

Vince
JUNE 1972

FDA PAPERS

**MORE INFORMATION
FOR THE PUBLIC**

**Safe Food Handling
In the Home**

**KEEPING THE KICK
IN ANTIBIOTICS**

CHILD SAFETY



NOTE TO SUBSCRIBERS

Heretofore, this magazine has been directed at two audiences: the industries that manufacture our foods, drugs, cosmetics and other products regulated by FDA, and the consumer who uses these products.

Hereafter, it will be directed exclusively at one audience: the American consumer who buys and uses the products regulated by FDA—and who needs to understand the safe use of products and the actions this Agency is taking on his behalf.

This magazine will be written in easy-to-understand, nontechnical language. We will, of course, continue to maintain the same high standards of accuracy and quality design that has made this magazine unexcelled.

The transformation of this magazine into one tailored exclusively to the needs and concerns of consumers is part of a larger effort by the Food and Drug Administration to educate consumers about the products FDA regulates.

To reflect this magazine's new emphasis, the next issue will have a new name. FDA Papers is no more. The new name: FDA Consumer.

Consumer safety is the mission of FDA. And FDA Consumer is an important tool toward fulfillment of that mission.

The law provides for FDA's regulation in interstate commerce of food products to assure that food is wholesome and safe to eat. When these conditions are met and the food is purchased by the householder, FDA's responsibility ends. But not its interest.

The sanitation practices FDA requires of the food industry apply equally in the home. If the homemaker fails to consciously observe these basics, the protection intended by the law can be wasted and the Agency's work be in vain.

As an Agency dedicated to protecting the consumer's health and well-being, FDA believes the homemaker not only should know how to follow proper sanitation practices in purchasing, transporting, holding, and preparing food, but should know why they are important to the family's health. "Safe Handling of Foods in the Home" (see page 18) is intended to help the homemaker take over responsibility where the Federal Government's ends.

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

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

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

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CHILD SAFETY

by Malcolm W. Jensen

Children are our most precious resource. They are our future. From the Food and Drug Administration's standpoint, the safety of products used by children and of products which pose a potential threat to them is of paramount importance. Enforcement of laws dealing with the safety of products used by children rests with FDA's Bureau of Product Safety, directed by Malcolm Jensen. In the first part of this interview, which appeared in FDA PAPERS last month (May 1972), Jensen discussed how his Bureau operates and what its responsibilities are. In this, the second part of that interview, Jensen discusses:

- Toy safety.
- Poison prevention.
- Flammable fabrics.
- How parents can help protect their children.

Q. *Mr. Jensen, toy safety is of great concern to every parent. Your Bureau enforces the Child Protection and Toy Safety Act, which was enacted by the Congress in 1969. What is your authority under that law?*

A. Under this law, our Bureau is empowered to remove and keep from the market toys and other children's products with electrical, mechanical, and thermal hazards. Since the law became effective in January 1970, the Food and Drug Administration has officially banned seven general types of toys. During the past year alone, more than 500 individual toy products have been banned.

We also have the authority to test for toy hazards. Data from these tests will be used to establish new regulations for increased safety in toys and equipment for children.

We can and do work with toy manufacturers on a voluntary basis in helping them design and manufacture safer toys and equipment. We are cooperating with them in establishing voluntary standards for the toy industry as a whole. At our request, the design, material, or fabrications of tens of thousands of toys have been modified voluntarily by manufacturers.

Q. *How is your Bureau set up internally to evaluate the safety of toys?*

A. Within the Bureau, we are establishing a unit called the Children's Hazards Division. This will be staffed by experts in the field of child safety. Many of FDA's decisions on specific toy safety issues have resulted from recommendations by another group, the Toy Safety Review Committee. This is composed of six staff members with expertise in engineering, pediatrics, injury data statistics, chemistry, and toxicology.

The committee meets once a week. It has examined more than 800 toy samples submitted by FDA inspectors, consumers, or industry. The committee tests, examines, and discusses each toy separately, evaluates any potential hazards, and develops recommendations for a course of action.

Q. *How many toys do you evaluate each year?*

A. I can't give you any specific figure. It depends a great deal on the complexity of the toy itself. A little rattle, of course, can be tested quickly simply by dropping it from the height of the average crib. A toy that is battery operated or that requires electricity takes longer to test.

During the period just before Christmas last year, we were able to evaluate enough toys to make it possible for us to have removed from the marketplace close to 400 types of toys. This represents at least two million individual toys that were removed because tests indicated they were too hazardous to be sold.

Q. *Is it your intention in the future to act against toys just before Christmas or will actions be taken year round?*

A. The Division's activities continue the year round. However, we try to concentrate our activities during November and December because, believe it or not, more than 80 percent of all toys sold in retail stores in the United State are sold during these two months. This is astounding considering that this is a four-billion dollar industry.

Q. *What about parents who may have already purchased some of these potentially hazardous toys? Were they informed of the removal?*

A. Yes, as a matter of fact, last year we engaged in quite a public information campaign to educate parents about the dangers of toys in general and about specific banned toys. We found that we reached some 34 million Americans, which is quite a large number for an educational campaign of that nature. In the future, we plan similar campaigns.

Q. *During previous regulatory efforts, your Bureau has been criticized for not naming banned toys by brand name. In the future, do you intend to name toys by brands?*

A. Of course. We are making available to the public our lists of banned toys. The lists include not only the names of the toys, but also their identification, code numbers if they are available, and the name of the producer or importer. We do this because we feel that the most capable enforcers of toy safety laws are the people who buy toys.

Q. *FDA also has been criticized for allowing identical packages to be used for redesigned toys as were previously used for banned toys. Can you comment on this?*

A. We plan to require that every toy have an identifying mark on the toy

itself and on its package. Then, any individual with a list of banned toys—and we hope the lists are widely distributed—can identify very quickly whether that toy has been banned.

Q. *Do you have any way of measuring how effective your toy safety program has been thus far?*

A. Yes. Every year the Toy Fair is held in February in New York City. All the prototypes of new toys are made available to prospective buyers. This is the earliest viewing of toys that will be sold for the coming Christmas. We had members of our Toy Safety Review Committee, our Children's Hazard Division, and other capable people going from booth to booth at the Toy Fair this year. They were greatly encouraged to see that the designers of toys really are giving greater consideration to safety aspects.

I feel we have made great strides in the area of toy safety. Of course, we can't guarantee that every toy will be free of potential hazards, but we do think we've made quite an impact on the market. It must be recognized that no toy is free from hazard. Any product, if misused, can pose a hazard. This is particularly true in the toy area because toys are for children who—as parents know—are curious and like to experiment. Thus, while we can seek the removal of unreasonable hazards, we can't stand over the shoulder of each child as he's playing with the toy.

Q. *What can a parent do to make sure that the toys his or her child plays with are safe?*

A. That's a very difficult question. First, the parent must know the capability of the child. It seems to me that the average parent—and I have three children myself—feels that his or her child is more advanced, stronger, better coordinated, and probably more intelligent than the average. The tendency is to purchase a toy that is too advanced for the child.

We are going to assist in alleviating this problem by proposing, in the not-too-distant future, a regulation that would prescribe minimum-age labeling for any toy to which a minimum age for its use can be assigned. Many toys today are labeled, "Recommended for children 3 to 5," for example. We think such a statement is not strong enough from the safety standpoint. We are going to require language such as, "Not recommended for a child under 3 years old." This will help guide the parent.

Parents also have the obligation to see that toys are properly used. This means parental supervision.

I can't emphasize this point too strongly. As I said before, any toy can be hazardous if it's used improperly. Children are children, and they simply do not know about hazards. It's up to parents to keep close watch on their own children. This is the most effective way we know of reducing injuries from toys.

Also, I should mention that a parent should be aware that a toy that is safe for one child may not be safe for another. For instance, a chemistry set is fine for a 12-year-old. But not for a 3-year-old. In households with several children, parents should be on the lookout to make sure that toys for one child are not misused by another. In the case of a chemistry set, misuse could be tragic.

Q. *What other items for children are you now looking at for regulatory purposes?*

A. Children's furniture is of concern to us. We are doing quite a bit of technical work in this area in an attempt to identify the causes or potential causes of injury.

Examples of the types of things we're studying are the slats in babies' cribs that are spaced so that a youngster can slip his head through between them but then cannot get it back. We're also looking at mobiles used on cribs and at all items where pivots or springs can catch a finger or toe and cause a laceration or even an amputation. Carriers that are slung over the shoulders of mom and dad have become extremely popular, and we think it may be necessary for us to develop safety standards for them.

Q. *Mr. Jensen, when you say you're looking at these items, does that mean that you actually test them yourselves. Just how much actual product testing do you do?*

A. To answer that question, let me give you an example. The testing laboratory of the Division of Children's Hazards evaluates the hazards on approximately 50 different types of toys each week. Toys are subjected to typical misuse conditions for determination of hazards such as sharp points, sharp edges, and small parts, which present an ingestion and aspiration hazard. In addition, the National Bureau of Standards tests for acoustical and other highly technical hazards.

Q. *Let's turn now to another subject of great importance to the safety of children. We're referring to safety closures—that is, packages which contain substances of potential danger to children and which must be packaged in such*

a way as to make it difficult for children to open them. What are your responsibilities and authority under the Poison Prevention Packaging Act passed by Congress in 1970?

A. This law was signed by the President on December 30, 1970. It authorizes us to establish standards for packages and to identify products used in and around the home that should be packaged to be child-resistant. By "child-resistant" we mean a package that is extremely difficult for a child to open but which can be opened by an adult.

Q. How do you determine which substances ought to be placed in child-resistant packages? What are your criteria?

A. We determine which substances are potentially most hazardous for accidental ingestion by children from the thousands of reports turned in each year by the Poison Control Centers. We review medical literature and study the results of special investigations. From this data, we select substances which are involved in fatalities or serious personal injury or illness.

You may know that most accidental ingestions of toxic substances are suffered by children under five years of age. Therefore, the law covers items customarily stored around the household even when such products may not be destined for use around the household. Regulations cover a variety of hazardous substances, economic poisons, foods, drugs, cosmetics, household fuels in portable containers, boat maintenance items, model airplane fuels, and similar products.

Q. Now, FDA has been criticized for not implementing this important law swiftly enough. Can you comment on that?

A. Yes, I'd be happy to, because some misimpressions may have been formed among people who don't understand how the law works. The law says that the Secretary of the Department of Health, Education, and Welfare must appoint a technical advisory committee made up of 18 persons. This committee was appointed in late April 1971, and held its first meeting in the middle of May of that year.

Under the terms of the statute, no official action can take place without prior discussion by the technical committee. This means that we could not begin to define a test standard for a safety closure or to determine which products should be affected by a packaging regulation until that committee had had an opportunity to meet and deliberate.

Q. What happened after the May meeting?

A. The committee agreed with us that our first job should be to establish a test procedure for determining the adequacy of safety packaging.

There had to be some way for us to determine whether a package was truly effective in stopping children from getting at its contents yet that could at the same time be opened by normal adults.

Of course, this was not a brand new field. For many years before, safety packaging had been developed and tested. In 1966, FDA, in fact, had appointed a special committee to study safety packaging, so we had quite a bit of material to draw on.

In July 1971, we published for comment a test standard for safety packaging. That test has now been adopted in final form and is being applied to specific product categories.

Q. Could you describe that test?

A. We gather 200 children aged 42 to 51 months. The children are selected to represent as closely as possible children of that age—that is, we have boys and girls, big boys and big girls, children of different ethnic and cultural origins, etc.

With the children working in pairs, we give each child a package and ask him or her to open it. We allow five minutes. Following this five-minute effort, an adult demonstrates the opening of the package and informs the children that they can use their teeth or anything else at their disposal. Then there is an additional five-minute period for the children to attempt to open the package.

For a safety closure to pass our test, 170 out of the 200 children must not be able to open the package during the first five minutes. At least 160 children out of the 200 must be unable to open it during the second five minutes. If a package can't meet these standards, it is not acceptable.

But that's not all. To be acceptable, a package also has to be openable by 90 out of 100 normal adults who are given the package with no more instructions than appear on the package. They are also given five minutes.

Q. Which products must be packaged in safety packaging?

A. Well, we promulgated our first requirements for aspirin and aspirin-

containing drugs, because aspirin has for years been the leading poisoner of children, probably because it's found in just about every home. All aspirin and aspirin-containing products must be in safety packaging by this August. We have been informed that more than 750 million packages a year will be affected. We hope that safety packaging will cut down on the number of injuries each year from this type of product. We also have final regulations covering certain liquid furniture polishes containing petroleum distillates and liquids containing methyl salicylate.

Q. *What other products in the near future will have to be in safety packaging?*

A. A great, broad range. Let me list just a few. First, practically all prescription drugs. Then, paint thinners of all kinds, drain cleaners both alkaline and acid base, auto products such as methyl alcohol de-icers and ethylene glycol used for antifreeze preparations, over-the-counter drugs that contain iron, and most pesticides. We're really moving quite rapidly in this area, because we believe it is a high priority field.

Q. *This seems to indicate that by the end of 1972, or soon after, a great variety of products will be in child-resistant packages. Will this insure that children will be safe from potentially poisonous products in and around the home?*

A. No, as a matter of fact, it's only the start of efforts to reduce these sorts of injuries. All we can do is to require that the substances be packaged in child-resistant containers. Obviously, if the container cover is not used properly or if the potentially hazardous substance is placed in another container, then the hazard remains. As I said before in reference to toys—we can't stand over the shoulders of parents. We can only make toys and packages as safe as possible. Then it's up to parents to protect their children.

Q. *Does everyone—even people with no children or people with handicaps such as arthritis—have to purchase safety packaging?*

A. No. The law provides that a manufacturer producing one or more packages in an appropriate child-resistant package can produce one size with a regular closure.

But people with children in the house should avoid purchasing such packages. And here I'm including grandparents whose grandchildren visit them.

In the case of prescription drugs, either the physician or the patient may ask for a container with a

regular cap. Again, our advice is that child-resistant packaging be used in all cases, except when a regular closure is absolutely needed.

Q. *This discussion about the Poison Prevention Packaging Act leads us into the area of poison control. Can you describe FDA's poison control program?*

A. This program is a really outstanding example of Federal-State-local cooperation. We coordinate the program through our National Clearinghouse for Poison Control Centers here in Washington. The program involves 583 individual poison control centers all over the country.

The National Clearinghouse is responsible for gathering information on poisonous substances that come into homes and thus can be misused by children. The main purpose of the program is to get proper information to the centers themselves, so that when physicians call, information can be instantaneously available.

Q. *How many accidental ingestions of toxic products are there every year?*

A. Enough to make accidental ingestions a major health hazard. Our statistics indicate that there may be as many as a million accidental ingestions a year of toxic products. More than half involve children under five. There are too many deaths each year from these accidents.

Our statistics indicate that products that cause the greatest number of injuries per year among children under five are aspirin products, particularly the candy-flavored children's variety. This has been so for some time. However, our data indicate that fatalities have been drastically curtailed from a high of over 500 per year to 284 annually in 1968-69, the latest period for which data are available. We attribute this reduction to the educational activities of the Poison Prevention Program in which prompt treatment methods are emphasized to alleviate fatalities. We expect that there will be a still greater reduction in the number of accidental poisonings from aspirin when the Poison Prevention Packaging Act takes effect for these products next August.

