MICROWAVE OVENS: ARE THEY SAFE?

A New Program: Nutrient Labeling

TOWARD SAFER PRODUCTS

NEW ROLES FOR DRUG COMPENDIA

MEDICAL DEVICES
"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

Human nutrition is part of the magic biochemical process that places man in harmony with his environment, provides him with bone and sinew, and furnishes him energy and the wherewithal to live and perpetuate himself.

Our technological age has brought us to the point where nutrition has been placed to some extent in the hands of food processors who prepare our meals. Today, it is more important than ever that nutritional information about packaged food be given to the consumer.

FDA's nutritional labeling program (see page 4) seeks to do just that. It's a voluntary program for manufacturers which will bring nutritional information to the consumer on the labels of packaged foods. The success of the program depends on how well consumers take advantage of this vital information.
Section 705 [375] of the Food, Drug, and
Cosmetic Act.

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

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

by Harold C. Hopkins

FDA has proposed a major new program to provide consumers with nutrient labeling on foods. Success of the program hinges on industry cooperation and consumer understanding. Here's how the program came about, and how it works.

Elliot L. Richardson, Secretary of the Department of Health, Education, and Welfare (at head table), discusses FDA’s nutritional labeling program with consumer leaders in Washington, D.C. To his right is Barbara Burns, DHEW deputy assistant secretary for consumer services. To Richardson's left are Charles C. Edwards, M.D., Commissioner of Food and Drugs, and Merlin K. DuVal, M.D., assistant secretary for health and scientific affairs.
We can’t fool Mother Nature but that hasn’t stopped us from prying into her secrets. One of her most complex is nutrition. It is so vital to life and health that it has always been of the most intense concern, but only in recent times have we begun to comprehend the elaborate balance of calories, proteins, fats, carbohydrates, vitamins, and minerals required for an adequate and wholesome diet.

And only in the past few years have we begun to realize that the modern trend to processed and formulated foods can affect the amounts of these nutrients that were almost always present in adequate amounts in foods produced and prepared at home by the simpler, traditional methods of the past.

It is therefore more important than ever that the food processor today pass on essential nutritional information about modern packaged foods to the person it benefits most—the consumer. Acting in response to demands from consumers, nutritionists, and others concerned with public health, FDA has proposed a program to assure that this health-related information will be furnished to the consumer in a form understandable and useful in planning the family’s food budget and seeing to the proper nourishment of its members.

“The increasing number of processed and formulated foods makes it difficult for consumers to identify the nutritional qualities of the products they purchase.” These are FDA’s opening words in announcing its proposal to develop standardized labeling for packaged foods that will provide the consumer understandable information about the product’s nutritional contents. FDA’s announcement was in the March 30 Federal Register.

Participation by individual food companies in the nutritional labeling program will be strictly voluntary. But any manufacturer that decides to adopt the program must use a standardized format so that listings will be uniform, in terms that the consumer can learn quickly and use when making shopping decisions and value comparisons. The information will be easy to locate and identify on the package, and to read and understand.

The information would be carried on the label under the heading, “Nutritional Information,” and would be based on commonly accepted serving sizes or units, such as a cupful, tablespoonful, or slice. The weight of this serving may also be expressed in grams (28.3 grams make an ounce).

Information would include calories; fats, carbohydrates, and proteins; and the five vitamins and two minerals generally recognized by nutritionists and other health experts as likely to be inadequate in the diets of persons who through ignorance or poor dietary habits do not eat “balanced” diets.

Nutritionists feel these seven vitamins and minerals are “key” nutrients and that a person who eats foods containing all will be likely to obtain the necessary amounts of the many additional vitamins and minerals considered essential to health.

The total number of calories in each of these serving units would be listed to the nearest five calories under the FDA program. The amounts of protein, fats, and carbohydrates would be listed in grams. The seven vitamins and minerals considered as “key” nutrients would be listed for each serving unit in percentages of the Recommended Daily Allowances (RDA) for adults.

These vitamins and minerals, and the RDA’s established for adults by the Food and Nutrition Board of the National Academy of Sciences-National Research Council “Recommended Dietary Allowances” in 1968, are—

Vitamin A (5,000 International Units), vitamin C (60 milligrams), thiamin (1.5 mg), riboflavin (1.7 mg), niacin (20 mg), calcium (1,000 mg), and iron (18 mg). Protein, in addition to being listed by gram weight, would be listed in percentage of the RDA (65 grams).

Other vitamins and minerals, for which listing would be optional with the manufacturer, and the RDA’s for them are: vitamin D (400 International Units), vitamin E (30 International Units), vitamin B₆ (2 mg), folacin (0.4 mg), vitamin B₁₂ (6 mg), biotin (0.3 mg), pantothenic acid (10 mg), phosphorus (1,000 mg), iodine (0.15 mg), zinc (15 mg), magnesium (400 mg), and copper (2 mg). If any of these are listed, the percentage of the RDA would be stated.

Although participation in the nutritional labeling program will be voluntary for any food manufacturer, it may reasonably be expected that the makers of many basic food products will employ nutritional labeling in the form finally approved by FDA, and that competition and other factors will motivate others to follow suit.

FDA will require that nutrients in a food product truthfully reflect the amounts claimed on the label, and has the laboratory capability to measure the amounts present. But it should be noted that the Agency does not require specific amounts of nutrients in any food.

FDA does not anticipate any difficulties monitoring labeling claims since the Bureau of Foods’ Division of Nutrition, from its experience in regulating special dietary foods and standards of identity for food, knows which vitamins and minerals pose the biggest difficulties in food processing and thus knows when a claim seems excessive.

The voluntary labeling program does not affect the Agency’s existing mandatory labeling requirements for special dietary foods. Special dietary foods generally are those in which any of certain specifically named nutrients have been added or in which certain other substances have been purposely added, reduced, or removed. They include food supplements, such as vitamin or mineral preparations, or foods manufactured with special dietary properties, as for infants, for weight control or dietary management of diseases, for content of nonnutritive materials, for persons subject to allergies, and for control of salt intake.

FDA is developing an order based on the Agency’s 1968–70 hearings concerning foods for special dietary
Other FDA Nutritional Programs

The White House Conference on Food, Nutrition, and Health, in addition to generating FDA's nutritional labeling program, has also provided the impetus for other FDA actions and programs concerning nutrition.

The conference recommended that FDA develop standards for nutritional content of specific foods or classes of foods, either under the existing system of mandatory standards of identity and quality for certain foods, or by development of nutritional guidelines for voluntary adherence by industry. Although FDA is revising some existing food standards to increase nutritive values, the Agency has decided to emphasize setting nutritional guidelines for foods by classes.

The Agency's first proposed nutritional guideline, developed under contract with the NAS-NRC Committee on Food Standards and Fortification, covers precooked frozen "heat-and-serve" dinners, and was published in the Federal Register last December 23. The guideline proposes specified amounts of protein, vitamin A, thiamin, riboflavin, niacin, and iron for each 100 calories of the product. Vitamin and mineral content is based on number of calories because a person's caloric intake is fairly constant over a period of time and this will assure that he receives an adequate amount of nutrition with his regular calorie intake.

The NAS-NRC committee has recommended a second nutritional guideline for frozen, canned, and dry products defined as main dishes—such as frozen pot pies, canned beef stew, and dry macaroni-and-cheese mixes. Additional classes under consideration include meal replacements, breakfast cereals, baked cereal-based products, juice drinks, and products containing simulated meats prepared with protein from soy beans or other vegetable sources.

FDA also has proposed to change its standards of identity for enriched flour and enriched bread to increase the iron content. This action results from the ten-State CDC study pointing to iron deficiency anemia in a substantial part of the population. A petition had been submitted by the baking industry asking that the iron enrichment level be increased. Iron deficiency is believed to affect, at least to some extent, high and middle income population groups as well as low income groups. It is caused, at least in part, by the shift of much of the population to occupations and recreational activities requiring less physical effort and therefore a lower calorie intake. At the same time, less iron is occurring in food from extraneous sources such as iron cooking vessels, which are less frequently used in most homes than formerly.

The proposal would also increase the levels of calcium, thiamin, riboflavin, and niacin. Flour so enriched would enhance the nutritive value of nonstandardized products made from it.

The Agency is considering the possibility of improving the quality of protein in certain standardized cereal foods and prescribing safe conditions for use of added amino acids in cereal proteins. Animal proteins such as meat, fish, and milk are "complete" proteins containing all the essential amino acids, but vegetable proteins usually lack one or all of these. Indiscriminate addition of amino acids can produce foods harmful to health.

FDA has made two other moves of nutritional interest. Because many people develop goiter from lack of iodine in their diet, the Agency has ordered that all packages of table salt be labeled to say whether the salt has been iodized. If not, the label must state: "This salt does not supply iodide, a necessary ingredient." The other action has been to encourage manufacturers to submit, for FDA inspection, all informational materials on nutritive values that these companies offer consumers upon written request.

uses which will establish the Recommended Daily Allowances as the basis for labeling all special dietary foods.

Our knowledge of the importance of the proteins, carbohydrate, and fat components of food to adequate diet and health dates from the middle of the 19th Century, and the health significance of vitamins and minerals in food began to become apparent with studies begun early in the 20th. But only in the past few years have we learned through statistical studies of the deficiencies of these nutrients in our food, and how deficiencies in diet may be affecting the health of some of the public at large and selected segments of the population based on age, sex, and family income.

One of the first clear indications that the U.S. diet might be less than optimal was revealed in the 1965 Household Food Consumption Survey on food purchase and use conducted by the U.S. Department of Agriculture. Compared to a similar USDA study conducted in 1955, it showed that more than 30 percent of low income families had poor diets. Diets were "poor" in a smaller percentage of higher income families, but in families with incomes over $10,000 a year 9 percent had "poor" diets. There was an apparent increase in the
number of families consuming a “poor” diet as compared with 1955.

Although the USDA study covered only food use and not nutritional health, preliminary results of other studies in the Department of Health, Education, and Welfare reported clinical and biochemical signs of inadequate diets. A nationwide study by DHEW’s Children’s Bureau of about 5,000 preschool children from all socioeconomic groups reported iron deficiency anemia, height and weight values below normal standards, and biochemical indicatives of poor nutrition for vitamin C and riboflavin. The initial report found no obvious evidence of malnutrition, but said “there did seem to be a relation between poverty, diet, growth achievement, and biochemical evidence of suboptimal nutrition.”

A larger study involving 29,612 low income families in ten States and New York City, the National Nutrition Survey, was begun in 1968 and completed in 1970 by DHEW’s Center for Disease Control. It indicated anemia caused by iron deficiency, low serum vitamin A levels, and, in young children, reduced height and weight.

These statistical findings were underscored by statements of concern from nutritionists and welfare workers and by television documentaries and other publicized reports. They helped create a growing pressure that led to the December 1969 White House Conference on Food, Nutrition, and Health. This conference of food and health experts from many fields—governmental, educational, professional, industrial, and consumer interest—resulted in a number of recommendations concerning food. It was the recommendation of Panel III-2 on New Foods that engendered a positive response by FDA and resulted in the Agency’s nutritional labeling proposal.

The panel said: “Every manufacturer should be encouraged to provide truthful nutritional information to consumers about his products to enable them to follow recommended dietary regimens.” (Another recommendation from the conference was the genesis of FDA’s concurrent nutritional guidelines program to establish basic nutritional values for processed foods.)

FDA’s first problem in responding to the nutritional labeling mandate was to determine whether consumers would be interested in and use nutrition information on the labels of packaged foods, and whether a labeling system could be devised that would adequately inform the consumer about nutritional contents and educate him on nutrition and a good diet. FDA felt the labeling system should include information of practical use to the consumer on the most significant nutrients in a form that would be easy to understand in terms of daily food intake for all members of the family. Such labeling would have to be complete, yet simple.

Research by institutional, private, and industry groups indicated consumers were interested in nutritional labeling on food packages and that such labeling influenced purchasing practices and choices and educated the consumer as to nutritional needs. Further research was carried out independently, with FDA cooperation and under contract with the Agency, to determine the degree of consumer response to nutritional labeling and understanding and use of the information, as well as to determine the best system or format for providing information on the label.

The findings reinforced earlier studies as to consumer attitudes and education of the consumer via labeling. Three basic systems were studied—numerical percentages, adjective descriptions, and pictorial representations of nutrients. Consumers generally were able to make informed nutritional judgments using all three, but lower income groups without a high school education did better with the numerical percentage system. Accordingly, FDA incorporated this system in its nutritional labeling proposal.

The FDA-sponsored study also indicated consumers felt there should be several other benefits from nutritional labeling, such as increasing confidence in the food industry, providing manufacturers incentive to try to make foods more nutritious, encouraging advertising to promote consumer education, showing food manufacturers’ concern for consumer welfare, and giving consumers information they feel they have a right to know.

With publication of its proposal for nutrient labeling, FDA has been taking part in a series of briefings around the country to acquaint food processors and others with the background of concern among nutritionists, health professionals, and consumers, and to answer questions, resolve problems, encourage participation, and to tell what is expected of food companies to make the program work. FDA feels the time and effort spent in testing the labeling system at all consumer educational and economic levels will pay off in increased consumer awareness and education about the importance of adequate and proper nutrition.

Harold C. Hopkins is editorial director of FDA Papers.
The fastest growing FDA Bureau is its Bureau of Product Safety. In addition to enforcing the Hazardous Substances Act, the Child Protection and Toy Safety Act, the Poison Prevention Packaging Act, and portions of the Flammable Fabrics Act, it is concerned with items used in and around the home that are not covered by other statutes. Malcolm Jensen heads FDA’s Bureau of Product Safety. This is the first of two interviews with him about his Bureau’s activities. In the second part he will discuss with the editors of FDA PAPERS enforcement of laws pertaining to child safety, including toys and poison prevention. In this, the first half of the interview, Jensen discusses:

- Scope of the Bureau.
- How the Bureau gets data.
- Contacts with consumers.
- Industry compliance.
- Detergents.
- Consumer education.
Mr. Jensen, the Bureau of Product Safety regulates a greater variety of products than any other Bureau in FDA. Can you list some of the products you regulate and some of the laws your Bureau enforces?

