

FDA **CONSUMER**

SEPTEMBER 1972

**NUTRITION
SENSE AND NONSENSE
THE CONSUMER SPECIALIST
FDA AND THE AGE
OF THE CONSUMER
RADIATION AND HEALTH**





If the variety of her tasks in educating and helping the consumer means anything, each of FDA's 26 consumer specialists might better deserve the title of consumer generalist. For 20 years she has competently got FDA's message to the public and got the public's message back to FDA. She has thrived, and so has this agency, on her knack for handling just about any problem involving the consumer. Largely because of the consumer specialist's dedicated work with diverse groups, an informed consumer today can be a schoolgirl, a schoolmarm, or a grandmother. She ably advises the consumer about the fine art of survival in the marketplace, dispenses tips on better health and protection for money spent, and gives civic organizations a compelling reason for sitting on those hard seats. She is one of FDA's most direct personal lines to the people the Agency is trying to protect. To catch the consumer specialist in action, turn to page 10.

quotes

“It would be wrong indeed if we delude ourselves into believing that science alone has created today’s wave of consumer expectations. Yes, we have the miracles of modern science; yes, we have the marvels of modern communications; and yes, we have the most widely informed public in history.

“And these do, in fact, help explain today’s consumer movement. But to leave the explanation here is to treat the symptoms and not the cause; it is to ignore the reality that we have today more product quantity than quality, more industry promises than performance, and more concern, perhaps, for reaping profits than for earning them.

“... What we have today is a vicious cycle of discontent. A frustrated consumer turns first to industry, then to Congress; Congress mirrors consumer discontent in new and tougher laws. The burden is then passed on to the regulatory agencies, and finally back to industry.”

Charles C. Edwards, M.D., Commissioner of Food and Drugs, at the International Association of Insurance Council, White Sulphur Springs, West Virginia, July 8, 1972.

“During the next several months there will be significant changes on the nutrition scene in this country. These changes will form the base for an all-out nationwide effort to inform the consumer in useful, understandable ways about the food he is buying. And they will allow him to make sounder choices in his diet, based on greater knowledge at the time of purchase.

“We are going to see the establishment and use of nutritional guidelines for processed foods; we are going to see meaningful nutrient labeling—based on a great amount of research into what would be most useful; we are going to see actions on ingredient labeling that will no longer keep the consumer in the dark as to what he is really buying.

“We are—in short—going to see a new direction and a new emphasis on nutrition—fostered by the consumer, sponsored by the Government, and in some cases welcomed by the industry.”

Sherwin Gardner, Deputy Commissioner of Food and Drugs, at the Conference on Child Nutrition, New Brunswick, New Jersey, June 27, 1972.

Elliot L. Richardson

Secretary, U.S. Department of
Health, Education, and Welfare

Merlin K. DuVal, M.D.

Asst. Secretary for Health
and Scientific Affairs

Charles C. Edwards, M.D.

Commissioner of Food and Drugs

Charles H. Dick

Asst. Commissioner
for Public Affairs

Wayne L. Pines/Editor

Harold C. Hopkins/Editorial Director

Jesse R. Nichols/Art Director

Joan M. Galloway/Managing Editor

Frederick L. Townshend/Production Mgr.

FDA CONSUMER, the official magazine of the Food and Drug Administration, is published monthly, except for combined July-August and December-January issues. Subscriptions may be ordered from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402, at \$3.50 a year (\$1.00 additional for foreign mailing).

Address for editorial matters: **FDA CONSUMER**, PA-20, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852.

Articles published in **FDA CONSUMER** are in the public domain and text may be republished without permission. Use of funds for printing this publication approved by the Director of the Office of Management and Budget November 22, 1971.

FDA CONSUMER was previously known as **FDA PAPERS**.

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 judgements, decrees, and court orders which have been rendered under this Act, including the nature of 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.

Radiation and Health

4

The director of FDA's Bureau of Radiological Health tells how radiation can affect health and how FDA helps protect the public from unnecessary radiation.

The Way to a Consumer's Heart: FDA's Consumer Specialist

10

For an agency whose mission is to protect the public, she's a must.

How You Can Be an Extension of FDA

15

You can help the FDA do a better job of protecting you. Here's how.

Teflon and Aluminum Cooking Utensils

16

Food cooked in most cooking utensils generally is safe to eat and there's little cause for concern.

Nutrition Sense and Nonsense

18

As the "facts" about these "claims" indicate, representations by health quacks should be taken with a grain of salt.

FDA and the Age of the Consumer

23

Today's consumer is making significant demands on the Federal Government. Here's how FDA responded.

News Highlights

27

Regional Reports

32

State Actions

35

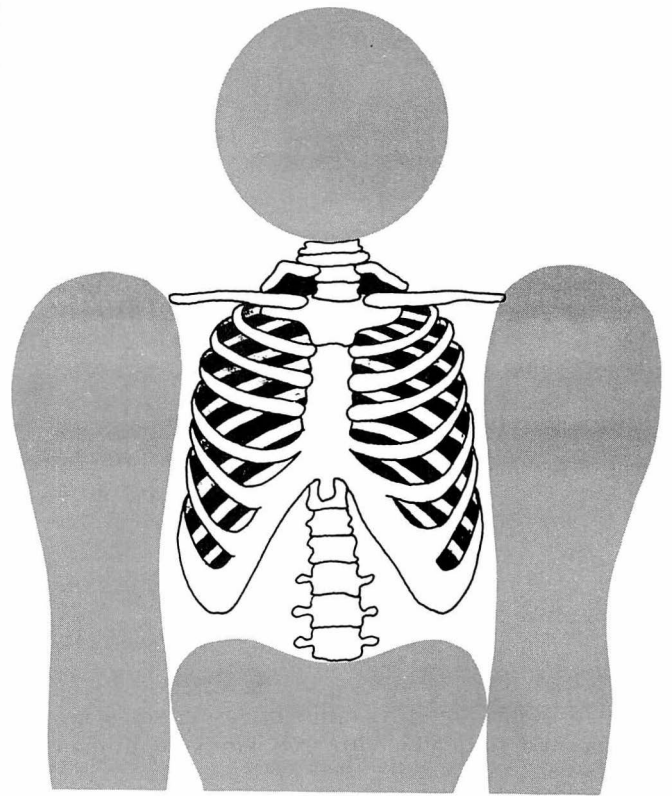
Seizures and Postal Service Cases

36

Notices of Judgment

38

RADIATION AND HEALTH



Radiation is one of the most unusual agents over which FDA has responsibility. Radiation cannot be seen. It is a form of energy in motion. Used properly, it contributes substantially to man's welfare. Used inappropriately, it can create serious risks to human health. The legislative responsibility for electronic product radiation control, as well as the responsibility for improving protection in the use of radiation and radioactive materials, rests with the Bureau of Radiological Health, which joined FDA in May 1971. This Bureau is headed by John Villforth, a Public Health Service commissioned officer with a background in engineering. In this interview with the editors of FDA CONSUMER, Mr. Villforth covers a wide range of subjects, such as:



John Villforth

- What radiation is.
- Radiation hazards.
- Possible genetic effects of x rays.
- Diagnostic x-rays equipment.
- Microwave ovens.
- Color television receivers.
- Industrial radiation.
- What consumers can do to help improve radiation protection.

Q. *Mr. Villforth, your Bureau regulates electronic products that emit radiation. Just what is radiation?*

A. Basically, radiation is a form of energy in motion. When it interacts with matter such as cells in the human body, it can damage or destroy them in various ways. The specific effects depend upon the type of radiation. For example, the damage produced by x rays may not be the same as that produced by microwaves. A laser beam can produce injury of still a different kind.

Our job is to investigate all kinds of radiation to find out if a potential for biological harm exists. We determine the nature of that harm and the risks it imposes on the population, and try to do something about minimizing people's exposure.

Q. *Specifically what kind of biological harm are we talking about?*

A. In the case of x rays and radiation produced by radioactive materials, we are concerned basically with two kinds of human health effects. First are the long-term effects of low levels of exposure, such as leukemia and other forms of cancer that may not show up for many years. Of course, extremely high levels of radiation have immediate effects on the individual, but generally the levels of exposure that we deal with are not of this magnitude.

Our second concern is with possible genetic effects of ionizing radiation. Damage to reproductive cells may cause changes or mutations that may produce health defects in offspring. These may be magnified through future generations.

I should emphasize that any level of ionizing radiation is considered, for purposes of radiation protection, to have a potential for biological effect. In other words, there is no known ionizing radiation level that may be characterized as completely "safe."

Microwave radiation has not yet been definitely found to produce genetic effects, although effects on chromosomes have been reported. Nevertheless, this form of radiation concerns us because of its potential for damage by raising the temperature of body organs. It may also have a potential for health effects at quite low levels, particularly through interaction with the nervous system.

We need to know more about low-level microwave radiation effects and these are currently being investigated. The eye is especially vulnerable to microwaves because of its inability to dissipate heat readily. Animal experimentation has established that microwaves can cause cataracts. Reliable human data is not yet available on this.

Q. *There is a normal level of naturally occurring radiation. What kind of radiation is this and what effect does it have on humans?*

A. We are constantly being bombarded by so-called cosmic radiation. We are also exposed to radiation from the small amounts of naturally occurring radioactive materials such as uranium and thorium in the soil. Other naturally occurring elements like potassium are also slightly radioactive, and the radiation from the potassium in our bodies may have some subtle effects on us.

Our concern is that the additional radiation we may receive from industrial or medical products or from fallout may increase our total exposure. I mentioned previously that there is no level of radiation that can be characterized as being "safe." We want, therefore, to keep man-made radiation levels as low as possible in relation to its benefits, so that radiation hazards are minimized while benefits are maximized.

Q. *To what extent does radiation pose a threat to human health? Is it something each of us ought to worry about?*

A. It's difficult to quantify the hazards posed by radiation. I've been concerned about this problem for some time. Many of our programs depend on the public's understanding of what we are trying to do and the public has to know what the risks of radiation are.

Radiation, at the doses we're dealing with, does not produce unique diseases. It simply *increases the risk* of certain diseases which exist in the population already, such as leukemias and cancers.

This is similar to what we know about cigarette smoking and lung cancer. Remember that lung cancer is a disease which is contracted by both smokers and nonsmokers, but the risk among smokers is considerably greater. Of course that doesn't mean that everyone who smokes will develop lung cancer, but simply that the odds are increased if a person smokes. It's the same with radiation. The more radiation one receives over a lifetime the greater the risk that deleterious effects will occur.

Another point of confusion concerns the magnitude of the risks. Given the doses of radiation to which individuals are normally exposed, the risk of demonstrable harm *to an individual* is quite small. On the other hand, when this risk is extended over a large group of people, the number of those affected can become considerable.

It's a matter of simple arithmetic. Suppose a per-

son receives a certain amount of radiation and the risk of his developing some radiation-induced disease as a result is on the order of, say, one in ten thousand. This would certainly seem to be an acceptable risk, if the radiation is for some beneficial purpose. But now suppose that half of the population, or about a hundred million people, receive this same amount of radiation. We'd then be dealing with 10,000 affected individuals.

If you understand these concepts, you can see why we're greatly concerned about population exposure to x rays. It's also why we are doing everything we can to see that population exposure is reduced as much as practicable. But I don't believe individuals should worry about the ordinary radiation exposures received in everyday life.

Q. *Mr. Villforth, can you describe some of your Bureau's responsibilities in regulating radiation sources?*

A. The Bureau of Radiological Health establishes standards and regulations to protect public health and safety from radiation produced by electronic products, and—under a general public health mandate—radiation that may be emitted from certain radioactive materials. We operate under several authorities. One is the Radiation Control for Health and Safety Act of 1968, which established the radiation control program over electronic products. The other is the Public Health Service Act which authorizes us to cooperate with and assist public agencies, institutions, and scientists in efforts to improve radiation protection. We also operate under the Food, Drug, and Cosmetic and Hazardous Substances Acts that provide most of the legislative authority for FDA.

Q. *What do you mean by electronic products?*

A. An electronic product, under the Radiation Control Act, is any product that uses an electronic circuit and that may generate ionizing or nonionizing radiation, or sound waves.

Q. *Can you give some examples of electronic products?*

A. Yes. The most common electronic products that we've dealt with are color television receivers and microwave cooking ovens. Others include medical and industrial x-rays machines, laser diathermy devices, and ultrasonic cleaners.

Q. *We presume that, like all other FDA Bureaus, you deal mainly with a benefit-risk ratio. That is the benefit of these prod-*

ucts to mankind and to individuals must outweigh any risks. Is that correct?

A. That's correct. The most common use of the benefit-risk equation is in x-ray diagnosis. X rays are used in more than half the medical diagnoses in this country. Thus, the benefits from the use of x ray are enormous, and we can accept some risk, though we try to keep it as low as practicable.

On the other hand, we have x-ray emissions from television receivers. These emissions, when they occur, are unnecessary by-products of the electronic circuits in certain TV receivers. Therefore, they must be eliminated to the fullest possible extent. Since there is no benefit from x rays in a TV set, there should be no biological risk

Q. *Your Bureau's basic goal is to reduce unnecessary exposure of the population to radiation. How do you go about doing this?*

A. We approach the problem in two ways. First, under the Radiation Control for Health and Safety Act, we establish and enforce performance standards for radiation emitting products. Second, we engage in programs to improve the competence and protective practices of people who use radiation.

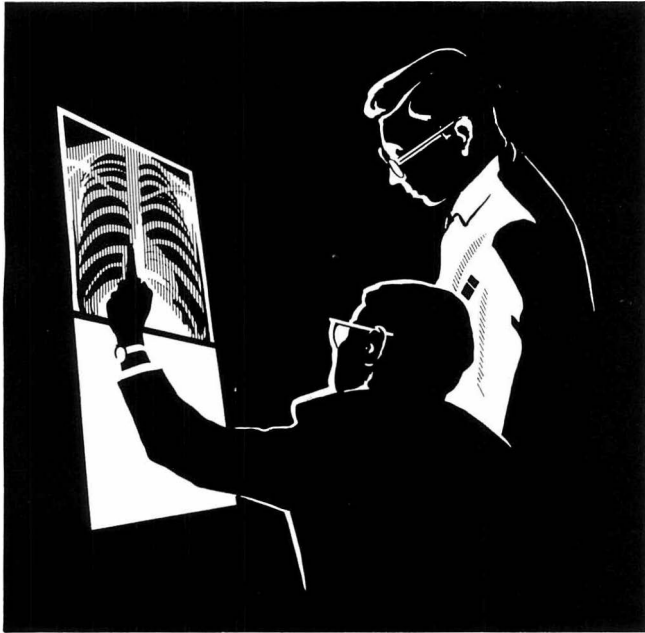
Q. *What is the Bureau doing to upgrade the performance of radiation users?*

A. Our biggest effort in this area concerns those who deliver radiation to others—physicians, dentists, x-ray technologists, and so on. For example, there are techniques which x-ray technologists can use to minimize exposure of their patients. If these techniques were universally practiced, population exposure would be reduced significantly.

To reach the technologist with this information we produce and distribute training packages and work with their professional organizations to promote radiation safety. We also help States establish programs to license or certify people who operate x-ray machines.

Another of our goals is to improve the teaching of radiation protection in medical schools. In this connection we've developed a Radiological Health Sciences Learning Laboratory for medical students which is now being tested in five universities and will probably be extended to a number of others within a year.

Q. *How does your Bureau conduct its regulation of radiation emitting products?*



A. Unlike many other Federal regulatory enactments, the Radiation Control for Health and Safety Act requires that standards developed under its authority be performance-oriented, as opposed to design-oriented. For instance, a color television receiver must be designed by the manufacturer so that whatever radiation leaks from the set must be less than the established performance level. The method by which a manufacturer achieves this level is up to his ingenuity in using available technology.

Q. Does this mean that you have premarketing clearance over electronic products that have a potential for radiation leakage?

A. No. This means that once a standard is established for a class of products, the manufacturer must meet the standard or he cannot market the product. If he does market a product which seems to meet the standard, and if it is later determined to violate the standard, or if it is defective in terms of his own standard, then he may be required to replace, repair, or refund the product.

Q. How do you go about setting standards for electronic products?

A. The setting of standards is based on what knowledge we have of the biological effects of radiation and the recognition that this knowledge must be translated into engineering concepts. Perhaps one of the best examples is color television.

The color television receiver x-ray emission limit was based on the criteria that the public should not

be exposed to more than a small fraction of natural background radiation. This criteria was translated into a requirement that limits the exposure rate at the surface of the television receiver. So, we start with the basic biological effects and work backward to take into consideration the engineering aspects of the set and the method of measurement to be used by the manufacturer.

Q. Besides color televisions what other electronic products do you have performance standards for?

A. We have performance standards for microwave ovens and for medical and dental diagnostic x-ray machines. We also have a standard for certain electron tubes used in high schools and colleges to demonstrate scientific phenomena and in performing the experiments. The tubes sometimes produced unnecessary x radiation. We felt there was no justifiable reason for students to be exposed to unnecessary x rays.

Q. You mentioned before that one adverse effect of too much radiation could be genetic. This must be one of your major concerns since genetics can affect future generations. Recently you conducted a study to determine, among other things, the current levels of reproductive organ exposure to x rays. Can you describe that study and its conclusions.

A. The study you refer to is the X-ray Exposure Study of 1970. This was a followup of a similar study conducted in 1964. The purpose of both was to determine trends in medical and dental x-ray experience throughout the country and to determine from these trends the amount of radiation being received by the population that could affect the health of present and future generations.

The 1970 results indicated that although the rate of medical x rays had increased about ten percent over 1964, the genetically significant dose had decreased by about 35 percent.

Q. Does this mean that people in the United States are receiving more x-ray examinations but that the effect this may have on future generations is not believed to be as great as it was eight years ago?

A. That's correct. It means that the educational and corrective action programs that have been developed by States, professional groups, and by this Bureau have reduced the impact from this increased use of medical radiation, as far as genetic effects are concerned.

Q. *Is the present rate at which the American population is being exposed to diagnostic x ray acceptable?*

A. I am satisfied that the x-ray exposure study has demonstrated the willingness of the various health professions to take precautions on behalf of the public health. I am not satisfied that everything is being done to reduce x-ray exposure, however. We expect to see still further reductions in genetic exposure as a result of our radiation control standard for diagnostic x-ray equipment and our educational efforts directed at users of radiation in the medical field.

Q. *Is there anything the consumer can do to reduce the risk of exposure to excessive radiation from x-ray machines?*

A. Well, we believe the prime responsibility rests with the physicians and technologists who administer or supervise the use of diagnostic x rays. But one thing the consumer can do is to call attention to the need for protective devices.

