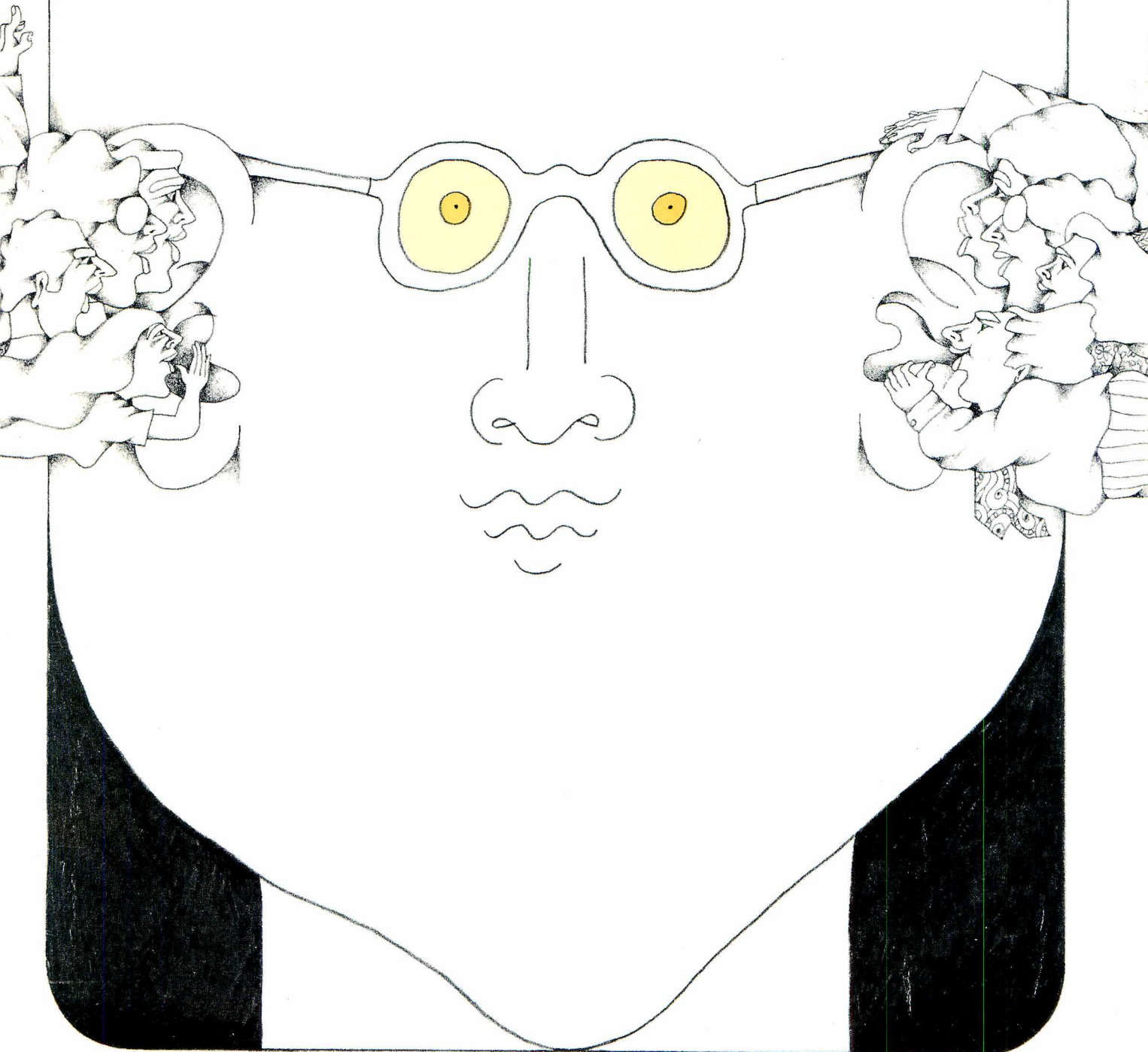


FDA

MARCH 1973

# CONSUMER

FDA Listens:  
A Survey  
of Consumer  
Opinion





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## This Month

**T**his month, the director of FDA's Bureau of Drugs presents his reasons for concluding that there is no significant therapeutic difference between brand-name and generic versions of antibiotics or other classes of drugs. Dr. Henry E. Simmons reports on his Bureau's testing of 20,000 batches of antibiotics a year in its Washington laboratory and 19 other drug classes at FDA's St. Louis laboratory. In "Brand vs. Generic Drugs: It's Only a Matter of Name," he points out the significance of the conclusion in terms of health care quality.

