Federal agencies are considered, *per se*, to be engaged in interstate commerce. Therefore, shippers of animals that

At a feeding lot an FDA inspector uses a probe (opposite page) to obtain a sample of medicated cattle feed for analysis.

Medicated broiler feed (upper left) should be withdrawn prior to slaughter as directed on the labeling instructions.

Above right, after FDA endorsement of the Animal Drug Certification Program, C. D. Van Houweling, D.V.M. (left), director, Bureau of Veterinary Medicine, and Fred H. Holt, executive vice president, Animal Health Institute, meet to discuss details.

Below right, implementation of the Animal Drug Certification Program is the subject of a talk between C. W. (Bill) McMillan (right) executive vice president—Washington affairs, American National Cattlemen's Association, and Bob Johnson, Jr., a Colorado cattle producer who is a past president of the association's Executive Committee.

S. L. McHenry, Ed.D., is industry information officer in the Bureau of Veterinary Medicine.

contain unauthorized residues to plants operating under Federal inspection are subject to prosecution or other legal action under the FDC Act for introducing an adulterated food into interstate commerce.

When a food animal producer markets his animals, either directly to a meat packer or through a commission agent, he is asked to sign the certificate (shown below). One copy is given to the buyer, and one copy is retained by the seller.

Commissioner of Food and Drugs Charles C. Edwards, M.D., speaking to members of the American National Cattlemen's Association, said, "Your indication of willingness to embark on this program will go a long way in assuring the consuming public that meat products are wholesome and free of residues." But he added this warning: "I feel it is important to emphasize that whenever we document the fact that residues are present in edible parts of a slaughtered animal, we will take appropriate action. I feel also that vigorous enforcement on the part of FDA will enhance the possibility of

success of your proposed program."

C. D. Van Houweling, D.V.M., director of the Bureau of Veterinary Medicine, commented in a speech to the Colorado Grain and Feed Dealers Association, that we "commend industry for its development of the withdrawal certification program. If properly used, it will do much to help all of us in our obligation to assure the consumer of safe and wholesome food. I urge you to support this program in any way you can, because if a voluntary program such as this is not successful, the industry will surely be faced with more restrictive regulations governing the use of animal drugs and the possible loss of valuable meat production tools. I do not have to tell you how significantly your operations would be affected if some of the drug products you now use would no longer be available to you."

In the certification program, producer organizations are responsible for distributing forms to their members. Marketing groups provide these forms to all of their member

market agencies, dealers, and auctions that handle slaughter livestock, and are asked to request certification when livestock are marketed.

Livestock transit insurance companies which insure livestock while in transit are asked to send certification forms to all branch offices so they can be distributed to their trucker customers. This cooperation is vital for reaching the small feeder who normally sells at a central public or auction market.

The animal drug industry, through AHI, will coordinate public relations and communications with the FDA and USDA in the program. Drug manufacturers are also asked to promote the program in customer orientation sessions and through their advertising.

FDA endorses and supports the voluntary withdrawal certification program as a valuable informational and educational program to consistently remind producers of their responsibilities under the law and thus promote voluntary compliance with Federal law and FDA regulations.

MEAT PACKER'S COPY

Animal Drug Certification

No. 902502

In marketing _____ (DATE) _____
(NUMBER) (CATTLE, HOGS, POULTRY)

☐ I certify that all drugs and feed additives received by these animals have been used in conformity with the feed or drug manufacturer's dosage directions and withdrawal times.

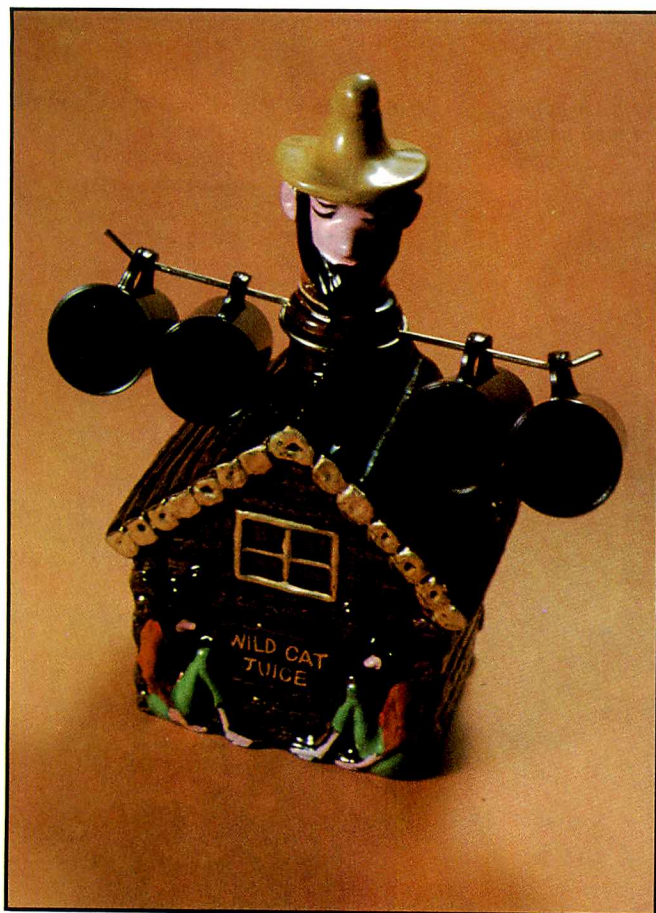
☐ I certify that these animals have not received drugs or feed additives.

SIGNED: _____
(OWNER / FEEDER / FEEDLOT MANAGER)

ADDRESS: _____

Note: IMPORTANT: All slaughtered animals are subject to inspection for drug residues. Animals containing unauthorized residues will be condemned and the parties responsible for these residues are subject to prosecution under the Food Drug and Cosmetic Act.

Certificate for use in the withdrawal program endorsed by the Food and Drug Administration



TOXIC METALS

IN EARTHENWARE

by Benjamin Krinitz
and Robert K. Hering

This "Wild Cat" decanter intended to contain alcoholic beverages is from Japan and samples averaged 65.4 ppm of lead, or a range of 9.2 to 182.5 ppm in various items in the sample.

a year ago by the widespread public concern and reaction that followed the publication of an article in the November 1969 issue of *Good Housekeeping* magazine (and subsequently reprinted in substantially the same form in *Readers Digest* magazine). The article described how a family of five in California had almost died of lead poisoning as a result of their prolonged use of a Mexican handcrafted earthenware pitcher. The pitcher, used as a container for orange juice over a three-year period, contained an amount of lead which caused toxic accumulations in the bodies of a physician, his wife, and their three children.

As a result of this event and FDA's preliminary examination of Mexican earthenware, the Agency in February 1970 issued a warning to the public that prolonged use of some Mexican pottery as food or beverage containers could result in lead poisoning. A few days later FDA instituted a surveillance program to determine if earthenware products reaching American markets from countries other than Mexico were also potentially hazardous.

The program required each FDA District to collect and examine three samples of earthenware imported from each of 11 major exporting countries. The investigational program soon disclosed that the problem of acid-extractable lead was not limited to products of Mexico alone. As a result of these findings, FDA's 17 District offices have continued to monitor the problem; the upshot has been that over 400 entries from 19 different countries that were offered for import to this country have been denied entry because of leaching of excessive amounts of lead. The study also showed that cadmium, a heavy metal more toxic than lead, may also be extracted under the same acidic conditions when this metal is used in glazing or decorating processes that are improperly carried out. Excessive levels of

Many visitors to FDA's New York District office have been impressed by a stunning collection of colorful pottery and earthenware on display in the reception room. To some who have been puzzled at the sign marked "danger" that accompanies the exhibit, the receptionist has used an analogy to explain that these brilliant and beautiful products intended for the home may be likened to a poisonous snake: they are beautiful, but dangerous! Dangerous because of their leachable lead content.

In the past the Food and Drug Administration has from time to time sampled and tested pewter and earthenware for lead, an insidiously toxic metal that under certain conditions may be leached or extracted through a chemical reaction when such vessels contain foods of an acidic content.

Lead has been used since ancient times as an ingredient in glazing compounds by potters to impart a smooth surface and brilliant or enhanced coloring to ceramic products. Although FDA knew that toxic amounts of lead could be leached from some pottery products under certain conditions, the Agency was not really aware until a little over a year ago of the extent and seriousness of this problem involving ceramic products imported to or produced in the United States.

FDA's involvement was intensified more than

Yellow plate from Italy with leaf decoration was found to contain 92-325 parts per million lead in individual plates, and an average of 160 ppm for all items in the sample.

Blue cup and saucer from Italy averaged 534 ppm of lead among items in sample.

Samples of this plate with rings of color, from Italy, contained an average of 0.78 ppm cadmium.



Brown and white teapot came from Canada and samples averaged 21 ppm of lead.

Samples of this white plate from Italy with fruit and leaf decorations contained an average of 11.3 parts per million leachable lead.

Beer mugs from Portugal averaged 9.4 ppm of lead. The one on the right tested at 13.8 ppm lead and the one on the left 2.0 ppm.

cadmium were extracted from over 40 of the entries examined and these also were denied entry.

Earthenware as a food contact surface is covered under the Food Additive provisions of the Federal Food, Drug, and Cosmetic Act. Under the provisions, no harmful substance is permitted to migrate from the surface into a food or beverage. In the absence of specific regulations or tolerances, the FDA has established an interim action guideline of 7 parts per million for lead and 0.5 parts per million for cadmium. Both these guidelines are considered safe and realistic within the meaning of the law.

Ironically the problem of lead poisonings attributable to lead salts is believed by some to have plagued man from his earliest civilizations. Some historians have suggested that the decline of the patrician families in the later years of the Roman Empire was due at least in part to lead poisoning. The hypothesis is that wide use of lead-based

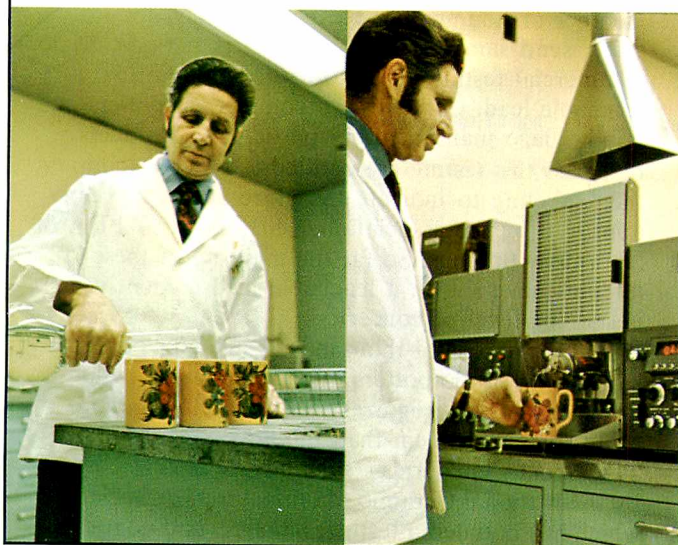
pewter by the members of the Roman nobility led to the early demise of many of them. The poorer Romans, who could not afford pewterware and therefore used goatskin bags and unglazed clay vessels, escaped such poisoning.

Through the ages, lead salts such as lead oxide and lead chromate have been used in the glazing of various ceramic products, including earthenware vessels such as bowls, cups, pitchers, and plates. Lead salts are especially prized by potters because when properly used they produce an acid-resistant surface, impart a special brilliance to the vitreous glaze, and tend to enhance the color value of the pigments used in ceramic decoration. Salts of other heavy metals such as cadmium, cobalt, chromium, and tin are also used to impart color to ceramic products.

A glaze containing lead salts is applied to ceramic items and these products are fired at high temperatures. If the glazes are properly formulated, applied, and fired, the lead salts are sealed into the glaze



Field testing kit for on-the-spot detection of acid extractable lead in sample of earthenware is used by Inspector Robert K. Hering, coauthor. At left, an acetic acid solution is poured into the earthenware mug shown and allowed to remain 30 minutes. This solution is then placed in a vial containing a buffer solution and a color reagent is added. At right, positive indication of acid extractable lead is the resulting red color in bottom of vial, caused by reaction of reagent and lead in the acetic acid solution. Confirmatory testing is done in the laboratory with additional units of sample. If the color in the vial had been green, the test for leachable lead would have been negative and the earthenware passed.



In the laboratory, samples of products in which extractable lead has already been detected are tested by Chemist Benjamin Krinitz, coauthor, to determine the quantity of lead present. At left, mugs being tested are filled with acetic acid solution and allowed to stand for 24 hours at room temperature. At right, the solution is then aspirated into a flame in an atomic absorption spectrophotometer and the instrument provides a reading of the amount of lead present in the solution.

and are not extractable or leachable by food components that come into contact with the surface. If not properly processed, the lead salts or other heavy metals are readily extractable by acidic foods. Some acidic foods or beverages—all of which may extract lead or heavy metals at a greater rate if warm or hot than if cold or if the food or beverage is allowed to stand in the container for long periods—are fruit juices, soft drinks, wines, cider, coffee, all foods containing vinegar (such as salads, salad dressings, mustard, pickles), sauerkraut, cooked fruits, and tomato products. There are many others.

Lead is a cumulative poison in the human system. V. J. Brookes and M. B. Jacobs in their book, *Poisons* (second edition), said, "Chronic lead poisoning is caused by continuous absorption of small quantities of lead. It is dangerous because of the cumulative effect on the blood vessels, heart, kidneys, and nervous system."

Many countries, aware of the potential hazard of

improperly glazed ceramics, have devised standards and testing procedures to detect and measure acid-extracted lead. FDA employs a laboratory procedure in which an acid solution comparable in acid content to some acidic foods is allowed to remain in the ceramic vessel for 24 hours at room temperature. The solution is then analyzed for lead or other toxic metals by atomic absorption spectrophotometry.

A field screening kit has been developed by New York District for use by its import inspectors in on-the-spot testing for heavy metals. Those samples found suspect are collected for confirmatory testing in the District's laboratories. The application of this testing kit is being evaluated by FDA for possible use in all District offices.

As FDA's surveillance and testing program got underway, the substantial number of detentions began to have an economic effect on the importers and resulted in a deluge of questions from importers,

foreign governments, and trade representatives about what corrective actions they might take to alleviate the problem. New York District's import specialist, John Zaic, held frequent sessions with members of the Japan Pottery Inspection Association, Japan Trade Center, Italian-American Chamber of Commerce, Societe Francaise de Ceramique, and consular officials from Italy, France, and Portugal.

As a result of these meetings, JPIA instituted a program of analyzing all exports from Japan before shipment to the United States. The analytical reports are sent to the importer of record along with the invoice. Some of the French shippers also are having their earthenware pretested by Societe Francaise de Ceramique in Paris.

The continuing problem of imported earthenware was underscored in February this year when FDA issued a news release warning consumers that some items of pottery from Italy, containing high levels of leachable lead, had entered the country and had reached retail channels. This warning also was transmitted to State authorities in efforts to remove this pottery from the market.

Because of this continuing concern over the occurrence of leachable heavy metals in imported ceramic products, FDA's Office of International Affairs scheduled a one-day meeting in Washington April 15 that was to be attended by FDA officials and representatives of industry trade associations, importers, foreign manufacturers, and embassies of pottery exporting countries. The discussions were to go into a history and assessment of the problem, the Agency's regulatory compliance responsibilities, analytical methodology, and possible solutions, including the encouragement of pretesting of products before export to assure compliance with FDA's action guidelines.

As the significance and extent of the problem involving imports become more apparent, FDA also turned attention to domestically produced pottery. Some violative products were found and additional surveillance is needed to determine if the problem is widespread. The Agency plans a sampling and testing program covering the majority of the principal United States manufacturers.