Other substances that are particularly hazardous because they cause extremely serious injury and illness are petroleum-based liquid furniture polishes and lighter fluids for cigarettes and charcoal. Even half a teaspoon of these substances in a child's respiratory system can be fatal. Other substances that are extremely hazardous are methyl salicylate or oil of wintergreen, which is used as external medica-

tion; iron preparations; and the fluids we mentioned before—methyl alcohol de-icers, ethylene glycol antifreeze solutions, and paint and varnish thinners and removers.

Q. *Do you have any evidence that poison control centers are reducing the number of accidental poisonings each year?*

A. Yes. Deaths from accidental ingestions have been cut by half in the past three or four years. We believe at least part of the credit should go to the poison control centers.

Q. *Let's turn to another subject of interest to all—flammable fabrics. Most people, of course, go through their entire lives without being confronted with the problem of flammable clothing. But when clothes do go up in flames, particularly when the accident involves small children, the results can be tragic. Your bureau develops data for standards under the Flammable Fabrics Act. Based on your data, can you state at the present time that the Flammable Fabrics Act has led to the availability on the market of only flame-resistant clothes?*

A. No, we cannot. Unfortunately, clothes today are not flame-resistant, and parents should be fully aware of this.

The Commerce Department has issued a standard that would require flame-retardant material in nightwear sold for children in sizes 6X and smaller. However, this regulation will not become effective for more than a year.

The most important thing we can say about materials is that practically everything we wear today has the potential to burn. The main source of ignition, of course, is the match. Children play with matches and either set something in the house on fire or set their own clothing on fire.

Every parent ought to be aware that tragedy really does lurk in the home and other places where children play. Parents should exercise extreme caution to see that ignition sources of every kind are kept away from children.

Q. *What about clothes that go up in flames instantly upon being touched by any heat at all? Has the Government removed these from the market?*

A. Yes. Perhaps the best example is the so-called "torch sweater" which was a fuzzy type rayon sweater sold during the 1940's. The same brushed-rayon fabric was also used for

children's cowboy chaps. Such products provided the basis for enactment by the Congress of the Flammable Fabrics Act. These "explosive" items have been removed from the marketplace.

Q. *You pointed out before that most of our clothes are flammable. What are the chances that someday the level of flammability will be reduced and that we will be protected in this regard?*

A. I think the chances are excellent. Once standards are effective for children's sleepwear, the industry can take advantage of new methods and new technology and apply them to other clothing.

Q. *With respect to child safety, Mr. Jensen, it appears that your bureau is moving to improve the safety of toys and of packaging but that ultimately the responsibility must rest with the parent. Is this a correct analysis?*

A. Yes. I cannot emphasize too strongly that children will be protected from hazards—real and potential—only to the extent that parents take time and effort. We can remove many dangers from toys, but we can't teach children how to play with them. We can require safety closures on packages containing hazardous substances, but we can't force mothers to keep the closures on containers. There is only so much we in the Federal Government will ever be able to do with respect to child safety.

Parents *must* be selective in the products they bring into their homes, and they must make sure that products are used correctly. This is the key not only to child safety but to the safe use of any products. Everything has the potential for danger. We urge consumers to read the labels and, above all, to be careful.

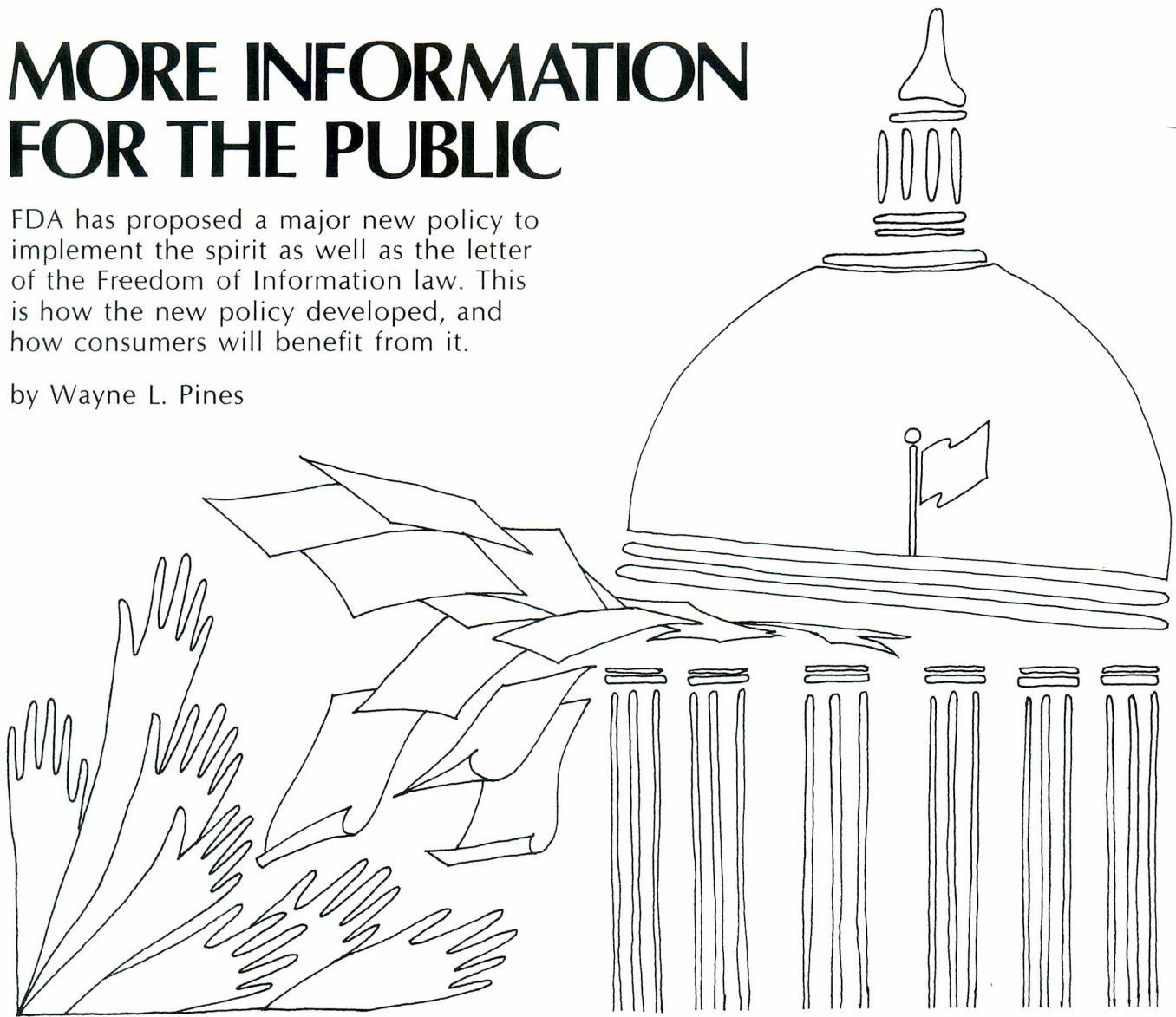


Malcolm W. Jensen is director of FDA's Bureau of Product Safety.

MORE INFORMATION FOR THE PUBLIC

FDA has proposed a major new policy to implement the spirit as well as the letter of the Freedom of Information law. This is how the new policy developed, and how consumers will benefit from it.

by Wayne L. Pines



The access of the public to information generated and accumulated by its government is one of the major features that distinguishes the United States from less democratic nations.

Democracy works best when the public has access to information needed to understand what the government is doing, and to hold accountable those officials who make decisions in the public's name.

Like other rights, however, the public's right to know is not absolute. There are times when other rights—such as an individual's right to privacy or the government's right to keep military secrets—transcends the right to know.

It is this delicate balance, between the right to know and other equally basic rights, that over the years has proved to be such a troublesome problem for the administrators of our laws. More often than not, the public's right to know has been compromised.

Fear that the balance had swung too far away from access to information led Congress in 1966 to enact the "Freedom of Information" law. It imposed on the executive branch of the government the obligation to make

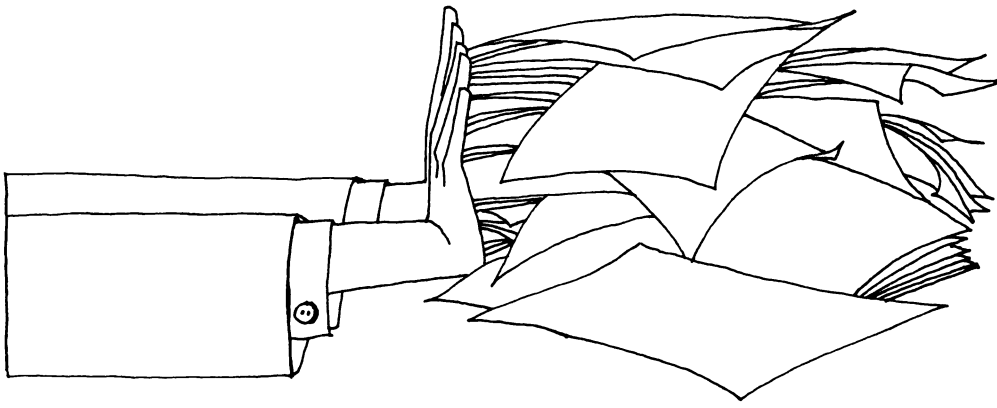
sure that more information would be made available to the public.

Under this law, availability of information was to be the rule. Withholding was to be the exception and was restricted to nine categories, such as personnel and medical records, trade secrets, investigatory files for law enforcement purposes, internal memos, and information that could endanger the Nation's foreign policy or defense.

The Food and Drug Administration recently took a major step toward clarification of its position on access of the public to information with a view toward implementing the spirit as well as the letter of the Freedom of Information law. This proposed new regulation was published for comment on May 5.

The proposal represents FDA's attempt to balance its commitment to the public's right to know with its obligation under the law to keep certain information confidential.

On the one hand, FDA is obligated to make avail-



able to the public information needed to protect the public health. FDA's mission is to protect the consumer from avoidable hazards. The better educated and informed the consumer is about products FDA regulates, and about the basis for regulatory restrictions, the more successful FDA's regulatory efforts will be.

On the other hand, FDA is a regulatory agency required by law to gather and evaluate information that private companies guard carefully. Disclosure of such information to other firms could affect the originator's competitive position and chip away at the integrity of America's free enterprise system.

The confidentiality statutes were enacted by the Congress to prohibit Federal agencies from disclosing information that, if known to a competitor, could place a company in an unprotected position. Such information includes sales and revenue figures, advertising and marketing plans, money-saving techniques, technical and scientific processes, product formulas, and other proprietary data.

The proposed new FDA policy sets forth the specific types of information which in the future will be made available to the public on request. Furthermore, it shifts the burden from the public, which had been required to justify the release of data, to the industries and other submitters of information, who under the new policy would have to justify confidentiality.

The soul-searching and thought that went into FDA's decision to break with tradition in developing its proposal took the Agency back to the purposes for which the Freedom of Information law was enacted.

At that time, the Attorney General explained the philosophy behind the legislation:

"If government is to be truly of, by, and for the people, the people must know in detail the activities of government. Nothing so diminishes democracy as secrecy.

"Self-government, the maximum participation of the citizenry in affairs of state, is meaningful only with an informed public. How can we govern ourselves if we know not how we govern?"

"Never was it more important than in our times of mass society, when government affects each individual in so many ways, that the right of the people to know the actions of their government be secure."

FDA officials first began giving serious thought to changing the Agency's position on Freedom of Information in 1970, soon after the present Commissioner, Charles C. Edwards, M.D., joined the Agency. At that time he asked his staff to find ways to make more in-

formation available to the public.

Among factors influencing Dr. Edwards' move was the consumer movement, which by 1970 was going full strength. Consumer demands were at a new high. So were consumers' expectations. As the primary regulatory agency in the health field, FDA found itself with a public visibility it had never experienced before. Demands that FDA and other regulatory agencies account for their decisions and release important data came from many organizations and individuals, and from the Congress, too.

By 1970, the environment had also become a major national issue. The public rightfully looked to FDA for leadership and scientific expertise in coping with some of the major challenges posed by the new interest in environmental controls. A short-sighted information policy could only hamper these objectives.

Drafting of the new policy began in the fall of 1971, on instructions from Dr. Edwards. The proposal, unprecedented in Government for its detailed "open-door" approach, was published for comment only after the most thoroughgoing discussion by FDA officials.

The proposed regulation made clear the Agency's attempt to balance the public's right to know against other rights:

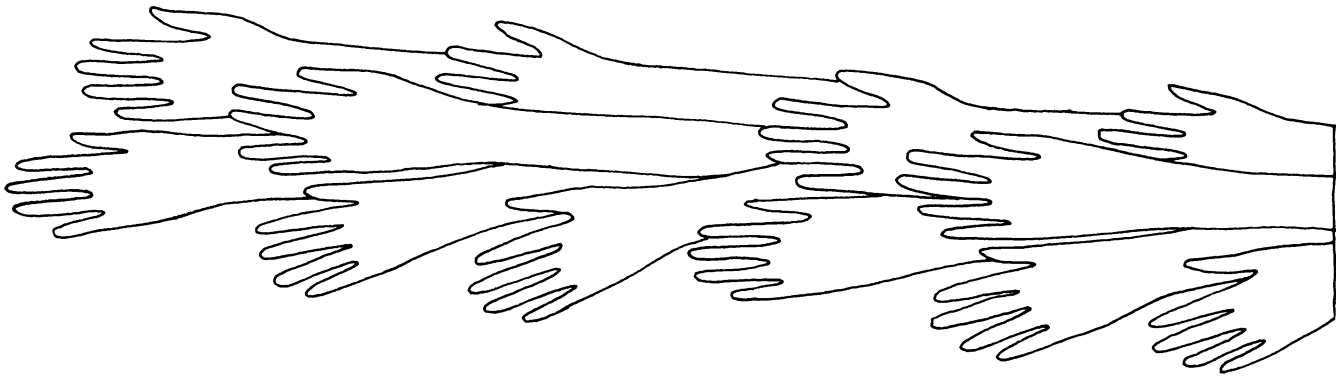
"The Freedom of Information Act adopts a general rule that, except where specifically exempt, all documents in government files shall be made available to the public. The Commissioner fully endorses this approach.

"Public disclosure should be the rule rather than the exception. Accordingly, all information in FDA files will be available for public disclosure unless they fall within one of the explicit exemptions contained in that act or other applicable statutes."

Among the specific kinds of information, heretofore kept "secret," that would be made available to the public under the proposed regulation:

- Information FDA considered in deciding whether to take criminal action against an individual or firm for an alleged legal violation. This information would be released only after FDA has closed the file—either by deciding to drop criminal action or upon completion of the case. If FDA decides not to seek criminal action, the name of the person or firm who was under investigation would not be disclosed.

Any information that FDA considers to be a bona fide "trade secret" or that was gathered with a guarantee of confidentiality would be withheld by the Agency.