FDA exists to serve the consumer, and thus what consumers think is very important to FDA. This month, in the first of a series of articles, the results of a consumer survey are detailed. Future FDA activities, especially in the area of consumer education, will be based in part on surveys like these. In "FDA Listens: A Survey of Consumer Opinion," Philip G. Kuehl and Mary Ellen Simon report unexpected findings—for example, that most consumers consider prescription drugs significantly safer than over-the-counter drugs. The authors then go into detail on consumer attitudes about toy safety. Follow-up articles will deal with food, prescription drugs, over-the-counter drugs, and toiletries and cosmetics.

One of FDA's special concerns is a group of consumers who cannot read labels, and would not pay much attention if they could: young children. Two articles in this month's issue focus on efforts to prevent children from accidentally poisoning themselves or otherwise injuring themselves with common household products or even their own toys. In "Warning: Hazardous to Children," FDA Historian Wallace F. Janssen traces the evolution of laws designed to protect children. In a second story, "Poison Prevention Packaging: New Protection for Children," Georg S. Maisel of the Bureau of Product Safety explains the new safety packaging now required for many household products that pose a danger to inquisitive young children.

## Quotes

**“I**t has taken a long time and a great deal of work to develop a sound and beneficial nutrition labeling system . . . No effort I can think of in FDA history has had more broadly based input or been more carefully considered.

“Nevertheless, we are not marking an end to our efforts here today, but a beginning. We now have a program on paper. It is scientifically sound and practically feasible. Whether it actually works to improve the nutritional well-being of Americans now depends, as I see it, on three vital points:

“First, the reason and the responsibility with which we in FDA implement the program that has been developed;

“Second, the degree to which industry accepts the program as an opportunity to be seized rather than a change to be opposed;

“And, finally—and perhaps most important—the willingness of the American people to use the new information on the nutritional value of foods that this program will make available to them.”

*Charles C. Edwards, M.D., Commissioner of Food and Drugs, at a press conference announcing a 12-part program on food labeling, Washington, D.C., January 17, 1973.*

**“T**he purpose of labeling is twofold: to inform the prospective purchasers as to what the product is and what it contains, and to sell the product to the prospective purchaser. We in the Food and Drug Administration do not worry too much about the second part, since we believe that the seller can usually be depended upon to use labeling that will sell his product to the consumer. We are, however, quite concerned with the first part, since one of the basic purposes of the Food, Drug, and Cosmetic Act is to insure that the label on the package properly tells the consumer what the product is and what is in it.”

*Taylor M. Quinn, director, Division of Regulation Compliance, Bureau of Foods, at the Food and Drug Law Institute, Washington, D.C., December 13, 1972.*

## Consumer Forum

**I**n future issues the space on this page will be reserved for a new feature of FDA CONSUMER, a page we are calling CONSUMER FORUM. It gives you, the consumer, the opportunity to have your views published in FDA CONSUMER.

Letters of any length are acceptable, depending on content and interest, but letters of 150 words or less have a better chance of being published. Letters must be signed, but we will withhold the name upon request and for valid reason. We will, however, use initials if we don't use the name. We reserve the right to condense letters to a suitable length for publication.

Letters to CONSUMER FORUM can be on any topic of concern to FDA—foods, drugs, cosmetics, household chemicals, toys, vaccines, radiation, medical devices. But remember—if you have a complaint about a specific product, or you feel a product is hazardous, you should channel your comments to the FDA District office nearest you. You will get the quickest action on a consumer complaint by going directly to the District.

Send letters to CONSUMER FORUM, FDA CONSUMER, PA-25, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.



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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 charge and the disposition thereof.