For example, young men of reproductive age might ask to have gonadal shields. And, since radiation damage is cumulative over a long period of time, it's prudent to protect young boys in this manner as well.

Women of child-bearing age who are to receive x rays of the pelvis or lower abdomen might call to the attention of their physicians the timing of their menstrual cycles. Sometimes it's possible to schedule the x-ray examination for that time during the cycle when the physician will be sure he is not x-raying a newly formed embryo. This kind of precaution should be taken because the developing embryo is extremely sensitive to radiation, particularly during the early stages of pregnancy.

Q. *How often should someone be x-rayed by a dentist?*

A. The need for an x ray is determined by the dentist or physician treating the patient. There are no set rules as to the frequency with which someone should be examined. The American Dental Association has discouraged the annual full-mouth x-ray examination and has said that a patient should receive examinations based on clinical findings in the mouth.

Another problem the consumer can do something about arises when he changes dentists. The new dentist may want a complete x-ray series. The patient should call the attention of his new dentist to previous x rays and try to get these transferred.

The same situation, of course, applies in medical care. An individual should call to the attention of the physician past medical x rays that might have a bearing on future health.

Q. *Recently your Bureau recommended that mass screening programs, usually employing mobile x-ray equipment to detect tuberculosis and other chest diseases, be discontinued. What was the basis for that recommendation?*

A. This recommendation was supported by the Department and by the American College of Radiology and the American College of Chest Physicians. It said the use of x rays for mass screening members of the general population should be discouraged because these procedures were not productive in diagnosing new cases of tuberculosis and because the amount of radiation associated with many of these mobile units was far in excess of the radiation received from the conventional chest x ray in a hospital setting.

Q. *Mr. Villforth, many of us remember the radiation scares of the late 50's and early 60's in which there was national concern that increased radioactivity from bomb testing could pose a hazard. Is there any cause today for such concern?*

A. The moratorium on atmospheric weapons tests has greatly reduced the introduction of new quantities of environmental radioactivity. During the early 60's, when the weapons testing program in both Russia and the United States was in full force, there was concern that radioactivity might be a problem with respect to our country's food supply, especially milk. Today this problem has all but disappeared.

Q. *Let's turn now to some specific products for which your Bureau has set performance standards. Can the American consumer be assured that microwave ovens bought today will pose no radiation hazard?*

A. Yes. The Bureau of Radiological Health continues to do several things to assure that microwave ovens pose no radiation hazard. First, we have set a standard which limits radiation emissions from microwave ovens. The standard also requires ovens to incorporate certain protective mechanisms.

Specifically, the standard requires that each oven have two safety interlocks to prevent the generation of radiation when the door is open. Our observation was that one interlock was inadequate in some situations.

In addition to the standard, we review manufactur-

ers' quality control programs, we visit manufacturers' facilities to see that they meet specifications, and we test ovens in our laboratory. We also cooperate with the State radiation control programs to get data on ovens that are used in homes, and work with other Federal agencies, such as the Veterans Administration and the military.

As a result, I think we can be assured that there is adequate surveillance of these products to see that the public is not exposed to radiation emissions above levels of the standard. Finally, the Bureau supports research to expand our knowledge of microwave radiation biological effects.

Q. *Then as far as the Bureau is concerned, there is no reason at all why a consumer should not purchase a microwave oven if it suits his or her household.*

A. That is correct. But the purchaser should be sure that the oven is received in good condition and that it is operated according to the manufacturer's instructions. The Bureau has prepared a pamphlet that consumers will find helpful as guidance on the proper care and operation of microwave ovens. Copies may be obtained from the Bureau of Radiological Health (RH-50), 5600 Fishers Lane, Rockville, Maryland 20852.

Q. *Let's turn to another product you mentioned before, television sets. Have all TV set x-ray hazards been eliminated?*

A. We conduct a TV surveillance program similar to the microwave oven program. From all of our surveillance information, we are very pleased to see that the industry has been most responsive in designing new features into color sets that leave little chance that we will have any TV receiver x-ray problems in the future. For example, many television components, such as voltage regulator or shunt regulator tubes, that posed problems in earlier models have been eliminated by engineering modifications.

Q. *Are children who sit very close to TV sets exposed to any more radiation than an adult who watches from a distance?*

A. We see no reason for limitations to be placed on children or anyone else in watching color TV insofar as radiation exposure is concerned. Anyone can sit as close as he wants.

Q. *Mr. Villforth, microwave ovens and televisions are consumer products. Your Bureau also is responsible for industrial uses of radiation. Does industrial use pose any undue hazards to the workers?*

A. There is always a potential for hazards. Yes, the Bureau is concerned with protecting the public health and safety from industrial use of such products as x-ray machines, microwave heating devices, and lasers.

We have collaborative programs with the National Institute for Occupational Safety and Health to examine the working environment where these products are used, and we are considering establishing performance standards where appropriate. For example, one performance standard under consideration will be for industrial x-ray devices. And we also will have a standard for lasers.

Q. *Quite a bit of the work of your Bureau involves setting of performance standards which manufacturers have to carry out. Are you pleased with the cooperation that you've received from manufacturers of electronic products that produce radiation?*

A. Yes. Our concern in the beginning was that manufacturers would be reluctant to make the necessary changes in their products. This has not proved to be true. We find that once the industry understands its responsibility, it is generally willing to make the necessary design changes to meet the conditions of a performance standard.

Q. *What other products might pose radiation hazards in the future?*

A. In the electronic product field we are looking at a whole new spectrum of electronic devices that didn't exist ten or twelve years ago. We will consider performance standards for these products, many of which will be household items in the future. Now being developed are ultrasonic dishwashers and products using new concepts in electronic heating and cooking.

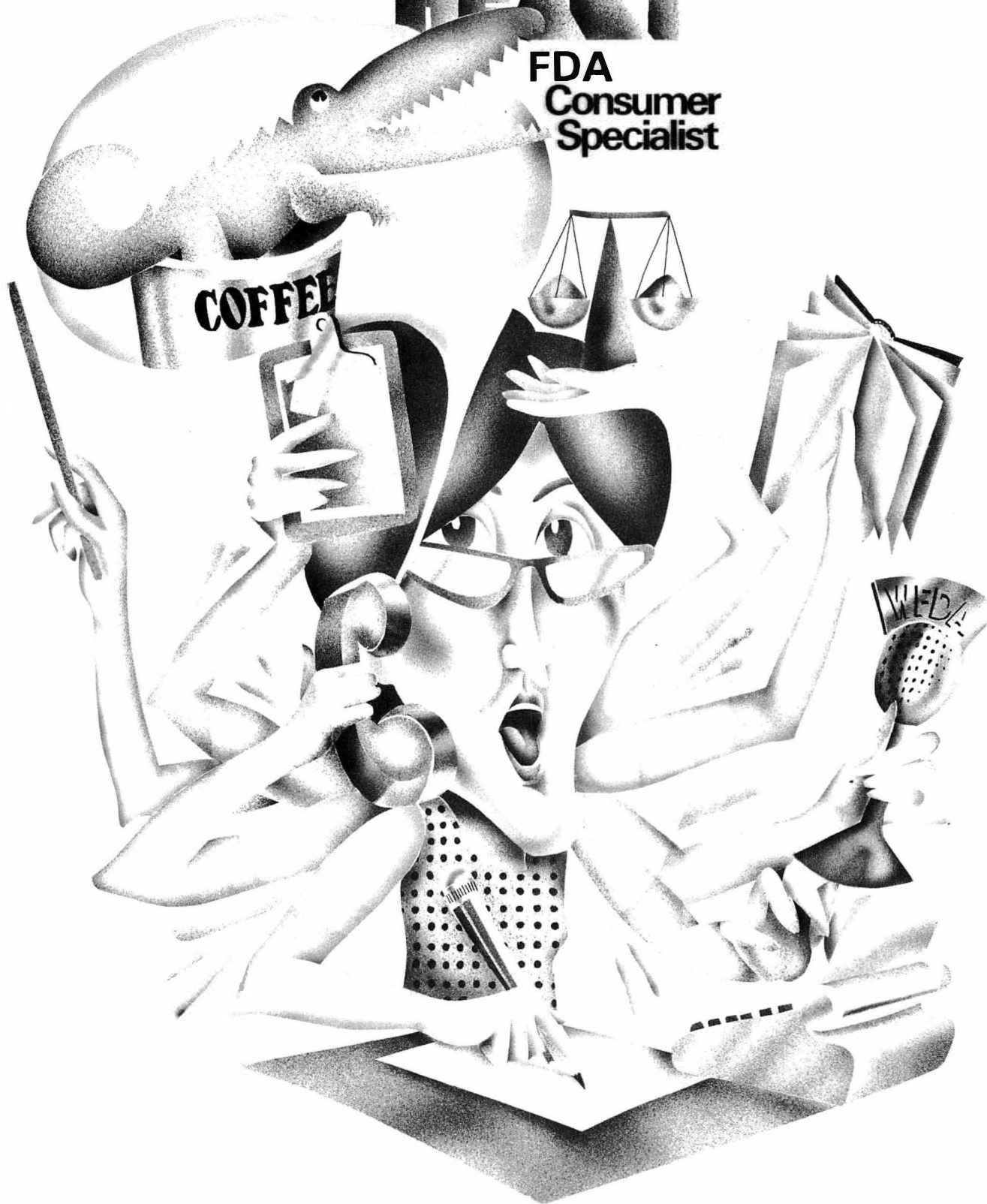
Q. *Your Bureau seems to maintain close tabs on the development of new products. What philosophy do you bring to your research and regulatory efforts?*

A. To be responsive to consumer needs and to discharge our responsibilities in protecting public health and safety, we have tried not only to correct problems we face today, but also to be in a position to prevent future problems from arising.

If we have one overall philosophy, it is to keep on top of our area to avoid the development of any problems. This preventive approach, I believe, provides the consumer with the type of protection he can expect and deserves from electronic products and from radiation.

THE WAY TO A CONSUMER'S HEART

FDA
Consumer
Specialist



"Help me!" she implored, "There's an alligator in my coffee."

One morning last year the consumer specialist in one of FDA's field office residential posts arrived at work to find the telephone ringing. The housewife at the other end was nearly hysterical.

"Help me!" she implored, "There's an alligator in my coffee."

After restoring calm, the FDA expert on consumer problems patiently obtained enough information to dispatch a trained FDA inspector to the consumer's home. He found the housewife's story too true to be good.

A newly opened three-pound can of coffee contained, not an alligator, but a dead salamander five inches long. The upset housewife was provided the proper instructions for registering her complaint with FDA for action.

Similar occurrences, not always so melodramatic, are repeated daily in the offices of FDA's 26 consumer specialists. In each case the consumer specialist draws on her background, training, experience, and common sense to give the consumer the kind of assistance needed for full protection under the laws administered by the Agency.

It is her job to maintain close and continuing touch with those people whom the statutes were written to protect, and to find out the concerns consumers have about specific products, and the problems of health, safety, and economic well-being associated with them.

FDA's consumer specialists form an élite corps of specially qualified women who handle consumer complaints and inquiries at the field level and who conduct countless formal and informal activities intended to inform and educate the public. These activities are designed to

enable the consumer to take full advantage of the protection provided by law and to buy and use products under FDA regulation with maximum benefits in health, safety, and value.

Consumer specialists have proved indispensable to FDA field operations. They handle a multitude of difficult and demanding situations and assignments with skill and tact. They have saved many an FDA administrator's day by getting quickly to the heart of public concerns about specific products or FDA policies. They also have often stepped in to substitute for the boss in making speeches and presentations to consumer groups.

Today it is hard to imagine that they have not always existed. They in fact first came on the scene only 20 years ago.

FDA has always been a small agency in terms of the immense size and production of the industries it regulates. From the beginning it has had to make every person on the payroll count in tangible protection and benefits to the consumer. For a time after World War II the Agency had little time to think of needs that were becoming more and more obvious—what consumers could do to help FDA protect them, and what FDA could do to help them protect themselves.

By 1952 the time was over-ripe for the consumer specialist. On a modest scale and on a part-time basis FDA hired the first few such women, then known as "Consumer Consultants." The results in better communication with the consumer were soon apparent, and by 1964 there was a full-time consumer specialist in each of FDA's 17 field offices, operating as part of the FDA Consumer Education Program.

There are now 26 consumer specialists assigned to FDA's 19 field offices. Since some field offices have more than one, the

second consumer specialist is sometimes stationed in a residential post in a major population center and serves a specific territory of States or counties under the field office jurisdiction. To keep up with the move toward consumerism, FDA plans in the near future to double the present number of consumer specialists.

To work with maximum effectiveness, the consumer specialist must know what her agency is doing and thinking in all areas and on all subjects as they affect the consumer. Besides keeping up with the flow of correspondence and telephone communications between FDA headquarters and her field office, she and her fellow consumer specialists meet several times a year with the director of the Office of Consumer Affairs in Washington to compare notes on current problems of concern to consumers. Here she is briefed on agency activities and plans for the future and provides her own input for consideration by policy-making officials at headquarters who may benefit from her direct contact with the consuming public.

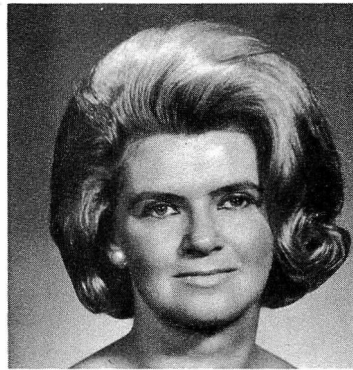
The roles and responsibilities of FDA's consumer specialists are far reaching. In her home office and in her exchanges with consumers and consumer groups, an FDA consumer specialist keeps her eyes and ears open for specific types of consumer complaints or problems and relays significant findings to those at her field office and FDA headquarters who can do something about it.

She meets with local organizations and groups seeking consumer protection information. She appears before groups of both school teachers and students, before health professionals and other professional associations, before parents and aged citizens, and before ethnic groups and poor people.

(continued)



Yolán L. Harsanyi
Region I—Boston
(Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont)



Jeanne M. Devers
Region III—Philadelphia
(Pennsylvania, Delaware, Maryland, Virginia, West Virginia, District of Columbia)



Dorothy F. Dunn
Region V—Chicago
(Michigan, Illinois, Indiana, Ohio, Minnesota, Wisconsin)



Lois M. Meyer
Region II—Buffalo
(53 upstate counties in New York State)



Anne B. Lane
Region III—Baltimore
(Maryland, Virginia, West Virginia, District of Columbia)



Marguerite Robinson
Region V—Chicago (Illinois)



Mary Gill
Region II—New York
(Five boroughs of New York City; Nassau, Suffolk, Westchester, Rockland Counties)



Wilhelmina M. Lombardi
Region IV—Atlanta
(North Carolina, South Carolina, Tennessee, Kentucky, Georgia, Alabama north of Montgomery)



Marie A. Ekvall
Region V—Chicago
(Illinois)



Naomi Driver
Region II—New York
(Five boroughs of New York City; Nassau, Suffolk, Westchester, Rockland Counties)



Carol Young
Region IV—Tampa Resident Post
(Florida, Mississippi, Alabama south of Montgomery)



Catherine A. Knarr
Region V—Cincinnati
(Ohio)



Diane M. Place
Region V—Detroit
(Michigan)



Hazel L. Wallace
Region VI—Dallas
(Texas, Oklahoma, New Mexico)



Helen C. Keaveny
Region VIII—Denver
(Colorado, Utah, North Dakota,
South Dakota)



Joan Bergy
Region X—Seattle
(Washington, Oregon, Idaho,
Alaska)



Eilany M. Goossens
Region V—Indianapolis Resident
Post
(Indiana)



Josephine S. Whiteside
Region VI—New Orleans
(Arkansas, Louisiana)



Julia S. Hewgley
Region VIII—Laramie Resident Post
(Wyoming, Montana)



Blanche L. Erkel
Region V—Minneapolis
(Wisconsin, Minnesota)



Lorena Meyers
Region VII—Kansas City
(Kansas, Nebraska, western Mis-
souri)



Elaine G. Roentgen
Region IX—Los Angeles
(Arizona, California south of San
Luis Obispo)



Leona Allman
Region VI—Dallas
(Texas, Oklahoma, New Mexico)



Mary-Margaret Richardson
Region VII—St. Louis Resident Post
(Iowa, most of Missouri)



Irene Linda Malbin
Region IX—San Francisco
(Nevada, Hawaii, California north
of San Luis Obispo)

She provides FDA educational information for radio and television stations, newspapers, and other information media. She gives FDA's viewpoint to industry conventions, to State and local officials, and to general audiences.

She is responsible for the field office Consumer Phone, a separate telephone line in her office that local consumers may dial to hear recorded messages on current topics of interest concerning products that FDA regulates, actions the Agency is taking, or simple tips on looking after health and safety or making a dollar stretch farther.

As she learns her business and the problems of concern in her territory, the effectiveness of the consumer specialist increases and along with it her value to her agency and the public.

She probably meets more people and more kinds of people than anybody in the field office. Everybody is a consumer, from a schoolboy to a grandmother. She provides them information they can use to their benefit. Often they educate her in return.

She also has her share of frustrations, usually from people who don't fully understand FDA's functions or the law's limitations. Sometimes she is thrown questions for which there are no ready answers.

A sign of FDA's accelerated programs on a number of fronts involving unfit or dangerous products removed from the marketplace was indicated in one exasperated consumer's call to a consumer specialist. The inquiry: "What do I throw away today?"

One consumer specialist's mere appearance put a dampening effect on a questionable commercial enterprise. Arriving to speak before a civic group, she noticed a salesman had set up a display of exercise machines that had been banned by FDA. When the salesman found out who was present, he declined

an invitation to comment to the group on his display and removed the merchandise as soon as he prudently could.

A good consumer specialist who isn't achieving rapport with her audience uses her head to find out why—and sometimes her feet. One whose presentation to a group of migrant teachers and teacher aides wasn't going over wondered why until she found that her fine dress shoes were getting more attention than her talk. The reason: everybody else was wearing tennis shoes. She repaired to her car and put on a pair of tennis shoes she kept there for driving comfort. When she returned, the audience was hers.

Some consumers are so impressed with the message they receive that they are willing to go to almost any length to follow advice. After a consumer specialist spoke to his class, a fifth grader wrote:

"Dear Miss Consumer Specialist, I enjoyed you talking with us and I will keep my Baby Boy Out of the can of drain cleaner I Hope you come again your friend Samuel M."