- The records of any informal regulatory actions by FDA, such as a letter to a company asking for recall of a defective product.
- Tests or research conducted by FDA, after the final report is completed.
- Data submitted by a manufacturer to prove the safety, effectiveness, or function of a food additive, color additive, or antibiotic drug, unless a company can justify confidentiality.
- Scientific data on the safety and effectiveness of drugs, except unpublished data for a new drug or other data that a firm can justify withholding.
- All ingredients in products regulated by FDA, unless withholding can be justified.
- Methods and procedures for conducting tests, unless a firm can demonstrate that they are a trade secret or are unique.
- The existence of an application for a new drug, unless extraordinary reasons dictate against disclosure.
- All information submitted to FDA by the public, physicians, the industries, or professional groups which are not part of an application. The person who submitted the information can ask that it be kept confidential. If FDA disagrees, then it will allow the person to withdraw the information, since the voluntary submission of information hinges on the public's good will.
- All correspondence or summaries of discussions with members of the public and Congress, company officials, or other nongovernment employees, unless the material contains bona fide confidential information.

The intent of the policy is not to make it possible for citizens to walk into FDA offices and rummage through file cabinets. Nor is it to turn the Agency into a reference library for anyone who wants scientific information, or to bog down government employees in an endless search for documents. It is intended, however, to provide the public access to documents that will contribute to an understanding of the bases for FDA decisions.

Whoever wants a document will have to identify it with some specificity. It will then be made available to him if the regulation permits. There will be a nominal charge for copying unless the person can prove indigence and that disclosure is in the public interest. The precise details of the dissemination process have not yet been worked out, and may not be until after the Agency sees how many requests it receives and what sort of information is asked for.

The possible long-term impact of the proposed

Freedom of Information policy cannot be measured at this time. But one effect will be in the scientific area. As Commissioner Edwards said in announcing the proposal:

"FDA files contain vast amounts of scientific data which have been developed over the years to prove safety and effectiveness for a variety of drugs and other products. Much of this data can help eliminate duplication of costly scientific research if widely known and applied."

Opening of FDA's drug, food additive, color additive, and other application files would enable the entire scientific world to have access to vast amounts of tests and data. Scientists will be able to learn not only what tests have been conducted, but what the results are and, perhaps more importantly, what tests have failed. The benefits of such knowledge are incalculable.

From the standpoint of the consumer, two more immediate effects are likely from the policy change. First, consumer organizations that monitor FDA activities will be able to do their jobs more effectively and responsibly with better access to information. Sophisticated consumer advocates will be able to contribute their own interpretations to scientific data and policy decisions.

The second immediate effect on consumers will be to encourage FDA employees to become more attuned to consumer needs and views, because the bases for their decisions will be subjected to public scrutiny to a greater extent than before.

The press also stands to benefit from the proposed new information policy. The availability of additional information will make more effective reporters' efforts to monitor FDA in the public interest and to keep readers educated about FDA activities.

The proposed FDA policy, if adopted, should go a long way toward fulfillment of the basic right of every citizen to have access to information generated and accumulated by its government. It will provide a more realistic balance between the public's right to know and the need of a regulatory agency to keep certain information confidential. The rights of those who submit the information as well as the rights of the public must be guaranteed by the policy.

FDA believes its general approach to freedom of information balances these rights appropriately, and carries out the spirit of the Freedom of Information law.

Wayne L. Pines is editor of FDA PAPERS.

KEEPING THE KICK IN ANTIBIOTICS

To be sure that antibiotics continue to be potent enough to do their primary job—treating disease in humans—FDA has proposed further restrictions on their use in animal feeds.

by Harold C. Hopkins

The discovery and adoption to our use of antibiotics—some of Nature's most potent disease fighters—has been one of the outstanding contributions to health and well-being in history.

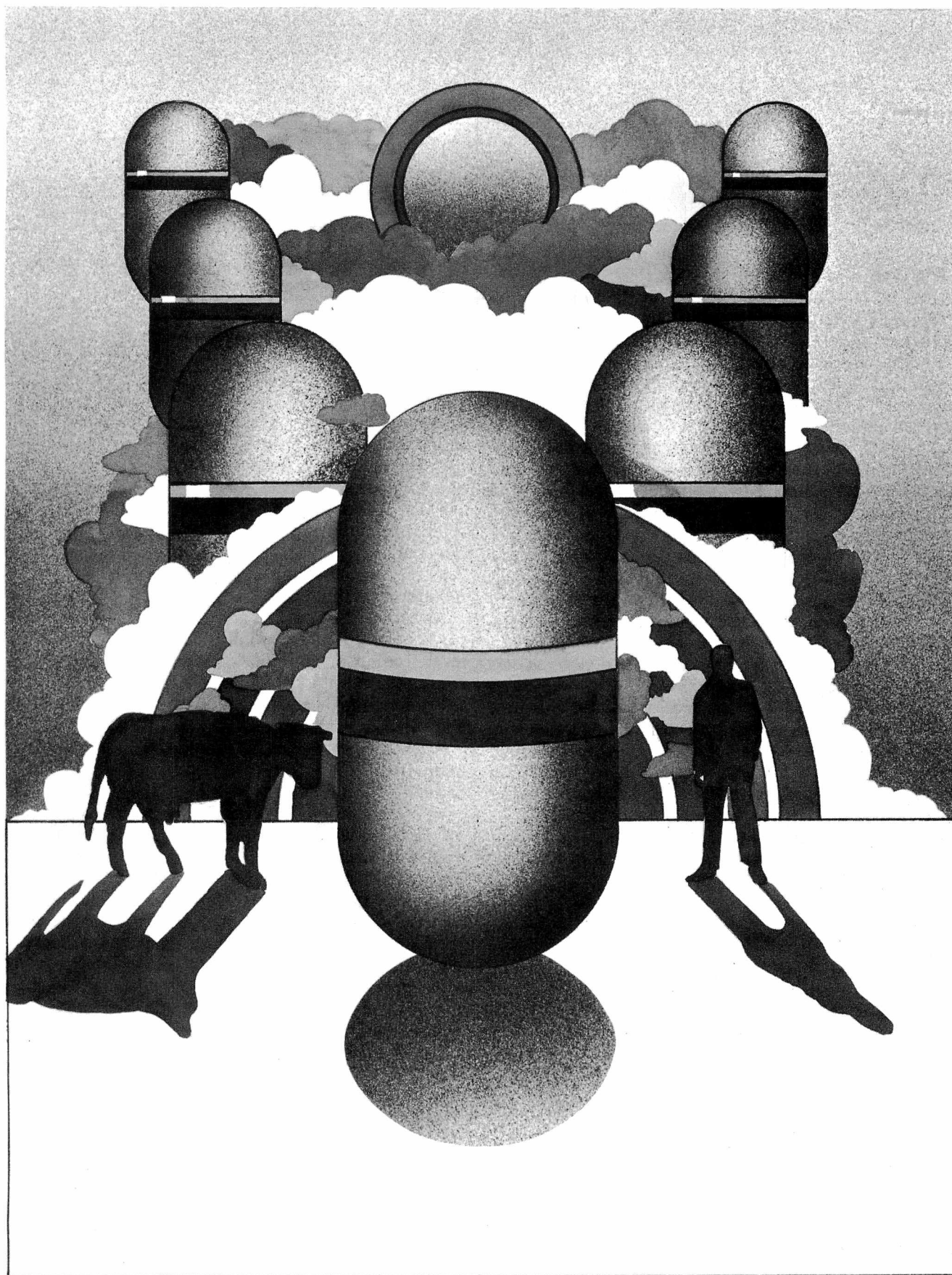
Our widening knowledge and development of antibiotics has placed us in a position to conquer or alleviate many diseases that afflict man and animals. And the extensive but less publicized use of antibiotics in feeds to increase the rate of weight gain of food-producing animals has made it possible for American agriculture since the late 1940's to provide animal protein more efficiently and in steadily increasing amounts to meet the demands of an expanding population.

To many consumers it may be a bit of a surprise therefore to learn that FDA for some years has limited the use in animal feeds of antibiotics and the sulfonamides, mainly as a precaution in the interest of human health. And that FDA recently proposed even further restrictions.

This proposal, based on the recommendations of FDA's Task Force on the Use of Antibiotics in Animal Feeds, is the latest and most comprehensive of several actions on the use of antibiotics in animals dating back to 1965. FDA is now considering comments on the proposal.

The use of antibiotics in animals has two important aspects. First, economics. No one can argue with the fact that antibiotics have resulted in an increased supply to the American consumer of meat, milk, and eggs. These foods can be produced more rapidly, with less feed and less costs, than without antibiotics.

But FDA must weigh this considerable benefit against the second aspect—the potential threat to health. And



whenever any risk appears, FDA must always resolve questions in favor of health protection.

The principal concern in the health area has been about two possible hazards:

1. That antibiotic residues in meat, milk, or eggs may produce harmful allergic reactions in hypersensitive humans;

2. That unrestricted use of antibiotics in animals may make antibiotics less useful for treatment of disease in humans. There is disagreement among scientists about whether this second concern is realistic.

The dual use of antibiotics—at concentrated or therapeutic dosages in humans and animals to treat diseases, and at low levels in feeds to promote faster growth in food-producing animals—has been widely discussed in recent years.

The problem is that some bacteria exposed to low levels of antibiotics for prolonged periods in animals develop a resistance to some of these drugs. Some of these bacteria can cause disease. If the resistant bacteria find their way into the human system, they may successfully fight off antibiotic treatment, making it less effective for treatment of humans.

Concern over this question increased after Japanese scientists in 1959 discovered a resistance phenomenon, now known as the “R factor,” among some intestinal bacteria. The “R factor” is the capability of bacteria to transfer antibiotic resistance to the same or another species by simple contact.

“R factor” transfer can involve resistance to several antibiotics even though only a single antibiotic is used.

To those who are concerned—and there are those who remain unconvinced—the corollary is that the R factor will result in larger amounts of disease-causing bacteria in animals. Humans may become exposed to these large numbers of antibiotic-resistant bacteria from animals which are a major source of our food. After this resistance develops, antibiotic treatment may be less effective in humans.

In an effort to evaluate these concerns about low level use of antibiotics in feeds, Charles C. Edwards, M.D., Commissioner of Food and Drugs, in April 1970 appointed a Task Force to assess all the relevant information available. The 16-member group, headed by C. D. VanHouweling, D.V.M., director of FDA’s Bureau of Veterinary Medicine, met with representatives of the scientific community, livestock and poultry producers, and feed and drug manufacturers. All members attended a seminar in New York on the problems of drug-resistant bacteria.

Part of the Task Force traveled to Great Britain to obtain more details about a British study, published in November 1969 and called the Swann Committee Report. This study, sanctioned by the British Government, recommended that antibiotics be divided into “feed” and “therapeutic” categories, and that only antibiotics not used for treating disease in humans be permitted at low levels in feeds for growth promotion of animals.

The Commissioner asked that the FDA Task Force undertake a comprehensive review of the usage and actual value of antibiotics in animal feeds, including—

- The acquisition of the R factor by organisms through animal feeding practices.

- The possibility that organisms and the R factor could be transferred to bacteria that cause disease in humans.

- The economic impact of restricting the use of antibiotic feed additives.

As part of its work, the Task Force considered FDA’s studies over the past several years on the effects of low level feeding of antibiotics to animals; symposia and consultations with outside experts in 1956, 1965, and 1967 on nonmedical uses of antibiotics in animal feeds; and other documentation.

After reviewing relevant literature and hearing testimony from experts, the Task Force felt these conditions existed:

- Use of antibiotics, especially in low levels, favors the development of resistance to many antibiotics by bacteria bearing the R factor.

- Animals receiving antibiotics at both therapeutic and low levels become reservoirs of antibiotic resistant bacteria, both disease-causing and nondisease-causing, and such reservoirs can produce human infections.

- The prevalence of bacteria bearing the R factor with resistance to many antibiotics has increased in animals and is related to the use of antibiotics.

- Resistant bacteria have been found in meat and meat products.

- There has been an increase in the prevalence of resistant bacteria in humans.

The Task Force said the objectives of the meat-producing industry and the Government should be the most effective use of antibacterial drugs in food-producing animals, minimization or elimination of animals as a source of public health problems, and production of food and fiber as efficiently as possible without endangering the environment.

The group identified three primary areas of con-

cern: human health hazard, animal health hazard, and antibiotic effectiveness. Committees of the Task Force proposed guidelines for measuring or determining hazards to human and animal health and for evaluating the efficacy and benefits from low level use of antibiotics in animal feeds.

The Task Force concluded that use of antibiotics in animal feeds may increase weight gain or feed efficiency or both, but said this varies with the animal's environment, species, age, amount and type of antibiotics used, and other undefined factors. It noted that a review of efficacy of antibiotics for this purpose is under way in FDA's Bureau of Veterinary Medicine.

It said antibiotics are effective at therapeutic levels for treatment of animal disease, but efficacy at lower levels in feeds for this purpose has not been adequately established.

It said several factors lead to the "logical conclusion" that use of antibiotics in animals may constitute a health hazard to humans, but said such a hazard has not been "fully documented."

The Task Force said a qualified estimate of the economic value of using antibiotics at low levels in feed totals more than \$400 million, but that this would not all be lost through restriction of antibiotics use, since some would continue to be available for growth promotion.

It suggested a need for determining how well animals respond to antibiotic treatment for disease after receiving antibiotics at low levels in their feed.

It suggested the desirability of reserving some antibiotics exclusively for human use.

It felt that research is needed to find methods other than antibiotics to improve weight gain and feed efficiency in animals.

It noted that FDA and others are reviewing the problem of possible antibiotic residues occurring in meat and meat products when drug withdrawal times are not observed.

The Task Force recommended research into animal diseases for which antibiotics are used but where their function is unclear; the safety of using antibacterials for man and animals; efficacy of antibacterials for all present uses; and other ways to control animal disease and promote growth.

The Task Force's recommendations for restricting the use of antibacterial drugs in animal feeds and what FDA is doing to implement them:

1. That FDA review the effectiveness of low and intermediate levels of antibiotics used alone or in combinations in feed and discontinue any ineffective uses.

Since the Task Force made this recommendation known some time before submitting its formal report, FDA acted early and identified more than a thousand antibiotic combinations which are being removed from the list of combinations authorized to be marketed. The data on the effectiveness of these drugs is inadequate. The makers have not provided this information and have indicated their unwillingness to supply the necessary data for efficiency.

2. That FDA prohibit the low level use in feeds of antibiotics that are also used in human therapy if they fail to meet criteria developed from the Task Force's recommended guidelines, and that such antibiotics be permitted in animals only by a veterinarian's prescription for treatment of disease. Named specifically were the tetracyclines, streptomycin, dihydrostreptomycin, neomycin, spectinomycin, the penicillins, and the sulfonamides.

FDA is developing criteria for data the Agency will require from manufacturers to demonstrate the safety and effectiveness of such drugs. Manufacturers who wish to continue marketing such drugs for low level use in feeds must assure the Agency they will undertake tests to show safety and effectiveness. They must also make regular progress reports on these tests, or FDA approval for this use will be withdrawn.

3. That antibiotics most critically needed for treatment of disease in man not be used at all in animal feeds. The specific antibiotics named: chloramphenicol, semi-synthetic penicillins, gentamicin, and kanamycin.

FDA has never approved any of these drugs for use in animal feeds.

4. That FDA undertake additional research on the safety and effectiveness of antibiotics used in animals and on the diseases for which antibiotics are used as the principal treatment.

FDA has expanded its contracted research significantly and plans still further expenditures in the future. Most of these studies are intended to develop information to answer the questions raised by the Task Force.

5. That industry begin immediately to develop other drugs that can be used in feeds to increase growth rate and feed efficiency.

FDA concurs and hopes manufacturers will be able to develop other drugs useful for this purpose.

Harold C. Hopkins is editorial director of FDA PAPERS.