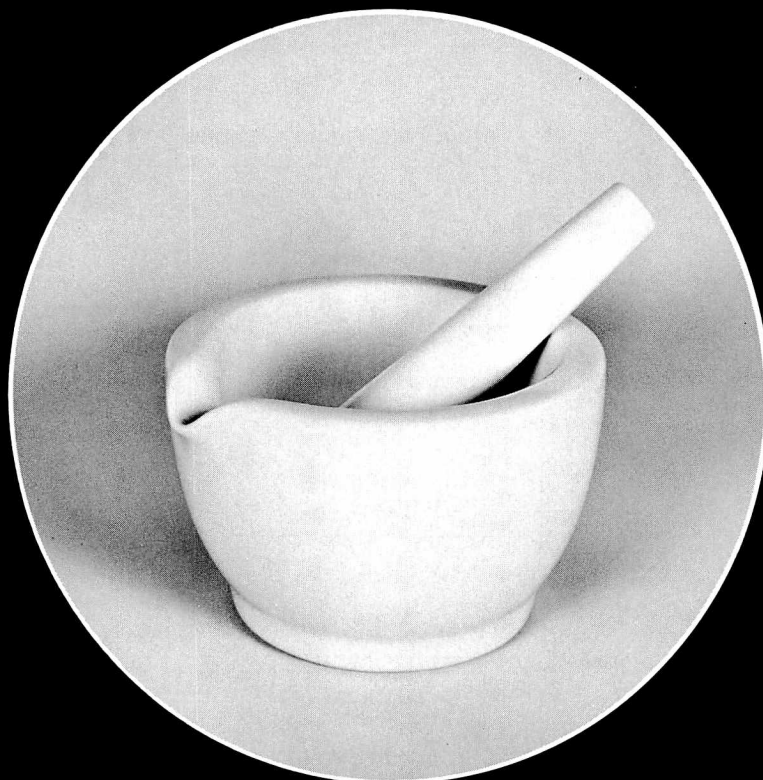
(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from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

**FDA**  
**CONSUMER**  
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**Brand vs. Generic Drugs:  
It's Only a Matter of Name**



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by Henry E. Simmons, M.D., M.P.H.

*It's one of the most significant issues in the prescription drug area today: are "generic" drugs equivalent to "brand" drugs? Each side has its proponents. Some of the traditional views of the brand-generic controversy are no longer accurate. In this article, Henry E. Simmons, M.D., director of FDA's Bureau of Drugs, presents his views on this subject and tells what FDA is doing to assure that all drugs are of the highest quality. This story is based on a speech Dr. Simmons presented before the California Council of Hospital Pharmacists in San Diego September 30, 1972.*

Generic equivalency is one subject we've always been very much concerned about at FDA. I am constantly discouraged at the quality of the dialogue in this important area—an area significant not only because of the quality of health care in this Nation, but also because it is a basic economic issue as well. The pronouncements made by members of the various camps are often biased and, occasionally, frankly and intentionally misleading or exaggerated.

The generic-brand issue presents us at FDA with a unique opportunity as well as a major responsibility.

As the world's largest repository of original and frequently unpublished information on drugs, we are in a unique position to be able to examine both sides objectively. Unlike either side in this issue, we achieve no financial gain regardless of which camp carries the day.

With our responsibility for the public welfare, we and the public "lose" if the American patient does not receive drugs of uniformly high quality. We and the public "win" only if both generic and brand manufacturers consistently produce a quality product.

This then is the Government's role in the public interest: to do everything within its power to assure that *all* drugs—generic and brand, made by big and small

manufacturers—are both safe and effective, honestly labeled, and of the quality necessary to produce the intended effect. We must maintain a surveillance system which will assure that this quality continues once it is attained. Should quality be found wanting, appropriate steps must be taken to correct the situation or stop production. We must also assure that physicians are provided sufficient information on drugs so that the wisest therapeutic decisions can be made on behalf of the American people.

We recognize our responsibility and accept it. We are aware that the job cannot be done if manufacturers do not also recognize and accept their responsibility. Fortunately, in general, drug manufacturers, large and small, generic and brand, have accepted their responsibility and are taking appropriate steps to fulfill it.

Given our responsibility, how do we meet it? What are the programs and resources of the Federal Government, specifically the Food and Drug Administration that are addressed to this area? To understand this, let me examine some facts about the rapidly changing and growing FDA.