The domestic industry for a decade has been conducting research to develop analytical methods for detecting leachable lead in pottery under the sponsorship of the United States Potters Association (USPA) and the International Lead Zinc Research Organization, Inc. (ILZRO). More recent research under this same sponsorship has sought to develop sound data on the proper formulation and firing temperatures required to minimize the release of lead from lead-containing glazes. A result of this research was the publication in 1970 of findings in ILZRO Manual No. 1, "Lead Glazes for Dinnerware," available free from Lead Industries

Association, Inc., 292 Madison Ave., New York, N.Y. 10017. Although these published findings on glazes have been generally accepted, the analytical method has since been modified by the FDA for regulatory purposes. The laboratory analytical method currently used by FDA for regulatory purposes is capable of extracting more lead. This procedure, "Determination of Lead in Pottery," is available from the Division of Regulatory Guidance, Bureau of Foods, FDA, 200 C Street, S.W., Washington, D.C. 20204.

Under the same trade group sponsorship the domestic pottery industry has worked closely with FDA in holding meetings involving additional research efforts. One current research project seeks to measure the rate of migration of lead in pottery to specific food products. The industry, through the U.S. Potters Association, has established its own Dinnerware Surveillance Program, in which member or nonmember participants may, for a fee, send samples of their products periodically to commercial testing laboratories for assay of leachable lead. Currently 16 commercial potters and hobby glaze manufacturers participate. Products that pass this testing are entitled to carry a stamp on their labeling to indicate the glaze used has been approved by the association. USPA informs FDA of laboratory findings. So far the majority of these findings have shown a leachable lead content well below the level of concern.

There are tens of thousands of amateur potters and small-scale studio potters in addition to the major firms and FDA recognizes that these may present a far greater problem than the larger manufacturers. The Agency encourages such efforts as that by the National Ceramic Manufacturers Association, which has initiated a testing, labeling, and education program involving the use of commercially available hobby glazes. This association cautions hobbyists to use only those glazes labeled as suitable for contact with food or beverages when properly applied and fired.

FDA will continue its sampling and testing program for earthenware to which the American consumer may be exposed. The Agency also will continue to encourage efforts by the domestic and foreign pottery industries and importers to assure the safety of their products. The Agency is redirecting manpower, facilities, and funds to this important area. We are cognizant that only by continuing vigilance and alertness to potential danger can we protect the public from the possibility of poisoning by heavy metals in earthenware. We feel certain that FDA's surveillance program, together with the cooperation of the domestic industry and that of exporting countries and their governments, as well as importers, will enable us to assure the American consumer that he can use earthenware in his home without concern for possible hazards.

field reports

ATLANTA DISTRICT In a followup to a complaint received by the District last fall that Columbiana Seed Co., Dyersburg, Tennessee, was selling pesticide-treated seed corn to farmers who used it as hog feed, both Federal and State officials became involved in a prolonged investigation that resulted in recalls as well as seizures of such treated seed corn. The District's investigation, which included visits to hog farmers and collection of samples from the Dyersburg firm and from the farmers found using the treated seed corn for hog feed, revealed that a relatively widespread problem existed. As a result of the investigation, FDA accomplished seizure October 27 at the firm of over 187,000 pounds of treated seed corn contaminated with residues of captan and dieldrin. Under pressure from Tennessee State authorities, the firm successfully recalled most of the outstanding seed that had been distributed to area hog farmers and is holding it pending final disposition of the seized lots.

Further investigation pointed to two North Carolina seed firms, McNair Seed Co., Inc., and Pioneer Corn Co., Inc., both of Laurinburg, which revealed similar sales of treated seed corn. Cooperating North Carolina State authorities assisted in promptly halting continued sales and use of such seed for hog feed, and the State embargoed 3,000 hogs on farms using treated seed from the Laurinburg distributors. FDA then accomplished seizure of a total of 630 50-pound bags of treated seed corn, adulterated with residues of captan, dieldrin, and methoxychlor, that was being held by McNair Seed Co., and by a local hog farmer. Since it could not be established that all the contaminated seed in possession of this distributor was in interstate movement, North Carolina Department of Agriculture officials embargoed additional stocks of the treated seed.

The District's investigation of Pioneer Corn Co. encompassed activities at two hog farms leased by the firm, and established that excessive residues of captan were present in the bagged seed corn, bulk feed, and corn in the feeding troughs. State officials took action against all the corn and hogs involved in this instance, since interstate movement could not be established.

BALTIMORE DISTRICT FDA's prosecution against Wampler Foods, Inc., Harrisonburg, Virginia, a manufacturer of animal feeds, was terminated January 13. Over the objection of the Assistant U. S. Attorney, the court allowed the defendant to enter a plea of nolo contendere to two of the six counts charged. Chief District Judge Ted Dalton of the U. S. District Court at Roanoke then levied a total fine of \$500—\$250 per count—and dismissed the other four counts. FDA charged the firm had produced feeds that were adulterated and mis-

branded because they did not conform to Current Good Manufacturing Practice regulations, lacked adequate directions for use in their labeling, lacked name and quantity of each active ingredient in their labeling, and were animal drugs without an effective New Animal Drug Application.

A U. S. marshal recently seized 585 EZ Breathe Electronic Air Cleaner devices with accompanying literature in possession of a firm at Winchester, Virginia. The devices, valued at \$21,645, were manufactured and shipped to Virginia by M-Tron Industries, Inc., Yankton, South Dakota. FDA charged the article was misbranded because labeling statements represented the device as adequate to filter the air in a 15 x 15-foot room in 14-18 minutes, totally removing all particles from the air, including bacteria and viruses. The device was found inadequate for such purposes.

District representatives participated in a recent seminar held for 40 sanitarians from Baltimore, Harford, and Carroll Counties in Maryland. The session, part of a one-week conference, covered general inspectional techniques, bacteriological inspections, the Fair Packaging and Labeling and Child Protection Acts, disaster work, and bakery inspections.

BOSTON DISTRICT As a result of the recent findings of excess mercury levels in some fish, a large manufacturer of seafood products in the District area has decided to examine all lots of raw fish for mercury before processing. The firm estimates the cost of equipment, instrumentation, and installation for this purpose will be \$25,000.

At the firm's request, the District conducted an in-plant workshop January 21 for the Howard Johnson Co., Boston. The workshop was on good manufacturing practices as related to the production of convenience foods.

Piantadosi Baking Co., Inc., Everett, Massachusetts, pleaded guilty on January 19 to FDA's charges that it operated an insanitary bakery, and was fined \$250. One of the firm's officers was fined the same amount.

BUFFALO DISTRICT Filth in food and other products offered for import continues to be a problem for the District. Among the detentions made in January were, from Italy, \$2,400 worth of macaroni that contained insects, insect fragments, human hair, paint and metal fragments, and other foreign materials; from Canada, about \$400 worth of farfel noodles that contained rodent filth, date-filled cookies valued at about \$535, containing insect and rodent filth and human hairs, and

about \$2,700 worth of canned frozen lobster meat containing *E. coli* bacteria. The District also detained three lots of first-aid dressings from England, valued at about \$1,500, found to contain bacterial contamination.

CINCINNATI DISTRICT The Federal Executive Board/Federal Business Association of Greater Cincinnati recently honored George F. Calloway, a chemical analyst who serves as the District's equal opportunity officer, for his outstanding contribution to minority and youth employment programs. Mr. Calloway established a course in chemistry which he offered to students at a local high school.

FDA charges of adulteration with rodent filth and insanitary storage have brought about seizure of 72,800 pounds of flour, sugar, and cornmeal mix in possession of the Super-Value Stores, Inc., warehouse at Xenia, Ohio.

DALLAS DISTRICT Kenneth Hansen, District laboratory branch chief, appeared on the program of the third annual Animal Health Conference for Livestock Men held in Houston in January, and discussed FDA's monitoring of foods for residues. Also representing FDA was Dr. C. D. Van Houweling, director of the Bureau of Veterinary Medicine, Washington, who spoke on the Agency's role in preventing occurrence of drug residues in meat. The conference was sponsored by the Texas Veterinary Medical Association and the Texas A & M University.

The Southwestern Peanut Growers Association is continuing its policy of cooperation with the District for prevention of violations and better handling of foods. Representatives of the association called the District office to report a recent fire in one of the association's peanut storage houses and to discuss their proposed method of handling damaged and suspect peanuts. Because of this independent action, which is only one of a long, continuing cooperative policy by the association, District inspectors have been released from much surveillance and follow-up work.

Through the efforts of Bob Adams, in the District's special programs branch, a milk program has been set up with 16 cities throughout the District area whereby either city sanitarians or milk inspectors will collect milk for approximately six samples to be submitted to the District laboratory for pesticide residue analysis.

DENVER DISTRICT The variety of work in Region VIII and the all-around expertise of its personnel are shown in the types of legal actions taken by the District office in February. Frozen swordfish valued at \$1,257 and totaling 1,905 pounds was seized while in possession of Seattle Fish Co., Denver, because of mercury contamination. Approximately 2,000 more pounds of swordfish at other locations in the area was removed from commerce by voluntary destruction.

Because of lack of adequate directions for use and because the product is a new drug for which no approved New Drug Application exists, Viron I, a drug for human use, was seized while in possession of a local firm. The drug had been manufactured and shipped to the area by Lincoln Laboratories, Inc., Decatur, Illinois. Medicated animal feed valued at \$567 was seized while in possession of the manufacturer, John Ewing Co., LaSalle, Colorado, because it was a new drug without an approved New Drug Application; was misbranded due to lack of adequate warnings; carried false and misleading claims; and failed to declare on its label the presence of sulfamethazine, which it contained. To complete the picture, a violation in which the net quantity of contents did not conform to the Fair Packaging and Labeling Act led to the seizure of 104 pounds of boned salt codfish at Denver in possession of Booth Fisheries.

Among other activities the District held a workshop February 10-11 at Salt Lake City, Utah, in which participants were from the Utah State Departments of Agriculture and of Health and from local health departments. The workshop was a followup to one the District held last year that dealt with Current Good Manufacturing Practice regulations. Methods of reporting conditions found in food establishments was the main theme this year.

DETROIT DISTRICT Repackaging without applying proper labeling in conformance with the law brought about a recent seizure of olive oil valued at \$9,600. The product, packaged in a variety of different-size containers ranging from four ounces to one gallon, was seized at Mario's Food Products Co., Division of Beatrice Foods Co., Detroit. After receiving the olive oil in bulk quantities, the firm had repackaged it into consumer-sized containers that were not labeled in accordance with the Fair Packaging and Labeling Act.

KANSAS CITY DISTRICT The Topeka (Kansas) Mill & Elevator Co., Inc., has buried over 1.6 million pounds of previously seized aflatoxin-contaminated white corn, under FDA supervision, following approval for such disposition by the U. S. District Court of Kansas at Topeka.

District Court Judge George Templar ruled in FDA's favor December 18, 1970, after a trial of the issues—the question of legality of seizure in 1966 of the total amount, which consisted of a shipment of 448,000 pounds of aflatoxin-contaminated corn that had been returned to the Topeka firm and which it had combined with 1.2 million pounds of “good corn”; and whether the seized corn was an adulterated food because of the “added poisonous and deleterious” nature of the product. In ruling for FDA, the court stated that disposal of the corn would have to follow the Agency's direction and could not be used for human or animal consumption. Court costs, disposal expenses, and costs of loss of the produce involved were to be borne by the firm.

In deciding that the aflatoxin was an additive, the judge said that FDA had shown corn can be grown,

stored, and distributed without producing the mold growth. Witnesses for FDA established that aflatoxin is a known carcinogen and said there is no way to set an acceptable tolerance level for it in food.

LOS ANGELES DISTRICT On an alert from FDA of a possible hazard in a new drug that they had produced, five manufacturers in the Los Angeles District area recalled or held from sale estradiol valerate injections in which estradiol isovalerate replaced some or all of the active ingredient declared on the label. FDA's analysis showed that the raw materials used in production of the drug contained estradiol isovalerate, and in some cases, free estradiol. The raw material had been imported from Italy, and most of the lots had been distributed by Vivion Chemical Co., San Carlos, California. When the firms were informed by FDA that presence of the isovalerate compound caused the drugs to be new drugs without approved New Drug Applications, and that there was a health hazard due to the free estradiol content, the firms recalled the goods that had been distributed and held stocks in their plants.

A lot of 48 tons of cottonseed found by FDA to contain aflatoxin was seized at a feed dealer in Santa Fe Springs, California, where it had been shipped by Parker Valley Gin, Parker, Arizona. The dealer had intended the cottonseed to be used as feed for dairy cattle, but withheld it from sale while FDA analyses were being made and legal action taken.

Various aspects of sterile disposable medical devices were discussed at a workshop held by the District January 19 at Los Angeles. Talks given by representatives from FDA, industry, and a local hospital covered requirements of the law; problems of production, sterility testing, and quality assurance; and hospital needs and viewpoints. Approximately 130 people attended, representing 37 companies located throughout the United States, 13 local hospitals, the California Bureau of Food and Drugs, and FDA.

MINNEAPOLIS DISTRICT Because a concerned consumer complained to the proper authorities, a manufacturer was forced to correct a potential hazard involving his product—which illustrates the power the consumer may have if he uses it constructively. In June 1970 the consumer notified the District office that the label tag on a toy dog bank he had purchased was anchored with a metal tack and that easily removed, pointed upholstery tacks were used for the eyes. The complainant's year-old daughter had swallowed the tack from the label, but fortunately suffered no injury. When the accident occurred and before the consumer contacted FDA, the Wisconsin manufacturer had been notified of the problem and had begun working on it prior to the District's summer inspection and subsequent warning by letter. Affixing the tag label with a strong glue corrected a part of the problem but did not satisfy one of the largest distributors of the toy, who notified the manufacturer last November that he would no

longer stock the item until elimination of the hazard of upholstery-tack eyes. A month later the distributor received a shipment of the toys with the eyes consisting of securely glued-on plastic discs, which appear to present no further hazard.

NEW ORLEANS DISTRICT Adulteration was the chief reason for the District detaining imports offered for entry at the port of New Orleans during January, with misbranding a close second. Products detained because of adulteration included four lots of insect-infested coffee valued at \$149,457, decomposed catfish fillets valued at \$757, and one lot of mercury-contaminated tuna, of undetermined value. Misbranded articles, with a total value of \$8,911, included canned sardines, canned olive oil, and candy toys, all with inconspicuous labeling, and canned mackerel with false labeling.

NEW YORK DISTRICT On March 24, Beech-Nut, Inc., Rochester, New York, destroyed 3,982 cases of strained and junior baby food products packed at its Rochester plant in August 1970. Two products were involved, and both had been found by FDA's examination of official samples to contain cockroach fragments. These samples were two of those which were the subject of a recent hearing. Following this hearing, the firm's management concluded that they would destroy all remaining stock of the same coded products involved and still in their possession. Destruction was witnessed by the District's resident inspector at Rochester.

The District's Science Branch has developed a classification scheme based on the nuclear magnetic resonance spectra of 21 sulfonamides, and is sending the spectra and accompanying data to the *Journal of Pharmaceutical Sciences* for review and subsequent publication. A number of therapeutically useful sulfonamide drugs are often analyzed in FDA laboratories. Nuclear magnetic resonance spectroscopy is ideally suited to the identification of these drugs, since their solubility in suitable solvents makes attainment of desired solution concentration possible. In the new scheme, NMR spectra have been classified into four main groups after which the identification of a specific compound follows. This scheme provides rapid and simple identification of these drugs when they are encountered as unknowns.