We are concerned with two basic types of products. First are chemicals used in and around the home. These include everything from detergents to paints and paint thinners. Such products are covered by the Federal Hazardous Substances Act, which gives us the authority to see that they are properly labeled if there is a potential hazard in their use or in exposure to them.

The second type of product we are concerned with is "engineering-type" products. These fall under two statutes. The Child Protection and Toy Safety Act, an amendment to the Hazardous Substances Act, provides authority for us to assure that toys and other articles intended for use by children are designed and assembled to minimize potential hazard to children.

The second statute is the relatively new Poison Prevention Packaging Act. Under it, we are authorized to see that household substances which could be detrimental to a child's health are packaged in such a manner as to make them difficult for a child to open.

We have one other statute, the Flammable Fabrics Act, which is peculiar in that the responsibility for its administration is divided among four agencies of the Federal Government. Our job at FDA is to gather and analyze data on injury, death, and economic losses as the result of the flammability of fabrics and similar materials and to make the data available to the Commerce Department, which promulgates standards. Once the standard is set, the Federal Trade Commission enforces it for products made domestically. The Treasury Department does the same for imports.

With such a vast variety of products to worry about—virtually everything in and around the home—it must be difficult to determine which products are hazardous. How do you monitor the marketplace?

I would be less than perfectly frank if I didn't admit that our resources are so critically short that we are not actually monitoring the marketplace now. Instead, we set priorities within our Bureau on the basis of information that comes in from many sources. Among them are Poison Control Centers, complaints from consumers and legislators, and, of course, our National Electronic Injury Surveillance System (NEISS). Based on this information, we identify those areas where we can best utilize our resources to have the greatest impact on the health and safety of the American people.

Can you explain how NEISS works?

Yes, I'm delighted to, because it's an effort that is truly in the public interest. NEISS is the only system of its kind.

As I explained before, to set priorities properly we have to know where and how accidents are happening. NEISS is a data collection system for product-related injuries that occur in the United States that are serious enough to require medical treatment or that incapacitate persons for a day or more. Of course, this does not include auto accidents and other accidents which involve products regulated by other Federal agencies.

The NEISS system involves 119 hospitals throughout the country which have been selected because they are representative of the population. Under contract to us, these hospitals report on a 24-hour basis information on every product-related injury that comes to their emergency rooms. This information enables us to determine with reasonable accuracy what types of injuries are occurring among the American people and which products are implicated.

About how many injuries take place annually?

The most frequent estimate of injuries in the United States every year is 20 million. That figure doesn't mean very much unless we determine to what extent a product's design or assembly was at fault and to what extent its user was just careless. Through adroit application of the NEISS data, followed up by carefully selected and conducted in-depth investigations, we can determine the product's contribution and learn what we in the Federal Government can do to eliminate the hazard.

How is the NEISS system set up? Where does the information come from, and how does it get to you?

I'll start at the beginning. In or near each of the emergency rooms of these 119 hospitals, there is located a teletypewriter connected through the telephone system with our computer in Washington. Data from emergency admission forms are encoded by a specially-trained operator and are punched into the typewriter at any time during the day.

The typewriter holds the data until the wee hours
of the morning or late hours of the night. Then, FDA's computer here in Washington calls each of the hospitals and receives the data. The next day we have that data plus all of the totals built into the computer program.

Thus, we can identify immediately those products that are high on what we call the "severity-frequency index"—products that are involved most frequently in injuries and where the injuries are most severe.

Q. Does NEISS identify products by brand name?
A. No. Only by category. But when an in-depth investigation is ordered, we include not only the brand name, but also the model, serial number, and all other information we can get.

Q. NEISS seems to have unlimited potential for expansion. Do you have any such plans?
A. Our immediate plans are to seek to expand it to the extent that we will receive data on all product-related injuries, rather than only those that come to emergency rooms. In the far future, we hope to monitor patients admitted routinely into hospitals, patients in clinics, patients treated by physicians, and, ultimately, people who are treated or treat themselves at home. The more information we receive, the better we can determine what regulation needs to be accomplished.

Q. Now we know how you gather your information. Once a product has been deemed hazardous, what does your Bureau do?
A. Under the law we have three choices: seizure, injunction, and prosecution.

A seizure is a civil action against a specific lot of goods. Manufacturers have the options of forfeiting the goods, of contesting the seizure in court, or of petitioning the court for permission to modify the goods to comply with governmental regulations.

An injunction is also a civil action and is usually in the form of a court order to stop a certain specified prohibited action, such as the manufacture or sale of a toy deemed to be hazardous.

A prosecution is a criminal action and can be brought against an individual or firm for violating the law. Guilty persons may be fined or in extreme instances even imprisoned.

Q. What are FDA's limitations under the law?
A. First, no law authorizes us to take corrective action on thermal, electrical, or mechanical hazards that are part of products used in and around the home by adults. This includes, of course, all appliances. That's one great big void. I should say parenthetically, however, that we do seek to do a great deal to get the appliance industry to correct some ills voluntarily. But the law does not cover such products.

Another serious limitation relates to the point in the marketing system at which the Hazardous Substances Act and other laws come into application. As is typical with many such statutes, our Act goes into effect only after a product has entered interstate commerce.

This has led some consumer leaders to advocate premarketing clearance for potentially hazardous products. Our position is that premarketing clearance isn't needed and should not be authorized at this time, because there are other ways the situation can be handled, such as the voluntary safety standards now being formulated by the toy industry with the assistance and encouragement of our Bureau.

Let me also add that Congress has under consideration several bills that would authorize an agency of the Federal Government to establish mandatory standards for all consumer products. Most people are predicting that such legislation will eventually be enacted by the Congress.

Q. Under the present laws, are American consumers getting adequate protection from hazardous products?
A. I can say with confidence that with the resources in manpower and dollars available to our Bureau, the American consumer is making one of the best possible investments. This shouldn't be interpreted to suggest that every single product under our jurisdiction is safe. They're not.

People should be aware that inherent in practically every product is some kind of a hazard. For example, many people cut their tongues or lips licking envelopes. Even a baseball bat can be used improperly. All consumers should be aware that products should be used only as intended. Toys in particular should be selected with great care.

Let me add editorially here that one problem that seems to be increasing in intensity is that some individuals believe that if adequate statutes were enacted and if executive authority were properly pursued, every single product would be entirely safe and product injuries would decline to zero. Obviously, this isn't true.

To answer the question: Everything is not safe, everything is not free of hazard, but we believe
that we in the Bureau of Product Safety have had a great impact on the retail market.

Q. Under the budget submitted to Congress by the White House, the Bureau of Product Safety would receive a substantial increase for fiscal year 1973, which starts this July 1. It would be the largest percentage increase of any FDA Bureau and would allow you to expand beyond the present 140 employees. What do you intend to do with this money?

A. Let me say first that in my view the recommendation for a large budget increase is a recognition by the White House of both the needs of FDA and its capabilities to fulfill important consumer protection responsibilities.

With the additional funds, we will first of all develop an engineering laboratory, which will enable us to test more products and thus establish safety standards. There is no such laboratory in FDA at the current time.

We will also devote greater attention to the setting of standards. This is the magic word in the Bureau of Product Safety—"standards." A standard is a precise method of communication between buyer and seller, producer and user. Our job is to develop standards that relate to safety in product design and performance.

In addition, we will increase our field staff. Better surveillance and compliance programs will be developed.

Q. As a result of your limited resources, you often work "behind-the-scenes" with manufacturers to make sure that products are safe. How does this process work?

A. Let me answer your question by giving a recent example. Most homes have room vaporizers which are used for colds and a group of very small children. Vaporizers are plugged into house current and produce steam through the boiling of water.

Our data, plus consumer complaints, indicated that vaporizers were being placed on unstable tables, where they could fall. The result could be serious scalds. We were convinced such accidents were occurring and that there was a technical way for vaporizers to be redesigned to alleviate the problem.

We did a little engineering work and found that a vaporizer with a reservoir temperature less than 130°F could still produce the desired steam. We invited all manufacturers of these vaporizers to meet with us here in Washington, together with the not-for-profit standard-setting organization, Underwriters Laboratory.

We explained the problem and presented our data. The manufacturers agreed to change the design of their vaporizers so that vaporizers would have only a low reservoir temperature. As a matter of fact, early this spring all manufacturers of vaporizers moved over to the new design.

This example shows the utilization of minimum manpower to accomplish a maximum task. We believe that, to the extent possible, we should use voluntary cooperation because it extends our capabilities to do the job without building the Government empire that taxpayers are so worried about.

Q. Can you cite another example of how you are working with manufacturers in the best interests of consumers?

A. Well, as a result of telephone calls, letters, personal contacts with consumers, and meetings at which consumers are present, we identified some problems relating to home ranges or ovens.

Warning lights, uniformity in control buttons, and the relative hazards of quick-heating electric burner units are some of the stove features now being studied.

These studies are important because the domestic cooking stove continues to be one of the household products most frequently associated with burn injuries. Of approximately 1,200 fabric ignition accidents investigated by the Bureau, stoves were sources of ignition in more than 20 percent of the cases, second only to matches and smoking materials.

Although the data is still limited, I believe stoves are more hazardous to young children; they are unaware of potential danger because of the absence of visible flame.

Our surveys show that accidents often occur when children climb onto a stove top or when adults or children inadvertently turn on surface burners and ignite clothing. We have encountered at least one case where clothing ignition resulted from contact with the oven of an electric range.

So, we find that design features as well as operational characteristics contribute to serious injury. In the future, to reduce stove-related burn injuries manufacturers will have to give careful consideration to design features and to modify consumer products. A program of consumer education is also needed.

Q. You said this problem came to your attention through complaints by consumers. What contacts do you have with consumers?

A. We have regular, informal meetings with people who represent consumer organizations. At every opportunity, we attend
formal meetings with consumers.

As you are aware, the growth of consumer organizations in this country is astounding. I learned just recently that some 43 States have formal consumer organizations and that others are being formed. Many universities are also involved in consumer affairs, and, of course, there are national organizations such as the Consumer Federation of America and the National Consumer League.

We also have close contact with the publishers of consumer periodicals like Consumers Union and Consumers Research. Our effort is to refine and increase our lines of communication with consumers.

Q. Let's say that a housewife has a problem with a product. Is there any way she can get in touch with FDA to tell you about it?

A. Whenever a housewife encounters a safety problem, we would hope she will consider letting us know. We need this information. A consumer can look in the telephone directory and see if the Food and Drug Administration's District office is listed under "United States Government." The District offices are also listed in FDA PAPERS. Consumers can call or write these offices.

If there is no office nearby, we encourage letters to us here at headquarters. In every case we would like to have the product as clearly identified as possible and the accident described as well as it can be. We can assure anyone who writes that his inquiry will be answered. Our mailing address is:

U.S. Department of Health, Education, and Welfare
Food and Drug Administration
Bureau of Product Safety
5401 Westbard Avenue
Bethesda, Maryland 20016

Q. Mr. Jensen, you've been with FDA a little more than a year. Have you been generally pleased with the cooperation the industries have given you?

A. Well, I suspect we will never achieve perfection. I would have to say, however, that on the whole, once members of an industry are made aware of the statute or even of the opportunity to cooperate, the response has been excellent.

The problem is that safety is a new concern in this country. Product safety in particular. There are many manufacturers of consumer products who, even though they have broad engineering talent, have limited safety engineering talent. But once a firm learns what the law requires, the response is excellent.

Q. Are you generally pleased with the cooperation and concern shown by consumer advocates who operate in the Washington, D.C., area, and by consumers in general?

A. The principal problem is that we really don't hear from spokesmen for consumers as often as we would like. In addition, we frequently don't hear enough specifics to enable us to identify a problem area and address our resources to the solution. We hope that as time passes and as more consumers become aware of the existence of this Bureau and of our desire and ability to serve, that the contacts will be more frequent and more precise.

Q. Mr. Jensen, let's turn to a problem that housewives have to face—namely, household detergents. There's been some confusion on this, much of it generated by the Federal Government. What advice do you have for housewives who use detergents?

A. A discriminating housewife, particularly one with small children, has four concerns in the purchase of a household detergent. First is price. I don't mean the retail price of the product, but the price per wash. This has to be calculated in the home. The second concern is the effectiveness of the product. Does it provide the level of cleanliness that is desired or required? This is a matter of personal judgment.

The third concern is safety. If there is a cautionary label on the detergent box that says, "Harmful if swallowed" or "Irritating to the eyes," that product should be stored with great care, particularly when children are around. In many cases, it might be advisable for the mother of small children to consider products that don't require cautionary labeling.

The fourth consideration is the impact of the product on the environment. My personal view is that it would be presumptuous of a Federal official to attempt to exercise judgments for the individual housewife. We are attempting to provide her, however, with basic information on which to base her decision.

Q. Can you suggest other products whose hazards can be reduced by homemakers themselves?

A. Yes. The very serious hazards of fabrics that are flammable can be reduced by homemakers' careful selection of styles and fabrics
for garments purchased for members of the family.

It has long been recognized that the weight and weave of a fabric determines how easily it ignites and how fast it burns. For instance, fabrics with light, open weaves or fuzzy naps burn more readily than those with tight weaves and flat, smooth finishes.

Also, ease of exposure to an ignition source is influenced by a garment’s design. For example, a lightweight dress with a full skirt and ruffled sleeves is more likely to ignite and will burn faster than a man’s heavyweight, body-fitting work uniform. We have to remember, however, that while clothing design may reduce some accidents, it will not be as effective as the use of flame-retardant fabrics.

Garments for the elderly and the physically handicapped—both groups are statistically “high risks” in flammable fabrics accidents—should be easy to put on or off. Then they could be removed quickly in case of accident. They should be of flame-resistant fabric whenever possible. Wool, for example, is naturally flame-resistant. Cotton, on the other hand, is highly flammable. The synthetic blends vary. Shoppers should read labels carefully to get as much information possible about the possible flammability of the product.

