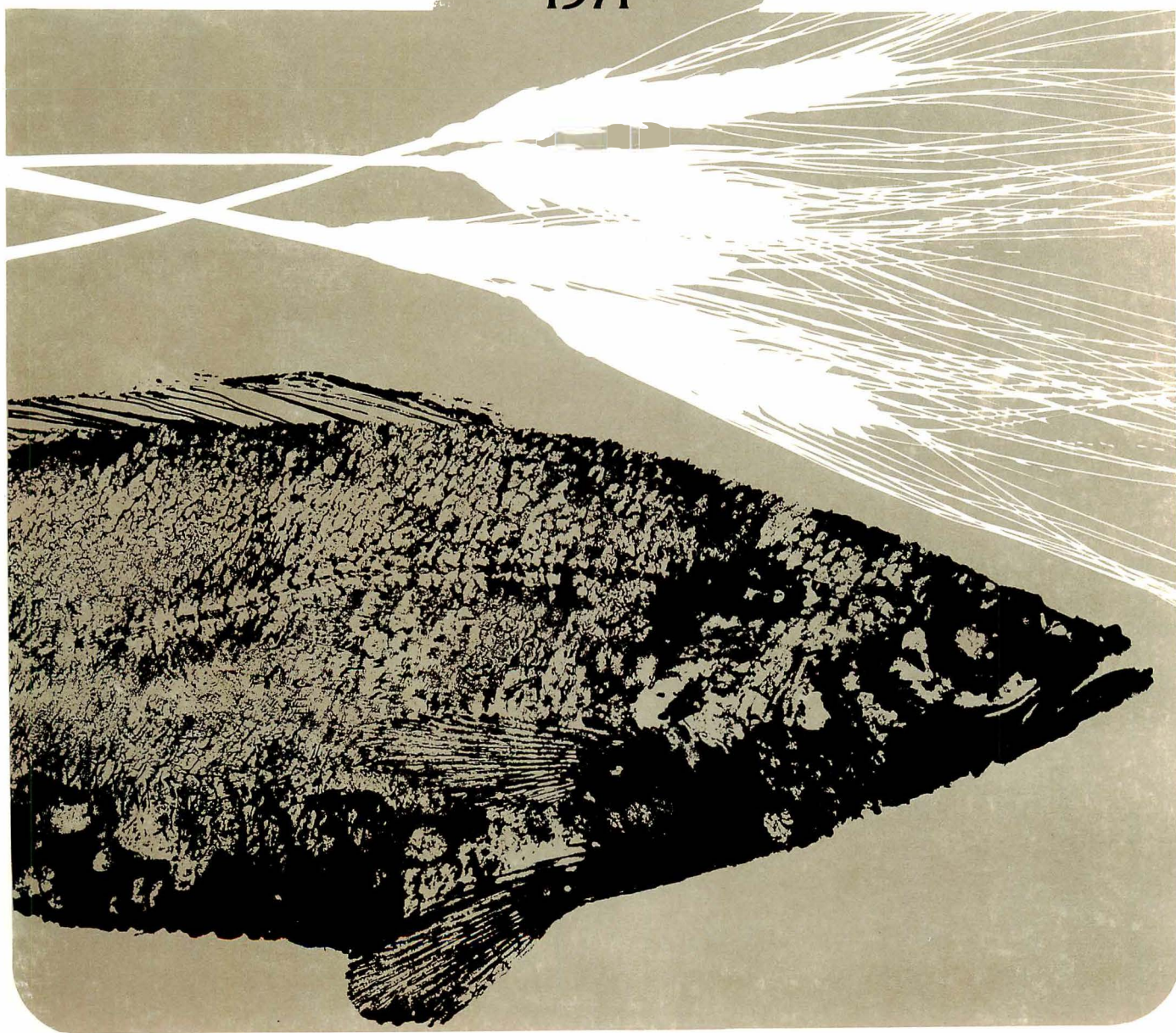


DEC. 1971-JAN. 1972

FDA PAPERS

FDA
ANNUAL
REPORT
1971



The Food and Drug Administration is the principal consumer protection agency of the Federal Government by virtue of its mission to enforce the Federal Food, Drug, and Cosmetic Act, the Federal Hazardous Substances Act, and other related laws.

FDA's major task is to prevent adulteration or misbranding of foods, drugs, medical devices, and cosmetics. It is likewise concerned with the safety of a host of chemical products, appliances, toys, and electronic equipment which produces radiation.

Annual reports of the Food and Drug Administration and its predecessor agencies have been published for more than 100 years. They provide a record of stewardship more comprehensive than any other on the activities of this Agency. In these times, especially, such a record is needed to balance the picture provided by day-to-day reporting. This document sums up the literally thousands of actions which constitute FDA's total performance in consumer protection. Much of the material is not available in any other format.

Unless otherwise noted, the program statistics and fiscal data are for the Fiscal Year ending June 30, 1971. For completeness and usefulness to the reader the actions reported include important developments of the calendar year 1971.



Charles C. Edwards, M.D.
Commissioner of Food and Drugs



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

Harvey W. Wiley, 1844-1930

Father of the Federal Food and Drugs Act of 1906

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

Most consumers know the Food and Drug Administration from what they read in the press or hear occasionally in a newscast. News being what it is, consumers have limited information about the laws or the agency which enforces them.

That is why we decided to publish FDA's Annual Report as a special issue of FDA PAPERS.

The Report is a comprehensive summary of the Agency's activities. It is FDA's only public accounting which covers all actions of major public interest and coordinates scientific, regulatory, legal, and fiscal information in a narrative format.

The Report is organized along product lines, corresponding generally to the statutory divisions and the FDA's organizational structure. Background information is frequently included to explain current developments in laymen's terminology.

Although distribution of the Report has been limited, it has been a valuable reference tool for many purposes.

quotes

"As a part of this quality control system, both the FDA inspectors and certain of your own employees will be required to receive special training. We propose to establish special schools in several areas of the country, accredited, and in some cases sponsored by the FDA, to certify every retort room supervisor and can seam inspector in the industry; every person in these positions will be required to complete these brief courses within one year after the schools are opened. This will be a continuing program of certification. It will be patterned somewhat after the certification program in California, the only State to have such an extensive plan.

"At the same time that these schools will be opening, we will also establish courses for our own food inspectors, in an effort to better prepare them for their role in the quality control program."

Charles C. Edwards, M.D., Commissioner of Food and Drugs, at the Annual Convention of the National Canners' Association, Miami, Florida, January 18, 1972.

"This intensive review of food safety is not happening because we have hit the panic button. We are not doing it because we believe foods are unsafe. If we believed that, we would be acting against the unsafe additives, of course.

"Rather, this effort rises out of our revised thinking about safety. We are conducting a review of food safety to be certain that we are using 1970 scientific knowledge to evaluate ingredients for which scientific determinations were made in an earlier period.

"We also suggest that the responsibility for a rational review of the GRAS list must be shared by the industry. If the public interest is to be served in a manner which will prevent undue public concern or alarm, industry is going to have to carry a burden commensurate with its obligation to the public."

James D. Grant, deputy commissioner of the Food and Drug Administration, at the International Symposium on the Conversion and Manufacture of Foodstuffs by Microorganisms, Kyoto, Japan, December 7, 1971.

Elliot L. Richardson
Secretary, U.S. Department of
Health, Education, and Welfare

Roger O. Egeberg, M.D.
Asst. Secretary for Health
and Scientific Affairs

Charles C. Edwards, M.D.
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PHOTOGRAPHY: NIH, upper 30;
George Tames—Medical World News, 38; FDA.

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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.

Advisors to the Editor*

H. Nelson Fitton, Department of Agriculture; **George Creel**, Department of Housing and Urban Development; **William J. Cotter**, Post Office Department; **Henry Scherer**, Department of Commerce; **Dr. Milner B. Schaefer**, Department of the Interior; **Dr. Sam Kaim**, Veterans Administration; **Dr. Peter V. Siegel**, Federal Aviation Agency; **Dr. Spofford G. English**, United States Atomic Energy Commission; **Dr. Harve J. Carlson**, National Science Foundation; **Howard J. Lewis**, National Academy of Sciences; **Arthur Settell**, Bureau of Customs.

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

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The Year in Review

1971 was a year of intense activity and major actions to protect the public. It was unique in FDA history for the number of health problems calling for emergency action. It was also unique for public interest in FDA activities and in the response to these activities, by industry and consumers.

Public warnings and total product recalls were needed for foods and drugs contaminated by bacteria or heavy metals. Lead glazes in ceramic wares revived one of the oldest problems in food protection. Hundreds of actions were taken to remove ineffective drugs and hazardous toys from the market. But the public was also protected in countless other ways, by literally thousands of routine actions unknown to the majority of the consuming public. Balancing the "scare" headlines was the simple fact that the laws are working as intended by Congress, to protect the consumer, and that confidence in the overall excellence of foods, drugs, and other consumer products is justified. Progress was achieved notwithstanding known deficiencies in compliance, in facilities, and in scientific knowledge needed to resolve many problems which concern the Agency.

Court cases to enforce the laws increased to 845, compared with 674 started during the previous fiscal year (see Table 1). Product recalls reported to FDA, most of them voluntary actions, increased from 1,427 to 1,986 (Table 6).

Appropriations increased from \$88 million in fiscal 1970 to \$95.8 million in 1971, and \$110 million (estimated) in the current fiscal year 1972.

An important new responsibility, administration of the Radiation Health and Safety Act, came to FDA with the transfer of the Bureau of Radiological Health, formerly in another unit of the Public Health Service. This Bureau is concerned with reducing the public exposure to radiation from such familiar sources as TV sets, microwave ovens, and medical X-ray equipment (see "Radiological Health Protection").

Establishment of pesticide residue tolerances for foods, a program pioneered and developed to a high level of scientific capability, was transferred December 2, 1970, to the new Environmental Protection Agency. Enforcement of the tolerances continues as one of the

important food protection programs of the FDA.

Interest in FDA activities was shown by the 25 public hearings before 18 committees of Congress at which the Commissioner or other top officials were the principal witnesses. Such hearings involved FDA for 35 days, not including the man-years spent in preparation. Some 5,500 mail inquiries from Congressmen were answered.

Consumer mail was another major workload, with over 33,000 responses from Washington staff offices. Thousands more were prepared by Bureau and field personnel. Because of the diversity of FDA programs, and the questions asked, most replies required special preparation.

Such questions, complaints, and comments are a valuable source of information to FDA on the consumer's needs and problems. Automated data processing of consumer inquiries is being developed to provide FDA decision-makers with up-to-the-minute facts on the consumer's interests.

To bridge a critical information gap a new FDA Drug Bulletin was launched, alerting over 600,000 physicians, pharmacists, and other health professionals about important changes in drug labeling and use.

Other significant activities of 1971 included:

- Actions to ensure effective drugs: more than a thousand official notices called for evidence to support drug claims, make changes in labeling, or to withdraw drugs from the market.
- Protecting thousands of patients and volunteers who take part in testing investigational drugs, by new regulations and monitoring of clinical studies.
- Investigations to develop more and better nutrition information on food labels, and to ensure nutritional quality of manufactured food products.
- Preparatory activities to implement stronger control over therapeutic devices from hearing aids to heart-lung machines.
- Protection from injury of persons who wear glasses

by requiring impact-resistant lenses, and to ensure that new contact lenses will be safe.

- Development of a computerized system for fast reporting of product-related injuries, so that remedial steps can be undertaken promptly.
- Protection of children by banning over 300 unsafe toys and "child safe" packaging of hazardous articles.
- Launching of a mass review of all "home remedies"—such products as antacids, cough remedies, laxatives, and analgesics—to ensure they are capable of fulfilling the claims made for them and that they are adequately labeled.

In another highly significant development, FDA sought and received the former biological warfare research facilities at Pine Bluff, Arkansas, for research on the toxicology of chemicals and drugs, especially their long-term, low-dose effects.

Details on these and many other FDA actions and programs are given in the various sections of this report.

Conforming to the President's order of May 21, 1969, on regionalization of the Department of Health, Education, and Welfare, and to meet recognized needs for stronger central direction, a reorganization of the field structure of the Food and Drug Administration, begun in 1970, was completed in 1971. Now FDA is represented throughout the country by ten Regional Offices with 19 District Offices. In addition, there are 97 Resident Inspection Posts which serve as headquarters for one or more inspectors. This provides the Administration with representation to the consumer and the regulated industries in 114 communities. These offices carry out the basic responsibilities of the FDA relating to foods, drugs, cosmetics, therapeutic devices, hazardous household substances, flammable fabrics, children's toys, and various other consumer products.

The field organization is administered by the newly created Executive Director of Regional Operations. Through the ten Regional Directors, this office directs the 2,100 field employees.

Nationwide consumer protection programs, developed by the Bureaus of Foods, Drugs, Veterinary Medicine, Product Safety, and Radiological Health, are carried out by inspectors, scientists, food and drug officers, consumer specialists, and consultants under supervision of the Regional and Deputy Regional Directors.

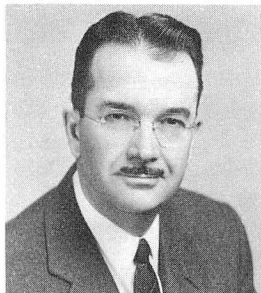
Cooperative activities with State and local food, drug, and other health agencies are an important part of FDA's regional operations. On June 23, 1971, the Commissioner announced a new policy of cooperation with the States. This is a full partnership, work-sharing approach based on greater use of formal and informal agreements between FDA and State agencies. It is designed to move positively toward the support of uniform

State legislation and increased use of FDA training programs for State officials.

There is a gap between what the public expects FDA to do and what the Agency is in fact empowered to do. Often consumers are not aware of the scope of the law, or in the scientific facts needed to apply it. Likewise, consumers often are not aware of the protection which is provided. FDA is working in many ways to close the consumer information gap. Its Consumer Specialist Program, 20 years old in 1972, was a pioneering recognition of the consumer's right to be informed. The consumer specialists—now 26 in number—carry on a nationwide two-way communication program with local organizations, teachers, civic leaders, and individual citizens. Through workshops, seminars, speaking engagements, consumer phone messages, press, radio, and TV, millions of consumers receive needed factual information and answers to their questions. FDA, in turn, receives vital intelligence concerning such matters as defective or mislabeled products and consumer views on proposed regulations.

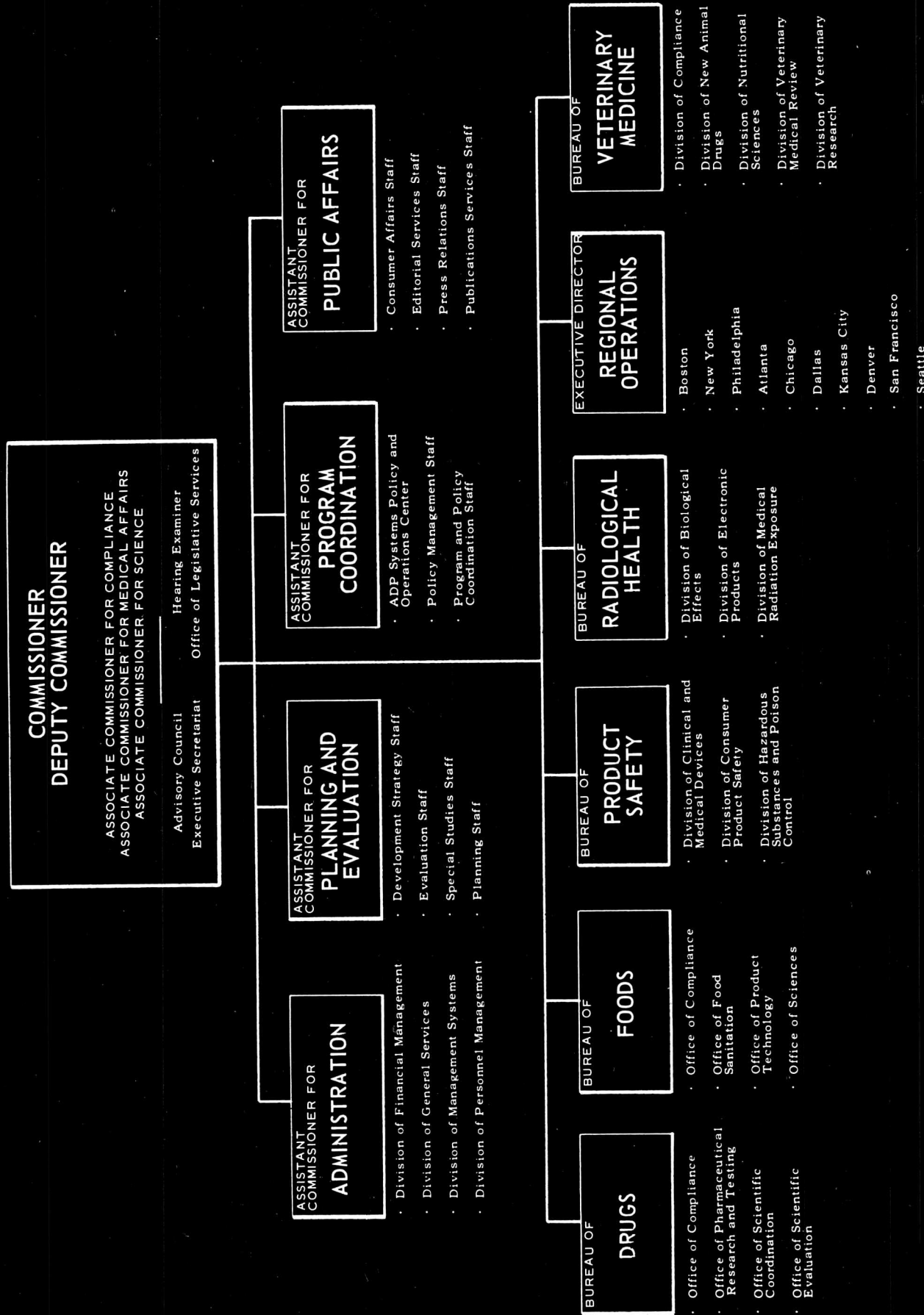
Consumer representation on FDA Advisory Committees is being actively sought. Specifically, new national advisory committees on foods, drugs, product safety, and veterinary medicine will have consumer representatives. The Committee on Poison Prevention Packaging already has consumer representation.

The size and complexity of the industries regulated by the Food and Drug Administration are constantly increasing. FDA inspectors—fewer than 700—carry on surveillance of over 63,000 food establishments and 10,000 manufacturers of drugs, medical and dental devices, and cosmetics. Thousands of other firms are subject to laws dealing with household chemical products and equipment, toys, and electronic products which produce radiation. The retail value of all products under FDA jurisdiction is over \$230 billion. Almost 38 cents of every dollar spent by consumers goes for these products. The current annual cost of FDA protection is approximately 53 cents per person.



Wallace F. Janssen, who directed production of FDA's 1971 Annual Report, has had a hand in the project for more than 20 years with the Agency. For 15 of those years, under Commissioners Dunbar, Crawford, and Larrick, he was FDA's Director of Information. Before 1951, he was for 20 years a business journal editor covering the food, drug, and cosmetic industries, and FDA, from Minneapolis, New York, and Washington. This year's Report is his first contribution to FDA Papers.

FOOD AND DRUG ADMINISTRATION



REGIONS AND DISTRICTS

FOOD AND DRUG ADMINISTRATION

○ REGIONAL OFFICES
The Roman Numerals identify regions.
Regional boundaries are indicated.

ALASKA X

HAWAII IX

PUERTO RICO II

GUAM II

REGIONAL OFFICES
The Roman Numerals identify regions.
Regional boundaries are indicated
by the separations in the map.

- DISTRICT OFFICES
- RESIDENT INSPECTION POSTS
- DISTRICT BOUNDARIES (within regions)

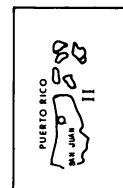
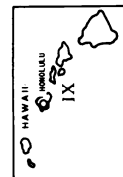
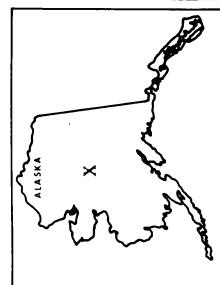


Table 1.—Seizures, prosecutions, and injunctions instituted by the Food and Drug Administration during FY 1970 and FY 1971

	Seizures		Prosecutions		Injunctions		Total	
	1970	1971	1970	1971	1970	1971	1970	1971
Foods	268	510	33	47	23	11	324	568
Drugs	174	164	8	4	1	2	183	170
Devices	116	49	1	0	0	0	117	49
Cosmetics	5	8	0	0	0	0	5	8
Hazardous Substances	45	49	0	1	0	0	45	50
Totals	608	780	42	52	24	13	674	845

Table 2.—Court actions under the Federal Food, Drug, and Cosmetic Act and Federal Hazardous Substances Act during fiscal year 1971, as reported to the Department of Justice

	FDC Act				FHS Act	
	Total	Seizures	Prosecutions	Injunctions	Seizures	Prosecutions
Pending July 1, 1970	325	266	45	14	15	1
Reported to Department of Justice during the fiscal year	794	726	50	18	48	1
Total pending during the year ..	1,119	992	95	32	63	2
Terminated during the year	756	695	55	6	33	1
Pending June 30, 1971	363	297	40	26	30	1

In 51 of the 55 prosecutions terminated, fines were imposed totaling \$102,881.00, exclusive of court costs.

Table 3.—Allocation of FDA funds in percent and dollars

	Fiscal year 1970* (percent)	Dollars (thousands)	Fiscal year 1971* (percent)	Dollars (thousands)	Fiscal year 1972* (percent)	Dollars (thousands) (estimated)
Foods	34	30,183	38	36,430	39	43,363
Drugs	39	34,402	37	35,050	36	39,360
Cosmetics	2	1,278	1	1,085	1	1,130
Devices	1	1,064	1	1,126	1	1,407
Product Safety	16	14,384	16	15,306	16	17,608
Unallocable	8	6,829	7	6,871	7	7,107
Total allocations**		88,140		95,868		109,975

* Adjusted to reflect program changes resulting from the transfer of FDA's pesticide tolerance setting activities to the Environmental Protection Agency and the transfer of the Bureau of Radiological Health to FDA. Pesticide tolerance enforcement is included in the Foods allocation.

** Does not include fees collected for testing and certification of antibiotics, insulin, and color additives.

**Table 4.—Domestic inspections and sample examinations accomplished:
FY 1970 and FY 1971**

	FY 1970		FY 1971	
	Inspections*	Sample Examinations**	Inspections*	Sample Examinations**
Foods	15,432	34,666	14,843	39,825
Drugs	8,004	24,642	8,369	19,035
Devices	1,203	695	702	552
Cosmetics	644	494	652	371
Hazardous Substances	1,392	801	1,436	942
Totals	26,675	61,298	26,002	60,725

* Represents program category inspections, not establishment inspections. During an establishment inspection, more than one program category may be covered (e.g. salmonella contamination, food sanitation, and natural poisons).

** In some instances, multiple examinations are made on a particular sample and each examination is tabulated.

**Table 5.—Import sample examinations, wharf examinations, and lots detained:
FY 1970 and FY 1971**

	FY 1970			FY 1971		
	Sample Examinations*	Wharf Examinations	Lots Detained	Sample Examinations*	Wharf Examinations	Lots Detained
Foods	17,010	13,006	2,356	21,693	17,647	3,577
Drugs	371	1,171	4,279	625	3,388	5,575
Devices	131	339	125	307	1,865	348
Cosmetics	129	396	61	123	685	123
Hazardous Substances ...	244	2,909	53	449	3,331	77
Totals	17,885	17,821	6,874	23,197	26,916	9,700

* In some instances, multiple examinations are made on a particular sample and each examination is tabulated.

Table 6.—Recalls initiated and monitored during FY 1970 and FY 1971

	1970		1971	
	Number	Percent	Number	Percent
Foods	355		292	
Drugs	927		1,543	
Prescription drugs		76		74
Nonprescription		20		18
Veterinary drugs and medicated feeds ...		4		8
Devices	90		50	
Cosmetics	44		15	
Hazardous products	11		86	
Totals	1,427		1,986	

Protecting the Healthfulness and Safety of Food



French fries for freezing are sampled by an FDA inspector for testing in the District laboratory.

Actions dealing with potentially harmful products were combined with programs to prevent contamination and to improve quality and labeling.

How the law works to protect the healthfulness and safety of the Nation's food supply was demonstrated in many ways during 1971.

Even the public warnings and product recalls needed in emergency situations showed the effectiveness of protection provided through scientific administration of the laws and regulations. This is a point that is frequently missed. The U.S. consumer has justified reasons for confidence in the overall safety and quality of the food supply.

Consumers have become increasingly knowledgeable and concerned about health, the environment, and the quality and safety of food and other products. Interest in consumer protection reached a new high in 1971.

No single incident caused greater public concern than a recall of vichyssoise soup after a botulism fatality. This required a nationwide public warning and an all-out campaign to remove the implicated product from the market. As a result of conditions found in the plant and its products, FDA sought as a precautionary measure the total recall of all of the company's soups and sauces. (See "Foodborne Infection.")

In midyear a massive program for testing fish for mercury, especially tuna and swordfish, was completed. Final statistics showed the problem of mercury in tuna to be less serious than was feared initially. The immediate problem was brought under control and a program launched to assure industry-FDA monitoring of future production.

Mercury in swordfish proved to be a more difficult problem. When most lots examined were found to contain excessive levels, FDA recommended that the public refrain from eating swordfish. The Agency is continuing to detain all imports of swordfish exceeding 0.5 parts per million of mercury. (See "Chemicals in Foods.")

High levels of lead and cadmium were found in some kinds of table pottery, primarily of foreign origin. Both metals may be absorbed by foods and beverages. Several hundred import shipments were detained at ports of entry. Although FDA determined that the pottery does not present an imminent health hazard, it warned consumers not to store acid foods or beverages in ceramic dinnerware. The Agency also developed a program to assure adequate control of domestic production from this time on.

A major opportunity for FDA to enhance food safety came when the President announced in late 1969 that the Nation would discontinue all research on biological warfare. In January 1971 the President took the second step to transform the Army's biological warfare laboratories at Pine Bluff, Arkansas, into a new health research institution, the National Center for Toxicological

Research. At ceremonies April 14, 1971, FDA's Commissioner Edwards accepted administration of the facility on behalf of FDA and the other Government agencies which will use it. "At this National Center," he said, "we will come to know and measure more precisely, the long-term effects of such substances as pesticides, food additives, and therapeutic drugs."

Nutritional quality of foods has become an increasingly important concern of the public, FDA, and the food industry. With highly formulated foods, the consumer cannot tell the nutritional value of the products he buys. Nutrition programs started last year made progress in 1971 with actions to improve labeling and to insure the nutritional content of selected food products. (See "Nutrition and Special Dietary Foods.")

Promotion of voluntary compliance by the food industry continued as an integral part of FDA's consumer protection mission. Eleven food plants signed self-certification agreements with FDA; five plants are committed (in the state of formulating specifications); and others have indicated an interest.

Court actions to secure compliance with food regulations increased materially, from a total of 324 in fiscal year 1970 to 568 in fiscal 1971 (Table 1). Most of the increase was in seizure cases, from 268 in 1970 to 510 in 1971. Criminal prosecutions increased from 33 to 47. Injunction cases declined, with 11 cases instituted, compared with 23 the previous year. Import detentions also increased (see "Imports" and Table 5). The number of voluntary recalls of defective food products declined, but some recalls involved many shipments and very large quantities (Table 6).