SAFE HANDLING OF FOODS IN THE HOME

by Madean Horner

Matthew is sick and his mother is worried. Was it something he ate? Perhaps the chicken she roasted has spoiled.

The chicken may or may not have made Matthew sick, but his mother should know and care that home kitchens are more frequently involved in outbreaks of "food poisoning" than any other place where food is served. She should also know what she can do to prevent illness caused by food from occurring in her home.

The Food and Drug Administration's Bureau of Foods is responsible for assuring the safety and wholesomeness of the American food supply. Its regulation provides the public with assurance that foods purchased in the store will be safe, nutritious, and wholesome. Modern technology has produced an abundance of high-quality convenience foods that seldom, if ever, make people sick.

But this doesn't mean that further precautions are not needed at home. Quite the contrary. Absolute protection is never attainable. And many homemakers overlook their own responsibilities for selective buying, proper home storage, hygienic food preparation, and sanitary practices.

OBSTACLES

Every homemaker wants to make sure the food her family eats is safe. Some obstacles stand in her way, however.

First, family customs and personal habits affect day-to-day food handling practices. Some of

these practices carry potential for food poisoning.

For example, people once avoided putting hot food in an old-fashion icebox because it melted the ice and the other food spoiled. This habit became so firmly established that many people are unwilling to put hot food in an electric refrigerator even though they know it will easily overcome the heat load and cool the food quickly.

Or, the wife who works or who plans a long shopping trip may leave frozen meat for the evening

meal on the counter top to thaw, even though she knows it will probably stand at room temperature for several hours, and possibly spoil.

Second, advertising and labeling of foods stress their good qualities, but seldom mention any potential hazard associated with misuse of the product. But almost any food can cause illness if handled improperly.

Many people also assume they can handle foods with quality grades less carefully than other foods. However, a quality grade

FOODBORNE ILLNESS ACQUIRED BY EATING AT VARIOUS TYPES OF SERVING OPERATIONS* (1969-1970)

Place of Acquisition	Outbreaks	Cases
Restaurants, Cafeterias, and Delicatessens	243	14,496
Homes	289	3,321
Schools	64	24,755
Camps, Churches, and Picnics	38	3,350
Other	103	6,089
TOTAL	737	52,011

*Adapted from Table 10, page 16, *Foodborne Outbreaks-Annual Summary, 1970*, Center for Disease Control, U.S. Dept. of Health, Education, and Welfare.



DON'T use cans with bulges or that are seriously dented. The bulge or dent may indicate that the contents are contaminated.

does not insure that the food will remain free of contamination during processing, distribution, or preparation of food at home, although it probably was free of contamination when purchased.

Another obstacle to improving home food handling is the difficulty of showing that insanitary practices in the home really caused illness. A victim may be reluctant to blame an illness on food because it would embarrass the cook.

CONTAMINATION

The problem is compounded because insanitary practices do not cause illness unless there is a combination of several conditions.

To become a vehicle for disease transmission, food must contain a disease-producing agent (such as bacteria, toxin-forming mold, virus, etc.) or be handled in a way that permits contamination from the person preparing it or the surroundings.

Food, if contaminated, must provide an environment in which the agent can survive and perhaps reproduce. Even then, an illness may not occur. However, if a susceptible person, such as an infant, an elderly person, someone incapacitated with other illness, or sometimes even someone seemingly healthy eats enough contaminated food to cause symptoms, all the necessary conditions will be met, and illness results.

HOW TO SHOP

Just because it takes a combination of insanitary practices to produce illness, this doesn't mean housewives can disregard the potential hazard of careless food handling unless there is outright spoilage. A homemaker can become too complacent about the importance of sanitary practices because the mistakes she makes do not always add up to create the conditions necessary to pro-



CONDITIONS THAT LEAD TO FOODBORNE ILLNESS

1. Presence of disease-producing agent.
2. Food conducive to agent survival.
3. Contamination of food by agent.
4. Persistence of agent during food preparation.
5. Consumption of contaminated food by susceptible individual.
6. Consumption of enough contaminated food to cause symptoms.



DON'T taste any food that doesn't seem right. Very often a food's odor or appearance can indicate that something is wrong.



NEVER store food in a cabinet with a drain-pipe running through it, such as under the kitchen sink. This is unsafe because of possible leakage, and because it is difficult to seal off the openings through which the pipes pass.



NEVER leave leftovers on the table after a meal. They should be stored immediately in the refrigerator.

duce illness. But they could someday.

Insuring that the food you eat is safe begins on your shopping trips to the grocery store.

Carefully examine each item to detect possible spoilage, a torn package, an imperfect seal, or a bulged can. Don't buy such items.

Check display cases to determine if frozen foods are stored

above the "frostline" or "load line" (the line marked on grocery freezer cabinets to indicate the safety level).

Make sure perishable products, such as milk or raw meat, are refrigerated and that delicatessen items, such as barbecued chicken or desserts, are stored at recommended temperatures that do not permit bacteria to multiply.

Reject any products which are

not correctly stored.

Buy perishable foods in small quantities.

Read labels carefully.

Thoughtful reading may not be easy in a busy grocery store, but a careful examination of labels at home will be informative. The labels will describe the ingredients, any special precautions for storage, and perhaps directions for serving.



NEVER buy food stored above the "frostline" or "load line" in supermarkets (left).

DON'T diaper your baby in places which might come into contact with food, and always wash your hands after diapering babies (lower left). **DON'T** use the same knife to cut uncooked meats and other foods, as contamination could spread from one food to another (below).



If the information seems deceptive, confusing, or inadequate, return the item or at least don't buy it again. If you have an objection to a container, a display arrangement, a product, or its label, tell the store manager.

If you suspect a law has been violated, report to the local health department or Food and Drug Administration office. Often a consumer can assist in correcting a problem which is potentially hazardous.

Buying in large quantities may save a trip to the grocery store, but stockpiling food supplies which cannot be used in a reasonable period of time may lead to the food's deterioration and spoilage. The convenience of quantity buying can then be lost.

TRANSPORTATION

When you leave the store, proper transportation of food is important. This primarily means keeping temperature changes to a minimum.

Leaving a sackful of groceries in the car on a hot day hastens spoilage. If disease-producing bacteria are present, they may multiply and cause illness when the food is eaten. A wise shopping rule is to make the grocery store the last stop before returning home.

STORAGE

Proper storage of food means keeping it away from filth, pests, and household chemicals, and putting it away promptly under the best conditions for its protection.

Frozen foods should be kept in a freezer at 0° F or below. Perishables should be refrigerated at 45° F or lower. Products which will keep in a cupboard, such as most canned or dried foods, may usually be stored in a cool, dry cabinet.

Be careful, because perishable items are sometimes packaged in plastic bags, jars, or cans that resemble those used for non-

perishables. If a perishable is accidentally stored without refrigeration, it may become unsafe to eat because of bacterial growth, and should be discarded even though it may not look spoiled.

Food storage areas should be built to keep out filth and pests. A cabinet with a drainpipe running through—such as under the kitchen sink—is not a safe place to store food because of possible leakage, and because it is difficult to seal the openings through which it passes, and rodents and insects can enter. Food cupboards should be cleaned frequently to remove dust which could contaminate the food with micro-organisms when stored cans or packages are opened.

Also, food storage areas should not be used for other purposes. A common cause of home accidents is the mistaken substitution of a household chemical for a food ingredient because both happen to be stored in the same area and have a somewhat similar appearance. Cleansers, solvents, paints, polishes, pesticides, and cosmetics can be harmful when swallowed and should never be stored with foods.

A system of identifying the time of storage is valuable so that the oldest items will be used first. Most foods deteriorate gradually, even under ideal storage conditions, and when kept too long frequently become inferior in quality. If the container also deteriorates, the food may become contaminated.

The homemaker should examine foods when she prepares them for abnormal appearance or odor that might indicate spoilage. Any evidence of spoilage should be a signal to discard the food in some way that does not permit it to be eaten by animals. Animals may also be harmed by it.

PREPARATION

When preparing food, the most

important requirement for safe handling is constant attention to rules of personal hygiene and food sanitation in the kitchen. As elementary as the rules are, failure to observe them is responsible for more cases of illness caused by food than all other mistakes made in handling foods at home.

The multiple demands of family life create situations which invite disregard of safe culinary practices unless the homemaker keeps them always in mind. Consider the mother who has just begun to prepare dinner when she realizes the baby's diaper needs changing. At about the same time, she receives a telephone call from her husband saying that he is bringing a visitor home for dinner who must then go to the airport.

It would not be surprising if she forgot to wash her hands or sliced a hard-boiled egg with the same knife she had used to open the package of frozen raw chicken. She might be tempted to stuff the chicken before it is completely thawed and then be forced by the visitor's travel schedule to serve the meal before

RULES FOR FOOD HANDLING

1. Wash hands.
2. Use clean utensils and equipment.
3. Scrub raw food products.
4. Cook food thoroughly.
5. Serve promptly.
6. Refrigerate quickly.
7. Thaw frozen food under controlled conditions.
8. Avoid thawing and refreezing.
9. Discard questionable foods.

the chicken is thoroughly cooked.

Any combination of such factors can be a potential cause of illness.

TEMPERATURE

Temperature control is the most effective way to protect food against hazardous microbial contamination. The accompanying table shows critical temperatures for the preservation and preparation of food for serving. (You may wish to clip and post this table for future reference.)

The length of time that food is held at these temperatures is also important because the time-temperature relationship determines what happens to any microbial contaminants. Storage of frozen food at 0° F or below prevents micro-organisms from growing and kills some cells, but it does not destroy all of them. Thawing causes microbial growth and chemical changes to accelerate as the temperature rises. Unless thawed foods are used promptly, they will begin to spoil and may be dangerous to eat.

Refrigeration at 35° to 45° F is effective for short-term storage of perishable products. The danger zone lies between 45° F and 115° F, where both infectious bacteria and toxin-producing micro-organisms may grow rapidly.

In this temperature zone, foods may undergo a doubling of the bacterial population every 15 to 30 minutes. Holding perishable foods at temperatures in the danger zone should be avoided or kept to the minimum time necessary for preparation and serving.

Cooking foods such as pork roast or stuffed turkey until the innermost part of the food reaches 165° F will kill all infectious micro-organisms, though it may not destroy the most heat-resistant spores or toxins. The homemaker should use a thermometer to determine the time required for the food to reach

CRITICAL TEMPERATURES FOR SAFE FOOD HANDLING

OPERATION	INTERNAL TEMP. °F
Home canning	240-260
Cooking	165 or more
Warm holding	140 or more
DANGER ZONE	45-115
Refrigeration	35-45
Frozen storage	0 or less



DON'T leave food to defrost in the kitchen when you're leaving home for the day. It could spoil.



NEVER leave groceries in a hot car for any length of time. It hastens spoilage. Make the grocery store the last stop before returning home.

this critical temperature because this time will vary with the method of cooking as well as with the kind and amount of food.

Cooked foods should be served as soon as possible. When warm holding is necessary, the temperature should be kept above 140° F to destroy subsequent contamination and prevent bacterial growth.

If cooked foods are to be kept for later use, they should be refrigerated immediately, *without* preliminary cooling. Leftovers should always be refrigerated promptly, also. Refrigerating the food in layers less than four inches deep will reduce the time

it is in the danger zone.

Few people today do home canning, which is fortunate because it is an uncertain method of preserving food. Unlike commercial canning plants, the ordinary home kitchen does not have reliable controls to assure that the internal temperature of every can reaches 240-260° F for the specified time.

Underprocessed canned vegetables and meats can develop lethal concentrations of botulinal toxin. Any evidence of swelling, decomposition, or other abnormality is sufficient reason to destroy the entire lot.

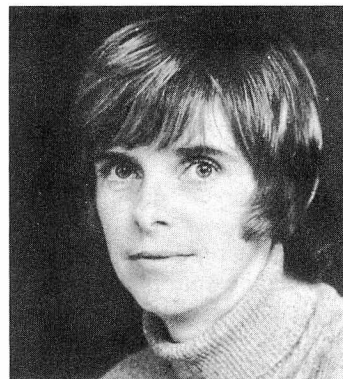
The homemaker can largely prevent diseases caused by food

in the home by following sanitary practices such as discarding abnormal or spoiled foods, using clean utensils and work surfaces, keeping hot foods hot and cold foods refrigerated, cooking thoroughly, and minimizing delays between preparation and serving.

Mishandling of foods that allows the introduction, survival, and growth of disease-producing micro-organisms is usually the result of apathy, ignorance, poor judgment, or carelessness. Any major improvement needs the concerned, informed effort of every person who buys and serves food in the home.

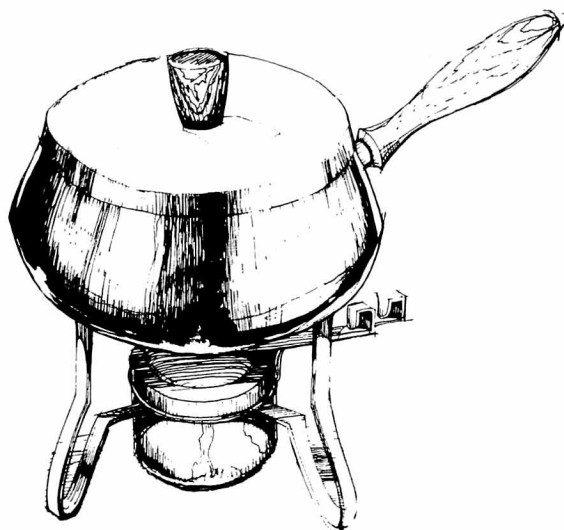
FOR MORE INFORMATION

1. "Keeping Food Safe to Eat—A Guide for Homemakers." U.S. Dept. of Agriculture Home and Gardening Bulletin No. 162. Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. (10 cents)
2. "Hot Tips on Food Protection." PHS Pub. No. 1404. Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. (10 cents)
3. "Cold Facts About Home Food Protection." PHS Pub. No. 1247. Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. (5 cents)
4. "No Picnic." PHS Pub. No. 1623. Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. (5 cents)
5. "From Hand to Mouth." PHS Pub. No. 281 48 pp. Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. (5 cents)
6. "You Can Prevent Foodborne Illness." PHS Pub. No. 1105. Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. (5 cents)
7. "How the Consumer Can Report to the FDA." FDA Fact Sheet No. G-3. Office of Consumer Affairs, FDA—Rockville, Maryland 20852. (Free)



Madean Horner is a free-lance consumer writer and a housewife.

Tabletop Hazards: FONDUE POTS



Fondue, a Swiss dish that has become popular in the United States, can be a welcome addition to any dinner. But misuse of fondue pots can lead to serious injury. Here are some tips from FDA's Bureau of Product Safety on how to select a fondue pot, and how to use it in your home.

An excited, distracted hostess takes a pot of nearly boiling cooking oil from the stove to carry it to the guests for whom she is serving fondue. The charred and loosened pot handle turns in her hands and the scalding oil spills over her arms and lower body. Result: a hurried trip to the nearest hospital emergency room for treatment of painful second and third degree burns.

A curious three-year-old boy reaches for the tiny flickering flame under a chafing dish. The hot food spills over his exploring fingers. The boiling water in the bottom pan splashes onto his face and eyes. Result: injuries severe enough to require hospital admission.