Q. Can you list some rules for consumer safety pertaining to the hazards of flammable fabrics?

A. Yes. First, teach children that fire is dangerous. Matches are not toys and should never be played with. Second, everyone should select clothing carefully, remembering that tailored styles and tightly-woven fabrics without naps can mean a higher level of safety. Avoid frilly, loose-fitting garments and keep in mind that some fabrics are naturally more flame-resistant than others.

Third, don’t use open heaters without guards to avoid any possible ignition of clothing. And finally, be sure that everyone in your home uses fire cautiously and carefully.

Q. Your advice to housewives on the safe use of household products indicates that consumer education is an important part of your function. What are you doing to educate consumers?

A. The Bureau’s educational program is designed to assist consumers to buy wisely and use carefully all products—with a few exceptions—found in homes, recreational areas, and institutions.

The Bureau prepares and distributes pamphlets and brochures directly to the public, as well as press releases, television and radio presentations concerning potential hazards of consumer products.

Consumer Specialists located in each of the 17 FDA District offices provide consumers with information on foods, drugs, cosmetics, therapeutic devices, toys, and a variety of hazardous substances through the various media. They have direct contacts with community and business groups through workshops, seminars, film showings, and lectures. They distribute pamphlets and other publications. Product safety consultants are also located in regional FDA offices. They are technical field experts in product safety and work primarily with industry and State and local government officials. Product safety consultants coordinate surveillance, follow up injury investigations, and conduct in-depth interviews on injuries reported to our National Electronic Injury Surveillance System. They deal with educational institutions, lab testing facilities, and professional organizations interested in consumer safety.

Q. For the future, Mr. Jensen, are you encouraged about reducing the number of accidents related to home products?

A. Yes, indeed we are. Our Bureau staff believes that as home products are designed and manufactured for safety and as the community is informed of the need for careful use of all home products, that we hopefully will see a decline in the statistics that mean death and injury for too many of our people.

Malcolm W. Jensen is director, Bureau of Product Safety. Before joining FDA in 1971, he had been with the National Bureau of Standards since 1951.
Microwave ovens can save time—but are they safe? FDA’s Bureau of Radiological Health has tested ovens and has established performance guidelines for them. Here’s what FDA has done to assure the safety of microwave ovens, and what you ought to know before you buy or use them.
Microwave ovens—those “electronic ovens of the future” that can cook a hot dog in 25 seconds and a five-pound roast in 38 minutes—have recently been deemed by the Food and Drug Administration to be safe enough for use in the home.

Like other modern technological conveniences, however, microwave ovens possess some potential for injury in addition to being beneficial. Microwave ovens bring with them the potential hazard of radiation exposure. If not properly controlled, microwaves can produce effects ranging from a slight tingling of the skin to serious burns and eye cataracts.

SAFETY FIRST

FDA has prompted manufacturers of microwave ovens over the past two years to make numerous safety design changes. The result: Ovens which FDA believes are safe, but which must be used properly to avoid injury.

Microwaves are an invisible form of energy which are reflected by metal surfaces, but are absorbed by and raise the temperature of many other materials. In microwave ovens, the waves are produced by a wave generator and are distributed throughout the cavity of the oven by a fan. There is no radiological contamination of the food. It is simply cooked more rapidly than by conventional methods.

FDA, of course, does not take a position on the advisability of purchasing a microwave oven for home use. That decision is up to the individual housewife, who must decide whether a microwave oven suits her requirements and pocketbook. The primary advantage of a microwave oven is that it saves the housewife time.

Microwave ovens will come into greater use as prices decrease. They have been available for a decade now, but were too high priced for the average homeowner. In the past year the price has come down to $400 or less.

FDA’s authority over the safety of microwave ovens derives from the Radiation Control Act enacted by Congress in 1968 to reduce the hazards of radiation exposure. Regulations promulgated by the Food and Drug Administration’s Bureau of Radiological Health establish guidelines for manufacturers in several areas of oven performance. Under the regulations, manufacturers must submit for Government testing a sample of each model intended for sale. The primary concern of the Government testing program is the radiation safety of the oven.

To be deemed safe under current standards, microwave ovens must have at least two safety switches for assuring that the oven will not operate while the door is open. Operation when the door is even partially open can lead to radiation exposure and potential injury.

FDA also requires that the failure of one mechanical or electrical component must not lead to the failure of all the safety switches. Ovens produced before October 6, 1971, may not meet these standards. Consumers using these older models should make sure the oven is turned off before opening the door.

Ovens manufactured after that
date must contain a certification label which states the month, year, and place of manufacture, as well as that it conforms to all Government standards.

**DESIGN FEATURES**

In 1970, a Government-industry survey concluded that approximately 10,000 of the 200,000 microwave ovens then in use possessed a "strong potential" for microwave leakage exceeding the maximum permissible levels established by law. The tests included ovens in private homes and commercial establishments. The three design features judged by the Government as most important for microwave oven safety were door seals, safety switches, and a viewing screen cover.

**Door seals:** Door seals are intended to provide a tight fit between the oven door and the cavity in which the food is cooked.

Though not required by law, the "choke type" door seal is considered superior. The seal consists of rubber or similar material within a groove to prevent radiation leakage. This type of seal lasts longer and allows for more efficient cleaning.

Another door seal is the "capacitive pressure" or "metal-to-metal" type. This is a thin metal plate that acts as an electrical contact strip and as an insulator. When the door is closed, the plate is forced against the oven surface to prevent radiation leakage. When the door is open, the plate is slightly raised along one of its edges.

If the capacitive pressure door seal is used on a door that hinges along the bottom, food spilled while being removed from the oven can accumulate under and around the plate. Food build-up around the plate can lead to radiation leakage if the plate does not lie flat.

The third type door seal consists of an exposed metallic or rubberized gasket. The effectiveness of such a seal depends on good contact between the gasket and the oven surface. Food build-up can lead to less efficient contact and possible radiation leakage.

**Viewing screen:** All models now being manufactured must have doors which prevent insertion of small objects. This was not always the case. The doors of many older models contain a perforated screen for viewing the food being cooked. Ovens that include a solid glass or plastic cover over the viewing screen are judged safer than those without such protection.

The perforations themselves do not result in radiation leakage. However a long, thin object can be inserted through the door and into the cavity of those without a cover. A curious child inserting an object such as a coathanger could transmit radiation to the outside, thereby causing possible injury to himself and others. Persons contemplating the purchase of an older model should consider only ovens with a cover over the viewing window.

**Safety switches:** Safety switches are designed to insure that the oven is turned off before the door is opened. All ovens presently being manufactured must contain at least two safety switches, one of which must be concealed. The reason for concealment is two-fold. The first is to prevent damage to the switch. The
second is to prevent adjustment by the user.

Many of the switches tested by the Government in 1970 were neither efficient nor reliable for their intended purpose. Several ovens had as many as three switches, but none had all the features deemed by the experts as necessary for greatest effectiveness.

For example, some switches were not activated soon enough to prevent radiation leakage when the door was opened rapidly. A suggestion by Government inspectors was that the main switch be activated not by the movement of the door, but by the preliminary movement of the handle itself. This advice has been followed by the makers of many presently available models.

In addition, several ovens possessed multiple safety switches, yet the failure of one part of the oven caused failure of the entire safety switch system. Ovens manufactured after October 6, 1971, are not susceptible to such failures.

The present FDA standards concerning radiation leakage should provide assurance to consumers that today’s microwave ovens are safe. Nevertheless, consumers should carefully inspect design features before purchasing an oven.

To insure long-term, safe operation, the Food and Drug Administration suggests that the oven contain at least the following features:

- A door seal that is easy to keep clean.
- Two independent safety switches.
- A door through which no small objects can be inserted.

Even more important is the need for proper care after purchase. Here are some general hints for proper care of microwave ovens:

- Follow the owner's manual.
- Clean the interior, door, and door seals regularly.
- Have the oven serviced regularly by an authorized serviceman.
- Never use metal cooking containers. Use only paper, earthenware, or glass cookware.
- Never operate an empty oven.
- Never attempt to adjust the safety switches.

This monkey has been outfitted with a microwave applicator helmet. The monkey is trained to perform certain manual tasks, then is subjected to microwave radiation. Further measurements are made during and after exposure to determine the effects of microwaves on the brain.

This machine measures the amount of radiation absorbed by an animal, such as a mouse who is placed within the small metal apparatus at center.

- When using ovens manufactured before October 1971, stay at least an arm's length away from the door.

A free brochure titled “Facts About Microwave Ovens” is available from the Bureau of Radiological Health, Office of Information, 1901 Chapman Avenue, Rockville, Maryland 20852.

Peter G. Thomas is a free-lance writer.
Ever notice the letters U.S.P. on your aspirin bottle? Or the letters N.F. on that bottle of calcium lactate tablets in your pharmacy?

Or U.S.P. on the bottle of milk of magnesia in your medicine cabinet?

Those letters—U.S.P. and N.F.—indicate that the manufacturer or distributor of these drugs represent them as meeting the standards of strength, purity, and quality described in the “official” compendia.

The compendia are books which specify the chemical identity and purity of selected, therapeutically-important drugs, and tests for assuring that the finished product is of the highest quality. They also specify some packaging and storage requirements for these drugs.

The compendia are published by two private, professional organizations—the U.S.P. by the United States Pharmacopeial Convention (USPC) and the N.F. by the American Pharmaceutical Association (APhA). The two volumes are important pillars of consumer protection for many prescription and over-the-counter drugs available in your pharmacy.

The drug standards set by U.S.P. and N.F. are legally enforced by the Food and Drug Administration. This unique arrangement makes the United States the only country in the world in which the setting of drug standards enforced by the Government remains in the hands of private organizations. This allows the Federal Government to take advantage of medical and pharmaceutical expertise throughout the Nation.

In recent years the compendia have worked closely with FDA—which is responsible for monitoring the quality of the American drug supply—on problems beyond the traditional setting of standards for specific drugs. This story is about some of the recent problem areas on which FDA and the two compendia have cooperated.
What Are U.S.P. and N.F.?


UNITED STATES PHARMACOPEIA

The first national pharmacopeia was published in 1820, resulting from a United States Pharmacopeial Convention (USPC) called by a group of physicians representing various State medical societies. The objectives of the convention are summarized in the preface to the first Pharmacopeia:

"The National Formulary, an official compendium... does reflect or mirror the advancing front of our technology... But in what is perhaps a more obscure role, it nudges and prods, focusing the attention and resources of industry and regulatory agencies on important problems." John V. Bergen, Ph.D., director, National Formulary, before the Technicon International Congress on Automation, Tokyo, August 20, 1971.

NATIONAL FORMULARY

The National Formulary (N.F.), the second volume making up the "official" compendia, is published by the American Pharmaceutical Association. Its publication resulted from the need to standardize a large number of drugs that had not been selected for inclusion in the U.S.P., but nevertheless were being prescribed extensively by physicians or used by patients. The first N.F., issued in 1888, contained extensively used dosage forms not described in the U.S.P., as well as standardized names and formulas. Since drugs were compounded then largely by the individual pharmacist, standardized formulations for preparing drug products were needed.

Beginning with the sixth edition in 1936, the National Formulary reflected the modern trend toward large-scale pharmaceutical manufacturing. Although drugs were formerly admitted to the N.F. according to their extent of use, in 1961 the N.F. Board approved the present policy that drugs are admitted only on the basis of their recognized therapeutic value.

Now both the U.S.P. and N.F. use therapeutic merit as the basis for selecting drugs for inclusion in the compendia. Drugs selected for one compendium, however, are not also listed in the other.

Today, the U.S.P., conforming to the best state of knowledge of the day, performs four traditional functions:

- selects drugs
- establishes names
- sets standards and dosage forms
- encourages physicians and pharmacists to use them

The consortium that produced the first U.S.P. in 1820 was entirely medical. Pharmacists joined in the work of revising the pharmacopeia shortly thereafter, and now the Convention includes representatives from every college of medicine, and college of pharmacy, and all State and national associations of professionals. In addition, seven agencies of the Federal Government are represented, including the Food and Drug Administration and the Office of the Secretary of Health, Education, and Welfare.
DRUG TESTING

One example of this cooperation occurred in 1970, after FDA discovered that some ipecac syrup on the market contained ephedrine. Ipecac is a drug that induces vomiting and can be used as a first aid measure for certain poisons.

The amount of ephedrine in the syrup was not harmful in itself, but it posed a hazard because it prevented the ipecac from having its intended effect. This meant, for example, that a mother whose child had swallowed something poisonous might have given the child ipecac syrup to cause vomiting, but the ephedrine content may have caused the ipecac to be ineffective. Those lots of ipecac syrup identified as containing ephedrine were recalled by the manufacturer.

FDA communicated this problem to U.S.P., and the two organizations concluded that the test procedures set forth in the U.S.P. for ipecac syrup could not detect the presence of ephedrine, because U.S.P. tests cannot detect all forms of adulteration. U.S.P. took immediate action to modify the test procedure and replace it with a more comprehensive one.

Now, because of this cooperative effort, housewives can be more confident that the ipecac they purchase labeled Ipecac Syrup U.S.P. will work when it is needed.

Another way in which FDA works with the compendia to improve drug testing involves the National Center for Drug Analysis, FDA's laboratory in St. Louis, which conducts a continuing surveillance program over the Nation's drug supply. The center was founded in 1967. Because of the huge volume of drug samples that needed to be tested—the goal at the time was 30,000 a year—the center developed automated testing procedures and instrumental methods of analysis.

Previously, however, most drug testing was done by hand, which took considerable time. The manual process was described in the U.S.P. or N.F. But neither compendium recognized automated testing methods as official tests.

After FDA showed that automated testing was providing the same results as the hand method, U.S.P. and N.F. changed the compendia to allow for alternate methods, as long as the results could be shown to be of equal accuracy. (If any discrepancy exists, of course, only the official manual method can be utilized.) Thus, FDA as well as manufacturers now are able to do more testing by automated methods to provide the consumer with better drug surveillance.