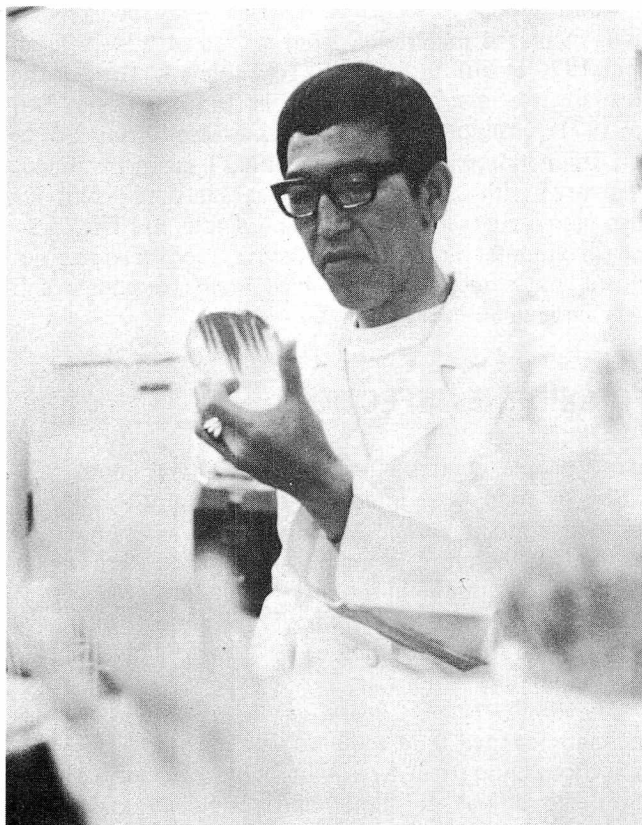
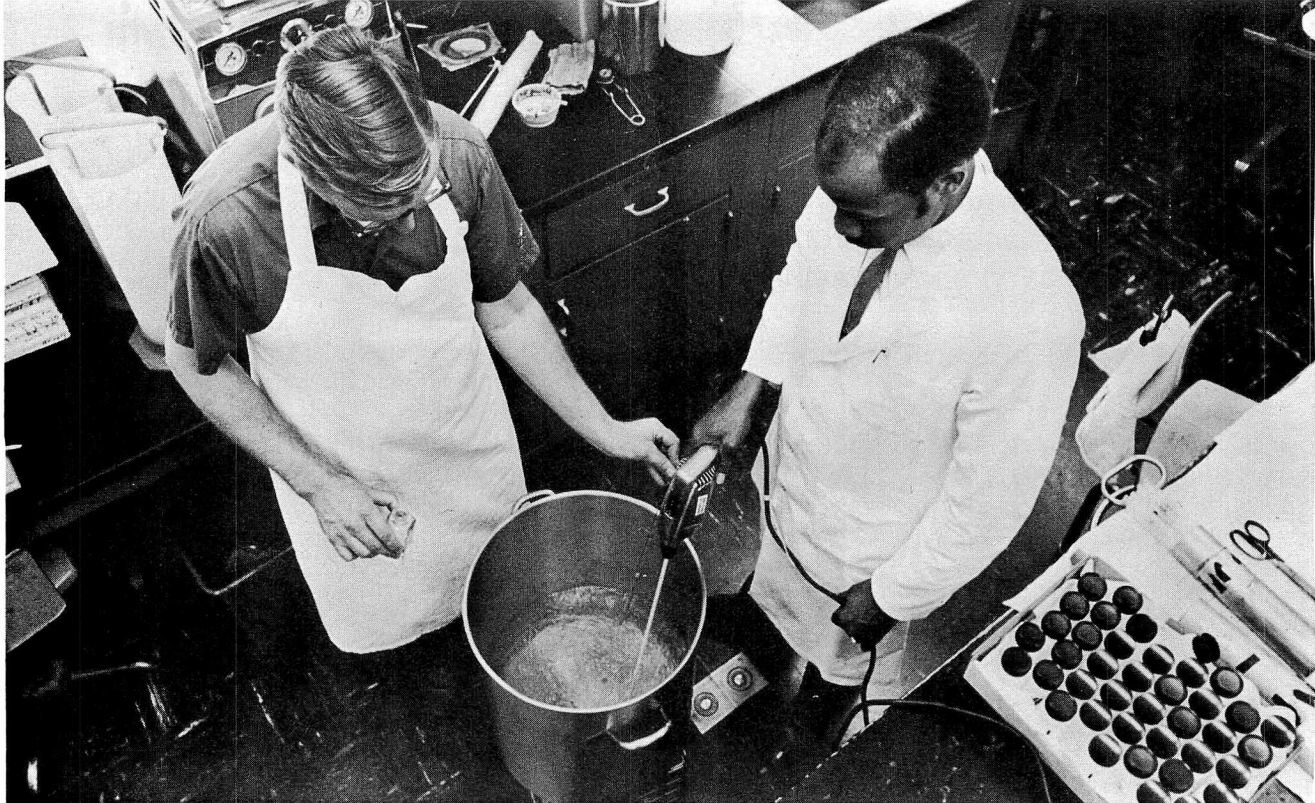
FOODBORNE INFECTION

More people continue to be afflicted, and more seriously, by foodborne infections than by any other kind of food contamination. Microbiological contamination of food is, therefore, a major cause for concern which promises to continue in the foreseeable future.

The many strains of *Salmonella* were most frequently the cause of food poisoning in 1971 and involved in the most regulatory actions, as in prior years.

The discovery of *Clostridium botulinum* in a commercially canned food required extraordinary FDA action. Botulinum toxin type A in vichyssoise soup caused the death of one consumer and serious illness of another in New York. Most of the soup had been distributed in the northeast section of the country. Federal, State, and local food and drug officials and those of the State and Federal Departments of Agriculture visited over 28,000 wholesale and retail establishments in the resulting recall. Later, the same type of toxin was found in a product of another soup manufacturer. The product was recalled by the company. No injuries were reported.

Four outbreaks of food poisoning from *Vibrio parahaemolyticus* occurred in Maryland from eating Chesa-



Uniformity in State and Federal tests for food-borne pathogens is the goal of a "split sample" testing program. Above, microbiologists at FDA's Cincinnati District begin the preparation of a culture medium. At left, Dr. Riichi Sakazaki, eminent Japanese authority on *Vibrio parahaemolyticus*, examines a Czebalski salt gradient plate while serving as a consultant in FDA's Division of Microbiology.

peake Bay crabs or crab salad, the first known such incidents in the United States. In one outbreak 550 people attended a feast of steamed crabs. About 16 hours later 320 became ill with symptoms of diarrhea, severe abdominal cramps, nausea, vomiting, fever, headache, and chills. A number were hospitalized.

V. parahaemolyticus has been recovered from all parts of the marine environment and seafood products from both polluted and presumably unpolluted water. This organism thrives better in warm weather than in cold and is killed by thorough cooking.

A joint FDA and State program was started for the microbiological testing of foods for pathogens, indicator organisms, and total count. Fifty-six State laboratories participated in the initial distribution of samples. This split-sample program is designed to encourage uniform testing and to improve the precision of methods.

Type A staphylococcal enterotoxin was found in nationally distributed dry hard sausage from two manufacturers. Its presence was confirmed in samples submitted by the Department of Agriculture and from several States. The products had caused food poisoning in various parts of the country—the first outbreaks of this type.

Studies were completed on the heat resistance of oncogenic viruses in milk and milk products. The viruses studied are relatively sensitive to heat and were inactivated by the pasteurization processes used for dairy products. The effects of viruses in foods on human health are relatively unknown. Research data indicate that they may be common in our raw food supply.

A cooperative FDA-USDA-American Meat Institute study was started on the inhibition of *C. botulinum* types A and B by nitrates and nitrites in comminuted refrigerated meats. This is being done to establish the minimum concentration of these chemicals that is effective in preventing growth of *C. botulinum*.

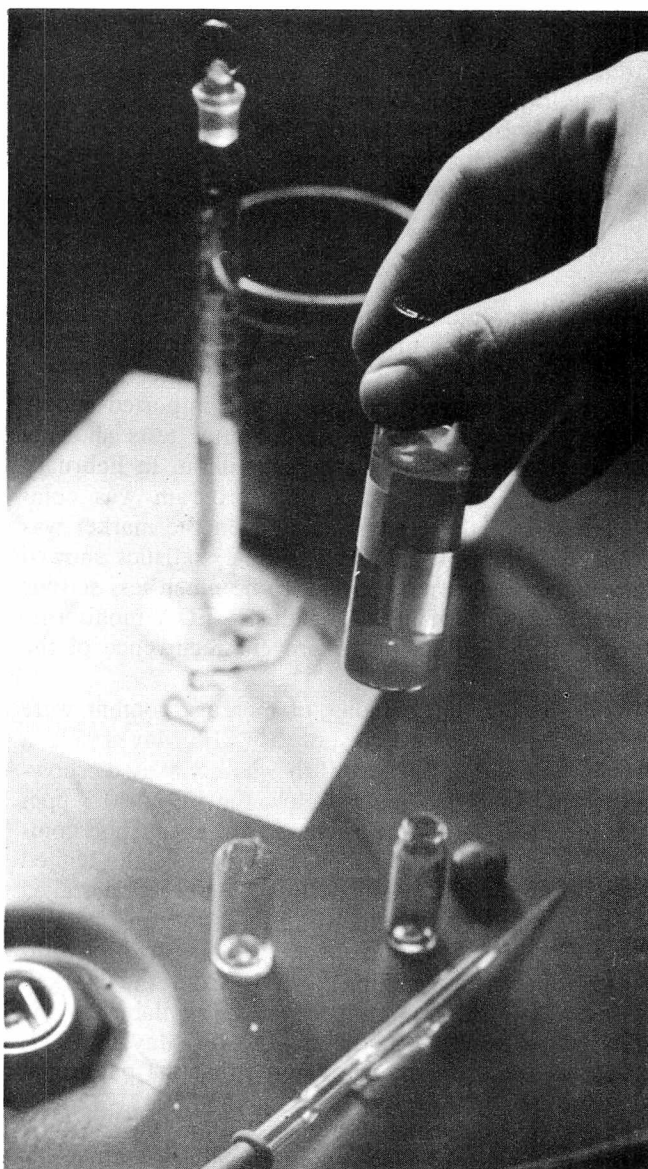
CHEMICALS IN FOODS

Industrial chemical contamination of the environment and its residues in foods caused increasing concern during the year.

Pollution of waters with industrial wastes and agricultural runoff has adversely affected marine species. Certain agricultural crops have been affected by metallic pollutants in the air. Metals have also found their way into food from contact with food processing equipment, from glazed pottery containing leachable metals, and from accidents involving direct addition of toxic metals, e.g., irresponsible channeling of mercury treated seed grain. In a special FDA survey of mercury pollution, all 75 known chloro-alkali plants in the United States were investigated and some fish from waters pol-

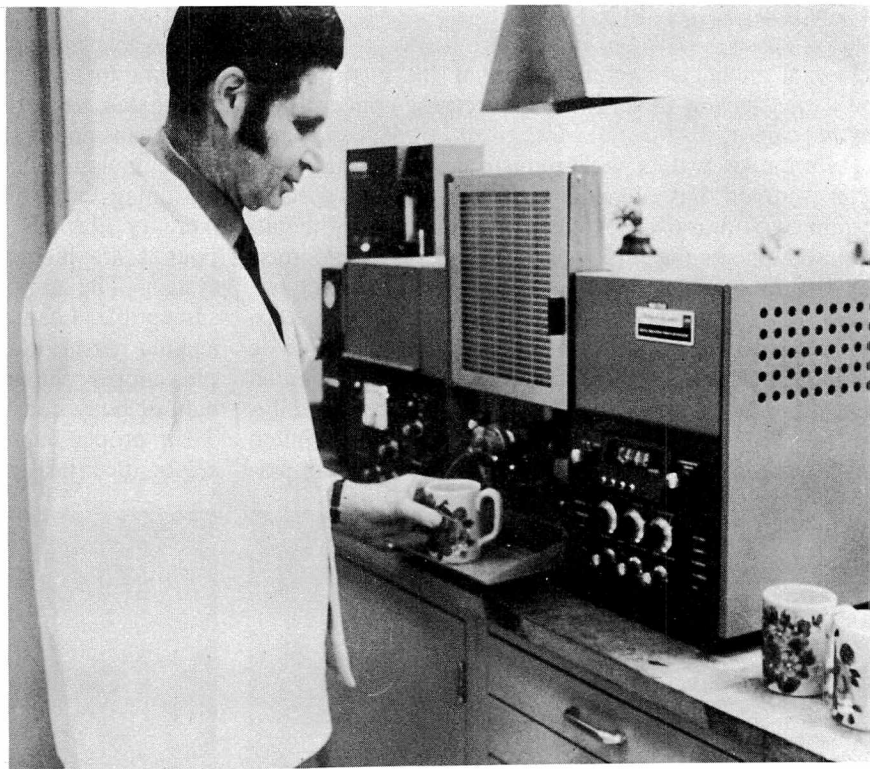
luted by the process were found with residues exceeding FDA's interim guideline of 0.5 parts per million.

Some metals, e.g., mercury and lead, are not readily eliminated from the human body but are deposited in the organs and tissues or bone, thus producing an incipient cumulative hazard. Animal studies and reported poisoning cases have shown that even low levels of mercury affect the kidney and some alkyl mercury compounds are highly injurious to the brain and nervous system. The unborn and very young are particularly susceptible. Lead accumulates in the bone marrow and anemia results. But some metallic elements (for example: copper, zinc, manganese, selenium, and cobalt) are natural body constituents essential for mammalian life. Their proper balance is critical and deficiencies or excesses affect health.



Lead in glazes of ceramic ware, a food contamination problem in Roman times, became an FDA problem in 1971. FDA Inspector Robert K. Hering (above) demonstrates a new field test kit for on-the-spot detection of acid extractable lead in earthenware.

Using an atomic absorption spectrophotometer, FDA Chemist Benjamin Krinitz is determining the quantity of lead which could be extracted by acid foods from earthenware mugs. Materials which contact foods are subject to regulation as food additives if they are absorbed.



Mercury in tuna and swordfish required a massive sampling and testing program. With full industry cooperation, over 12 million cans of tuna—between 3 and 4 percent of the country's domestic and imported supply—were removed from the market after tests showing mercury in excess of 0.5 parts per million. In February 1971, FDA announced that this program was completed and that the tuna remaining on the market was within the established limit. The final statistics showed the problem of mercury in tuna to be much less serious than was feared initially. An industry-FDA monitoring program has been set up to prevent recurrence of the problem.

While testing tuna, studies of mercury content were begun on 19 other species of fish. In May 1971, a three-month survey of swordfish was completed, showing only 42 of 853 samples below the FDA's 0.5 ppm guideline. The data were reviewed by an ad hoc committee of scientific and medical experts from the United States and Canada. Extensive recalls were undertaken by the leading food chains. FDA seizures totaled 832,000 pounds. Swordfish brokers cooperated by withholding up to four million pounds from the market. However, swordfish continued to be available to the public at or over the guideline, and on May 6, 1971, FDA issued a notice recommending that the public not eat swordfish.

PCB's (polychlorinated biphenyls) are a family of industrial chemicals widely used for at least 40 years. While there is no imminent threat to the safety of the food supply from PCB's, the FDA conducted research aimed at assessing the scope and significance of long-term low-level human exposure. Seizures involving

PCB's in fiscal 1971 included such commodities as shell eggs, catfish food, fishmeal, and trout chow.

Dioxins (chlorodibenzo-p-dioxins), highly toxic to man and animals, have been detected in a number of samples of foods and food materials. A method was developed to help determine the presence of these compounds. Further studies are in progress. Emphasis is being placed on chlorophenols as a potential source of chlorodioxin impurities which may indirectly contaminate food. Four methods of analysis for chlorodioxins in commercial chlorophenols are currently under study by 12 laboratories.

Pesticide tolerances. Lower tolerances for residues of DDT and its metabolites in many raw agricultural food commodities were published in the *Federal Register* in December 1970. DDT residues in the soil, air, and water will gradually diminish in the environment with increasing restriction against its use. The proposed tolerances were set high enough to avoid jeopardizing current crops containing unavoidable residues, and low enough to prevent direct use of the pesticides on prohibited crops. This was the last pesticide tolerance-setting by FDA, this function having been transferred to the Environmental Protection Agency by a Presidential order effective December 2, 1970. Enforcement of pesticide tolerances continued as an FDA function.

In addition to the previously mentioned problem of lead and cadmium contamination in table pottery, FDA found these heavy metals in imported enamelware. Five major voluntary recalls of enamelware contaminated with cadmium occurred, including enamelware from Hong Kong, and fondue pots from Switzerland.

FDA analysis of a nationally marketed brand of im-

ported candy beads revealed high levels of cadmium (a toxic heavy metal) that presents a moderate to severe health hazard to children. At least 15 injuries attributed to the beads were reported. A public warning was issued and recall instituted.

FOOD ADDITIVES

In his Consumer Message of October 1969, President Nixon charged FDA to review the safety of the approximately 600 items on the list of substances "generally recognized as safe" (GRAS) published by FDA in 1959-1961. To meet the intent that all substances for addition to food have a modern toxicological evaluation, FDA is including in this major project other substances previously sanctioned or identified as GRAS in unpublished correspondence.

By contract to FDA the Food Protection Committee of the National Academy of Sciences-National Research Council developed and tested a questionnaire designed to obtain current production information from suppliers, manufacturers, and users of substances on the GRAS list.

Within FDA, a GRAS Review Branch was established to expedite activities connected with the review.

The first and basic regulation of many contemplated in the project was published June 28. This order established the criteria by which FDA will measure the eligibility of a specific substance to be classed as GRAS. Under the order, all substances requiring any limitations for safety must be approved by specific food additive regulations.

Taking its first action under the new criteria, FDA removed saccharin from the GRAS list and issued a provisional regulation restricting its use.

During the fiscal year, 110 new food additive petitions were received and 51 orders published involving food additive regulations, exclusive of veterinary products.

As of June 30, 1971, approximately 2,752 food additives were covered by formal regulations. In addition, 561 substances for direct use in food for humans, 108 substances for indirect use in food packaging, and 46 compounds for providing trace minerals in animal food were listed as "generally recognized as safe."

Ethylene oxide was authorized on July 28, 1970, as a fumigant for control of micro-organisms and insect infestation in ground spices and other processed natural seasonings, except mixtures with added salt.

An amendment to the regulations on August 4, 1970, permitted the use of herring (genera *Clupea* and menhaden), as additional raw material in the production of whole fish protein concentrate by solvent extraction with isopropyl alcohol.

A carbohydrase and cellulase enzyme preparation derived from the mold *Aspergillus niger* was authorized on December 16, 1970, as an aid in the removal of shell from edible tissue in shrimp processing.

KEEPING FOOD CLEAN

Problems of food sanitation are characterized by the use of filthy or decomposed raw materials or by unsanitary conditions in food plants which may cause product contamination. The finished product may or may not be a threat to the consumer. However, such contamination often indicates more serious conditions which may be detrimental to health.

Sanitation problems are not limited to any one particular industry or commodity. They can occur in any food establishment, particularly those which handle products that are especially susceptible to filth contamination or decomposition.

In 1971 an increasing number of consumer and trade complaints and FDA inspections during work in other program areas indicated a deterioration of food establishment sanitation. Almost every FDA District reported food sanitation problems. Rodent and insect contamination, as well as decomposition and spoilage, continued to constitute the majority of violations.

With a constantly growing basic workload and numerous special assignments, FDA inspectors are unable to maintain routine coverage of food industry establishments. In fiscal 1971 the Agency had about 210 full-time food inspectors to cover over 63,000 establishments producing \$130 billion worth of products annually (retail value). Testifying before the health subcommittee of the House Committee on Interstate and Foreign Commerce, August 3, 1971, the Commissioner said food plants are now inspected by FDA about once every six years. When violations are suspected, inspections are, of course, more frequent. About 50 additional food inspectors are to be recruited in fiscal 1972.

FDA Districts have accelerated their efforts to insure cleanliness of foods. Many seizures, product recalls, and import detentions resulted, often involving large quantities of unfit products. Inspection of a cocoa bean warehouse, following up on a trade complaint, disclosed insect infestation and rodent evidence resulting in the seizure of 878,400 pounds of cocoa beans. An import lot of 28,000 bags of cocoa beans, valued at \$1.0 million, was detained.

Sorting, reconditioning, or relabeling of detained or seized goods must be done under FDA supervision with the owner paying all costs. If the goods cannot be made to comply with the law, destruction may be ordered, or carried out voluntarily. Frequently firms destroy violative goods to avoid the possibility of court proceedings. A cookie manufacturing firm voluntarily destroyed 80,000 pounds of insect-infested flour and other raw materials. Another firm voluntarily destroyed approximately 250,000 pounds of glazed fruit due to rancidity, decomposition, and insect contamination.

National food manufacturers are taking greater interest in the condition of warehouses which handle their products, following an FDA inspection of a wholesale grocer which showed national brands of various foods contaminated by insects and rodents.

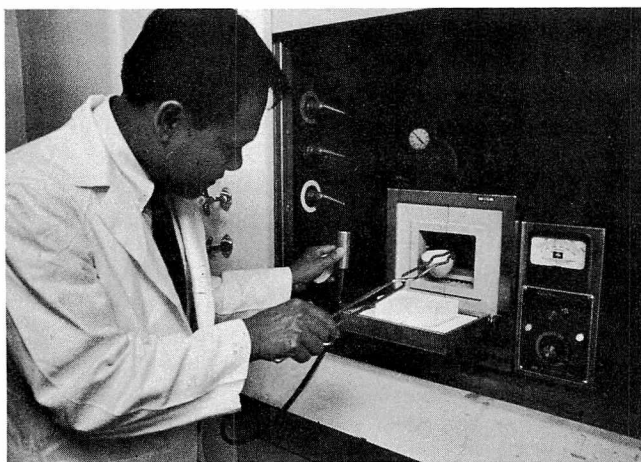
FOOD STANDARDS ACTIVITIES

The Federal Food, Drug, and Cosmetic Act requires that reasonable standards for foods be established when such action is needed "to promote honesty and fair dealing in the interest of consumers." The purpose of this program is to establish standards that will prevent debasement in composition of foods and thus protect the health, nutrition, and pocketbook of the consumer.

Standards went into effect for mixed nuts, grated cheese, and peanut butter. The peanut butter standard became effective after the Supreme Court refused to hear objections to a decision by the Court of Appeals upholding the FDA standard requiring 90 percent peanuts.

The mixed nut standard is designed to stop the deception of consumers by products represented as mixed nuts which are predominantly peanuts. If the weight of any one kind of nut exceeds the combined weight of the others, the name "mixed nuts" must be followed by the percentage of that kind. At least four kinds of tree nuts must be used, and no one ingredient may be less than 2 percent or more than 80 percent of the mixture. Label pictures must reasonably indicate the contents. The fill of container is fixed at 85 percent of the "apparent" size of the package.

Standards of identity and quality for cherry pie were published. The identity standard prescribes in general terms what a cherry pie is and how it shall be labeled. The quality standard prescribes the minimum amount of cherries that must be present and the minimum weight for a pie in a pan of a particular diameter, and limits the amount of blemished cherries that may be present. The quality standard further requires that if the requirements are not met, the pie must be labeled "below standard in quality" because it contains "too few cherries," "blemished cherries," or is "too shallow" as the case may be. These standards have not yet become effective because of industry action to block some



Analysis of food for mineral content begins when the sample is converted to dry ash in a muffle furnace, removing its organic matter.

of the provisions in the quality standard.

Twelve existing food standards were amended. Typical changes included allowing: the optional use of ascorbic acid as a dough conditioning agent in bread and in whole wheat flour; the use of a new acidification process in the manufacture of cottage cheese; the use of slightly sweetened water as a packing medium for canned fruit cocktail; and the use of xanthan gum as an optional ingredient of French dressing.

Six temporary permits for test marketing of foods deviating from standards were issued. Several of these were to permit the use, as a packing medium, of a juice from a fruit other than the fruit being packed; for example, canned peaches packed in clarified grape juice. Another was to permit the addition of an increased level of nutrients to enriched flour for use in direct food distribution programs for the needy.

NUTRITION AND SPECIAL DIETARY FOODS

Consumers' concern about the quality of foods grows as more and more new products appear and the processing of conventional foods primarily for the sake of consumer convenience becomes more complex.

FDA took three actions which will help consumers to better assure their ability to make wise selections from the growing array of food products. The first was to promote the testing of three specific types of nutrition labeling on selected food products by five food chains around the country. One contract study is testing the practicality of the labeling methods by monitoring consumer purchase behavior in a home delivery system in which food purchases are made from a catalog. Another project in the search for a workable nutrition labeling system is a contracted study to measure consumer attitudes toward nutrient labeling. Results of the investigation are expected to show what, if any, benefits there are to consumers which are not reflected in product sales. An important part of the study is relating attitudes to demographic characteristics of the individuals sampled.

The second Food and Drug Administration action was publication of a proposal concerned with labeling of the fat components of foods to help consumers who wish or need to control their fat intake.

Third was publication of a proposal to foster a wider consumer use of iodized salt by use of a simple label statement explaining its special nutritional importance to prevent goiter.

Nutritional wholesomeness of individual foods, especially those which are major contributors of calories to the diet, is one characteristic which must not be lost with new developments in food technology. Of equal importance to informing consumers of a food's nutrient content is assuring that the expected quality is actually present. Nutritional guidelines for composition of specific classes of processed and formulated foods is the approach being taken. A special committee of the Na-



In studies of trace minerals, a laboratory aide uses a capillary tube to take blood from the wing vein of a two-week-old Japanese quail, to test for anemia. Below, a food shopper muses as he fills his cart.



tional Academy of Sciences-National Research Council, organized under an FDA contract with the Academy, outlined the general principles which should be applied and sent to FDA its first guideline recommendation for frozen "heat and serve" convenience dinners. Published on December 23, 1971, this proposed specification sets minimum levels for protein, vitamin A, thiamin (vitamin B), riboflavin (vitamin B₂), niacin, and iron, based on the food's caloric content. It calls for a source of protein derived primarily from meat, poultry, fish, or cheese; potatoes, rice, or other cereal products; and a vegetable other than potatoes. Other food components may also be used in addition to the three named. Manufacturers complying with the guidelines would be permitted to indicate this on their labels.

A new class of foods called "textured protein products" is rapidly entering the marketplace in many forms. Assuring the nutritional quality of products made from them but resembling familiar foods of high quality was the purpose of a proposed standard of identity published in midyear.

Two important developments have resulted thus far from the hearings on special dietary foods labeling which ended last year. One was publication of a tentative regulation on infant foods, defining the expected nutritional quality of formulas intended as the sole diet of infants. The second was receipt of the hearing examiner's report by the Commissioner on labeling of foods for special dietary use and composition of dietary supplements. The latter report should serve as a basis for revised regulations on fortified foods.

POCKETBOOK PROTECTION

During a period in which the Government is seeking to control inflation, FDA actions to protect the consumer's pocketbook have increasing importance. The cost of deceptive and misleading food labeling has never been measured but must be very great in terms of what consumers could save if such practices were eliminated.

The consumer has been confused by packages and labeling. Net contents statements have frequently been inconspicuous and in varying units, making value comparisons difficult. Size designations, such as "large," "family," and "jumbo" are misleading when inconsistent among similar products. "Cents-off" have not always been passed on to the buyer. Slack-filling of containers has become apparent to consumers only after opening the containers at home.

During fiscal year 1971, FDA increased its efforts in all these areas to assure the public that foods are packaged and labeled in accordance with the laws enforced by the Agency.

At the request of the White House Conference on Food, Nutrition and Health, FDA initiated a study of the net weight practices of food manufacturers by reviewing and checking net weight control procedures during every regularly scheduled inspection of food packaging establishments.

In May 1971, a regulation was published declaring foods misbranded if the labeling bears deceptive statements or illustrations as to their geographic origin. The regulation, published as a proposal last year, was issued

under enforcement provisions of both the Federal Food, Drug, and Cosmetic Act, and the Fair Packaging and Labeling Act.

In May 1971, FDA also published and invited comment on a proposal by LABEL, Inc. (Law Students Association for Buyers' Education and Labeling), to require the listing of all ingredients on the labels of all foods. The proposal would amend current regulations and make ingredient listing mandatory by order of predominance in standardized foods, as is presently required for nonstandardized foods. Subsequently the Agency concluded that existing law does not authorize the proposed regulation, and that legislation is needed. In the meantime, voluntary action for complete ingredient labeling will be encouraged.

FAIR PACKAGING AND LABELING ACT

The fiscal year 1971 was the first in which the Fair Packaging and Labeling Act was vigorously enforced. Industry compliance has been good, but not complete. Approximately 100 seizures were made of foods and cosmetics for labeling violations of this law. Several hundred shipments of foreign-made products were detained at ports of entry.

Regulations to insure honesty in "cents-off" and other price representations on labels of foods, drugs, and cosmetics were announced June 30, 1971. Revised, final regulations were published in the *Federal Register* on December 30, 1971. The new rules, compatible with those issued by the Federal Trade Commission for other consumer products, are broader in scope. Whereas the FTC rules apply only to labels, the FDA regulations include labels and all associated packaging, labeling, and point-of-sale displays.