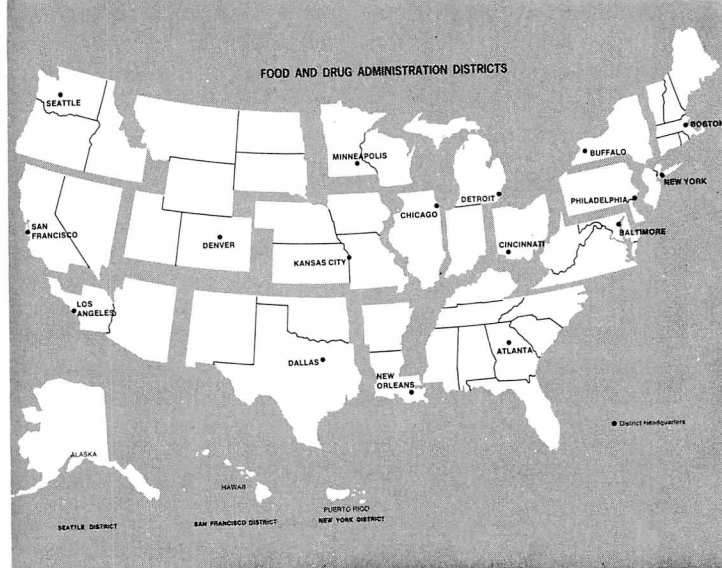
PHILADELPHIA DISTRICT In the recently concluded fish sampling and examining program, the District collected a total of 545 samples of tunafish, of which 67 were from lots offered for entry at the port of Philadelphia. Of the latter, six lots were found to contain mercury at levels exceeding 0.5 parts per million. The original importers are authorizing recall with eventual return of violative entries to the countries of origin. The District also sampled five lots of imported swordfish, of which two lots were found to be in excess of the 0.5 ppm guideline. These two lots, both in import status, have been denied entry.

SAN FRANCISCO DISTRICT Of the 102 commercial detentions by the District during February, coffee accounted for almost 50 percent. Based on its charges that the product had been stored under conditions whereby it may have become contaminated, the District issued 50 detentions on crude coffee, valued at greater than \$3 million, which had been stored and transported in a vessel infested with mice. The District ordered inspection of the ship after workers reported that mice were present in at least two of its holds. The lots of coffee are presently undergoing reconditioning by local surveyors under the supervision of District personnel.

Another vessel found to have rat infestation discharged some 77,000 pounds of crude coffee at San Francisco in late January. This lot of coffee, valued at \$38,000, was detained due to the presence of rodent urine.

SEATTLE DISTRICT William H. Meyers, doing business as Nampa-Caldwell Naturopathic Clinic, Basic Health Clinic, and Basic Health Center, Nampa, Idaho, was sentenced in the U.S. District Court for the District of Idaho, Southern Division, on January 26 for violating the Federal Food, Drug, and Cosmetic Act. On December 14, Mr. Meyers had entered a plea of guilty to illegally dispensing the drug, prednisolone. In passing the sentence of six months' imprisonment, which he suspended, and of three years' probation, Judge Ray McNichols sternly warned Mr. Meyers and made it a special condition of his probation that he not receive or dispense any medications that the law prohibits him from receiving or dispensing.

Starting in 1968, FDA became aware of the defendant's illegal sales of prescription drugs through complaints received from several physicians, from the Arthritis Foundation, from the Idaho and Oregon State



Boards of Pharmacy, from arthritis sufferers, and from Congressmen on behalf of complaining constituents. Some of these complaints involved damage to the health of users of the drugs received from Mr. Meyers. When FDA investigated, it found that the defendant had developed a mail-order business primarily in prednisolone tablets for the treatment of arthritis. The drug is a highly potent steroid that is to be used only under the careful supervision of a physician licensed by law to practice medicine. Mr. Meyers was not licensed by the State of Idaho either as a chiropractor or naturopath.

On August 20, 1969, FDA warned the defendant about his illegal activities, and he stated that he had discontinued dispensing prescription drugs as of August 1. In a continuing investigation, FDA found that between August 25 and September 10 Mr. Meyers made in excess of 80 shipments of drugs to "patients" in Oregon, Washington, California, and in Idaho. The charge on which he was sentenced in January involved a shipment of prednisolone tablets to an Oregon consignee.

FDA DISTRICT OFFICES

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

BALTIMORE 900 Madison Ave.
Baltimore, Md. 21201

BOSTON 585 Commercial St.
Boston, Mass. 02109

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

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

CINCINNATI 1141 Central Pkwy.
Cincinnati, Ohio 45202

DALLAS 3032 Bryan St.
Dallas, Tex. 75204

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

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

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

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

MINNEAPOLIS 240 Hennepin Ave.
Minneapolis, Minn. 55401

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

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

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

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

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

HEW REGIONAL OFFICES I-X

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

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

PHILADELPHIA 401 North Broad St.
Philadelphia, Pa. 19108

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

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

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

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

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

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

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

product safety report

ELECTRICAL BURNS AND SHOCKS TO CHILDREN

Extension Cords

The electric extension cord is an integral part of contemporary living. Increased use and availability of electrical appliances in apartments and homes have made the individual's need for extension cords almost mandatory. It is rare, even in newly constructed dwellings, that a sufficient number of electrical wall outlets are distributed in such locations that the use of extension cords is unnecessary.

FDA's Injury Study Units in Boston and Denver have investigated 20 accidents in which children have suffered electrical burns of the mouth involving extension cords. The intense heat produced in this type of accident almost invariably results in tissue damage to the lips with the tongue often involved. Healing is slow and permanent scarring of the mouth and lips often results.

Contrary to what might be believed, these accidents are not from children biting and chewing through the insulation on the cord. The accidents investigated involved two sequences—first, infants ranging from a few months of age and who are teething to children of about three years of age sucking or chewing on the receptacle of the cord; second, children attempting to disconnect the extension cord from an appliance service cord. In the latter sequence, since a child may not have the strength to pull apart a tight-fitting connection, he resorts to putting one end of the connection in his mouth and pulling on the other end with both hands. This sequence involved five accidents to children from four to nine years of age.

Regardless of how the accident occurs, electrical contact with resulting injury is quite similar. Saliva serves as the conductor, the moist mucous membranes of the mouth and lips offer little resistance to the flow of current, and an electrical arc results. The intense heat emitted by the arc causes tissue damage in a fraction of a second. If the child's body is well grounded—for example, if he is sitting in a wet diaper against a heating register that is grounded through the furnace—the accident could prove fatal.

Information concerning the manufacturer of the extension cords was not available in all the investigated cases. Some cords had been thrown away before the investigator arrived; one extension cord had been assembled by the victim's father. Only two of the 20 investigated cases indicated that the connection between the extension cord outlet and

the appliance service cord plug fit well and was easily engaged and disengaged. One of these two cases involved the homemade unit. Most of the extension cord sets checked in the Denver marketing area were found to fit poorly when the extension cord was disconnected from a power source and the plug end connected to the same cord's receptacle. In many cases, it was found impossible to make the junction complete so that no part of the electrodes was exposed.

Similar conditions were noted when a random selection of extension cords was taken from a store's supply and tried with other appliance service cords in the same store. The plug end of the extension cords, almost without exception, fit easily and snugly into standard wall outlets. This implies that the problem lies in the manufacture of the receptacle end of the extension cord.

One of the slots in an electrical outlet is connected to a "hot" wire and the other to a neutral wire. For current to flow, some material that will conduct electricity must complete a circuit between the "hot" wire and the neutral wire or ground. A small quantity of saliva, an excellent electrolyte, will start the flow of current between the "hot" and neutral wires in the extension cord terminal when the child places it in his mouth.

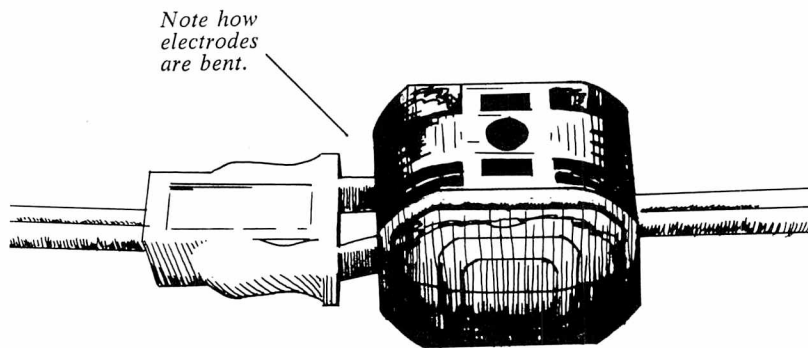
A review of the 15 cases investigated where sucking or chewing on the extension cord outlet was involved indicates that: All of the victims were between eight and 37 months old with the average age approximately 22 months and the median age 21 months. Nine were 24 months or younger. Eight victims were females; seven were males. Seven injuries occurred between 5 and 10 p.m.; six between 7 and 11 a.m.; and two after 11 a.m. and before 5 p.m.

In 10 of the 15 cases, the victim's mother was supervising the child at the time the injury occurred. The other five victims were supervised by a father, a babysitter, a grandfather, a grandmother, or an older brother. Eight cases stated that the supervisor was not in the same room with the victim. The other seven indicated that the supervisor was in the same room, but was not watching the victim at the time the injury occurred.

Electrical appliances for which the extension cords were used included: four lamps, four television sets (one had been previously disconnected), four clothes irons (one had been previously disconnected), and two sewing machines. One case occurred in a beauty salon, where the extension cord was connected to an electric hair clipper.

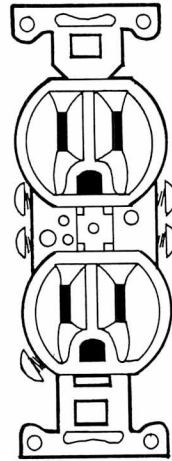
Two extension cords had no service cord plugs

Extension Cord Receptacle



Safety Outlet

Conventional grounded duplex outlet.



in them at the time the victims placed the receptacle end of the cord in their mouths. In 10 of the 15 cases, the electrodes were partially exposed. In one of these cases, it was believed that the victim partially disengaged the plug; in another, it was indicated that he may have. In only one case was it stated that the connection between the appliance service cord and the extension cord was completely closed. This information was not available for two of the cases. In only one of the 15 investigated cases involving sucking or chewing on the cord was the comment made that the cord was easily pulled apart, and this was the homemade cord. In almost all of the other cases, it was stated or implied that the junction between the receptacle end of the extension cord and the plug of the appliance service cord did not fit properly and that it was difficult to close the gap between the two units.

All of the accidents occurred in the home except the one in a beauty salon. Nine of the 15 occurred in the living room, three in the dining room, and two in a bedroom.

A review of the five cases involving attempts to disconnect an extension cord from an appliance service cord indicates that: Two victims were four years old. The other three were seven, eight, and nine. Three were females; two were males. The three youngest were females. All of the injuries occurred between 4 and 9 p.m.

A 17-year-old sister and 16-year-old brother were supervisors at the time one of the victims was injured. The other four victims were being supervised by their mothers. In two instances, the victims were trying to disengage the extension cord from lamp cords. The other three appliances involved were a set of

Christmas tree lights, a toy oven, and a television set.

Only one case definitely indicated that the electrodes were exposed prior to the victim's placing the extension cord junction in his mouth. The other four investigations did not determine this information.

Three of the accidents occurred in the living room and two in a bedroom of the victims' homes.

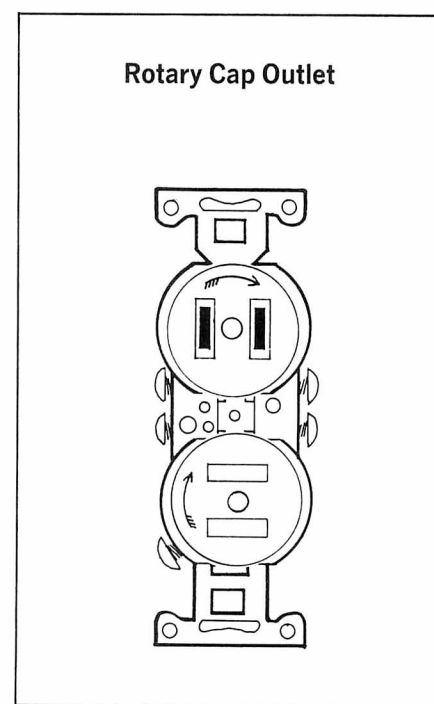
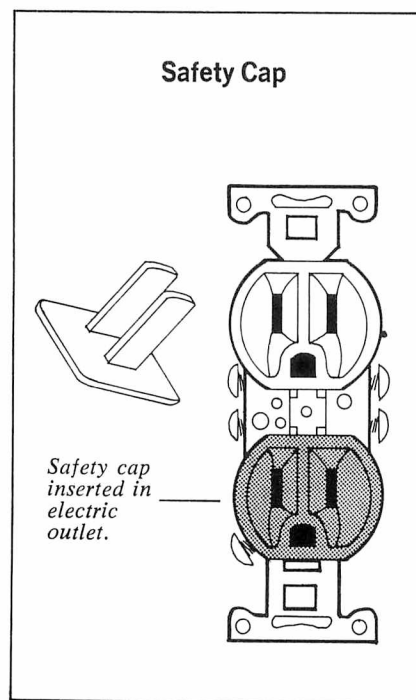
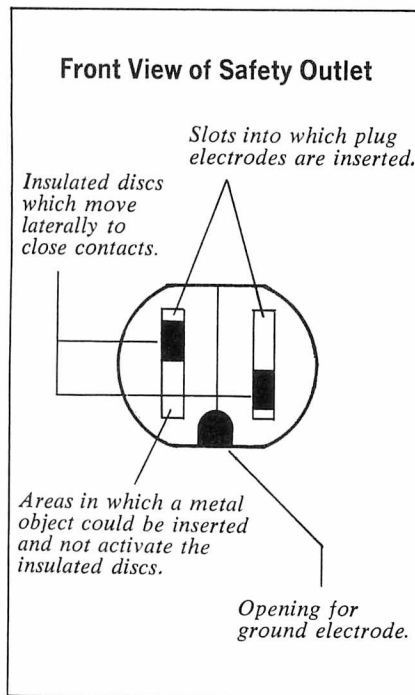
How can children be protected against such injuries associated with extension cords?

Builders and local manufacturers can help. The Uniform Building Code, less restrictive than the National Electrical Code, is generally incorporated into the ordinances of small city and county governments. It presently allows 12 feet between outlets, necessitating the use of extension cords in many cases. If outlets were no more than six feet apart, the need for extension cords could be reduced or even eliminated.

A person buying extension cords should inspect them to make sure that they are made to fit snugly into the wall outlet and that the receptacle is compatible with the plug appliance of the service cord.

On a semipermanent extension cord installation, the unused receptacles and the total connection should be covered securely with electrical tape—especially in the living room, since it appears this is the room in which most of the accidents occur. For instance, the two empty outlets on an extension cord's three-outlet receptacle form an excellent pathway for saliva to make electrical contact when a child places the receptacle in his mouth.

Furniture and furnishings should be arranged so that the number of extension cords needed can be reduced as much as possible. Essential cords should be



as short as possible, of heavy gauge, high quality, and with a receptacle that will accommodate only one service cord plug.

Metal Objects in Wall Outlets

The Denver Injury Study Unit has investigated 15 accidents in which children received burns and electric shocks from placing metal objects in wall outlets. The Boston Unit has investigated two accidents of this type, and two that occurred in this manner were reported from the University of Michigan's National Burn Information Exchange.

In eight of the 17 investigated cases (15 from Denver, two from Boston), the victims received burns on the thumb, index, and long fingers of one hand. One had four fingers burned on one hand. The rest had one or two fingers or portions of their hands burned. One child was burned on the thumb, index, and long fingers of both hands.