NITROGLYCERIN TABLETS

A recent case where immediate collaborative action between U.S.P. and FDA was required involved nitroglycerin tablets, used by patients who suffer from acute angina attacks. The problem that precipitated this action emerged from a report of an advertising promotional premium being distributed to independent pharmacies in the Midwest.

The campaign involved a pen-shaped plastic container distributed by pharmacies as a dispenser for nitroglycerin tablets. The dispenser bore the name of
the pharmacy and said: “Nitroglycerin tablets. One under tongue for chest pains.”

A pharmacist who received one of these plastic containers questioned its adequacy. He notified U.S.P., which in turn notified FDA. The Agency ran tests by placing fully potent nitroglycerin tablets in the plastic case. The tests indicated a 50 percent loss of potency when the tablets were held in the dispenser for one day and up to 80 percent loss after three days. This rendered the tablets not only virtually worthless, but a potential health hazard to patients who need potent nitroglycerin. All the plastic containers were recalled, with the cooperation of pharmacists and the State boards of pharmacy.

U.S.P. and FDA conferred on this matter, and later announced proposed changes in the packaging and labeling requirements of nitroglycerin. Because of the volatility of nitroglycerin preparations, FDA proposed for the first time that the container in which the manufacturer placed the drug was to be limited to 100 dosage units, and that the drug was to remain in the original container until used by the consumer. Additionally the label must contain a conspicuous warning to help the consumer use the drug so as to prevent loss of potency.

**EYE PREPARATIONS**

Another proposal by FDA—to require the sterility of all eye (ophthalmic) preparations including ointments—is an interesting example of collateral action by FDA and the compendia.

As early as 1964, investigations by pharmaceutical manufacturers, physicians, and FDA revealed that some liquid eye preparations contaminated with pathogenic micro-organisms were responsible for serious eye injuries and, in some cases, loss of vision. FDA and the compendia at the time required sterility of ophthalmic liquids. A similar requirement for eye ointments was considered desirable—but technical problems of manufacturing and testing made it unfeasible at that time.

Early in 1971, however, an acceptable test procedure became available which made it practical for the N.F. to propose such a requirement for N.F. eye ointments. As a result of an article-by-article evaluation, sterility requirements of two of the four ophthalmic ointments for which N.F. sets standards were proposed to be included in the next N.F. supplement. U.S.P. is also proposing sterility requirements for ophthalmic ointments and has proposed definitive methods for the testing.

FDA independently completed a survey of manufacturers of eye ointments in the fall of 1971. It was found that sterile ointments could be produced, and that reliable test procedures were available.

With the technical problems solved, FDA proposed sterility requirements for all eye preparations, including ointments.

**SURVEILLANCE**

Recently, in another program, FDA joined with U.S.P. and the American Society of Hospital Pharmacists in a surveillance program under which hospital pharmacists report drug defects and other problems to U.S.P. and FDA. The reports stem usually from observations made by hospital pharmacists during the course of their work. This Drug Product Defect Reporting Program, in its first nine months of use, resulted in more than 1,200
reports and in several recalls of defective drugs and devices. This program is being expanded on a pilot basis to include nurses and community pharmacists.

As an example of the sort of things found, one pharmacist noted that a batch of tablets varied in thickness. This led to an investigation which showed that the firm had a problem in making a satisfactory granulation for the batch. A recall of this batch resulted from an observation by a single alert pharmacist—and the American public was protected from a potential hazard.

INTRAVENTOUS FLUIDS

A major joint program, recently implemented by U.S.P. and FDA, calls for an evaluation of problems associated with large volume intravenous injections. These injections are used to replace body fluids, to administer drugs, or to feed people who can’t eat by mouth. About 100 million injections are given each year via bottles or plastic bags that hang at patients’ bedsides.

Last year, a large number of intravenous solutions were recalled after being found to have a potential for contamination during hospital use. The recall focused attention on the problem of microbiological contamination of intravenous injection fluids.

FDA asked U.S.P. to investigate and evaluate current manufacturing and hospital procedures to improve the quality of patient care in the administration of intravenous solutions. Under a contract signed in April 1972, U.S.P. will convene a coordinating committee with representatives from professional organizations that would be affected by any decisions. Among the organizations are the American Hospital Association, the American Society of Hospital Pharmacists, the American Nurses Association, the American Medical Association, and the Department of Health, Education, and Welfare’s Center for Disease Control.

The committee members will serve, as they always do for U.S.P., on a voluntary basis. FDA will fund the costs of convening and administering the panels and for some outside research in this critical area. The panels will concentrate on new or improved methods of production, packaging, and administration of intravenous injections. Another area of concern will be how to improve the compendial and FDA standards for the injection fluids. The aim of the joint program is to improve the quality of the solutions and the equipment and practices used in their administration. This is an area in which U.S.P.’s expertise can mesh with FDA’s in a major consumer protection effort.

THE CONTINUING COOPERATIVE PROGRAM

Many of the activities performed by U.S.P., N.F., and FDA are so closely interrelated that there has been an increasing need for the two compendia to work with FDA in the interests of consumer protection.

The two compendia, as described in the examples cited above, no longer see their roles as exclusively setting drug standards. The compendia have an expertise that has been and can further be used by FDA to help in its vital role of consumer protection.
FDA'S MEDICAL DEVICE PROGRAM

by
David M. Link and Larry R. Pilot

What FDA is doing to improve its current surveillance of medical devices, and to prepare for the day when new legislation affords consumers additional protection in this area.

In July 1966 the Food and Drug Administration filed suit in Federal court to prevent the sale and distribution of an electrical machine called the "Relaxacizor." The producer of the machine claimed it could improve the figure and reduce girth. This wonder machine, of course, did not come cheap. Its cost ranged from $200 to $400.

FDA charged in court that the machine was unsafe to use without medical supervision and that it was dangerous to health when used according to the instructions in the labeling. To the FDA, the Relaxacizor was a classic case of a misbranded device—one with false or misleading claims in the labeling or which could pose a danger to the health of the consumer when used as directed.

The courts agreed with FDA's position—four years later. In an opinion rendered in April 1970, the United States District Court in Los Angeles ruled that the Relaxacizor could be used only under a doctor's prescription. The court said the labeling must inform the physician that the Relaxacizor could be hazardous and should not be used on the chest, during pregnancy, and when certain physical disorders exist, including several for which consumers may have used the machine.

Despite this ruling in support of FDA's position, it had taken several years and $500,000 for the Federal Government to accomplish this degree of consumer protection. During the decade the manufacturer had promoted the Relaxacizor to the public, some 400,000 had been sold. The American public had been exposed to a potential health risk, and may have been bilked out of millions of dollars.

In addition to becoming a classic case of misbranding, the Relaxacizor case became a classic demonstration of the difficulty facing FDA when it attempts to prosecute cases under the present device law.

The Federal Food, Drug, and Cosmetic Act provides that FDA can take action against medical devices only after the products have been marketed. The present law also places the burden upon the Government to demonstrate clearly that a device is misbranded or adulterated, rather than requiring the manufacturer to prove safety and efficacy before marketing or to meet a product standard.

Present provisions do not assure the consumer that a medical device is safe and effective. Under current law, for example, it is possible for an individual to fabricate an unsafe and ineffective medical instrument or other complex device and sell it to an unsuspecting physician, or to promote an unsafe and worthless device to the public. FDA can take action only after the device is sold, and an irresponsible manufacturer can tie up the case for many years in the courts.

Fortunately, most devices today are not ineffective medical instruments or quack machines. Most important devices are made by reliable companies that carefully develop and test their products. And most physicians are competent enough to recognize a fraudulent device. But still, they must rely on the manufacturers' statements and claims of safety and effectiveness,
and the average consumer has even less knowledge and information on which to make a judgment. This situation will become even more critical in the future. More complex, sophisticated, and technologically challenging instruments are being developed each day. Even now, only specialized technicians can use some of these devices properly. Physicians and consumers have no way of knowing the hazards and potential dangers of some of the devices they use. In addition, there is evidence of tremendous growth in the device area. The use of artificial implants in the body and of electronic diagnostic and therapeutic devices has increased dramatically in the past few years. Additional growth is on the horizon. It is estimated that the total retail sales of medical devices in 1971 was more than $3 billion. This could double over the next ten years.

President Nixon recognized the need for additional legal controls over medical devices in his consumer message to the Congress on October 30, 1969. The President said:

"Certain minimum standards should be established for [medical] devices; the government should be given additional authority to require premarket clearance in certain cases. The scope and nature of any legislation in this area must be carefully considered. . . ."

During the same period, the United States Supreme Court also made clear its concern for the regulation of medical devices. In 1969, the court refused to review a lower court decision which held that a nylon suture applied by a mechanical locking device and used to tie off blood vessels during surgery could be regulated as a drug, which requires approval by the Government before it can be sold.

In a second case, the Supreme Court in 1969 overruled a lower court and held that antibiotic sensitivity discs—products used to determine which antibiotic should be prescribed to combat a particular patient’s illness—also should be regarded as drugs, rather than devices, and approved by the Government before marketing.

The President’s message and the two court cases focused attention on the possible need for legislation to increase Government controls over devices. Legislation to accomplish this already has been introduced on Capitol Hill. The legislation is designed to afford the American public greater protection now and in the future from poorly made, untested, and unscrupulously promoted devices that may pose a health hazard greater than the conditions they are said to aid.

The Food and Drug Administration and its parent Department of Health, Education, and Welfare played a major role in the development of the legislation now being considered by Congress. FDA also has taken steps to increase its current capabilities to regulate medical devices under existing law, and to prepare for the day when new controls are passed by the Congress.

The first step in the development of legislation occurred late in 1969 when the Secretary of HEW appointed a committee to recommend procedures to assure the consumer a larger measure of protection from unsafe and ineffective devices. This committee was headed by Dr. Theodore Cooper, director of the National Heart and Lung Institute, and became known as the “Cooper Committee.”

It met extensively with a wide variety of people, including consumers, physicians, engineers, manufacturers, trade and standard setting associations, and device experts. The Committee's conclusions, released in September 1970, confirmed the concern expressed earlier by the President. The Committee found that "comprehensive data to qualify the magnitude of medical device hazards could not be identified."

It added:

"Almost everyone acknowledged that problems do in fact exist and that a predictable increase in the complexity and sophistication of medical devices requires action now to prevent the emergence of even more serious and complex problems in the foreseeable future."

The Committee recommended that an inventory of all present devices be taken to determine the extent of the present market. Once the inventory was completed, the Committee further suggested, devices should be divided into three classes:

1. Those that should be exempt from standard-setting.
2. Those for which standards should be set for performance and safety.
3. Those requiring approval by the Government before marketing. (continued)
In its concluding remarks, the Cooper Committee expressed concern about the need to assure that research on medical devices is not damaged by any regulatory system. The Committee pointed out that its recommendations embodied "a plan for regulation of medical devices that would, in the view of the study group, help achieve the dual objective of consumer protection and continued progress in the development of effective medical devices. Regulation, however, while clearly needed, is only one element of the increased public-private effort that will be required to achieve this objective."

The Committee added: "The study group, along with others who have intensively examined the medical device field, believes that research and manpower training are essential both for progress in device technology and for adequate protection against the hazards that can be associated with the improper use of medical devices. We urge the Secretary to seek every appropriate opportunity to support research and manpower development so that the regulation of medical devices will be balanced by efforts to assure continued progress in this important health field."
After reviewing the Cooper Committee Report, HEW Secretary Richardson asked FDA to develop an inventory of all marketed devices and then carry out the classification procedure. His thinking was that no matter what type of regulatory system is established by Congress, the Government will still need a list of all devices, and should know which devices need the most attention.

FDA began this mission in late 1970. It met with organizations representing the medical device industry and medical groups. Working together with these groups, FDA developed a questionnaire for distribution to manufacturers throughout the United States. The questionnaire asked each firm for the names of all the devices it makes, plus information on each device such as use, proximity to the body when used, the material from which made, and where normally used.

The questionnaire was mailed in March 1971 to 4,000 addressees. About 2,000 responses were received. The data has been compiled and the inventory compilation now consists of about 12,000 devices, of which 8,200 are distinct entities. These devices, produced by more than 1,100 manufacturers,

These illustrations indicate the variety of devices regulated by FDA. A: Heart pacemaker; B: Neck brace; C: Total artificial hip joint; D: Electronic heart monitor; E: Electrosurgical device; F: Electronic thermometer; G: Blood pressure meter; H: Automatic intravenous device; I: Artificial heart valve; J: Splints.
represent about 90 percent of all the devices now being marketed in the United States.

Having completed the inventory, FDA then turned to the more difficult chore of classifying devices into the three categories suggested by the Cooper Committee. The Agency established two pilot panels, one in orthopedics and the other in the cardiovascular area, consisting of experts from outside the Agency. The panels included physicians who use devices in these specialties, scientists and engineers, industry representatives, and a knowledgeable consumer. The panels met separately in November and December 1971 to develop a system for classifying devices and to classify a limited number of devices into regulatory categories.

FDA's efforts to develop a proper method to classify devices is still continuing. By this June, the Agency hopes to start a classification procedure which will be helpful in identifying the areas of concern which require further action.

While it was undertaking the inventory, FDA continued its surveillance of the medical device market, dealing with products including sterile disposable devices such as surgeon's gloves, jelly-filled teething rings, cardiac pacemakers, hypodermic needles, oxygen units, surgical sponges, prophylactics, and air purifiers.

An important step designed to strengthen the capabilities of the FDA involved the transfer in September 1971 of all device activities from the Bureau of Drugs to the Office of the Associate Commissioner for Medical Affairs. This transfer resulted in an enlarged staff as well as increased visibility for FDA's regulation of this area.

While FDA's efforts have been underway, the Administration introduced into Congress a bill intended to assure the safety and effectiveness of medical devices. The bill was designed to encompass the major recommendations of the Cooper Committee by providing a system where devices used or intended to be used in life-threatening situations and which may present an unreasonable hazard would be subject to premarketing scientific review.