Sponsors of a "cents-off" promotion are required to print the number of "cents-off" on the label. The retailer must then stamp on the package the single price to be paid by the consumer and must post a placard or shelf marker listing the product's regular price.

Commodities to be labeled with size representations such as "economy size," "bargain size," "budget pack," and "big value" must be priced at least 5 percent less than the lowest price per unit of weight, volume, or measure of all other sizes of the same product offered simultaneously.

Introductory-offer items must bear on their label the anticipated after-introductory-offer price; introductory offers can last no longer than six months and may be used only for products that are new, substantially changed, or being introduced for the first time in the marketing area.

Sponsors of coupon promotions not redeemable at the retail store are required to reimburse the consumers for cost of redeeming their coupon by mail.

The "cents-off" regulation limits to no more than three the number of promotions for any single size commodity in the same trade area within a 12-month

period, and requires a lapse of 30 days between promotions for any package size. The promotion may not be conducted in a trade area more than six months in a 12-month period and may not exceed 50 percent of the item's total sales.

The regulations governing frequency and duration of the savings representation promotions were to become effective January 29, 1972; the introductory offer, coupon, and economy size provisions on March 31, 1972; the "cents-off" labeling rules on June 30, 1972.

To obtain facts needed for regulations on slack-filling and package size designations, the FDA negotiated cost-reimbursable contracts with 11 State regulatory agencies. During the fiscal year, 11,000 samples representing 55,000 packages were examined by the State laboratories for slack fill. These data will serve to identify foods and food groups which will be investigated as to their filling and packaging practices to secure the facts needed for the proposed regulations.

The cost-reimbursable-type contract program with the States proved so successful that the FDA entered into new contracts with ten State agencies during fiscal year 1971 to perform a retail survey with a twofold objective:

1. To ascertain the impact of the Fair Packaging and Labeling Act in the marketplace and to gain an accurate and timely insight into the level of compliance with regards to foods and cosmetics.

2. To update information on the types of savings representations presently being employed on retail packages, an appraisal of the incidence of abuses, and if possible, a dollar estimate of the money the consumer is being bilked out of by such economic cheats.

Other activities which protect the economic interests of consumers are reported in sections dealing with Food Standards and Nutrition.

COOPERATIVE PROGRAMS IN FOOD SANITATION

The milk, shellfish, and food service programs differ from other FDA food protection activities in being largely advisory to State and local agencies.

Food Service Sanitation

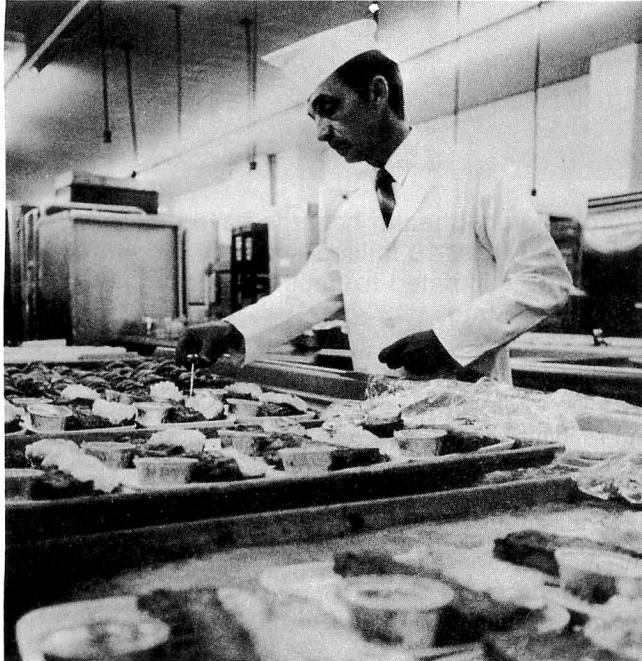
A recommended "Ordinance and Code Regulating the Processing of Eggs and Egg Products" was printed and distributed.

Kentucky and Maryland adopted food service sanitation laws based on the 1962 Food Service Sanitation Manual. Twenty-seven States have thus far adopted such laws.

Meetings were held with five milk and food equipment standards groups and 17 standards were considered, developed, and/or revised. Assistance was also rendered to the Illuminating Engineering Society, Food

Service Facilities Subcommittee, in revising its recommended illumination levels in food service establishments.

A proposed "Special Orientation Program Leading to Standardization of New Regional Food Service Sanitation Consultants" was developed. Services to the States included various training projects and assistance in evaluating and standardizing their food service sanitation programs.



Sanitarian of FDA's Interstate Travel Sanitation Branch checks the temperature of prepared entrees at an airline catering plant. This firm prepares 20,000 meals a day.

Milk Sanitation

Adoption of the FDA-recommended 1965 Pasteurized Milk Ordinance was increased to 28 States when Virginia and Tennessee revised their milk sanitation regulations to conform with the Ordinance. Studies were completed on six projects related to the processing and packaging of milk.

Guidelines were issued for the Control of Abnormal Milk, including testing procedures for somatic cells. The list of Certified Interstate Milk Shippers was published on a quarterly basis. This list contains the names of approximately 1,600 shippers participating in the program.

Twenty-two State Milk Sanitation Rating Officers were certified or recertified as part of FDA responsibilities under the Interstate Milk Shippers Program. To assure the validity of the ratings, 289 Interstate Milk Shippers were check-rated. Nine Regional Seminars were conducted for the purpose of bringing about uniform application of the requirements of the 1965 PMO and IMS Agreements.



This FDA inspector is checking the temperature of cooked crabs that are waiting to be picked.

Shellfish Sanitation

The National Shellfish Sanitation Program controls the sanitary production, harvesting, processing, and marketing of safe shellfish for interstate shipment.

The Shellfish Sanitation staff conducted comprehensive evaluations for 22 States and published 24 Interstate Shellfish Shipper Lists. It also issued a policy statement on labeling shellfish shipments. Three studies were completed on microbiological and viral indices important to FDA's understanding of shellfish control measures in growing waters. Seventy sewage treatment plant plans were reviewed for pollution effects on shellfish waters. Reports were prepared on the U.S. scallop industry and the Japanese shellfish program.

Two training courses were conducted in Rhode Island and Louisiana on Shellfish Growing Area Surveys and Evaluation of State Shellfish Sanitation Programs. There were 74 field investigations associated with sanitary surveys.

Action was begun to withdraw FDA endorsement of two State shellfish sanitary control programs, but corrective steps were taken and the programs strengthened to an adequate level.

ADMINISTRATION OF OTHER ACTS

Public Health Service Act.—FDA now administers Federal Quarantine Regulations (CFR Part 72) which establish sanitation requirements for interstate passenger conveyances and public facilities on interstate highways.

A regulation was issued restricting the discharge of human and other wastes from railroad trains.

FDA continued publication of the Official Classification Lists of Acceptable: Airline Catering and Watering Points, Bus Servicing Areas and Catering Points, Milk

and Frozen Dessert Sources, Railroad Watering Points, and Vessel Watering Points for Interstate Carrier Use.

Guidelines were released for Evaluating Aircraft Lavatory Servicing Vehicles Construction and for Evaluating Aircraft Potable Water Servicing Vehicle Construction.

The Interstate staff reviewed 288 equipment items, two conveyance sewage treatment systems, and 1,268 vessel plans, including eight on-site vessel construction inspections.

Tea Importation Act. All tea imported into the United States is required to be examined for compliance with quality standards set by the U.S. Board of Tea Experts. A total of 149,018,214 pounds was examined in the fiscal year, of which 13 lots, totaling 602,103 pounds, were rejected. Six of the 13 rejections were taken to the Board of Tea Appeals and the FDA examination was upheld in all of them. New Orleans has become the leading U.S. port of entry for tea, due largely to the location of new plants for the production of instant tea.

Federal Filled Milk Act. The third prosecution in the history of the Filled Milk Act (1923) and the first in nearly 28 years was terminated in March 1971, with a thousand dollar fine against the corporation, Cumberland Farms Northern, Inc., Portsmouth, New Hampshire. This law prohibits interstate distribution of milk products in which the butterfat content is replaced with vegetable oils to make them resemble milk or cream.

Federal Import Milk Act. Permits were renewed for importation of canned milk from Denmark and New Zealand. Exporting countries must have acceptable sanitary controls.

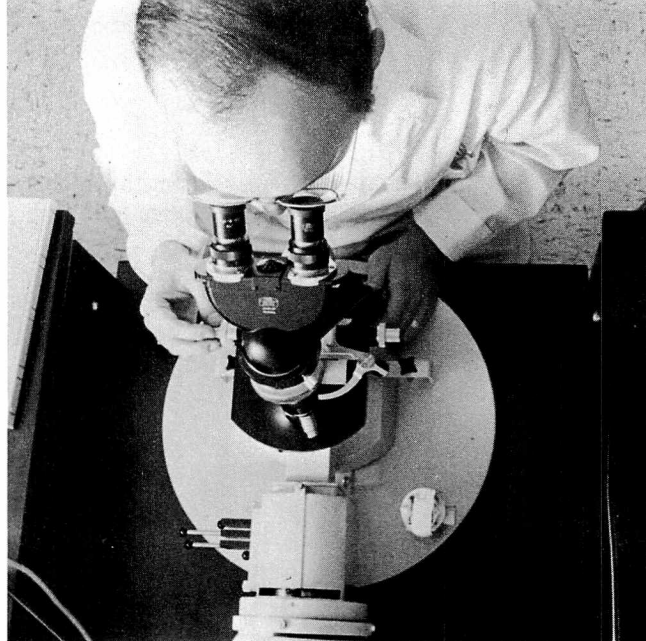
FOOD RESEARCH

Bacteriological Problems

Clostridium botulinum type E produces a lethal toxin which causes botulinum food poisoning. An improvement was made in the screening test by which food samples containing the organism can be separated for more conclusive tests. The ability of *Clostridium botulinum* antibodies to fluoresce is being used to classify various strains with regard to their comparative toxicities.

A nontoxic organism that closely resembles *Clostridium botulinum* has been found to produce substances, called boticins, which act against bacteria and interfere with the detection of toxic organisms; information gained from studies of the boticins will be used to improve methods of detection.

A similar bacterial organism, *Clostridium perfringens*, also causes foodborne illness although its consequences are less serious than those of *C. botulinum*. Improvements in the growth medium used in test methods permit the quantity of this toxic organism to be estimated very closely and the new medium has proved useful in the examination of foods associated with outbreaks of foodborne disease caused by *C. perfringens*.



Microbiological health hazards have high priority at FDA. At least 10 million cases of foodborne illness are estimated to occur annually in the United States.

Other studies produced improvements in methods for detecting *Salmonella* and *Staphylococcus* enterotoxin, and to identify *Vibrio parahaemolyticus* in seafood.

Pasteurization Techniques

For many years, bacterial contamination of milk and dairy products has been controlled by pasteurization. Because of changes in dairy technology, the industry is interested in pasteurization by relatively high temperatures for short periods of time. Studies were carried on to evaluate the effectiveness of pasteurization by direct steam injection.

Similar studies have been made of pasteurization of egg products, and equipment of improved design has been recommended. It has also been found that the pasteurization process affects other tests of the cleanliness of eggs. Investigation showed that the problem is due to an enzyme present in high concentrations in egg white. The high temperatures of pasteurization cause the enzyme to become more active and this in turn causes the bacteria to disappear, resulting in lower microscopic counts.

Mycotoxin Research

Studies have continued on the highly toxic mycotoxins produced by naturally occurring molds. Improvements have been made in the official methods for aflatoxins in cottonseed, peanut butter, brazil nuts, and corn. A short-cut test was developed which screens out contaminated corn samples for further tests, with considerable saving of time, work, and materials. The problem of obtaining a suitable, uniformly contaminated sample for analytical comparison has also been solved. Poultry feed and poultry litter on two Ohio farms were examined for aflatoxin-producing molds; of 103 isolates

tested, 13 (11 of them from poultry feed) were found to contain toxic fungi. The mycotoxin sterigmatocystin can now be identified in grain by its tendency to fluoresce. Studies are also being conducted to determine the toxicity to poultry of patulin, another member of this toxic group of compounds.

Adulteration Problems

Work was carried out to establish the normal composition of foods and to detect adulteration of various foods with cheaper substitutes. A method which will detect as little as 10 percent skim milk powder in fresh fluid milk was modified for regulatory use, and a procedure was developed to detect the presence of added foreign fats in vegetable oils such as peanut oil. A number of infant foods were tested for their content of trace elements essential to human health; some were found to be deficient in copper, others in zinc, and most of them were deficient in iron.

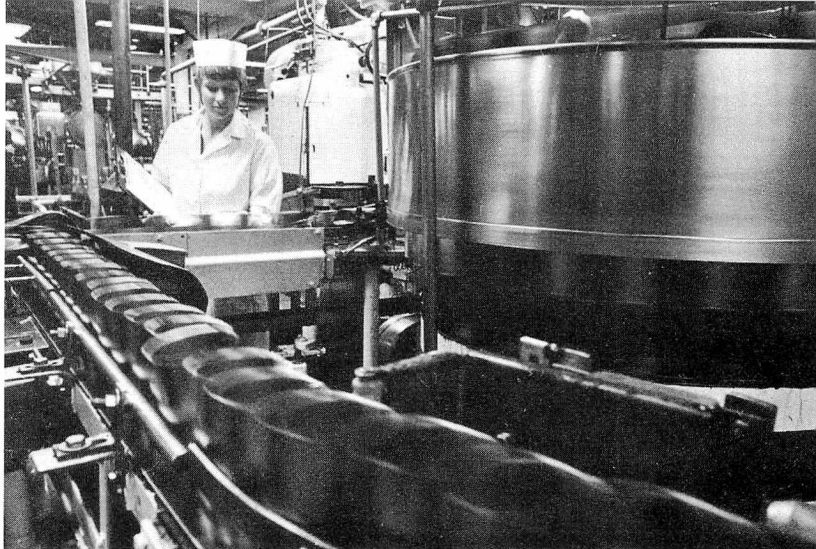
Certain compounds, such as ethylenediamine-tetraacetic acid (EDTA), which is approved for many foods uses, have the ability to tie up metals so that they cannot be utilized by the body. A number of such compounds were tested in chicks. Of the 10 compounds tested, none affected the chick's utilization of calcium but they did affect utilization of iron and manganese. The effects depended on the form and amount of the compound present.

Nitrosamines, some of which have shown to be carcinogenic to test animals, have been identified at very low levels in samples of smoked fish treated with nitrite-nitrate as a preservative to prevent botulism. Nitrosamines have also been detected in samples of untreated fish. Since some meat products are also processed with nitrite-nitrate, a number of processed meats were examined for the presence of nitrosamine by the method previously developed at FDA. None of the samples contained as much as 10 parts per billion, the limit of detection for the method, although a single sample of ham appeared to contain traces of nitrosamines.

Monosodium glutamate (MSG), widely used as a seasoner or flavor enhancer, has been reported to cause adverse effects. In studies with rats, MSG was not found to impair brain development nor affect reproductive function. The chief effects noted were hyperirritability in weanling rats, and a rough, shaggy-hair coat which persisted for about three-four weeks.

Cadmium, which is naturally present in food, water, and air, can produce cardiovascular and respiratory diseases if exposure to it is excessive. Studies with Japanese quail as a test animal showed that iron, vitamin C, and to a lesser extent, copper and the amino acid L-cysteine help protect against the toxic effects of cadmium.

Cyclamates are no longer permitted in foods, but interest continues in their effects. When rats were fed diets containing low levels of cyclamate, fat metabolism was found to be affected, and metabolism of glucose increased. Bladder lesions were observed in rats fed



The "woman's viewpoint" is becoming well represented among FDA inspectors. Over 30 are now employed. Women laboratory and medical scientists—chemists, bacteriologists, physicians, pharmacists—number around 250.

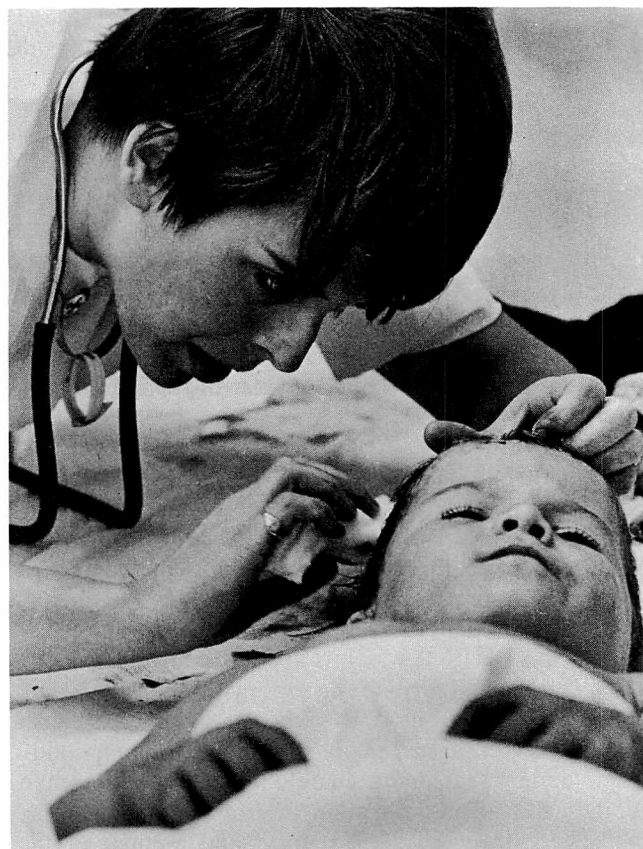
cyclamate for long periods of time, and several rats developed bladder tumors. Another study showed that seven of 11 rats converted cyclamate to one of its metabolites, cyclohexylamine, which has been found to cause chromosome aberrations in laboratory animals. When cyclohexylamine was given to rats at high dose levels, sperm cells were affected.

PCB's. In recent years FDA has found that certain industrial chemicals present health problems similar to those caused by pesticides.

Methods have now been developed to distinguish PCB's from pesticides and from the dioxins. The dioxins were the toxic materials chiefly responsible for the chick edema disease which decimated poultry flocks over 10 years ago. Members of this class of chemicals differ in their toxicities. A study was made of the manner in which the various dioxins were distributed through the tissues of test chickens fed a fatty material containing dioxins. It was found that the more chlorine the particular dioxin contained, the less likely it was to be absorbed by the tissues; 92 percent of these higher chlorinated compounds were excreted. The lower chlorinated compounds were found in the bones, hearts, intestines, kidneys, livers, and skin of the test chicks but not in the adrenals, testes, or brains.

A method was developed for detecting the presence of the dioxins in chlorophenols, and a number of commercial samples were examined and found to contain small quantities of dioxins. It has also been learned that the toxicity of the herbicide 2, 4, 5-T is due chiefly to its contamination during manufacture by one of the dioxins. A method has now been developed to separate the dioxin from the herbicide for identification. Commercial samples of 2, 4, 5-T when given to hamsters caused abnormal fetuses and other reproductive damage, whereas 2, 4-D (structurally similar) did not have any significant effects on reproduction, confirming the conclusion that the toxic effect was due to the contamination of 2, 4, 5-T with dioxins rather than to the herbicide itself.

Drug Actions for Effectiveness and Safety



Consumers and patients were protected by thousands of individual regulatory or voluntary actions to insure quality and eliminate defective or ineffective products.

Major public health and medical problems of the Nation were dealt with by the Food and Drug Administration during 1971. A few of these activities came to public attention but most went unnoticed. This report is intended to provide a more complete accounting of the Agency's drug activities.

Highest priority was again given to a long-range effort—FDA's program to ensure the effectiveness of the country's drug supply. Dealing mainly with prescription drugs introduced since 1938, some 1,100 official statements were published during the year to put drug manufacturers on notice that better evidence to support claims must be presented, or labeling changed, or the products withdrawn from the market.

The determinations on effectiveness are made by the best qualified medical experts in the country. Their knowledge is being focused on each drug, to carry out the mandate of the law that effectiveness be shown by "substantial evidence."

New policy on combination drugs—those containing two or more active ingredients—resulted from the reviews for effectiveness. Hazards of drug use are much increased when more than one drug is taken simultane-

ously. The hazards can be balanced by rational combinations of drugs to deal with specific conditions. In brief, the new policy requires that each ingredient contribute to the claimed effect of the combination, and that the combination be safe and effective for a significant number of patients who require such concurrent therapy.

Probably the most far-reaching result of the drug effectiveness program will be, not the ineffective products taken off the market, but the lasting improvement of patient care through drugs that accomplish their intended purpose.

The public takes more doses of drugs for self-medication than by prescription. To require that prescription drugs meet high standards of effectiveness, but not those purchased for self-medication, leaves an obvious gap in consumer protection. Initial steps were taken to launch a comprehensive review of over-the-counter drugs to assure that they are safe and effective and that the labeling of these home remedies is true and clearly understandable to the user. Details on the scope and plans for this project were announced publicly by the Commissioner on January 4, 1972.

Some 16,000 physicians are presently testing investigational new drugs on about 60,000 patients each year. To safeguard such patients, notice of these investigations must be given to FDA. A new regulation requires a 30-day waiting period before administering the drugs to humans, giving time for FDA medical officers to review the proposed studies. Over 1,000 such reviews were completed in fiscal 1971.

Methadone, when used for heroin addiction, is an investigational drug. Approximately 300 physicians and clinics are testing it under FDA regulations. Six clinics were closed during fiscal 1971 when it became apparent that they were not controlling their studies to prevent abuse.

FDA's tally of drug lots recalled from the market totaled 1,543 in fiscal 1971, compared to 927 the previous year. Most of these were voluntary actions by the manufacturer, some not involving any law violation. A few were associated with serious medical emergencies.

Recalls and seizures of Digoxin, Digitoxin, and digitalis were necessary when FDA analysis disclosed serious variations in potency. An industry-wide "voluntary certification" program was instituted, in which samples of all production batches were submitted for FDA testing and approval.

A total recall of Abbott Laboratories' intravenous solutions was undertaken because of bacterial contamination. Over 300 cases of septicemia and nine deaths of patients on IV therapy were reported by some 21 hospitals. More than 5.5 million bottles of 105 products were recovered and destroyed by the firm under FDA supervision (see "Drug Recalls").

Communicating the great volume of important new information to the medical profession is one of today's important public health problems. FDA is involved because of its responsibility to enforce the law on drug

labeling and prescription drug advertising. Required information has little value unless it reaches those who diagnose and prescribe. A new effort to close the drug information gap is the FDA Drug Bulletin, now reaching some 600,000 physicians and other health professionals in the United States and other countries. Particularly, it informs physicians concerning new, medically significant information requiring label changes to safeguard the patient.

This introduction covers only a few highlights of the year's work. Additional, more detailed information is presented in the sections that follow.

INVESTIGATIONAL NEW DRUG ACTIVITIES

The Federal Food, Drug, and Cosmetic Act requires that before a sponsor of a new drug investigation may test the compound in human beings, he must first submit to FDA a Notice of Claimed Investigational Exemption for a "New Drug" (IND). In the past the sponsor was allowed to begin administering the new drug to humans immediately after filing the IND. To allow a reasonable time for review of research plans, a regulation was published requiring a delay of 30 days between IND submission and the beginning of studies. FDA may now prevent the exposure of human beings to investigational drugs where risks outweigh benefits, before that exposure takes place.

FDA medical officers completed 1,015 reviews of investigational drug studies during fiscal 1971. Some 938 original submissions were accepted and reviewed, but 366 submissions were not accepted due to deficiencies in the proposed studies.

Substantial progress was made in expediting the review of IND's. At the year's end only one IND was over 30 days old without safety review. This trend was due to the increasing familiarity of product managers with their new responsibilities.

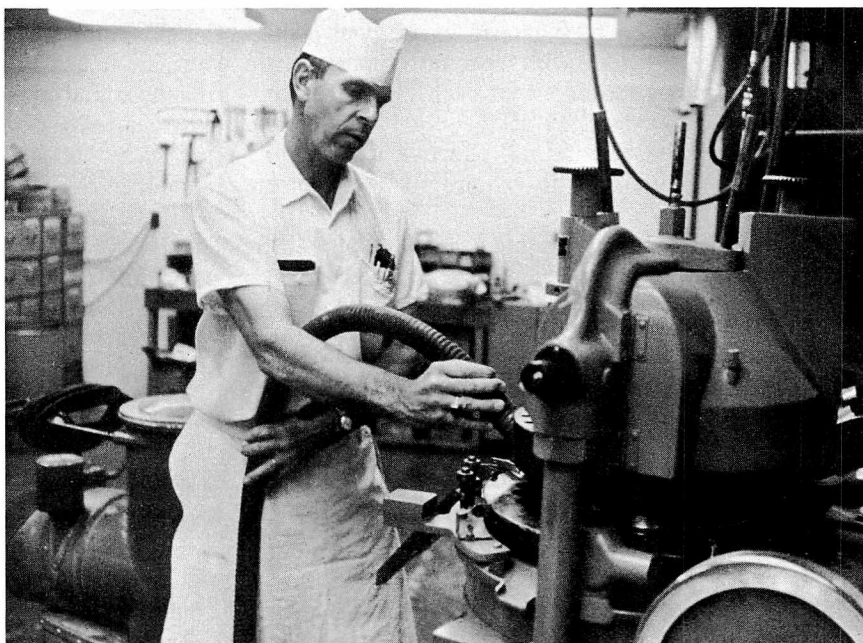
The approval last year of L-dopa for Parkinson's disease contained a unique condition that studies of the drug be continued after marketing. This was done to allow the benefits of the product to reach those in greatest need, while making further evaluations of the hazards of the drug. Anticipating other similar situations, FDA published a proposal this year to require a fourth phase of clinical studies for certain drugs and to provide for provisional marketing of such drugs.

CLINICAL INVESTIGATION MONITORING

Reviewing the clinical investigations of new drugs under the 3,252 IND's which were active at the end of fiscal 1971 is a major workload.

Systematic surveillance of clinical research studies was carried out in 13 investigations of individuals and 19 inspections of facilities. These led to 49 drug manufacturing and laboratory inspections to follow up on problems uncovered. Seven investigations and inspections resulted in recommendations for action.

Drug integrity: Operator cleaning residual drug material from a tablet press after completion of a tableting run.



In the fall of 1969, visits by medical officers and District inspectors to pharmaceutical firms were instituted to observe how they monitor their clinical investigations. In February 1970, the on-site program was expanded to include laboratory visits by pharmacologists from the Bureau of Drugs to evaluate performance in that area. This year (August 1970), visits by District inspectors to drug company research directors were begun to evaluate their compliance with the investigational drug regulations.

Many drug studies, especially in their early stages, are carried on in establishments such as nursing homes, hospitals, mental institutions, and prisons. When instances of poorly conducted research came to FDA's attention, it was concluded that additional protection was needed for the persons taking part in these studies. A regulation was issued requiring that all human drug studies on such patients be approved and supervised by a committee appointed by the institution. Duties and responsibilities of such committees are similar to those required under research contracts and grants from the Department of Health, Education, and Welfare. The FDA regulations, however, require at least one member of each committee to be a nonphysician.

Methadone, widely used for maintenance treatment of heroin addiction, has not been approved by FDA as safe and effective for this use. Approximately 300 physicians and clinics have submitted investigational drug applications to FDA for this use of methadone and have initiated studies. When it became apparent that not all investigators were controlling their studies to prevent abuse, FDA issued instructions to all sponsors regarding compliance with the general new drug regulations. Six clinics have since been closed, as a result of FDA investigations. FDA works closely in this program with State and local authorities and with the Federal Bureau of Narcotics and Dangerous Drugs.

NEW DRUG APPLICATIONS

Applications for approval of new drugs received in fiscal 1971 totaled 229, of which 99 had not previously been submitted. Twelve submissions were rejected as inadequate. Completed reviews increased in fiscal 1971 to 256 as compared to 193 in 1970. Applications for 26 drugs were approved, eight of which are considered as new single chemical entities: Lysodren Tabs (mitotane), for treatment of inoperable adrenal cortical carcinoma of both functional and nonfunctional type; Efudex and Fluoroplex Topical Solution (fluorouracil) for actinic or solar keratoses; Dexon Polyglycolic Acid Sutures (absorbable surgical sutures); Rubratrope-57 and Rubratrope-60 (cyanocobalamin) capsules for diagnosis of addisonian (pernicious) anemia and a diagnostic adjunct in other defects of intestinal vitamin B₁₂ absorption; FUDR (fluoxuridine) for palliative management of carcinoma; and Narcan (naloxone hydrochloride), a narcotic antagonist for reversal of narcotic depression.