Other accident reports tell of spattering bits of meat that become sparks to ignite pots of hot oil, oil drippings that burst into flames on hot stoves and burner units, liquid fuel cans that explode as burner units in chafing dishes and fondue pots are refueled. Around the country, the National Electronic Injury Surveillance System has tabulated this and other data

on injuries received in accidents from tabletop cookery.

Further investigation of these accidents shows that open flames, liquid fuels, boiling water, hot cooking oil, and often inattentive or distracted cooks are factors that contribute to serious and painful injuries in all age groups.

For years, tabletop cookery has meant chafing dishes, coffee carafes, spirit kettles, egg cookers—all heated by electricity or the open flames of burning alcohol. The recent popularity of fondue cookery, however, has been associated with an increase in serious and painful accidents.

A fondue is a dish of melted cheese. There are also "meat" fondues. Fondues have caught on rapidly in recent years. They are an informal and relaxed way of entertaining. Both children and adults enjoy the excitement of cooking over the open flames.

For preparing fondues at the dining table, there are three basic sources of cooking heat: liquid alcohol, solid alcohol, and electricity.

Liquid alcohol is widely used. It is clean, easy to store, reasonably cheap, and burns with a hot, clear, almost odorless flame. A disadvantage is that the flame is almost invisible and there is the possibility that a cook will believe the flame has been extinguished when it is not. If more fuel is added to a hot or still burning unit, there may be a flaming flare-up and explosion with the flames traveling on the fuel vapors and causing the can of fuel to explode in the cook's hands when more fuel is being added.

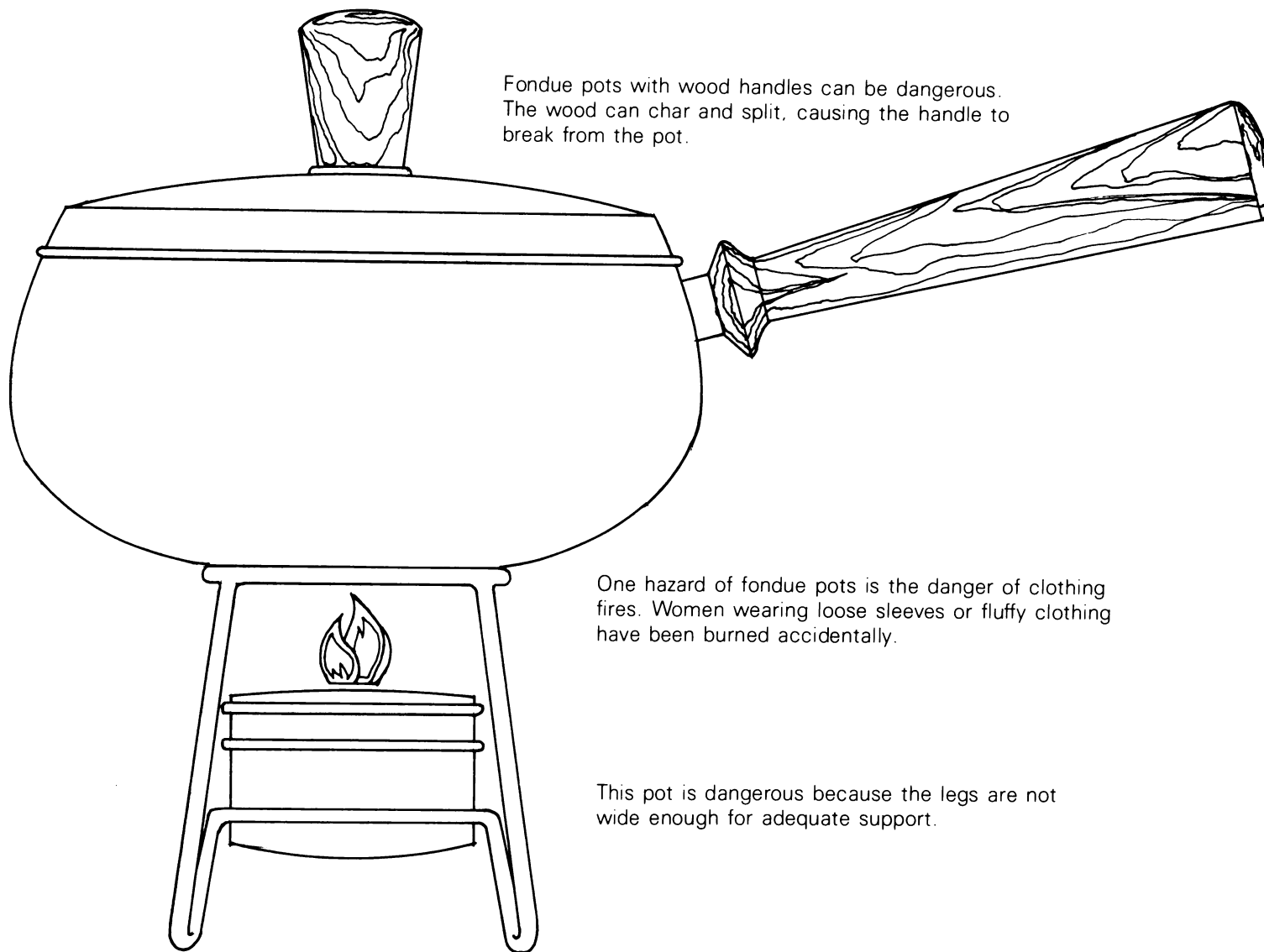
In one recorded case, the hostess was adding alcohol to a burner she thought was no longer lit. The residual alcohol in the burner ignited and flames spread to the bottle of alcohol she was holding, igniting her clothing. She was admitted to a hospital with second degree head, neck, and arm burns over 30 percent of her body.

In another accident, both the cook and her husband, standing three feet away, were burned when flames ignited their clothing. The woman suffered second degree arm burns.

Solid alcohol is a clean, easy-to-use, nonspilling fuel. Covering the can seals it and stops all flames quickly, efficiently, and safely. When the can of fuel is in use, flames and heat can be regulated simply by sliding the lid across the top opening. Because the fuel is solid, it is not as likely as liquid alcohol to be accidentally ingested by curious youngsters. The fuel's solidity also eliminates the hazard caused when fuel is added to still hot burners that can ignite and explode vapors and the can from which they come.

But there are disadvantages, too. As with liquid alcohol, the open flames are hazardous—to the woman in fluffy party clothes who reaches across the dining table or to a child who is curious about fire in any form.

Electricity used for fondue cookery lacks the



Fondue pots with wood handles can be dangerous. The wood can char and split, causing the handle to break from the pot.

One hazard of fondue pots is the danger of clothing fires. Women wearing loose sleeves or fluffy clothing have been burned accidentally.

This pot is dangerous because the legs are not wide enough for adequate support.

excitement of open flames. A nearby wall outlet is a necessity. Extension cords running down from the table and across the floor can be dangerous.

There are advantages in using electricity, however. An electric pot in place on the table eliminates the injury potential present when hot liquids are transported from stove to table, the possibility that vapors from heated fuel may ignite, and the dangers associated with refueling.

Dangers may exist in the general design of fondue pots. The taller, more graceful looking pot bases are dangerous because they are easier to tip and spill. Wooden handles on pots may char or become loose from heat and grease spillage. The loose handles can turn or come loose entirely, causing the pot's scalding, burning contents to spill. The rivets of some pot handles become loose or softened from heat. Screw-on handles become loose when screw threads

wear with use. Earthenware pots recommended by Swiss recipes for cheese fondue may crack when in direct contact with the higher heat of kitchen stoves.

Here are some suggestions for safe use of fondue pots as prepared by the Bureau of Product Safety:

1. Select fondue pots with permanently bonded, heat resistant handles.
2. Select fondue pots with covers for both pots and burner units.
3. Select a fondue pot with a broad-based stand for increased stability. If possible, choose a pot with a grease shield at the perimeter of the base.
4. Always place a tray under a fondue pot when cooking to catch any spillage and provide insulation for the table surface.
5. Before attempting to refuel, be sure that the flame is completely extinguished and that the burner has cooled for several minutes.

news highlights

Grant Resigns As FDA Deputy Commissioner; Sherwin Gardner Named Acting Deputy

James D. Grant resigned as deputy commissioner of FDA, effective May 31.

Sherwin Gardner, assistant commissioner for planning and evaluation, was named acting deputy commissioner.

Charles C. Edwards, M.D., Commissioner of Food and Drugs, accepted Mr. Grant's resignation, "with deep regret and with gratitude for the many lasting contributions Mr. Grant has made during more than two years as deputy commissioner.

"During the time Mr. Grant has served in FDA, the Agency has undergone significant expansion in the responsibilities assigned to it by the Congress and by the Executive Branch," Dr. Edwards said.

"This growth and increased activity has been accomplished simultaneously with a major internal reorganization. In all of these matters, Mr. Grant has played a vital role. He has been especially active in program management and in the continuing effort to improve the decision-making procedures within the Agency," he added.

"I am personally grateful for his unfailing good advice and counsel and all of us in FDA wish him continued success in the future," Dr. Edwards said.

Mr. Grant will enter private industry as Assistant to the Chairman of the Board of CPC, International, a worldwide food company with headquarters in Englewood, N.J.

Before joining FDA in January 1970, Mr. Grant was deputy to Dr. Jean Mayer, Special Consultant to the President. He helped organize and conduct the White House Conference on Food, Nutrition, and Health in 1969.

Before joining FDA in October 1970, Mr. Gardner spent six years with Booz, Allen, and Hamilton, a management consulting firm in Chicago.

FDA Intensifies Regulatory Program To Eliminate Insanitation in Food Plants

FDA has announced an intensified regulatory program designed to eliminate insanitary conditions in the Nation's food plants.

In announcing the expanded program, Charles C. Edwards, M.D., Commissioner of Food and Drugs, pointed out that FDA in recent years has devoted the majority of its inspectional resources to microbiological contamination problems.

"It has become apparent, however, that there has been a general decline in the food industries sanitation practices," Dr. Edwards said. "This has been shown by recent FDA inspections and confirmed by a report of the General Accounting Office which concluded that serious insanitary conditions exist in the food industry."

Dr. Edwards pointed out that the proposed 1973 budget for FDA would provide for 300 additional food plant inspectors and would make it possible to carry out the sanitation inspectional program without lowering the level of inspection for microbiological contamination.

"While we must continue to give high priority attention to microbiological problems such as salmonella and botulism which can present a serious hazard to health, we cannot tolerate a decline in general sanitation practices. We, therefore, intend to take prompt, vigorous action to assure good housekeeping operations, including cleanliness of personnel, equipment, and premises and elimination of all conditions that attract vermin and rodents," Dr. Edwards said.

FDA Takes Several Steps To Remove Unsafe Toys

FDA recently has taken a number of additional actions to remove unsafe, banned toys from the market.

The actions include 12 seizures of more than 4,000 toys since January 1, field inspection trips by toy surveillance teams, and a meeting with representatives of trade associations to discuss ways of improving toy recalls from retail stores.

Officials of FDA's Bureau of Product Safety met with representatives of the National Retail Merchants Association, the National Retailers Association, the American Retail Federation, the Association of General Merchandising Chains, and other retailers to study ways of speeding up removal of banned toys from store shelves.

One of the problems is that retailers report they are unable, in many cases, to differentiate the unsafe toys from those which have been redesigned to meet safety standards.

To meet this problem, retailers have formed an ad hoc committee to consider better methods of accomplishing recalls, and will report to FDA within four weeks. FDA is considering publication of a regulation which will require a coding stamp on each toy to identify the manufacturer and the date it was placed on the market.

FDA surveillance teams have worked with public

interest groups in three cities to survey for unsafe toys in retail stores. These surveys were made and appropriate corrective actions taken in Little Rock, Arkansas; Minneapolis; and Seattle.

FDA is presently developing a consumer deputy program to assist consumer interest groups in searching out unsafe toys in retail stores throughout the country. This program is another step in FDA's program to enlist the aid of consumer groups in its enforcement actions. In addition, FDA inspectors have attended toy fairs in New York and Dallas to identify potentially hazardous toys which manufacturers are asked to correct before marketing.

Five of the 12 toy seizures were "Roly-Poly Pony" musical rocking horses, manufactured for Childhood Interests, Alan Jay, Roselle Park, New Jersey. Other seizures included various plastic toys imported or manufactured by Happy Mates, Division of Electro-Plastic, Inc., Newark, New Jersey, and rattles, manufactured for or by Stahlwood Toy Manufacturing Co., New York, N.Y., and Baby World Co., Inc., New York, N.Y. The plastic toys were banned after they were found to have the potential for causing laceration, puncture wounds, injury, aspiration, ingestion, or other injury.

Highly flammable toy clown dolls, imported by Cut-Rate Linoleum Stores, New Orleans, Louisiana, and two lawn dart games, manufactured by Hasbro Industries, Pawtucket, Rhode Island, and Regent Sports Corp., Hauppauge, New York, accounted for the remaining seizures.

Child-Resistant Packaging Proposed For Lighter Fluids, Turpentine

FDA has announced proposals to require special "child-resistant" packaging for two types of household products which have caused injury, illness, and death to children under five years of age.

The first proposed regulation requires special packaging for certain liquid kindling and illuminating preparations containing 10 percent or more of petroleum distillates, such as charcoal and cigarette lighter fluids.

The second proposal would require special packaging

for household substances in liquid form which contain 10 percent or more turpentine. These substances include paint thinners, certain furniture polishes, and household solvents.

FDA's Bureau of Product Safety said both types of products, when ingested or aspirated by children, may cause serious or fatal chemical pneumonitis. In addition, turpentine products are reported to be capable of systemic poisoning affecting the kidneys and central nervous system.

FDA's National Clearinghouse for Poison Control Centers reports 2,062 ingestions and 249 hospitalizations due to household substances containing turpentine from 1968 through 1970. Two resulted in death. During the same period, 3,189 ingestions of kindling and illuminating preparations caused 369 hospitalizations and nine deaths of children under five years of age.

The action is being proposed under the provisions of the Poison Prevention Packaging Act.

OTC Drug Review Proposal Made Final To Be Effective in July; Changes Few

FDA's final adoption of its proposal of last January 4 to review over-the-counter or nonprescription drugs (see FDA PAPERS, February 1972) was published in the *Federal Register* May 11 with only a few changes. The order becomes effective in 60 days from that date except for any provisions that may be stayed by the filing of "proper objections."

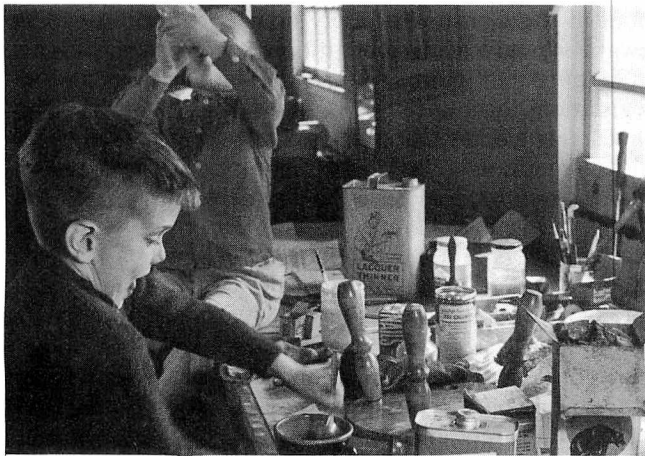
The final order disposed of 98 objections, suggestions, or questions raised in 43 comments, rejecting most arguments. The comments covered every part of the proposal and its accompanying preamble, FDA noted.