Neither FDA nor the consumer specialist is in it just for back-pats, but it's nice to hear a compliment like that paid to the Agency by one man attending a consumer education meeting, who sought out the consumer specialist afterward to say that he wouldn't mind paying taxes at all "if more could be spent to help the consumer—as the FDA is doing."

But what about the consumer specialist herself? One glowed the rest of the day after she read this letter from a fifth-grade schoolgirl: "I enjoyed having you here today. I think you are very nice. This is the first time we have ever had someone as nice as you. I think you are pretty. I have learned something about consumer protection today."



Charles H. Dick is Assistant Commissioner for Public Affairs.

How You Can Be An Extension Of FDA

If you come across a food, drug, medical device, cosmetic, hazardous substance, or toy that you believe may be mislabeled, insanitary, or otherwise harmful, you will perform a public service by reporting it to the Food and Drug Administration.

The information you supply to FDA can and often does lead to detection and correction of a violation. Many products have been recalled or removed from the market because of action initiated by a consumer.

FDA can't take action solely on the basis of your complaint, of course. But it will investigate promptly, in accordance with the requirements of the law. And if a hazard is found, FDA will seek to remedy the situation within the bounds of the law.

Here are some guidelines to follow in reporting hazards to FDA.

BEFORE YOU REPORT

Before you report to FDA about the possible hazards of a product, ask yourself these questions:

- Have I used the product as labeled?
- Did I follow the instructions carefully?
- Did an allergy contribute toward the bad effect?
- Was the product old when I opened it?

Make sure you've taken all these factors into consideration before you report a possible hazard to FDA. The hazard may lie in improper use of a product rather than in an inherent defect.

With a medicine, for example, you may suspect the product is harmful if you experience an unusual reaction. You should report this to your doctor immediately.

But the reaction may be a "side effect" rather than an indication of a defect. It may not be necessary to inform FDA about it. Your physician will be the best guide.

WHERE TO REPORT

You may refer your complaint in writing or by phone to the nearest FDA Field office or resident inspection station.

FDA has 10 Regional offices, 19 District offices, and 97 resident inspection stations throughout the United States. See the map on page 34 for the Regional and District office nearest you.

In other major cities not listed, you can find the address and phone number of the nearest FDA office in the telephone directory under U.S. Government, Department of Health, Education, and

Welfare, Food and Drug Administration.

If you wish, you may write about your complaint directly to FDA headquarters. **The address is Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.** The complaint will reach the correct person.

HOW TO REPORT

Report your grievance as soon as possible after it occurs. Give your name, address, telephone number, and directions on how to get to your home or place of business.

State clearly what appears to be wrong.

Describe in as much detail as possible the label of the product. Give any code marks that appear on the container. For example, markings on canned foods are usually embossed or stamped on the lid.

Give the name and address of the store where the article was bought, and the date of purchase.

Save whatever remains of the suspect product or the empty container for your doctor's guidance or possible examination by FDA.

Retain any unopened containers of the product you bought at the same time.

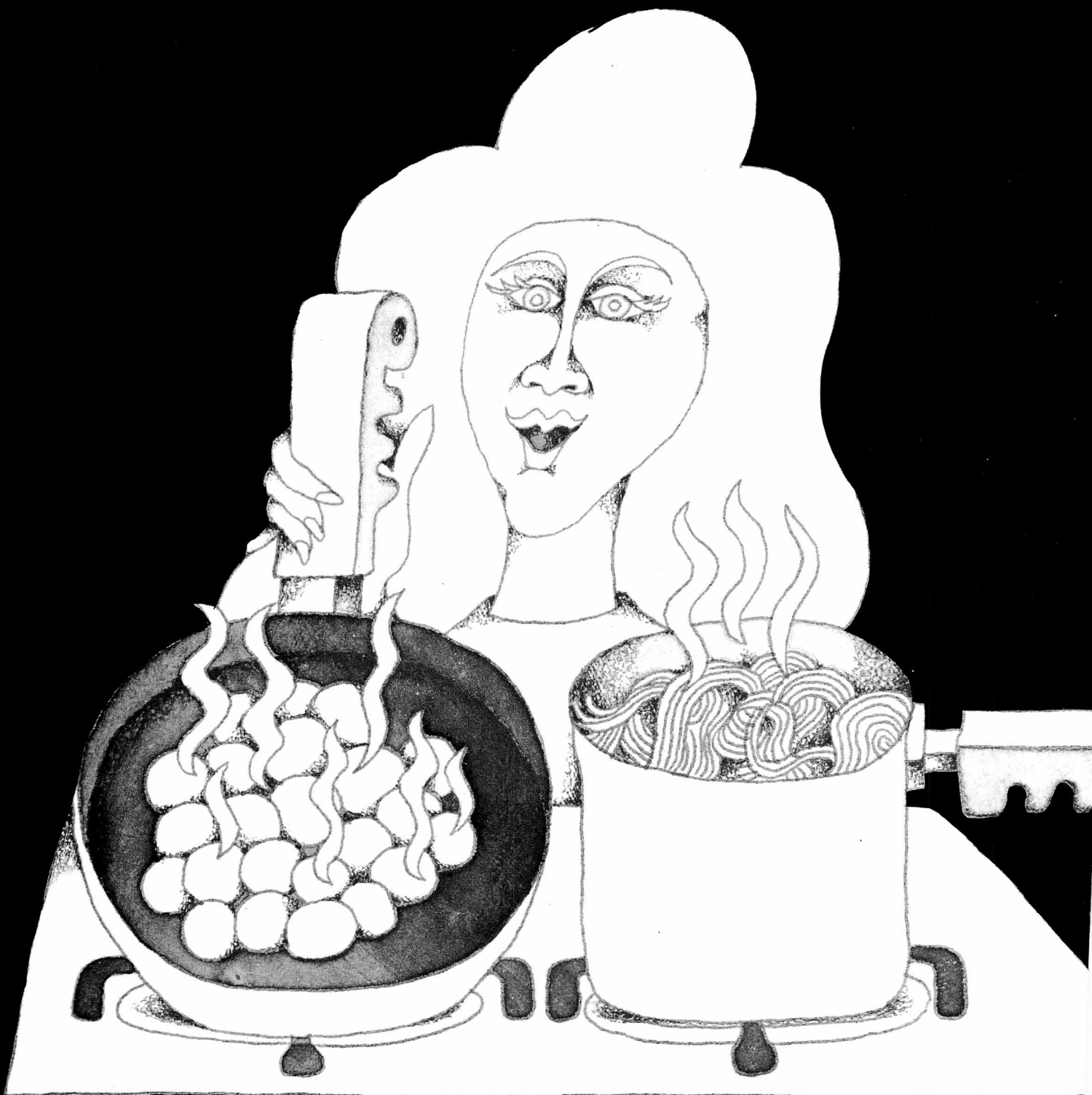
If an injury is involved, see your physician at once.

Report the suspect product to the manufacturer, packer, or distributor shown on the label, and to the store where you bought it.

FDA has limited jurisdiction over certain consumer products. If you have complaints about any of the following, these are the Federal agencies to inform:

- Suspected false advertising—*Federal Trade Commission.*
- Meat and poultry products—*U.S. Department of Agriculture.*
- Sanitation of restaurants—*local health authorities.*
- Products made and sold exclusively within a State—*local or State Health Department or similar law enforcement agency.*
- Suspected illegal sale of narcotics or dangerous drugs (such as stimulants, depressants, and hallucinogens)—*Bureau of Narcotics and Dangerous Drugs, U.S. Department of Justice.*
- Unsolicited products by mail—*U.S. Postal Service.*
- Accidental poisonings—*Poison Control Centers.*
- Dispensing practices of pharmacists and drug prices—*State Board of Pharmacy.*
- Pesticides, air and water pollution—*Environmental Protection Agency.*

Teflon and Aluminum Cooking Utensils



Consumers writing to FDA often express concern about the safety of their cooking utensils, such as Teflon-coated pans and aluminum cookware. FDA knows of no material commonly used for cooking utensils—such as Teflon, aluminum, copper, glass, steel, or tin—that is unsuitable for this use.

FDA does not recommend any particular type of cooking utensils. The composition of cooking utensils is of concern to FDA because the section of the law dealing with food additives provides that any substance which may become part of a food or that may change its characteristics must be safe for use.

Over the years, many consumers have expressed their concern to FDA that food prepared in certain utensils may be injurious to health. They question whether a cooking utensil with metal surfaces could become part of the food or change a food's characteristics during cooking.

The safety of frying pans and other pans coated with the material trademarked Teflon has been one frequently expressed concern. Teflon is a tough non-porous resin which permits frying of foods without the use of fatty materials. Utensils coated with Teflon are often advertised as being easy to clean.

FDA scientists believe that pans coated with Teflon are safe for conventional kitchen use. The manufacturer of this material has submitted information to FDA to demonstrate safety in commercial preparation of foods by methods comparable to use of frying pans in the home.

When a dry Teflon-coated pan is heated to high temperatures, the resin will decompose, but

the decomposition temperature is well above that at which fats give off smoke. The toxicity of fumes from a Teflon-coated pan with dry heat is somewhat less than that of fumes produced by ordinary cooking oils.

To determine whether continued use of a Teflon-coated pan increases the chance of food contamination, the manufacturer made tests of foods cooked in newly coated pans and those that had been in use for some time. Results were compared with the same food cooked in an uncoated aluminum pan. Checking for fluoride, an index to Teflon residue, analysts found about the same amount in the food cooked in the new Teflon and the plain aluminum pans. Slightly more was found in the Teflon pans that had undergone longer use—but all amounts were within safe limits.

Consumer letters also ask about aluminum cookware. Some consumers report that salesmen for other cookware have tried to convince them that cooking with aluminum is injurious to health. These salesmen claim that aluminum utensils gradually become coated with a gray substance which can be dissolved with baking soda. This indicates, they claim, that food containing soda will dissolve this gray material into the food.

This substance is an oxide and is harmless, FDA scientists say. Aluminum is the third most abundant element in the earth's crust and therefore occurs naturally in many foods. Aluminum compounds such as alum have a number of uses in foods. Ingestion of the quantities involved in all instances is entirely safe.

NUTRITION

SENSE & NONSENSE

The American food supply not only is the most abundant in the world, it is also unsurpassed in variety, cleanliness, and nutritional value.

The Food and Drug Administration has been a leader in developing nutritional programs which manufacturers can adopt to make it easier for consumers to understand the value of their food.

Among these programs are nutrient labeling, which provides that food labels contain a statement of nutritional value (see FDA Papers, May 1972), and nutritional guidelines, which provide that certain nutrients be included in processed foods.

These programs are intended to improve the nutritional quality of the American food supply and to educate consumers about the need for a well-balanced diet.

Despite these efforts, quackery still exists in the food area. Nutrition quacks can persuade you of the validity of their position. Very often, they also have something to sell.

Here are some of the "claims" made by health quacks, and the "facts," as written by Food and Drug Administration nutritional experts.



Claim: Our soil has lost its vitamins and minerals; thus our food crops have little nutritional value.

Fact: Plant nutrients are added to the soil in fertilizers, and food crops produced contain the expected nutritional value.



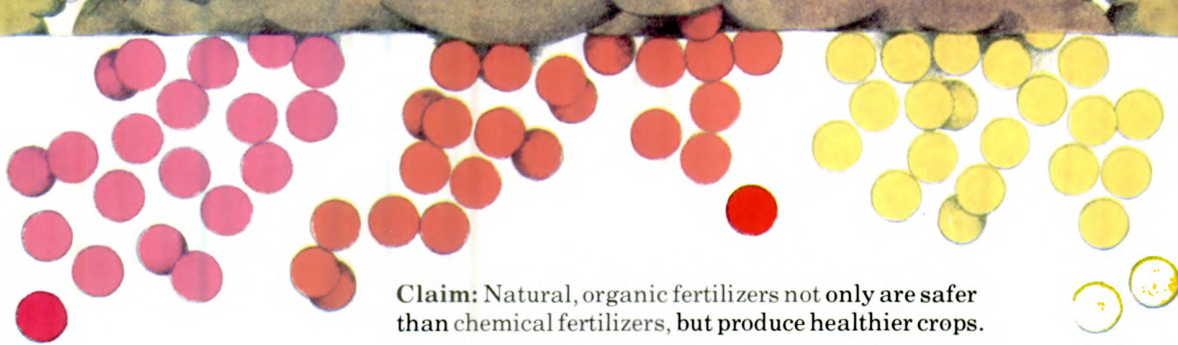
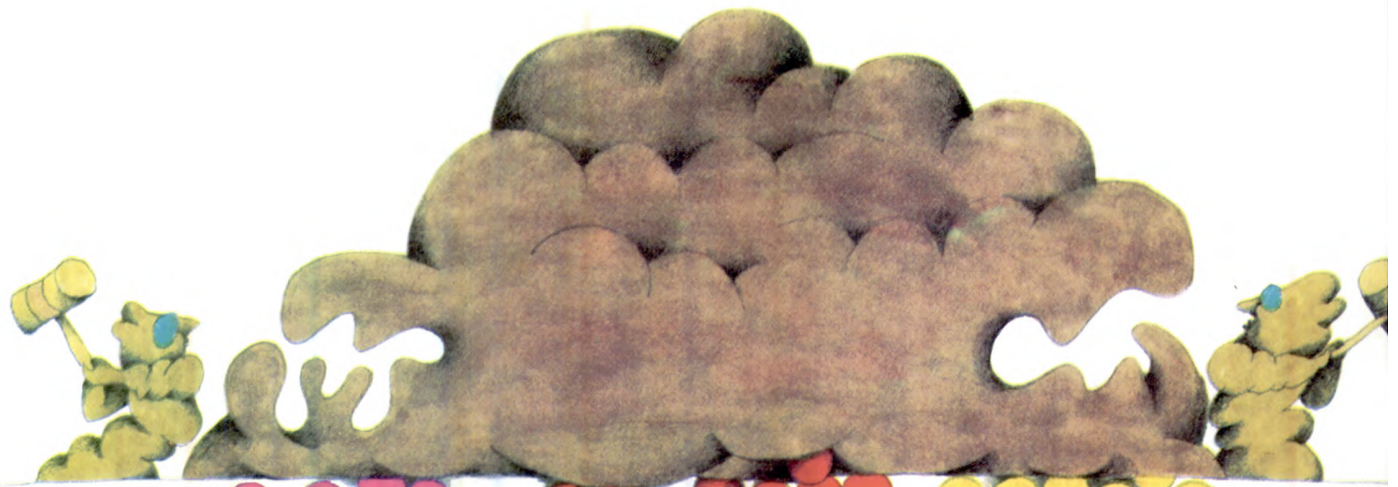
Claim: You are what you eat.

Fact: In one sense, yes. But you are also what heredity and environment have contributed.

Claim: Chemical fertilizers are poisoning our soil.

Fact: Modern fertilizers are needed to produce enough food for our population. There is no scientific evidence to indicate that the soil is being poisoned.





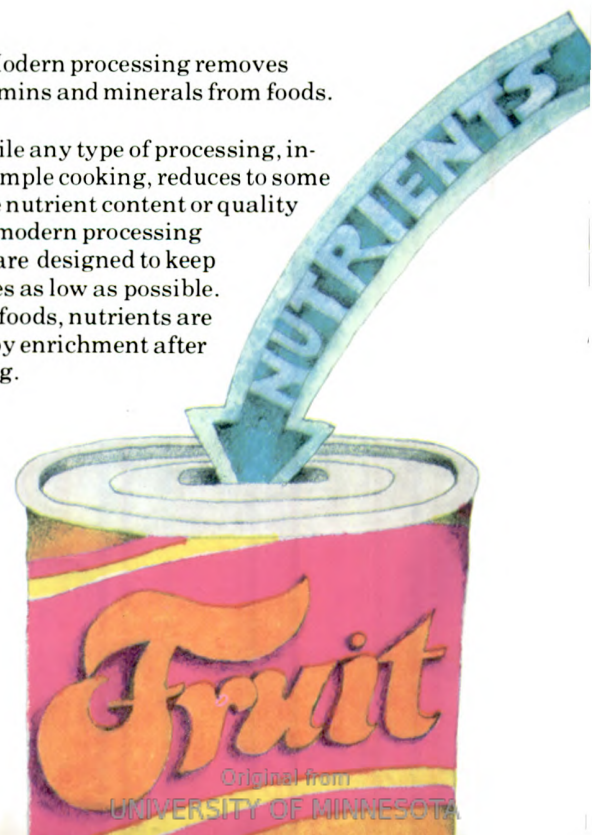
Claim: Natural, organic fertilizers not only are safer than chemical fertilizers, but produce healthier crops.

Fact: Organic and chemical fertilizers produce crops of equal quality and are equally safe. However, chemical fertilizers are easier to use than organic fertilizers because organic ones cannot be absorbed as such by plants. They must be broken down by bacteria in the soil until they finally become the same chemical elements—potassium, phosphorus, and nitrogen—that are supplied directly and more quickly by modern chemical fertilizers.



Claim: Modern processing removes most vitamins and minerals from foods.

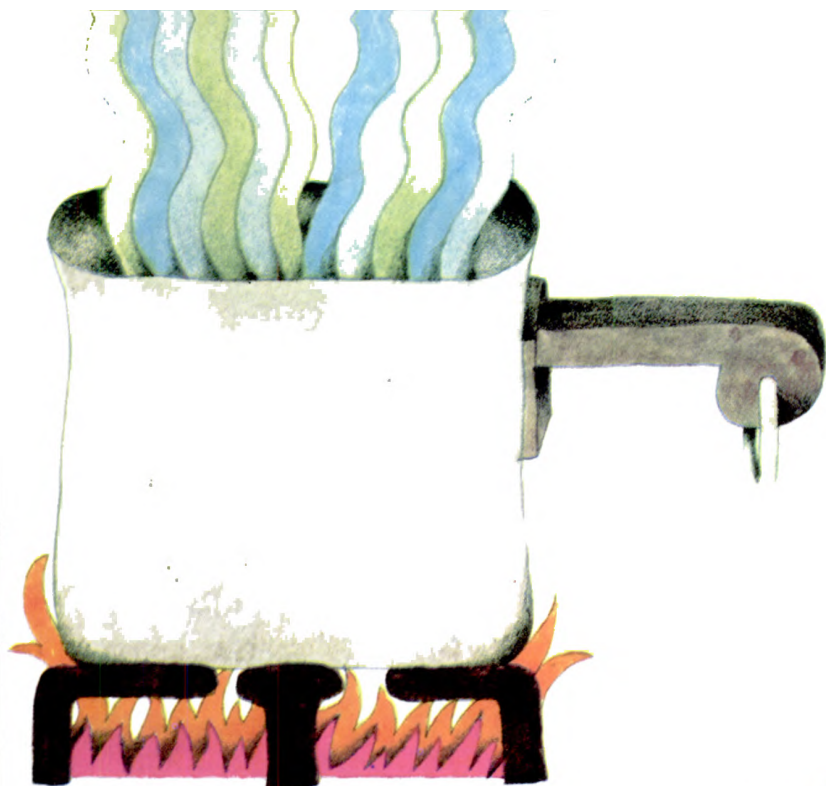
Fact: While any type of processing, including simple cooking, reduces to some extent the nutrient content or quality of foods, modern processing methods are designed to keep such losses as low as possible. For some foods, nutrients are restored by enrichment after processing.