The pace of NDA reviews accelerated despite diversion of manpower to other programs such as investigational drug review, and at the end of the year, 91 NDA's were under review, only nine of which were over 180 days old—down from 118 under review at the beginning of the year, 16 of which were over 180 days old. This indicates that the Bureau of Drugs has been able to more rapidly review and reach decisions on the safety and efficacy of new drugs proposed for marketing. Of 109 NDA's the Bureau found not approvable, major deficiencies were found in data relating to manufacturing (74 percent), clinical efficacy (63 percent), and labeling (62 percent).

After approval of an NDA, the manufacturer is required to submit records and reports on any new significant information learned during marketing, such as

new adverse reactions to the drug. During the 1971 fiscal year, 3,282 reports were received containing such information. To reduce administrative workloads and obtain a clearer picture of the products on the market with approved NDA's, 2,752 inactive NDA's were identified and withdrawn with the manufacturers' concurrence. Most of these were for products no longer manufactured or which had not been manufactured. This mass withdrawal also reduced the workload associated with evaluating the efficacy of drugs marketed between 1938 and 1962. These actions left approximately 5,300 original approved NDA's on FDA's books, of which about 4,700 are still subject to review for effectiveness.

In order to ensure the continuing safety and efficacy of products with approved NDA's after marketing, the Bureau of Drugs evaluates changes in formulation, manufacturing procedure, and other modifications to NDA's in the form of supplements. This workload increased from 2,109 supplements received in fiscal 1970 to 2,253 in fiscal 1971.

Guidelines for Research Sponsors and Investigators

To speed the development of new drugs so their benefits reach the consumer as quickly as possible, it is important that the industry and research community understand the nature and extent of scientific evidence required to judge safety and efficacy. Much effort was given during fiscal 1971 to development of clinical guidelines for drug manufacturers and investigators. With improved understanding, there should be fewer hazards to those exposed to investigational drugs and higher quality data to support New Drug Applications. The clinical testing guidelines are being sent to specialty medical societies for comment. Initial responses have been favorable, and the guidelines should be completed during fiscal 1972.

DRUG EFFECTIVENESS

The FDA Drug Efficacy Study Implementation program (DESI) continued to have top priority during 1971. Through "DESI" the Agency is evaluating the efficacy of several thousand drugs marketed before the passage of the 1962 Drug Amendments. Previously the law required premarketing approval for safety only. The initial efficacy evaluations were made by expert committees of the National Academy of Sciences—National Research Council, which submitted 2,824 reports covering over 4,300 drug formulations.

Numerous law suits filed by prescription drug manufacturers challenged FDA's implementation of the study, but strong court decisions have upheld FDA's actions. In the most recent of these, the U.S. Court for the District of Delaware held that the Commissioner may require that a genuine and substantial issue of fact be raised as a condition for granting a hearing on a drug affected by the study implementation. A request by the Pharmaceutical Manufacturers Association for a preliminary injunction against FDA action was denied (see "Decisions of the Courts").

To expedite the program a DESI Project Office was organized in the Office of the Bureau Director to manage the complex reviews, evaluations, and publications concerning the NAS/NRC reports, a large undertaking.

The Project Office completed FDA review of all the submitted reports by November 1, 1970. Efforts were directed toward removing drugs from the market or removing claims and indications from the labeling when evidence of effectiveness was lacking. Administrative steps to remove the following drugs from the market were completed: penicillin-streptomycin combinations, penicillin-sulfonamide combinations, tetracycline-oleanomycin (or trolindomycin) combinations, parenteral



Drug integrity: Plant control chemist tests a drug during the manufacturing process.



Drug integrity: Checking the adjustment and operation of a capsule filling machine for correct fill.

dihydrostreptomycin, and thyroid-amphetamine combinations.

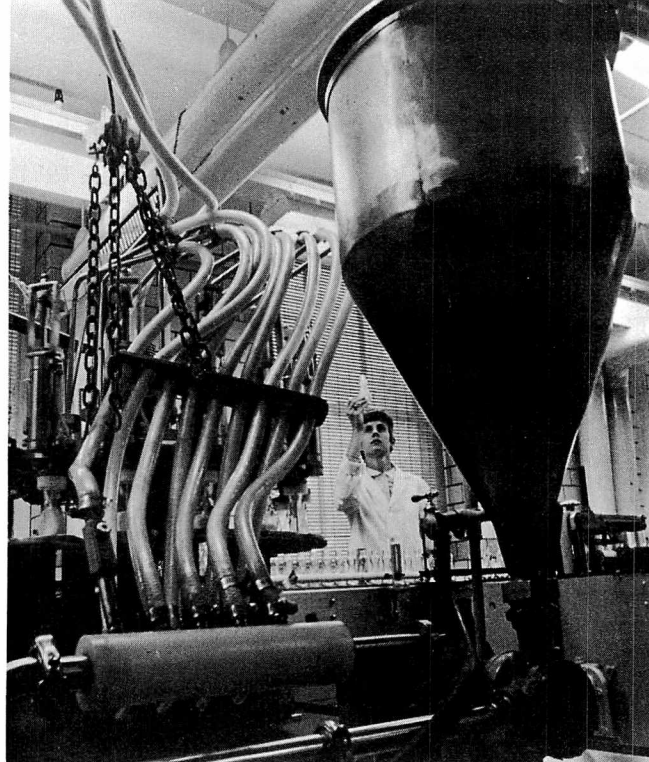
The labeling of many marketed drugs has been revised to narrow the scope of recommended use to only those claims for which safety and efficacy have been shown. Among these were sodium heparin, chlorpromazine, anti-depressants, and curare-type drugs.

During fiscal 1971, *Federal Register* notices were published concerning drugs involved in 1,163 of the NAS/NRC reports, bringing the total of 1,715 published reports, and completing 62 percent of the initial implementation. A total of 159 NDA approvals were withdrawn, removing ineffective products from the market. Industry responses are increasing, generating additional data to justify continued marketing of products not found effective.

When the NAS/NRC efficacy review shows a drug to be both safe and effective, manufacturers of like products not covered by an effective NDA may submit an abbreviated NDA (ANDA) if there are no unusual manufacturing problems associated with the drug. An abbreviated NDA need not contain the detailed clinical data normally required for approval. ANDA receipts have kept pace with implementation publications, from three received in fiscal 1969 to 543 in 1971. Increasing manpower has been devoted to the review of these applications to allow the continued marketing of effective products.

Further litigation with the drug industry is expected, and extensive market surveillance and compliance activities will be needed to assure the public that all effective drugs covered by the Study are properly labeled and that all ineffective drugs are removed from the market.

The Study generated a massive workload. Perhaps its



Drug integrity: Inspector checks the quality and cleanliness of containers prior to filling.

greatest impact will be in generating action to identify deficiencies in scientific data and to improve claims of effectiveness for the wide spectrum of drugs which remain after the ineffective drugs are eliminated.

As the FDA moves to evaluate remaining claims and to bring labeling into line, the program will directly affect drug advertising (annual investment by drug companies in drug promotion estimated at \$800 million). Indirectly, consumer payments for drugs may be affected through the removal of expensive proprietary products and greater use of lower cost generic products. A further benefit should be improved patient care through the improvement of drug use. The impact of DESI on the drug industry, the physician, the patient, and the FDA will be direct, long-lasting, and unprecedented.

Over-the-Counter Drug Products Evaluation

Late in fiscal 1971, the FDA Commissioner testified before the Senate Select Committee on Small Business that FDA plans to review the composition and the promotion of over-the-counter (OTC) drugs to assure that they are safe and effective and that their labeling is understandable to the lay public. This extensive program should benefit nearly every American since the large majority of drug dosages consumed by the public are sold over-the-counter. Formal planning was started and the review began in fiscal 1972. Overall philosophy of the project will be developed by an FDA National Advisory Drug Committee. The goal is to modernize the entire field of home remedies—ensure that they are safe and effective in the light of present knowledge, and described fairly and adequately with labeling in everyday language so the consumer can make an intelligent choice and use of the many such drugs on the market.



Automated turbidity readings of test cultures by a recording spectrophotometer determine the potency of antibiotics at the rate of one sample every 12 seconds.

Drug Experience Information Monitoring

To assess the safety of drugs, both before approval and after marketing, comprehensive drug experience information is needed. Much of this information can only be obtained from wide usage in medical practice. Various methods have been tried to collect, store, and process this kind of medical information. A committee of the National Academy of Sciences was asked to study the problem. It recommended that since the FDA is the principal national repository for such information, it should be the developer and manager of a new National Drug Experience Reporting System.

The proposed system would provide information on adverse reactions observed by physicians, on the epidemiology of drug usage, on intoxications and drug abuse, and on interactions observed during the intensive monitoring of selected groups of in-patients and out-patients. This approach, the Committee felt, would permit more careful monitoring of new drugs during the post-marketing phase, promote identification of rare adverse effects more rapidly, and would encourage more careful drug use by physicians and patients. It would also place FDA in a position to provide a valuable consultative service to physicians.

A comprehensive proposal for such a National Drug Experience Reporting System was completed during fiscal 1971, for initial development during 1972. To provide resources for the new system, the existing Hospital Reporting Contract System and Kaiser-Permanente Research Contract were phased out.

ANTIBIOTICS AND INSULIN CERTIFICATION

Each batch of antibiotics and insulin drugs is required by law to be tested and certified by the Food and Drug Administration. This service is supported by fees paid by the manufacturers. It is the most comprehensive control of drug quality administered by any Government agency.

During fiscal 1971, 26 Antibiotic New Drug Applications were approved, including some for new anti-infective



Drug integrity: Antibiotic testing in the FDA National Center for Antibiotics Analysis. Biologists checking groups of mice for mortality after a safety test.

agents: Rifampin for tuberculosis; Trobicin (spectinomycin) for gonorrhea; Keflex (cephalexin monohydrate), an oral cephalosporin; and Monocin (micycline), a nonphotosensitizing tetracycline with a broader spectrum than other tetracyclines.

Some 15,500 antibiotic and 348 insulin batches were certified or released in FY 1971. Less than 0.75 percent of the batches were found with defects. In order to speed the process between production and distribution of antibiotics, a procedural change was instituted to allow firms to submit samples for certification prior to completion of their tests and assays. Such concurrent testing by the National Center for Antibiotics Analysis and the firms should noticeably quicken the flow of antibiotic products. Further efforts to improve this process through automation were undertaken at the National Center.

As a result of review of efficacy, some 30 antibiotic products are no longer certified, including penicillin-sulfa combinations for oral use, penicillin-streptomycin combinations for intramuscular injection, and oral tetracycline-triacetyloleandomycin combinations.

SURVEILLANCE AND COMPLIANCE ACTIVITIES

While it is important that the safety and efficacy of drugs be established before marketing, it is also important to assure that once on the market drugs continue to be manufactured properly and labeled correctly.

An FDA-sponsored program to expedite reporting of drug defects was started late in 1970 in cooperation with other agencies of the Public Health Service. It coordinated reports of observed drug defects from PHS hospitals and dispensaries throughout the United States. This effort was expanded during fiscal 1971 through a cooperative Pilot Drug Product Defect Reporting Program involving the American Society of Hospital Pharmacists (ASHP), the U.S. Pharmacopeial Convention (USP), and the Bureau's Product Research and Surveillance Staff. In this program, 6,000 ASHP pharmacists serving in some 3,000 civilian hospitals report to the USP, which forwards the reports to FDA.

National Drug Quality Surveys

FDA's National Center for Drug Analysis at St. Louis, Missouri, is developing high speed, automated analysis of selected drug classes, sampled in such a manner that the quality of the drug may be evaluated nationwide. Over 1,600 batches of drugs were analyzed during fiscal 1971 representing over 75,000 individual assays.

Based on serious potency variations found in testing cardiac glycosides at the National Center, a "voluntary certification" program was undertaken to ensure a safe and effective market supply of the drugs. Digoxin and Digitoxin tablets from several manufacturers are still being submitted for assay prior to marketing.

National Drug Inventory

A total census of both prescription and over-the-counter drugs manufactured and marketed in the United States has never been taken. FDA has no authority to require such information from manufacturers. A complete and current listing of all marketed drugs would, however, provide valuable base-line data for many drug quality programs. Plans were initiated in 1971 to conduct such a national drug survey on a voluntary basis, beginning in fiscal 1972. Although legislation has been proposed to require such data of manufacturers in the future, FDA is starting with the voluntary effort.

Regulatory Activities

A decrease in the total number of court cases involving drugs occurred during the fiscal year, with 170 new cases started compared with 183 the previous year (see Table 1). Voluntary recalls of drugs, on the other hand, increased from 927 reported in 1970 to 1,543 in fiscal 1971 (Table 6). These figures include all kinds of drug products, with human drugs involved in about 67 percent of the court cases and 92 percent of the recalls.

Several contested cases raised the legal question

"what is a new drug?" In a seizure of Asper-Sleep, a night-time pain reliever, the Government charged that this new combination of old drugs was not generally recognized by experts as safe and effective for its intended uses, and therefore required premarketing approval. The court found, on the testimony of expert Government witnesses, that "the absence of appropriate medical evidence, whether adverse or tending to show safety and effectiveness, constitutes proof that a drug is a 'new drug' . . ." An appeal was stayed pending the outcome of FDA's planned review of effectiveness of over-the-counter drugs discussed previously (see also "Decisions of the Courts").

Lack of information concerning the safety of an inactive ingredient in Xerac, a preparation for acne, made it impossible to evaluate the safety and effectiveness of the entire combination, according to the charges in another seizure case. After testimony by experts on both sides, the court held that Xerac is a new drug. An appeal has been filed.

Drug Advertising

The 1962 Drug Amendments established regulatory control of prescription drug advertising to assure that these ads, which are aimed at a professional audience, present a balanced picture of a drug, including warnings, precautions, and possible adverse reactions. Regulations to carry out this provision were adopted by FDA in 1963 and have since been revised to spell out in detail the legal requirements, the latest being issued on June 12, 1971.

A total of 15,707 prescription drug advertisements were monitored in fiscal 1971, resulting in the cancellations of 83 different journal advertisements and other selected promotional labeling pieces. Other remedial actions included corrected advertisements and several "Dear Doctor" letters.

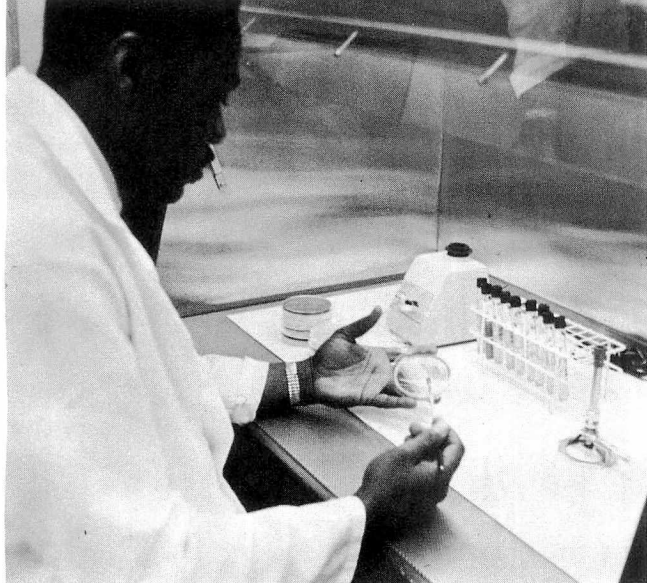
At the beginning of the year, advertising review of package inserts for NDA's and antibiotic applications prior to approval became part of the standard review process. The purpose of this review is to screen out unjustified promotional language which may contribute to false or misleading advertising.

Postal Service Collaboration

A wide variety of nonprescription drugs and devices are promoted by mail. From FDA's beginning it has collaborated with the U.S. Postal Service in actions against hazardous and ineffective products under postal fraud statutes. This effort consists largely of medical review of evidence collected by Postal Inspectors and testimony at fraud hearings. During fiscal 1971, FDA submitted 145 medical reports to the Postal Service for use in fraud cases and responded to 160 requests for information on other cases.

Drug Recalls

Important drug recalls included removal from the market of subpotent and superpotent shipments of Digitoxin and Digoxin tablets, mentioned previously; vi-



Drug integrity: Plant microbiologist streaking agar plates with a sterile needle to further identify microbial contaminants found in a drug preparation.

tamin C tablets with undeclared sodium ascorbate; and Abbott intravenous solutions.

The recalls of the Abbott products resulted from reports between October 1970 and March 1971 from eight hospitals in seven States concerning some 150 septicemias and nine deaths of patients receiving intravenous solutions. All eight hospitals were using the Abbott products. Later reports increased the number of cases to 350 from 21 hospitals. The company was made aware of the problem through reports from the hospitals and the Center for Communicable Disease Control at Atlanta, Georgia. A CDC investigation demonstrated bacterial contamination of the outer surface of cap liners in the screw cap closure system. Abbott had partially converted to this new closure system between April and September 1970.

On March 13, 1971, FDA and CDC issued statements advising hospitals and the public of the 150 cases of septicemia reported by the hospitals among patients receiving Abbott fluids. Specific precautions were advised in the administration of the products if their use was necessary. The company advised all customers of these precautions by letter on March 15.

On March 22, FDA issued a public warning to all hospitals and other health care facilities to stop using the Abbott IV solutions "unless absolutely necessary." A total recall followed.

The emergency posed a massive problem of coordination. Since Abbott was the largest producer, many hospitals could be left with no IV fluids. Production was discontinued and emergency requests for Abbott products were handled under FDA supervision. Only those orders which could not be filled by other companies were honored. In these cases extremely careful administration was advised.

Once recall was recommended the company moved swiftly and effectively. Over 5.5 million bottles of 105 different IV products were recovered and destroyed. FDA monitored Abbott's packaging changes to eliminate the contamination problem and the company's return to production.

A boom in sales of vitamin C (ascorbic acid), set off by press publicity on theories of Dr. Linus Pauling that it prevents colds, resulted in mass substitutions of sodium ascorbate for ascorbic acid. A public warning was issued on the health danger to persons who must restrict their sodium intake. Numerous recalls of mislabeled sodium ascorbate were made, largely from health food stores. One recall involved over 8.8 million tablets.

DRUG RESEARCH PROGRAMS

Intramural Research

Scientific expertise is involved in practically all FDA activities, but particularly in the area of regulatory action. Thus, drug research in FDA is concerned primarily with the methods used to ensure compliance with standards of safety, purity, potency, and effectiveness of drugs. The pharmaceutical laboratory staff has worldwide recognition of its capabilities in developing new laboratory methods.

In April 1971 the Bureau laboratories played a leading role in collaborative studies with the USP to establish the first USP human chorionic gonadotropin reference standard and to replace USP standards of corticotropin and of heparin. Pharmacology and toxicology studies were conducted on drugs subject to abuse, such as amphetamines, barbiturates, analgesics, and tranquilizers. L-dopa induced an antiexcitation effect when studied in mice treated with central nervous system stimulants. A collaborative study of antibiotic susceptibility discs and control cultures was organized, leading to official publication of a proposal to certify only "high content" antibiotic susceptibility discs and only one for each "family" of antibiotics, and to endorse a standardized clinical laboratory method for testing bacteria. Bioavailability assessment methodology and actual drug tests were also pursued at an accelerated rate.

Extramural Research

Specific questions requiring special resources or access to populations for clinical study can make research contracting the most productive approach. A significant example of contract research is the monitoring of adverse drug reactions discussed in the Drug Experience Information Monitoring section above.

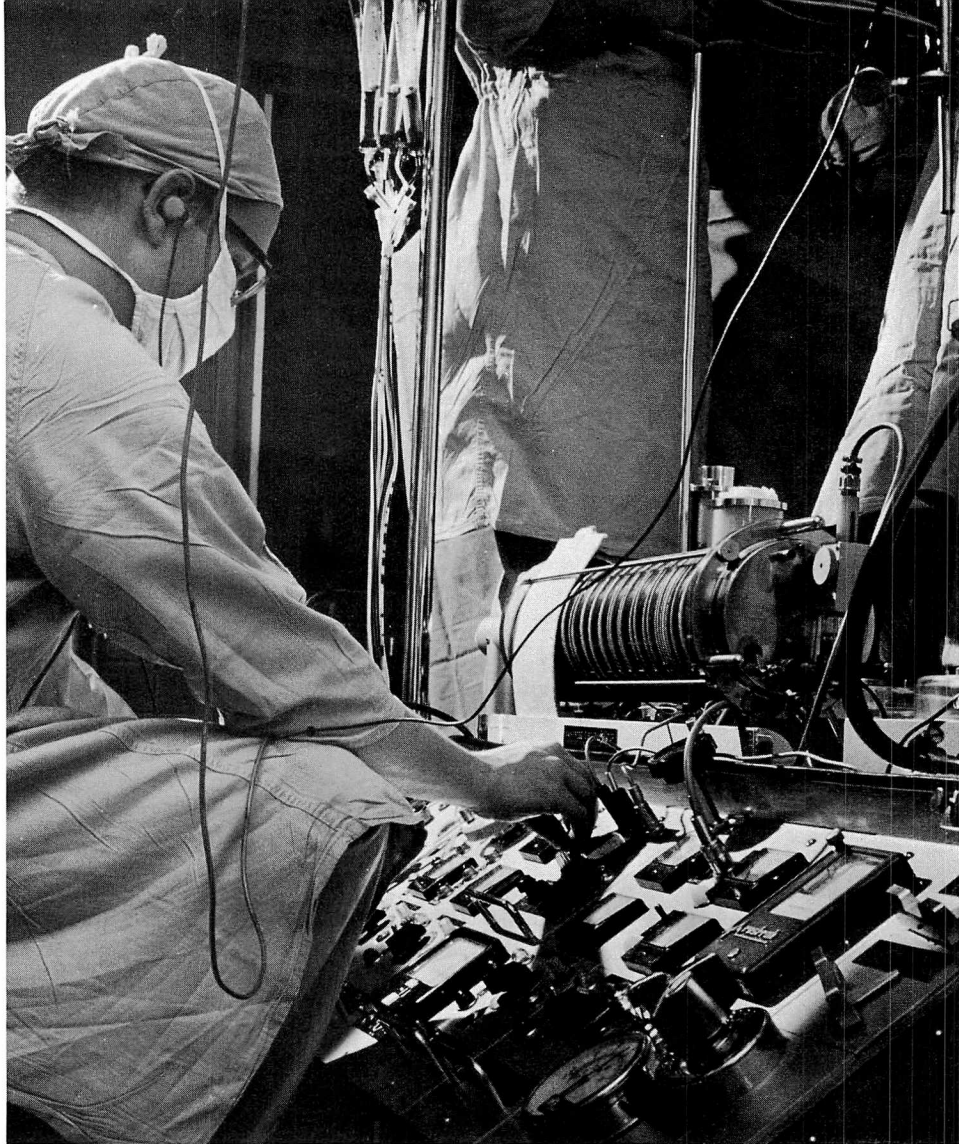
Research in Yugoslavia on the long-term effect of oral contraceptives was continued with funds provided by Public Law 480. These studies under FDA direction are investigating the metabolic effects of oral contraceptives and their influence on cervical cytology, fertility, and the outcome of pregnancy.

Biopharmaceutics was another area of interest, and contracts were continued to study the availability and equivalency of marketed drug products as well as the development of associated laboratory methodology.

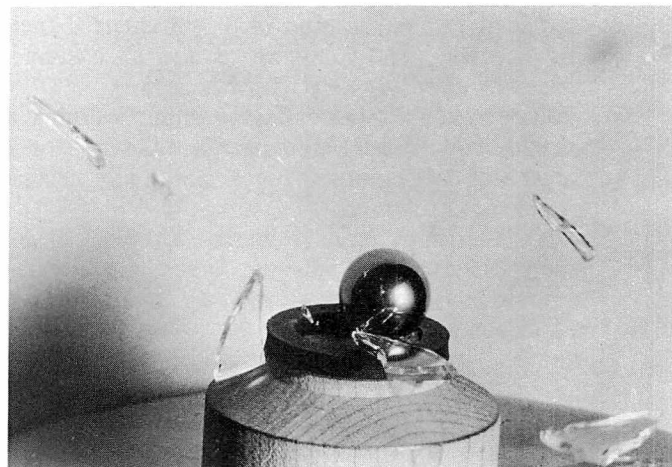
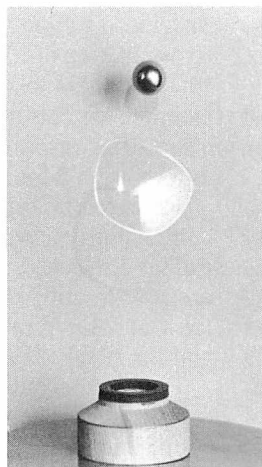
Other research contracts involved computer analysis of antimicrobial susceptibility tests, drug therapy in ureteral colic, drug induced teratogenesis in primates, and support of the Armed Forces Institute of Pathology registry of tissue reactions to drugs.

Regulation of Medical Devices

A separate unit was established to undertake an expanded program dealing with therapeutic, diagnostic, and clinical devices.



A National Heart Institute technician monitors a heart-lung machine during surgery to correct an anatomical defect inside a patient's heart. The machine completely takes over the vital blood pumping and oxygenating duties of the heart and lungs while the open-heart operation is in progress.



The greater safety of impact-resistant eyeglasses is demonstrated by standard testing procedures in the FDA regulation. The heat-tempered lens on the left has been struck by a steel ball dropped 50 inches. The lens, which had been resting on the neoprene base, bounced into the air unbroken. The ordinary crown eyeglass lens on the right was shattered.

With no specific statutory requirement for premarketing approval of therapeutic devices, regulatory action may now be taken only when lack of safety or effectiveness constitutes "misbranding" and thus a violation of the Food, Drug, and Cosmetic Act. Although some devices have been ruled by the courts to be subject to premarket approval as "new drugs," enforcement is necessarily "after the fact," aimed at correction of a problem after it is known to exist and after a violation can be proved in court. This may also mean after injury to the consumer or patient.

To date, control has been largely through investigations leading to court actions, some 90 percent of which have dealt with products sold on an over-the-counter basis. Consequently, professional medical devices have received little attention although many of the more serious problems that are considered to exist are found in this area.

Legislation has been proposed to require review of new and marketed therapeutic and clinical devices intended for use in hospitals, clinics, and physicians' offices in order to determine those which should:

- (1) be exempt from any controls;
- (2) be subject to material or manufacturing standards;
- (3) be reviewed to determine safety, reliability, and efficacy prior to marketing.

Anticipating the need for precise and detailed information, FDA established in fiscal 1971 a "Program to Improve FDA's Knowledge of the Medical Device Industry, Its Products, and Their Hazard Potential." The Agency developed an inventory questionnaire which was pilot-tested and subsequently distributed to the industry. Replies are now being received. Industry comments on a proposed device classification proposal are also being sought and received. Development of a joint FDA/industry/medical profession classification program has begun. Procedures will be completed, and classification by categories is expected to begin in fiscal 1972.

Effective September 2, 1971, responsibility for device activities was transferred from the Bureau of Drugs to the Associate Commissioner for Medical Affairs. The enlarged staff of this unit is charged with evaluating the safety and effectiveness of therapeutic, diagnostic, and clinical devices and with initiating actions to prevent the production and distribution of misbranded devices.

Compliance Activities

Surveillance activities were increased during the year to deal with problems involving such products as sterile disposable devices (surgeons' gloves, etc.), jelly-filled teething rings, cardiac pacemakers and microwave radiation, ozone generators, X-ray machines, fistula needles, oxygen units, surgical sponges, quack devices, moldy prophylactics, speech clarifier devices, acupuncture devices, and air purifiers.

Acting in collaboration with the Bureau of Radiological Health, the Bureau of Drugs assisted in an investigation of defective X-ray equipment resulting in repairs being made by the manufacturer on more than a thousand of the devices. The Bureau also assisted in securing correction of radio interference problems with cardiac pacemakers. A report on hazards of nonionizing

radiation from microwave diathermy units was completed.

Court cases and recalls involving devices declined sharply, reflecting the higher priority of actions this year to deal with emergencies of various kinds. There were 109 regulatory actions involving devices, including 48 recalls and 16 seizures (see Tables 1 and 6). Commercial import detentions prevented entry of such devices as misbranded massage sets, vibrators, and defective clinical thermometers.