In its list of 26 therapeutic categories to be reviewed in its Over-the-Counter Drug Products Evaluation Program, FDA added a dermatological product category, and deleted the menstrual products category on grounds the latter are adequately covered by other categories.

For clarification, the names of some categories were changed, namely, anti-infective to anti-microbial; mouthwash to oral hygiene aids; and antihistamine to allergy treatment products. FDA explained that oral hygiene aids will cover a much wider range than simply mouthwash products. Substitution of allergy treatment products for antihistamines will reduce the products in that category, since antihistamines appear in a number of other categories listed, such as sleep aids and cold remedies, and will be considered in these categories as used.

FDA said its order does not preclude a panel reviewing more than one category and said the Agency also may find it necessary to convene more than one panel to cover those drugs in the "miscellaneous" category.

The final order also made it clear that a person appearing before a panel with information or views on a particular therapeutic category will not lose his right



to raise "appropriate legal or other objections to the monograph" at some later point. "The full cooperation and participation of all interested persons is requested in order to make this review as successful as possible," FDA said.

FDA Halts Manufacture of Human Drugs By South Hackensack, N.J., Manufacturer

FDA has stopped the manufacture and distribution of all human drugs by the Marshall Pharmacal Corp., South Hackensack, New Jersey.

FDA assays of the firm's digoxin product showed variances in individual tablet potency ranging from 60 per cent to 212 per cent of declared tablet strength. Digoxin is used widely for treating congestive heart failure and stabilizing heartbeat.

FDA has been granted a permanent injunction against the firm by the U.S. District Court in Newark. Under terms of the injunction the firm is ordered to stop manufacturing or shipping of any human drug until its methods, facilities, and controls for manufacturing, processing, packing, and storing drugs are proven to conform with current good manufacturing practices as required by law.

Action leading to the May 1 court order was part of a unique program FDA initiated in the fall of 1970. In October of that year the Agency began a voluntary certification program to assure the quality of all brands of digoxin and digitoxin. The result was that the Agency tested nearly every batch of these cardiac drugs before distribution by manufacturers.

Thirty-nine firms have been sampled and the results confirm that lack of tablet uniformity was a common problem in all firms. Most manufacturers have corrected the problem by now.

Seattle Poison Control Center Becomes Fifth Linked to FDA

The Poison Control Center in Children's Orthopedic Hospital, Seattle, has become the fifth medical unit linked to FDA's computer-based network for providing instant information on accidental ingestion of poisons and other substances.

The electronic system, which provides a "read-out" on the face of a cathode ray tube much like a television set, also serves poison control centers in Boston, Detroit, Kansas City, and New Orleans. All five terminals are linked to FDA's National Clearinghouse for Poison Control in Washington, D.C.

The National Clearinghouse computer contains information on ingredients, toxicity, symptoms, and recommended treatment for more than 5,000 household substances. Eventually, the computer will have approximately 50,000 household products on file.

FDA Proposes Sales Ban On Fireworks for Agriculture

A proposal to disallow the sale of fireworks for agricultural purposes has been announced by FDA.

In previous regulatory actions, FDA has banned for general sale explosive fireworks containing more than two grains of powder, such as Cherry Bombs, M-80 Salutes, and aerial bombs. However, an exemption was made for using these firework devices to scare birds away from agricultural crops.

Charles C. Edwards, M.D., Commissioner of Food and Drugs, said the exemption for crop protection has been grossly abused by some manufacturers and distributors who make the fireworks available to the general public. "Bootleg" fireworks have caused deaths and serious injuries.

Dr. Edwards also announced that FDA has received a petition from the National Society for the Prevention of Blindness (NSPB) to ban all fireworks. FDA will publish the petition for public comment, which provides an opportunity for interested persons to submit appropriate data on both sides of the question.



While Acting Deputy Commissioner of Food and Drugs Sherwin Gardner looks on, Malcolm W. Jensen, center, director of FDA's Bureau of Product Safety, accepts a commendation on May 17 from W. Jeff Keirns, Chairman of the Consumer Safety Glazing Committee. The award was given in recognition of the Bureau's efforts in helping the Committee promote model safety glazing legislation for States. The model legislation requires that safety glazing materials such as wire glass, tempered glass, laminated glass, and rigid plastics be used in doors, windows, enclosures, and panels. It was developed to help prevent accidents involving breakage of ordinary glass in doors and hazardous locations, which occur at the rate of 250,000 annually in the United States. Thus far, such legislation has been enacted in 18 States. The Committee was formed three years ago, with a membership from the glass and plastic industry, trade and manufacturing groups, unions, and national and governmental safety groups.

FDA INCREASES IMPORT INSPECTION CAPABILITIES

FDA has increased its capabilities to inspect imported foods and drugs by acquiring three mobile laboratories which are completely equipped to perform analytical testing at dock-side. The van pictured on this page was photographed when it was displayed at FDA headquarters at 200 C Street., S.W., Washington, D.C. This van was later assigned to the New York District. A similar lab has been assigned to FDA's San Francisco District. The Philadelphia and Baltimore Districts will share the third van. The vans will solve one of the major problems posed by FDA's import inspection program: the inability of permanent labs to handle the number of analyses of import samples generated by FDA inspectors.



Charles C. Edwards, M.D. (center), Commissioner of Food and Drugs, shows the mobile laboratory to Elliot L. Richardson (left), Secretary of the Department of Health, Education, and Welfare, and DHEW Assistant Secretary for Health and Scientific Affairs Merlin K. DuVal, M.D. This van was also displayed in front of the Rayburn House Office Building, where it was viewed by members of Congress.



Inside the van, Richard Klug (arm extended), assistant for import operations in FDA's Office of the Executive Director of Regional Operations, explains how a constant temperature water bath is used to rapidly defrost frozen food to make it amenable for testing for possible decomposition. With him are (left to right) Secretary Richardson, Assistant Secretary DuVal, and Commissioner Edwards.

field reports

ATLANTA Concluding a recent three-week trial in the U.S. District Court for the Northern District of Georgia, at Gainesville, Judge Sydney O. Smith condemned 12,414 thirty-pound cans of frozen whole eggs packed by Golden Egg Products, Oneonta, Alabama. The condemnation terminated cases involving seizures made in Detroit; Boston; Miami and Orlando, Florida; and Columbus, Georgia. The Government had charged that one lot contained *Salmonella* organisms, and that all lots were decomposed and had been packed under insanitary conditions whereby they may have become contaminated with filth. The judge condemned all lots as packed under insanitary conditions, but did not find that they were decomposed. The one lot containing *Salmonella* was condemned under that charge as well. The total value of the eggs at the time of seizure was \$78,668.

FDA personnel at the Atlanta Field Office and at the Louisville, Kentucky, resident post were put on an emergency standby recently because of an accident involving liquid chlorine gas. On March 19 a barge, containing four cylinders of the gas weighing approximately 600 tons, broke loose at Louisville while being towed up the Ohio River and lodged against a pier column at a point where the water rushes over the McAlpine Dam.

The Office of Emergency Preparedness set up temporary headquarters, where the officials met daily with FDA resident inspectors for briefings with considerable input by FDA regarding possible danger and the effects of chlorine gas on foods and drugs. Kentucky health authorities were alerted, and a standby status was initiated for Atlanta Field Office personnel.

On Easter weekend, while the chlorine-laden barge was stabilized and transfer of the liquid chlorine commenced, 4,000 persons in the immediate area were evacuated. Two of the four tanks were located in the submerged rear section of the barge, making transfer difficult. Although a crack had been discovered in the barge and there was a possibility it might break in two and sink, transfer took place without any further accidents.

BALTIMORE The consumer is not always aware of the behind-the-scenes benefits from Federal Government regulation in the marketplace. An example is the cooperative response from the food chain, Acme Markets, Inc., Baltimore, after a recent District inspection, which revealed insanitary conditions, and a followup regulatory letter to the firm. Acme informed Baltimore District officials that as corrective measures to eliminate

the problem of rodents and improve warehouse sanitation, the firm has hired ten additional sanitation employees, bought \$5,000 worth of heavy-duty cleaning equipment, and initiated more stringent control of stock rotation. Such measures, which conform more closely to FDA's Current Good Manufacturing Practice Regulations, mean cleaner food products for the consumer.

BOSTON Geri-Twins, Organex, and Acerola-C, valued at approximately \$5,000, have been seized at the Nature Food Centers, Cambridge, Massachusetts. The FDA complaint alleges that the products are misbranded in that they are falsely and misleadingly labeled as dietary supplements.

After the Boston Field Office followed up a recent alert, herring valued at approximately \$10,000 was seized in San Juan, Puerto Rico. Officials from the Division of Consumer Protection, Maine State Department of Agriculture, notified the Field Office that the Port Clyde Packing Co. at Rockland, Maine, had canned herring and labeled it as "Sardines." Boston FDA officials contacted the FDA District office in San Juan. Samples were collected and analysis showed that the product was in fact pieces of mature sea herring and not sardines as labeled.

BUFFALO A division of the Chesebrough-Ponds, Inc., Watertown, New York, voluntarily destroyed 242,187 clinical thermometers valued at approximately \$70,000, under the surveillance of an FDA inspector from the Buffalo District. The thermometers were destroyed because of defects primarily due to inaccurate calibration, which caused them to fail to meet specifications of both the company and the U.S. Bureau of Standards.

FDA ordered seizure at Norwich, New York, of 98 cases of the detergent concentrate "Concern," valued at approximately \$1,850. This was the last known lot still on the market of this toxic and irritant detergent which failed to bear the required cautionary labeling. This action was the last of a series in which 24 separate seizures were made, with the assistance of several other FDA Districts, resulting in the removal from consumer channels of almost \$100,000 worth of this hazardous substance. Although the manufacturer, H. T. Developments, Inc., Buffalo, agreed last June to relabel all of the product then in commerce, the firm declared bankruptcy and did nothing further to bring the product into conformance with the law.

CHICAGO A U.S. marshal for the Northern District of Illinois recently destroyed 385 cubic yards of materials (see photo below) seized at the Vanderhill International Pharmaceuticals Ltd., Chicago. The destroyed materials included drug raw materials, in-process and finished drugs, some vitamin products, packing materials, labels, and containers, and represented a possible drug or vitamin dosage of as many as 524 million individual units worth approximately \$400,000 at wholesale. Seizure had taken place early in 1971 based on a charge that the firm failed to comply with FDA's Current Good Manufacturing Practice Regulations.

This firm was the successor to LTC Pharmaceuticals, Inc., Chicago, which was placed in bankruptcy by its operating manager. LTC Pharmaceuticals, Inc., was the successor to Bates Laboratories, Chicago, which had consented to a preliminary injunction action brought by FDA in 1967, based on similar charges.



CINCINNATI Catherine Knarr, District consumer specialist, participated in a series of programs titled "Consumerama—Food '72" held recently in northern Ohio. She discussed labeling, current labeling regulation, and Fair Packaging and Labeling Regulations at the four sessions, each of which had an audience of 650-700 people.

DALLAS Armando Gomez, a trade commissioner with the Mexican Government, visited the District office recently to discuss the laws enforced by FDA as they relate to Mexican imports. He asked that the Dallas District office contact him when it encounters a significant problem with such imports so he can advise his government concerning the need for corrective action.

Mr. Gomez is one of four trade commissioners assigned to the United States. His main objective is to

promote Mexican imports, and his area covers 28 southern States. He reports to the Mexican Institute of Foreign Trade in the Department of Industry and Commerce.

DETROIT Because of various violations, the District ordered seizures of beans, mushrooms, cherries, and a vitamin preparation. Great Northern beans and navy beans valued at over \$2,000 were seized at a Detroit wholesaler because the labeling of the products did not comply with the Fair Packaging and Labeling Act. The beans were packed by N. K. Hurst Co., Indianapolis.

Canned mushrooms packed and shipped by Great Lakes Mushroom Cooperative in Warren, Michigan, were seized in Kansas City, Kansas, and Tampa, Florida, after Detroit District found from samples taken during an inspection that the product contained live micro-organisms. The combined lots were valued at over \$3,000.

Dark sweet pitted cherries packed by Suttons Bay Packing Co., Suttons Bay, Michigan, were seized in Pittsburgh because they were substandard. A District establishment inspection and sample analysis revealed excessive blemishes on the cherries.

Ponodyne capsules, an analgesic vitamin preparation manufactured by Kapco, Inc., Kalamazoo, Michigan, were seized because the drug lacked substantial evidence of effectiveness as a fixed combination. The firm had continued to market the product after FDA announced its lack of effectiveness in the *Federal Register*.

LOS ANGELES The District's newly installed consumer phone message in Spanish has been well received in the Los Angeles area. The voice of Mary LoVetere, District chemist, who records the messages, is heard frequently on the Spanish-programmed Radio Station KWKW. Jaime Jarrin, news director for the station, told the District that he places a great deal of importance on this service to the Spanish-speaking community. He requested as many consumer phone messages as possible so that he may "air" them on a daily basis.

Elaine Roentgen, District consumer specialist, presented a lecture on packaging and labeling to 88 persons enrolled in a series of consumer education classes sponsored by the San Diego Imperial Counties Labor Council, AFL-CIO.

MINNEAPOLIS H. P. Roberts, deputy regional food and drug director, committed the District to a follow-up action on banned toys after meeting with the Min-

nesota Public Interest Research Group. MPIRG recently completed a survey of hazardous toys in 41 Twin Cities' stores and afterward held a press conference. Representatives of local news media attended, and the newspapers and Twin Cities television stations presented the story. When Mr. Roberts met with the group on April 4, they presented him a list of the stores visited and a list of the toys which in their opinion were dangerous and/or banned by FDA. Mr. Roberts then said the District will ferret out the banned toys and remove them from store shelves.

A lot of peanut butter was destroyed recently after representatives of the suburban village of Bloomington, Minnesota, requested District assistance in supervising destruction of the product, which was manufactured locally. When District inspectors investigated, they found that the lot, consisting of 1,226 cases of peanut butter manufactured from 7,500 pounds of peanuts, was adulterated with aflatoxin, a toxin produced by a mold, and was therefore unfit for use. The adulteration had been discovered by the manufacturer in a routine analysis. The product was destroyed by bulldozing into a landfill and covering over with earth.

Following a report from FDA's Detroit District regarding pesticide residues found in hothouse-grown lettuce, Minneapolis District surveyed the hothouse lettuce growers in its area. One grower was found to have violative residues of PCNB, another grower's lettuce was contaminated with sulfotepp, for which there is no tolerance, and a third grower's lettuce was contaminated by both pesticides in violative amounts.

Since no interstate commerce was involved, the District gave this information to the Minnesota Department of Agriculture for appropriate action. The State has collected additional samples of lettuce which substantiates FDA findings of over-tolerance amounts and misuse of pesticides. State officials promise vigorous regulatory action after evaluating the results.

In connection with the District's investigation of injuries reported through the NEISS (National Electronic Injury Surveillance System) program, it looked into 39 snowmobile accidents and found that 28 adults and 11 children under age 18 were involved. There were 23 night accidents and 16 day accidents involving injuries to the face and numerous middle body, arm, and back injuries, as well as injuries to the lower extremities.

The Minnesota State Department of Natural Resources reported that there were 32 deaths in the State

during the winter due to snowmobile accidents.