Claim: Pesticides are poisoning our Nation.

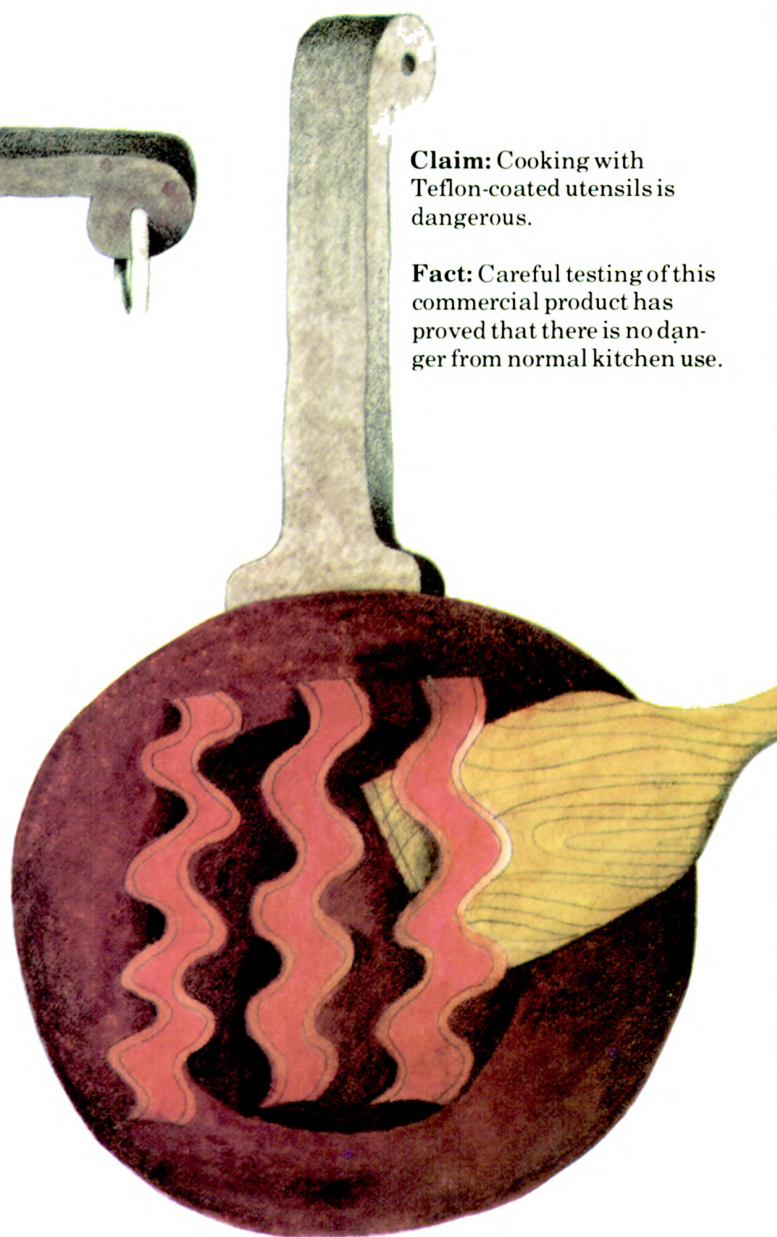
Fact: When pesticides on food crops leave a residue, FDA and the Environmental Protection Agency (EPA) make sure the amount will be safe for consumers. If any is allowed, the amount is set at the lowest level that will accomplish the desired purpose, even though a larger amount might still be safe.

Digitized by Google



Claim: Aluminum cooking utensils are dangerous to health.

Fact: Cooking in aluminum utensils is harmless. Aluminum is the second most abundant mineral element in the soil and therefore occurs naturally in many foods.



Claim: Cooking with Teflon-coated utensils is dangerous.

Fact: Careful testing of this commercial product has proved that there is no danger from normal kitchen use.

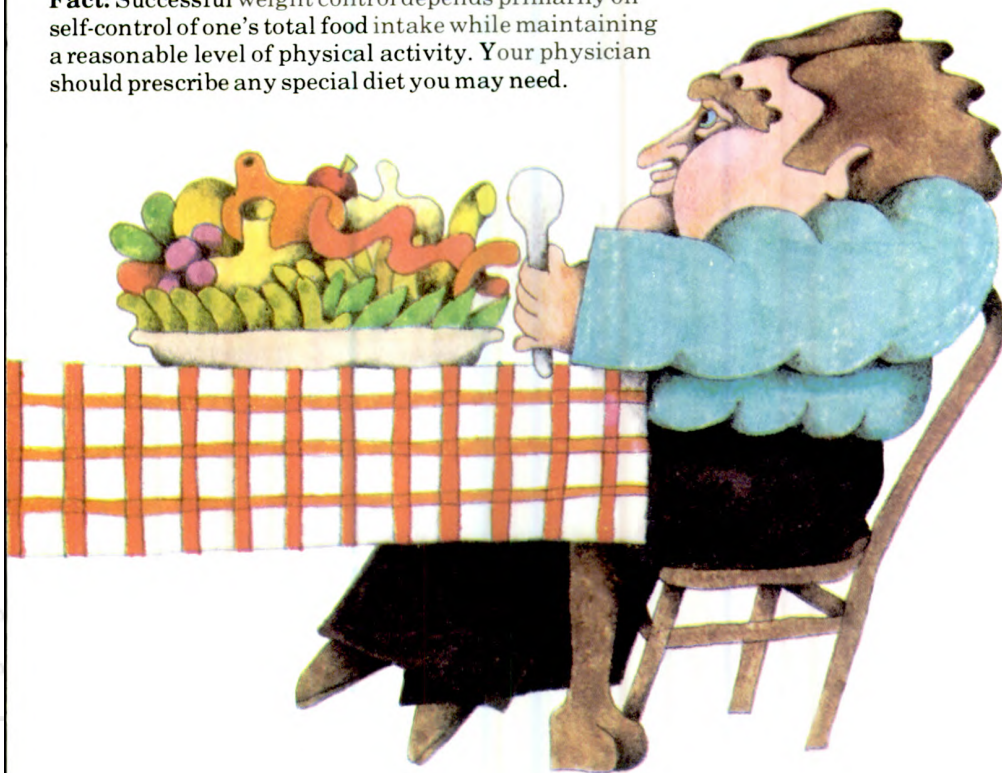


Claim: If you have an ache or pain or are just feeling tired, you are probably suffering from a vitamin deficiency.

Fact: Most people feel tired or suffer aches and pains at one time or another. These are symptoms which may be caused by overwork, emotional stress, disease, or lack of sleep, as well as by poor nutrition. If such symptoms persist, you should see your physician. It is difficult for the average person to accurately diagnose the cause of these symptoms.

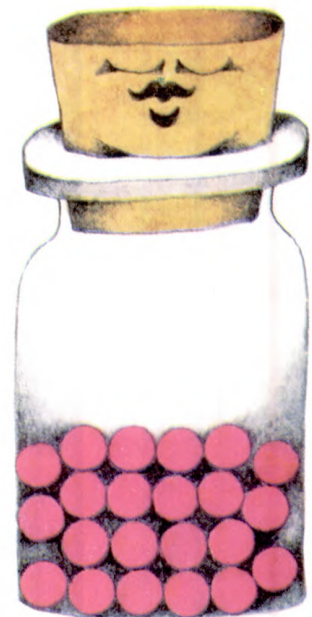
Claim: You have to eat special foods if you want to lose weight.

Fact: Successful weight control depends primarily on self-control of one's total food intake while maintaining a reasonable level of physical activity. Your physician should prescribe any special diet you may need.



Claim: Vitamins from natural sources are much better than synthetic vitamins.

Fact: Vitamins are specific chemical compounds. The human body can use them equally well whether they are synthesized by a chemist or by Nature.



Claim: Everyone should take vitamins, just to be sure.

Fact: Most healthy individuals whose diet regularly includes even modest amounts of meat and eggs, milk products, fruits and vegetables, any bread and other cereal products need not resort to dietary supplements. Some persons under a doctor's care or in institutions need dietary supplements because of special conditions which restrict their ability to eat a well-balanced diet. Modest supplementation with certain vitamins is also generally recommended during infancy, pregnancy, and while breast feeding. But generally, if you eat a well-balanced diet, you don't need vitamin supplements.



FDA and the Age of the Consumer

by Wayne L. Pines

Today's better educated and more affluent consumer is making significant demands on the Federal Government. The Congress has responded with new and stronger laws. The Food and Drug Administration has responded with new program initiatives to enforce these and earlier laws. Here's a summary of what consumers are demanding, and how the Government is responding.

The American consumer today is the best informed and most militant in history. Scientific achievements have raised consumer expectations to a peak never before known in this country. Greater affluence and broader educational opportunities have made consumers more concerned about their environment and their health, and more demanding that products be safe, effective, and honestly labeled and promoted.

Consumerism has had an enormous impact on the Federal Government by speeding the development of legislative and administrative programs. The new laws enacted by Congress in response to consumer expectations have substantially expanded and strengthened the consumer protection activities of the Federal Government. Enactment of these strong new laws indicate that the public has again turned to the Government, as it did during previous consumer movements, for assistance in dealing with technological and scientific advances.

Virtually all of these new laws have been assigned to the Food and Drug Administration, the primary Federal agency responsible for translating congressional intent into increased consumer protection. This "Age of the Consumer" has placed on agencies like FDA the obligation not only to enforce these laws as effectively and efficiently as resources allow, but also to develop new programs, within the limits of the laws enacted by Congress, to provide the public with the protection it deserves.

New Programs

FDA has moved recently on a number of fronts to develop new program initiatives with a view toward more effective fulfillment of the Agency's consumer protection mission. Close examination of these re-

cent new programs indicates the direction consumer protection is taking on the Federal level. It also reflects what consumers are demanding and how the Federal Government is responding.

Considered as a totality, most of these consumer demands and Government responses fall into three broad categories:

1. *Better labeling:* Consumers expect products to be more informatively and honestly labeled. Increasingly, consumers look to labeling as an objective guide to help them determine which products they should purchase. Hand-in-hand with better labeling goes more honest packaging. Consumers are demanding, in the words of Flip Wilson's Geraldine, that "what you see (on the label) is what you get."

2. *Safer products:* Consumers no longer are willing to accept technological advances or conveniences without assurance of safety—that is, assurance that the benefits from a product outweigh the risks. They are demanding protection from substances that can't be seen but have the potential for harming their persons or contaminating their environment. "Safety first" is more important today than ever before.

3. *A larger role for consumers:* Consumers no longer are willing to accept unchallenged the decisions of others in matters affecting their health and well-being. They want and expect to evaluate things for themselves. They are demanding that the Federal Government be more responsive to their needs and wants. Consumers want to know how agencies like FDA operate, and how and why they reach specific decisions.

Nowhere have these three demands been felt more strongly than at the Food and Drug Administration. And in each of these areas, FDA has, within the lim-

its of the laws and of financial resources, attempted to meet what it perceives to be the needs and desires of consumers. All of these program initiatives have been developed or announced in the past three years.

More Information

For example, consumer demands for more informative and more honest labeling led FDA to initiate a program in cooperation with the food industry to provide nutrient information on the labels of foods. The program was based on a careful evaluation of tests showing that consumers want and will use information about the calories, vitamins, minerals, and other contents of their foods. The program is voluntary for manufacturers, but any firm that chooses to participate must follow the standard format prescribed by FDA. This format was field tested to determine its degree of comprehension by the general public.

A similar program involves the establishment by FDA of voluntary guidelines for the food industry to follow in setting nutritional values for formulated foods. For example, guidelines will be set for the nutritional contents of such foods as frozen TV dinners. Consumers thus will be provided with important nutrients at levels they have reason to expect to be present in widely-used processed foods. Products that follow FDA's guidelines will be labeled according to a standard format to enable easy understanding by the public.

FDA also has proposed a new policy to provide for more accurate food labeling. Under the proposal, the "common" name of a food must indicate the percentage of any characterizing ingredients when the proportion of those ingredients influences the price of the food or its acceptance by consumers. For example, an orange drink must indicate on the label the amount of orange juice, so that consumers can compare one orange drink with another to determine which contains the largest percentage of orange juice.

Taken in their totality, these programs will revolutionize the commercial system of food labeling in the United States.

Another area in which consumers have demanded better information is over-the-counter medicines. In 1962 Congress amended the Federal Food, Drug, and Cosmetic Act—one of the basic laws under which FDA operates—to require that all drugs actually provide the therapeutic benefits claimed for them. Before 1962, only proof of safety had been required.

To implement the 1962 law, FDA has undertaken a massive and unprecedented review program to assure that as many as one-half million over-the-counter drugs are effective as well as safe for self-

treatment and are accurately and honestly labeled. Never before has such a massive product review been undertaken by the Federal Government. This program will take at least five years to complete. When it is completed, the American public will have a greater assurance that over-the-counter drugs are safe and effective for self-treatment of mild, self-limiting conditions. The program will also prevent consumer deception caused by exaggerated promotion based on false label claims.

Another consumer demand for more information led to a requirement imposed by FDA in 1970 on manufacturers of oral contraceptives. Consumer concern about proper use of "The Pill" led FDA to require that manufacturers include in each package of oral contraceptives a statement to the patient that the drug is powerful, can cause side effects in some users, and should not be used at all by some women. The statement also informs women that their physicians can supply them with a special booklet explaining in greater detail the benefits and potential hazards of oral contraceptives. This approach was unique in that for the first time it directed information about a prescription drug to the patient. It was a major step in improving the amount of labeling information provided to the consumer, so that women can make their own decision on whether to use "The Pill."

The Federal Government's responses to consumer demands for more honest packaging of products is embodied in the Poison Prevention Packaging Act of 1970 and in the Fair Packaging and Labeling Act of 1966, both enforced by FDA. The 1970 law requires safety packaging for household products that have been or could be injurious to children. FDA has published requirements for child-resistant packaging for a wide variety of potentially injurious products, including aspirin, furniture polish, oil of wintergreen, and "abuse" drugs such as amphetamines and barbiturates.

Under the Fair Packaging and Labeling Act, FDA has promulgated regulations which assure that implied "savings"—such as the "cents-off" claim for a food, drug, cosmetic, or device, or offers involving a coupon—will actually be realized in value received by the consumer.

Safer Products

If consumer demands for more honest labeling and packaging have been intense, then the demand for safer products has been ever greater. No single area has provided such a challenge to the Government as consumers' demands that hidden dangers be eliminated from products.

FDA's responses to these demands range from rulemaking proposals—such as those to eliminate the use of lead in paint and restrict the use of hexa-

chlorophene—to comprehensive programs such as those designed to reduce human exposure to x rays and to review the safety of hundreds of commonly used chemical food additives.

The proposal concerning lead in paint is intended to eliminate for future generations a problem that has caused considerable illness and even death in the present and past generations. The use of lead, a poisonous substance, in paint is a problem because when paint chips off walls or household items, some small and curious children are inclined to eat it. This can cause brain damage and death if the paint contains substantial amounts of lead. The FDA proposal would restrict lead in paint to trace amounts.

The proposed hexachlorophene policy involves restrictions on an antibacterial chemical that has been widely used for more than 20 years with no apparent ill effects. Recent scientific evidence, however, indicates that hexachlorophene, when used improperly or indiscriminately, can cause brain damage in animals. FDA thus has proposed that the use of hexachlorophene be eliminated from cosmetics and that its use be restricted in a wide variety of human products, for safety's sake. FDA's goal is to eliminate frivolous uses of this antibacterial and to tighten controls over those uses considered necessary by health experts.

Also in the interest of public safety, FDA has published performance standards for diagnostic and therapeutic x rays. The standards were promulgated under the 1968 Radiation Control for Health and Safety Act. They are intended to improve the handling and design of equipment, and to make technicians and professionals more discriminating in the use of x rays. Again, the idea is to protect the public from hidden dangers implicit in the possibilities for misuse, overuse, or outright abuse of some of our technological advances. A recent report developed by FDA showed that while the use of x rays has increased in recent years, the exposure of radiation that can affect man's genes has decreased.

FDA's evaluation of a large number of chemicals added to foods and previously regarded by experts as "safe" is unprecedented in scope and impact. The need for this program became clear after FDA banned the artificial sweetener cyclamate because it was shown to cause cancer in laboratory test animals. More than 600 chemicals which over the years have been generally recognized as safe for use as food additives are being reevaluated to make sure they are safe by the standards of today's demanding consumer and by the test of modern technological measurement.

Another initiative taken by FDA in the interests of protecting the public involves proposed restrictions on a group of industrial chemicals known as PCB's

(polychlorinated biphenyls). This family of chemicals has been used for more than 40 years in a wide range of products from electrical transformers to carbon paper. Through industrial accidents and direct contamination, traces began to show up in the food supply. FDA has proposed regulations to eliminate all foreseeable sources of direct or accidental PCB contamination in foods, animal feeds, and packaging material. FDA specifically has acted to keep PCB's out of recycled paper used in food packaging.

In the inspection area, FDA recently ordered an intensified program to eliminate insanitary conditions in the Nation's 60,000 food plants. During a recent three-month period, FDA inspected 550 food plants.

To help protect children from unsafe products, FDA has stepped up its inspection of plants that make children's products, from toys to furniture. In the last fiscal year, FDA inspected more than 600 such plants, double the number inspected the previous year. As of July 1972, FDA has banned 800 toy products judged to be hazardous under the 1968 Child Protection and Toy Safety Act. The Agency has undertaken 14 seizures of 14,000 individual toys whose manufacturers were unable or unwilling to recall them voluntarily. Thus far, three million individual toys have been banned from the U.S. market under FDA directives.

Consumer demands for safer products also have led FDA to require that eyeglasses contain treated lenses capable of withstanding severe impacts, a requirement intended to eliminate accidental injuries suffered each year by persons wearing fragile eyeglasses. The Agency also has developed a voluntary program with the cosmetic industry whereby manufacturers may provide ingredient information and adverse reaction complaints to FDA. This program ultimately should lead to safer cosmetics.