Since most of the victims were small children, it was difficult to learn exactly what happened at the time of the accident. However, in seven cases there was adequate evidence that the children received a substantial electric shock. For example, one parent reported the child was thrown across the room, and another said the child became pale and fainted.

The victims ranged in age from 20 months to six years. Eight were three years old. Males are more frequently involved than females in almost all kinds of accidents, but in these cases females outnumbered males almost two to one. Nine of the 11 females were three years of age or younger.

In 12 cases, the metal object inserted in the outlet was a hairpin. In two other cases a hair clip and barrette were used. Objects used were not identified in three cases. Eleven of the 17 victims were alone in

the room at the time of the accident. Three others were with other children. An adult was in the room at the time of the accident in only two cases.

This information was not available for one case. Twelve accidents occurred in bedrooms and three in living rooms. The two remaining accidents occurred in other unidentified areas of the home.

Unfortunately, the innocent looking wall socket lulls both parents and children into a feeling that it is harmless, but the electric current behind this innocent-looking facade is enough to cause burn injuries and to give a child a substantial electric shock.

How can children be protected against such injuries associated with wall outlets?

An inexpensive and effective action is to insert plastic safety caps in all wall outlets that are not in use.

A second approach is to consider the use of rotary cap outlets. These outlets have caps that must be rotated 90 degrees before the electrodes of the plug can be inserted in the slots. When the plug is removed, the spring loaded cap returns to its closed position. Unfortunately, this type of outlet is not designed for a system with grounded outlets. Therefore, although it could be effective in older homes, the effectiveness of the grounding safety feature in new buildings would be lost.

Another alternative would be to use a safety outlet that will accommodate a grounded plug and not allow current to flow if a metal object is placed in only one slot. Such an outlet is designed so that a metal object must be placed in both slots before current will flow from it. Even then, risk of injury to a child from inserting a metal object in both slots is reduced due to the design of this type of outlet.

news highlights

Second Warning Issued Against Use Of Two Poison Meat Tenderizers

FDA on March 19 repeated an urgent warning to consumers and restaurant owners in seven eastern and central States to refrain from using a meat tenderizer labeled "Spice of Life" or "Country Tavern" because some jars and cans of the product contain pure sodium nitrite, a deadly poison at high levels in foods.

The product, distributed regionally in Virginia, New Jersey, New York, Ohio, Kansas, Michigan, and Minnesota, is packaged in one and one-quarter pound jars and two and one-quarter ounce tins.

The jars are labeled "Spice of Life Meat Tenderizer" and sold primarily to restaurants and bars. The smaller containers, intended for retail marketing, are labeled "Country Tavern Meat Tenderizer."

An unknown quantity of the product was sold between March 1969 and October 1970. Several units, FDA said, contain 100 percent sodium nitrite.

The FDA action followed the death March 14 of a Maryland resident who ate garlic-flavored toast at a Washington, D.C., restaurant on which some of the mislabeled product had been sprinkled. A "Spice of Life" jar taken from the restaurant and examined by FDA scientists and the District of Columbia Health Department was found to contain 100 percent of the potentially deadly chemical.

The mislabeling problem was first brought to FDA's attention last November following a complaint by a Virginia restaurant owner that meat on which the "Spice of Life" product was placed turned green. After the Virginia Department of Agriculture and Commerce confirmed the presence of sodium nitrite in the containers, FDA issued a public warning November 19.

At that time, The Mutual Spice Company, Division of HyGrade Food Products, North Bergen, New Jersey, repacker of the product, initiated a voluntary recall from the retail level of the two meat tenderizer brands.

In issuing the warning, FDA advised restaurant owners especially to carefully check their stock to be sure that none of the mislabeled product is used.

FDA Begins Takeover of Arkansas Labs To Set Up Toxicological Research Center

The first step in converting an Army biological warfare experiments plant to a facility for improving consumer protection took place in special ceremonies April 14 at the Arsenal at Pine Bluff, Arkansas. Commissioner of Food and Drugs Charles C. Edwards, M.D., was presented a "right of entry" letter by Lt. Gen. W.W. Vaughan, deputy commanding general of the U.S. Army Material Command.

The Army is discontinuing research in biological warfare in response to a Presidential Order. The highly sophisticated equipment and staff at the Pine Bluff plant now will begin shifting to function as the National Center for Toxicological Research. In this new role, the facility will provide a national resource for projecting through animal studies the effects on man of an increasing array of chemicals in his environment.

In accepting the Army's authorization to begin conversion, Dr. Edwards said the action "represents a decisive step toward fulfillment of the commitment to improved environmental health and increased consumer protection."

Also present and participating in the ceremony were Senator John L. McClellan; Representative David Pryor, fourth Congressional District; Arkansas State Senator Knox Nelson, representing the Governor of Arkansas; Col. John Stoner, commanding officer of Pine Bluff Arsenal; and Dr. David W. Mullen, president of the University of Arkansas.

The new National Center for Toxicological Research will be a separate operation from the Pine Bluff Arsenal. The facility will occupy 504 acres of former Arsenal property. It will include 33 buildings with 1.7 million square feet of floor space.

Demilitarization of the biological warfare unit is expected to take 48 weeks. The Food and Drug Administration, Environmental Protection Agency, and other participating agencies will occupy the various laboratories as they become available.

FDA will administer the new facility but EPA and a number of other Government agencies will use the

Center for assessing potential health hazards from chemicals in foods and drugs and from environmental sources.

Commissioner Edwards said research activities at the Center will "not interfere or compete with the considerable contributions of private laboratories; neither will it relieve manufacturers of their responsibilities for assuring safety of their own products." He also reassured the 225 persons presently employed at the facility that FDA, EPA, and other cooperating agencies will insure opportunities for their continuing and productive employment.

Senator McClellan noted that the new facility offers opportunities for the University of Arkansas to strengthen its scientific research and education programs while making a significant contribution to the welfare of mankind.

Congressman Pryor lauded the conversion of the facility to peaceful purposes and cited benefits to the local community as well as to the Nation.

Early April Status Report Cites Events Concerning Contaminated Abbott Product

A status report on continuing efforts by Government and industry to solve the problem of contamination of intravenous solutions produced by Abbott Laboratories was announced April 2 by Commissioner of Food and Drugs Charles C. Edwards, M.D. As of that date, the announcement said:

1. FDA and the Center for Disease Control at Atlanta, Georgia, as well as Abbott are continuing intensive investigations to pinpoint the specific cause or causes for the contamination problem apparent in the Abbott screw-cap closure system. FDA presently has eight inspectors and a microbiologist at the Abbott plant in North Chicago. Nine other Chicago District inspectors are occupied full time on other phases of the investigation.

The Agency has completed its investigation at Abbott's other source of fluid production in Rocky Mount, North Carolina. Information is being evaluated and detailed laboratory analyses are in progress. All production at the North Carolina facility has been suspended by the company voluntarily.

While the overall investigation continues, Abbott's North Chicago plant is producing limited amounts of IV fluids to meet emergency hospital orders. All such orders are filled only after FDA investigation reveals that a hospital has exhausted all possibilities of obtaining fluids from sources other than Abbott. In meeting

the emergency production Abbott has with FDA approval switched from the elastomer to the Gilsonite plastic liner for the screw-cap closure. Gilsonite was used routinely by Abbott until February 1970 when Abbott began the introduction of the elastomer liner on some products.

An increasing incidence of contamination of the Abbott product can be traced to change to the elastomer liner. The Gilsonite liner appears to offer greater protection against the contamination problem, but the FDA believes that additional steps must be taken to assure that closures using the Gilsonite liner can be used satisfactorily in routine hospital practice.

Dr. Edwards said that FDA was sparing no effort to complete a thorough and prompt investigation of the Abbott situation. "Only when we are convinced that we have all the facts, will FDA make a decision on what further regulatory action, if any, is required," he said.

2. Abbott advised FDA that in addition to its continued intensive work on its present closure system to assure maintenance of sterility in the thread and cap component areas, it is evaluating the possibility of entering the market with a rubber bung-type closure system on some of its intravenous products. Other manufacturers of IV solutions presently employ this kind of closure. With the bung closure a hollow spike on the administration apparatus is forced through the rubber stopper. The system requires no cap removal as with the present Abbott system.

The company has experience with the bung-type closure and all components of the system have a proven use record.

FDA and Abbott scheduled a meeting early in April to consider the proposal. Abbott has been advised that FDA will require the full manufacturing and control data normally required for the introduction of a new product of this type. As soon as the FDA is assured of the safety of the proposed new closure system, Abbott will be permitted to institute production and distribution of this type of product.

3. Through its 17 District offices, FDA continues to coordinate and monitor the recall of all Abbott IV solutions. The recall was ordered March 22 after CDC data showed 350 cases of septicemia associated with IV infusion therapy in 21 hospitals using the Abbott solutions. At least nine deaths have been reported.

The recall necessarily is a phased recall and no absolute deadline can be set for completion. No Abbott solutions are being withdrawn from any hospital or other user until substitute fluids can be assured.

Before Abbott started the recall FDA had determined that adequate supplies from other manufacturers

were available on a short-term basis to meet the national need for about eight million units of IV fluids per month.

While the overall supply was determined to be adequate the logistics of getting this supply to where it is most needed and at the time needed is causing predictable difficulty. Noting the problems many hospitals had in supplying emergency needs, Dr. Edwards said: "The situation, however, is in hand at this time and we feel confident that no hospital will be without access to this vital therapeutic tool. At the same time the need to find permanent relief from the present supply situation is demonstrable and FDA is most hopeful that Abbott will be able to solve its closure problem and return to production as soon as possible.

"The one requirement FDA will insist upon," said Dr. Edwards, "is that Abbott return to the market only after we in FDA are convinced on the basis of good scientific data that the contamination problem has been resolved."

4. Abbott has advised FDA that the company is ordering recall of three of its Ion-O-Trate list numbers after testing by the company revealed microbial contamination of the glass thread area and the cap components. The company's Ion-O-Trate products provide additives such as potassium chloride and sodium chloride for IV solutions. Only Ion-O-Trate products with screw-cap closures similar to those on the larger volume IV solutions are involved.

Distribution of this product is limited. Abbott reports that only 625 customers receive shipments. Some 350 Abbott salesmen personally will carry out the recall.

Proposed Safety Standards Published For Class of Vehicles for Infants

New regulations proposed in the *Federal Register* of April 16, 1971, by the FDA would establish safety standards in the design and manufacture of a popular vehicle for infants, variously described as baby bouncers, walkers, or jumpers.

Commissioner of Food and Drugs Charles C. Edwards, M.D., noted that a partial list of injuries caused by these devices and reported to the FDA in the past 15 months includes 21 amputations or near amputations of fingers and other severe finger injuries to infants ranging from 4 months to 3 years of age. In addition to the finger injuries, lacerations and abrasions of the face have also been reported.

FDA had issued a warning to the public on February 26, 1971, describing the devices as potentially hazard-

ous and a cause of injuries to babies. Approximately 400,000 such vehicles are produced each year and more than a million are currently in use. Some manufacturers already have redesigned their products to incorporate safety features.

The new regulations are proposed under the Toy Safety and Child Protection Act of 1969 and would require that the frames of the devices be constructed so as to prevent scissoring or pinching. Coiled springs that expand to allow space for insertion of any portion of a child's anatomy would be required to be covered or designed to prevent injuries.

The proposed regulations would prohibit any holes, slots, cracks, or hinged components that might cause injury. Special provisions would also be made to prevent accidental collapsing or folding of the device.

Laundry Detergent Seized as Toxic, Manufacturer Agrees to Relabeling

In two separate, but coordinated actions, the Federal Government on March 8 seized 1,145 cases of laundry detergents on charges that the labeling failed to meet requirements of the Federal Hazardous Substances Act.

Commissioner of Food and Drugs Charles C. Edwards, M.D., said biological testing showed the two detergents "to be toxic, corrosive to skin and to cause severe eye irritation."

The two products are Ecolo-G Controlled Suds and Bohack No Phosphate Controlled Suds Detergent, both manufactured by the North American Chemical Corp. of Paterson, New Jersey. The Bohack product is distributed by H.C. Bohack Co., Inc., of Brooklyn, New York.

FDA announced later in the month, on March 31, that North American Chemical Corp. will relabel Ecolo-G and Bohack no-phosphate laundry detergents to include a danger warning to consumers on the package.

U.S. District Court Judge Orrin Judd in New York has supported the FDA contention that the two products were "misbranded, hazardous substances."

Officials of the detergent manufacturing company have agreed to affix sticker labels to their products in both wholesale and retail outlets in 44 States.

FDA said biological testing had shown the two detergents "to be toxic, corrosive to intact skin and the cause of severe eye irritation." Without proper labeling, the detergents were in violation of the Federal Hazardous Substances Act, FDA charged.

New labeling on the seized products will include the

following warning: "DANGER—MAY CAUSE BURNS—HARMFUL IF SWALLOWED—EYE IRRITANT. Contains sodium metasilicate. Avoid contact with skin, eyes, and mucous membranes. In case of external contact, flush with water. For eyes, flush with water for 15 minutes and get immediate medical attention. If swallowed, give large quantities of water or milk. Follow with citrus juice or dilute vinegar. Call physician immediately. KEEP OUT OF REACH OF CHILDREN."

The seizure of approximately 140 cases of Ecolo-G (each containing four packages) was made at 7000 Sheriff Road, Landover, Maryland, in possession of the Grand Union Co.

A second seizure of approximately 1,050 cases (each containing four packages) of Bohack No Phosphate Controlled Suds Detergent was made at the H.C. Bohack Co., Metropolitan and Flushing Avenues, Brooklyn, New York.

Malcolm W. Jensen, acting director of FDA's Bureau of Product Safety, said the seizures were based on failure of the packages to bear adequate labeling warning consumers of the hazards that could result if the products were accidentally swallowed or otherwise misused and failure of the labels to give adequate information on what to do if consumers are accidentally injured by the product.

Mr. Jensen said the two products are highly alkaline and animal tests showed them to be toxic when accidentally swallowed, a severe eye irritant, corrosive to the skin, and, in some cases, corrosive to mucous membranes. A number of new detergent products have been introduced and marketed during the last year in specific response to concern for environmental problems, he noted. "Some of these low-phosphate products have been tested and found to be currently in compliance with FDA regulations regarding product safety," he said. "Ecolo-G and Bohack No Phosphate Detergent are the only two which, to this time, have been found to be inadequately labeled."

15-month Reorganization of FDA Complete, Reports Dr. Edwards

Completion of a major Agency-wide reorganization has been announced by Commissioner of Food and Drugs Charles C. Edwards, M.D. Final steps in the reorganization involved restructuring of the Bureau of Foods and creation of a bureau devoted entirely to product safety.

The reorganization, carried out along product lines, was outlined by Commissioner Edwards in January 1970, shortly after his appointment as FDA head. Final changes in the plan were recently approved by Secretary of Health, Education, and Welfare Elliot Richardson.

The new structure, Dr. Edwards said, "represents a significant change in the FDA approach in management. It is designed to help us respond more effectively to today's demands, and to better meet the challenges of the future."

Other previously announced steps in the reorganization were creation of a Bureau of Drugs and restructuring of the Bureau of Veterinary Medicine. Within the new structure, only the latter Bureau existed when Dr. Edwards became Commissioner.

FDA believes the Bureau of Product Safety, previously an office in the Bureau of Foods, will enable the Agency to better carry out its responsibilities under the Federal Hazardous Substances Act, the Toy Safety Act, the Flammable Fabrics Act, and the Child Protection and Toy Safety Act. Other Bureau functions include operation of FDA's National Injury Surveillance System and vigilance over household products and appliances that have potential for personal injury.