Some 145 reports in medical literature on adverse effects or injury by devices were reviewed. Thirty samples were examined, and 43 follow-up field investigations were initiated. Twenty-four corrective actions were recommended. Over a thousand advisory opinions were given in response to requests and questions.

Assisting the State of Pennsylvania in a case against Hush-Tone Speech Clarifier, Inc., FDA had clinical studies performed at a Veterans' Administration Hospital and at the Cleveland Speech and Hearing Clinic. This research showed that the device is worthless to filter out background noise and clarify speech for the deaf. Similar studies at Wayne State University (Detroit) produced the same findings. In this device, costing about 35 cents to make, audio sound activates a small tuning fork. Thousands were sold, mainly to older people, for as much as \$179. An FDA seizure of the device is also being contested. The State Court has not rendered its decision pending the outcome of the Federal case.

Litigation continued against the Diapulse Corporation of America, promoters of a device widely sold to doctors, and claimed to provide adequate and effective treatment for more than a hundred diseases and conditions. The corporation has been operating since 1968 under a preliminary injunction prohibiting certain claims. An FDA suit for a permanent injunction against all claims for allegedly ineffective uses was heard in a lengthy trial during the fall of 1971. A preliminary decree was rendered in favor of the Government.

The second trial of a seizure of Hubbard "E-Meters" was concluded June 10 in the Federal Court for the District of Columbia. The E-Meters are used in a process called "auditing" in a pseudo-medical philosophical system called "Scientology," claimed to be a religion. A detailed decision found the devices misbranded and ordered the Founding Church of Scientology to restrict their use to religious purposes and to inform users that they have no scientific or medical value (see also "Decisions of the Courts").

In September 1970, FDA published a requirement that all new eyeglasses and sunglasses be fitted with impact-resistant lenses. This requirement is intended to protect the millions of eyeglass wearers from eye damage that may be caused by broken lenses. In order to provide for the development of an adequate supply of impact-resistant lenses and to facilitate an orderly changeover to these lenses, the effective date of the requirement was December 1, 1971. After that date all lenses manufactured must be impact-resistant, except when the physician or optometrist finds that the impact-resistant lenses will not fulfill the visual requirements of a particular patient.

Cosmetics and Color Additives

Consumer safety is the objective of these two dissimilar but related programs.

The hazard to consumers from exposure to cosmetics is not clearly known. The possibility of hazard may be great. If therapeutic claims are made for cosmetics, they are legally drugs, and may require premarketing approval as "new drugs," but there is no requirement under the law that other cosmetics be tested for safety prior to marketing. The manufacturers are not required to disclose to FDA the composition of such products. The responsibility rests with the manufacturer to determine their safety.

FDA's information about the composition of cosmetics is compiled from trade and scientific literature, its own analysis of samples, and whatever manufacturers are willing to reveal. FDA's major source of information about possibly harmful, adulterated, or misbranded cosmetics is consumer complaints.

Data generated in the cosmetic injury complaint program will be used in the future to substantiate the objective of increased protection against safety hazards for cosmetic consumers.

In fiscal 1971, 256 complaints were received from consumers who believed they were adversely affected by the use of particular cosmetic products, as compared with 228 complaints in FY 1970. It is estimated that this represents only a small fraction of the total reactions.

At meetings with members of the Cosmetic, Toiletry and Fragrance Association during 1971, FDA stressed the importance of making their complaint files available to the Agency. The Association formally submitted two petitions for the voluntary registration of cosmetic formulations and manufacturers, respectively, which were published in the *Federal Register*. Many comments on these petitions were received by FDA, and revisions based on these comments are being made.

BACTERIAL CONTAMINATION

It has been found that a number of cosmetic products show unacceptable levels of microbial contamination. The extent of microbial control used in the production of cosmetics varies with the manufacturer since there are no promulgated governmental standards on microbial quality that these products must meet. However, in order to combat the growth of micro-organisms in cosmetic products, manufacturers employ preservatives, some of which can be toxic to humans. Among these are mercuric compounds, hexachlorophene, and formaldehyde.

Bacterial contamination of body lotions and eye makeup was a recurring problem during the year. In one instance, the contaminated product was promoted for use on cuts and burns.

Several FDA District offices reported recalls or seizures of *Pseudomonas*-contaminated cosmetic products. Some of the products were eye liners, liquid complexion makeup, night cream, hospital lotion, and facial cleansers. Infections can occur in skin breaks, burn areas, damaged mucous membranes, or in irritated eyes. *Pseudomonas* infection can be serious and sometimes cause blindness. Victims have been mainly aged or debilitated persons in hospitals or nursing homes, burn patients, and infants.

DELETERIOUS INGREDIENTS

FDA scientific and regulatory personnel conferred with two manufacturers of bubble bath products known to use the deleterious alkylaryl sulfonate as a major ingredient of their products. Both firms agreed to reformulate their products. All other manufacturers using this detergent as a major ingredient of bubble bath were also asked to reformulate. A large number of consumer complaints had been filed with FDA. Injuries included urinary tract infections and skin rashes. A survey is underway to determine if any other manufacturers are marketing alkylaryl sulfonate bubble baths.

RESEARCH ON COSMETICS

In recent years concern has increased about the contamination of cosmetic products by microbial organisms. The organism *Pseudomonas aeruginosa* poses a serious hazard to vision in damaged eyes. FDA studies with rabbits and monkeys showed that the healthy, intact eye resists *Pseudomonas* infection but an eye which has been scratched or irritated might be susceptible. Thus the hazard is increased for users of eye cosmetics who also wear contact lenses or who use potentially irritating shampoos.

Because of the presence of these and other bacterial organisms, it is necessary to include preservatives in cosmetics. The presence of as little as 0.01 percent of formaldehyde was found to cause skin sensitization. To detect these very low levels of formaldehyde, an assay based on the ability of formaldehyde to form a colored, highly fluorescent product was devised. Another approach to screening cosmetics for the presence of chemical preservatives led to a microbiological test which can be used to examine 26 samples simultaneously.

Mercury is still used as a cosmetic preservative and antibacterial agent since its toxicological hazard in cosmetics is not yet resolved. Data on the extent and levels of use in cosmetics are being accumulated. Mercury was determined in 282 cosmetics, of which 19 contained mercury at levels from 1 to 70 ppm. Improved methods for determining mercury have been developed.

The possibility was suggested that 2,4-toluenediamine (2,4-TDA), a constituent of hair dyes, might be carcinogenic. As a check, samples of 2,4-TDA and of hair dye bases both with and without 2,4-TDA were painted on the skin of test mice. No evidence of carcinogenicity has been observed to date.

Various constituents of cosmetic products can cause allergic reactions in some users. To gain more information on these reactions, and in response to consumer

complaints, a number of compounds are being investigated for their tendency to cause skin sensitization. In conjunction with these studies, it is essential to be able to identify the compound and determine its concentration in the cosmetic, since manufacturers are not required to give this information on the label. Accordingly, methods were developed to identify the sunscreens in suntan preparations and to determine the presence of castor oil in lipsticks; both assays use gas chromatography.

Following an FDA study showing that hexachlorophene can cause brain damage in rats, considerable work was done on this compound which is used in a large number of cosmetic products. The FDA study showed that newborn rats given 10 mg/kg/day exhibited signs of central nervous system poisoning and degeneration of cerebral white matter. It still is not certain whether the results obtained in rats can be extrapolated to human beings. A number of laboratory personnel who use products containing hexachlorophene in their work were tested to determine the levels of hexachlorophene in their blood. In conjunction with these studies, an improved method for measuring hexachlorophene content of blood was developed.

(Action taken to restrict the use of this ingredient was announced in January 1972.)

New studies are underway to determine hazards to consumers of inhaling aerosol propellants used in cosmetic products.

COLOR ADDITIVE CERTIFICATION

Under the Federal Food, Drug, and Cosmetic Act the only "color additives" which may legally be used are those on a "permitted list." Samples from each batch manufactured must be submitted to FDA for tests of purity, unless the color is one exempted by the regulations. If the sample conforms to the specifications, a certificate is issued and that batch of the color is released for use. The manufacturer pays a fee for this service.

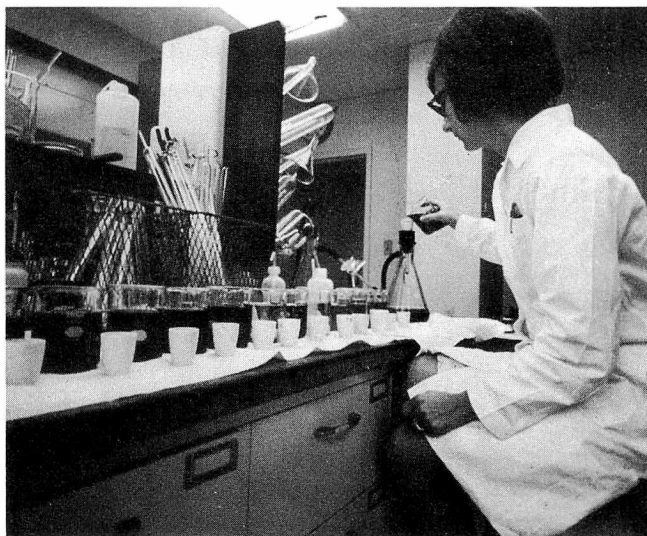
During fiscal 1971, 2,635 batches of colors were analyzed, and 20 batches were rejected. This compares with 1970 figures of 2,548 batches analyzed and 41 rejections.

A new color, FD&C Red No. 40, was formally listed by publication of specifications in the *Federal Register*. This was the first new color to be approved by FDA in several years.

It was found that gamma irradiation of FD&C Red No. 3 in dilute aqueous solution caused extensive decomposition, which raises questions about the proposed use of radiation sterilization for colors and cosmetics. Irradiation studies of D&C Orange No. 5 showed similar decomposition of aqueous solutions.

Six improved methods for the analysis of intermediate or subsidiary colors were developed, as part of the continuing effort to assure the purity and safety of color additives. A new and sophisticated instrument, the liquid chromatograph, is being adapted to the analysis of small amounts of impurities in color additives.

A pathology review on the brains and other organs of dogs fed FD&C Orange No. 17 was completed. The



An FDA chemist tests a color sample with a flask filtering process to determine whether insoluble matter exceeds the specifications.



Results of a skin sensitivity test of a cosmetic ingredient on a miniature breed of pig. The skin of this animal resembles human skin more closely than that of most other species.

findings indicated no damage to the central nervous system or other organs.

Studies are being made of the toxicity of FD&C Red No. 2, the most widely used of all food colors. Several years ago, Russian workers reported that FD&C Red No. 2 had adverse effects on reproduction and was carcinogenic in rats; they reported giving the color to the animals for 14 months at 1.5 and 7.5 milligrams per kilo of body weight per day. In the FDA laboratories, rats were fed FD&C Red No. 2, several of its metabolites, and an impurity commonly present in the color at various levels from 2 to 200 mg/kg/day. Preliminary results indicate that there is an effect on reproduction at high levels of the color; the study has not been underway long enough to evaluate the possibility of carcinogenicity. Similar studies are being made of FD&C Red No. 40, the new color listed as a replacement for FD&C Red No. 2.

Veterinary Drugs and Animal Feed



Drugs for disease prevention are essential to economical mass production of poultry. But use of medicated feeds must be stopped prior to slaughter, as directed by the labeling.

Protecting human health through the regulation of animal drugs and feeds is the special concern of FDA's Bureau of Veterinary Medicine.

Protecting human health through the regulation of animal drugs and feeds is a special concern of FDA's Bureau of Veterinary Medicine. Drugs have become critically important in the prevention and treatment of devastating animal diseases, some of which are transmissible to man.

Efficient animal protein production in the United States is, therefore, dependent upon control of animal diseases through the prudent use of drugs. It is estimated that 80 percent of the animal protein consumed by Americans originates from animals fed medicated feeds. With such widespread use of animal drug products, FDA has the responsibility to assure consumers that meat and poultry products are free of any potentially harmful residues.

The dimension of the disease control problem is reflected in the annual volume of livestock slaughtered for

human consumption—about three billion poultry, 86 million swine, 40 million cattle (including calves), and 10 million sheep. The U.S. food supply is unique in its abundance of high quality animal protein.

Applications to market new animal drugs increased from 1,039 to 1,372 during the fiscal year 1971—a gain of nearly 25 percent. Investigational New Animal Drug Applications were somewhat less than the previous fiscal year—2,013.

The New Animal Drug Amendments of 1968 were fully implemented on September 12, 1971, when all regulations on new animal drugs and medicated feed were consolidated under Section 512 of the Federal Food, Drug, and Cosmetic Act.

On August 10, 1970, the FDA Commissioner approved the following division of responsibilities with respect to animal feeds. The Bureau of Veterinary Medicine will have the responsibility for processing all New Animal Drug Applications, and will be scientifically responsible for the safety of feed and pet food for animals, including the nutritional and clinical efficacy of food additives and drugs as well as their safety to animals. The Bureau of Foods will be responsible for the safety

of all food for man, including that from food-producing animals. All enforcement and surveillance activities with respect to animal feed, except those involving pesticide tolerances and color additive regulations, will rest with the Bureau of Veterinary Medicine, but it may call upon the Bureau of Foods for support in regulatory cases. Because of the close relationship between animals and humans in disease, nutrition, and food contamination problems, each Bureau will promptly notify the other of any problems in these areas.

To absorb increased workloads and new responsibilities growing out of earlier FDA structural changes, the Bureau of Veterinary Medicine was reorganized on November 12, 1970, with divisions for Nutritional Science, Compliance, New Animal Drugs, Veterinary Medical Review, and Veterinary Research.

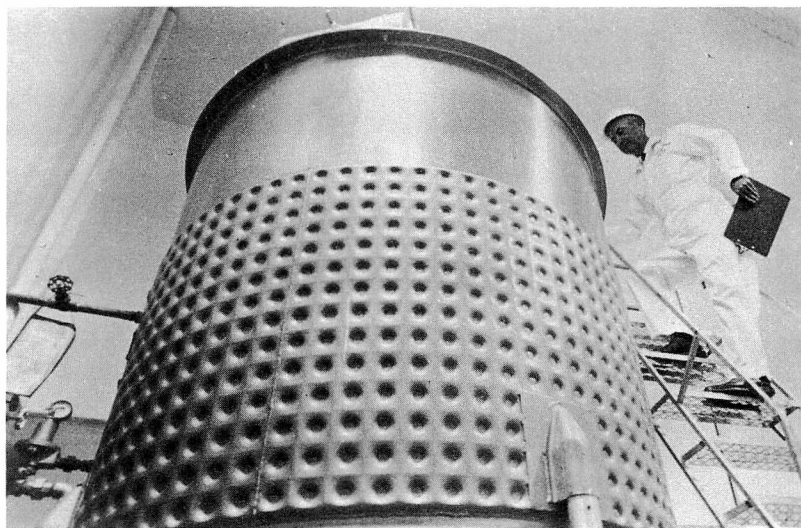
SURVEILLANCE ACTIVITIES

The Federal Food, Drug, and Cosmetic Act requires that all medicated feed mills register as drug establishments and be inspected at least once every two years. The Act specifies that medicated feeds be manufactured under conditions which conform to current good manufacturing practices. The law also states that those wishing to manufacture medicated feeds containing new animal drugs shall submit for approval Medicated Feed Applications (FD-1800). Thus, the Act provides for FDA to exercise appropriate control over the manufacture of medicated feeds to ensure that they are safe and effective under their intended conditions of use.

An increase in FDA surveillance was found necessary this year because State authorities have not been able to take over responsibilities in this area as planned when Federal activities were cut several years ago. Particularly, FDA could not be sure that all mills were complying with the Current Good Manufacturing Practice Regulations or meeting the commitments in their approved Medicated Feed Applications. More active enforcement of the Federal Act was undertaken.

Under liaison arrangements with FDA, the Consumer and Marketing Service of USDA continued to monitor meat for drug residues, and to report residues over tolerance to FDA for regulatory consideration. USDA inspections are performed under the Federal Meat Inspection Act, as amended in 1967, and the Poultry Products Inspection Act, as amended in 1968. During the 1971 fiscal year, FDA issued 73 "warning letters" to livestock owners in follow-up action on these reported residues. Such notices refer to the illegal residues found in the meat samples analyzed by USDA, and request the livestock owner to advise FDA concerning what action he proposes to prevent recurrence of illegal residues in animals (including poultry) offered for sale. Further enforcement action is taken, if needed.

The Federal Food, Drug, and Cosmetic Act specifically declares that: (1) in the case of a new animal drug, or a drug that is covered under the provisions of the Food Additive Amendments to the Act, that unauthorized, unapproved residues shall be considered unsafe and, therefore, constitute adulteration of the product under Federal law; (2) the interstate shipment of an adulterated product is prohibited. The Act thus pro-



FDA inspector takes a look into a mixing tank for medicated feed to see if it has been properly cleaned between batches.

vides for the safe use of animal drugs, which, when fed in accordance with the directions for use, will not leave unauthorized residues in the edible products of treated animals. FDA has the authority under the Food, Drug, and Cosmetic Act to prosecute in those cases in which misuse of animal drugs results in unauthorized drug residues.

Responsibility for monitoring drug residues in food animals rests with the Consumer and Marketing Service of the U.S. Department of Agriculture. USDA has requested more funds for fiscal year 1972 to increase substantially the number of tests in its sampling program for drug residues in animals.

ENFORCEMENT ACTIONS

Compliance actions for fiscal 1971, summarized below, show an increase in enforcement activities for three six-month periods since the Bureau of Veterinary Medicine was reorganized. For example, there were seven times as many seizures during the third period as there were during the first one. There has been a continued increase in all regulatory activities.

Six Month Periods Beginning

Action	Jan. 1, 1970	Jul. 1, 1970	Jan. 1, 1971	Total FY '71
Seizures	14	36	60	96
Citations	1	16	55	71
Prosecutions	0	2	5	7
Injunctions	0	2	6	8
Total	15	56	126	182

Bacterial contamination (*Salmonella*) in animal by-product meal used for feed continued to be a serious problem. Under a liaison arrangement dated November 3, 1967, FDA is notified by USDA whenever rendering plants are found contaminated with *Salmonella* and fail to follow USDA's Recommended Sanitation Guidelines



At a western feed lot (above), an FDA inspector samples medicated cattle feed for laboratory determination of its drug content. Below: Consumer protection is the aim of FDA's regulation of veterinary drugs and livestock feed.

in their plant operation. FDA will then make an establishment inspection of these firms and take whatever regulatory action is deemed necessary. On June 30, 1971, there were 136 rendering plants (out of 901 total) being investigated by FDA, and USDA was supervising a voluntary program for 765 firms processing animal by-products meal.

FDA prosecuted one firm for adulteration of meat scraps through the addition of a poisonous and deleterious substance (*Salmonella* organisms); also for preparation and storage under insanitary conditions. The firm was enjoined on June 29, 1971, from shipping adulterated animal by-products meal.

On June 30, 1971, another firm pleaded guilty to interstate shipment of veterinary injection drugs that were adulterated, prepared under conditions whereby they could become contaminated, and not made in accordance with FDA's Current Good Manufacturing Practice Regulations.

The U.S. District Court in Indianapolis prohibited a firm from shipping for food purposes beef steers or grain containing unsafe pesticidal chemicals. The cattle had consumed a feed made in part from seed grain containing illegal residues of dieldrin.

VETERINARY DRUG EFFECTIVENESS REVIEW

Forty-two drug approvals were withdrawn, and 49 notices of opportunity for hearings were published—as a result of veterinary drug efficacy evaluations by the National Academy of Sciences-National Research Council. Altogether, the veterinary drug scientists reviewed 706 animal drugs and classified them as follows:



127, or 18 percent, effective
395, or 56 percent, probably effective (more information needed)
166, or 23.5 percent, probably not effective
18, or 2.5 percent, not effective

In a major part of this program, the Bureau of Veterinary Medicine started a review of some 2,000 different antibiotic-containing combinations on the market (both pre- and post-1962) for efficacy. This was undertaken because scientific data providing substantial evidence of their effectiveness was lacking. To justify the use of a combination product, sponsors must show that each

drug contributes to the overall effectiveness of the product. There are 61 basic drugs (antibiotics, coccidiostats, hormones, wormers, etc.) which have been combined in products that go directly into feeds.

COMPLIANCE ACTIVITIES

Effectiveness of consumer protection in use of animal drugs and feeds depends very greatly on voluntary compliance, encouraged by educational activities. It is impossible to check every farmer to ensure compliance, or to test samples from every animal slaughtered. Mass communications were used in fiscal 1971 to reach more than a million livestock producers concerning such problems as illegal pesticide and drug residues, mycotoxins, and bacterial contamination (chiefly *Salmonella*) in feed. Educational efforts were directed specifically to the 10,000 medicated feed mixers, the 25,000 veterinarians, and the two million commercial farmers—including livestock, dairy, and poultry producers.

FDA works in liaison with the other Federal agencies, particularly the USDA and the U. S. Office of Education. Information is channeled to the 15,000 extension workers (including the staff in 3,000 counties), and 12,000 agricultural teachers who instruct over 4,000 adult-farmer students and about the same number of Future Farmers in high schools. Most of the commercial farmers are reached through one of these information sources.

On its own initiative, the livestock industry launched a new system to assure consumers that meat products will be free of illegal drug residues. The nationwide program calls on all livestock and poultry producers to certify in writing when marketing their animals that they have followed label directions when using animal drugs. Such directions specify "withdrawal periods" which the Food and Drug Administration and the U. S. Department of Agriculture require to be observed for assurance that products from treated animals are free of harmful residues.

Nearly two million animal drug withdrawal certificates were distributed to food animal producers, feed and drug salesmen, meat packers, terminal markets, and truckers across the country. In addition, more than 125,000 printed leaflets outlining the program's basics have been distributed. The effort is strongly supported by the industry and its press. It is directed by a National Animal Drug Certification Committee with membership from ten national livestock and allied industry organizations.

When a food animal producer markets his animals, either directly to a meat packer or poultry processor, or through a commission agent, he is asked to sign a certificate which reads:

"I certify that all drugs and feed additives received by these animals while in my possession have been used in conformity with the feed or drug manufacturer's dosage directions and withdrawal times." or "I certify that these animals have not received drugs or feed additives while in my possession."

VETERINARY DRUG RESEARCH

During FY 1971, the Bureau research staff developed an extremely sensitive analytical method for the detection of aflatoxin—a poisonous substance derived from molds—that has caused much economic loss due to poor feed efficiency and low growth rate among food producing animals. The method is capable of detecting aflatoxin as low as 0.2 parts per billion, and will greatly increase FDA's ability to detect the presence of this toxic material in food products for animal and human use.

Studies were completed last year on certain antibiotic and sulfonamide preparations to determine how long these materials persist in the milk, tissues, and major organs of animals following treatment. Such information is essential for guidelines and regulations to control drug residues. The preparations included penicillin, dihydrostreptomycin, sulfamerazine, sulfathiazole, and sulfamethazine. The studies involved dairy cows, swine, calves, sheep, turkeys, and chickens.

Research is also in progress to learn more about the ability of bacterial organisms to develop and transfer resistance following the treatment of animals with antibiotics, as well as what significance this may have when man is exposed to resistant strains of bacteria.

Other studies included safety evaluation of several drugs that are used for treatment of internal parasites. A drug testing program was conducted to determine the safety of analgesic and anesthetic preparations and a number of other products.

TASK FORCE ON ANTIBIOTICS IN FEED

A Task Force of veterinary and public health scientists appointed by the FDA Commissioner continued its investigation of potential health hazards from drug-resistant bacteria in animals receiving antibiotics. Areas of study included the usage and actual value of antibiotic feeds, the acquisition by selection of the R-factor by organisms through animal feed practices, the possibilities of transference of organisms and the R-factor to human pathogens, and the economic impact of restricting the use of antibiotic feed additives upon manufacturers and users.

Appointment of the Task Force followed recommendations of a British group (Swann Committee) that use of antibiotics in animal feed be drastically curtailed. The U.S. group participated in seven conferences and some members visited England to obtain additional information. On this trip it was learned that some of the Swann Committee's report would be implemented. Under contemplated plans in Britain, antibiotics will be divided into two classes, for feed and for treatment. Feed antibiotics are those used for growth stimulation, and not used to treat animal or human diseases, and will be available for farmers to use in feed up to 100 grams per ton. The treatment antibiotics will be available only for the use of a veterinarian or on his prescription, according to British plans.

'Product Safety'—a Large and Diverse Field



First step in a product injury surveillance report: Emergency room nurse (left photo) takes the case history which will go by teletype to the FDA computer in Washington. Above: Malcolm Jensen (right), director of FDA's Bureau of Product Safety, and William Waslick, deputy chief of Injury Data Management, go over a printout reporting product-related accidents of the previous day.

Hazardous household chemical products, toys, fireworks, flammable fabrics, and accidental poisoning are major interests of the FDA Bureau of Product Safety.

The importance of product safety laws and programs administered by the Food and Drug Administration is shown by keen and growing public interest in these consumer protection activities. Unsafe toys, phosphate versus nonphosphate detergents, fireworks, flammable fabrics, and child-safe packaging for hazardous products were some of the problems dealt with by the FDA Bureau of Product Safety in fiscal 1971.

Established in October 1970, the new Bureau is responsible for administration of the Federal Hazardous Substances Act as amended by the Child Protection and Toy Safety Acts of 1966 and 1969, and the Poison Prevention Packaging Act of 1970. Accident prevention research and control programs are carried on under the broad authority of the Public Health Service Act. The Bureau also administers certain research provisions of the Flammable Fabrics Act.

The great variety of products involved in all these laws and programs immediately creates serious problems of priorities, planning, and budgeting. Which products are most frequently involved in accidents and injuries? How many injuries occur, and how serious are they? What is the manufacturer's responsibility? Public and private agencies have sought answers to such questions for many years. In 1971, however, a major break-

through occurred in the "epidemiology" of product-related accidents. This was the launching of the National Electronic Injury Surveillance System (NEISS).

This unique data gathering and interpretation system is now providing current, over-night reporting of product-related injuries treated in hospital emergency rooms. Daily reports are received from statistically selected hospitals. The injuries are recorded as treated by the hospital personnel and the data reported by teletype. The coded information is transmitted to the FDA computer in Washington during the night and compiled into detailed case printouts for headquarters review the following morning.

A major advantage of the NEISS system is its statistical validity, not present in earlier, voluntary reporting. It also eliminates the time lag of mail reporting and makes possible the immediate investigation of selected cases. Based on such investigations, decisions can be made on remedial steps such as design changes, revised standards, product recall, or consumer educational programs.

Approximately 14,570 injury reports had been received on more than 500 categories of household products as of September 30, 1971. When NEISS is fully operational, data will be collected from 119 hospitals on approximately 720,000 emergency room cases annually. Of these, some 36,000 cases will be selected for follow-up, 3,600 of which will be the subject of immediate in-depth field investigation. Plans are being developed to include other sources of data such as death certificates, physicians' offices records, and clinics.

With a systematic approach to discovery, analysis, and solution of product safety problems, FDA is capable of managing an increasing number of such problems.

Existing statistical data show some 30,000 deaths and 20 million injuries, a majority being product-related, occur annually in or near homes. In fiscal 1971, steps to make some of these products safer were taken. For example, the maximum temperature level will be lowered in the water reservoir of *vaporizers*, new safety features have reduced some of the hazards associated with *power mowers*, an educational program was developed to alert the consumer to the dangers of *flammable liquids*, and information gathered by the Bureau on *safety glass* is being used to promote the development of building ordinances to require its use in hazardous locations.

HAZARDOUS SUBSTANCES ACT

The principal statute administered by the Bureau of Product Safety is the Federal Hazardous Substances Labeling Act of 1960 (now called the Federal Hazardous Substances Act). The Act as originally written provided for the labeling of products classified as hazardous. After amendment in 1966 and again in 1969, the Act's requirements were extended. Now, when it is determined that cautionary labeling is not an adequate solution for a hazard, the substance (or product) can be declared a "banned hazardous substance." Also, a hazardous substance can be subject to seizure (a court action that has the effect of removing a lot or lots of the substance from market shelves).

Banned Fireworks.—With certain specified exceptions, sale to the public of an explosive firework containing more than two grains of powder is prohibited. FDA worked closely with the Internal Revenue Service and State and local law enforcement officials in 1971 to crack down on illegal sales. As a result, the courts ordered more than 80 seizures of illegal fireworks.