In the drug safety area, FDA undertook a major study of the use of antibiotics in animals. It looked into the possibility that human health may be affected by the possible buildup of bacterial immunity to antibiotics when used in animals. The Agency is now implementing a program to make sure that antibiotics remain useful in the fight against human disease through proposed restrictions on their use in food animals.

Still another action taken by FDA to provide greater assurances of safe drugs involves the Drug Efficacy Study in which 4,000 prescription drugs have been evaluated for effectiveness and accurate labeling. This project is one of the most important ones ever undertaken to improve drug therapy in the United States. FDA has removed several widely used but ineffective drugs from the market, and has demanded more accurate labeling for many others.

(continued)

The initial phase is now nearing completion.

Larger Role

The third demand by consumers is that they have a voice in the deliberations of their Federal Government. To meet this demand, FDA has proposed what it believes to be the most far-reaching policy of any Government agency with respect to access of the public to documents. Under the policy, large numbers of documents in FDA's files would be made available to the public. This will enable consumers to monitor more closely FDA's major decisions.

The policy represents an attempt by the Agency to encourage citizen participation in FDA affairs. Bona fide trade secrets will remain confidential, but fewer facts will be kept secret solely at FDA's discretion.

Also in the information area, FDA has begun the development of several systems that would provide more data to the Agency so that it can base its regulatory decisions to a greater extent on consumer-related experiences. For example, FDA has developed a National Electronic Injury Surveillance System connected to 119 hospital emergency wards across the country. The data from this system will be used to determine which products are causing the most injuries, either by faulty design or consumer misuse. This information is used by FDA and industry to eliminate product defects and to alert consumers on safe use of household products. The Agency also is developing a system to provide it with more adverse experience reports on drug use. This will enable FDA to assure safer and more effective medicines.

Perhaps the most significant information resource established in the past months has been the National Center for Toxicological Research in Pine Bluff, Arkansas. This Center is administered by FDA. Long-term tests on chemicals will be conducted to provide FDA and other Government agencies with additional scientific data. More than 5,000 animals are already involved in tests.

Also in the information area, FDA coordinates some 580 Poison Control Centers all over the country which can provide consumers and health professionals with immediate information in the case of accidental poisonings. This system is now being computerized in five large cities.

To communicate important information to consumers and others interested in FDA decisions, the Agency has begun to establish a communications network. An extensive program has been launched to educate the public about the dangers of misusing the products regulated by FDA. As part of this education effort, FDA has refocused its official monthly magazine toward an exclusively consumer-oriented audience. This magazine has been renamed FDA CONSUMER.

To communicate more effectively with the medical profession, pharmacists, and other health professionals, FDA has started a *Drug Bulletin* which provides them with important recent information. This information can be translated into better health care by professionals. With a circulation of 600,000, the *Drug Bulletin* is the most widely distributed publication reaching physicians and health professionals.

The Agency also has expanded the introductory part of its official *Federal Register* documents to make clearer to consumer leaders the basis for its decisions. And to bring the consumer even more into the regulatory picture, FDA recently began a program with consumer groups to improve surveillance of the toy market. The Agency has given its support to and has helped organize a "citizen army" to search out unsafe toys in retail stores. Pilot programs have been established in four cities. Under the program the consumer groups will be armed with information compiled by FDA on banned and potentially hazardous toys. This program, if successful, can be extended to other products.

FDA Responds

All these programs—for more honest labeling, safer products, and a larger voice for the consumer—represent FDA's response to what it sees as the demands and higher expectations of consumers. These programs are designed with one intention—to provide American consumers with the protection in the marketplace they have reason to expect in this modern age.

As Charles C. Edwards, M.D., Commissioner of Food and Drugs, said recently: "Throughout the FDA it is our daily business to recognize and to respond to higher consumer values—and where we can and should, to shape those values through communication as well as regulation. . . . In my judgment, the many major actions we have taken are responsible actions, aimed at reasonable regulation and at restoration of public confidence in both industry and Government."

Much, of course, remains to be done. Labels today are not always adequate, despite Federal actions. All products are not "safe" by today's standards. And the Federal Government is not always as responsive as it could be.

But in the past few years much has been accomplished in affording the consumer greater protection in the marketplace. And with the consumer demanding more every day, it is not unreasonable to expect that in the future he will receive it—in an amount and kind that will cause these decades in our history to become known as The Age of the Consumer.

Wayne L. Pines is editor of FDA CONSUMER.

news highlights



FDA Bans DES As Growth Stimulant In Animals; New Scientific Data

FDA has ordered an end to the use of diethylstilbestrol (DES) as a growth stimulant in animal feeds.

Charles C. Edwards, M.D., Commissioner of Food and Drugs, said: "New scientific data developed by the U.S. Department of Agriculture and received by my office on July 28, 1972, casts serious doubt on our ability to set rules for the use of DES in animal feed that will insure against residues remaining in animal livers at time of slaughter.

"The Delaney amendment of the Food, Drug, and Cosmetic Act explicitly forbids any such residues. Since regulatory requirements of the law cannot be met we have no choice but to discontinue approval for use of the chemical in animal feed," he said.

All production of DES for use in feeds has been stopped.

Dr. Edwards emphasized that the withdrawal order is an administrative action dictated by strict provisions of law which govern the use of products, such as DES, which have been shown to induce cancer in test animals. He pointed out that levels found in livers of animals were far lower than those used in tests, and

The subject of DES was discussed at a public meeting of FDA's National Drug Advisory Council July 25. It was the first FDA advisory committee that was open to the public. In the future, all such meetings will be open to the public, under an order from President Nixon on June 7.

that the action was not based on any known hazard to human health.

DES has been used in the feed of cattle and sheep for nearly two decades, without a single known instance of human harm.

"Therefore," said the Commissioner, "in order to avoid an abrupt disruption in the production of the Nation's meat supply, the FDA will permit existing stocks of DES for feed to be used until January 1, 1973.

"This will permit an orderly phase-out and will provide the animal feeding industry an opportunity to switch to implants or to other methods of meat production," said Dr. Edwards.

The final withdrawal decision was predicated on new scientific evidence developed by the USDA's Agricultural Research Service. This new study used an extremely sensitive radioactive tracer technique and showed that detectable residues could occur in cattle livers, even after withdrawal for seven days in con-

formance with current regulations. Prior to this experiment, all available tests had shown no measurable traces of DES in animal livers 48 hours after withdrawal.

On this basis, Dr. Edwards said, "We can only conclude that the animal feeding and pharmaceutical industries are unable at this time to suggest restrictions that are reasonably certain to be followed in practice and will at the same time eliminate all possibility of detectable residues. A hearing, therefore, would serve no useful purpose."

Use of DES as implants will continue to be allowed, pending results of tests now underway by the USDA. It has never detected a residue when implants were used as the sole source of DES. Implants have been shown to be approximately as effective as DES in feed, even though used at a dosage level at least 30 times lower than that used in feed.

(For background on DES, see FDA CONSUMER, July-August 1972, which contains an interview with Dr. C. D. VanHouweling, director of FDA's Bureau of Veterinary Medicine.)

Two FDA Actions Expected to Lead to Decrease in Post-Transfusion Hepatitis

A significant decrease in post-transfusion hepatitis, a disease which causes 1,500 to 3,000 deaths annually in this country, is expected to result from two actions by the FDA's Bureau of Biologics.

The first action, which took effect July 1, is a requirement that all federally licensed blood banks must test each donor for the presence in his blood of the hepatitis antigen (the so-called HAA factor). Only if the donor's blood tests negative can it be accepted for transfusion. About 85 percent of blood collections in the United States are through federally licensed facilities.

The second action, announced in the *Federal Register* July 28, is FDA licensure of a new hepatitis test procedure far more effective than the tests now available. The new test was developed and introduced by Abbott Laboratories, Chicago.

In announcing the licensing of Abbott's new test, Bureau of Biologics Director Harry M. Meyer, Jr., said: "It is apparent that the use of this new technique, extensively tested by the Bureau, will significantly increase the detection of units of blood harboring the hepatitis virus."

Previously licensed tests have been capable of detecting only 20-25 percent of the bloods implicated in causing post-transfusion hepatitis.

Child-Resistant Packaging Exemptions Proposed for Some Drug Products

FDA has proposed that certain aspirin preparations and some "abuse" drugs be exempt from standards requiring special "child-resistant" packaging. A second

proposal would exempt certain aspirin-containing effervescent tablets from standards requiring safety packaging for aspirin products.

The first proposal would exempt human drugs in dosage form not intended to be taken orally and all drugs for veterinary use. The nonoral dosage form drugs would include suppositories, ampules, aerosols, and ointments which contain aspirin or "abuse" drugs.

FDA has promulgated regulations under the Poison Prevention Packaging Act of 1970 requiring special packaging for aspirin preparations. They became effective August 14. Special packaging for all drugs listed under the Comprehensive Drug Abuse Prevention and Control Act of 1970 is required as of October 24. The proposals would amend those standards to exclude the two categories.

The first proposal is being published in response to petitions from manufacturers on the basis of lack of injury data for nonoral dosage forms. Exemption for veterinary drugs is based on difference in dosage unit sizes, distribution, and usage patterns as related to human drugs. FDA's Bureau of Product Safety and Bureau of Veterinary Medicine will evaluate the need for safety and Bureau of Veterinary Medicine will evaluate the need for safety packaging of animal drugs and publish separate standards at a later date.

The second proposal was published in response to a petition by an aspirin manufacturer, who contends that children are deterred from accidental ingestions of these products because of their effervescent properties.

Tepper Succeeds Lindsay As Associate Commissioner for Science

The appointment of Dr. Lloyd B. Tepper as Associate Commissioner for Science has been announced by Charles C. Edwards, M.D., Commissioner of Food and Drugs. Dr. Tepper succeeds Dr. Dale R. Lindsay, who is now Associate Director of Medical and Allied Health Education at Duke University Medical Center. Dr. Tepper will coordinate the scientific effort underlying FDA's regulatory role in consumer protection.

Dr. Tepper comes from the University of Cincinnati Medical School where he was Professor of Environmental Health. He also served as Associate Director of the Kettering Laboratories, established to do research on lead in fuels and their effect on health and the environment.

Widely known as a specialist in occupational health, Dr. Tepper has specialized in the effects of heavy metals such as lead and beryllium on man. Before joining the University of Cincinnati, Dr. Tepper was a physician with the Division of Operational Safety, Atomic Energy Commission.

Dr. Tepper received his medical degree from Harvard in 1957. He attended Harvard as an Atomic Energy Commission Fellow in Industrial Medicine, where he also took the degrees, Master of Industrial Health in 1960 and Doctor of Science in 1962.

CONSUMERS HELP FDA LOOK FOR BANNED TOYS

FDA has enlisted the assistance of volunteer consumer groups in its campaign to protect the public from dangerous toys. The pilot program is operating in Chicago, Seattle, and Atlanta, and plans are underway to include several other cities during the pilot phase. Volunteers, acting as "consumer deputies," visit a retail establishment in their areas looking for toys that have been banned by FDA. The deputies have no legal authority and can only point out to the store manager that he is offering a banned toy for sale. If the store manager refuses to remove the toy from his shelves, the consumer deputy can report back to the FDA District office, where an official inspector begins an investigation. The consumer deputy program represents a means by which local consumers can work with local businessmen to provide increased protection and safety by supplementing FDA's inspection capabilities.



FDA's new consumer deputy program kicked off in Chicago July 17 in the Chicago District office with four women deputies representing the Illinois Home Economics Association's Homemaking Sections. The deputies will canvass Chicago area toy stores and retail outlets to find unsafe toys which have been banned by the Agency. Clockwise around the table from left are Marcia Pauly, Park

Forest, Ill.; Mrs. John Page, Mount Prospect, Ill.; Dorothy Gregory, Palatine, Ill.; Meribeth Tooke, LaGrange Park, Ill.; FDA Consumer Specialist Marguerite Robinson; Chicago District Deputy Regional Food and Drug Director William R. Clark; Fred Halverson of FDA's Bureau of Product Safety; Richard Silverman of FDA's Office of General Counsel, and Donald Coleman, FDA program analyst.



Seattle Consumer Specialist Joan Bergy (left) instructs three new consumer deputies in their duties after the program was launched in Seattle July 20.

The deputies, who are all mothers or about-to-be mothers, are from left Martha Thornock, Mary Ellen Grimes, and Andrea Mangold.

FDA Requires New Labeling for Laundry and Cleaning Products

Manufacturers of 25 household laundry and cleaning products have been required to revise or add cautionary labeling during the past year.

Adequate cautionary labeling on such products is required by the Federal Hazardous Substances Act

to warn against possible eye and skin irritation and injury from ingestion.

Since June 28, 1971, FDA has tested 38 household laundry and cleaning products. Of these, 25 were found to need revised or additional labeling. The manufacturers

have been advised and have either accomplished or are in the process of making these changes.

FDA has now tested a total of 77 household laundry and cleaning products and required new labeling or additional warnings on 50.

The following are the 25 products for which FDA has required additional or revised labeling during the past year:

1. **Cure Detergent**
Malco Products, Barberton, Ohio
no phosphate
requires label No. 4
2. **Cal-Met Detergent**
N. B. Purdy, Wauconda, Ill.
no phosphate
requires label No. 4
3. **Imperial Detergent**
Imperial Detergent, Corona, Calif.
no phosphate
requires label No. 4
4. **Stop and Shop Hi-Power Blue Det.**
Witco Chemical, Paterson, N.J.
no phosphate
requires label No. 4
5. **Staff All Purpose White Det.**
Staff Supermarkets, Jericho, N.Y.
no phosphate
requires label No. 4
6. **Shop Rite New Blue**
Theobald Industries, Kearny, N.J.
contains phosphates
requires label No. 4
7. **Caleo Dishwashing Det.**
Fremont Industries, Shakopee, Minn.
no phosphate
requires special label (A)
8. **Fedcal Dishwashing Det.**
Coast Detergents, Los Angeles, Calif.
no phosphate
requires label No. 6
9. **Grand Union Detergent**
Ultra Chemical Co., Paterson, N.J.
no phosphate
requires label No. 4
10. **Purex Det.**
Purex Corporation, Lakewood, Calif.
no phosphate
requires special label (B)
11. **News Detergent**
Purex Corporation
no phosphate
requires special label (C)
12. **Laundry Prep**
Douglas Research & Chemical Co., Fraser, Mich.
no phosphate
requires special label (D)
13. **White King Detergent**
White King, Inc., Los Angeles, Calif.
contains phosphates
requires label No. 2
14. **Super Saver Detergent**
Witco Chemical Co.
no phosphates
requires label No. 4
15. **De Laval Detergent**
Bonevitz Chemical Co., Burlington, Iowa
contains phosphates
requires label No. 4
16. **CP-30 Detergent**
Associated Chemists, Portland, Oreg.
no phosphate
requires label No. 4
17. **GHD Formula 300 Papillon Dishwashing Det.**
GHZ Enterprises, Buffalo, N.Y.
no phosphate
requires label No. 3
18. **Parade Detergent**
Stanson Detergent Co., Teaneck, N.J.
no phosphate
requires special label (E)
19. **Spic & Span Cleaner**
Procter & Gamble, Cincinnati, Ohio
contains phosphates
requires special label (F)
20. **Modway Dishwashing Det.**
Pequa Industries, Massapequa, N.Y.
contains phosphates
requires special label (G)
21. **Cascade Dishwashing Det.**
Procter & Gamble
contains phosphates
requires label No. 2
22. **Sweetheart Lime Dishwashing Det.**
Purex Corporation
no phosphate
requires label No. 4
23. **Ajax**
Colgate-Palmolive, New York, N.Y.
contains phosphates
requires label No. 3
24. **HLD Detergent**
Chemical Associations, Inc., Houston, Tex.
no phosphate
requires label No. 4
25. **Clorox II Bleach**
Clorox Co., Oakland, Calif.
no phosphate
requires label No. 3

Labels 2, 3, 4, and 6 to be used for products as indicated. Standard labels 1 and 5 are not required for any of these products, and hence are not indicated here.

2. Detergents that are toxic and are eye irritants:

**CAUTION: HARMFUL IF SWALLOWED
EYE IRRITANT**

Contains _____ *

If swallowed give water or milk.

In case of eye contact, flush with water.

Call a physician.

Keep out of the reach of children.

3. Detergents that are moderate eye irritants:

CAUTION: EYE IRRITANT

Contains _____ *

Avoid contact with eyes.

In case of eye contact, flush with water for 15 minutes and get medical attention.

Keep out of the reach of children.

4. Detergents that are toxic and severe eye irritants:

**WARNING: INJURIOUS TO EYES
HARMFUL IF SWALLOWED**

Contains _____ *

Avoid contact with eyes and mucous membranes and prolonged skin contact.

For eye contact, flush with water for 15 minutes. Get prompt medical attention.

If swallowed, give large quantities of water or milk.

Call a physician.

Keep out of the reach of children.

6. Detergents that are toxic and corrosive to tissue:

**DANGER: MAY CAUSE BURNS
TO SKIN AND EYES
HARMFUL IF SWALLOWED**

Contains _____ *

Avoid contact with skin, eyes, and mucous membranes.

In case of external contact, flush with water.

For eyes, flush with water for 15 minutes and get immediate medical attention.

If swallowed, give large quantities of water or milk.

Call physician immediately.

Keep out of the reach of children.

* Insert name of component or components that contribute substantially to the hazard.

Special statements A, B, C, D, E, F, and G to be used as indicated:

- A "CAUTION: EYE AND SKIN IRRITANT

Contains _____ *

Avoid contact with eyes and prolonged contact with skin.

For eye contact, flush with water for 15 minutes and get medical attention.

In case of external contact, flush with water.

Keep out of the reach of children."

(*) Insert name of component or components which contribute substantially to the hazard.

- B and C "May be harmful if swallowed" be added to the front panel of both of these packages.

- D No objection to the cautionary labeling printed on the package except for the fact that the statements of hazard "Severe irritant. Harmful if swallowed" are printed in lower case letters. These statements must be printed in capital letters.

- E The type size of the statements of hazard "MAY IRRITATE EYES HARMFUL IF SWALLOWED" should be increased to 12 point type as required by the regulations.

- F "DANGER: INJURIOUS TO EYES In case of eye contact, flush with water for 15 minutes. Get prompt medical attention. Keep out of the reach of children."

- G The following statements should be included on the front panel when the bottle is reprinted: "WARNING: INJURIOUS TO EYES HARMFUL IF SWALLOWED Read precautions on side panel."