The system intended for devices would place heavy emphasis on the use of outside expert panels. They would review data submitted by the manufacturer and provide FDA an opinion on whether the product should be approved for marketing. In addition, the legislation would require that other devices for which premarket clearance is deemed unnecessary be made subject to standards. The development of these standards also would place heavy reliance on nongovernment experts.

The Administration bill joined other legislative proposals for extending the Government's authority over medical devices.

All the bills are designed to provide the consumer with additional safeguards in the medical device area. Meanwhile, FDA is increasing its surveillance and related activities to afford the consumer the best protection possible under the current law.
More than 34,000 radiation-producing electronic products were modified by manufacturers last year as a result of FDA efforts to reduce radiation exposure from electronic equipment. Twenty-two electronic product manufacturers took corrective actions.

The figures are based on a summary of 1971 FDA Bureau of Radiological Health compliance actions taken to remedy a situation in which an electronic product either:
- did not meet the requirements of a standard issued under the Federal Radiation Control for Health and Safety Act, or
- was found to have a radiation emission defect related to its safe use, or
- did not meet the manufacturer’s own design specifications for radiation control.

Corrective actions involved about 15,000 television sets, 35 TV projection devices, 100 television monitors, 11,000 microwave ovens, 8,000 medical diagnostic x-ray machines, and 200 x-ray diffraction and spectrographic units.

Manufacturers responded to requests for remedial action by replacing or adjusting equipment components, redesigning products or components, or ceasing production. In all cases where a radiation problem was identified, purchasers of the faulty product were notified.

Some of the most significant compliance actions involved medical and industrial x-ray equipment. In one instance, an x-ray machine of the type used in hospital wards was found to give off x-rays after the equipment was turned off. Correction kits were installed in machines in use.

In another case, two employees received skin burns on their hands when the safety interlock system—a mechanism for automatically turning off radiation when the cabinet door is open—failed on two occasions to shut off the x-ray tube of an industrial x-ray machine cabinet. Interlock systems were corrected by the manufacturer in about 200 machines of the same model.

In another instance, a consumer type of microwave oven was found to be potentially operable with the door open so that users might be exposed to dangerous radiation levels. No injuries to users were reported, however. Defective door safety interlock switches were identified as the problem. The manufacturer is replacing all interlocks on that model oven—whether faulty or not—with newly designed interlock switches.

In addition, four television receiver manufacturers also were involved in compliance actions last year. In the case of two companies, x-ray emissions were higher than those designated by set designs, but were still below limits set by the Federal TV set standard. Tube replacements achieved the desired receiver x-radiation control. The Federal limit was exceeded—although not significantly—in a model line of each of two other manufacturers. Corrections required tube replacements in one case and picture tube shielding in the other.

Mobile X-raying Equipment Shouldn’t Be Used, FDA Says

The use of mobile equipment for x-raying members of the general population for tuberculosis and other chest diseases should stop, according to a new policy statement prepared by FDA, the American College of Chest Physicians, and the American College of Radiology.

The kind of equipment found in highway vans in many parts of the country is not productive as a screening procedure for chest disease detection, the statement said.

The statement supersedes a 1958 policy declaration by the Surgeon General of the Public Health Service that emphasized that mass chest x-rays should be conducted “selectively” with groups “at high risk of tuberculosis infection.”

Records of the number of mobile x-ray units still being used are not available. Twenty-eight States had
registered one or more x-ray vans for use in 1970, but several of these have since discontinued use of the equipment. The 1970 information will be updated after July 1 this year, FDA's Bureau of Radiological Health said.

Child-Resistant Packaging Proposed for Methyl Alcohol

A proposal to require special "child-resistant" packaging for products containing 4 percent or more methyl alcohol (methanol) in liquid form has been announced by FDA.

Household products included in the proposal are windshield washer antifreeze, automobile gasoline antifreeze, certain paint thinners, paint and varnish removers, brush cleaners, and shellac solvents.

Methanol toxicity is documented in medical literature as being responsible for hundreds of deaths and numerous cases of permanent blindness. FDA's National Clearinghouse for Poison Control Centers reports 44 ingestions of methanol by children under five years of age from 1968 through 1970. Of these, three were hospitalized.

Genetic Dosage from Medical X-rays Dropped from 1964 to 1970

Preliminary results of a nationwide survey reveal a significant drop between 1964-1970 in the genetic dosage received by the U.S. population from medical x-rays. The findings come from an FDA study in cooperation with the National Center for Health Statistics.

The study showed a reduction of about 35 percent in the annual Genetically Significant Dose (GSD)—an index of the effect that x-rays may have on future generations. The reduction estimate is based on a comparison of preliminary data from the 1970 survey with data from a similar 1964 study.

The decrease came despite a 10 percent increase in the rate of x-ray examinations received by Americans during the six-year interval. A total of 76 million persons is estimated to have received medical x-ray examinations during 1970, compared to 67 million during 1964.

Data from the study indicated that x-ray beam restriction was achieved in two-thirds of examinations, compared to less than half in 1964. Failure to restrict the beam to the part of the body being examined is considered one of the chief causes of unnecessary x-ray exposure.

Report Urges Improved Standards To Lower Deaths from Burning Clothes

FDA has announced publication of the third annual report on "Studies of Deaths, Injuries and Economic Losses Resulting from Accidental Burning of Products, Fabrics, or Related Materials."

The report recommends additional and improved standards to reduce the flammability of clothing, which, in turn, will reduce deaths and injuries resulting from burning clothing. The Department of Commerce is responsible for establishing standards under the Flammable Fabrics Act.

The report is based on in-depth studies of 1,245 burn injuries and deaths. In addition, 4,600 burn accidents reported by the National Burn Information Exchange are analyzed. Three high-risk groups are identified as needing additional protection. These are children (generally under 10 and wearing street clothes), the elderly (over 65, female, and generally wearing nightclothes), and the physically handicapped.

The report estimates 3,000 to 5,000 deaths and 150,000 to 250,000 injuries occur each year from burns associated with flammable fabrics, and that the directly related financial loss exceeds 250 million dollars.

Copies of the 150-page report, which is required annually under the Flammable Fabrics Act, may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, at a cost of $1.75 per copy.
Field Reports

Atlanta  Timberlake Grocery Co. of Thomasville, Georgia, Inc., and Robert H. Guy, an official of the firm, were fined a total of $750 in open court at Columbus after pleading guilty to criminal charges of holding rice and lima beans in a building accessible to rodents, whereby the food may have been contaminated with rodent filth. At arraignment, the defendants attempted to enter a plea of nolo contendere. The judge refused to accept the plea when he found through questioning the defendants' attorney that the firm had been prosecuted in 1958 by the Federal Government after pleading guilty to the same type of charges.

Baltimore At the request of the Red Cross, several Baltimore District inspectors recently examined two lots of food left behind when the S. S. Hope sailed from the port of Baltimore after repairs and donated to the Red Cross by the storage facility at the dock. The food was to be used in the disaster areas of West Virginia following the floods of February 25 and 26. FDA's examination revealed the products, 7,700 pounds of non-fat dry milk and 2,940 pounds of corn syrup, were unfit due to gross insect infestation and damaged containers. The Red Cross declined the offer and the foods were destroyed.

An initial FDA inspection of a new manufacturing firm in Easton, Maryland, revealed a serious rodent infestation and contamination of potato flour, cornmeal, potato starch, and sodium caseinate stored in the firm's warehouse. With the cooperation of Maryland State and Talbot County Health Department officials, who embargoed the entire warehouse, the District effected seizure of most of the lots of these ingredients involved, preventing their use in the manufacture of food products.

Boston Muro Pharmaceutical Labs, Quincy, Massachusetts, voluntarily withdrew the entire lot of its product, White's Ophthalmic Ointment #2, from the market after Boston District officials informed the firm that part of the lot had been seized at the University of Iowa Hospital and Clinics, Iowa City, because of excessive contamination with metal particles.

Approximately 3,600 pounds of flour and cornmeal was seized at B. Rothstein & Co., Inc., Dorchester, Massachusetts, because of rodent contamination. The Government charged the adulteration took place after the firm received the products in interstate commerce.

Buffalo Pennwalt Pharmaceutical Division, Strasenburgh, at Rochester, New York, recently voluntarily destroyed 9,258 50-cc. ampules of the drug 3% Nemacaine-CE by burying. The lot represented not only the product recalled from the firm's California distribution warehouse but also what was on hand at its warehouse in Rochester. The catalogue value was $32,406. FDA had found through a routine check that the drug was subpotent and/or contained more of a break-down product than permitted by the National Formulary monograph. Federal seizure had been approved for the lots held at Rochester, but the firm elected to destroy all in lieu of seizure.

Cincinnati FDA's recent inspection of a food warehouse in Columbus, Ohio, disclosed widespread signs of rodents and cockroaches. Inspectors from the Ohio Department of Agriculture and from the City of Columbus Health Department were asked to assist. The State inspector obtained voluntary destruction by the firm of a lot of rodent-defiled flour, and the city inspector obtained lists of shipments and warned the firm that should any of the products be found adulterated in the shipments, they could not be distributed within the city. FDA is keeping the firm under surveillance.

Dallas FDA, industry, an import association, and the Mexican Government are working together to protect the consumer from exposure to pesticide residues in fresh strawberries imported from Mexico.

FDA detained two entries of the berries at Hidalgo, Texas, because they were adulterated with endrin, an agricultural pesticide. The berries, valued at $8,132, were labeled as from "Grower #44." Later, Ike Griffin, Jr., president of the Hidalgo importing firm, Griffin Holder Co., visited the District office to discuss the detentions. Mr. Griffin said that he and the recently
formed U.S. Strawberry Importers Association have been in contact with the director for international relations of the Mexican Department of Agriculture, Ramos Cantoral, about the endrin problem. Mr. Cantoral reportedly informed the association that the Mexican Government would “send soldiers to plow the fields of Grower #44” if provided with documents showing that the grower in question was shipping adulterated strawberries. Reportedly, his government wants to set an example for other growers.

At Mr. Griffin’s request, Dallas District will send Mr. Cantoral a report of analysis concerning the two samples in question. This is the same form provided to U.S. growers and dealers. Mr. Griffin said that although his firm has refused to accept berries from Grower #44, there is a possibility that he is entering his production into the U.S. through another grower.

DETOUR Atlas Pharmaceutical Laboratories, Inc., Detroit, has entered into a Consent Decree of Permanent Injunction concerning the manufacture of injectable drugs under conditions which did not conform to FDA’s Current Good Manufacturing Practice Regulations. The firm is discontinuing manufacture of injectables as a result.

KANSAS CITY Kansas State Fire Marshal Robert W. Wolfe recently confiscated 581 gross of Class B Special fireworks, valued at approximately $4,000, at an Oswego, Kansas, wholesale fireworks firm. The lot included Cherry Salutes and Bulldog Salutes. The owner was charged with improper storage of explosives, failure to maintain proper records, and with two counts of sales of illegal explosives. The last was the result of purchases by FDA inspectors in June and July 1971.

Accompanying the fire marshal were Kansas City FDA Inspector Herb Smith, and several deputy State fire marshals and assistant attorney generals from Kansas.

LOS ANGELES The District’s consumer specialist, Elaine Roentgen, recently addressed 300 parents and teachers attending an all-day nutrition seminar in San Bernardino, using “The Now Nutrition” as her topic. She also developed and wrote the “Flammable Fabrics Instructor’s Handbook,” being used as a teaching vehicle in adult education classes at 10 colleges comprising the San Diego Community College system. It is also being used, in conjunction with slides, by trained firemen from the Barstow Fire Department’s Fire Prevention Bureau to teach fire prevention at the eighth grade level in the Barstow city schools. The handbook, with slides, is also being used in two Barstow adult education classes that have an enrollment of 104 persons. See’s Candy Co., Los Angeles, initiated voluntary correction, at an estimated cost of $52,000, as a result of a recent FDA inspection disclosing wooden splinters in candy the firm was manufacturing. The subsequent correction involved the destruction by burial of 15 tons of candy, 730 moulding-starch trays, and 5,880 pounds of moulding starch.

NEW ORLEANS FDA has completed prosecution in two cases in Louisiana, both charging illegal sale of Class B fireworks.

Michael J. Cali, Sr., New Orleans, was given a 90-day suspended sentence on each of four counts, fined a total of $2,000, and placed on three years’ probation after pleading guilty to four of six counts in the indictment handed down by a Federal Grand Jury at New Orleans. The background of the case covered a total of 19 sales during four fireworks seasons, a State confiscation of fireworks, three FDA inspections followed by warning letters or citations, and a final sale of fireworks after the last hearing. The presiding judge noted it would be difficult for the court to be lenient in passing sentence, since the illegal sale of such fireworks has the potential to cause untold damage to persons unknown to the seller. He then related an FDA case tried before him involving a child maimed and partially blinded from an explosion caused by fireworks sold illegally.

In a court at Baton Rouge, Charlie Murry, trading as C & M Sales, Denham Springs, Louisiana, pleaded guilty to four counts of illegally selling Class B fireworks and was sentenced to a year’s probation on each count, to run concurrently, with the provision that he not violate any local, State, or Federal law during that time.

NEW YORK The F. W. Woolworth Co., New York, is working in close cooperation with the New York District to remove from sale and destroy a variety of toys that the FDA Bureau of Product Safety has declared to be banned hazardous substances. The firm is currently recalling from all its retail stores banned toys which include Roly Poly with Musical Chimes, Toy Plastic Hammer, Musical Fashion Dolls (four styles), Toy Wooden Duck, Plastic Eichhorn Picture Blocks, and assorted plastic bugles and accordions. These items were analyzed by the FDA Bureau and found to have small objects or parts with the potential to cause laceration and/or puncture-wound injuries, be aspirated or ingested, and/or cause asphyxiation.

As a result of FDA’s efforts to find and remove hazardous toys from the market and the resulting recalls the firm has made, Woolworth plans to examine all
new toys for possible hazards prior to purchasing them.