Charcoal Briquettes.—More than 30 persons have died from carbon monoxide poisoning in recent years from burning charcoal in tents, trailers, automobiles, boats, and other enclosed areas. As of August 1972, charcoal will be required to carry specific warning labels on the danger of burning charcoal in confined or enclosed areas.

Asbestos.—A proposal was published that garments containing asbestos fibers be required to bear warning labels. Asbestos fibers released from garments can be toxic if inhaled and cause serious illness.

Detergent Packaged in Food Cartons.—Colgate-Palmolive recalled one of its products, Crystal Clear, an automatic dishwashing detergent packaged in a milk-carton-type container, when the courts ruled that products under the Federal Hazardous Substances Act are prohibited from being packaged in identifiable food, drug, or cosmetic containers. Subsequently, several other hazardous products packaged in milk cartons were recalled from the market.

Enzyme Detergents.—Reports in scientific journals of workers suffering from sensitivity reactions when exposed to pure enzymes in industrial plants caused the



Thousands of "household chemical" products bear safety labeling required by the Federal Hazardous Substances Act.

Bureau of Product Safety to contract for two clinical studies to determine the sensitizing ability of small amounts of enzymes in commercial detergents. The Bureau also collected all available scientific information on enzymes and contracted with the National Academy of Sciences to review the literature and render an opinion on the hazards associated with enzymes. The Academy reported November 17, 1971, that the average enzyme laundry detergent product in normal use by consumers has not produced more primary skin irritation than similar products containing no enzymes.

Nonphosphate Detergents.—Conservationists' concern for the environment led detergent manufacturers to replace phosphates with NTA, thought at that time to be an acceptable substitute. Subsequent testing by the Government proved NTA capable of strongly binding with heavy metals—metals which can be toxic. The Surgeon General has received the detergent industry's cooperation to refrain from producing detergents with NTA until further scientific determinations are made.

Alkaline Detergents.—In an effort to avoid the problems with both phosphates and NTA, detergent manufacturers began producing alkaline detergents. However, to achieve a comparable washing quality, manufacturers used increased amounts of silicates and sodium carbonates to levels which have caused damage to skin and eyes of test animals.

In March, two highly alkaline detergents, Ecolo-G and Bohack's Controlled Suds, were seized by FDA because the packages lacked required cautionary labeling. Following this, studies were made of an additional 39 nonphosphate and low-phosphate detergents and, as a result of the tests, labeling changes were required on 25 brands. The Bureau of Product Safety is continuing to test detergents to assure that hazardous products are appropriately labeled.

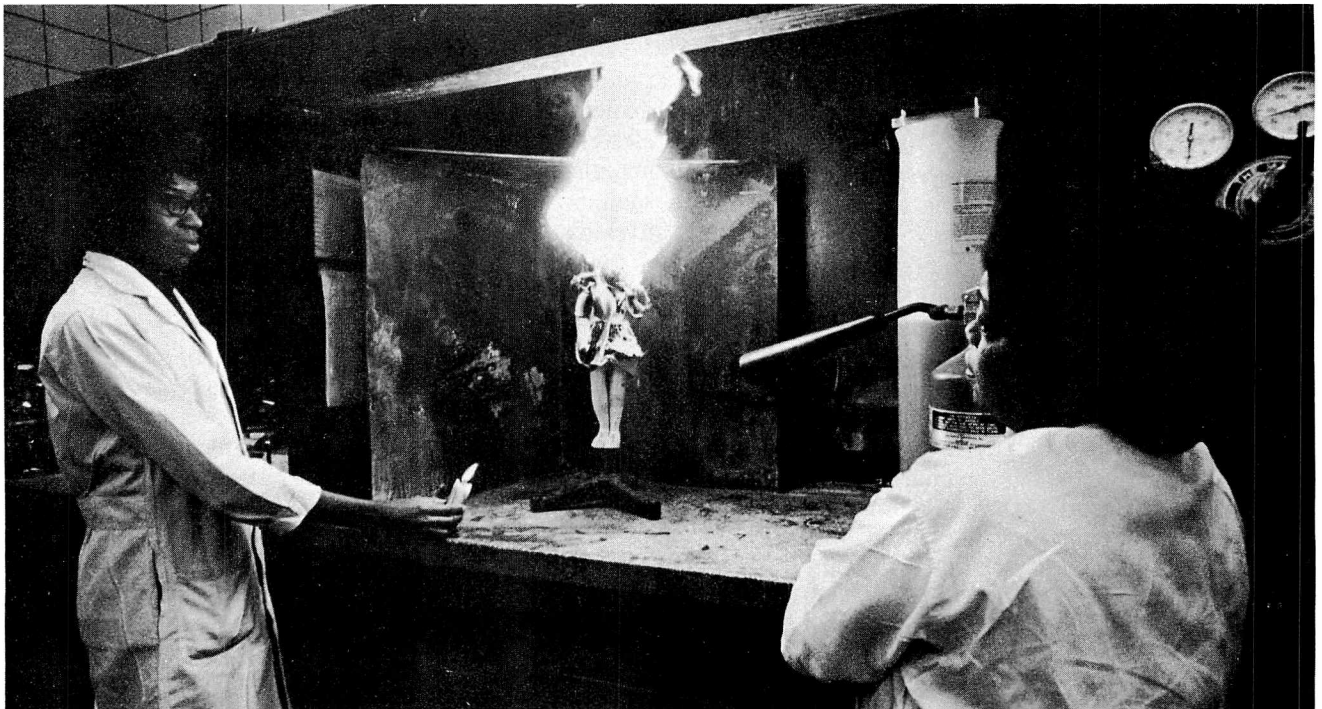
CHILD PROTECTION AND TOY SAFETY ACT

The past year has seen increased public concern over the potential for danger in some toys. FDA placed heavy emphasis on toy safety resulting in many significant actions and considerable publicity. Many educa-

The age of the child is an important consideration in selecting toys. FDA must rely on the consumer's judgment for this aspect of toy safety.



A flammability test (below) on doll's hair in the FDA District laboratory at Philadelphia. Note the fire extinguisher at the right.

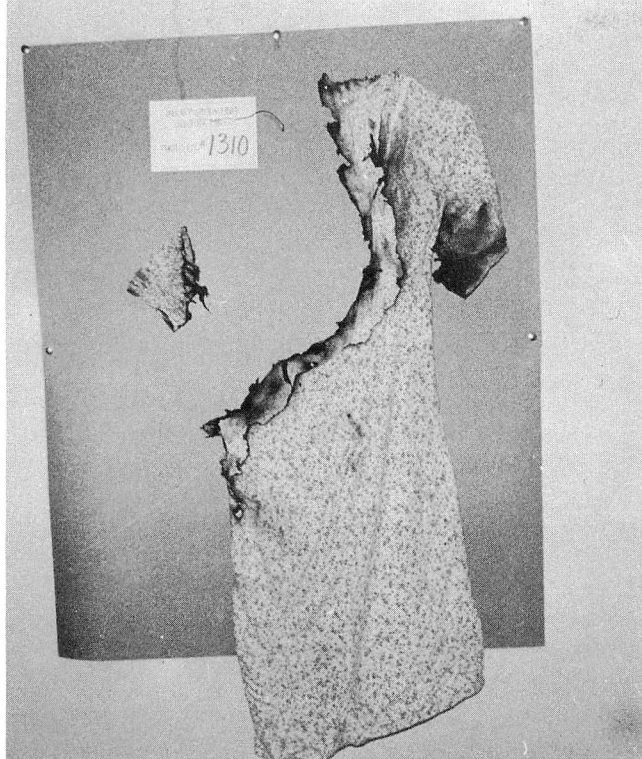


tional articles are being published on this topic. Increased safety for young children at play is expected.

There are approximately 1,200 toy manufacturers in the United States who produce 3 to 4 billion dollars worth of toys annually. In addition, there are an estimated 83,000 importations of toys annually. All these contribute to the 700,000 toy injuries and the 8 million injuries from toys, sports, hobbies, and recreational equipment that are estimated to occur each year.

FDA has the authority under the Child Protection and Toy Safety Act of 1969 to seize and ban from the market toys and other children's articles with electrical, mechanical, or thermal hazards. Acting under the authority of this Act, the Agency has banned as hazardous substances more than 300 individual toys in seven classes:

- toy rattles and similar toys made with rigid wires or sharp protrusions that could puncture or lacerate or that contain small, loose objects that could be aspirated or ingested when the toy is broken.
- noisemakers with components that could puncture or lacerate or with small, loose objects that could be aspirated or ingested when the toy is broken.
- dolls and stuffed animals with internal or external components that could lacerate or puncture.
- toy caps that produce noise above 158 decibels.
- lawn darts and other pointed "adult" toys intended for outdoor use that are inadequately labeled or sold in children's toy stores.
- baby bouncers/walkers and similar infant vehicles with hinged components, holes, slots, or cracks which



Burn case history: The cotton housecoat and nightgown were worn by a 78-year-old woman as she reached across a gas stove. She died in a hospital 14 days later—one case in over 1,000 investigated by FDA in 1971.

could puncture, pinch, lacerate, or amputate.

■ clacker balls unless manufactured and tested in accordance with published standards.

FDA is currently developing regulations to ensure the safety of electrical and thermal toys, paint used on toys, pacifiers, and toys with projectiles.

Over a hundred toys were voluntarily corrected by toy firms after being identified by FDA as containing potential hazards. The following are examples of such actions: A manufacturer removed sharp nails from a toy lawn mower. "Safety" electrical plugs are now being used on more electrical toys. A "steam/spray" feature has been eliminated in some toy irons. Toy dart guns and similar pointed toys have been redesigned so rubber suction cups on the dart will be securely fastened.

The Bureau of Product Safety has established a six-member Toy Safety Review Committee which has examined more than a thousand toys for mechanical hazards. The evaluations provided by the Committee serve as the basis for determining whether to ban specific toys, the necessity for developing new regulations to eliminate significant hazards, and recommendations for voluntary redesign of potentially hazardous toys by the manufacturers of those toys. Tests for mechanical, electrical, and thermal hazards of toys have been conducted by both the Bureau of Product Safety and the National Bureau of Standards through an interagency agreement. Flammability and chemical hazards of toys continue to be tested by FDA.

Bureau personnel are also working with industry associations to develop meaningful voluntary standards for home playground equipment, minibikes, bicycles, preschool children's toys, baby cribs, and playpens.

POISON PREVENTION PACKAGING ACT

FDA administers the Poison Prevention Packaging Act of 1970 which seeks to protect small children from accidentally swallowing poisonous chemicals and harmful drugs by requiring "child-resistant" packaging on products designated by the Secretary of Health, Education, and Welfare.

To administer this law, FDA has published a testing method for determining the effectiveness of a safety closure. It calls for the testing of 200 children between 42 and 51 months of age, evenly distributed as to age and sex. Resistant effectiveness of not less than 85 percent without a demonstration and no less than 80 percent after a demonstration of the proper way to open the package is specified. Adults must also be tested, with the requirement that not less than 90 percent of them are able to open the container after instruction.

There are approximately 75,000 ingestions of poisons reported to FDA through Poison Control Centers, and 300 deaths in the United States annually among children under five. Acting under the law, FDA proposed that the following products be packaged in child-resistant containers:

■ Aspirin, the leading cause of fatalities and hospitalization of children under five who have ingested poisons.

■ Furniture Oil Polishes containing 10 percent or more petroleum distillates. Approximately 15 percent of the fatal poisonings of children under five in the United States are caused by the accidental ingestion of petroleum distillates. Although furniture polishes containing mineral seal oil represent only a small proportion of



Many drugs and other potentially toxic products must have safety closures to comply with the Poison Prevention Packaging Act. These "combination caps" must pass FDA tests showing they are hard for small children to open—but not too difficult for adults.

petroleum distillates, they cause the highest percentage of pulmonary complications.

■ **Methyl Salicylate.** There were 176 accidental ingestions of methyl salicylate (oil of wintergreen) by children under five in a three-year period, 1968–70, which put 33 children in the hospital. Eight of these children died.

■ **Household Liquid Drain Cleaners.** Approximately 326 children accidentally ingested liquid drain cleaner containing more than 10 percent sodium potassium hydroxide in the past three years. No antidote is of value in preventing esophageal injury from this type of cleaner.

■ **FDA has also proposed regulations to require special packaging for around 4,300 products subject to the 1970 Drug Abuse Prevention Act.**

POISON CONTROL PROGRAM

The Bureau of Product Safety operates the National Clearinghouse for 583 autonomous Poison Control Centers throughout the United States. The Clearinghouse supplies the Centers with emergency information on potential poisons, such as toxicity data on new products, formulations, symptoms, and treatment information for common household products and drugs that may be accidentally ingested. In return, the Poison Control Centers voluntarily submit poisoning reports to the National Clearinghouse. These reports are coded in a central data bank which serves to alert the Bureau about new products that are frequently ingested and thus require Federal action.

The Bureau has recently established a pilot project which utilizes cathode ray tubes to connect the National Clearinghouse, through the FDA computer, directly to four Poison Control Centers. The cathode tube may revolutionize the distribution of poisoning prevention information through rapid transmittal display of the information graphically and instantly with potential for immediate update.

Pamphlets, speeches, and TV and radio spots were distributed to fill more than 2,500 requests for promotional materials for National Poison Prevention Week. This year, "live copy" spots were sent to 5,200 radio and TV broadcasters with their preference in format, that is, discs for radio, "Sound-on-Film" for TV.

FLAMMABLE FABRICS ACT

Approximately 8,500 deaths are caused by fires each year and more than 2 million persons suffer burns serious enough to require medical attention or restricted activity. To assist in the effort to reduce burns and deaths from fires, the FDA's Bureau of Product Safety shares with three other Government agencies the responsibility for implementing the amended Flammable Fabrics Act which covers wearing apparel and interior furnishings. The Bureau, in cooperation with the Department of Commerce, is responsible for conducting a continuing study and investigation of deaths, injuries, and economic losses resulting from accidental burning of products, fabrics, or related materials. FDA submitted approximately a thousand burn investigation reports during the fiscal year to the National Bureau of Standards to assist it in determining needs for fabric flammability standards, such as the Children's Sleepwear standard proposed by the Department of Commerce.

Radiological Health Protection

Newest of FDA responsibilities is to reduce unnecessary human exposure to man-made radiation from electronic devices—from TV sets to dental X-rays.



More than 90 percent of all human exposure to man-made ionizing radiation in the United States results from diagnostic X-ray procedures.

The Bureau of Radiological Health was assigned to the Food and Drug Administration on May 17, 1971, by directive of the Secretary of Health, Education, and Welfare. FDA thus became responsible for reducing unnecessary human exposure to man-made radiation in the use of electronic products and in the application of radiation in the healing arts.

Responsibility for the control of environmental man-made radiation and for the regulation of radioactive materials produced in nuclear facilities lies respectively with the Environmental Protection Agency and the Atomic Energy Commission.

Bureau of Radiological Health programs are conducted under general provisions of the Public Health Service Act, but more specifically under the 1968 amendment to the Act, the Radiation Control for Health and Safety Act (P.L. 90-602). In late January 1971, about 40 percent of the Bureau's resources were transferred to the EPA. This left the Bureau with fiscal 1971 resources of 389 employee positions and \$10.3 million. About \$2.9 million of the budget was allocated for grants and contracts to support research and training and applied research. Principal functions of the Bureau now include: (1) regulation of radiation from consumer electronic products, (2) control of radiation used in the healing arts, (3) control of occupational exposures to radiation, (4) support of research, technical assistance, and training related to electronic products, healing arts, and occupational radiation, and (5) assistance to State and local radiation control programs.

ELECTRONIC PRODUCT RADIATION CONTROL

The Radiation Control for Health and Safety Act requires the Secretary of Health, Education, and Welfare to prescribe performance standards to control man-made radiation from U.S. produced and imported electronic products if he determines that such standards are necessary for the protection of public health and safety.

Any manufactured or assembled product is covered by the Act if it emits radiation and contains an electronic circuit or functions as part of an electronic circuit. The Secretary has delegated to the Bureau responsibility for day-to-day administration of the Act.

Many possible relationships between different kinds of man-made radiation and human health must be considered in standards to protect people from three kinds of electronic product radiation—ionizing, nonionizing, and sonic.

Ionizing radiation has the ability to separate electrons from atoms and thus create ions, which are electrically charged and capable of disrupting life processes. Non-ionizing radiation, although unable to create ions, also may adversely affect human health. X-rays are a form of ionizing radiation. Microwaves and visible light are examples of nonionizing radiation. Sonic radiation is a form of sound.

Science thus far has been unable to determine if there is a dose level for ionizing radiation so low that it may be regarded as safe. The question of a safe dose level for nonionizing radiation also needs further study. The Bureau, therefore, believes that all man-made radiation should be avoided except when the risk of exposure is counterbalanced by medical or other direct benefits to the person exposed.

STANDARD SETTING ACTIVITIES

A radiation control standard for microwave cooking ovens used in homes and commercial food establishments was issued on October 6, 1970. Under the standard, no oven manufactured after October 6, 1971, may leak radiation above one milliwatt per square centimeter prior to purchase and five milliwatts per square centimeter during its useful life.

The standard requires each oven to be equipped with at least two safety interlocks to insure that the microwave generator is shut off when the oven door is opened. One of the interlocks must be concealed. The standard provides, in addition, that a mechanical or electrical failure of a single oven component will not cause the interlocks to be inoperative.

The third and final stage of the television receiver X-ray control standard went into effect on June 1, 1971. Previous stages required sets to meet the Federal X-ray emission limit of 0.5 milliroentgen per hour even though user and service controls were so maladjusted as to produce maximum radiation. Under the third stage, a set also is required to comply with the limit when a single circuit or part failure occurs.

A proposed standard to improve the radiation control performance of diagnostic X-ray equipment used in the healing arts was completed and officially published for comment in the *Federal Register* on October 8, 1971. The standard—actually a number of specific standards—was in development for about three years under a high priority, since more than 90 percent of all human exposure to man-made ionizing radiation in the United States results from diagnostic X-ray procedures.

The proposed standard would require limitation of the X-ray beam to the size of the film or fluoroscope screen. The use of beams larger than needed has been a frequent cause of unnecessary X-ray exposure. Another provision would permit the X-ray technologist to know, with greater confidence, machine settings that will provide needed picture quality without retakes, thus eliminating one of the causes of retakes and helping to reduce unnecessary exposure. The standard also would establish leakage limits for the X-ray tube assembly.

Drafts of standards for nonmedical cabinet X-ray equipment and lasers were prepared during fiscal 1971. Cabinet X-ray machines have many uses in industry and research as, for example, in studies of the internal structure of materials. Many of these uses pose potential radiation hazards for workers.

High-powered laser light beams, known to be capable of serious eye and skin injury, are used in industry, research, and medicine, usually under carefully controlled conditions. Some low-powered lasers, however, have been reduced sufficiently in cost to permit their

use in high school and college classrooms where user control is not easily exercised. Low-powered lasers are known to be capable of causing eye injury in experimental animals. Further study is necessary to determine whether low-powered lasers, under use conditions for which they are designed, may be classroom safe.

X-RAY EXPOSURE STUDY

Much of what the Bureau does to protect people is based on data on radiation exposure from X-ray equipment used in the healing arts. The most recent source of such data is the 1970 study of the exposure of the U.S. population to radiation from X-ray procedures for disease diagnosis or treatment. This study, conducted with the cooperation of the National Center for Health Statistics and State and local public health agencies, was begun in April 1970 and data collection completed by the middle of September 1971. Methods employed assured comparability with data from an earlier (1964) Public Health Service X-ray exposure study.

Preliminary 1970 findings were made public before the American Roentgen Ray Society on September 29, 1971, and the American Public Health Association on October 11, 1971. The preliminary data showed that, despite increases both in the total number of persons who received X-ray examinations and the rate of examinations per 100,000 persons, the population exposure to X-ray may have been less in 1970 than in 1964. About 130 million Americans were estimated to have received one or more X-ray examinations during 1970. This was about 20 percent above the 1964 figure. The rate of examinations per 100,000 persons went up 10 percent. The estimates were based on a 1970 civilian, noninstitutionalized U.S. population of 200 million, compared to 187 million in 1964. Findings pointed to:

- Improvements in X-ray beam limitation and other patient protection practices. Indications were that beam limitation, to reduce unnecessary exposure, was effected in about two-thirds of the examinations in comparison with less than half in 1964.

- A substantial decrease in the use of miniature films in mass chest X-ray examinations, indicating a trend toward greater use of standard X-ray (radiographic) equipment with less exposure.

- A decline in X-ray examination rates among persons at the ages of greatest fertility—between 15 and 29.

Final results of the study will not become available until analysis has been completed of exposure levels from the 1970 use of X-ray in the healing arts. A report containing some of these estimates is expected to be published during 1972.

The 1970 study confirmed the 1964 study as to the value of beam limitation and other approaches to improved diagnostic X-ray control through equipment design and protective measures. This suggests that, in addition to fuller use of proper protective devices and

procedures, progress in reducing unnecessary X-ray exposure also will require improvement in deciding when X-ray procedures are needed to obtain diagnostic information.

PRODUCT SURVEILLANCE

Both television technicians and receivers were checked in a survey of X-ray exposure conditions in 70 Baltimore, Maryland, TV repair shops. The survey, completed in fiscal 1971, found the public health significance of radiation exposure to be minimal for technicians working in the shops.

A survey of more than 4,700 microwave cooking ovens in use in the United States during the calendar year 1970 was conducted jointly by the Bureau and manufacturers. About 10 percent of the ovens tested were found to leak microwave radiation above the voluntary industry maximum of 10 milliwatts per square centimeter. The survey was completed before the Federal microwave oven radiation leakage limit became effective. The industry voluntary limit was the only standard in effect at the time. It therefore is significant to note that, largely as a result of the survey, corrections were made voluntarily in many of the estimated 10,000 ovens believed to have had a "strong potential" for exceeding the industry maximum.

At about the time the survey of microwave home and commercial cooking ovens was getting under way, the Bureau reported on a survey of industrial microwave equipment. The report stated that all such equipment, used principally in industrial processing, had been found to be designed to prevent microwave emissions higher than the voluntary industry limit for cooking ovens. The authors of the report recommended regular inspection of user installations, a recommendation manufacturers generally have adopted for improved worker safety.

About three months after the second phase of the television receiver standard went into effect on June 1, 1970, Bureau staff members tested 259 color and black-and-white receivers at manufacturing plants or storage facilities of 20 U.S. producers of home TV's. All sets tested were found to comply with the Federal X-ray emission limit under operating conditions required by the first two phases of the standard.

A variety of other tests is conducted to assure compliance with electronic product standards. Tests are made, for example, to determine how much radiation may be emitted under a number of equipment operating conditions and to evaluate the effectiveness of new designs in minimizing emissions. Life tests also are performed to detect changes that may occur in radiation leakage levels during product use.

Arrangements have been made with the Federal Communications Commission for the Bureau to use one of its laboratories to check the radiation control capabilities of models of electronic products. The tests have made it possible to detect radiation emission problems in new devices before they are mass-produced for the consumer market.

A laminographic dental X-ray machine of a type that provides, in a single exposure, a continuous view of the

mouth and supporting structures, was evaluated. The unit functions by rotating the film and X-ray tube around the patient's head. As a result of this study, the manufacturer has agreed to incorporate, in new equipment of this type, certain changes recommended by the Bureau to improve X-ray exposure control.

COMPLIANCE ACTIONS

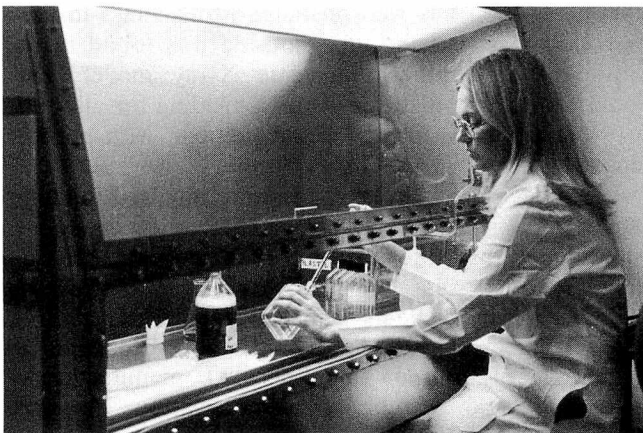
Regulations under the Radiation Control for Health and Safety Act require all U.S. and foreign manufacturers of certain radiation-producing electronic products to submit written reports on factory radiation-control testing for each model and an annual report summarizing test results thereafter. During fiscal 1971—the first full year the reporting regulations were in effect—more than 600 reports from 375 manufacturers were processed.

Guidelines were prepared to assist manufacturers in filing initial and annual reports on quality control tests on accelerators; analytical X-ray equipment; cathode ray, shunt regulator, and high voltage rectifier and regulator tubes; high voltage vacuum switches and interrupters; industrial X-ray equipment; lasers; microwave ovens; microwave diathermy and heating equipment; TV receivers; and ultrasonic devices.

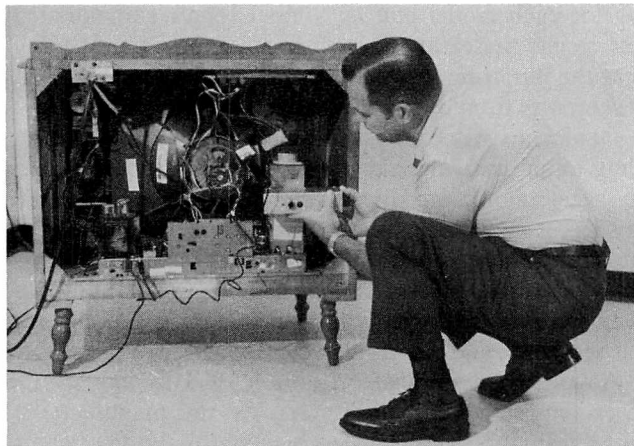
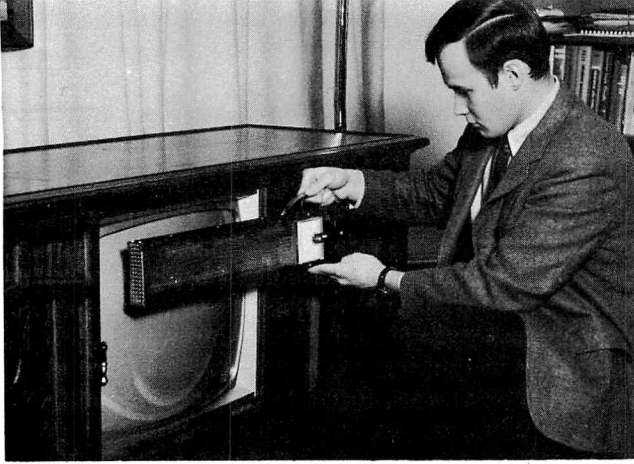
Actions were completed in fiscal 1971 in eight of 12 cases requiring corrective action by the manufacturer under Radiation Control Act regulations. Four remaining actions are expected to be completed next year.

Some of the most significant actions involved X-ray equipment. In one instance, two employees of a manufacturing concern received skin burns on the hands when the safety interlock system failed to shut off the X-ray tube as a product was put into position for examination in an industrial X-ray machine cabinet. Interlock systems were corrected by the manufacturer in about 200 of these machines.

In another case, a technician's hand was exposed when a shutter failed to close on an X-ray diffraction device. The manufacturer is completing a program to replace the faulty shutter mechanism with an improved version on all similar units.



FDA's "rad health" biologists have shown that exposure of animal cells to ultraviolet or X-radiation increases the probability that they will be transformed by viruses into cells with tumor-forming capacities.



X-ray emissions from TV sets were a major problem during the past year. Pictures show demonstration of new instruments developed by Bureau engineers for use by TV servicemen to detect emissions exceeding the Federal standards.

A fluoroscopic diagnostic X-ray machine was found to permit radiation to leak around the shutter edges. The manufacturer installed additional shielding on all fluoroscopes of this model that required modification.

A mobile diagnostic X-ray machine of the type used in hospital wards was found to emit radiation after the equipment was turned off. The emissions were caused by the continued flow of electricity stored in a capacitor tube. Correction kits were installed in machines in use.

Shielding around the tube housing was found to be insufficient in another diagnostic X-ray model. The manufacturer provided temporary shielding for all units in use and is now correcting the problem with permanent shielding.

Four television manufacturers were involved in compliance actions. In the case of two companies, emissions were higher than the X-ray control performance required by set designs, but still were below the Federal limit. Tube replacements achieved the desired control for each make. The Federal limit was exceeded in a model line of each of the other two manufacturers. Corrections required tube replacements in one case and picture tube shielding in the other.