The following 13 products were found to be adequately labeled or to require no labeling:

1. **Giant Low Phosphate**
*Giant Supermarkets
Washington, D.C.*
2. **Finish Dishwashing Det.**
*Economic Laboratories
St. Paul, Minn.*
3. **Electrosol Dishwashing Det.**
*Economic Laboratories
St. Paul, Minn.*
4. **Bold Det.**
Procter & Gamble
5. **Lady Elizabeth Det.**
*Chemithon Corporation
Seattle, Wash.*
6. **C-20 Detergent**
*Mt. Hood Chemical
Portland, Oreg.*
7. **Punch Detergent**
Colgate-Palmolive Company
8. **Duz Detergent**
Procter & Gamble
9. **Fels Naptha Det.**
Purex Corporation
10. **Octagon Det.**
Colgate-Palmolive Company
11. **Cook's Pure Laundry Det.**
*Cook Coffee Company
Maple Heights, Ohio*
12. **GHD Formula 200**
*GHZ Enterprises
Buffalo, N.Y.*
13. **Crystal Clear Dishwashing Det. (As repackaged)**
Colgate-Palmolive Company

regional reports

ATLANTA Shelby Wholesale Grocery Co., Hattiesburg, Mississippi, and Clarence J. Domergue, warehouse manager and partner, pleaded guilty before a magistrate at Jackson, Mississippi, to a charge of causing food received in interstate commerce to become adulterated while held in a rodent-infested warehouse. The firm was fined \$150 on each of three counts and placed on three years reporting probation. Mr. Domergue was fined \$50 on each of three counts and placed on two years reporting probation. The remaining four counts of the seven count information were set aside pending probation.

BALTIMORE A shipment of frozen shrimp was involved in an accident while in transit in Virginia. An inspector from the Virginia Department of Agriculture and Commerce supervised the salvage and destruction operation in Virginia and notified Baltimore District.

The portion of the lot determined fit because it remained frozen was transferred to another refrigerated van and moved into Maryland. The District office worked through the Maryland Health Department's Bureau of Consumer Health Protection to have the lot held by a Prince Georges' County official until FDA laboratory examination verified that there was no decomposition or bacteriological contamination. The lot was then released by the county for shipment to consignees in the Northeast.

BUFFALO Consolidated Midland Corp., Brewster, New York, has been fined \$1,500 for shipping Carbasone tablets that were not produced under good manufacturing practices and which are dangerous to health when used as prescribed in its labeling. The charges by the FDA involved one interstate shipment of a lot of the drug which had deteriorated from age, was repacked without checking, and was shipped interstate. The firm was fined for both the adulteration and the misbranding, \$750 on each count.

About \$8,000 worth of cyclamate sweetener and cyclamate sweetened products together with remaining stock of sodium cyclamate were destroyed in June under FDA supervision. A manufacturer of these artificially sweetened products in the Buffalo District had held the products in anticipation of FDA lifting its ban on cyclamates but gave in and buried them.

CINCINNATI A visit was made to the Shriner's Burns Hospital, Cincinnati, Ohio, by Warren Mathers, Bureau of Product Safety, and William H. Damaska, inspector, to discuss a cooperative contract concerning

reporting of injuries from flammable fabrics.

Cincinnati District has investigated reports from local Ohio authorities to the effect that roadside fireworks stands were selling Class B fireworks to out-of-State customers to evade Ohio law. Several FDA purchases of these illegal Class B fireworks were made prior to July 4. The investigation is continuing.

The U.S. Department of Agriculture notified the District that its assay of a tissue specimen from a beef animal delivered to a Massillon, Ohio, slaughterhouse contained residues of diethylstilbestrol (DES). The District's investigation established that the grower had used both DES implant and feed containing DES. Both the USDA and Ohio Department of Agriculture veterinarians have been alerted and are monitoring feeding practices of the grower and the movement of his cattle to market.

DALLAS A new FDA exhibit developed by Dallas District consumer specialists has been used to extend consumer education to programs and areas where a specialist cannot be present. The exhibit was used at four significant meetings during June by the Office of Community Affairs and Planning, State of Oklahoma, and at a dietetic meeting in Dallas. Packets of informational materials are also provided for each participant at the meetings.

MINNEAPOLIS The District was informed by Pat Dewing of the "Action News" program on WCCO-TV in Minneapolis that a Woolworth store on the Nicollet Mall in downtown Minneapolis was selling Tanya suntan lotion marked with the same code numbers of a lot that was supposedly recalled earlier. An inspector was dispatched to the store and he found eight tubes and three jars of the Tanya suntan lotion with codes of a lot that earlier had been found contaminated with *Pseudomonas*. The material, distributed by Tanya Hawaii Corp., was promptly destroyed by the Woolworth buyer.

A nut processor in the Twin Cities voluntarily destroyed 6,800 pounds of sliced almonds on June 8. The product had an estimated retail value of \$13,000. Destruction was the result of analysis of a Minneapolis District surveillance sample which showed high levels of aflatoxin. The product destroyed was recalled by the nut firm from 306 retail accounts.

A Wisconsin manufacturer recently destroyed 2,066 cases of sauerkraut juice, valued at \$3,822, after sam-

ple analysis found obnoxious particles in the product and the net contents were found to be 2 percent short of the declared quantity. The action followed numerous consumer complaints about the product.

Roundy's, Inc., a grocery warehouse in Milwaukee, Wisconsin, was fined \$900 and the warehouse manager \$300 on June 16 for operating an insanitary warehouse. The charge against the president of the firm was dropped by the U.S. attorney, although at the sentencing the president commented to the court that he had hired the manager because of an awareness of the insanitary conditions under which the warehouse was operating.

NEW ORLEANS "FDA will get you if you don't watch out" was the word passed along in the retail fireworks trade during the July 4 holiday season. Many undercover buys were attempted in Louisiana by New Orleans District's Inspection Branch and only some were successful. A vigorous and successful campaign against sale of illegal Class B fireworks during the 1971 Christmas season resulted in many sellers telling FDA's undercover buyers this time that they are not selling Class B's because FDA has cracked down.

District import detentions for the month of June totaled about \$150,000. Some of the detentions were 224,000 pounds of green coffee beans worth \$89,900, for insect damage; frozen shrimp worth \$33,000, for decomposition; bamboo shrimp (a toy novelty item), worth \$1,200, that had poisonous jequirity beans for eyes; toys worth \$1,950, banned hazardous substances; canned mandarin oranges worth \$4,900, misbranded and damaged cans; olive oil worth \$1,500, misbranded under the Fair Packaging and Labeling Act and therapeutic claims; frozen whiting worth \$8,600, misbranded; bonemeal worth \$2,000, contaminated with *Salmonella*; and canned mushrooms worth \$5,100, for false and misleading claims.

NEW YORK The District participated along with other Federal agencies in a health and nutrition fair sponsored June 10 by the Head Start Program of the Paterson Task Force in New Jersey. The request for participation by Federal agency members of the Federal Executives Board came from the Chairman of the Paterson Consumer Affairs Committee, the organization that developed from the "Paterson Project."

Health and nutrition information booths, pamphlets, and films were provided. There were also nonprofit drawings, food concessions, and rides for the children. Kathy Kluser of the Federal Trade Commission demonstrated the dangers of banned toys and Sylvia Lindsey of the Veterans Administration distributed nutritional, both oral and written, guidance material. The U.S. Department of Agriculture and the State of New Jersey contributed colorful posters, and thousands of FDA fact sheets in English and Spanish were distributed in packets.

A current project of the Paterson Consumer Affairs

Committee is a directory of consumer services with a problem-oriented index in both English and Spanish. The directory owes a lot to the concepts found in the "Call for Action" directory compiled by radio station WMCA in New York and published by the New York Urban Coalition.

A long-range project of the Committee is to place additional consumer education material in the curriculum of the Paterson school system. For this purpose, the regional commissioner of the Office of Education, Robert Seitzer, is cooperating. The PCAC's Education Subcommittee is planning a series of seminars for target segments of the community such as businessmen, clergy, lawyers, and housewives.

Spanish/English consumer phone messages have now reached Mexico. The latest FDA messages, along with back issues and Spanish fact sheets on aspirin, O-T-C drugs and self-medication, were forwarded to Patrino De La Pena, Unidad Esperanza, Mexico.

FDA has awarded a contract to the National Board of the Young Women's Christian Association to undertake three youth-directed consumer education projects in Orange, New Jersey, Baltimore, Maryland, and Atlanta, Georgia. FDA consumer specialists from Atlanta and New York will participate in the workshop and subsequently, along with the Baltimore consumer specialist, provide technical assistance to the YWCA Youth Groups.

Life magazine photographed dishware at FDA in New York on June 22 for its "Consumer's Watch" feature. It is mostly pictures. Emphasis was on storage of acidic food, amateur pottery, etc.

PHILADELPHIA Lacy B. Ward, product safety consultant, sat on a consumer affairs panel at the West Chester State College School Community health education workshop on June 30. The panel was headed by Jean M. Devers, assistant to the regional director for consumer affairs, Region III, FDA.

Mr. Ward presented an overview of FDA's current activities involving the Hazardous Substances Act, Child Protection and Toy Safety Act, Flammable Fabrics Act, and Poison Prevention Packaging Act. He also exhibited examples of banned toys and other hazardous items. Some of the known regulatory findings of the Bureau were also discussed, provoking a number of questions and comments from the audience. The operations of the National Electronic Injury Surveillance Study program was of special interest to the club. The panel was part of a workshop presentation by the college's Department of Health and Physical Education for which college credit is granted. Others on the panel included Leonard Galloway, agent in charge, Pennsylvania Bureau of Consumer Protection, and Beth Karkut, associated with the "Mr. Fixit" column in the *Philadelphia Bulletin*. Other scheduled panelists were unable to appear because of commitments imposed by flood conditions in the State.

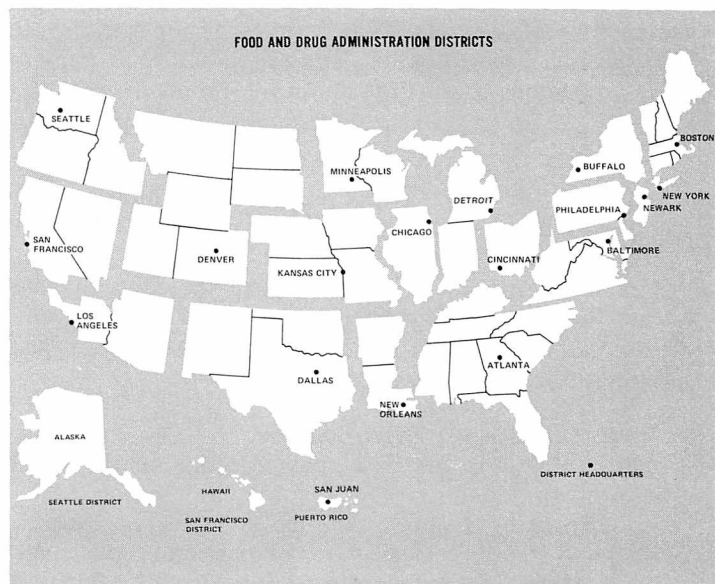
The Region III radiological health representative is currently spot-checking microwave oven dealers and distributors concerning Federal recording requirements.

Dealers are required to maintain the following information for the sale of each microwave oven manufactured under the performance standard since October 6, 1971: Name and mailing address of the dealer, the distributor, or the purchaser to whom the oven was transferred; name of manufacturer and brand name of oven; model number and serial number or other identification number of the oven; and date of sale, lease, or award. This information must be retained five years from the date of sale, award, or lease of an oven.

SAN FRANCISCO A Federal Government motion for preliminary injunction of a California packer of canned fruit cocktail was filed in the Northern District of California, San Francisco, on June 5, alleging the product had been packed under insanitary conditions and contained machinery mold. The hearing on this injunction had been postponed several times by stipulation with an agreement that the firm would not ship the product, packed during the 1971 season, until the hearing is held.

The District detained 62 commercial lots offered for entry during the month of June. A lot of frozen rock lobster tails shipped from the Philippines and valued at \$6,000 was detained because of decomposition.

SEATTLE Seizure of 568 battery-powered Apollo Mini Cars imported from Chenfuh Toys Manufacturing Co., Ltd., Taiwan, Republic of China, took place



June 22. The toys were labeled in part, "Kids love riding on these supertoys." They are electric automobiles accompanied by a plastic bottle containing a quantity of sulfuric acid to be used to activate the car's battery. The Mini Cars are banned hazardous substances within the meaning of the Federal Hazardous Substances Act, since examination disclosed that the activated battery leaks under reasonably foreseeable conditions of storage or use. The Mini Cars were imported by Universal Specialties, Boise, Idaho, through Portland, Oregon. Prior to the seizure action, approximately 30 cars had been marketed during the 1971 Christmas shopping period.

FDA REGIONAL AND DISTRICT OFFICES

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

BALTIMORE 900 Madison Ave.
Baltimore, Md. 21201

BOSTON 585 Commercial St.
Boston, Mass. 02109

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

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

CINCINNATI 1141 Central Pkwy.
Cincinnati, Ohio 45202

DALLAS 3032 Bryan St.
Dallas, Tex. 75204

DENVER New Customhouse Bldg.
Rm. 513/20th & California Sts.
Denver, Colo. 80202

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

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

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

MINNEAPOLIS 240 Hennepin Ave.
Minneapolis, Minn. 55401

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

NEW YORK 850 3rd Ave.
Brooklyn, N.Y. 11232

NEWARK Rm. 831, 970 Broad St.
Newark, N.J. 07102

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

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

SAN JUAN P.O. Box 4427
San Juan Station, P.R. 00905

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

HEW REGIONAL OFFICES I-X

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

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

PHILADELPHIA 401 North Broad St.
Philadelphia, Pa. 19108

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

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

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

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

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

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

SEATTLE Arcade Plaza Bldg.
1321 2nd Ave., Seattle, Wash. 98101

state actions

New York Settlements The New York Department of Agriculture and Markets announced in June that more than 150 cases involving alleged violations of the State's pure food laws were settled during May by the department. Penalties paid in the 154 compromise administrative settlements amounted to \$12,400. An additional 70 cases were referred to the State's Attorney General for settlement because no compromise was reached.

Fined for Insanitation The Texas Department of Health, Division of Food and Drugs, recently filed a case against James R. Hollis, owner of Brazos Poultry and Produce, Bryan, Texas, for selling food which had been held under insanitary conditions. Mr. Hollis was fined \$200 plus costs and sentenced to 15 days confinement on May 24. The confinement was probated.

State Milk Rater The FDA Milk and Food Program's Special Program Branch of Region III has completed the certification of Mrs. Margaret Bush as a State Food Service Sanitation Rating Officer for the State of Maryland. This certification is a new milestone within the Special Program Branch in that Mrs. Bush becomes the first woman in the United States to be certified by FDA as a State food service sanitation rating officer.

Idaho Food Standards At the invitation of Idaho health officials, James Shoemake, regional milk and food consultant with FDA's Seattle Field Office, attended a meeting June 23 concerning a State proposal to adopt food standards for selected retail food commodities. Idaho officials recently concluded a food sampling survey consisting of a bacteriological analysis

of 973 retail food samples which they analyzed for standard plate count, coliform, and staphylococcus organisms. The sampling survey results were discussed, and the officials concluded that they would prepare a rough draft of the study for further consideration with the ultimate objective of developing and adopting bacteriological standards for some retail foods.

Ohio Consumer Center The Ohio Department of Agriculture opened its Consumer Information Center at Columbus in June, Gene R. Abercrombie, Ohio director of agriculture, has announced. It is headed by Mark R. List, consumer information specialist. Persons wanting to call the Center can reach Mr. List by telephone at (614) 469-8383. They can call this number at any time, day or night. Mr. List's appointment to the post was announced by Governor John J. Gilligan.

Ingredients Statement A proposed regulation that all packaged commodities sold in Ohio be accurately labeled has been made by the Ohio Department of Agriculture. The label would show the nature of the product sold, the accurate amount, and the identity of the manufacturer, packer, or distributor. Most food products would also be required to show a statement of ingredients. Enforcement of the regulation if adopted would be the responsibility of the department's Divisions of Foods, Dairies and Drugs, and Weights and Measures.

Organic and Natural Oregon's Department of Agriculture has scheduled public hearings on its proposed regulations to establish definitions and standards of identity for organic and natural foods.

Irvin Mann, Jr., State agriculture director, said organic and natural food stores have increased to the point where they are an integral part of food marketing and this appears to make it necessary for special standards for them to operate and to be inspected under State food laws. He said store owners and their customers must be able to depend on statements that their products are "organic" or "natural," since State law requires that retail food products be truthfully labeled and advertised. The law is impossible to enforce without basic standards of identification and definitions, he said. The hearings were scheduled August 24 in Eugene and September 15 in Portland.

How to Stop a Turtle Live turtles are slow movers and they're going to stop altogether in Oregon, at least their shipment, unless the shipment is accompanied by a certificate that they're free of *Salmonella*. The certificate, required after July 1, must be issued by the chief livestock health official of the State of origin after laboratory analysis shows that at least six turtles in each lot are *Salmonella*-free in four examinations over a period of several days.

The Oregon Department of Agriculture regulations were written to protect State citizens against *Salmonella*. Dr. E. L. Henkel, department supervisor of disease control, noted that there are some 250 reported cases of salmonellosis a year in his State and that about 14 percent of these have been traced to turtles. The department said recent studies show that there are up to 300,000 cases of turtle-borne cases of salmonellosis each year in the United States, primarily among children who have handled pet turtles.

seizures & postal service cases

SEIZURE ACTIONS charging violation of the Federal Food, Drug, and Cosmetic Act and the Federal Hazardous Substances Act are published when they are reported by the FDA District Office.