FDA today is an agency of more than 6,000 people with a budget of over \$150 million. FDA's drug responsibilities are vested in the Bureau of Drugs, which has about 1,000 people backed by a field force

of about 400 inspectors.

The Bureau of Drugs is a highly technical bureau with approximately 120 physicians, 100 microbiologists, 50 pharmacists and pharmacologists, and 50 chemists, plus statisticians, epidemiologists, and other professional personnel.

No new drug can be marketed in this country until teams of physicians, pharmacists, chemists, and statisticians from the Bureau of Drugs have completed a thorough assessment of it. Any firm wanting to place a new drug on the market not only must first develop data to show that it is safe and effective, but also must demonstrate to FDA's satisfaction that adequate controls have been provided to assure proper identification, quality, purity, and strength of the new drug.

In this context the New Drug Application must include a list of all the components; a statement of the composition of the new drug dosage form; a description of the facilities and personnel involved in the manufacture of the drug, which is verified by factory inspection; acceptance specifications and test methods for the raw materials and new drug substance to assure uniformity from batch to batch; a description of the manufacturing process for the final dosage form, which includes manufacturing process, packaging, and labeling; a description of the analytical controls, specifications, and test procedures for the drug; and stability studies to assure continued quality for the time it will be in a retail outlet before being used by the consumer. All of these data are carefully reviewed, and approval is given only after all the requirements are satisfied.

Whenever other manufacturers want to place chemically equivalent drug products on the market, they must submit for FDA approval adequate data to demonstrate the equivalency of the product. It then goes through the same review. All

firms are bound by the same regulations governing proper manufacturing processes.

The Bureau of Drugs operates two large modern laboratories for drug research and methodology development and for drug analysis. These two analytical laboratories are the National Center for Antibiotics Analysis, in Washington, and the National Center for Drug Analysis, in St. Louis. Both help assure the high quality of drugs we have in this country.

The National Center for Antibiotics Analysis is a 150-man team working in a highly automated laboratory. It is responsible for testing the potency, purity, and stability of every batch of every antibiotic before it is marketed in this country.

Before marketing, samples of every batch of bulk antibiotics and the finished dosage form are submitted to FDA for analysis. The batches from which the samples are taken are kept in quarantine until FDA completes its analyses. Along with the samples the firm submits data on the batch, such as formula and the firm's own test results.

If the samples meet all of the requirements, the batch is certified by FDA. Only such batches can be released for marketing in this country.

Any qualified firm may decide to make the same product. This is the so-called "me-too" product, since it must meet all the requirements of the original one.

Many "me-too" manufacturers and brand name manufacturers use bulk antibiotic ingredients from the same few bulk producers. After the drug has shown comparability, the firms must put batches on stability test and report every three months for a specified period of time and at least yearly thereafter. Any significant problem with the drug must be reported immediately to FDA. Additionally, we collect post certification samples at random

*"We are confident there is no significant difference between so-called generic and brand name antibiotic products on the American market."*

from the market as a further check on the continued quality of antibiotics.

Each year our National Center for Antibiotics Analysis receives approximately 20,000 samples for examination. The rejection rate is approximately 1 percent. These rejects cannot be marketed.

*Based on many years of experience with this program, we are confident there is no significant difference between so-called generic and brand name antibiotic products on the American market. Any antibiotic offered for sale in the United States, regardless of whether it is brand or generic, has met the same high FDA standards.*

A similar certification program is conducted for every batch of insulin produced in the United States.

Another important drug quality program conducted by FDA is at the National Center for Drug Analysis in St. Louis. This 50-man laboratory is unique in having automated equipment for the analysis of a large number of tablets of a particular drug product.

Since 1970, our St. Louis lab has completed the study of 19 classes of drugs, including adrenocorticosteroids, major and minor tranquilizers, urinary antibacterial

agents, central nervous system depressants, antithyroid agents, cardiac glycosides, coronary vasodilators, anticoagulants, oral contraceptives, and others.