NEW ORLEANS The District has undertaken a survey program considered to be of importance in this geographical area. The survey calls for the analysis of 24 samples of root crops to find if residues of mirex, a pesticide, are present. The root crops are taken from areas in Louisiana where mirex has been used for control of fire ants to determine if any residue is being translocated from the soil into the root crops.

Richard Carlton, of the Louisiana State Department of Agriculture, has offered FDA the services of his office to determine the areas in which mirex is being used and to collect the required samples.

NEW YORK In conjunction with its "project inner city," in which the District consumer specialist works with organized groups, Region II held a recent all-day consumer orientation briefing on the many activities of FDA as they relate to the consumer. A speaker from each of the New York District branches made a presentation, including slides and film, on his aspect of FDA's activities. A discussion and question-and-answer period followed.

Various socioeconomic and ethnic groups were represented by 24 leaders of community groups and agencies from throughout New York City. They showed enthusiasm and interest in the inner city project, and many requested that District representatives attend community meetings to address consumers directly. Others requested additional orientation seminars at Region II to fill in and update information and to secure additional materials and ideas for dissemination to their groups, clinics, schools, etc.

An incident reported to the Newark District points up the potential danger in a container of drugs not adequately resistant to opening by children. A college professor at Newark notified the District that one of his students, while checking out her purchases at a grocery store, noticed that the carton containing the bottle of aspirin for children she was buying was open. Closer examination revealed a cracked safety cap, tooth marks, and no aspirin in the bottle. Her two-year-old son, sitting in the shopping cart, pointed to the bottle and said, "Good." Apparently, while the mother was talking with friends in the market, the child had opened the carton, removed the safety cap from the bottle with his teeth, and had eaten the aspirin. He was treated at a nearby hospital.

The bottle and cap have been sent to the Bureau of Product Safety for review, and FDA's Atlanta District

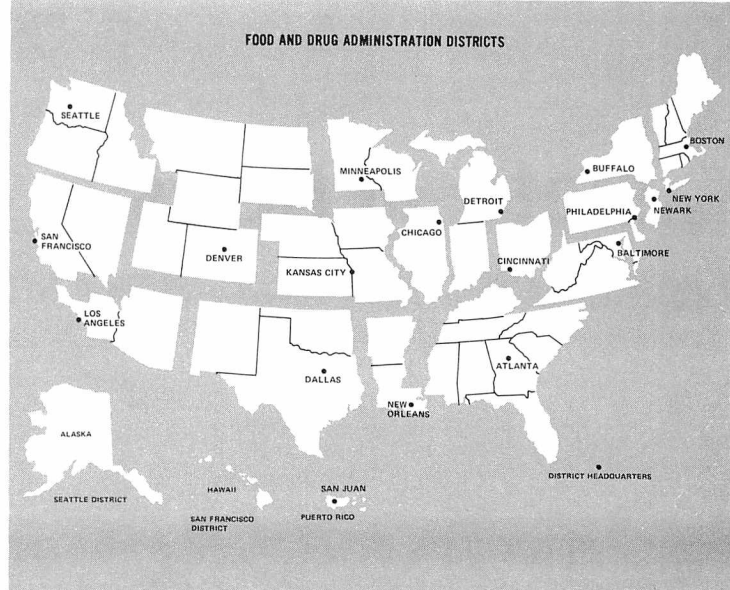
has been notified, since the manufacturing firm is in that area.

PHILADELPHIA FDA's Region III personnel have been participating in a program called "Stop Obesity Sensibly" (SOS), in cooperation with the hospitals of the Delaware Valley. The program is held twice a year at Philadelphia in nine two-hour sessions at the Albert Einstein Medical Center's Health Education Department.

FDA's input to the program involves the medical and nutritional fields.

The sessions have reached an estimated 15,000 people, and taped sessions will be incorporated into a book of consumer information on weight reduction, now being prepared by the Albert Einstein Medical Center.

SAN FRANCISCO Yaron Laboratories, Inc., trading as American Chemical & Drug Co., Foreign Trade Zone #3, San Francisco, was permanently enjoined after a hearing in a U.S. District Court in San Francisco from shipping the new drug "PAX" in interstate commerce without an effective New Drug Application. The firm



ships drugs primarily to Vietnam. In an original court order in February, a preliminary injunction was granted enjoining the firm from shipping not only this particular drug but others also designated as new drugs. The recent order was revised to apply to "PAX" only.

Earl Fruit Co., DiGiorgio, California, was fined \$500 after pleading guilty in a U.S. District Court at Fresno to a three-count information alleging interstate shipment of peanuts contaminated with rodent urine.

SEATTLE Joan Bergy, District consumer specialist, recently presented six workshops on home safety and drug education for elementary teachers in the Moses Lake and Ephrata areas of Washington.

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

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

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

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

Cyclamate A Food Grades and Standards Division inspector, W. McLullen, of the Florida Department of Agriculture and Consumer Services, recently ordered and supervised the destruction of 41,200 cases of beverages containing cyclamates. The lot was in the possession of a wholesaler at Miami, who had been holding it since 1970. At one time the dealer firm indicated its intention to export the product, but never did, so destruction was ordered.

Peanuts Seized An inspector from the Food Section of the Virginia Department of Agriculture and Commerce seized several stored lots of oil-stock peanuts at the Suffolk Oil Mill, Suffolk, Virginia, after they were found to be contaminated by birds. The contamination was discovered during a routine inspection by an FDA inspector from the Baltimore District and reported to the State unit. The seized peanuts are to be reconditioned under State supervision.

Suffolk Oil Mill is one of 692 firms in Virginia whose coverage is shared through formal agreement between FDA's Baltimore District and the State.

Drug Firm Fined The New York State Board of Pharmacy held a hearing at Albany at which it charged Fox Drug Co., Carthage, New York, with failure to comply not only with the Board of Pharmacy regulations but with FDA's Current Good Manufacturing regu-

lations. The charges were specifically related to a recent joint inspection by the Board and FDA Buffalo District inspectors. An FDA inspector testified at the hearing, and showed color photographic evidence illustrating crowded conditions and poor warehousing practices. Although the firm's license was not suspended, it was fined \$2,500.

Coho Salmon Under the supervision of the Fisheries Section of the Michigan Department of Natural Resources, 1.5 million pounds of coho salmon was destroyed recently by burial in a Grand Rapids, Michigan, landfill. The salmon had been in the custody of the department since FDA found it contained residues of DDT, a pesticide chemical, and PCB's, industrial chemicals, both harmful to health. Most of the fish was from the 1970 harvest season and was the last lot held by the State. The burial operation, which lasted more than a week, posed no ecological problems, State experts said.

Struvite—Not Glass Jane Wyatt, consumer officer for the Oregon Department of Agriculture, says that based on a number of complaints recently about pieces of glass being found in canned tuna, the consumer should be told what is really being found. In most cases, it is a harmless, legal substance known chemically as magnesium ammonium phosphate hexahydrate bearing the mineralogical name of

struvite.

Struvite is found more often in canned tuna or shrimp, but may be found in other canned seafood products. It is composed of natural constituents of fish or shellfish made up of mineral elements supplied by the sea water in which the fish or shellfish live. The crystals, which appear to be particles of glass, form as a result of the sterilization of the seafoods in their processing, and ordinarily are not of a large enough size to attract attention. While the fish or shellfish are alive, the minerals have an important role in the life processes.

A National Canners Association circular on "Crystals in Canned Seafoods and Fish" says NCA does not know when the crystals in processed seafoods were first noticed, but that they attracted attention in a rather spectacular way in 1917, during World War I, when struvite was found in a can of tuna and it was suspected that ground glass had purposely been added by an enemy agent. At that time, the crystals were identified by the U.S. Food and Drug laboratory in San Francisco as harmless magnesium ammonium phosphate.

During World War II there were a few "ground glass" rumors again, and the FDA in 1942 issued a news release about the crystals, assuring the public that they were harmless.

There are two ways the consumer can determine whether she has found struvite crystals or glass. Since the struvite crystals are about the same

hardness as table salt, they can be crushed to a powder with the thumb nail or can be dissolved in a few minutes by boiling them in a little vinegar or lemon juice. Glass is not soluble in such weak acids.

Seminar for Consumers Taking the approach that an informed consumer is a wiser shopper, three State agencies combined their efforts recently to present a seminar designed to educate the consumer on the meats and poultry she uses. The seminar, titled "Consumer Awareness: Meats and Poultry," was held April 14 at Eugene by Oregon's Department of Agriculture, its Board of Education, and the State University Cooperative Extension Service, and was open to all interested persons. The one-day session covered all aspects of meat merchandising, meat regulations, grading systems, and sanitation standards.

Violation of Embargo The Minnesota Department of Agriculture brought a court action against a Minneapolis warehouse recently for violation of embargo. The department had cooperated with FDA's Minneapolis District by placing an embargo on three lots of insect-infested popcorn pending Federal seizure. In the interim, the warehouse shipped part of one of the lots under embargo, and the State took action. The court found the defendant guilty and placed the firm on probation for one year. A \$300 fine was suspended.

Legislative Actions Two significant pieces of legislation enacted in New Jersey recently will implement protection involving toy safety and safety glass installations.

A Senate Bill which became effective January 1 specifies a 1 percent maximum for lead in paint for toys and living interiors. An Assembly Bill which became effective March 28 culminated four years effort to enact a model safety glazing bill to help reduce cutting and piercing injuries.

The Assembly Bill, which also implements FDA Program Circular 7329.06A, requests FDA to set up a consumer safety glass committee at the State level. This committee would be supported in every way possible by both State and FDA with consumer information materials such as audiovisual aids, pamphlets, etc., and programs that PTA, school boards, educational groups, and community groups would find informative and instructive.

Salvage Operation Cleanup Missouri Division of Health officials have completed the task of supervising the possible salvage or disposal of over 200 tons of unfit food products the department had embargoed last fall on the premises of an eastern Missouri salvage operator, where they had been held under insanitary conditions.

False Claims for Tea The California Bureau of Food and Drug took action against the Squaw Tea

Co., Portola, California, for distributing tea that was falsely claimed to be effective in the treatment of cancer and arthritis. The firm was fined \$100 in the Portola Justice Court.

Bubble Gum in Ice Cream? It's the truth and it's considered to be a little something extra for youngsters. But Vergil Simmons, assistant administrator for food and dairy products in the Dairy and Consumer Services Division of the Oregon Department of Agriculture, says the addition of bubble gum to ice cream is illegal. This kind of treat is not approved by either the State or Federal government.

In a recent letter to the department from Robert A. Tucker, acting director of the Division of Federal Relations, Office of the Executive Director of Regional Operations, FDA, Mr. Tucker said, "Bubble gum is not one of the optional characterizing ingredients permitted by the standard for use in ice cream." Mr. Simmons said this holds true for Oregon as well. Therefore, since Federal restrictions would prevent interstate movement of ice cream with bubble gum and it is illegal in Oregon, such ice cream is subject to seizure in the State.

Mr. Simmons said that besides being illegal, bubble gum in ice cream is a possible hazard. The gum hardens when cold, and an unsuspecting youngster could break a weakened tooth on it, or a very small child might accidentally choke on it.

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 24 actions to remove from the consumer market products charged to be violative was reported in April. These included 17 seizures of foods: 10 involved charges concerning contamination, and 7 involved charges concerning economic and labeling violations. Other seizures included 5 of drugs (including 4 of veterinary and medicated feed), and 2 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD / Contamination, Spoilage, Insanitary Handling		
Popcorn/Charlotte, N.C. 2/14/72	Manley, Inc./Tarkio, Mo. (M,S)	Prepared and packed under insanitary conditions; insect-damaged kernels, larvae.
Potato flour/Kansas City, Mo. 3/21/72	Adams Transfer and Storage/Kansas City, Mo. (D)	Held under insanitary conditions; insect contaminated.
cornmeal, potato starch, sodium caseinate/Easton, Md. 2/14/72	Tidewater Foods Corp./Easton, Md. (D)	Held under insanitary conditions; rodent gnawed.
Rice, long grain, enriched, parboiled, all purpose flour, prepared mixes/Chicago, Ill. 2/7/72	Holleb & Co./Chicago, Ill. (D)	Held under insanitary conditions; rodent and bird contaminated.
Soups, Bon Vivant/Boston, Mass. 3/16/72	Bon Vivant Soups, Inc./Newark, N.J. (M,S)	Prepared under insanitary conditions; defective and abnormal cans.
Kalamazoo, Mich. 2/22/72	"	"
Bronx, N.Y. 3/9/72	"	"
Tuna, canned/New Orleans, La. 3/3/72	Bares Terminal Warehouse/New Orleans, La. (D)	Decomposed.
Honolulu, Hawaii 3/7/72	Hawaiian Tuna Packers/Honolulu, Hawaii (D)	"
Wheat germ meal/Paradise, Calif. 3/1/72	Lassen Foods, Inc./Paradise, Calif. (D)	Held under insanitary conditions; rodent contaminated.
Economic and Labeling Violations		
Chili sauce/Greenville, S.C. 3/7/72	W. T. Garner Food Co./Winston-Salem, N.C. (M,S)	Label vignette depicting ground meat on a frankfurter and prominent word "Chili" are false and misleading, since article contains no meat other than beef fat.
Grape juice, Muscat, Concord/Baltimore, Md. 2/11/72	Lipshultz Kosher Fruit Products Co./Brooklyn, N.Y. (M,S)	Not in conformity with the Fair Packaging and Labeling Act.
Mini-Lobsters/Landover, Md. 3/20/72	California Crayco, Sub. of Frosty Fish Co./Wilmington, Calif. (M,S)	False and misleading name "Mini-Lobsters," since article is crayfish.
Nuts, mixed, dates/Detroit, Mich. 2/16/72	D. De Franco & Sons d/b/a New England Tomato Co./Los Angeles, Calif. (M,S)	Not in conformity with the Fair Packaging and Labeling Act.
Pecan halves/Charleston, S.C. 2/3/72	H. M. Thames Pecan Co., Inc./Mobile, Ala. (M,S)	"
Sea-Pak onion rings/St. Simons Island, Ga. 2/24/72	Tradewinds Co., Inc./Brownsville, Tex. (M,S)	Mislabeled as "onion rings," since product consists of small onion bits breaded together to form a ring.
Tomatoes, canned/Joplin, Mo. 2/28/72	Allen Canning Co./Van Buren, Ark. (M,S)	Below quality standard for canned tomatoes.
DRUGS / Human Use		
Various drugs/Chicago, Ill. 3/10/72	Maizel Labs, Inc./Chicago, Ill. (M)	Not in conformity with good manufacturing practice.
Veterinary / Medicated Feed		
Mol-Mix 32-006, 32-150 liquid animal feed/Henderson, Colo. 3/1/72	American Fertilizer & Chemical Co./Henderson, Colo. (D)	New animal drug without effective approved New Animal Drug Application; contains diethylstilbestrol.
P-M-S feed initiator/Loveland, Colo. 3/15/72	Prescription Premix/Minatare, Nebr. (M,S)	"
Sodium sulfamethazine/Irene, S. Dak. 2/15/72	Neese & Sons Co./Ankeny, Iowa. Made in Denmark. (S)	"
V-22 C & S pellets/Fort Collins, Colo. 3/15/72	Ranch-Way Feed Mills/Fort Collins, Colo. (D)	"
HAZARDOUS SUBSTANCES		
RELTON R-7 rust preventative/Oklahoma City, Okla. 3/8/72	Relton Corp./Arcadia, Calif. (M,S)	Lacks required conspicuous labeling statements; labeling reads "Non-Toxic," which negated the required statements.
Toy hammers, plastic, suction toy, rattle balls/Columbus, Ohio 3/13/72	Imported from Hong Kong.	Banned hazardous substances.