A total of 26 actions to remove from the consumer market products charged to be violative was reported in June. These included 11 seizures of foods: 2 involved charges concerning poisonous and deleterious substances, 2 involved charges concerning contamination,

and 7 involved charges concerning economic and labeling violations. Other seizures included 1 of food additives, 2 of dietary food, 9 of drugs (including 5 of veterinary and medicated feed), 1 of cosmetics, and 2 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD / Poisonous and Deleterious Substances		
Ladyfish, frozen/San Francisco, Calif. 5/16/72	A. A. Richards & Co./Mobile, Ala. (M,S)	Contains mercury, an added poisonous and deleterious substance.
Meat and bone meal/Bonnors Ferry, Idaho 5/2/72	Spokane Rendering Co./Spokane, Wash. (M,S)	Contains Salmonella micro-organisms.
Contamination, Spoilage, Insanitary Handling		
Breeding mix/Los Angeles, Calif. 5/9/72	Central Fish and Oyster Co./Los Angeles, Calif. (D)	Held under insanitary conditions; rodent contaminated.
Shrimp, frozen, Campeche Bay brand/ Chicago, Ill. 5/25/72	Congeladora Y Empacadora De Mariscos/ Campeche, Camp., Mexico (P)	Contain a decomposed substance.
Economic and Labeling Violations		
Cherry ice, Italian ices/Columbus, Ohio 5/16/72	Mazzone Enterprises, Inc./Cicero, Ill. (M,S)	Below standard of identity for water ices, since articles contain less than 0.35 percent of lactic acid; not in conformity with the Fair Packaging and Labeling Act.
Fish cakes, frozen/Boston, Mass. 5/24/72	Sea Pass Corp., Div. Vita Food Products/ St. Louis, Mo. (M,S)	Not in conformity with the Fair Packaging and Labeling Act.
Macaroni, Pasta Zara/Buffalo, N.Y. 5/8/72	Silton Importing Co., Ltd./Concord, Ont., Canada (S)	
Milk, dry, whole/Denver, Colo. 5/9/72	Double D Foods/Industry, Calif. (M)	Label fails to bear name and place of business of manufacturer, packer, or distributor; no accurate statement of the quantity of content on packages; cans failed to bear labels with the common or usual name of the food.
Pickles, canned/Des Moines, Iowa 5/22/72	Hamilton & Sons Canning Co., d/b/a Foods, Inc./New London, Wis. (M,S)	Not in conformity with the Fair Packaging and Labeling Act.
Sexton citrus salad/Forest Park, Ga. 5/11/72	John Sexton Co./Forest Park, Ga. (D)	Label fails to bear common or usual name of the food and of each ingredient.
Taco shells/Denver, Colo. 6/5/72	Rosarita Mexican Foods Co., Div. of Beatrice Foods Co./Mesa, Ariz. (M,S)	Not in conformity with the Fair Packaging and Labeling Act.
Food Additive		
Sunshine Krispy Saltines/Sayreville, N.J. 5/4/72	Sunshine Biscuits, Inc./Dayton, Ohio (M,S)	Contain Ronnel, an unsafe food additive.
Vitamins—Dietary Food		
Inland sea water/Franklin Park, Ill. 5/5/72	TM Research Labs, Inc./Hooper, Utah (M,S)	False and misleading claims to be of special dietary value due to 42 specified minerals; quantity of contents declaration not separated from other lettering, and type size too small.
TM-42 Concen-Trace, low sodium TM-42 Concen-Trace/Portland, Oreg. 5/1/72	Marine Minerals, Inc./Hooper, Utah (M,S)	Not in conformity with the Fair Packaging and Labeling Act.
DRUGS / Human Use		
Citrate of Magnesia/Detroit, Mich. 5/23/72	National Wholesale Drug Co./Detroit, Mich. (D)	Not in conformity with good manufacturing practice; lacks directions for use.
L-Caine 1% brand of Lidocaine hydrochloride, #M5937, 50 ml. size; #M2832, 20 ml. size; bacteriostatic sodium chloride injection, #M42858, 30 ml. size/Indianapolis, Ind. 5/9/72	Maizel Labs/Chicago, Ill. (M); Maizel Labs., Div. Myers-Carter Labs./ Chicago, Ill. (S)	Not in conformity with good manufacturing practice.
Special Formula 3039/Detroit, Mich. 6/6/72	R. N. Tassie, M.D./Detroit, Mich. (D)	
Tidy nursery toys (soother beads)/ Seattle, Wash. 5/11/72	Tidy Ties Corp./Monroe, La. (M,S)	Below purported quality and purity; beads contain nonsterile fluid with yeast, mold, and other viable micro-organisms.
Veterinary / Medicated Feed		
Furafac suspension Furazolidone 150 mg/cc/Christiansted, St. Croix, V.I. 5/31/72	Caribe Chemical Co., Inc./Christiansted, St. Croix, V.I. (D)	New animal drug without effective New Animal Drug Application.
Ideal calf booster rumen bolus, Ideal cattle booster bolus (dietary supplement)/ Nampa, Idaho 6/1/72	Ideal Laboratory/Modesto, Calif. (M,S)	“; false and misleading claims to stimulate and promote faster rumination in calves (calf booster rumen bolus); as an aid in the treatment of ketosis and milk fever and to stimulate rumen activity (cattle booster bolus).

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Veterinary / Medicated Feed (cont'd)		
Kleen-Kure triple sulfa bolus, Kleen-Kure Kalf Kaps/Milwaukee, Wis. 5/31/72	Masti-Kure Products Co., Inc./Norwich, Conn. (M,S)	New animal drugs without effective New Animal Drug Application; inadequate directions for use; false and misleading claims.
Medicated feed, dry/Omaha, Nebr. 5/25/72	Cargill Nutrena Feed Division/Sioux City, Iowa (M)	New animal drug without effective New Animal Drug Application; contains DES (diethylstilbestrol) and melengestrol acetate; not in conformity with good manufacturing practice.
Protein supplement, liquid/Lewiston, Utah 5/31/72	Feed Service, Inc./Idaho Falls, Idaho (M,S)	New animal feed without effective New Animal Drug Application; contains diethylstilbestrol; inadequate directions for use; inadequate warnings to discontinue feed use 7 days before slaughter and not to feed to breeding or dairy animals.
COSMETIC		
Conditioning egg shampoo/Oklahoma City, Okla. 5/22/72	Trylon Products Corp./Chicago, Ill. (M,S)	False and misleading claims; not in conformity with the Fair Packaging and Labeling Act.
HAZARDOUS SUBSTANCES		
Color-Kote preserver/Denver, Colo. 5/30/72	G.H.Q. Sports Products/Yucaipa, Calif. (M,S)	Not in conformity with the Poison Prevention Packaging Act.
Hasbro wing darts/Marlow Heights, Md. 5/5/72	L & H Sales Co., Inc./Marlow Heights, Md. (D)	Sharp pointed toy with the potential for causing puncture wound injury; fails to bear required warning statements.

U.S. POSTAL SERVICE actions taken in medical cases as authorized in the Mail Fraud Statute (18 U.S.C. 1341) and/or the False Representation Statute (39 U.S.C. 3005) as reported by the Assistant Postmaster General—Inspection Service.

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

- March 24, 1972: False Representation Order issued against **Thornton**, 406 South 2nd Street, and **Thornton Lab**, 324 South First Street, Alhambra, California 91802. Advertising and sale by mail of products called "Hypnotic Pills" and "Mad Dog Weed," represented as effective sex stimulants.
- April 19, 1972: False Representation Order issued against **R H** at P.O. Box 239, Gary, Indiana 40401 (46401). Advertising and sale by mail of a product called "Mexican Spanish Fly in Liquid Form," represented to be effective as a sex stimulant.
- April 19, 1972: False Representation Order issued against **P.O. Box 239** and **P.O. Box 239, Dept. 7**, Gary, Indiana 40401 (46401). Advertising and sale by mail of a product called "Knock Out Drops," represented to be effective as a sex stimulant.
- May 4, 1972: False Representation Order issued against **Alan Distributing Co.**, 10917 Winner Road, Independence, Missouri 64052. Advertising and sale by mail of a product called "D-Alpha Tocopheryl Acetate," represented to be effective as a sex stimulant.
- May 12, 1972: False Representation Order issued against **Arthur David Wilbanks a/k/a Arthur David Pearce**, d/b/a **Andrews Associates**, at P.O. Box 13281, Station K, Atlanta, Georgia 30324, and **Wilbanks, Limited**, at P.O. Box 645, Mableton, Georgia 30059. Advertising and sale by mail of a formula represented as enabling users to grow chest hair.
- May 23, 1972: False Representation Order issued against **Grapefruit Diet**, 7046 Hollywood Boulevard and **P.O. Box 3689** at Hollywood, California 90028. Advertising and sale by mail of the Grapefruit Diet, which was represented to cause a weight loss of 10 pounds in 10 days and a continued loss of 1½ pounds every two days thereafter.
- May 25, 1972: False Representation Order issued against **Yvette**, 152 West 42nd Street, Suite 536, New York, New York 10036. Advertising and sale by mail of a product called "Beer or Cola Pills," represented to be effective as a sex stimulant.

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

- April 17, 1972: **Diversified Products Co.**, P.O. Box 7218, San Diego, California 92107. Advertising and sale by mail of "U.S. Women Ski Team Diet," represented to be a diet plan which will cause a loss of 20 pounds in 14 days.
- April 18, 1972: **Terzal**, Dept. F, Box 254, Crystal City, Missouri 63019. Advertising and sale by mail of a product called "Desk Sitters Diet," represented to be an effective diet for losing weight. Advertising and sale by mail of a product called "Secret Formula," represented as enabling users to lose up to four inches in girth in 90 minutes.
- April 25, 1972: **American Image Corp.**, 276 Park Avenue South, New York, New York 10010. Advertising and sale by mail of "Baby Face" Formula" to rejuvenate the facial appearance of female users and enable them to look up to 20 years younger in only two short months.
- April 28, 1972: **Branik Products Corp.**, 3401 N.W. 36th Street, Miami, Florida 33142. Advertising and sale by mail of a product represented to be effective as a sex stimulant.
- May 8, 1972: **Doyle Sales Corp.**, 3415 N.E. 2nd Avenue, Miami, Florida 33137. Advertising and sale by mail of a product called "Body Magic Cream," represented as a muscle developer.
- May 12, 1972: **Good Drugs**, P.O. Box 549, Oak Park, Illinois 60303 and **Good Pharmaceutical Co.**, Merchandise Mart Bldg., P.O. Box 3042, Chicago, Illinois. Advertising and sale by mail of two products called "Pep-Good" and "Stay-Good," represented to give users fast energy and alertness.
- May 17, 1972: **USAF Diet**, P.O. Box 752, Encino, California 91316. Advertising and sale by mail of the Air Force Diet, represented to be a diet plan which will cause a loss of 10 pounds in 10 days.
- May 24, 1972: **Vigor and Vitality**, 7008 S.W. 4th Street, Miami, Florida 33144. Advertising and sale by mail of a product called "La Fem Climax Cream," represented to be an effective sex stimulant for women.
- May 24, 1972: **Rand Surgical Supplies**, 7008 S.W. 4th Street, Miami, Florida 33144. Advertising and sale by mail of a product called "P.E.P.P.," represented to be an effective sex stimulant for men.
- May 24, 1972: **Sister Fannie Howard**, 6921 South Vernon, Chicago, Illinois. Advertising and sale by mail of a product called "Instant Love Potion," represented to be an effective sex stimulant.
- May 24, 1972: **Pan-American Medical Services**, Monterrey, Mexico. A petition for a Foreign Mail Stop Order has been filed for advertising and sale through the mails of a diagnostic service for treatment of arthritis, rheumatism, and heart conditions.
- May 25, 1972: **North American**, 537 South Dearborn Street, Chicago, Illinois 60605. Advertising and sale by mail of a method called "Slim-Pak Plan," advertised to be an effective weight-reducing plan.
- May 25, 1972: **American Image Corp.**, 276 Park Avenue South, New York, New York 10010. Advertising and sale by mail of "Conover Fashion Model Tablets," promising desired weight losses without strenuous exercise or starvation dieting.
- May 25, 1972: **Plazaplan Products**, 225 Lafayette Street, New York, New York 10012. Sale through the mail of a product called "SEVENTH VEIL," alleged to be a wrinkle remover.

notices of judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Animal feed, at Horsey, E. Dist. Va.

Charged 5-26-71: when shipped by Keystone Rendering Co., Inc., the article, labeled in part "By-Products Brand 50% Ground Meat & Bone Meal & FM . . . Manufactured for By-Products, Inc., Wilmington, Delaware," contained the added poisonous and deleterious substance *Salmonella*; 402(a)(1). Default decree ordered destruction. (1)

Bass fish, at Detroit, E. Dist. Mich.

Charged 5-12-71: when shipped by Sandusky Fisheries, Inc., Sandusky, Ohio, the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (2)

Bonita fish, frozen, two seizure actions at Seaside Heights, Dist. N.J.

Charged 5-13-71: when shipped by Blue Ribbon Fish Co., and Carter Fish Co., New York, N.Y., the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decrees ordered destruction. (3)

Corn for animal feed, four seizure actions at Lancaster, Dist. S.C.

Charged 3-23-71: when shipped by FCX Washington Warehouse Service, Washington, N.C., and unknown shippers in Georgia and North Carolina, the articles intended for use as animal feed, although labeled in part "Treated Seed Do Not Use For Food Feed or Oil Purposes," contained the added pesticide chemicals methoxychlor, dieldrin, and captan, and the methoxychlor and dieldrin were in excess of the prescribed tolerance and there was no tolerance or exemption therefrom for captan; 402(a)(2)(B). The articles were claimed by R. H. Collins Grain Co., Ralph J. Hunter, Buford Milling Co., Inc., and Dwight Mingo, Lancaster, S.C., who admitted to possession of the grain feed described in the complaints and stated that a sample had been examined by a university and found not to be harmful to either animals or human beings and determined to be fit for its intended usage as hay or swine feed. The Government served interrogatories on the claimants and moved for summary judgment. The court granted the Government's motions for summary judgment and ordered the articles destroyed. (4)

Corn for animal feed, at Laurinburg, M. Dist. N.C.

Charged 1-5-71 and amended 8-10-71: while held by McNair Seed Co., Inc., Laurinburg, N.C., the article contained the added pesticide chemicals methoxychlor, dieldrin, and captan for which there was no tolerance or exemption on grain for animal feed; 402(a)(2)(B). Consent decree ordered destruction. (5)

Cottonseed for animal feed, at Paramount, C. Dist. Calif.

Charged 5-11-71: while held for sale, the article contained the added poisonous and deleterious substance aflatoxin; 402(a)(1). Default decree ordered destruction. (6)

Cottonseed for animal feed, at San Marcos, S. Dist. Calif.

Charged 2-3-71: while held for sale, the article contained the added poisonous and deleterious substance aflatoxin; 402(a)(1). Default decree ordered destruction. (7)

Feed for fish, Purina Catfish Chow, at Montgomery, M. Dist. Ala.

Charged 8-18-71: when shipped by Ralston Purina Co., Memphis, Tenn., the article contained the added poisonous and deleterious substance polychlorinated biphenyl compound; 402(a)(1). Default decree ordered destruction. (8)

Feed pellets for fish, Purina Trout Chow, at Lumber City, S. Dist. Ga.

Charged on or about 8-24-71: when shipped by Ralston Purina Co., Richmond, Ind., the article contained the added poisonous and deleterious substance polychlorinated biphenyl compound; 402(a)(1). Default decree ordered destruction. (9)

Swordfish chunks, at San Diego, S. Dist. Calif.

Charged 5-12-71: when shipped by local fishing vessels after the swordfish were caught in waters outside the territorial limits of California, the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (10)

Swordfish fillets, frozen, at New York, S. Dist. N.Y.

Charged 7-8-71: when shipped from Taiwan, China, the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (11)

FOOD/Contamination, Spoilage, Insanitary Handling

Brazil nuts and cornhusks, at Los Angeles, C. Dist. Calif.

Charged 8-17-71: while held for sale, the articles contained insect filth and were moldy, rancid, and/or decomposed; 402(a)(3), 402(a)(4). Default decree as to cornhusks ordered destruction. Consent decree as to the brazil nuts authorized release to Los Angeles Nut House, Los Angeles, Calif., for salvaging. (12)

Crabmeat cakes being processed, at Philadelphia, E. Dist. Pa.

Charged 7-14-71: while held for sale, the article contained crabmeat, which had been shipped by Barwick Brothers Fish & Crab Co., Inc., St. Augustine, Fla., which contained coagulase positive staphylococci and bacterial filth, and which had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (13)

Ginger, at Brooklyn, E. Dist. N.Y.

Charged 5-27-71: while held for sale, the article contained moldy, decomposed ginger; 402(a)(3). Default decree ordered destruction. (14)

Mushroom chips, canned, Great Lakes, at Denver, Dist. Colo.

Charged 6-22-71: when shipped by Great Lakes Mushroom Cooperative, Warren, Mich., the article contained maggots—402(a)(3); and the article fell below the standard of fill for canned mushrooms, since the 603 x 700-size cans contained less than 68 oz. of mushrooms—403(h)(2). Consent decree ordered destruction. (15)

Peanuts, shelled, at Brooklyn, E. Dist. N.Y.

Charged on or about 6-25-71: while held by Havmor Food Products, Inc., Brooklyn, N.Y., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (16)

Sugar, at Erie, W. Dist. Pa.

Charged 5-25-71: while held by Nickel Plate Mills, Inc., Erie, Pa., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (17)

Sugar, at Tulsa, N. Dist. Okla.

Charged 5-21-71: while held by Akin Distributors, Inc., Tulsa, Okla., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (18)

FOOD/Economic and Labeling Violations

Avocado salad dip, frozen, AVO, at Albuquerque, Dist. N. Mex.

Charged 6-3-71: when shipped by Ashley's Frozen Foods, El Paso, Tex., the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not separately stated from other printed label information appearing above the declaration on each alternate principal display panel, the quantity of contents was not within the bottom 30 percent of one of the principal display panels in lines generally parallel to the article's base, and the quantity of contents appearing on one principal display panel having an area of more than 5 square inches was in a type size less than 1/8 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Default decree ordered destruction. (19)

Codfish, boned, salted, Bofisco, at Denver, Dist. Colo.

Charged 2-3-71: when shipped by Booth Fisheries, Inc., Chicago, Ill., the article 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 declaration was not separated from other printed label information below the declaration, and the quantity of contents was expressed as "Net Weight 1 Lb. (16 Ounces)" instead of "Net Weight 16 Ounces (1 Lb.)"; 1453(a)(2), 1453(a)(3)(A)(i). Default decree authorized donation to charitable institution. (20)

Shrimp, frozen, Ocean Harvest, at Buena Park, C. Dist. Calif.

Charged 6-1-71: when shipped by Industria Pesquera, Guayaquil, Ecuador, the article 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 declaration was not separated from other printed label information appearing below the declaration, the quantity of contents declaration was expressed as "Net Weight 1 Lb." instead

of "Net Wt. 16 Oz. (1 Lb.)," and the quantity of contents statement appearing on the principal display panel having an area of more than 25 square inches was in a 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). Consent decree authorized release to Alvin R. Lantz, Buena Park, Calif., for salvaging. (21)

Soy protein patty mix, Allied, at Ada, E. Dist. Okla.