Shielding also was used to correct above-Federal-limit X-ray emissions from commercial projection television equipment of two manufacturers.

A part in the high voltage circuit was identified in FY 1971 as the cause of above-limit X-ray leakages

from a line of television monitors used in TV broadcasting studios. Correction was accomplished by replacing the part in all monitors in which the voltage was too high.

BIOLOGICAL EFFECTS RESEARCH

Bureau-conducted or supported biological research reflected new emphasis on nonionizing radiation effects. For example:

- Microwaves were found to produce no harmful effects on monkey learning abilities after the animals had received radiation doses up to about five watts. The monkeys were exposed for about a half hour once a day for 60 days. The research was started in the Bureau's Rockville, Maryland, laboratories in September 1971.

- A joint study, begun this year, seeks to determine if an association exists between military occupations involving the use of microwave or radar equipment and physical disability discharges of service personnel.

- Research was launched in the Rockville laboratories in 1971 to determine what effects nonionizing radiation may have on animal embryos. Selected for the investigation were embryos at a life stage believed particularly sensitive to the radiation.

An investigation, also conducted in the Rockville laboratories, found that exposure of mouse cells to ultraviolet light increases the probability that they can be transformed by viruses into cells that resemble tumor cells.

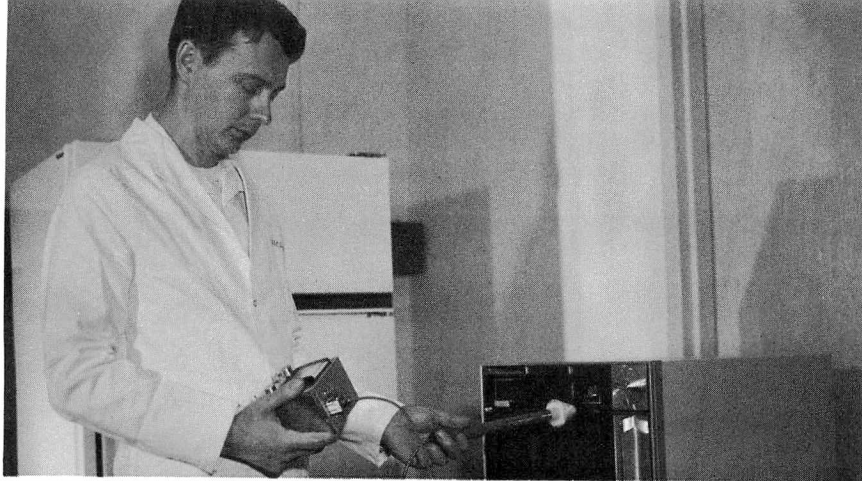
Concern for long-range ionizing radiation effects is further reflected by work at the Collaborative Radiological Health Laboratory at Colorado State University where unborn or young beagles are being given single exposure to learn what effects may be shown after 10 or more years. The study, begun in 1967, is expected to shed light on the ionizing radiation sensitivities of fetuses and growing young dogs as these may be related to humans.

APPLIED RESEARCH

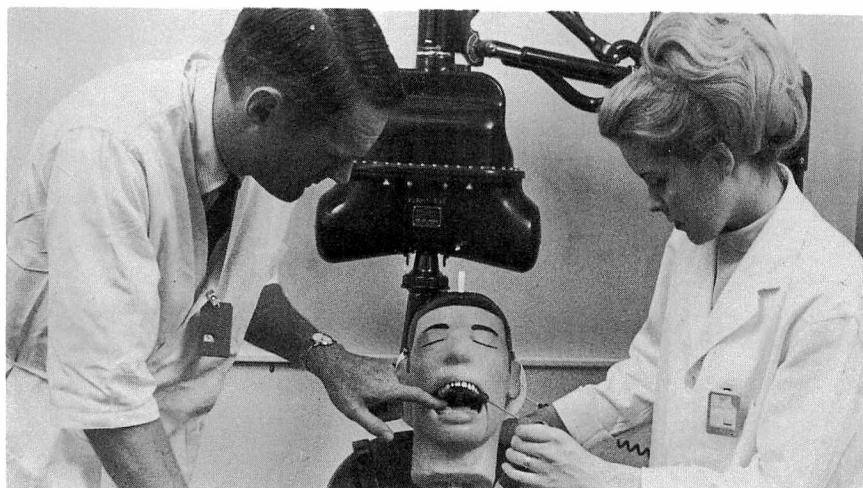
An improved system for leak-testing sealed radium sources with reduced operator exposure was developed in a Bureau laboratory. The system is based on a photographic leak test procedure developed in 1968.

Development of a portable monitor for indicating the biological hazard of laser radiation was completed with Bureau support. The instrument is designed to simulate laser radiation responses in the human eye.

The Bureau has responded to several critical needs for instruments for measuring electronic product radiation. One of these was the need of TV service technicians for instruments for checking home sets for possible X-ray emissions above the Federal standard. To help meet this need, two simple detection instruments were developed. Either of them may be made with parts costing an estimated \$15 to \$25. This development was



Electronic technician uses a meter developed by the Bureau to check microwave ovens for radiation leakage. It can be assembled by oven servicemen from readily available parts.



Bureau scientists demonstrate a dental manikin developed for training dental assistants and students in correct use of X-ray procedures. The manikin is made of materials which simulate the resistance of human bone and tissue—making use of “live” subjects unnecessary.

followed, in fiscal 1971, by the design of an easy-to-make and relatively low-cost meter for measuring possible radiation leakage from microwave cooking ovens.

Protection to Users of Radioactive Materials

Efforts to improve protection in the medical use of radioactive materials have been conducted for many years. Examples of this work in fiscal 1971 include:

- Analysis of data, gathered in a 1968–1970 survey of Wisconsin medical radium facilities, showed that about 220 of 300 persons monitored for radium exposures received larger-than-background doses. The survey was conducted by the Radiation Protection Section of the Wisconsin Division of Health.
- Development of a simple, low-cost approach to conducting clinical xenon studies. Xenon diagnostic studies—known as perfusion and ventilation procedures—are useful for documenting lung function. The Bureau’s method substantially reduces cost by preparing injectable xenon from gaseous xenon.

TRAINING ACTIVITIES

Four medical schools accepted invitations to affiliate with the Bureau-supported Radiological Health Sciences Education Project. The affiliates will establish model educational facilities for teaching basic radiological health science and good radiological procedures to medical students, hospital residents in radiology, and others. The University of California, Los Angeles; the University of Connecticut, Hartford; the Johns Hopkins

Medical Institutions, Baltimore, Maryland; and the Meharry Medical College, Nashville, Tennessee, have agreed to set up demonstration instructional programs based on the Radiological Health Science Laboratory developed earlier by the San Francisco Medical Center under Bureau contract.

The University of Alabama Dental School developed a pilot training program for radiology teachers in dental auxiliary schools. The broad objective of the program, developed under a Bureau contract, is to enable teachers to present dental radiology courses that meet minimum State requirements for student instruction.

Bureau interest in radiological health training has resulted in the issuance of many publications for the guidance of both students and professional users of radiation-generating equipment. New publications this year include (1) a manual to promote safety in high school and college classroom use of lasers and (2) a pamphlet to encourage the wider use and proper processing of fast film in dental X-ray examinations.

Model Ionizing Radiation User Licensing Law

Model State legislation was developed this year and distributed to State health agencies for use in establishing minimum educational and training standards for persons using ionizing radiation in the healing arts. The model law would require State certifications of competence to be obtained by all users of X-radiation and radioactive materials in the diagnosis or treatment of disease. The requirement would apply not only to medical and dental assistants, but also to physicians, dentists, and other licensed practitioners.



FDA's mobile labs go directly to the docks in the new "ship-to-ship" import program.

Import Inspection Activities

New "ship-to-ship" and "circuit rider" operations are increasing efficiency of a program that involves over \$25 billion of consumer expenditures.

Import inspection increased substantially, resulting in detentions of 9,700 shipments at U.S. ports, 42 percent more than last year (Table 5). Wharf examinations increased from 17,821 to 26,916, due to the testing of a new strategy to deal with a constantly increasing volume of imported products.

The new import program, partially in effect only a few weeks of fiscal 1971, is a revolutionary change from former procedure. Two basic concepts are involved: "ship-to-ship" inspections at major ports, and "circuit rider" coverage of smaller ports which handle a large volume of products crossing the Mexican and Canadian boundaries.

Formerly inspectors spent much time checking ship manifests to select lots for sampling. In ship-to-ship coverage, two-man teams go directly to the piers where cargo is being landed, collect samples, and make immediate dockside examinations. Specially designed mobile laboratories have been ordered so inspectors can drive onto the piers with their testing facilities. Similar mobile

labs will also be used for the "circuit rider" (port-to-port) operations reaching places like Pembina, North Dakota (fish and grain), or Brownsville, Texas (fruits and vegetables). The United States now has over 500 ports of entry for goods subject to customs.

Import surveillance, a major FDA activity, has been much affected by changes in foreign trade. Tonnage of foods, drugs, etc., has increased over 65 percent in the past 10 years. Whereas bulk commodities were predominant in the past, a great amount of imported foods, drugs, and other products now arrive in finished form. Containerization of shipments is making it necessary to provide inspection service at inland points when sealed containers have moved directly from ocean to land carriers.

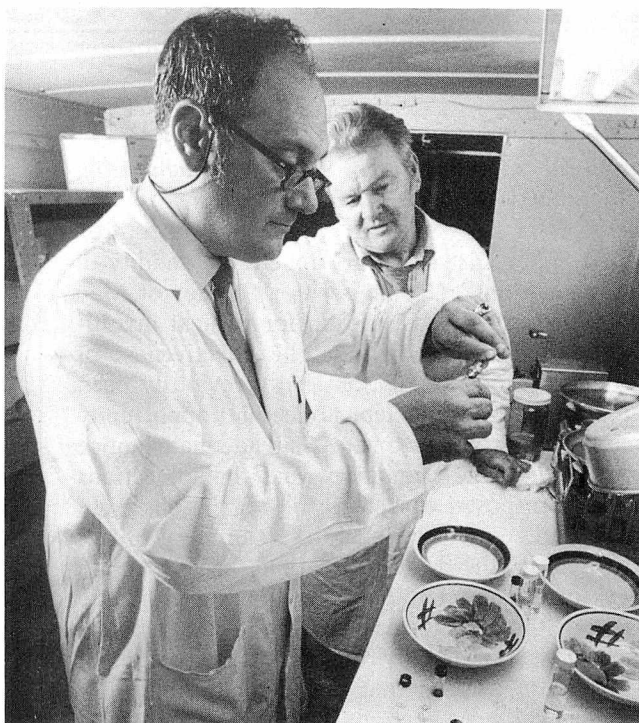
A key factor in the new FDA import strategy will be a mandatory "RIE" reporting form (Report of Import Entry) on which importers will report all shipments of articles subject to FDA inspection—from noodles to toys. The RIE would replace four official forms now in use. This is expected to save many man-years of inspection time. Planned as a data source for computer processing, the form should supply workload information needed to improve the efficiency of import inspection.

An Assistant for Import Operations at FDA headquarters is providing central direction of import activities. He will coordinate a stepped-up program of saturation sampling of problem products, and intensified inspection of borderline operators backed by court actions if necessary.

Voluntary industry cooperation to promote compliance will continue to be sought and encouraged. Segments of the importing trade, for some years, have been working to get commodities "cleaned up" before shipment to the United States, avoiding the delay and expense of detention. In some areas, the spice trade for example, this cooperation has been very successful.

Overseas, FDA inspection and technical advice can be provided on a request basis, and by cooperative agreements with foreign governments. FDA international services give help to countries which want to improve their products so they will meet the U. S. requirements—the same as for domestic producers. To provide information, a new edition of the FDA booklet "Requirements of the United States Food, Drug, and Cosmetic Act" was issued.

Import shipments subject to FDA regulation are now estimated at \$25 billion annually, approximately 12.5 percent of the \$200 billion total U. S. consumer expenditures for such products, conservatively figured. Inspection, therefore, must continue to be very selective, around 6 percent of the total entries. Mercury-contaminated fish, cheeses containing excessive pesticide residues, drugs not approved for safety and effectiveness, filth-contaminated foods, and improperly labeled products were the leading categories listed in the FDA Monthly Summary of Import Detentions in 1971.



Inside the lab (top photo), FDA inspectors are doing a *lead* determination on imported table pottery. Import inspection of foods and drugs is a long-standing collaboration between U. S. Customs and FDA. A damaged shipment of canned tomatoes (bottom photo) is spotted by Customs. FDA then takes over the inspection and detention of the goods.

Decisions of the Courts

Pharmaceutical Manufacturers Ass'n v. Richardson, 318 F. Suppl. 301 DC Del. 1970.

A United States District Court upheld the validity of the "May regulations" (Commissioner's Order of May 8, 1970) which established criteria for clinical investigations submitted to demonstrate the effectiveness of drug products. Similar regulations had previously been invalidated for lack of sufficient notice and opportunity for comment, but the court held that adequate notice was given on the May regulations and that objections were properly disposed of before the regulations were made final. The court also upheld the summary procedure provided in the May regulations which allows withdrawal of a New Drug Application or antibiotic certification without a formal hearing if the medical documentation submitted by the person requesting a hearing shows on its face that no adequate and well-controlled clinical investigations have been conducted or identified on the drug. Since the court held that this procedure was not a violation of constitutional due process, and since the issues were legal and not factual, the court denied the plaintiff's motion for an injunction and granted the Government's motion to dismiss the case by summary judgment.

Pfizer, Inc. v. Richardson, 434 F.2d 536 CA 2, 1970.

A Court of Appeals denied a petition by a pharmaceutical manufacturer to review a final order of the FDA repealing regulations certifying six antibiotic drugs manufactured by the company and revoking all certificates of safety and effectiveness thereunder, holding that the FDA may by regulation insist that reasonable grounds justifying a formal hearing include adequate and well-controlled clinical investigations. Subsequently, in *CIBA-Geigy Corp. v. Richardson*, No. 35614, July 16, 1971, the same court held that the same rules apply with respect to the opportunity for hearing in new-drug withdrawal proceedings.

United States v. Xerac Alcohol Acne Gel, No. 70 C 106, DCND Ill., ED.

A District Court held that, standing alone, evidence in the form of testimony from a qualified expert that he has knowledge of a drug or has used it does not constitute an adequate basis upon which to conclude that the drug is generally recognized among qualified experts as safe and effective for its recommended use. Rather, the court held, the absence or lack of ready availability to qualified experts, of a body of published medical and scientific data, including literature describing adequate testing of the drug, established that the drug is not generally recognized as safe and effective and is a new drug.

Marko Durovic d/b/a Duga Labs v. Richardson, No. 69 C 32 DCND Ill., ED.

The promoters of Krebiozen had sought a declaratory judgment so as to begin legal interstate distribution of the product. However, the drug was held to be a "new drug" within the Food, Drug, and Cosmetic Act and not within the "grandfather clause" exemptions.

Lemmon Pharmacal Co. v. Richardson, DCED Pa., 319 F. Supp. 375 1970.

A District Court granted a motion for summary judgment against a drug manufacturer, finding that its product Obestat was a "new drug" within the Food, Drug, and Cosmetic Act. The court held that the determination of actual safety and effectiveness of a particular drug is one of the essential functions of the Food and Drug Administration and is within the jurisdiction of the Agency.

United States v. Kaybel, Inc., 430 F.2d 1346 CA 3, 1970.

An Appeals Court reversed a conviction of a corporation and its officers for distributing a new drug in interstate commerce without the required New Drug Application, holding that if the manufacturer has an approved NDA for its package of the drug, repackaging by the distributor does not require a separate NDA by the distributor.

United States v. Roux Laboratories, 437 F.2d 209 CA 9, 1971.

A Court of Appeals reversed a summary judgment granted by the District Court in a seizure of cosmetics alleged to contain unsafe color additives. The court held that the pleadings and affidavits raised material issues of fact as to whether quantities of silver nitrate, silver sulfate, and pyrogallol contained in the product were unsafe color additives, which would render the product subject to seizure, or "dilutents," which would not come within the scope of the Act. The court held that *Toilet Goods Association v. Finch*, 419 F.2d 21 (2 Cir. 1969) relied upon by the District Court, did not bar the FDA from proceeding against cosmetics that contain additives that are unsafe because they have not been listed or exempted under the regulations.

R. B. Jarts, Inc. v. Richardson, 438 F.2d 846 CA 2, 1970.

A Court of Appeals denied a petition by a manufacturer to review a regulation which classified lawn darts as a "banned hazardous substance" unless they carry a specific warning and are not sold in toy stores. The court held that the firm, which admitted that lawn darts could be and were used by children but which refused to label them as "Not a Toy for Use by Children" or to refrain from selling them in toy stores, could not deny that the darts were a "toy or other article intended for use by children" presenting a mechanical hazard, and thus a banned hazardous substance.

United States v. Chalaire, 316 F. Supp. 543 ED La., 1970.

The District Court convicted the owner and the bartender of a Louisiana bar, who sold out-of-state Class B fireworks (silver kings and cherry bombs) to minors, of violation of the Federal Hazardous Substances Act. The court held that sale of such fireworks to an adult without first inquiring if a child would use them results in the fireworks so sold being banned hazardous substances. The court noted that knowledge and willfulness were not necessary for a conviction under the Act, although these elements were present in this case.

United States v. Thriftmart, Inc., 429 F.2d 1006 CA 9, 1970.

A Court of Appeals affirmed a District Court's opinion that oral consent by a warehouse manager was sufficient to authorize an FDA inspection of premises where food was stored without a search warrant and without a specific reminder that the manager could insist on a search warrant. The inspector had been told to "go ahead" after presentation of a notice of inspection to the manager; he found insect infestation and the firm was subsequently prosecuted for holding food under insanitary conditions. The Appeals Court held that an inspection under the Act is not a criminal search but an administrative inspection, and that a showing "that reasonable administrative standards for inspection have been established and are met in the inspection in question" was equivalent to probable cause to suppose a violation, as required for criminal search warrants.

The same United States Court of Appeals also reversed and sent back for reconsideration a lower court holding that evidence collected during an inspection of a food warehouse was to be suppressed because the FDA inspector had no search warrant. *United States v. Alfred M. Lewis, Inc.*, 431 F.2d 303 (C.A. 9, 1970). The Court of Appeals held the evidence was constitutionally obtained, even without a search warrant, because the inspection was an administrative inspection, not a search, made with the voluntary consent of the warehouse manager, at a reasonable time, after presentation of credentials and a written notice.

L & M Industries, Inc. v. Kenter, 321 F. Suppl. 1131
EDNY 1971.

The District Court held that the Food and Drug Administration did not act arbitrarily in detaining an imported food which appeared to be misbranded. The plaintiff had applied for release of the food for relabeling, but had not provided information, including the composition and manufacturing details, which was needed by FDA before it could determine whether proper labeling could be devised.

United States v. An Article . . . Hubbard Electrometer . . . Founding Church of Scientology, et al., DC DC
July 1971.

The long "E-meter" case resulted in a decision by a District Court to condemn all of the devices and associated literature, awarding costs to the Government. The court specifically found that the "E-meter" was a "device" under the Act, that the literature was labeling for the device, and that the device was misbranded, both by misrepresentations and by failure to bear adequate directions for use. The court held that Scientology was a religion for purposes of the case only and, therefore, because of the asserted religious use of the device, declined to order destruction of the devices and allowed future use of the device and literature only if accompanied by a disclaimer of any scientific or medical benefit.

Church of Scientology of California v. Richardson, 437
F.2d 214 CA 9, 1971.

A Court of Appeals upheld the summary judgment of a District Court which confirmed detentions of skin galvanometers ("E-meters") because they appeared to be misbranded in that they did not bear adequate instructions for use. The importers of the devices sued to enjoin the FDA from instituting the detention and, thus, denying admission and to stop the return of the devices to their country of origin, and for damages, claiming infringement of religious freedom since the device was used in a religion. The District Court held for the Government, saying that religious freedom did not include the freedom to violate the Federal Food, Drug, and Cosmetic Act. The Appeals Court agreed and specifically held that religious literature could be considered as labeling of a device used in that religion so long as claims about use and benefits of the device were presumed truthful.

notices of judgment

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

Cottonseed, at Hanford, E. Dist. Calif.

Charged 1-28-71: while held for sale, the article contained an added poisonous and deleterious substance, aflatoxin; 402(a)(1). Consent decree authorized release to Hollandia Dairy, Inc., Hanford, Calif., for salvaging. (1)

Cottonseed, at Santa Fe Springs, C. Dist. Calif.

Charged 2-12-71: when shipped by Parker Valley Gin Co., Parker, Ariz., the article contained an added poisonous and deleterious substance, aflatoxin; 402(a)(1). Consent decree authorized release to United Dairy-men's Association of Calif., Santa Fe Springs, Calif., for salvaging. (2)

Fish fillets, Kurokawa Marlin, frozen, at Honolulu, Dist. Hawaii.

Charged 5-10-71: when shipped by Mitidi Abe, Tokyo, Japan, the article contained an added poisonous and deleterious substance, mercury; 402(a)(1). Default decree ordered destruction. (3)

Noodles, at Toledo, N. Dist. Ohio.

Charged 4-26-71: when shipped by Viviano Macaroni Co., Carnegie, Pa., the article contained *Salmonella* micro-organisms; 402(a)(1). Default decree ordered destruction. (4)

Swordfish chunks, frozen, at Denver, Dist. Colo.

Charged 2-18-71: when shipped by Slade Gordon & Co., Somerville, Mass., the article contained an added poisonous and deleterious substance, mercury; 402(a)(1). Default decree ordered destruction. (5)

Swordfish fillets and steaks, frozen, 2 seizure actions at Buffalo, W. Dist. N.Y.

Charged 3-19-71: when shipped from Japan, the article contained an added poisonous and deleterious substance, mercury; 402(a)(1). Default decrees ordered destruction. (6)

Swordfish steaks, at Raleigh, E. Dist. N.C.

Charged 3-29-71: when shipped by Blue Water Seafoods, Cleveland, Ohio, the article contained an added poisonous and deleterious substance, mercury; 402(a)(1). Default decree ordered destruction. (7)

FOOD/Contamination, Spoilage, Insanitary Handling

Beans, dried, pinto and lima, at Columbia, Dist. S. C.

Charged 3-3-71: while held by Merchants Wholesale Grocery, Columbia, S.C., the articles were rodent gnawed and contained rodent hair fragments and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (8)

Candy, Jelly Bird Eggs, at Erie, W. Dist. Pa.

Charged 3-8-71: when shipped by Farley Candy Co., Skokie, Ill., the article contained wood chips; 402(a)(3). Default decree authorized donation to public institution for use as animal feed. (9)

Cassia and cumin seed, at Detroit, E. Dist. Mich.

Charged 3-10-71: while held by A. E. Staley Manufacturing Co., Detroit, Mich., the articles were held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (10)

Chips, garlic flavored, at St. Paul, Dist. Minn.

Charged 4-15-71: while in transit, via Admiral Merchants Motor Freight, Inc., St. Paul, Minn., the article was held under insanitary conditions, since antimony trioxide in the trailer with the bakery product had sifted onto the bakery product; 402(a)(4). Default decree ordered destruction. (11)

Flour, at New Orleans, E. Dist. La.

Charged 3-25-71: while held by P. A. Menard, Inc., New Orleans, La., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (12)

Grits and cornmeal, at Charlotte, W. Dist. N.C.

Charged 2-10-71: while held by Statesville Flour Mills Co., Charlotte, N.C., the articles contained insect and rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree authorized donation to charitable institution for use as animal feed. (13)

Oregano, whole, and sage leaves, at South San Francisco, N. Dist. Calif.

Charged 2-18-71: while held by Presco Food Products, Inc., South San Francisco, Calif., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (14)

Peach halves, canned, O'Sage, at Nashville, M. Dist. Tenn.

Charged 3-18-71: when shipped by Cherokee Products Co., Haddock, Ga., the article was unfit for food, since it had a phenolic or disinfectant-like taste and odor; 402(a)(3). Default decree ordered destruction. (15)

Peanuts, at Shreveport, W. Dist. La.

Charged 3-25-71: while held by Julius Gamm Co., Shreveport, La., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for reconditioning. (16)

Peas, field, with snaps, canned, Miss America, at Nashville, M. Dist. Tenn.

Charged 4-30-71: when shipped by Miss America Foods, Inc., Cullman, Ala., the article was unfit for food by reason of having an off-flavor similar to kerosene; 402(a)(3). Default decree ordered destruction. (17)

Pecan pieces, at Fairfield, S. Dist. Ohio.

Charged 3-3-71: when shipped by Nut Tree Pecan Co., Albany, Ga., the article contained *E. coli* and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for reconditioning. (18)

Pecan pieces, at Piqua, S. Dist. Ohio.

Charged 4-13-71: when shipped by Dasher Pecan Co., Valdosta, Ga., the article contained *E. coli* and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Dasher Pecan Co., for reconditioning. (19)

Potato products, frozen, at Kansas City, Dist. Kans.

Charged 3-26-71: when shipped by Chef Reddy Foods, Inc., Othello, Wash., the articles were prepared and packed under insanitary conditions; 402(a)(4). Default decree authorized delivery to public institution for use as livestock feed. (20)

Saimin and Chow Funn oriental grain product, at Los Angeles, C. Dist. Calif.

Charged 4-21-71: when shipped by Taiyo, Inc., Honolulu, Hawaii, the articles contained insect and rodent filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (21)

Vinegar, at Billings, Dist. Mont.

Charged 3-31-71: when shipped by Speas Co., Denver, Colo., the article was unfit for food by reason of being cloudy and containing slimy masses; 402(a)(3). Default decree ordered destruction. (22)

FOOD/Economic and Labeling Violations

Cookies, sugar wafer, Sunbeam, at Fort Worth, Tex.

Charged 4-1-71: when shipped by American Wafer Co., Joplin, Mo., the article was in violation of the Fair Packaging and Labeling Act in that the principal display panel of the package had an area between 25 and 100 square inches and the statements of the net quantity of contents stated on the panel contained letters and numerals in a type size of less than 3/16 inch high; 1453(a)(3)(C)(i). Default decree authorized donation to charitable institution. (23)

Fish, frozen, at Gloucester, Dist. Mass.

Charged 9-11-70: when shipped by F. W. Bryce, Gloucester, Mass., to Highland, N.Y., and thereafter returned to Gloucester, Mass., codfish had been substituted for haddock fish which the article was represented to be; the label statement "Haddock" was false and misleading since the article was codfish; the article was offered for sale under the name of another food, haddock fish; and the label lacked the common or usual name of the food, namely, codfish; 402(b)(2), 403(a), 403(b), 403(i)(1). Default decree authorized donation to a public or charitable institution. (24)

Guava jelly, at Hawthorne, S. Dist. N.Y.

Charged 1-22-71: when shipped by Groveland Products Co., Inc., Hallandale, Fla., the article lacked conformity to the standard of identity, since it was deficient in fruit juice ingredient; 403(g)(1). Default decree authorized donation to a charitable institution. (25)

Pimientos, at Bronx, S. Dist. N.Y.

Charged 1-22-71: when shipped by Perfect Packed Products Co., Inc., Henderson, N.C., bell peppers had been substituted wholly or in part for pimientos; red bell peppers were offered for sale under the name of another food, pimientos; and the label lacked the common or usual name of each ingredient of the article; 402(b)(2), 403(b), 403(i)(2). Default decree ordered donation to a charitable institution. (26)

FOOD ADDITIVE

Fruits, canned, at Toledo, N. Dist. Ohio.

Charged 5-7-71: while held by Oscar Joseph Stores, Inc., Toledo, Ohio, the articles contained the nonconforming food additive cyclamate; 402(a)(2)(C). Default decree ordered destruction. (27)

ANIMAL FEED

Feed, medicated, Custom Formula, at Cheyenne, Dist. Wyo.

Charged 1-14-71: when shipped by John Ewing Co., La Salle, Colo., the circumstances of the article's manufacture, packing, and holding lacked conformity with current good manufacturing practice; and the article contained the new animal drugs chlortetracycline and ammonium chloride, and lacked an effective approved New Animal Drug Application; and the label lacked adequate directions for use and lacked adequate warnings against unsafe use; 501(a)(2)(B), 501(a)(6), 502(e)(1), 502(f)(1), 502(f)(2). Consent decree authorized release to shipper for relabeling. (28)

DRUGS/Human Use

Acnotabs pancreatin-vitamin combination tablets, 3 seizure actions, at New York, S. Dist. N.Y., Mount Vernon, S. Dist. N.Y., and South San Francisco, N. Dist. Calif.