No Postal Service cases available for this issue.

notices of judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

Dog food, Iams Plus, at Chicago, N. Dist. Ill.

Charged 4-23-71: when shipped by Iams Food Co., Dayton, Ohio, the article contained the poisonous and deleterious substance *Salmonella* micro-organisms; 402(a)(1). Default decree ordered destruction. (1)

Spinach, chopped, frozen, at Tampa, M. Dist. Fla.

Charged 6-16-71: when shipped by Seabrook Farms Co., Inc., Seabrook, N.J., the article, labeled in part "Shurfine Chopped Spinach . . . Distributed by Shurfine-Central Corporation . . . Northlake, Ill.," contained the non-conforming food additive diazinon, a chemical; 402(a)(2)(C). Default decree ordered destruction. (2)

Swordfish chunks, frozen, at Mobile, S. Dist. Ala.

Charged 3-22-71: when shipped by Mogelberg Goods, Inc., Jersey City, N.J., the article, labeled in part "Waldman's Fish Company, Ltd., Montreal, Quebec," contained the added poisonous and deleterious substance mercury; 402(a)(1). The article was claimed by Star Fish & Oyster Co., Inc., Mobile, Ala., who neither admitted nor denied that the article was adulterated and consented to dispose of the article if in fact the article was contaminated. The Government moved for summary judgment. The court granted the Government's motion, condemned the article, and ordered it destroyed. (3)

Swordfish steaks, frozen, at Gloucester, Dist. Mass.

Charged 2-18-71: when shipped from Japan, the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Consent decree authorized release to Gorton Corp., Gloucester, Mass., for export to original foreign supplier. (4)

Swordfish steaks, frozen, 3 seizure actions at New York, S. Dist. N.Y.

Charged 7-8-71: when shipped by Kanematsu-Gosho, Ltd., Yokohama, Japan, the article, labeled in part "ECIC Brand . . . Swordfish Steaks . . . Product of Japan Packed for East Coast Intercontinental Corp., . . . N.Y.," contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decrees ordered destruction. (5)

FOOD / Contamination, Spoilage, Insanitary Handling

Almonds, shelled, and peanuts, shelled, at Brooklyn, E. Dist. N.Y.

Charged 7-28-71: while held by Jerissa Nut Co., Inc., Brooklyn, N.Y., the almonds contained rodent filth, and both the almonds and peanuts were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (6)

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

Charged 7-9-71: while held for sale, the article contained moldy and insect-infested cassia; 402(a)(3). Default decree ordered destruction. (7)

Cheddar cheese, pasteurized, at Pocatello, Dist. Idaho.

Charged 4-21-71: when shipped by Hi-Land Dairyman's Association, Murray, Utah, the article had been made from filthy milk and contained plant fragments, rodent filth, and manure; 402(a)(3). Consent decree ordered destruction. (8)

Coffee beans, at New Orleans, E. Dist. La.

Charged 10-4-65: while held for sale, the article contained moldy, decomposed beans; 402(a)(3). The article was claimed by Leon Israel & Bros., Inc., New Orleans, La., and the charges were denied. The Government moved for summary judgment on the grounds that claimant's answer to interrogatories and statements by others established that some of the coffee beans were decomposed as evidenced by molding and that accordingly there was no genuine issue of material fact. The claimant did not oppose the Government's motion for summary judgment for a decree of condemnation. Decree of condemnation authorized, upon petition of claimant, release to claimant for reconditioning. Thereafter the Government moved for destruction of the article on the grounds that claimant's process of reconditioning, by burnishing or brushing, had been completed and that the coffee beans were still not in compliance with the law.

At a hearing on the Government's motion, the District Court found that the reconditioned beans were fit for food under the standards of the New

York Coffee Exchange and authorized the export of the beans to a non-coffee producing country. The Government appealed. The Circuit Court said:

"The District Court used an erroneous standard in concluding that the coffee was in compliance with the Act and need not be destroyed. We vacate the decree of the District Court and remand the case for further proceedings.

"21 U.S.C. § 342(a)(3) provides that a food is deemed adulterated 'if it consists in whole or in part of any filthy, putrid or decomposed substance, or if it is otherwise unfit for food.' The District Court read the first clause of the quoted provision as being elucidated by the second so that the amount of decomposition made unlawful thereby is that 'which would with reasonable certainty render the article unfit for food.' 297 F. Supp. at 673. This court, along with others, has long held that the two clauses are independent and complementary, so that a food substance may be condemned as decomposed, filthy, or putrid even though it is not unfit for food. *Bruce's Juices v. United States*, . . . or condemned as unfit for food even though not decomposed, filthy or putrid, *United States v. 24 Cases, Etc.*, 87 F. Supp. 826 (D.Me. 1949). The single case relied upon by the District Court, *United States v. 1500 Cases, Etc.*, 236 F.2d 208 (7th Cir. 1956), adopts the accepted interpretation reached in the above-cited cases, albeit reluctantly. Thus the District Court's finding that the beans were not unfit for food does not preclude condemnation of them as adulterated.

"We turn to consideration of the standards to be used in determining if coffee beans are adulterated. The appellee contends that the statute lays down a rule of reason, allowing seizure and condemnation of only foods which deviate from the norm of purity to the extent of going beyond fair and safe standards. We recognize that 'It [the first phrase of § 342(a)(3)] sets a standard that if strictly enforced, would ban all processed food from interstate commerce. A scientist with a microscope could find filthy, putrid and decomposed substances in almost any canned food we eat.' *United States v. 1500 Cases, Etc.*, 236 F.2d 208, 210-211 (7th Cir. 1956). But the majority, in fact almost unanimous, rule is that the Act confers the power to exclude from commerce all food products which contain in any degree filthy, putrid or decomposed substances. * * *

"Unjustifiably harsh consequences of a completely literal enforcement are tempered by discretion given the Secretary (now the Secretary of Health, Education and Welfare). He is allowed to adopt administrative working tolerances for violations of which he will prosecute. * * *

"We remand the case to the District Court for it to determine under a correct reading of the statute whether the coffee is adulterated. It may accept as a judicial standard the allowable tolerances now permitted by the Secretary, whether published or not. A court may apply a stricter standard than the Secretary and hold a food substance adulterated though within the Secretary's tolerances. Considering the positive command of the statute, the power of the court to allow a greater departure from purity than the administrative tolerances is less certain.

"For all future purposes of this case the claimant is entitled to be told what the allowable tolerances are.

"Our remand is without prejudice to the claimant's again seeking (before or after any hearing on the condition of the coffee) authority from the District Court to further recondition it. We do not imply what action the District Judge, conversant with the facts, should make on such a petition, if filed.

"If the coffee is found to be adulterated it must be destroyed. Disposition of it is controlled by the first sentence of § 334(d). The exception to that subsection, adopted by amendment in 1957, authorizes under limited and prescribed conditions the export of articles condemned under § 334. Those conditions are not met in this instance, since the adulteration occurred after the coffee was imported."

Thereafter, the District Court ordered that the coffee beans be sampled, that analyses be made by experts for both the Government and the claimant, and that the reports of the analyses be submitted to the court. Upon the submission of both reports which both reflected that the coffee beans were within the Government tolerance, the court found that the coffee beans had been brought into compliance with the law and ordered them released to the claimant. (9)

Crabmeat, canned, at Emeryville, N. Dist. Calif.

Charged 6-16-71: while held for sale, the article which had been damaged in a hurricane and thereafter partially reconditioned at Biloxi, Miss., contained decomposed crabmeat and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (10)

Crabmeat, snow, canned, North Sea, at Somerville, Dist. Mass.

Charged 3-17-71: when imported from Japan by Nozaki Associates, Inc., New York, N.Y., the article was unfit for food because it contained approximately 40 crab hairs (setae) per ounce; 402(a)(3). Consent decree authorized release to importer for export to original foreign supplier. (11)

Hominy grits, at Columbia, Dist. S.C.

Charged 4-15-71: while held by Merchants Wholesale Co., Columbia, S.C., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (12)

Peanuts, flour, and black-eyed peas, at West Monroe, W. Dist. La.

Charged 6-17-71: while held by Simonton Grain Co., Inc., West Monroe, La., the articles were held under insanitary conditions, and the peanuts and flour contained rodent filth; 402(a)(3), 402(a)(4). Default decree ordered destruction. (13)

Pistachio nuts, at Terra Bella, E. Dist. Calif.

Charged 6-25-71: while held by W. D. Fowler & Sons, Inc., t/a Kerman Pistachio of California, Terra Bella, Calif., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for reconditioning. (14)

Shrimp, frozen, at St. Cloud, Dist. Minn.

Charged 7-6-71: while held for sale, the article contained decomposed shrimp; 402(a)(3). Default decree ordered destruction. (15)

Soups of various kinds, canned, 4 seizure actions at Minneapolis, Dist. Minn., Steubenville, S. Dist. Ohio, Rochester, Dist. N.H., Durham, Dist. N.H.

Charged 9-14-71, 10-22-71, 10-27-71, 11-11-71: when shipped by Bon Vivant Soups, Inc., Newark, N.J., the articles, labeled in part "S.S. Pierce Red Label Vichyssoise Cream Soup [or "Jellied Chicken Consomme" or other kind of soup] . . . Packed for S. S. Pierce Company Boston, Mass.," were unfit for food in that some cans of these foods had been found to be defective and abnormal, and in that the manufacturing procedures used did not assure proper sealing of the cans or adequate heat treatment of the sealed cans to prevent contamination and spoilage; and the articles had been prepared, packed, and held under conditions whereby they may have been rendered injurious to health; 402(a)(3), 402(a)(4). Default decrees ordered destruction. (16)

Wheat, at Morristown, Dist. S. Dak.

Charged 6-24-71: while held by Morristown Grain Co., Morristown, S. Dak., the article contained rodent and insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). The dealer filed a motion for discovery prior to answering the complaint, seeking an order that FDA sample the article, analyze the sample, and report the result of analysis. The court denied the dealer's motion. Thereafter, a consent decree authorized release to dealer for reconditioning. (17)

FOOD / Economic and Labeling Violations

Cookies, Jewel Windmill Assortment, Jewel Bakery Shop, Old Style Sugar, and Jewel Iced Blueberry Flavored Bars, at Denver, Dist. Colo.

Charged 4-7-71: when shipped by Jewel Home Shopping Center Warehouse, Barrington, Ill., the articles were in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration for the Jewel Bakery Shop cookies was not placed within the bottom 30 percent of the principal display panel—15 U.S.C. 1453(a)(2); since the Jewel Bakery Shop cookies Jewel Windmill Assortment and Old Style Sugar cookies had statements of quantity of contents appearing on principal display panels of more than 25 square inches in a type size less than 3/16 inch high—15 U.S.C. 1453(a)(3)(C)(i); since the Jewel Windmill Assortment had a quantity of contents declaration which was not separated from other printed label information appearing above and to the left of the declaration—15 U.S.C. 1453(a)(2); and since the quantity of contents statement for the Jewel Iced Blueberry Flavored Bars was stated as "Net Wt. 1 Lb. 4 Ozs." instead of "Net Wt. 20 Oz. (1 Lb. 4 Oz.)," it appeared on the principal display panel of more than 5 square inches in a type size less than 1/4 inch high, and it was not in conspicuous and easily legible bold-face print or type in distinct contrast by layout and color to other matter on the packages—15 U.S.C. 1453(a)(3)(A)(i), 1453(a)(3)(C)(i), 1453(a)(3)(B). Default decree authorized donation to charitable institution. (18)

Dressing for foods, at Seattle, W. Dist. Wash.

Charged 4-19-71: when shipped by Rods Food Manufacturing Co., Los Angeles, Calif., the labeling of the article, labeled in part "IMO Brand For Topping, Mixing, or Cooking . . . Mfg. by IMO Food Products, Inc., Los Angeles, Calif.," failed to bear the common or usual name of the article, and the label lacked the common or usual name of each ingredient, since it failed to identify water as an ingredient—403(i)(1), 403(i)(2); and the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not duplicated on the package lid, an alternate principal display panel—15 U.S.C. 1453(a)(2). Consent decree ordered destruction. (19)

Fish filets, frozen, at Somerville, Dist. Mass.

Charged 3-23-71: while held for sale, the article (which Mr. Boston Seafoods Corp., Boston, Mass., had packed from haddock and cod imported from Scotland and had labeled as "Finest Haddock Filets . . . Product of Canada") had had codfish substituted in part for haddock fish; the label was false and misleading as applied to a product which consisted in part of codfish and which had been imported from Scotland; codfish were offered for sale under the name of another food, and the label lacked the common or usual name of the food; 402(b)(2), 403(a), 403(b), 403(i)(1). Consent decree authorized release to Mr. Boston Seafoods Corp., Boston, Mass., for bringing into compliance. (20)

Praline candy, at New Orleans, E. Dist. La.

Charged 6-28-71: when shipped by Lamme's Candies Since 1885, Inc., Austin, Tex., the article labeled in part "Godchaux's . . . Chewie Pecan Pralines . . . Packed for Godchaux's . . . New Orleans, La.," was in violation of the Fair Packaging and Labeling Act, since the quantity of contents statement, appearing on the principal display panel with an area of more than 25 square inches, was in type size less than 3/16 inch high; 15 U.S.C. 1453(a)(3)(C)(i). Consent decree authorized release to the shipper for relabeling. (21)

Pretzels, at Chillicothe, S. Dist. Ohio.

Charged 4-22-71: when shipped by Quinlan Pretzel Co., Denver, Pa., the article, labeled in part "State Fare . . . Extra Thin Pretzels . . . Manufactured for Thorofare Markets, Inc., Pittsburgh, Pa.," was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not placed within the bottom 30 percent of the principal display panel area; 15 U.S.C. 1453(a)(2). Default decree ordered destruction. (22)

Shrimp, breaded, frozen, Thunderbird, and Thunderbolt, at Memphis, W. Dist. Tenn.

Charged 6-23-71: when shipped by Trade Winds Co. (subsidiary of W. R. Grace & Co.), Thunderbolt, Ga., the article failed to conform to the standard of identity for frozen raw breaded shrimp, since it tested as less than 50 percent shrimp material; 403(g)(1). Default decree authorized donation to charitable institution. (23)

FOOD ADDITIVES

Baking specialty mix, W.M.C., at Colorado Springs, Dist. Colo.

Charged 6-22-71: when returned to Wheat Products Co., Colorado Springs, Colo., from Birmingham, Ala., San Francisco, Calif., and Port Newark, N.J., the article contained the nonconforming food additives nitrites and nitrates, and the label lacked the common or usual name of each ingredient, since "sugars" and "mineral salts" are not the common or usual name of such ingredients; 402(a)(2)(C), 403(i)(2). Default decree ordered destruction. (24)

Feta cheese, at Methuen, Dist. Mass.

Charged 5-10-71: when shipped by A. Fantis, Inc., New York, N.Y., the article, labeled in part "Eurotrade European Trade Company L.T.D. . . . Thessalonika," contained the nonconforming food additive benzene hexachloride; 402(a)(2)(C). Default decree ordered destruction. (25)

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. June 1, 1972

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