Charged 5-12-71: when shipped by Globus Laboratories, Inc., Hackensack, N.J., the valuable constituent protein had been omitted or abstracted, the label statement "Soy Protein Concentrate (94.83%)" was false and misleading, since the article did not contain that much soy protein concentrate, and the label lacked the place of business of the manufacturer, packer, or distributor; 402(b)(1), 403(a), 403(e)(1). Default decree ordered destruction. (22)

VITAMINS/SPECIAL DIETARY FOODS

Aknemed Formula A (vitamin A) capsules, Formula B (wheat germ oil) capsules, and Formula C (riboflavin, vitamin C, and thiamine combination) tablets, at Birmingham, N. Dist. Ala.

Charged 12-14-70: while held by Aknell Corp., Birmingham, Ala., who was packaging from bulk the Aknemed Formula A, B, and C in boxes containing one bottle each of Formula A, Formula B, and Formula C, the labeling of the combined article bore the name "Aknemed," which falsely and misleadingly represented the article as an adequate and effective medicine for acne; the labeling lacked adequate directions for its intended uses for skin conditions, pimples, and acne; and the article was a new drug and its labeling lacked adequate directions for use and was not exempt therefrom, since no approval of an application was effective with respect to such drug and no notice of claimed investigational exemption was on file; 502(a), 502(f)(1). Consent decree authorized release of the bulk containers of vitamin A capsules, wheat germ oil capsules, and the riboflavin, vitamin C, and thiamine combination tablets, together with approximately 500 unlabeled bottles of wheat germ oil capsules, to the dealer for packaging and labeling the vitamin E capsules as a separate drug and for packaging and labeling the two kinds of capsules as separate dietary supplements. The decree also provided for the destruction of the rest of the article. (23)

Ascorbic acid (vitamin C) tablets, at St. Paul, Dist. Minn.

Charged 5-18-71: when shipped by Altair Laboratories, Inc., Perth Amboy, N.J., the circumstances of the manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice; 501(a)(2)(B). The shipper claimed the article and denied the charges. The Government served written interrogatories on the claimant. The claimant failed to answer the interrogatories and the article was ordered destroyed. (24)

Vitamin and mineral combination tablets, at Springfield, W. Dist. Mo.

Charged 4-12-71: while held for sale after manufacture by E. W. Huen & Co., St. Louis, Mo., from ingredients shipped in interstate commerce, the article had been manufactured, processed, packed, and held under circumstances lacking current good manufacturing practice, and the article's strength fell below its purported strength, since the article was approximately 45 percent deficient in vitamin A, approximately 50 percent deficient in vitamin B₁, approximately 26 percent deficient in vitamin B₆, approximately 75 percent deficient in vitamin C, and approximately 36 percent deficient in folic acid; 501(a)(2)(B), 501(c). Default decree ordered destruction. (25)

DRUGS/Human Use

Digitalis tablets, U.S.P., and digitoxin tablets, U.S.P., at Danbury, Dist. Conn.

Charged 2-17-71: when returned to Davis Edwards Pharmacal Corp., Danbury, Conn., the strength of the digitalis tablets differed from the U.S.P. standard—501(b); and the digitoxin tablets' strength differed from and their quality fell below the U.S.P. standard, since the article failed the tablet content uniformity requirement—501(b). Default decree ordered destruction. (26)

Estradiol valerate injection and testosterone enanthate with estradiol valerate injection, at Los Angeles, C. Dist. Calif.

Charged 5-24-71: while held by Titan Pharmacal Co., Inc., who manufactured the article using estradiol valerate imported from Italy, estradiol isovalerate had been substituted in part for estradiol valerate—501(d)(2); and the labeling of the estradiol injection was false and misleading in representing that the estradiol ingredient consisted solely of estradiol valerate, when the article consisted in part of estradiol isovalerate—502(a). Default decree ordered destruction. (27)

Grobese gland extract injection, Grobese peptone injection, dextro-amphetamine sulfate injection, and dextro-amphetamine sulfate gland extract combination injection, at Phoenix, Dist. Ariz.

Charged 5-8-70: while held by J. R. Verde & Co. (J. H. Everett Co.), Phoenix, Ariz., the labeling of all the articles, which had been manufactured and labeled by Meyers Carter Laboratories, Inc., using ingredients shipped in interstate commerce, lacked adequate directions for use and the articles were not exempt therefrom as prescription drugs, since their labeling lacked adequate

information for use for their intended purpose by licensed practitioners—502(f)(1); and the Grobese gland extract injection and Grobese peptone injection were offered for sale under the name of another drug in that the composition of each was different and they were offered for sale under the name "Grobese"—502(i)(3). The articles were claimed by the dealer who denied the charges. The Government filed a motion for summary judgment. Thereafter a consent decree authorized release to the dealer of the dextro-amphetamine sulfate injection for relabeling, and ordered the destruction of the other articles. (28)

Linger ointment, at Chicago, N. Dist. Ill.

Charged 5-18-71: while held by National Sanitary Laboratories, Inc., Chicago, Ill., who repacked the article which had been shipped in interstate commerce in bulk, the article contained *Pseudomonas denitrificans*; 501(a)(1). Default decree ordered destruction. (29)

Pangamic acid injection, at San Francisco, N. Dist. Calif.

Charged 11-13-70: when shipped by Glogau & Co., Inc., the article, labeled in part "Pangavite (Brand of Pangamic Acid Solution) . . . (Vitamin B15*) . . . Distributed by Yaron Laboratories, Inc., San Francisco, California," was a new drug without an approved New Drug Application; 505(a). Consent decree ordered destruction. (30)

Smoke-X medicated chewing gum, at Jacksonville, M. Dist. Fla.

Charged 6-15-71: when shipped by Amco Pharmacal Co., Chicago, Ill., the article contained approximately 811 percent of the declared iodine; 501(c). Default decree ordered destruction. (31)

Trihormogen estrone, progesterone, and testosterone suspension for injection, at Middletown, Dist. Conn.

Charged 2-23-71: when shipped by S. J. Tutag & Co., Detroit, Mich., the circumstances of the article's manufacture, processing, and holding failed to conform to current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (32)

Trio Reducing Pac containing theobromide combination tablets, benzocaine combination tablets, and leaflet, at Minneapolis, Dist. Minn.

Charged 5-26-69: when shipped by Super Products, Chicago, Ill., the article was a new drug without an effective approved New Drug Application—505(a); and the labeling of the article contained false and misleading claims about the "water reducers" and "taste depressants" contained in the article, and their necessity as an adjunct to diet control; false and misleading claims about the benzocaine combination tablets for nervous tension, for better absorption because of its timed-releases aspect, for use as a diet supplement and for use all year round; and false and misleading claims about the theobromide combination tablets for effective weight reduction by eliminating water; 502(a). The shipper claimed the article and denied the charges. The Government served written interrogatories on the claimant. The action was dismissed upon representations by counsel that the action had been settled, and thereafter the action was reinstated upon representations that the claimant-manufacturer was prepared to enter into a consent decree of condemnation. Subsequently, the claimant and successor LTC Pharmaceutical Corp. withdrew their claim, and a decree of condemnation ordered the article destroyed. (33)

DRUGS/Veterinary

Codesine Gel injectable, Super Endurance injectable, Iron Cacodylate injectable, Pepto-Liv injectable, and Super Speed Anemiaban injection, at Winnfield, W. Dist. La.

Charged 6-16-71: when shipped by Anthony Products Co., El Monte, Calif., the articles were new animal drugs, without effective approved New Animal Drug Applications—501(a)(5); the labeling of the Super Endurance injectable contained false and misleading claims for use for deficiencies of vitamins and for promotion of superendurance—502(a); the labeling of the Iron Cacodylate and Pepto-Liv injectables contained false and misleading claims for anemia in horses—502(a); and the labeling of the Super Speed Anemiaban contained false and misleading claims for use for iron and vitamin deficiencies—502(a). Default decree ordered destruction. (34)

Cough syrup for dogs, at Chicago, N. Dist. Ill.

Charged 5-26-71: when shipped by Eastern Laboratories, Inc., Vineland, N.J., the article labeled in part "Dogette Cough Syrup . . . Mfd. by Lora Laboratories, Inc., Chicago, Ill.," was a new animal drug without an effective approved New Animal Drug Application; the strength of the article differed from its represented strength, since it contained approximately 42 percent and 60 percent respectively of the declared amounts of dextromethorphan hydrobromide and chlorpheniramine maleate; and the labeling contained false and misleading claims for relief of dry, persistent, tickling coughs of dogs, for quieting and relaxing dogs, and for suppressing coughs, and that Lora Laboratories, Inc., was the manufacturer of the drug; 501(a)(5), 501(c), 502(a). Default decree ordered destruction. (35)

Cough syrup for dogs, at Minneapolis, Dist. Minn.

Charged 6-3-71: when shipped by Eastern Laboratories, Inc., Vineland, N.J., the article, labeled in part "Eidson Cough Check Syrup . . . Manufactured for Eidson Pet Products . . . Minneapolis," was a new animal drug without an effective approved New Animal Drug Application; the strength of the article differed from its represented strength, since it contained approximately 60 percent and 83 percent respectively of its represented dextromethorphan hydrobromide and chlorpheniramine maleate; and the label contained false and misleading claims for dry, persistent, tickling coughs in dogs, for suppressing coughs, and for quieting and relaxing dogs; 501(a)(5), 501(c), 502(a). Default decree ordered destruction. (36)

Furazolidone medicated premix, at Moorpark, C. Dist. Calif.

Charged 5-11-71: when shipped by Davis-Edwards Pharmacal Corp., Danbury, Conn., the article was a new animal drug without an effective approved New Animal Drug Application; 501(a)(5). Default decree ordered destruction. (37)

Vitamin injectable for animals, at Denver, Dist. Colo.

Charged 10-20-70: while held by Denver Veterinary Laboratories, Inc., who manufactured the article from drug ingredients shipped in interstate commerce, the article had been prepared and packaged under insanitary conditions, the circumstances of the article's manufacture, processing, and packing failed to conform to current good manufacturing practice, and the article lacked its purported purity and quality, since the article contained particulate matter; 501(a)(2)(A), 501(a)(2)(B), 501(c). Consent decree authorized release to Diamond Shamrock Corp., Cleveland, Ohio, for salvaging. (38)

MEDICAL DEVICES

Airox ozone generator for air and Airox ozone generator for water, at Dallas, N. Dist. Tex.

Charged 9-24-70 and amended on or about 10-1-71: when shipped by Pollution Control Industries, Inc., Stamford, Conn., and while held by Sanger-Harris, Division of Federated Department Stores, Inc., Dallas, Tex., the articles' labels, the shipper's instruction book, and copies of the dealer's newspaper advertisements which accompanied the articles bore the names "Airox Air Purifier" and "Airox Water Purifier" and other false and misleading claims for purifying air and water, sterilization, destroying bacteria and germs, reducing cross infection, and other therapy, which claims were false and misleading, since the articles were not effective for such purposes; and the labeling of the ozone generator for water lacked adequate warnings against unsafe use; and the ozone generator for water was dangerous to health when used as directed; 502(a), 502(f)(2), 502(j). Consent decree ordered destruction. (39)

Respirator, at Port Huron, E. Dist. Mich.

Charged on or about 7-9-69: when shipped by Crown Products Co., Cleveland, Ohio, the article, labeled in part "Res-Q-Aire Emergency Respirator . . . A Product of Machsa Incorporated Distributed Exclusively by Crown Products Co. . . . Cleveland Ohio . . . A Division of Chilcote Company," bore the name "Res-Q-Aire" and statements on the carton label and attached card which were false and misleading as to the adequacy and effectiveness of the article as a means of resuscitation, and other therapy; the labeling lacked adequate directions for use, and such cannot be written, since the article is neither safe nor effective for its intended purposes; its labeling failed to warn against use involving obstructions, aspirated objects and dentures, and involving children where the volume of air would be excessive; and the article was dangerous to health when used as directed by its labeling; 502(a), 502(f)(1), 502(j). Default decree ordered destruction. (40)

HAZARDOUS SUBSTANCES

Cherry bombs and M-80 firecrackers, at Bigelow, W. Dist. Mo.

Charged 6-29-71: while held by fireworks stand, Bigelow, Mo., the articles were banned hazardous substances intended to produce audible effects by more than 2 grains of pyrotechnic composition; 2(q)(1)(B). Default decree ordered destruction. (41)

Cherry bombs, M-80 firecrackers, Silver salutes, torpedoes, and aerial bombs, at Trenton, W. Dist. Mo.

Charged 6-29-71: while held by fireworks stand, Trenton, Mo., the articles were banned hazardous substances intended to produce audible effects by more than 2 grains of pyrotechnic composition; 2(q)(1)(B). Default decree ordered destruction. (42)

Dural contact cement and thinner, at Chicago, N. Dist. Ill.

Charged 6-15-71: when shipped by Dural Company, Inc., Milwaukee, Wis., the cement and the thinner were extremely flammable and presented special hazards by reason of their petroleum distillate contents, and they lacked a number of required label statements; 2(p)(1)(A.E.F. & I), 2(p)(2), 3(b). Default decree ordered destruction. (43)

Silver salute fireworks, at Goodlettsville, M. Dist. Tenn.

Charged 6-4-71: while held by George B. Evans Gift Shop, Goodlettsville, Tenn., the articles were banned hazardous substances intended to produce

audible effects by more than 2 grains of pyrotechnic composition; 2(q)(1)(B). Default decree ordered destruction. (44)

NOTICES OF JUDGMENT on Criminal Actions

FOOD

Aster Nut Products Co., Inc., Evansville, S. Dist. Ind.

Charged 4-20-71: when shipped, peanut granules contained insect filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea; fine. (45)

Bastian's Wholesale Grocery Co., a partnership, Joplin, W. Dist. Mo.

Charged on or about 9-22-71: modified food starch, pie filling and pudding mix, spaghetti, candy sticks, donut mix, macaroni, instant pie filling and pudding mix, and cracker crumbs, were held in a building accessible to rodents and insects and were contaminated by rodent and/or insect filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (46)

Illini Egg Products, Inc., and David Friedman, plant manager, Olney, E. Dist. Ill.

Charged 7-9-71: when shipped, frozen whole eggs contained decomposed eggs and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty pleas; fines. (47)

Modern Macaroni Co., Ltd., Honolulu, Dist. Hawaii.

Charged 11-17-71: when shipped, saimin and chow funn noodles, labeled in part "Hula Brand Products Oriental Type Alimentary Post Product SAIMIN [or "CHOW FUNN (Wheat)"] . . . Manufactured by Modern Macaroni Co., Ltd., Honolulu, Hawaii Packed for Taiyo Trading Co. Honolulu," had been prepared under insanitary conditions and contained insect and rodent filth; 402(a)(3), 402(a)(4). Guilty plea; fine and probation. (48)

P & C Food Markets, Inc., Syracuse, N. Dist. N.Y.

Charged 9-23-69: breakfast cereal and flour were held under insanitary conditions in a building accessible to rodents and exposed to contamination by rodents; 402(a)(4). Guilty plea; fine. (49)

NOTICE OF JUDGMENT on Miscellaneous Action

Cervical smear diagnosis kit, judicial review suit, Washington, Dist. Columbia.

Charged 3-26-70 in suit for judicial review and injunction by Tara Industries, Inc., Washington, D.C., against H.E.W. Secretary Finch and FDA Commissioner Edwards: that plaintiff was assigned property rights in "Estrindex"; that Estrindex was a kit containing swabs, specially treated test paper, and an instruction booklet and was intended for use in taking daily smears of cervical mucus for reaction with silver chromate in the test paper for the purpose of the determination of ovulation time; that plaintiff had not begun production of Estrindex but had instituted market research; that FDA had inspected plaintiff's Estrindex exhibit at a Scientific Society meeting and had attempted an inspection at the building of plaintiff's principal place of business; that access to plaintiff's office and records had been refused as unwarranted, since plaintiff claimed its product was not subject to the Food, Drug, and Cosmetic Act; that plaintiff's predecessor and assignor of Estrindex had twice been informed by FDA personnel that the product was not a drug; that FDA had reversed this view and written that Estrindex must be removed from the market and a New Drug Application submitted; that Estrindex had been recalled and a New Drug Application had been filed by the predecessor firm under protest, but the application had not been approved; that FDA had on two occasions alleged that Estrindex was being illegally "marketed" by plaintiff because it was not the subject of an approved New Drug Application; that plaintiff urged that Estrindex was not a drug within the meaning of the Food, Drug, and Cosmetic Act.

Accordingly, plaintiff demanded that the court adjudge: 1) whether or not Estrindex was a drug subject to the Food, Drug, and Cosmetic Act, and 2) if the Estrindex was not subject to that Act, that defendant be permanently enjoined from instituting any and all further actions against plaintiff for alleged violation of the Act. Both parties filed motions for summary judgment.

The court granted the defendant's motion for summary judgment and dismissed the action, having concluded that Estrindex was a new drug not generally recognized among qualified experts as safe and effective for its recommended use. (50)

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

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

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

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

FDA approval of new drugs



Ever wonder how FDA approves new drugs? What types of evidence FDA looks at before it lets a new drug be sold? How FDA keeps a careful watch over new drugs after they go on the market?

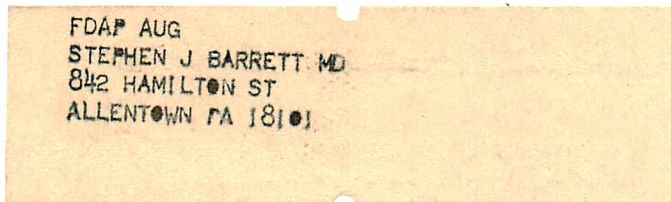
These questions, and many others, are answered in a booklet called "FDA Approval of New Drugs." It's especially written for consumers.

This 16-page book is available for 15 cents from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Ask for stock number 1712-0136.

UNITED STATES
GOVERNMENT PRINTING OFFICE
DIVISION OF PUBLIC DOCUMENTS
WASHINGTON, D.C. 20402

OFFICIAL BUSINESS

POSTAGE AND FEES PAID
U.S. GOVERNMENT PRINTING OFFICE



MAIL ORDER FORM

Mail to:
Government Printing Office
Superintendent of Documents
Washington, D.C. 20402

For Use of Supt. Docs.

Enclosed find \$_____ (check, money order, or Supt. of Documents coupons). Please enter my subscription for
FDA CONSUMER (formerly FDA PAPERS) at \$3.50 a year. (\$1 additional for foreign mailing.)

NAME _____

ADDRESS _____

CITY & STATE _____ ZIP CODE _____