A further change in Agency operations, FDA noted, resulted from the transfer of the former Office of Pesticides to the Environmental Protection Agency. Enforcement responsibilities covering acceptable pesticide residue levels in foods, however, remain with FDA.

July Start Set for National System For Injury Reports From Hospitals

A nationwide electronic system to provide overnight reporting of personal injuries treated in hospital emergency rooms will be inaugurated in July by the Food and Drug Administration.

The new system, to be known as the National Electronic Injury Surveillance System (NEISS), will be "a dramatic step forward in the Government's effort to reduce product-related injuries and deaths," according to Commissioner of Food and Drugs Charles C. Edwards, M.D.

More than 30,000 deaths and 20 million injuries, a majority product-related, occur annually in or near the home. Of these, approximately 8,500 deaths are caused by fires and burns. More than 2 million persons every year suffer burn injuries serious enough to require medical attention or restricted activity.

Malcolm W. Jensen, director of FDA's Bureau of

Product Safety, said the new system will provide information for prompt investigation and possible remedial action.

A statistical projection of national estimates will be made possible on the basis of injury reports drawn from more than 100 selected hospitals within the system. Injuries will be reported daily by hospital staff personnel using teletype equipment. During the night, a computer will "call" each terminal, collecting and sorting the data for presentation on the following morning.

When NEISS is fully operative, data will be collected on approximately 720,000 emergency room cases each year. Of these, some 9,000 cases will be selected for immediate in-depth field investigation. The system will report on injuries occurring in 350 categories of household products, including household appliances, home workshop tools, recreational equipment, and toys.

The new system is an expansion and further development of an injury surveillance network previously set up by FDA and a telephone reporting system developed by the National Commission on Product Safety. Future plans call for increasing reporting units to include hospital in-patient and physicians' office treatment.

FDA's Bureau of Product Safety, which will administer the program, has a broad mission to reduce product-related injuries and deaths. Through the Bureau, FDA enforces the Federal Hazardous Substances Act and has responsibilities under the Flammable Fabrics Act.

Major Changes Proposed by FDA In Antibiotic Disc Requirements

FDA published proposals in the *Federal Register* April 10 for major revisions of regulations covering discs used by physicians as guides in selecting antibiotics to treat specific kinds of infection.

The proposals encompass findings from a study by the National Academy of Sciences-National Research Council.

The Academy and an FDA advisory committee on anti-infective drugs have recommended standardizing the discs in size and strength. The advisory committee reported that the lack of standardization has in many instances reduced their dependability. FDA concurs, and is proposing to certify only single-strength quarter-inch size for antibiotics susceptibility discs.

Public Warned About Glass Particles In Two Shipments of Farina Cereal

The Food and Drug Administration warned consumers

on March 24 that some boxes of Farina Cereal manufactured by the Pillsbury Company, Minneapolis, Minnesota, at its plant in Springfield, Illinois, and distributed nationally, may contain glass particles and should not be used.

The product, marketed in retail stores under the name Farina Enriched Quick Cooking Hot Wheat Cereal, is sold in 27½-ounce cartons or in cases containing 12 cartons each. Two codes of the cereal, produced last November 23-24, are thought by Pillsbury to be affected. The contaminated product, FDA said, can be identified by the codes "KOW23" or "KOW24" imprinted on the top or bottom of the cereal cartons.

Pillsbury learned of the problem after a Connecticut resident complained of glass particles in Farina Cereal earlier this month. Acting on the complaint, Pillsbury checked plant records, examined samples, and linked the problem to glass breakage during product processing. The company then informed FDA it would recall the product from retail level and issued a press release March 23. The release was directed to news media in Connecticut and Massachusetts, the areas where the contaminated cereal was originally thought by the company to have been distributed.

New information obtained by FDA indicated distribution of the cereal was national, but no injuries associated with it have been reported, the Agency said.

Check of Metlox Pottery Completed; Lead Found in Two More Patterns

An intensive sampling program covering all 56 patterns of Metlox pottery, was announced by the FDA as completed and the Agency confirmed that some of the patterns contain excessive levels of leachable lead.

Two lead-contaminated patterns, identified by FDA March 26, are "Mission Verde" of the Poppytrail line and "Petalburst" of the Vernon line. In the latter pattern, only the dinner and salad plates leached excessive levels of lead. These patterns are in addition to six other patterns of the Metlox Poppytrail "Tempo" line recalled by the manufacturer earlier in March.

In releasing the results of the pottery survey, FDA said the manufacturer, Metlox Potteries, Inc., Manhattan Beach, California, is recalling all patterns containing violative or possibly violative levels of lead. Recall includes the entire "Tempo" pattern.

Pottery of the Metlox Poppytrail "Tempo" patterns under voluntary recall initiated March 1-2: Tempo Blue, pattern #441; Tempo Yellow, pattern #442; Tempo Beige, pattern #443; Tempo Terra Cotta (Orange), pattern #444; Tempo Olive Green, pattern #445; Tempo White, pattern #446. Holloware items are not labeled.

state actions

Iowa Official Commissioned L.B. Liddy, Secretary of the Iowa State Department of Agriculture, was commissioned January 12 as an officer of the Department of Health, Education, and Welfare involving animal feed compliance programs of the Food and Drug Administration. The State of Iowa thus becomes the third State in the FDA's Kansas City Field Office four-State Region to be selected for the joint State/FDA program.

In his letter of congratulation to Mr. Liddy, Commissioner of Food and Drugs Charles C. Edwards, M.D., stated in part: "In carrying out the responsibilities of this Commission, you will become involved in joint work planning and scheduling with the appropriate FDA District office, supervise the completion of certain FDA assignments by your staff and most important, play a key role on the State/Federal management team in reaching decisions affecting consumer protection in your area. I am aware that you already possess an outstanding reputation in the last factor, but I'm compelled to emphasize that both of us must now rely more heavily on each other's judgment."

Single System Action The New York State Board of Pharmacy held a disciplinary hearing March 19 against Sonorol Laboratories, the Bronx, at which the State utilized not only its own inspectional evidence but FDA's as well. New York District inspectors presented FDA's inspectional evidence showing non-compliance with Current Good Manufacturing Practice regulations. After all evidence was presented, Sonorol Laboratories' management stated they could not comply with the regulations and announced they were voluntarily discontinuing the manufacture of pharmaceuticals.

Sweetener Destroyed Officials of

the Puerto Rico Health Department recently ordered the destruction of 132,000 packets of artificial sweetener that contained 10 percent cyclamates. The action came about following an anonymous complaint to FDA's San Juan Section that the product was being used in a Puerto Rico government cafeteria.

Second-stage Lab Tests The food laboratory of the Oregon State Department of Agriculture had nearly completed its testing of foods for total mercury content, it announced in February, and was beginning to retest them for methyl mercury salts—the poisonous form of the chemical of greatest concern to man and the environment. According to Virgil Hiatt, the department's chief chemist, wheat flour and shellfish remained to be tested for total mercury content. Only traces of the total chemical had been found in random samples of foods tested up to that time. Science at this stage in its development considers these traces to be normal in nature, Mr. Hiatt said.

The laboratory was also undertaking new tests for methyl mercury salts in fish, beef, and eggs, and tests were to be extended to milk and other foods.

Seeks Injunction The Pennsylvania Bureau of Consumer Protection at a hearing January 25-26 before the Commonwealth Court at Harrisburg asked for a preliminary injunction to halt the promotion and sale of Hush Tone, a miniature tuning-fork device. The device is promoted as a speech clarifier and as a help for nerve deafness. The State's main element of proof was a report submitted in March 1970 by the Cleveland Hearing and Speech Center following its clinical study of the device in which it found the device worthless for such problems. Dr. David A. Metz, coauthor of the report, and Robert J. Kennedy, Divi-

sion of Clinical and Medical Devices, FDA, testified. The court denied immediate injunction and continued the case for a full hearing scheduled for May 17.

Commissioning Jim McHale, Secretary of the Pennsylvania Department of Agriculture, is now a commissioned officer in the Food and Drug Administration. The commission was presented to Mr. McHale by Loren Y. Johnson, deputy regional food and drug director for the Philadelphia District of the FDA.

Food Penalty Cases The New York State Department of Agriculture and Markets on February 23 released for publication a listing of food penalty actions it took in January. According to the Department's Commissioner, Don J. Wichham, a total of 230 firms doing business in the State, largely processors and sellers of food, were named in the penalty cases. Of the total number, 150 cases were settled by the department with many of them involving payment of civil compromise settlements, and the remaining 80 were referred to the State Attorney General for collection of a penalty in a civil action. Settlement payments made to the department in civil compromise totaled \$12,060.

Consumer Protection Six months after initiating its Consumer Protection Program, San Mateo County, California, successfully prosecuted a grocery store and its owner in Redwood City on 14 counts of possessing adulterated food and maintaining insanitary premises. The county based its charges on rodent and insect infestation that had been found in products stored on the grocery store premises. Judge Paul I. Myers of the Southern District Municipal Court at Redwood City fined the firm \$3,125.

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 76 seizure actions to remove from the consumer market products charged to be violative were reported in January. These included 42 seizures of foods: 5 involved charges concerning poisonous and deleterious substances, 23 involved charges concerning contamination, and 14 involved charges concerning economic and labeling viola-