SAN FRANCISCO R. J. Whitman Sales Co., San Francisco, and R. J. Whitman, Sr. and R. J. Whitman, Jr., officers of the firm, pleaded guilty in U.S. Magistrate Court to a three-count information that alleged food products were stored under insanitary conditions whereby they could and did become contaminated with filth. The magistrate assessed a fine of $750, with suspension of $600, and placed the firm and the individuals on probation for 18 months.

SEATTLE The consumer can take comfort that recent cooperative efforts of Federal, State, and local officials will curtail certain potential hazards relating to controls on electric blankets and electrical heat thermostats.

FDA's Region X alerted top health agencies in all States in the Region by letter after receiving fire reports from local fire departments and the Washington State Fire Marshal's office concerning the electrical hazards of such products. One fire department reported that during an 11-month period, seven fires resulted when the contact points fused in the controls on various brands of electric blankets. It also reported that over the past three years, nine fires were caused by the "shorting-out" of electrical heat thermostat controls, all manufactured by one firm.

FDA asked the State health agencies to notify the regional office of any similar incidents in their respective States. The regional officials also informed the Washington State Fire Marshal's office that as a result of its interest and reports, the Agency's Bureau of Product Safety has issued letters to manufacturers of the suspect electric blankets, to the manufacturer of the electric heat thermostats involved in the nine fires reported, and to Underwriters' Laboratories in regard to the fire hazards associated with these products.
Reducing Aid  The sale of a kit and its components advertised as an aid to reducing has been stopped in Florida. Embry L. Coalson, supervisor of Registration and Drug Programs in the Florida Division of Health, says that the product, called Soak and Wrap Reducing Kits, cannot be distributed legally in the State until it is properly registered with his office. This registration cannot take place until the FDA approves the kit as a new drug.

Mr. Coalson said that his office learned of the kit being manufactured in Florida from State officials in Pennsylvania. He requested that FDA personnel accompany him on investigational inspections of Rohala Products, Inc., and Analog Research and Development Corp., at Jacksonville, the two firms that were engaged in the assembly, promotion, and distribution of the kits. Mr. Coalson informed the firms of the State's requirements regarding their product and said distribution would be stopped until requirements were met.

The firms sought to legally restrain the Florida Division of Health from further action, but the court denied the request on grounds the firms had made no attempt to comply with the State's regulations regarding their product, and therefore, had not exhausted all administrative remedies.

Announces Inspection  The Ohio Department of Agriculture has announced that fresh fruits and vegetables purchased and delivered to mental hygiene and conventional institutions in the State will be inspected by department inspectors. The announcement said department inspectors will be present each time a delivery is made, and will reject any products which fail to comply with State specifications.

Consumer Service  The Office of Consumer Affairs of the Virginia Department of Agriculture and Commerce announces that it has opened an office in Falls Church to provide increased service to northern Virginia consumers in the Washington metropolitan area. Responsibility for receiving consumer complaints and forwarding them to the appropriate regulatory officials for investigation rests with Mary Ann Shurtz, coordinator, who also disseminates consumer education materials.

Mrs. Shurtz' office is at 7309 Arlington Boulevard, Suite 300, Falls Church 22042. The telephone number is 573-1286.

Follow-up Warning  After FDA had publicly warned consumers against Relaxacizor devices, the Pennsylvania Department of Health issued a news release to 375 newspapers and other news media within the State, warning against the use or further sale of the device because it has been deemed dangerous to health and life. Along with the warning was the photograph at the right showing some of the machines that had already been turned over to the department for safe disposal, with FDA's public warning placard in the background. The Relaxacizor, an electrical muscle-stimulator machine claimed to be effective in improving the figure and reducing girth, has been found by the court to have serious potential for damage to the heart and other vital body organs, may aggravate many medical conditions in susceptible persons, and be capable of causing a miscarriage.

Based on national distribution of the Relaxacizor, the department estimates that as many as 20,000 units may be currently in the hands of individuals in the State. Although a permanent injunction prohibits their further sale to the general public, some owners are attempting to sell them through classified advertisements. Such sales violate State and Federal laws, and are punishable by fine.

Department Reports  Insanitary conditions in retail grocery and other food establishments or processing plants made up the largest share of the violations involved in 202 actions brought by the State of New York Department of Agriculture and Markets in January. The department reports it collected more than $11,400 in penalties in 135 cases settled involving various violations of the State's laws pertaining to wholesomeness of food and related products. An additional 67 cases were referred to the attorney general when settlement could not be reached.
seizures & postal service cases

SEIZURE ACTIONS  charging violation of the Federal Food, Drug, and Cosmetic Act and the Federal Hazardous Substances Act

A total of 29 actions to remove from the consumer market products charged to be violative was reported in March. These included 21 seizures of foods: 1 involved charges concerning poisonous and deleterious substances, 14 involved charges concerning contamination, and 6 involved charges concerning economic and labeling violations. Other seizures included 1 of dietary food, 4 of drugs (including 3 of veterinary and medicated feed), 1 of prophylactics, 1 of cosmetics, and 1 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED

<table>
<thead>
<tr>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FOOD / Poisonous and Deleterious Substances</strong></td>
<td></td>
</tr>
<tr>
<td>Barvin Packing Co./Houston, Tex. (P,S)</td>
<td>Contains aldrin, a pesticide chemical not in conformity with regulations; prepared, packed, and held under insanitary conditions; false and misleading labeling.</td>
</tr>
<tr>
<td><strong>Contamination, Spoilage, Insanitary Handling</strong></td>
<td></td>
</tr>
<tr>
<td>Imported from Spain.</td>
<td></td>
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<tr>
<td>“shipped from Chicago, Ill.”</td>
<td></td>
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<tr>
<td>American Bakeries, Freund &amp; Taystee Div./St. Louis, Mo. (D)</td>
<td></td>
</tr>
<tr>
<td>Joe Kim’s Kim Chee/Honolulu, Hawaii (M)</td>
<td></td>
</tr>
<tr>
<td>Kentucky Warehouse Co., Inc./New Orleans, La. (D)</td>
<td></td>
</tr>
<tr>
<td>Magnolia Grocery Co./Carthage, Tex. (D)</td>
<td></td>
</tr>
<tr>
<td>F. G. Wool Packing Co./San Jose, Calif. (P)</td>
<td></td>
</tr>
<tr>
<td>“Prepared and packed under insanitary conditions; insect contaminated.”</td>
<td></td>
</tr>
<tr>
<td>Great Lakes Mushroom Corp./Warren, Mich. (P,S)</td>
<td></td>
</tr>
<tr>
<td>H. M. Thames Pecan Co., Inc./Mobile, Ala. (P,S)</td>
<td></td>
</tr>
<tr>
<td>Arrow Food Products, Inc./Carrollton, Tex. (D)</td>
<td></td>
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<tr>
<td>“Prepared and packed under insanitary conditions; machinery mold.”</td>
<td></td>
</tr>
<tr>
<td>Wholly or in part decomposed.</td>
<td></td>
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<tr>
<td>Held under insanitary conditions.</td>
<td></td>
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<tr>
<td>Moldy and insect infested.</td>
<td></td>
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<tr>
<td>Held under insanitary conditions; rodent contaminated.</td>
<td></td>
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<tr>
<td>E. coli.</td>
<td></td>
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<tr>
<td>Held under insanitary conditions; rodent contaminated.</td>
<td></td>
</tr>
<tr>
<td><strong>Economic and Labeling Violations</strong></td>
<td></td>
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<tr>
<td>Imported from Switzerland.</td>
<td></td>
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<tr>
<td>Allen Wholesale Co./Kenton, Ohio (D)</td>
<td></td>
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<tr>
<td>Madonna Italian Foods, Inc./Las Vegas, Nev. (D)</td>
<td></td>
</tr>
<tr>
<td>Guy’s Foods, Inc./Wichita, Kans. (M,S,D)</td>
<td></td>
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<tr>
<td>Buttons Bay Packing Co./Detroit, Mich. (M,S)</td>
<td></td>
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<tr>
<td>Nature Food Centres/Cambridge, Mass. (D)</td>
<td></td>
</tr>
<tr>
<td>“Net Wt. 16 Oz.” is inaccurate.</td>
<td></td>
</tr>
<tr>
<td>Inaccurate quantity of contents statement. Below standard quality for canned cherries.</td>
<td></td>
</tr>
<tr>
<td><strong>Vitamins–Dietary Food</strong></td>
<td></td>
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<tr>
<td>Nature Food Centres/Cambridge, Mass. (D)</td>
<td></td>
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<tr>
<td>False and misleading labeling as dietary supplements containing Natural Citrus Bioflavonoid Complex (Acerola-C) and Lemon Bioflavonoid Complex, Hesperidin Complex and Rutin (Geri-Twins and Organic Diet. Suppl.).</td>
<td></td>
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<tr>
<td><strong>DRUGS / Human Use</strong></td>
<td></td>
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<tr>
<td>Ponodyne capsules/Kalamazoo, Mich. 3/20/72</td>
<td></td>
</tr>
<tr>
<td>Inadequate directions for use.</td>
<td></td>
</tr>
</tbody>
</table>

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Veterinary / Medicated Feed

Animal feed premixes/Gainesville, Ga. 9/29/71

Naremco, Inc./Springfield, Mo. (M,S)

New animal drugs without effective approved New Animal Drug Application; false and misleading claims that one of the drugs, "Coli-Trol 80," is effective for reducing bacterial enteritis and diarrhea caused by E. coli. New animal drug without effective approved New Animal Drug Application. — contains diethylstilbestrol.

Liquid animal feed/Waverly, Mo. 3/22/72

National Molasses Co./Piper, Kans. (M,S)

Kay Dee Feed Co./Sioux City, Iowa (M,S)

Prophylactics

Prophylactics/Kansas City, Mo. 2/10/72

M & M Rubber Co./Kansas City, Mo. (D) (tested and packed)

Defective quality.

Hair brushes/Bladensburg, Md. 3/7/72

B & S Industries, Inc./New York, N.Y. (S)

Made in France

HAZARDOUS SUBSTANCE

Concern liquid laundry product/Norwich, N.Y. 3/9/72

H. T. Developments, Inc./Buffalo, N.Y. (M)

Lacks consumer protection information required by the Fed. Hazardous Substances Act; toxic and irritant.

U.S. POSTAL SERVICE

False Representation Orders issued by Judicial Officer Under 39 U.S.C. 3005

January 18, 1972: False Representation Order issued against Brewster Products at P.O. Box 908, Madison Square Station, New York, New York 10010, and 20 Branford Place, Newark, New Jersey 07102. Advertising and sale by mail of "Formula 11" method promising dramatic weight losses.

February 29, 1972: False Representation Order issued against Isabella of Paris, P.O. Box 239, Gary, Indiana 46401. Advertising and sale by mail of a product called "Love Pills," represented to be effective as a sex stimulant.

March 3, 1972: False Representation Order issued against Development Research, 210 Fifth Avenue, New York, New York 10010. Solicitations of orders and sales through the mails of “Formula LDX-33,” designated to nourish the sex organs and restore lost sexual interest, potency, or fertility.


March 7, 1972: False Representation Order issued against Grapefruit Diet Division, 2421 Colee Station, Fort Lauderdale, Florida 33303. Advertising and sale by mail of Grapefruit “Super C Diet” plan, represented as enabling users to lose ten pounds in only ten days without starvation dieting or exercising.


March 13, 1972: False Representation Order issued against Gwen, P.O. Box 239, Gary, Indiana 46401. Advertising and sale of products called “Frenchie’s Make Them Hot Pills” and “Frenchie’s Whisky Pills,” represented to be effective as sex stimulants.

March 14, 1972: False Representation Order issued against Brother Obadiah, 152 West 42nd Street, New York, New York 10036. Advertising and sale by mail of a product called “Magic Lure,” represented to be effective as a sex stimulant.

March 24, 1972: False Representation Order issued against Mid-West Novelties, 6921 South Vernon Avenue, Chicago, Illinois 60637. Advertising and sale of product called “Frenchie’s Spanish Fly Chewing Gum,” represented to be effective as a sex stimulant.

Complaints Filed by Law Department Under 39 U.S.C. 3005 (False Representation)

February 22, 1972: Natural Products, P.O. Box 10047, at Newark, New Jersey 07102, and 266 Middle Street, Portsmouth, New Hampshire 03801. Solicitations of orders and sales through the mails of “Seacreme,” represented as enabling users to wipe away ugly fat instantly from any area of their bodies without dieting, pills, or exercising.

February 23, 1972: Vibra Sales, Inc., 509 Fifth Avenue and 30 W. 47th Street, New York, New York 10017. Advertising and sale by mail of “The Original Waist-Away Belt” to remove and eliminate fat deposits from the mid-section of the wearer.

February 25, 1972: Andrews Associate, P.O. Box 13281, Atlanta, Georgia 30324. Advertising and sale by mail of a formula represented as enabling users to grow chest hair.

February 28, 1972: Thornton, 402 S. 2nd Street, Alhambra, California 91802. Advertising and sale by mail of a product called “Hypnotic Pills,” represented to be effective as a sex stimulant.

February 28, 1972: Thornton Lab., 324 South First Street, Alhambra, California 91802. Advertising and sale by mail of a product called “Mad Dog Weed,” represented as an effective sex stimulant.

March 13, 1972: Yevette, 152 W. 42nd Street, New York, New York 10036. Advertising and sale by mail of products called “Frenchie’s Make Them Hot Pills” and “Knock-Out Drops,” represented to be effective as sex stimulants.

March 21, 1972: Betta Health, 4459 NW 37th Avenue, Miami, Florida 33142. Advertising and sale by mail of a product called “Saxa-71,” represented as enabling males to rejuvenate their sexual desire and potency.

NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

Chubs, frozen, at Chicago, N. Dist. Ill.
Charged 12-17-71: when held by the dealer for reconditioning, the article contained the added poisonous and deleterious substance aflatoxin; 402(a)(1). Default decree ordered destruction. (1)

Chili peppers, at Seattle, W. Dist. Wash.
Charged 12-10-69: while held for sale, the article contained the nonconforming pesticide chemical DDT; 402(a)(2). Default decree ordered destruction. (2)

Corn, at Denton, E. Dist. Tex.
Charged 11-19-71: when shipped by Stelo Grain Co., Morley, Mo., the article contained the added poisonous and deleterious substance aflatoxin; 402(a)(1). Default decree ordered destruction. (2)

Feathermeal, at Jackson, S. Dist. Miss.
Charged 3-17-71: when returned to Griffin Industries, Jackson, Miss., from Memphis, Tenn., the article contained the added poisonous and deleterious substance Salmonella micro-organisms; 402(a)(1). Consent decree authorized release to shipper for reconditioning. (3)

Swordfish chunks, frozen, at Wilmington, C. Dist. Calif.
Charged 3-3-71: when shipped from Japan, the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (4)

Swordfish fillets, at Somerville, Dist. Mass.
Charged 3-17-71: when shipped from Japan, the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Consent decree authorized export to original foreign supplier. (5)

Swordfish steaks, Three Diamonds, at New York, S. Dist. N.Y.
Charged 11-19-71: when shipped by Semo Grain Co., Morley, Mo., the article contained the added poisonous and deleterious substance aflatoxin; 402(a)(1). Default decree ordered destruction. (6)

Charg ed 11-16-71, 9-13-71, 9-14-71: when shipped by Bon Vivant Soups, Inc., Newark, N.J., the articles were unfit for food in that some cans of such foods had been found to be defective and abnormal, and in that the manufacturing procedures used did not assure proper sealing of the cans to prevent contamination and spoilage; and the articles had been prepared, packed, and held under insanitary conditions whereby they may have become contaminated with filth or whereby they may have been rendered injurious to health; 402(a)(2), 402(a)(4). Consent decree in Denver action ordered destruction; default decree in San Francisco action ordered destruction; and a destructio n, by the dealer was voluntarily conducted under State supervision in the Ann Arbor action. (15)

Soups of various kinds and turtle meat, canned, Bon Vivant, and Ancora, 3 seizure actions at Houston, S. Dist. Tex., Pittsburgh, W. Dist. Pa., St. Paul, Minn.
Charged 11-17-69, 9-13-71, 9-14-71: when shipped by Bon Vivant Soups, Inc., Newark, N.J., the articles were unfit for food in that some cans of such foods had been found to be defective and abnormal, and in that the manufacturing procedures used did not assure proper sealing of the cans to prevent contamination and spoilage; and the articles had been prepared, packed, and held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health; 402(a)(2), 402(a)(4). Default decree ordered destruction. (16)

FOOD / Economic and Labeling Violations

Beans, kidney, Diana, at Miami, S. Dist. Fla.
Charged 12-11-70: while held by N. Polanco, Inc., Miami, Fla., who re-packed the article from bulk, the article’s bag label (“Net Wt. 14 Oz.”) and bale label (“12 Lb. Pkgs.”) were false and misleading as to quantity of contents, and the article was short weight, since the bags weighed an average of approximately 13.6 oz.; 403(a), 403(e)(2). Consent decree authorized release to the repacker for reconditioning. (17)

Cactus pear, brined, at San Antonio, W. Dist. Tex.
Charged 8-6-71: when shipped by Refrigo Renteria, Mexico, the article, labeled in part “Nopalis Al Natural Dona Maria ... Made in Mexico by Productos Marpe, S.A. ... San Luis Potosi, S.L.P. Mex.,” had its quantity of contents statement not placed in the bottom 30 percent of the principal display panel in lines generally parallel to the package base; the quantity of contents declaration was not separated from other printed label information and did not include the term “Net Wt.”; the quantity of contents statement was not within the bottom 30 percent of the principal display panel; the quantity of contents declaration was not within the bottom 30 percent of the principal display panel; and the articles had been prepared, packed, and held under conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health; 402(a)(3), 402(a)(4). Default decree ordered destruction. (18)

Charg ed 11-16-71, 9-13-71, 9-14-71: when shipped by Bon Vivant Soups, Inc., Newark, N.J., the articles were unfit for food in that some cans of such foods had been found to be defective and abnormal, and in that the manufacturing procedures used did not assure proper sealing of the cans to prevent contam ination and spoilage; and the articles had been prepared, packed, and held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health; 402(a)(2), 402(a)(4). Default decree ordered destruction; default decree in San Francisco action ordered destruction; and a destructio n, by the dealer was voluntarily conducted under State supervision in the Ann Arbor action. (15)

Honey, Scott’s, at Knoxville, E. Dist. Tenn.
Charged 3-1-71: when shipped by E. S. Landrum, Homerville, Ga., the article contained the nonconforming pesticide chemicals DDT, DDE, and DDD; 402(a)(2)(C). Default decree ordered destruction. (1)

Peaches, filberts, and brazil nuts, unshe lled, and sunflower seeds, at New York, S. Dist. N.Y.
Charged 7-8-71: when shipped by Mitsubishi Shoji Kaisha, Ltd., Tokyo, Japan, the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (7)

Charg ed 11-16-71, 9-13-71, 9-14-71: when shipped by Bon Vivant Soups, Inc., Newark, N.J., the articles were unfit for food in that some cans of such foods had been found to be defective and abnormal, and in that the manufacturing procedures used did not assure proper sealing of the cans to prevent contamination and spoilage; and the articles had been prepared, packed, and held under conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health; 402(a)(2), 402(a)(4). Default decree ordered destruction. (16)

Jenes, frozen, Hi-Pie, at Denver, Dist. Colo.
Charged 12-3-70: when shipped by Chef Pierre, Inc., Traverse City, Mich., the quantity of contents declaration was not separated from other printed label information appearing above it; the quantity of contents statement lacked the term “Net Wt.” and “Net Wt.”; the required separate statement of quantity content was qualified by “or more” appearing in conjunction with the statement; 15 U.S.C. 1543(a)(2), 1543(a)(3)A(), 1543(a)(3)C(), 1543(b). Consent decree authorized release to Turner Broth ers Co., Inc., Knoxville, Tenn., for relabeling. (19)
than 25 square inches, was in type size less than 3/16 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Consent decree authorized release to shippers for relabelling. (20)

Popcorn, at Knoxville, E. Dist. Tenn.
Charged 10-8-70: when shipped by National Oats Co., Delaware, Ohio, the articles labeled "KGA. E. Fancy Select Popcorn... Distributed by Independent Grocers Alliance Distributing Company, Chicago, Illinois," was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not within the bottom 30 percent of the principal display panel; the quantity of contents was expressed as "Net Weight 1 Pound," and "Net Weight 2 Pounds," instead of "Net Weight 10 Ohs. (1 Lb.)" and "Net Weight 20 Ozs. (2 Lbs.)." The quantity of contents statement, appearing on the article with the principal display panel of more than 25 square inches, was in type size less than 3/16 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(3)(C)(i)); and the article's statement "KGA Popcorn complies with all provisions of the Food, Drug, and Cosmetic Act of 1938" was misleading, since the article was misbranded under Chapter III of that Act, due to the above Fair Packaging and Labeling Act charges—403(a). Default decree ordered destruction. (21)

Rice, at Ponce, Dist. P.R.
Charged 3-29-71: when shipped by Liberty Rice Mill, Inc., Kaplan, La., the quantity of contents on the 3-lb. and 10-lb. bags was not placed within the bottom 30 percent of the principal display panel; the quantity of contents was expressed as "Net Weight 1 than 25 square inches, was in type size less than 3/16 inch high; and the quantity of contents on the 3-lb. bags was expressed as "3 lbs. Peso Neto (48 Oz.)" instead of "Peso Neto 48 Oz. (3 Lbs.)." 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(3)(C)(i). Consent decree authorized release to shipper for relabelling. (22)

Charged 3-29-71: when shipped by Arista Olive Co., Inc., New York, N.Y., the article, labeled in part "Krinos Feta Cheese Greece New York" contained the nonconforming food additive calcium iodide, since the labeling lacked adequate directions for its intended purposes; 501(a)(2)(C). Default decree ordered destruction. (23)

Beverages, carbonated, and fountain syrup for carbonated beverages, at Seattle, W. Dist. Wash.
Charged 10-2-70: when shipped by National Biscuit Co., Atlanta, Ga., the article, labeled "Pepsi-Cola Original" contained the nonconforming food additive aspartame, a taste enhancer, since the article consisted of a sugar substitute and the labeling lacked adequate warnings against unsafe use; and the articles were dangerous to health when used as directed since by reason of insufficient flow rate and quantity of oxygen, reliance upon its use would serve to delay or deny proper emergency measures in those life-threatening situations where an immediate adequate supply of emergency oxygen was needed; 502(a), 502(b)(2), 502(j). Default decree ordered destruction. (24)

Vegeburger, canned, at Collegedale, E. Dist. Tenn.
Charged 3-3-71: when shipped by Cedar Lake Foods, Cedar Lake, Mich., the article labeled in part "Collegedale Distributors Collegedale, Tenn." had a quantity of contents declaration that was not within the bottom 30 percent of the area of the principal display panel; the quantity of contents was expressed as "Net Contents 1-Lb. (48 Oz. 3 Lbs.)" and the quantity of contents, appearing on the principal display panel having an area of more than 25 square inches, was in type size less than 3/16 inch high; and the quantity of contents on the 3-lb. bags was expressed as "3 Lbs. Peso Neto (48 Oz.)" instead of "Peso Neto 48 Oz. (3 Lbs.)." 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(3)(C)(i). Consent decree authorized release to Collegedale Distributors, Collegedale, Tenn., for relabelling. (25)

Casseroles, plates, and cups, at Towson, Dist. Md.
Charged 12-23-70: while held by Universal Liquidators (Franklin W. Olson), Seattle, Wash., the articles contained the nonconforming food additive calcium cyclamate, 402(a)(2)(C). Franklin W. Olson, Seattle, Wash., claimed the articles and denied the charges, claimed that after acquiring the cyclamate beverages he had made arrangements for delivery of the articles for dispensation through prescriptions, and cross-claimed for damages against the Government. The Government moved for summary judgment. The court granted the Government's motion for summary judgment and ordered the articles destroyed. (26)

Charged on or about 2-3-71: when shipped by Arista Olive Co., Inc., New York, N.Y., the article, labeled in part "Krios Feta Cheese Greece New York," contained the nonconforming food additive benzoic acid, 402(a)(2)(C). Default decree ordered destruction. (27)

VITAMINS / SPECIAL DIETARY FOODS

Polien extract and vitamin combination tablets, Delta Farms, at Houston, S. Dist. Tex.
Charged 9-30-70 and amended 4-6-71: while held by Brentwood Corp. (Green Acres Health Food Store), Houston, Tex., who packaged the article from bulk tablets from Engelholm, Sweden, the label statement "Delta Products Div. Houston, Texas 77002" was false and misleading in representing and suggesting that Delta Products was the manufacturer of the article—403(a), 502(a); the label statement "Three tablets daily provide the adult daily minimum requirements of vitamins A, D, B, C, and Niacin" was false and misleading, since two tablets daily would provide the minimum daily requirements for these vitamins—403(a), 502(a); the accompanying leaflet entitled "Nature's Miracle Product" contained false and misleading claims for protecting health, revitalization, longevity, and natural disease prevention, of the article being a miracle food, of one pollen grain containing all amino acids, 7 natural vitamins, etc., and for aiding patients suffering from a wide range of physical ailments often where drugs have failed—403(a), 502(a); and the labeling lacked adequate directions for use and was not exempt therefrom, since the article was a new drug, and no approval with an application filed pursuant to Section 505(b) of the Act was effective with respect to such drug and no notice of claimed investigational exemption was on file; 502(f)(1). Default decree ordered destruction. (29)

DRUGS / Veterinary

Endlich prednisolone pyridoxine and vitamin combination tablets, Prednamen prednisolone chlorpheniramine and vitamin combination tablets, and Green prednisolone and zinc oxide combination ointment, at Greenwich, Dist. Conn.
Charged 2-10-70: while held by Hanian Pharmaceuticals, Greenwich, Conn., the articles were new animal drugs without effective approved New Animal Drug Applications—501(a)(5); the labeling of the Endlich tablets contained false and misleading claims for overcoming inflammation generally, neutralizing histamime, new hair growth, aiding liver function and fat absorption,

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skin conditions, and giving pets a feeling of well-being—502(a); the labeling of the Prednems tablets contained false and misleading claims for inflammation generally, skin conditions, otitis, conjunctivitis, appetite stimulation as a therapeutic tonic, and for geriatric patients—502(a); the labeling of the Oren cream contained false and misleading claims for ostitis externa, various skin conditions, pyoderma, and chelitis—502(a). Following failure of dealer to salvage articles pursuant to a consent decree, the court ordered the articles destroyed. (36)

**Oxytetracycline hydrochloride injectable for animals,** at Yakima, E. Dist. Wash.

Charged 7-5-71: when shipped by Wembly Laboratories, Belle Plaine, Minn., the article was a new animal drug without an effective approved New Animal Drug Application; 501(a)(5). Default decree ordered destruction. (27)

**Oxytetracycline hydrochloride injectable for animals,** at Fresno, E. Dist. Calif.

Charged 5-25-71: when shipped by Sioux Nation Supply, Inc., Sioux Falls, S. Dak., the article was a new animal drug without an effective approved New Animal Drug Application; 501(a)(5). Default decree ordered destruction. (27)

**Natamycin oxytetracycline hydrochloride injectable for animals,** at Sioux City, N. Dist. Iowa.

Charged 5-25-71: when shipped by Sioux Nation Supply, Inc., Sioux Falls, S. Dak., the article was a new animal drug without an effective approved New Animal Drug Application; 501(a)(5). Default decree ordered destruction. (27)

**Oxytetracycline hydrochloride injectable for animals,** at Fresno, E. Dist. Calif.

Charged 6-1-71: while the article was held for sale after manufactured locally by oxytetracycline shipped from Wisner, Nebr., the article, labeled in part "Oxy-Tet . . . 50 mg. Oxytetracycline Hydrochloride . . . Dr. C. A. Skiles, Ovis, Calif. [or "Hereford, Texas"];" was a new animal drug without an effective approved New Animal Drug Application; 501(a)(5). Default decree ordered destruction. (27)

**Natamycin oxytetracycline hydrochloride injectable for animals,** at Fresno, E. Dist. Calif.

Dr. Leland Haun, President of claimant corporation, testified that he cooperated with the Food and Drug Inspectors but only because he thought he had no choice, and thus the seizure was the result of illegal search, as a search warrant was not obtained. Not only is this testimony contradicted by the testimony of Inspector Anderson but it is uncontradicted that Mrs. Leland Haun voluntarily gave invoices, statements and samples involving the articles seized to the Inspector.