Charged 3-12-63 in the New York City seizure case: while held by Pannett Products, Inc., New York, N.Y., who had originally caused the shipment of these returned lots of the article, the label statement "Acnotabs an internal medication for Acne (pimples)" was false and misleading since the article was not adequate and effective for the treatment of acne (pimples); 502(a).

Charged 3-12-63 in the Mount Vernon seizure case: while held by Vernon Labs., Mount Vernon, N.Y., who had originally packaged and shipped these lots of the article on instructions of Pannett Products, Inc., New York, N.Y., a 53-bottle returned lot of the article bore the label statement "Acnotabs an internal medication for Acne (pimples)" which was false and misleading since the article was not adequate and effective in the treatment of acne (pimples)—502(a); and an unlabeled 600-bottle returned lot of the article lacked: the name and place of business of the manufacturer, packer, or distributor, an accurate statement of the quantity of the contents, and the common or usual name of the drug—502(b)(1), 502(b)(2), 502(e)(1).

Charged 1-2-64 and amended on or about 5-18-66 in the South San Francisco seizure case: when this lot of the article (bearing a new label) was shipped from Mount Vernon, N.Y., by Pannett Products, Inc., the label statement "Acnotabs an internal medication for the temporary mitigation in some cases of acne vulgaris" was false and misleading since the article was not effective for the mitigation or treatment of acne vulgaris; the labeling lacked adequate directions for use for the specific types or kinds of acne vulgaris cases for which the article was held forth to be effective; and the article was a new drug without an effective approved New Drug Application; 502(a), 502(f)(1), 505(a).

The three cases were removed to the District of New Jersey. Pannett Products, Inc., the claimant, denied the charges. Thereafter it was agreed prior to and at trial that the three cases involved common questions of law and fact which could conveniently be tried together; and the cases were subsequently *nunc pro tunc* consolidated for the purpose of trial. After trial of the cases by the court, the court said:

"These are three consolidated in rem actions commenced by separate libels following seizures after this Court's opinion in *United States v. An Article of Drug, etc. (Acnotabs)*, 207 F. Supp. 758 (D.N.J. 1962). The same drug and the same parties are involved. The ingredients in each tablet of the drug are:

Vitamin A—10,000 units	Vitamin C—100 mg.
Pancreatin—200 mg.	Pepsin—150 mg.
Ox Bile Extract—100 mg.	

"The Court found in its 1962 decision that the drug was misbranded. It permitted the claimant, Pannett Products, Inc., opportunity to bring the drug into compliance with the provisions of the Food, Drug and Cosmetic Act. The Secretary [of H.E.W.] and the claimant have never been able to agree upon an appropriate label and the claimant has attempted to relabel the drug in accordance with what it conceives to be the findings of this Court in the 1962 decision. The finding of fact in the 1962 decision most pertinent to disposition of these cases is that the effectiveness of the drug in the treatment of acne vulgaris had not been established by adequate testing which would justify the representations made by the labeling. Hence the door was left open for further testing of the drug by both the United States and the claimant-manufacturer, Pannett Products, Inc.

"At the consolidated trial of these matters, evidence as to what further testing disclosed was introduced; and the basic question is whether a proposed new label constitutes misbranding in violation of 21 U.S.C. 352(a).

"The only new label appearing on any of the bottles seized in each of the three actions reads as follows:

72 Tablets Acnotabs An internal medication for the temporary mitigation of pimples in some cases of acne vulgaris
Contains: Pancreatin, Bile Salts, Pepsin, Vitamins A and C. Usual dose: Take one tablet three times a day after meals or as directed by your physician. Distributed by Pannett Products, Inc. New York 17, N.Y. Pat. applied for.

"For clarity it might be well at this point to refer to each of the seizures involved. The seizure in Civil Action 399-63 was made on

March 13, 1963, at Vernon Laboratories, Mount Vernon, New York. That seizure involved 53 labeled bottles and 600 unlabeled bottles of the drug. The labeled bottles bore the label:

72 Tablets Acnotabs an internal medication for Acne (Pimples) Contains: Pancreatin, Bile Salts, Pepsin, Vitamins A and C

Usual dose: Take one tablet three times a day after meals or as directed by your physician. Pannett Products, Inc., New York, 17, N.Y. Pat. applied for 1960.

The seizure in Civil Action 400-63 also occurred on March 13, 1963, at the office of the claimant, Pannett Products, Inc., 370 Lexington Avenue, New York City, and consisted of 208 bottles of the drug bearing a label identical to that of the 53 labeled bottles involved in Civil Action 399-63. Civil Action 185-64 involved a seizure in the Northern District of California on January 2, 1964 of 61 bottles of the drug bearing the proposed new label mentioned above. Parenthetically, it may be noted here that the bottle labeling of the 53 bottles in Civil Action 399-63 and of the 208 bottles in Civil Action 400-63 are identical to the bottle label which the Court considered in its 1962 decision in conjunction with pamphlet labeling contained in the package in which the drug was contained for sale. Pamphlet labeling is not involved here.

"All of the articles of drug which were seized in the three libel actions had moved in interstate commerce prior to their seizure and a new drug application pursuant to 21 U.S.C. 355, 321(p) was never filed with the Food and Drug Administration.

"The conclusion reached by the Court is that libelant has established by a preponderance of the credible evidence that the drug, Acnotabs, is worthless in the treatment of acne vulgaris and that any representation of effectiveness by either the old or new bottle label is false and misleading and constitutes misbranding. As noted earlier in this opinion, the only new label involved is that which was on the bottles seized in the Northern District of California on January 2, 1964. The other bottles seized either bore no label or the bottle label that had been considered in the 1962 decision of this Court. Having moved in interstate commerce, the unlabeled bottles are misbranded by virtue of the provisions of 21 U.S.C. 352(b) and 352(e)(1).

"Claimant contends that the bottles containing the drug at the time of seizure were not in interstate commerce. 21 U.S.C. 334(a) provides in part:

Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, . . . shall be liable to be proceeded against while in interstate commerce or at any time thereafter. . . .

"[T]he language used by Congress broadly and unqualifiedly prohibits misbranding articles held for sale after shipment in interstate commerce, without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had received the articles at the end of the interstate shipment. *United States v. Sullivan*, 332 U.S. 689, 696 (1948). See also *United States v. Olsen*, 161 F. 2d 669 (9th Cir. 1947), where the Court noted that at the time the article was seized, it was not in interstate commerce. 'That, however, is immaterial; for, having been misbranded when introduced into and while in interstate commerce, the article was liable to be proceeded against and condemned at any time thereafter.' Id., at 670-71. The same drug was found to be misbranded in the 1962 decision prior to which it had moved in interstate commerce. Claimant's contention that the drug had been called back for purposes of relabeling and thus taken out of interstate commerce is without merit. Under the Act misbranded drugs may be seized at any time 'while in interstate commerce or at any time thereafter.' *Lee v. United States*, 187 F. 2d 1005, 1007 (10th Cir. 1951).

"Libelant has also contended that a new drug application was required for Acnotabs after the 1962 decision of this Court. The Court agrees. *United States v. Allan Drug Corporation*, 357 F. 2d 713 (10th Cir. 1966).

"Judgment of condemnation will be entered by separate orders in Civil Action 399-63, Civil Action 400-63, and Civil Action 185-64 in favor of libelant and against claimant, Pannett Products, Inc., with costs directing destruction of each lot of the seized drug pursuant to the provisions of 21 U.S.C. 334(d).

"Submit appropriate orders consistent herewith."

Thereafter, pursuant to orders of condemnation, the various lots of the articles were destroyed. (29)

Amphetcaps timed disintegration capsules, at Detroit, E. Dist. Mich.

Charged 8-7-70: when shipped by Bel-Air Surgical Supply, Los Angeles, Calif., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (30)

Digoxin tablets, U.S.P., at Melville, E. Dist. N.Y.

Charged 2-10-71: when shipped by Davis-Edwards Pharmacal Corp., Danbury, Conn., the circumstances of the article's manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice, and the article's strength differed from and its quality fell below the U.S.P. standard since the article failed to meet the U.S.P. test for content uniformity; 501(a)(2)(B), 501(b). Default decree ordered destruction. (31)

Lecithin aerosol spray, at Omaha, Dist. Nebr.

Charged 6-17-70: while held by Unidon International, Inc., Omaha, Nebr., who was labeling the article as "N-Dur Male Hygienic Aid," the label lacked the established name and quantity of each active ingredient and

the labeling lacked adequate directions for use; 502(e)(1)(A)(ii), 502(f)(1). Consent decree authorized release to the dealer for compliance operations. (32)

Richard's Formula "10" Analgesic, at Cuyahoga Falls, N. Dist. Ohio.

Charged 2-4-69: when shipped by L. Perrigo Co., Allegan, Mich., and while held for sale by Richard's & Associates, Inc., Cuyahoga Falls, Ohio, the article was a new drug without an effective approved New Drug Application and its labeling contained false and misleading claims that the article was an effective remedy for the pains and swelling of arthritis, gout, lumbago, rheumatism, and bursitis; that the article was completely safe and would not produce any undesirable side effects; and that the vitamins in the article were of value in the temporary relief of minor pain; the labeling was misleading since the statement against use for more than ten days unless directed by a physician was inconsistent with and contradictory to the statement advising repetition of the recommended regimen as often as necessary; and its labeling fails to bear an adequate warning against unsafe duration of administration, since the warning statement on the label against use for more than 10 days unless directed by a physician was contrary to the dosage recommendation; 502(a), 502(f)(2), 505(a). Answers to the Government's interrogatories were filed by the claimant, Richard's & Associates, Inc. Thereafter, a motion for summary judgment was filed by the Government and was granted by the court on 12-17-70 in an order wherein the court found the labeling of the article was false and misleading in certain respects and as such misbranded under Section 502(a), and because of such finding concluded that the issue on whether the drug was a new drug need not be decided. A decree was then entered ordering the destruction of the article. (33)

Theocomp capsules, Theofederal tablets, theophylline, ephedrine and phenobarbital combination tablets, Neo-Kek kaolin combination liquid, ephedrine sulfate capsules, and dextro-amphetamine with amobarbital capsules, at Miami, S. Dist. Fla.

Charged 7-24-68: while held by Barry Martin Pharmaceuticals, Inc., Miami, Fla., who had repacked some of the articles, the labeling of the capsules (an aminophylline ephedrine combination) and the Theofederal tablets (a theophylline ephedrine combination) lacked adequate directions for use—502(f)(1); the label of the ephedrine sulfate capsules failed to bear the prescription legend—503(b)(4); the label of the dextro-amphetamine with amobarbital capsules failed to bear the habit-forming warning, and their labeling failed to bear adequate directions for use—502(d), 502(f)(1); when shipped in bulk by Davis-Edwards Pharmacal Corp., N.Y. and while held by Barry Martin Pharmaceuticals, Inc., Miami, Fla., after being in part repacked, the labeling of the theophylline, ephedrine and phenobarbital combination tablets (bulk and repack) contained false and misleading claims that the tablets were adequate and effective for the treatment of hay fever, and the labeling (repack) failed to bear adequate warnings against use—502(a), 502(f)(2); when shipped by Bates Laboratories, Inc., Chicago, Ill., the labeling of the Neo-Kek liquid contained the false and misleading claims that the article was adequate and effective to afford certain relief from all diarrhea conditions, the label on the bottle failed to bear the name and place of business of the manufacturer, packer, or distributor, an accurate statement of the quantity of contents, the established name and quantity of each active ingredient, and the labeling lacked adequate directions for use and adequate warnings—502(a), 502(b)(1)(2), 502(e)(1)(A)(ii), 502(f)(1), 502(f)(2). Consent decree ordered destruction. (34)

DRUGS/Veterinary

Derma T-E-E-V testosterone enanate and estradiol valerate injection, at Los Angeles, C. Dist. Calif.

Charged 2-19-71: while held by Maury Biological Co., Los Angeles, Calif., who manufactured the article from estradiol valerate powder from Italy, estradiol isovalerate and free estradiol had been substituted wholly or in part for estradiol valerate and the representation in the labeling of the article that the estradiol ingredient of the article consisted solely of estradiol valerate was false and misleading; 501(d)(2), 502(a). Default decree ordered destruction. (35)

Formula 707 for horses, at Fergus Falls, Dist. Minn.

Charged 2-26-71; when shipped by John Ewing Co., La Salle, Colo., the article was a new animal drug without an effective approved New Animal Drug Application, and the article's labeling contained false and misleading claims to promote growth of colts, to keep horses in peak condition all of the time, and to promote high hemoglobin level and build up horses' blood; 501(a)(5), 502(a). Consent decree authorized release to Gerald S. Rufer, attorney for Double A. Western Shop, and John Ewing Co., Fergus Falls, Minn., for salvaging. (36)

Pet-Caps shale mineral tablets for animals, Shala-Caps shale mineral tablets, and Shala-Pro mineralized protein tablets, at Albuquerque, Dist. N. Mex.

Charged 5-7-70: while held by Shala-Min of New Mexico, Inc., Albuquerque, N. Mex., after repacking, the Pet-Caps were a new animal drug without an effective approved New Animal Drug Application and their labeling contained false and misleading claims, including claims concerning their efficacy in curing distemper and paralysis and in erasing old age symptoms in dogs—501(a)(5), 502(a); the labeling of the Shala-Caps tablets and the Shala-Pro tablets contained false and misleading statements that another article, Shala-Min, could produce amazing results of regeneration in cattle and in man and cause a rebuilding of energy and disappearance of aches and pains, that the Shala-Pro tablets would relieve the stress of a heavy protein diet, give renewed energy, increase the ability of the body to break down proteins and alleviate stress on the liver and kidneys—

403(a); and the label of the Shala-Caps tablets lacked the common or usual name of such food and the label of the tablets Shala-Pro lacked the common or usual name of each of its ingredients—403(i)(1)&(2). Consent decree authorized release to the dealer for compliance operations. (37)

MEDICAL DEVICES

Dynatone electronic muscle stimulator, at Atlanta, N. Dist. Ga.

Charged 3-29-68: when shipped by Dynatone, Inc., Wichita, Kans., the accompanying labeling contained false and misleading claims for trimming the body with effortless exercise, reshaping the waistline, tummy, hips, and thighs, without special dieting, and electronically exercising loose muscles; the article's labeling lacked adequate directions for safe use by a layman without the supervision of a physician and such directions could not be written because the layman could not reliably determine when use of the article was contra-indicated and may be harmful; the article's labeling lacked adequate warnings against use; and the article was dangerous to health when used with the frequency and duration recommended in its labeling; 502(a), 502(f)(1), 502(f)(2), 502(j). Dynatone Electronics Corp., New York, N.Y., claimant, filed an answer and a request for removal of the case to the Eastern District of New York. Thereafter pursuant to stipulation by the parties, the court entered an order for such removal. The claimant and the Government then served written interrogatories upon each other which were answered. The claimant subsequently withdrew its claim and answer and a default decree was entered ordering the article to be condemned and released to the U.S. Department of Health, Education, and Welfare. (38)

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

Charged on or about 10-23-70: when shipped outside the State of Texas, the labeling of the article lacked adequate directions for use since such directions could not be written for its use by laymen for the purposes for which intended and the article was not exempt from such requirement 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. (39)

Theramic model A-6DT40 electronic instrument, at Indianapolis, S. Dist. Ind.

Charged 9-10-70: when shipped by Dynapower Systems Corp., Los Angeles, Calif., the article failed to bear in its labeling adequate directions for use for the purposes intended since such directions could not be written for use by laymen of the article for such purposes, and the article was not exempt as an Rx device from the requirement of adequate directions since adequate information for its use could not be furnished under which practitioners could use the article safely and for the purposes intended; 502(f)(1). Default decree ordered destruction. (40)

HAZARDOUS SUBSTANCES

Dart game for use on lawn, at Robbinsdale, Dist. Minn.

Charged 4-19-71: while held for sale, the article was, by regulation, a banned hazardous substance since it was a sharp pointed toy usually intended for outdoor use having the potential for causing puncture wound injury; and the article was not exempt since it failed to bear the required labeling giving adequate directions and warning for safe use; 2(q)(1)(A). Consent decree authorized release to Montgomery Ward & Co., Chicago, Ill., for relabeling. (41)

Harrison Winter King methanol antifreeze, at Milwaukee, E. Dist. Wis.

Charged 1-11-71 and 1-18-71: while held by Harrison Oil Co., Inc., Milwaukee, Wis., who packed and labeled methanol in one-gallon cans, the article was a toxic substance and it lacked a number of required conspicuous label statements; (2)(p)(1). Consent decree authorized release to the packer for relabeling. (42)

M-80 firecrackers and other fireworks, at Tarkio, W. Dist. Mo.

Charged 7-16-71: while held by Ted's Tobacco & Grocery, Tarkio, Mo., the articles were, by regulation, banned hazardous substances, since they 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. (43)

NOTICES OF JUDGMENT on Criminal Actions

FOODS

Alfonso Gioia & Sons, Inc., t/a Bravo Macaroni Co., Rochester, W. Dist. N.Y.

Charged 1-6-71: when shipped, macaroni products, labeled in part "Bravo Large Bows [or 'Folded Egg Noodles' or 'Enriched Egg Noodles'] . . . Bravo Macaroni Co., Rochester, N.Y.," contained the added poisonous and deleterious substance *Salmonella* micro-organisms, which may render the articles injurious to health; 402(a)(1). Nolo contendere plea; fine. (44)

Carter-Murrell Baking Co., Inc., Kansas City, W. Dist. Mo.

Charged 1-26-71: when shipped, cherry-jelly rolls and apple turnovers had been prepared and packed under insanitary conditions; and sweet rolls were contaminated with rodent and insect filth and had been prepared and packed under insanitary conditions—402(a)(3), 402(a)(4); and while held for sale, puff pastry mix, dried milk, and dextrose were held under insanitary conditions and the puff pastry mix was contaminated with rodent filth—402(a)(3), 402(a)(4). Guilty plea; fine, plus costs. (45)

Meredith Fish Co., a corporation, and Joseph Lloyd Turnaciff, Sr., president, Sacramento, E. Dist. Calif.

Charged 12-15-70: when shipped, a quantity of frozen shrimp meat contained bacterial filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Nolo contendere pleas; fines. (46)

Safeway Stores, Inc., W. Dale White, distribution center manager, and **Clifford A. Tucker**, manager of firm's Garland warehouse, at Garland, N. Dist. Tex. Charged 3-19-71: flour and beans were held in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (47)

DRUGS

Wampler Foods, Inc., Harrisonburg, W. Dist. Va. Charged 12-21-70: while held for sale, a finished medicated animal feed labeled "Wampler's Turkey Grower" was prepared from dimetridazole which had been shipped in interstate commerce and from penicillin and other ingredients, which act resulted in the following: the feed was prepared under circumstances that did not conform to good manufacturing practice, and the feed contained dimetridazole and penicillin which in combination with each other in the feed were new animal drugs and no approval of a New Animal Drug Application was in effect with respect to the feed containing those new animal drugs—501(a)(2)(B), 501(a)(6); and, while held for sale, a finished medicated animal feed labeled "Wampler's Turkey Layer 100 Medicated" was prepared from erythromycin which had been shipped in interstate commerce and from penicillin, arsenic acid, and other ingredients, which act resulted in the following: the label of the feed was false and misleading since the feed contained more than the equivalent of 92.5 gm. per ton of erythromycin as declared on its label, the label lacked the established name of each active ingredient of the feed, and the labeling lacked adequate directions for use for the purposes for which the article was intended—502(a), 502(e)(1)(A)(ii), 503(f)(1). Nolo contendere plea; fine. (48)

NOTICES OF JUDGMENT on Injunction Action

Tupelo Processing Co., Inc., Tupelo, N. Dist. Miss. Charged 9-2-69 and amended 10-10-69 in a complaint for injunction: that the defendant was engaged in preparing, packing, holding, and distributing in interstate commerce, meat bone by-products which contained an added poisonous and deleterious substance, *Salmonella* micro-organisms, and which had been prepared, packed, and held at the defendant's plant at Tupelo, Miss., under insanitary conditions; 402(a)(1), 402(a)(4). Thereafter, pursuant to a stipulation, the Mid-South Milling Co. of Georgia (which had purchased substantially all the assets of the Tupelo Processing Co.) and the Government agreed to dismiss the action without prejudice; and Mid-South Milling Co. of Georgia agreed to refrain from directly or indirectly doing the acts complained of and from shipping in interstate commerce any by-product foods prepared and packed at the Tupelo plant unless and until certain methods, facilities, and controls were established and operated in conformity with practices which would assure that such foods were not contaminated with *Salmonella*. (49)

NOTICE OF JUDGMENT on Miscellaneous Action

Cyclamate-containing beverages, foods, and concentrates, a suit for mandamus, E. Dist. N.Y. Complaint filed 1-16-70 by Benjamin Eisenstadt, individually and on behalf of all other similarly situated members of the consumer public, against H.E.W. Secretary Finch in suit to compel performance of his duty under the Delaney Amendment: that the HEW Secretary ordered that the use of cyclamates be discontinued in the production of general purpose foods and beverages, but subsequently authorized an extension for certain food inventories and announced that cyclamate-containing foods and concentrates would be permitted to be sold on a nonprescription drug basis; that the initial order of discontinuance was based on the discovery that cyclamates had produced cancer in laboratory animals; that such order was compelled by the Delaney Amendment; that for the HEW Secretary to allow the present inventory of beverages containing cyclamates to be marketed for a period of time under certain labeling requirements was in violation of the Delaney Amendment; and that the HEW Secretary should be compelled to order off the market all cyclamate-containing beverages, foods, and concentrates and to permit their sale only as drugs upon prescription.

The HEW Secretary moved to dismiss the complaint on the grounds of lack of jurisdiction and failure to state a claim upon which relief may be granted. In granting that motion and dismissing the complaint, the court said:

"Preliminarily, the appropriateness of treating this action as a class action must be determined. Rule 23(a)(4), Fed. R. Civ. P., provides that as a prerequisite to a class action, a determination must be made that '... the representative parties will fairly and adequately protect the interests of the class.' No such finding can be made here.

"The complaint shows that plaintiff is the President of a manufacturer of a non-cyclamate artificial sweetener. In such circumstances, it cannot be found that he will fairly and adequately represent the interests of consumers of artificial sweeteners, whether his own or other cyclamate sweeteners. Furthermore, the complaint contains no allegation that plaintiff himself is a consumer of either cyclamate or non-cyclamate artificial sweeteners so that he is not even alleged to be a member of the class whose interests he seeks to represent. In addition, the interests of the consuming public itself are not uniform. Compare the case at bar (consumer interest in excluding cyclamates from market) with *Roßi v. Finch*, F. Supp. _____ (N.D. Calif. 1970) (consumer interest in retaining cyclamates on market). * * *

"The heart of this action, and the jurisdictional question before the

Court, involves the Delaney Amendment which '... is generally intended to prohibit the use of any additives which under any conditions induce cancer in any strain of test animal.' *Bell v. Goddard*, 366 F. 2d 177, 181 (7th Cir. 1966).

"Cyclamates were, prior to recent studies and reports, used in food from before January 1, 1958 and at that time were considered. '... through either scientific procedures or experience based on common use in food ...' to be '... safe under the conditions of [their] intended use ...' 21 U.S.C.A. § 321(s). Consequently, they were not 'food additives' as defined in § 321(a) and they were included in the Food and Drug Administration's list of ingredients in food which were generally recognized as safe [the "GRAS" list]. * * *

"Insofar as the Secretary's regulations regarding cyclamates were based upon his powers under § 348(d) in accordance with the Delaney Amendment, § 348(c)(3)(A), as plaintiff claims and defendant acknowledges, the route for review in a Court is via an objection to the Secretary under § 348(f)(1) with ultimate review in a Court of Appeals under § 348(g)(1).

"Plaintiff seeks to take this action entirely out of the orderly scheme of judicial review provided by the Federal Food and Drug Laws by contending that he only seeks to compel the Secretary to perform a mandatory duty. As a result, he contends, the mandamus statute, 28 U.S.C.A. § 1361, provides jurisdiction in this Court. He argues that he is not seeking review of any orders of the Secretary. In substance, however, plaintiff is really contesting and is aggrieved by the orders of the Secretary which allow cyclamates to be used in foods under the rubric of their being 'new drugs.' In reality, therefore, he seeks review of those orders without using the procedures of § 348(g).

"The language of § 353(b)(1)(B) and § 353(b)(3) indicates that the determination of whether or not to require a prescription for a new drug is within the discretion of the Secretary under the procedures established in 21 C.F.R. § 130.101(b). Whether or not use of a prescription is '... necessary for the protection of the public health' is not a reviewable question but rather it must be determined with the use of the expertise of the Secretary and those medical and scientific experts reporting to him. Whether a drug is toxic, or potentially harmful, or not safe for use except under a doctor's supervision is also in need of expert determination. Cases like *United States v. Article of Drug Labeled Decholin*, 264 F. Supp. 473 (E.D. Mich. 1967) (summary judgment denied on issue of toxicity, potentiality for harmful effect, and need for collateral measures to make safe for use), where questions such as the need for a requirement of a prescription were brought before a court for plenary examination because the drug in question apparently was not a 'new drug' subject to application and approval under 21 U.S.C.A. § 355 and exemption from prescription requirements under 21 U.S.C.A. § 353(b)(3), only serve to indicate the difficulty of such a determination by a court in the light of medical evidence. The issues involved in a requirement *vel* *non* of prescriptions for drugs are '... matters on which experts may disagree; they involve nice issues of judgment and choice ... which require the exercise of informed discretion ... [W]here the duty to act turns on matters of doubtful or highly debatable inference from large or loose statutory terms, the very construction of the statute is a distinct and profound exercise of discretion.' *Panama Canal Company v. Grace Sine*, 356 U.S. 309, 318 (1958).

"In such circumstances the Administrative Procedure Act, §§ 701 et seq., does not provide jurisdiction in a District Court to review agency action, at least where it is neither arbitrary nor capricious. See *Sugarman v. Forbragd*, 405 F. 2d 1189 (9th Cir. 1968)." (50)

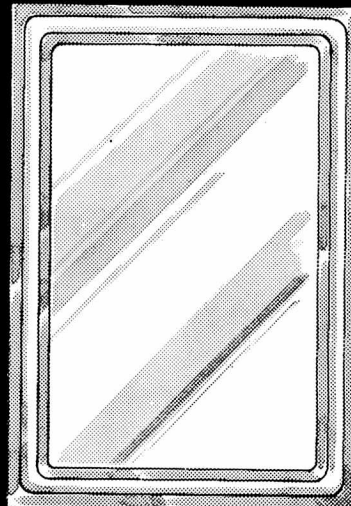
Notices of Judgment are given pursuant to section 705 of the Federal Food, Drug, and Cosmetics Act and section 13 of the Federal Hazardous Substances Act. Notices of Judgment report cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizure proceedings are civil actions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

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

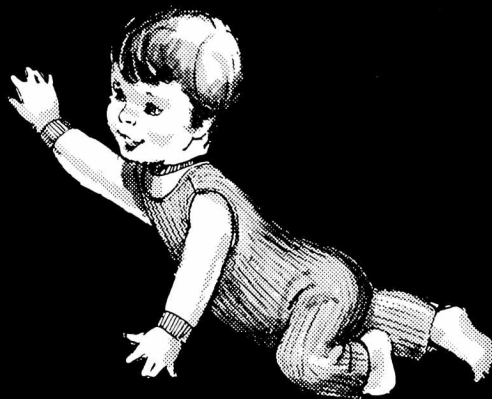
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Charles C. Edwards, M.D., *Commissioner of Food and Drugs*
Washington, D.C., December 1, 1971

search & destroy...



....for their sake



A STARTLING MESSAGE?

Not if you realize that dangers lurk in your home.
Children are curious. They see—they touch—they taste

- ... Pills on the bedside table
- ... Drain cleaner on the bathroom floor
- ... Furniture polish on the coffee table
- ... Paint thinner in a soft-drink bottle

Search out these dangers. Destroy the possibility of a poisoning happening.

- ... Lock up and separate medicines and cleaning products
- ... Keep household substances in original containers
- ... Always read the label



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