tions. Other seizures included 3 of food additives, 4 of vitamins and dietary food, 20 of drugs (including 8 of veterinary and medicated feed), 1 of cosmetics, 4 of medical devices, 1 of prophylactics, and 1 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DÉALER (D)	CHARGES
FOOD / Poisonous and Deleterious Substances		
Cottonseed meal/Draper, Utah 1/4/71	Casa Grande Oil Mill/Casa Grande, Ariz. (M,S)	Contains aflatoxin, a poisonous substance, which may render it injurious to health.
Logan, Utah 1/5/71	"	"
Eggs, frozen, whole/Roxbury, Mass. 1/15/71	J. Fleishman & Co., Inc./Roxbury, Mass. (M)	Contain Salmonella micro-organisms; decomposed.
Roxbury, Mass. 1/13/71	"	"
Seed corn, treated/Laurinburg, N.C. 1/7/71	McNair Seed Co./Laurinburg, N.C. (D)	Contains methoxychlor, dieldrin, and captan, pesticide chemicals not in conformity with regulations.
Contamination, Spoilage, Insanitary Handling		
Almond slices/Hopkins, Minn. 12/1/70	Continental Nut Co./Chico, Calif. (P,S)	Contain insect-damaged nuts.
Brazil nuts/Fairhope, Ala. 12/16/70	Schermer Pecan Co., Inc./Fairhope, Ala. (D)	Held under insanitary conditions; rodent contaminated.
Cashew nuts, shelled/Portland, Oreg. 12/1/70	Johnson Nut Co./Hopkins, Minn. (P,S)	Prepared and packed under insanitary conditions; insect contaminated.
St. Paul, Minn. 12/15/70	Imported from Brazil. Simab Corp./New York, N.Y. (S)	Moldy, decomposed, and insect contaminated.
salted/Little Chute, Wis. 11/27/70	Johnson Nut Co./Hopkins, Minn. (P,S)	Prepared and packed under insanitary conditions; insect contaminated.
Cheddar cheese/Plymouth, Wis. 12/2/70	Gunder Co-op Cheese Factory/Gunder, Iowa (M,S).	Prepared and packed under insanitary conditions.
Fish, crabmeat, frog legs, crabs, lobster tails/Somerville, Mass. 12/22/70	Slade Gorton Co./Boston, Mass. (P,S)	Decomposed.
Flour/Mobile, Ala. 12/1/70	City Sales Co./Mobile, Ala. (D)	Held under insanitary conditions; rodent contaminated.
sugar, cornmeal mix/Xenia, Ohio 1/12/71	Super-Value Stores, Inc./Xenia, Ohio (D)	"
Fruitcake/Salem, Va. 12/21/70	Kent Bakers, Ltd./Newark, N.J. (M,S)	Prepared and packed under insanitary conditions; insect and rodent contaminated.
Grain, mixed/Bonnars Ferry, Idaho 1/12/71	Tri-County Elevator Co./Conrad, Mont. (M); Lees Carney Co./Portland, Oreg. (S)	Contains charred, moldy, insect-contaminated grain, nails, and rocks.
Jelly rings/Columbus, Ohio 11/9/70	Farley Candy Co./Skokie, Ill. (M,S)	Contain wood chips.
Lima beans, pinto beans/Alma, Ark. 12/29/70	HLH Products/Alma, Ark. (D)	Held under insanitary conditions; insect contaminated.
Nectar peach halves in heavy sirup/Charlotte, N.C. 10/22/70	George Noroian Cannery/Dinuba, Calif. (M,S)	Insect contaminated.
Pecan pieces/Honolulu, Hawaii 12/11/70	John B. San Filippo & Sons, Inc./Chicago, Ill. (M,S)	E. coli.
Pidgeon peas/Hialeah, Fla. 1/12/71	R. H. Hammond & Co./Hialeah, Fla. (P,D)	Insect contaminated.
Potatoes, hash brown/Little Rock, Ark. 1/12 and 1/15/71	Prosser Packers, Inc./Prosser, Wash. (M); North Pacific Cannery & Packers, Inc. (S)	Prepared and packed under insanitary conditions; staphylococci.
Rice "Mahatma"/Minneapolis, Minn. 12/7/70	North Star Warehouse, Inc./Minneapolis, Minn. (D)	Held under insanitary conditions; insect contaminated.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Contamination, Spoilage, Insanitary Handling (cont'd)		
Spaghetti rings/Milwaukee, Wis. 12/2/70	V. LaRosa & Sons, Inc./Westbury, N.Y. (M,S) (shipped from Chicago, Ill., and Warminster, Pa.)	Insect contaminated.
Walnuts, in shell/St. Louis, Mo. 1/11/71	Continental Nut Co./Chico, Calif. (P,S)	Prepared and packed under insanitary conditions; insect contaminated.
Flint, Mich. 1/18/71	"	"
meats, salted, mixed nuts/Boise, Idaho 12/2/70	Johnson Nut Co./Hopkins, Minn. (P,S)	""; label statement (mixed nuts) "filberts, pecans" false and misleading.
nuggets/Sheboygan, Wis. 11/3/70	"	Prepared and packed under insanitary conditions; insect contaminated.
Economic and Labeling Violations		
Avo brand dip/Albuquerque, N. Mex. 1/25/71	Ashley's Restaurant/El Paso, Tex. (M); Ashley's Frozen Foods/El Paso, Tex. (S)	Not in conformity with the Fair Packaging and Labeling Act.
Candy/Mableton, Ga. 12/3/70	Lamme's Candy Since 1885, Inc./Austin, Tex. (M,S)	"
Coffee/Superior, Wis. 12/10/70	Andresen-Ryan Coffee Co./Duluth, Minn. (M,S)	"
Fish, frozen/Kansas City, Mo. 1/19/71	Empire Cold Storage Co./Kansas City, Mo. (D)	Name "halibut steaks" and label statement "Ingredients: . . . Northern Flounder" are false and misleading. Cut portions of Greenland turbot have been substituted for halibut steaks.
Kidney beans/Miami, Fla. 1/12/71	Nicholas Polanco/Miami, Fla. (D)	False and misleading bag label "Net Wt. 14 Oz." and bale label "12/1 Lb. Pkgs." Bags contain less than 14 ozs., and bales contain less than 1-lb. packages.
Milk chocolate rabbits/New Orleans, La. 1/25/71	Merlin's Candies, Inc./New Orleans, La. (D)	Net weight does not appear on principal display panel.
Noodles, ring, macaroni, large shells/ Milwaukee, Wis. 10/30/70	Vesley Foods, Inc./Cicero, Ill. (M); Sostrin Food Products/Chicago, Ill. (S)	Not in conformity with the Fair Packaging and Labeling Act.
Olive oil, pure, imported/Detroit, Mich. 1/20/71	Mario's Food Products Co./Detroit, Mich. (D)	"
Pimiento halves in vinegar/Philadelphia, Pa. 12/17/70	Perfect Packed Products Co./Henderson, N.C. (M,S)	Bell peppers have been substituted for pimientos; garlic was not declared on label.
Pineapple pieces, canned/Jacksonville, Fla. 12/10/70	National Merchandise Co., Inc./Jacksonville, Fla. (D)	Label fails to bear the correct name, tidbits, as provided by definition and standard of identity for canned pine- apple; not in conformity with the Fair Packaging and Labeling Act.
Popcorn, yellow and white/Culloden, W. Va. 1/12/71	National Oats Co./Delaware, Ohio (M,S)	Not in conformity with the Fair Packaging and Labeling Act.
Salad dressing/Miami, Fla. 11/17/70	Brundidge Foods, Inc./Brundidge, Ala. (M,S)	Not in conformity with the Fair Packaging and Labeling Act.
Tomatoes, canned, peeled/Boston, Mass. 1/12/71	International Canning Industry Co./Elias, Greece (M,S)	Fail to conform to standard of identity for canned peeled tomatoes due to excess peel.
Waffles, frozen/Milford, Del. 11/23/70	Bachman Foods, Inc./Reading, Pa. (M,S)	Not in conformity with the Fair Packaging and Labeling Act.
Food Additives		
Cranberry juice cocktail, low calorie, artificially sweetened whole plums/ St. Paul, Minn. 12/10/70	Security Wholesale Grocery, Inc./St. Paul, Minn. (D)	Contain calcium cyclamate, an unsafe additive not in con- formity with regulation.
Fruit cocktail, apricots, bartlett pears, cling peaches, all low calorie, artificially sweet- ened/St. Paul, Minn. 12/10/70	"	"
Pottery dishes/Towson, Md. 12/28/70	Imported from Mexico (M,S, unknown)	Lead leaching from earthenware dishes.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Vitamins—Dietary Food		
Banana Beverage/Dallas, Tex. 12/30/70	Worthington Foods/Worthington, Ohio (M,S)	Not in conformity with the Fair Packaging and Labeling Act; label fails to bear information concerning dietary properties.
Delta Farms pollen extract tablets/Houston, Tex. 10/2/70	Brentwood Corp./Houston, Tex. (P,D)	False and misleading claims of revitalizing old people and aiding patients suffering from a wide range of physical ailments.
Vitamin A acetate capsules/West Chester, Ohio 12/15/70	Eric Kirk and Gary, Inc./West Chester, Ohio (D)	Strength differs from USP standard set for vitamin A capsules.
Vitamin C, A & P Complex/St. Petersburg, Fla. 11/17/70	LTC Pharmaceutical Corp./Evanston, Ill. (M,S)	False and misleading claims that there was a vitamin P and that Rutin and Hesperidin Complex were vitamins of special nutritional benefits; label fails to bear dietary properties.
DRUGS / Human Use		
Aknemed—Formulas A, B, C, labels, inserts, cartons/Birmingham, Ala. 12/16/70	The Aknell Corp./Birmingham, Ala. (P,D)	New drug not approved for safety and efficacy; name implies to be an effective treatment for acne conditions, which it is not; inadequate directions for various skin conditions.
Bentex Ulcerine/Houston, Tex. 1/13/71	E. W. Heun Co./St. Louis, Mo. (M,S)	New drug not approved for safety and efficacy.
Chaser for hangover tablets/Dallas, Tex. 1/27/71	Comay Laboratories, Inc./Lake Forest, Ill. (M,S)	"
Chorionic gonadotropin/Houston, Tex. 10/7/70	Glogau & Co., Inc./Chicago, Ill. (M,S)	Below labeled strength.
Dental cushions/Woonsocket, R.I. 12/9/70	Durasol Drug & Chemical Co./Amesbury, Mass. (M,S)	False and misleading claims for preventing and relieving sore gums; lacked warnings that article was for temporary use only.
Mykocert, medicated vaginal tampons/Chicago, Ill. 1/29/71	Beutlich, Inc./Chicago, Ill. (D)	False and misleading claims for most vaginal infections; lacked adequate directions for use; new drug not approved for safety and efficacy.
Obestat Ty-Med tablets/Dayton, Ohio 11/2/70	Lemmon Pharmacal Co./Sellersville, Pa. (M,S)	New drug not approved for safety and efficacy.
Red Arrow calamine lotion USP XV with 1% phenol/Dallas, Tex. 12/30/70	Distribution Service Co./Dallas, Tex. (D)	Lack of good manufacturing practice; strength differs from and quality falls below USP standard for calamine lotion with 1 percent phenol.
Sulfapyridine/Louisville, Ky. 12/30/70	Lusher Laboratories, Inc./Dayton, Ohio (M,S)	Below USP quality standard.
Sun-Ray heat liniment/New Orleans, La. 1/4/71	Sun-Ray, Inc./Siloam Springs, Ark. (M,S)	New drug not approved for safety and efficacy; net quantity of content statement not on principal display panel and in proper type size.
Thyroid 1 gr. USP/Grand Rapids, Mich. 1/7/71	Pill Mill, Inc./Grand Rapids, Mich. (D)	Strength differs from USP standard set for thyroid tablets.
Plainview, N.Y. 12/31/70	Marshall Pharmacal Corp./South Hackensack, N.J. (M,S)	Moldy.
Veterinary/Medicated Feed		
Big A Crumbles/LaSalle, Colo. 1/19/71	John Ewing Co./LaSalle, Colo. (D)	Contain new animal drugs, chlortetracycline and sulfamethazine not approved for use in animal feed; lack of good manufacturing practice; inadequate directions for use.
15% Hi Energy Range Cube/Vona, Colo. 1/20/71	Bill Koeller/Vona, Colo. (D)	Contain neomycin, not approved in animal feed; false and misleading labeling suggests the article to be beneficial at calving time; inadequate directions for use.
Leamycin/Clovis, Calif. 1/8/71	W-W Inc. (Kem Vet, Inc.)/Wisner, Nebr. (M) (shipped from Fremont, Nebr.)	New animal drug not approved for safety and efficacy.
Lipidex, Equikof/Oakland, Calif. 1/5/71	Burns Pharmaceuticals, Inc./Oakland, Calif. (M,S)	"
Medicated animal feed/Cheyenne, Wyo. 1/14/71	John Ewing Co./LaSalle, Colo. (M,S)	Animal feed containing chlortetracycline and ammonium chloride, not approved for safety and efficacy in such feed; lack of good manufacturing practice; inadequate directions for use and warnings.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Veterinary/Medicated Feed (cont'd)		
Misty dog food/Washington, D.C. 12/16/70	Quaker City Packing Co./Allentown, Pa. (M,S)	Contains methyltestosterone, not approved for safety and efficacy in animal feed; false and misleading labeling to be effective to enhance aggressive characteristics in shy dogs and watch dogs.
Thiabendazole cattle wormer/Longmont, Colo. 1/19/71	Malo Feed Co./Longmont, Colo. (D)	Below labeled strength in thiabendazole.
22% Three-in-One Super Cube/Colorado Springs, Colo. 1/20/71	J. D. Ackerman, Turkey Track Ranch/ Colorado Springs, Colo. (D)	Lack of good manufacturing practice; inadequate directions for use and warnings necessary for the protection of the users.
MEDICAL DEVICES		
E Z Breathe electronic air cleaner/ Winchester, Va. 12/31/70	M-Tron Industries, Inc./Yankton, S. Dak. (M,S)	False and misleading claims to filter the air in 14-18 minutes, remove bacteria and viruses from the air, make breathing easier, reduce discomfort of asthma.
Oxygen, emergency, spheres and kits/ Baltimore, Md. 1/12/71	Sav-A-Life Oxygen Co./Bala Cynwyd, Pa., and Lansdowne, Pa. (M,S)	False and misleading claims for emergency first aid; inaccurate quantity of content statement; inadequate warnings against unsafe methods and duration of application which may be dangerous to health.
Oxygen mask (Respirex)/Los Angeles, Calif. 12/17/70	Tothas Miczka K.G./Westfalen, Germany (M,S)	False and misleading claims for treatment of heart attack, choking, accident shock, electrical shock, bronchial asthma.
Vacu-Maid vacuum cleaning device/ Murfreesboro, Tenn. 1/6/71	Vacu-Maid, Inc./Ponca City, Okla. (M,S)	False and misleading claims for preventing family epidemics, internal poisoning, skin infections, and respiratory disorders.
Prophylactics		
Sheik rubber Nos. 27 and 30/Milwaukee, Wis. 12/2/70	Julius Schmid, Inc./West Paterson, N.J. (M,S)	Defective quality.
Cosmetic		
Omni IV body cream/Miami, Fla. 12/22/70	R. W. Vandette/Miami, Fla. (Custodian)	Fails to bear the net quantity of contents declaration as provided by the Fair Packaging and Labeling Act.
HAZARDOUS SUBSTANCE		
Glass Ornaments/San Juan, P.R. 8/19/70	H. Hirai Trading Co., Inc./Tokyo, Japan (M,S)	Contain petroleum distillates which make ornaments combustible and a special hazard; label fails to state conspicuously distributor or seller and name of chemical.

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

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

January 25, 1971: False Representation Order issued against Dr. Sam Godo, P.O. Box 903, Manila, Philippines. Advertising

and sale by mail of a product called "KH3," represented to be effective in reversing the aging process.

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

January 21, 1971: **Bis-Cott Corp.**, 1199 Broadway, New York, N.Y. 10001. Solicitations of orders and sales through the mails of "Power-Plus" formula (pills), represented as a virility rejuvenation tonic enabling users to attain second-youth sexual restoration.

January 28, 1971: **Excelsior**, Dept. E151, 6311 Yucca, Street, Hollywood, Calif. Advertising and sale by mail of "Excelsior Tablets" and "Easy to follow plan," represented as enabling users to lose all the unsightly, unnecessary weight desired without starvation dieting.

notices of judgment

NOTICES OF JUDGMENT on Seizure Actions FOOD/Poisonous and Deleterious Substances

- Carrots**, at Grant, W. Dist. Mich.
Charged 7-10-70: when shipped by Romar Carrot Co., Guadalupe, Calif., the article contained a quantity of the pesticide chemical, dieldrin, in excess of the tolerance; 402(a)(2)(B). Consent decree ordered destruction. (1)
- Chubs, gutted, iced**, at Monmouth Beach, Dist. N.J.
Charged 11-3-69: when shipped by Acme Smoked Fish Corp., Brooklyn, N.Y., the article, labeled in part "Acme Smoked Fish Corp. . . . From Union Fisheries Corp. . . . Chicago, Ill.," contained the pesticide chemicals, DDT, DDE, TDE, and dieldrin for which no tolerance of exemption on fish had been prescribed; 402(a)(2)(B). Default decree ordered destruction. (2)
- Meat scraps, dried**, at Memphis, W. Dist. Tenn.
Charged 8-5-70: when shipped by Sars of Louisiana, Div. of Gulf Soap Corp., Baton Rouge, La., the article contained the poisonous and deleterious substance, *Salmonella* micro-organisms; 402(a)(1). Consent decree authorized release to the shipper for reprocessing. (3)

FOOD/Contamination, Spoilage, Insanitary Handling

- Butter**, at Louisville, W. Dist. Ky.
Charged 8-11-70: when shipped by Sugar Creek Foods, Louisville, Ky., and thereafter returned to the shipper from Cincinnati, Ohio, the article contained decomposed butter; 402(a)(3). Default decree ordered destruction. (4)
- Cornhusks**, at Phoenix, Dist. Ariz.
Charged 6-25-70: when shipped by George Walcher, Weimar, Tex., the article contained insect filth and moldy cornhusks; 402(a)(3). Default decree ordered destruction. (5)
- Egg yolks, frozen**, at Louisville W. Dist. Ky.
Charged 8-24-70: when shipped by Illini Egg Products, Inc., Olney, Ill., the article contained decomposed eggs; 402(a)(3). Default decree ordered destruction. (6)
- Milk, nonfat, dried**, at St. Louis, E. Dist. Mo.
Charged 7-9-70: when shipped by N. M. Swank Co., Inc., Iowa City, Iowa, the article contained insect fragments and burnt particles, and was unfit for food due to an uncharacteristic odor and flavor; 402(a)(3). Default decree ordered destruction. (7)
- Onion rings, breaded, frozen**, at Dallas, N. Dist. Tex.
Charged 7-24-70: when shipped by Miller's Prepared Potato Co., Inc., Blue Island, Ill., the article contained insect filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (8)
- Pecan pieces, Sunny South**, at Charlotte, W. Dist. N. C.
Charged 5-14-70: when shipped by Sunny South Pecan Co., Statesboro, Ga., the article contained *E. coli*; 402(a)(3). Default decree ordered destruction. (9)
- Rice**, at Tulsa, N. Dist. Okla.
Charged 7-23-70: while held by Downtown Warehouse Co., Tulsa, Okla., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (10)
- Soy grits, toasted**, at Vernon, C. Dist. Calif.
Charged 8-6-70: while held by Flour, Inc., Vernon, Calif., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Archer Daniels Midland Co., Decatur, Ill., for conversion to animal feed. (11)
- Spaghetti in a sauce, canned**, at Alma, W. Dist. Ark.
Charged 3-6-69: while held by HLH Products Division, Hunt Oil Co., Alma, Ark., who manufactured the article from flour shipped in interstate commerce, the article contained rodent hair and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). The article was claimed by the dealer, interrogatories were served by the Government and by the dealer, and subsequently answered. A Government request for admissions was also served on the dealer. Thereafter a consent decree of destruction was entered. (12)
- Sugar, beet, granulated**, at Baltimore, Dist. Md.
Charged 8-6-70: when shipped by Pine Street Trading Corp., New York, N.Y., from the premises of the Chesapeake Operating Co., Baltimore, Md., to Elizabethtown, Pa., and thereafter returned to Baltimore, Md., the article had been held under insanitary conditions in bags contaminated with antimony ore dust; 402(a)(4). Default decree ordered destruction. (13)
- Sugar, beet, granulated**, at Morgantown, N. Dist. W. Va.
Charged 7-1-70: when shipped by The Chesapeake Operating Co., Baltimore, Md., the article had been held under insanitary conditions in bags contaminated with antimony ore dust; 402(a)(4). Consent decree ordered destruction. (14)

FOOD/Economic and Labeling Violations

- Cheese dip, frozen, K-SO Dip**, at Denver, Dist. Colo.
Charged 7-20-70 and amended 7-31-70: when shipped by Ashley's Frozen Foods, El Paso, Tex., the article was in violation of the Fair Packaging and Labeling Act, in that the declaration of net quantity of contents was stated on only one of the two alternative principal display panels, since the net quantity of contents on the one panel was not separated from printed information above it; and in that the area of that panel was between 5 and 25 square inches and the net quantity of contents was stated in a type size less than $\frac{1}{16}$ inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Default decree authorized donation to charitable institution. (15)