"It therefore find no illegal search or seizure that would require the release of the drugs.

"The purpose of the Fourth Amendment is to interpose a detached and independent decision maker between the privacy of individuals and the otherwise unchecked zeal of enforcement officials. It was only after a complaint was filed in this court describing the articles seized to the Inspector."

The Court in Sudden Change expressed it: 'Against this background it is apparent that the District Court in Sudden Change erred in construing the same drug connotations as found by the Second and Third Circuits. As a result of the District Court's ruling these two claims and even the *ignorant, unthinking and credulous* consumer would not be led by these references to believe that the article was a drug; and the claimant had ceased to manufacture, promote, and sell the article destroyed, the court said:

"This is an in rem action involving the seizure, pursuant to complaint and monition, of veterinary drugs labeled 'Oxy-Tet' on the charge that it is adulterated within the meaning of 21 U.S.C. 351(a)(5).

The purpose of the Fourth Amendment is to interpose a detached and independent decision maker between the privacy of individuals and the otherwise unchecked zeal of enforcement officials. It was only after a complaint was filed in this court describing the articles seized to the Inspector."

"Dr. Leland Haun, President of claimant corporation, testified that he cooperated with the Food and Drug Inspectors but only because he thought he had no choice, and thus the seizure was the result of illegal search, as a search warrant was not obtained. Not only is this testimony contradicted by the testimony of Inspector Anderson but it is uncontradicted that Mrs. Leland Haun voluntarily gave invoices, statements and samples involving the articles seized to the Inspector.

"It therefore find no illegal search or seizure that would require the release of the drugs.

"The purpose of the Fourth Amendment is to interpose a detached and independent decision maker between the privacy of individuals and the otherwise unchecked zeal of enforcement officials. It was only after a complaint was filed in this court describing the articles seized to the Inspector."

End of medical section.

**Cosmetics / Beauty Products**

**Magic Secret**

waren shown to be effective for prolonged, continued use for removal of wrinkles, and the article lacked an effective approved New Drug Application—502(a); the article's labeling, considered in the promotional setting in which it was intended to be read and understood by the ordinary consumer under customary conditions of purchase and use, was false and misleading in presenting an exaggerated statement of what the drug would do and a misleading statement of how it worked; i.e., the labeling, in the setting in which it was used, conveyed the message which it was primarily directed that this was a newly-discovered article produced after years of research which would immediately and dramatically eliminate all her wrinkles (including crow's feet, puffy under-eye circles, and labs) from through its action of tightening, moisturizing, freshening, and toning her skin; that this facial and neck skin improvement could be accomplished in minutes and would last for hours. Because the drug was applied regularly for a week to ten days, but that the effectiveness might be interfered with irregular applications; and implication being that some permanent improvement may be expected from regular applications; that the drug had the capacity to provide a youthful appearance to the skin; and that this was a clear natural protein lotion which acted as an enhancer to cause the face and neck to be more pronounced and to eradicate all wrinkles; whereas in truth and in fact this article had only a temporary effect on wrinkles, regular applications did not provide any permanent benefits, the drug had no astringent action sufficient to draw the skin to the extent of eradicating wrinkles, including crow's feet, puffy under-eye circles, and laugh, smile, frown, and throat lines, and would not make skin youthful again—502(a); and the article was fabricated from two or more ingredients and its label lacked the established name of each active ingredient—502(a)(1)(A)(iv).

The article was claimed by the shipper who denied the charges. The Government served written interrogatories upon the claimant. The claimant answered some of the interrogatories and filed objections to the rest of them. Following a hearing before the court, the interrogatories objected to by the claimant were disposed of by the court, and the interrogatories and the cross-motion of claimant for summary judgment must be granted."

U.S. v. Hazel Bishop "Sudden Change" and U.S. v. Charles Pfizer & Co., "Coly Line Away," on briefs. The Government's motion for summary judgment and the claimant's cross-motion for summary judgment were filed and heard by the court. The court cited the Circuit Court opinion in the Sudden Change case to the effect that as long as the article claimed to give a "face lift without surgery" and "anti-aging puffs," it was deemed a drug. Thereupon, the court concluded that "Magic Secret" was not a drug, saying: "The only two claims made for "Magic Secret" which even approach the magnitude of the claims made in Line Away and Sudden Change are: 'Magic Secret is a 'pure protein' which causes an astringent sensation.' The promotional material does not emphasize these two claims and even the 'ignorant, unthinking and credulous' consumer would not be led by these references to believe that 'Magic Secret' would do other than alter their appearance. It is apparent that promotional claims made for 'Magic Secret' are less exaggerated than those reported in Line Away and Sudden Change. It cannot be said that they carry the same drug connotations as found by the Second and Third Circuits. As the District Court in Sudden Change expressed it: 'Against this background of a misrepresentation of face lifting, the inextricable connection to a fraudulent claim on the part of the consumer would not be led by these references to believe that the article was a drug; and the claimant had ceased to manufacture, promote, and sell the article destroyed, the court said:

End of medical section.

**Omniv IV body creme,** at Miami, S. Dist. Fla.

Charged 12-11-71: when shipped by Helene Curtis Industries, Inc., Chicago, Ill., the article was a new animal drug with an effective approved New Animal Drug Application; 501(a)(5). Default decree ordered destruction. (41)

**Cherry bombs,** at Blackwater, W. Dist. Mo.

Charged 6-24-71: while held by Jiles Service & Grocery, Blackwater, Mo., the article, labeled in part, that the claimant had ceased to manufacture, promote, and sell the article, that claimant was not presently planning to manufacture or sell the article, that claimant would conform to the Court of Appeals holdings in U.S. v. Hazel Bishop "Sudden Change" and U.S. v. Charles Pfizer & Co., "Coly Line Away," and that claimant would exclude from its labeling and promotional material representations that the article acted with "drastic power" or that the article's effect was enhanced by daily use. Pursuant to that stipulation, the appeal was vacated. (42)

**Hazardous Substances**

**Shoe enamels and shoe dye,** at Tampa, M. Dist. Fla.

Charged 6-24-71: while held by Jiles Service & Grocery, Blackwater, Mo., the article, labeled in part, that the claimant had ceased to manufacture, promote, and sell the article, that claimant was not presently planning to manufacture or sell the article, that claimant would conform to the Court of Appeals holdings in U.S. v. Hazel Bishop "Sudden Change" and U.S. v. Charles Pfizer & Co., "Coly Line Away," and that claimant would exclude from its labeling and promotional material representations that the article acted with "drastic power" or that the article's effect was enhanced by daily use. Pursuant to that stipulation, the appeal was vacated. (42)
Milwaukee, Wisconsin" were flammable and presented special hazards due to their methyl alcohol content, and their outer cartons and bottles lacked on their main panels and elsewhere a number of required conspicuous label statements: Green Brown Enamel—Z(0)(11), 2p(0)(12), 3p(0); Heel and Sole Enamel—Z(0)(11), Z(0)(1)(A, B, E, G, I & J), 3p(0); Brown Lightning Shoe Dye—Z(0)(11), 2p(0)(12), 3p(0). Default decree ordered destruction. (45)

NOTICES OF JUDGMENT on Criminal Actions

FOOD


Charged 6-4-71: when shipped, nuts, labeled in part (Counts 1,2,3,4 & 5 re- vincen. & 6) in the neighborhood of Fairmont Foods Company, Hopkins, Minnesota," had been prepared and packed under insanitary conditions and contained insect filth—402(a)(3), 402(a)(4); and filberts (count 6) and peanuts (count 7) were held in a build­ ing accessible to insects and was contaminated with insect filth—402(a)(3), 402(a)(4). Guilty plea by corporation to all counts; fine. Guilty plea by in­ dividual to count 7; fine. (46)

Marbo Quality Foods, Inc., and Martin N. Berberian, president, Fresno, E. Dist. Calif. Charged 5-18-71: rice was held in a building accessible to rodents, birds, and insects, and was contaminated with mammalian urine and insects; 402(a)(3), 402(a)(4). No contendere plea; fine. (47)

Merchants Terminal Warehouse Co., Inc., Omaha, Dist. Nebr.

Charged 7-22-71: powdered sugar and all-purpose flour were held in a build­ ing accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). No contendere plea; fine plus costs. (48)

Sea Gardens, Inc., Julius C. Sigman, president, and Ben H. Cox, Sr., vice president, Valona, S. Dist. Ola. Charged 6-2-71: when shipped, crab meat contained E. coli and bacterial filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). No contendere pleas; probabilities. (49)

DRUG


Charged 8-26-70: when shipped, Davoxin brand of Digoxin tablets, U.S.P., had been manufactured, processed, and packed under circumstances that lacked conformity with current good manufacturing practice, and the strength of the article differed from its quality fell below U.S.P. standards, since the article failed the U.S.P. content uniformity requirements; 501(a)(2)(B), 501(b). The defendants pleaded not guilty.

The defendants moved to dismiss the information and to suppress the inspectional evidence. In denying the defendants' motions, the court said: "Motion to Dismiss

"The first motion is a motion to dismiss the information insofar as it charges defendants with violations of 21 U.S.C. § 351(a)(2)(B) on the ground that the language 'current good manufacturing practice' is void for vague­ ness. This motion is denied. See United States v. Bel-Mar Laboratories, Inc., E.D. N.Y., 1968, 284 F.Supp. 875, 881-884.

Motion to Dismiss or in the Alternative to Suppress

"The second motion pending is a motion to dismiss the information, or, in the alternative, to suppress for use as evidence government, test results of the digoxin referred to since the Government is unable to furnish the de­ fendants with the very bottles from which test samples were taken in the case in question. Accordingly, this motion of defendants is also denied. Motion to Suppress

"The third motion pending is for suppression of evidence. Originally grounded on the lack of a search warrant, this motion now presents the issue whether defendants consented to the searches which resulted in the seizures of digoxin tablets. The issue of consent to a search by FDA inspectors has been raised in three recent cases, United States v. Hammond Milling Co., 5 Cir., 1969, 413 F.2d 608; United States v. Thriftmart, Inc., 9 Cir., 1970, 424 F.2d 1006; and United States v. Kramer Grocery Co., 8 Cir., 1968, 416 F.2d 294 F.Supp. 65. Only in the latter case did the court hold the search invalid because consent was lacking. The key facts in the Kramer case were that Mr. Kramer clearly didn't want to allow the inspection and in response to this clearly expressed opposition the inspector stated that he had a right to in­ spect, that Kramer couldn't do anything about it, that the law required it, etc.

"The present case does not approach the Kramer facts. At a preliminary meeting between defendant corporation and its representatives and representa­ tives of the FDA, defendants' consent was obtained for the ensuing inspec­tions. In their reply memorandum, defendants assert that the FDA officials misrepresented their authority to conduct inspections without a warrant. How­ ever, at the March 20 meeting, defendant corporation was represented by an attorney and the exchange of letters indicates that the meeting at which consent was obtained was held in a businesslike, cooperative manner. In any case, it is abundantly clear that the intimidation apparently present in Kramer could not have occurred.

"Defendants further argue that certain guidelines were established for the 'consent search' and that FDA officials did not comply with them, e.g., the FDA officials did not submit to defendants a written report of violations of current good manufacturing practices as required by the guidelines. In the court's opinion, the guidelines were set forth in an informal letter of September 29, 1969, which did not require writing specifically for the purpose of in­forming defendants of alleged violations. Furthermore, even if a writing for that purpose were required, the failure to provide one would not vitiate prior consent where oral reports of alleged violations were given to de­fendants on several, if not numerous, occasions, so that the defendant com­pilation had plenty of time to move in good faith to correct them. (See affidavit of John A. Hamilton, Jr., Supervising Inspector.) Accordingly the motion for suppression of evidence is denied.

"The defendants moved for a rehearing asserting their entitlement to an evidentiary hearing on their motion to suppress. The court cited Rule 41(e), Fed. R. Crim. P. in ordering the defendant to file a list of proposed issues of fact to be determined and witness whom they propose to call and whom they believe the Government should produce. The court also made the follow­ ing rulings:

Ruling I

"The defendants have argued that there was no genuine consent initially given for the Inspections at issue. The court rules as a matter of law that with respect to the question of initial consent or lack thereof to Food and Drug Administration inspections the burden is on the defendants to show ex­ pressed opposition on their part and direct, immediate intimidation by Food and Drug Administration officials. Cf. United States v. Kramer Grocery Co., 8 Cir., 1969, 416 F.2d 297.

Ruling II

"The defendants have also argued that the failure of the Government to follow certain guidelines for the inspections in question set forth in an ex­change of letters renders the search and seizures invalid. The court rules that the de­ficiency in the search and seizures is in the manner in which the inspections were conducted. In several instances, the Government, instead of providing the defendants with copies of the inspections in question set forth in the letter to the Government, made a copy available to the defendants. If it occurred, it did not vitiate the searches and seizures in question unless defendant can show that it was accompanied by bad faith or an unlawful purpose on the part of such officials."

Thereafter the defendants charged their pleas to no contendere and were fined. (50)

Notices of Judgment are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act and section 13 of the Federal Hazardous Substances Act. Notices of Judgment report cases involving seizure proceedings, criminal proceedings, and injunctive proceedings. The cases generally involve foods, drugs, de­ vices, cosmetics, or hazardous substances which were alleged to be adulterated or mis­branded or otherwise violative of the laws while in interstate commerce, or while held for sale after shipment in interstate commerce.

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

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

Charles C. Edwards, M.D., Commissioner of Food and Drugs Washington, D.C. May 1, 1972
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