- Crawfish Etoufee, frozen**, at San Antonio, W. Dist. Tex.
Charged 7-17-70: when shipped by Cajun Country, Inc., Breaux Bridge, La., the article, labeled in part "Cajun Country Crawfish Etouffe E . . . Breaux Bridge Fine Foods Compagnie, Inc., Breaux Bridge, Louisiana," was in violation of the Fair Packaging and Labeling Act, in that the quantity of contents declaration was not in the bottom 30 percent of the principal display panel; in that the area of that panel was between 5 and 25 square inches and the quantity of contents was stated in a type size less than $\frac{1}{16}$ inch high; and in that the label stated "Serves One or two" and lacked the net quantity of each such serving; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i), 1453(a)(4). Consent decree authorized release to the shipper for relabeling. (16)
- Flounder, frozen**, at Gloucester, Dist. Mass.
Charged 7-16-70: while held for sale after being repacked by Massachusetts Coastal Seafoods, Inc., Gloucester, Mass., codfish had been substituted for flounder, the label statement "Flounder" was false and misleading, and the label lacked the name and place of business of the manufacturer, packer, or distributor and the common or usual name of the article, namely, codfish; 402(b)(2), 403(a), 403(e)(1), 403(i)(1). Consent decree authorized release to F. W. Bryce, Inc., Montreal, Canada, for relabeling. (17)
- Honeys, clover, sage, orange, and clover-alfalfa, Miller's**, at Denver, Dist. Colo.
Charged 7-15-70: when shipped by Miller's Honey Co., Salt Lake City, Utah, the 1-lb. size jars of clover honey were approximately 3 percent short weight—403(e)(2); and all the honeys were in violation of the Fair Packaging and Labeling Act, in that both the 1-lb. size and 7-oz. size jars of clover honey had their label statements of identity and their quantity of contents declaration on lines not generally parallel to the jar's base, and the quantity of declaration was not separated from other printed label information appearing above and to the left of the contents declaration—15 U.S.C. 1453(a)(1), 1453(a)(2); the net quantity of contents of the sage, orange, and clover-alfalfa honeys were expressed as "Net Wt. 1 Lb." and "Net Wt. 1 Lb. 8 oz." instead of "Net Wt. 16 oz. (1 lb.)" and "Net Wt. 24 Oz. (1 lb. 8 oz.)"—15 U.S.C. 1453(a)(3)(C)(i); and the sage honey, the orange honey, and the 1-lb. size and 7-oz. size clover honeys had principal display panel areas of between 5 and 25 square inches and their net quantity of contents were stated in a type size less than $\frac{1}{16}$ inch high—15 U.S.C. 1453(a)(3)(C)(i). Consent decree authorized release to the shipper for relabeling. (18)
- Lollipops, liquor flavored**, at New York, S. Dist. N.Y.
Charged 12-26-67: when shipped by Four Star Candy Co., Inc., Newark, N.J., the article's labeling contained statements which were misleading, since they suggested and implied that the article was flavored with liquor, whereas it was not so flavored; 403(a). A. Freed Novelty, Inc., New York, N.Y., filed an answer denying that the labeling was misleading and affirming that the labeling was such that the ordinary individual under customary conditions of purchase and use would understand that the article contained no alcohol or liquor but merely simulating flavoring. A motion for judgment on the pleadings was filed by the Government and was denied by the court in an opinion in which it held that the motion should be treated as one for summary judgment and that it could not be concluded as a matter of law that no material issue existed with respect to the misleading character of the labeling. Thereafter an order for the discontinuance of the action was entered pursuant to stipulation of the parties. (19)
- Noodles, frozen, Grandma's**, at Salt Lake City, Dist. Utah.
Charged 7-20-70: when shipped by L.A. King Food Products Co., Inc., Denver, Colo., artificial color had been added to the article so as to make it appear better or of greater value than it was; its label lacked the common or usual name of each ingredient, since the artificial colors FD&C Yellow No. 5 and No. 6 had not been declared, and it contained artificial coloring and lacked a label stating that fact—402(b)(4), 403(i)(2), 403(k); and the article was in violation of the Fair Packaging and Labeling Act, in that the declaration of net quantity of contents was not in the bottom 30 percent of the principal display panel, in that the net quantity of contents was not separated from printed label information below it, in that the principal display panel had an area of between 25 and 100 square inches, and the net quantity of contents was stated in a type size less than $\frac{1}{16}$ inch high, and in that the label stated "Four Servings" and lacked the net quantity of contents of each such serving—15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i), 1453(a)(4). Default decree authorized donation to a public institution. (20)
- Salmon, smoked**, at Santa Rosa, N. Dist. Calif.
Charged 7-27-70: when shipped by Specialty Seafoods, Anacortes, Wash., the article, labeled in part "Specialty Brand Smoked Barbe-Cured Salmon . . . Packed for International Packing Co. . . . Minneapolis, Minn.," was in violation of the Fair Packaging and Labeling Act, in that the quantity of contents statement was not in the bottom 30 percent of the principal display panel, and in that the area of that panel was between 5 and 25 square inches and was stated in a type size of less than $\frac{1}{16}$ inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Default decree authorized donation to charitable institution. (21)
- Shrimp, frozen, Belle O'Sea**, at Milwaukee, E. Dist. Wis.
Charged 7-2-70: when shipped by Palacios Freezer, Inc. (subsidiary of Atlanta Trading Corp.), Palacios, Tex., the article was in violation of the Fair Packaging and Labeling Act, in that the net quantity of contents statement was expressed as "Net Wt. 3 Lbs." instead of "Net Wt. 48 Oz. (3 Lbs.)" and in that the principal display panel of the packages had an area of between 100 and 400 square inches and the net quantity of contents on the panel was stated in a type size less than $\frac{1}{16}$ inch high; 15 U.S.C. 1453(a)(3)(A)(i), 1453(a)(3)(C)(i). Consent decree authorized release to shipper for relabeling. (22)
- Soups, minestrone and vegetable, frozen, Kubro**, at Chicago, N. Dist. Ill.
Charged 5-25-70: when shipped by Kubro Foods, Los Angeles, Calif., the label statement "Positively . . . No Sugar, No Starches" was false and misleading, since the articles contained macaroni, potatoes, barley, peas,

beans, and other vegetables, which contained carbohydrates including sugar and starch; the label statement, "Kubro Soups are Richer & Tastier, yet have only 1/3 the Calories of Ordinary Soups," was false and misleading, since it was contrary to fact; and the articles were represented for special dietary use and lacked the percent by weight of protein, fat, and available carbohydrates and the number of available calories—403(a), 403(j); and the articles were also in violation of the Fair Packaging and Labeling Act in that the labeling stated "to make 5-6 servings . . . to make 2-3 servings" but lacked a net quantity statement for each such serving—15 U.S.C. 1453(a)(4). Consent decree authorized release to shipper for relabeling. (23)

Spaghetti, Golden Wheat, at Millard, Dist. Nebr.

Charged 6-29-70: when shipped by Creamette Co., Minneapolis, Minn., the article was in violation of the Fair Packaging and Labeling Act, in that the quantity of contents was expressed as "2 Lbs. Net" instead of "Net Wt. 32 Oz. (2 Lbs.)"; 15 U.S.C. 1453(a)(3)(A)(i). Consent decree authorized release to shipper for relabeling. (24)

Strawberry fruit filling, canned, Juliann, at Chicago, N. Dist. Ill.

Charged 7-17-70: when shipped by Emerald Foods, Inc., Emerald, Wis., the article was in violation of the Fair Packaging and Labeling Act, in that the declaration of net quantity of contents was not in the bottom 30 percent of the principal display panel; in that the net quantity of contents was expressed as "Net Wt. 1 Lb. 2 Ozs." instead of "Net Wt. 18 Oz. (1 Lb. 2 Oz.)"; and in that the principal display panel had an area between 5 and 25 square inches and the quantity of contents was stated in a type size less than 1/8 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i). Default decree authorized donation to a charitable organization. (25)

Tea mix, lemon-flavored, Lipton, at Philadelphia, E. Dist. Pa.

Charged 7-17-70 and amended 8-5-70: when shipped by Thomas J. Lipton, Inc., Flemington, N.J., the article was in violation of the Fair Packaging and Labeling Act, in that the label statement of net weight on the bottles was expressed as "Net Wt. 24 Oz." instead of "Net Wt. 24 Oz. (1 Lb. 8 Oz.)"; 15 U.S.C. 1453(a)(3)(A)(i). Consent decree authorized release to the shipper for relabeling. (26)

Tomato juice cocktail, Red Label, at Cranston, Dist. R.I.

Charged 7-29-70: when shipped by S. S. Pierce Co., Boston, Mass., the article was in violation of the Fair Packaging and Labeling Act, in that the declaration of net quantity of contents was not placed within the bottom 30 percent of the principal display panel, in that the net quantity of contents was expressed as "Net Cont. 1 Pt. 10 Fl. Oz." instead of "Net Contents 26 Fluid Oz. (1 Pt. 10 Oz.)" and in that the principal display panel had an area of between 5 and 25 square inches and the net quantity of contents was stated in a type size less than 1/8 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(3)(C)(i). Default decree ordered destruction or donation to charitable institution. (27)

VITAMINS/DIETARY FOODS

Cola beverage, New Diet Rite, at St. Paul, Dist. Minn.

Charged 10-13-70: while held by Gold Medal Beverage Co., St. Paul, Minn., who manufactured the article from a concentrate shipped in interstate commerce, statements on the bottle labels were false and misleading as to the absence of sugar and as to the presence of sodium cyclamate, .1 percent or less carbohydrates, and 1/6 or less calories per ounce; the bottle label failed to declare the ingredient sugar; [and the carton labels lacked a notice to disregard as incorrect any information on the bottles of the article which was contrary to that on the cartons, i.e. (carton) "Sugar Added No cyclamate . . . 6 Calories and approximately 1 1/2 grams of carbohydrates"; 403(a), 403(j)(2). Consent decree authorized release for relabeling. (28)

FOOD ADDITIVES

Lime beverage mix, and lime beverage concentrate, at Auburn, Dist. Mass.

Charged 6-12-70: while held for sale, the articles contained the non-conforming food additive, cyclamate; 402(a)(2)(C). Default decree ordered destruction. (29)

Noodles, 2 seizure actions, at Pocatello, Dist. Idaho.

Charged 9-29-70: when shipped by Pot O' Gold Noodle Co., Inc., Helena, Mont., the article contained the nonconforming food additive, chlordanes; 402(a)(2)(C). Default decree ordered destruction. (30)

DRUGS/Human Use

Digoxin tablets, U.S.P., at St. Petersburg, M. Dist. Fla.

Charged 8-17-70: when shipped by Morton Pharmaceuticals, Inc., Memphis, Tenn., the quality of the article, labeled in part "Cardioxin . . . Digoxin U.S.P." Manufactured For Daniels Pharmaceuticals, Inc. St. Petersburg, Florida, fell below U.S.P. standards, since the article failed the U.S.P. test for content uniformity; 501(b). Default decree ordered destruction. (31)

Frenquel azacyclonol hydrochloride tablets, N.F., at Vinita, N. Dist. Okla.

Charged 8-3-70: while held for sale, the labeling lacked adequate directions for use, and the article was not exempt from such requirement, since it was a new drug for which no approval of a New Drug Application was [currently] effective and no notice of claimed investigational exemption was on file; 502(f)(1). Default decree ordered destruction. (32)

Iodinated casein tablets, at Garfield, Dist. N.J.

Charged 10-24-69: when shipped by Beth Corp., Miami, Fla., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (33)

Iodinated casein tablets, at San Francisco, N. Dist. Calif.

Charged 10-1-69: when shipped by Beth Corp., Miami, Fla., the article was a new drug without an effective approved New Drug Application; 505(a). Consent decree ordered destruction. (34)

Lans Formula 4 lanolin-combination medicated skin lotion, at Oakland, N. Dist. Calif.

Charged 8-19-70: while held by Lura-Glo Products, Inc., who manufactured the article from ingredients shipped in interstate commerce, the circumstances of the article's manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice—501(a)(2)(B); the bottled article lacked an accurate statement of the quantity of contents—502(b)(2); both the bottled article and the article in bulk containers lacked the established name of each active ingredient and lacked adequate directions for use in the conditions for which it was offered, since those conditions were not amenable to treatment by laymen—502(e)(1)(A)(ii), 502(f)(1); and the bottled article was in violation

of the Fair Packaging and Labeling Act in that the net quantity of contents was not stated on the principal display panel—15 U.S.C. 1453(a)(2). Default decree ordered destruction. (35)

Vitamin, mineral, and hormone combination tablets, at Hollywood, S. Dist. Fla. Charged 4-20-70: when shipped by Bates Labs., Inc., Chicago, Ill., the article, labeled in part "Tablets Geriatricum Geriatric-Vitamins, Minerals and Lipotropic Factors with Hormones . . . Generix Drug Sales, Hollywood, Florida . . . Distributor," was manufactured and packed under circumstances that lacked conformity with current good manufacturing practice, and the article's labeling lacked adequate directions for use and did not comply with the Rx drug exemption requirements, since the labeling failed to bear an identifying lot or control number; 501(a)(2)(B), 502(f)(1). Default decree ordered destruction. (36)

DRUGS/Veterinary

Diethylcarbamazine syrup, at Brunswick, S. Dist. Ga.

Charged 10-26-70: when shipped by Babineaux's Pharmacy, Metairie, La., the article was a new animal drug without an effective approved New Animal Drug Application; 501(a)(5). Default decree ordered destruction. (37)

MEDICAL DEVICES

Dynabelt electronic muscle stimulator belt, at Kansas City, W. Dist. Mo.

Charged 5-5-69: when shipped by Dynatone Electronics Corp., Wichita, Kans., the accompanying leaflet contained false and misleading claims for effortless muscle exercise, taking inches off of problem areas such as waistline, tummy, hips, and back, giving trimmer, sharper figure, and the achievement and maintenance of such results without special dieting and weight loss; and the labeling lacked adequate warnings against unsafe use; 502(a), 502(f)(1). The shipper claimed the article and denied that the article was misbranded. The claimant and the Government served written interrogatories on each other. Following notice that the claimant had filed a petition for reorganization and after claimant failed to appear as ordered, a default decree ordering destruction was entered. (38)

Oxygen inhaler and cartridge, Air-Aid, at Miami, S. Dist. Fla.

Charged 4-7-70: when shipped by Universal Cryogenics, Inc., New York, N.Y., the labeling lacked adequate directions to supply emergency oxygen for lay medical use, and adequate directions for safe use could not be written, since the article contained an insufficient quantity of oxygen; 502(f)(1). Default decree ordered destruction. (39)

Respirator, at Myers, N. Dist. N.Y.

Charged 9-22-69: when shipped by Crown Products Co., Cleveland, Ohio, the article, labeled in part "For Every Breathing Difficulty . . . Res-Q-Aire Emergency Respirator . . . A Product of Machsa Incorporated Distributed exclusively by Crown Products Co. . . A Division of the Chilcote Company," bore the name "Res-Q-Aire" and statements on the carton label and attached card which were false and misleading as to the adequacy and effectiveness of the article as a means of resuscitation; the labeling lacked adequate directions for use, and such could not be written, since the article was neither effective nor safe for its intended purpose; the labeling lacked warnings against use involving obstructions, aspirated objects and dentures, and involving infants of children where the volume of air would be excessive; and the article was dangerous to health when used as directed by its labeling; 502(a), 502(f)(1), 502(f)(2), 502(j). Default decree ordered destruction. (40)

Theramic model A-6DT40 electronic instrument, at El Paso, W. Dist. Tex.

Charged 6-30-70: when shipped, the article's labeling lacked adequate directions for use for purposes intended, and adequate directions could not be written for use by laymen for such purposes; and the article did not comply with the Rx device exemption requirements, since adequate information could not be furnished under which practitioners could use the article safely and for the purposes intended; 502(f)(1). Default decree ordered destruction. (41)

Theramic model A-6DT40 electronic instrument, at Odessa, W. Dist. Tex.

Charged on or about 7-8-70: when shipped, the article's labeling contained false and misleading claims for the treatment of infections, otitis media, fractures, bone and tissue healing, smooth muscle spasm, bursitis, arthritis, low back pain, sinusitis, urinary tract infections, prostatitis, and hepatitis; its labeling lacked adequate directions for such uses, and adequate directions could not be written, since the article was worthless for such uses; and the article was dangerous to health when used in the dosage and with the frequency and duration recommended in its labeling, since it was ineffective for the treatment of the serious disease conditions represented, and by reason of its ineffectiveness it was unsafe for such use; 502(a), 502(f)(1), 502(j). Default decree ordered destruction. (42)

HAZARDOUS SUBSTANCES

Cherry bombs, and M-80 fireworks, at Kansas City, Dist. Kans.

Charged 7-2-70: while held by A. J. Eickhoff, Kansas City, Kans., the articles were banned hazardous substances within the meaning of the hazardous substances regulations, since they were intended to produce audible effects by a charge of more than 2 grains of pyrotechnic composition; 2(q)(1)(B). Default decree ordered destruction. (43)

M-80 firecrackers, "Scram" aerial bombs, and "Sky-Jet 1/2 Mile High w/Report" aerial bombs, at Smoot, Dist. Wyo.

Charged 7-6-70: while held by Shumway's Fireworks Stand, Smoot, Wyo., the articles were banned hazardous substances, since the articles were packed in a form suitable for use in the household and were intended to produce audible effects by a charge of more than 2 grains of pyrotechnic composition; 2(q)(1)(B). Default decree ordered destruction. (44)

NOTICES OF JUDGMENT on Criminal Actions

FOOD

Matson Terminals, Inc., San Francisco, N. Dist. Calif.

Charged 5-26-70: green coffee was held in a building accessible to rodents and was contaminated with rodent filth; 402(a)(3), 402(a)(4). Nolo contendere plea; fine. (45)

Sweeney & Co., Inc., and Warren C. Miller, general manager, McAllen, S. Dist. Tex.

Charged 4-14-70: flour was held in a building accessible to insects and was contaminated by insect filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (46)

NOTICES OF JUDGMENT on Injunction Actions

Yates & Wheeler, Inc., and George Yates, president, West Jefferson, M. Dist. N.C.

Charged 10-1-70: when shipped, cabbage contained the pesticide chemical, toxaphene, in excess of the tolerance; 402(a)(2)(B). Guilty plea by corporation; fine. Guilty plea by individual; probation. (47)

Lanpar Co., a corporation, Dallas, N. Dist. Tex.

Charged on or about 6-26-68 in a complaint for injunction: that the defendant was engaged in manufacturing, packing, labeling, promoting, and selling various drugs most of which were recommended by the defendants for use in the Lanpar Treatment for Obesity, in distributing such drugs in interstate commerce, and in holding a number of the drugs for sale after shipment of one or more of their components in interstate commerce; that a number of the drugs were manufactured and held under circumstances which lacked conformity with current good manufacturing practice, their strength differed from standards set forth in the U.S.P., or their strength differed from and their quality and purity fell below that which they purported to possess, and their labeling contained false and misleading representations with respect to their strength, quality, or purity; that the labeling of the drugs involved in the Lanpar Treatment for Obesity contained false and misleading claims that the drugs were safe and effective in the treatment of hypothyroidism, amenorrhea, and hypomenorrhea, could safely bring about weight loss without rigid dieting, would cause a change toward normal metabolism, and were safe and effective adjuncts in the treatment of all obesity; that the labeling of the drugs involved in the Lanpar Treatment for Obesity lacked adequate directions for use and that the drugs designated as Thyalis, Parloid, Digitalis Leaves, Thy-Odone, Desoxyephedrine, Ammonium Chloride, Cal-Trol, Bar-It, and Potassium Chloride were dangerous to health when used in the dosage, and with the frequency and duration recommended in their labeling; that the drugs in the Lanpar Treatment for Obesity were new drugs without effective approved New Drug Applications; and that the defendant was well aware that its activities were in violation of the law; 501(a)(2)(B), 501(b), 501(c), 502(a), 502(f)(1), 502(j) and 505(a).

Following the denial of a temporary restraining order the case came on for trial at the conclusion of which the court handed down its findings of fact and conclusions of law. The Government filed a motion for amended and additional findings of fact and conclusions of law, which was considered by the court, and thereafter a decree was entered enjoining the defendant, its successors, assigns, officers, agents, employees, representatives, and all persons in active concert or participation with any of them from doing the following acts:

(1) introducing into interstate commerce Parloid, digitalis, ethinyl estradiol, Thy-Odone, Ethimins, Progest-L, testosterone, Parmone, tetradol, Thyrac, Racs, Trep-En-Ol, ammonium chloride, potassium chloride, phenobarbital, amobarbital, Phe-Bel, Cal-Trol, Bar-It, desoxyephedrine, Cellobese, Encholzzyne, Glutain, Pepadain, As-Ma-Pa, and Heplan, or similar products until the methods, facilities, and controls for their manufacture, packaging, and holding were in conformity with current good manufacturing practices; (2) introducing into interstate commerce or holding for sale after such shipment any of the drugs described above in subparagraph (1) when accompanied by the Lanpar Technical Reports and Bulletins, Lanpar Clinical Reviews and leaflets, and any similar written, printed, or graphic matter previously sent to physicians; (3) introducing into interstate commerce or holding for sale after such shipment any of the drugs described in subparagraph (1) when accompanied by written, printed, or graphic matter which represented and suggested among other things that such drugs, singly or in combination, were safe and effective in the treatment of hypothyroidism, amenorrhea, and hypomenorrhea, could safely bring about weight loss, would cause a change toward normal metabolism, and were safe and effective adjuncts in treatment of all obesity; (4) making oral statements which contain the representations and suggestions referred to above in subparagraph (3); (5) introducing into interstate commerce any of the above-named drugs unless their labeling bore adequate directions to enable a layman to safely and effectively employ the drugs for their intended use or, in case of prescription drugs, unless their labeling bore adequate information for use including indications, dosage, side effects, precautions, and relevant hazards; (6) shipping in interstate commerce or holding for sale after shipment in interstate commerce any drugs (except those returned for reworking) unless and until the drugs were properly labeled and assayed to assure that their strength, identity, potency, and other characteristics were not different from that which they purported to possess; (7) introducing into interstate commerce or holding for sale after such shipment any digitalis product for treatment of obesity, Thyalis, or any drug containing a combination of thyroid and digitalis; (8) introducing into interstate commerce, or delivering after holding for sale after shipment in interstate commerce any digitalis products to any person whom the defendant has reason to believe may use such products in the treatment of obesity; (9) introducing into interstate commerce any thyroid or digitalis preparations unless their labels contain certain prescribed warnings; and (10) selling digitalis and thyroid drugs in any container holding more than 28 tablets or capsules so as to insure that the required warnings appear on each container received by the ultimate consumer.

The decree also ordered that each drug on hand in any facility owned or controlled by the defendant, which was not in compliance with the law or the decree, should be destroyed, reworked, or otherwise brought into compliance with the law and the decree; that all Lanpar Technical Reports and Bulletins, Lanpar Clinical Reviews, and leaflets be recalled and destroyed; that magnetic tapes of Lanpar symposia in possession of the defendant or previously sent to its customers be erased; that all drugs containing a combination of thyroid and digitalis be returned and destroyed or reworked to eliminate the active components of digitalis; and that all costs of court be taxed against the defendant.

The defendant filed a motion to alter and amend the decree of injunction which was overruled by the court. The defendant also filed an objection to the cost bill, which objection was allowed by the court to tax only those costs consisting of clerk and marshal fees, fees for witnesses, and docket fees. The court also, as a result of the Government's motion referred to above, subsequently filed amended findings of fact and conclusions of law. 293 F. Supp. 147 (1968). (48)

Potomac Creamery Co., Inc., and Joseph J. Kirk, president, Hagerstown, Dist. Md.

Charged 6-20-67 in a complaint for injunction: that the defendants had

been receiving from intrastate and interstate sources fluid milk from which they were preparing, packing, holding, and distributing nonfat dry milk to customers in interstate commerce; that the nonfat dry milk contained the added poisonous and deleterious substance, *Salmonella* micro-organisms, that the nonfat dry milk had been prepared, packed, and held at the defendants' plant at Hagerstown under insanitary conditions whereby such food may have been contaminated with filth and rendered injurious to health; and that by reason of FDA inspections, an FDA hearing, a recall and seizures, the defendants were well aware that their activities were in violation of the law; 402(a)(1), 402(a)(4).

A temporary restraining order and a preliminary injunction were entered that enjoined the acts complained of and enjoined the preparation and distribution of nonfat dry milk unless and until a number of specified conditions were met including the bringing into compliance of the stocks on hand of nonfat dry milk. Subsequently, the defendants were authorized to have the stock on hand reconditioned by another firm.

Thereafter, a consent decree of permanent injunction was entered, which dismissed the complaint as to the president, and which enjoined Potomac Creamery Co., Inc., from committing at its Hagerstown, Maryland, plant the acts complained of and from preparing at and distributing from that plant nonfat dry milk unless and until a number of specified conditions were met. (49)

NOTICE OF JUDGMENT on Miscellaneous Action

Meprobamate and meprobamate combination products, judicial review suit, U.S. Court of Appeals for 4th Circuit.

In Petitioned 2-29-68 by Carter-Wallace, Inc., a Maryland corporation, in a suit against H.E.W. Secretary Gardner and F.D.A. Commissioner Goddard for judicial review of the order imposing the added controls of the Drug Abuse Control Amendments of 1965 upon meprobamate and meprobamate combination products: that meprobamate was generally classified as a "tranquilizer," had been widely prescribed, and was marketed by Carter-Wallace under the brand name "Miltown"; that the order would adversely affect Carter-Wallace, due to the added Drug Abuse Control restrictions, due to changed acceptance of meprobamate by physicians, patients, and drug abusers, due to required relabeling by Carter-Wallace of its meprobamate, and due to competitive disadvantage of Carter-Wallace with respect to competitive products not subject to such added restrictions; and that the order was unreasonable, arbitrary, not in accordance with law, and in excess of statutory authority, because: (a) FDA failed to sustain its burden of proof concerning any connection between meprobamate's potential for abuse and its effect on the central nervous system; (b) the order was based on a presumption created by an unauthorized and invalid FDA regulation [21 CFR 166.2(e)]; (c) the order was erroneously based on a finding of a "potential for abuse" instead of "substantial past abuse"; (d) the meprobamate combination products were erroneously included; and (e) the Hearing Examiner had made a multitude of erroneous and highly prejudicial rulings.

The Court of Appeals affirmed the Commissioner's order, saying: that there could be no doubt about the sufficiency of proof that meprobamate had a depressant effect on the central nervous system, that the examination of the records as a whole led the court to conclude that meprobamate did have a potential for abuse, and such was proper basis for the order, that the Government's case did not rest on any presumption alleged by the petitioners to have been created by the regulation 21 CFR 166.2(e), that since the combination drug contained meprobamate, they were covered by the plain language of the statute, that Carter-Wallace's contention that the Examiner was biased was not supported by the record, and that there was no merit in Carter-Wallace's other complaints about the conduct of the hearing or in Carter-Wallace's charge that the Examiner and the Commissioner ignored Carter-Wallace's evidence. In reviewing the evidence of connection between the depressant effect of meprobamate and its potential to affect the health of an individual or the safety of the community, the court said:

"Though the record contains no direct evidence or verified theories to explain meprobamate's effect, the Commissioner's order does not lack evidentiary support. Circumstantial evidence, or indirect proof, can satisfy the requirement that an administrative order be undergirded by substantial evidence. *Dubin-Haskell Lining Corp. v. NLRB*, 375 F.2d 568, 573 (4th Cir. 1967), cert. denied, 393 U.S. 824 (1968). * * *

"We conclude that although the evidence is largely circumstantial, it substantially supports the Commissioner's findings that tolerance, withdrawal reactions, and euphoria are a result of meprobamate's central nervous system depressant effects. Physical dependence (as manifested by withdrawal symptoms and tolerance) and euphoria are among the characteristics of a drug that lead to its abuse. Therefore, taking into account our imperfect knowledge of how drugs injure people, we hold that substantial evidence supports the Commissioner's finding of a causal relation between meprobamate's depressant effect upon the central nervous system and its potential for abuse." 417 F.2d 1086 (1969); cert. denied 398 U.S. 938 (1970). (50)

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

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

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

Charles C. Edwards, M.D., Commissioner of Food and Drugs
Washington, D.C., April 1, 1971



‘WHAT IS YOUR QUOTIENT?’

“What Is Your QA Quotient?” is a series of 62 color slides (2" x 2") with a narrative script, produced by the Division of Industry Services, in the Office of Compliance of the Food and Drug Administration's Bureau of Drugs. It stresses the need for achieving quality assurance in the production and sterilization of sterile disposable medical devices. It will be useful in motivating management and all levels of employees toward achieving the highest degree of quality assurance by illustrating the importance of each individual's performance.

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Announcements

USAN BOOKLET NO. 9 The ninth edition of United States Adopted Names (*USAN 9*) for pharmaceutical use has been published, and is available from the USAN Division, United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, at \$2 per copy, payable in advance.

The new cumulative 150-page booklet, issued by the U.S.P. Convention in conjunction with the USAN program, lists all U.S. Adopted Names released during the years 1967-1970. It supersedes *USAN 8* and is a supplement to the main volume, *USAN 5*, which was published in 1967 and which is fully cumulative from the start of the U.S. Adopted Names program in 1961 through 1966. In addition to the 83 new names adopted and announced in 1970, *USAN 9* includes the content of last year's edition, *USAN 8*, and significant revisions of entries previously published. It also gives four of the revised appendixes in their entirety, namely, on USAN for radioactive pharmaceuticals, the guiding principles for coining U.S. Adopted Names, official and other established names, and FDA-established names. The last-named appendix includes all names that have been published as finally adopted by the Food and Drug Administration. Also included in the appendix are USAN listed by categories, index of trademarks and code and other designations, and names and addresses of firms concerned with the selected USAN.

Each main entry in the annual USAN List gives the U.S. Adopted Name, followed generally by the name broken into syllables with accents as an aid to pronunciation; graphic formula, molecular formula, and chemical name, to the extent known; claimed pharmacologic activity of the compound; trademark name(s) and name(s) of manufacturer(s); and code designation(s).

The two booklets, *USAN 5* (1961-1966) and *USAN 9* (1967-70), provide a complete list of U.S. Adopted Names. *USAN 5* will remain current until 1972, and is still available at \$1 per copy, with payment to accompany the order.

FPLA Manual Industry reaction after receiving the Fair Packaging and Labeling Manual prepared by FDA's Office of Compliance, Bureau of Foods, and now available to firms, trade associations, and other interested persons, has been most gratifying. Among some of the written comments from industry associations and its members to FDA following receipt of the manual are "Your Agency is to be complimented for preparing this important reference which will prove to be most helpful to us here on staff as well as to our members in complying with regulations and interpretations of the Fair Packaging and Labeling Act..."; "...fills a long-standing need for authoritative guidance..."; "...such material invaluable to our member companies...."

The manual, prepared for industry use as an authoritative reference source to the regulations and interpretations of the FPLA, is essentially the same as the one that has been supplied to the FDA field offices and to State officials. It has been updated to include all revisions, exemptions, and precedent material issued to date. As future changes occur, supplements will be mailed to those holding the manual. Since most industry members already have a copy of the Food, Drug, and Cosmetic Act, it has not been included. For those who now have the manual but do not have a copy of the Act, it will be sent on request.

Most questions that industry might ask about its compliance with provisions of the Act have been answered in the manual. For those industry members with further questions or a need for clarification of those already answered, please contact the Division of Regulatory Guidance, Fair Packaging and Labeling Branch (BF-314), or the Division of Compliance Programs, Industry Guidance Branch (BF-331), of the Office of Compliance, 200 C Street, S.W., Washington, D.C. 20204.