We have extended the study to 30 drug products representing the top 15 therapeutically significant drug classes. This study will cover every known manufacturer of these products. We believe in this way we will have reliable data upon which we can make meaningful judgments on an across-the-board basis.

Under FDA's new Freedom of Information regulations (see FDA PAPERS, now FDA CONSUMER, June 1972), we intend to begin publishing this data once it has been verified and we have assured ourselves it will present a true picture on a given class of drugs.

*On the basis of the data we have accrued to date, we cannot conclude there is a significant difference in quality between the generic and brand name product tested.*

There have been only a few exceptions turned up by our testing in St. Louis. One of these, digoxin, a heart drug, is the most prominent exception, as our studies showed quality and performance differences between different manufacturers' versions. We are taking action to assure that all digoxin now marketed meets uniform standards of quality.

Another important surveillance program is our Drug Product Defect Reporting Program. This is a jointly sponsored program by the American Society of Hospital Pharmacists, United States Pharmacopeia, and FDA.

It is a voluntary program in which hospital pharmacists across the Nation report defects they encounter in drug products, packaging, and labeling. Through this program, we have received hundreds of reports and have learned of several significant defects. We are finding defects in both brand and generic products.



In addition to these programs, we continue with the traditional approach to drug surveillance in the United States. This is routine inspection of drug plants by our field districts. We have 19 district offices, 95 resident posts, and 400 drug inspectors scattered across the Nation. They inspect drug firms to determine whether or not these firms are operating under current good manufacturing procedures. When necessary, evidence is gathered for possible legal action by FDA in the form of seizure, injunction, or prosecution.

These inspectors also monitor drug recalls to make certain defective products are actually removed from commercial channels. In 1972 we had 638 drug recalls. Of these, 291 were brand name and 347 generic products. Again, defects were encountered in big companies, small companies, brand and generic products.

In addition to our efforts to assure the quality of all drugs, brand and generic, developments are taking place in other areas. For years, the large brand name manufacturers have been major providers of generic drugs. Recent events indicate that more and more generics will be manufactured by traditionally brand name manufacturers. Also, as the number of drug substances increase, and as the expense involved in maintaining manufacturing facilities for a full line of drugs rises, more and more manufacturers—large and small, generic and brand—are selling to each other either bulk drugs or finished dosage forms.

This all makes it increasingly difficult for the average purchaser to know who really made the drug. In a number of instances, one manufacturer is providing to a large number of firms the same drug, which is then marketed under a wide variety of brand and generic names.

Thus it is difficult today for an individual health professional—and

*"We cannot conclude there is a significant difference in quality between the generic and brand name product tested."*

virtually impossible for the consumer—to really assess the quality of drugs. After all, each professional has limited experience with a particular drug. Evidence of some uncertainty is seen in the fact that some professionals prescribe the highest priced product when the same product is being offered at a substantial saving by equally large or experienced firms or offered by the same manufacturer generically at a lower price than the brand name drug would cost.

Some professionals seem to mistakenly equate "big manufacturer" or "brand name" with good, and "smaller manufacturer" or "generic" with bad. This impression is not borne out by the facts. Some of this confusion will be dispelled as we begin publishing the results of our national drug quality survey.

When this is done, I hope people will understand that a firm found to have produced a bad batch by these surveys should not necessarily be condemned or put out of business, because, as I have stressed, large and small have stumbled—and have corrected their defects and gone on to produce quality products. However, if a firm develops a pattern of poor performance or does not correct a defect once found, then corrective action will obviously be ap-

propriate, and we will not hesitate to take such steps.

In summary, what does this all mean, where do we stand in total drug quality today?

In my judgment, the total quality of the Nation's drug supply is high and is constantly improving. Marginal drugs and manufacturers are being removed. Those that remain are better tested than they have ever been before. We exceed in quality the drug supply of any other nation in the world.

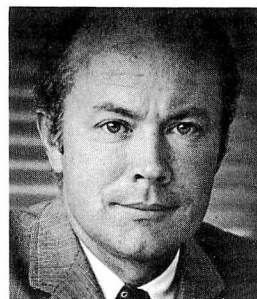
Is it good enough? Not yet.

Can it ever be perfect? Given the complexities of drug manufacturing, probably not.

Do we still find defective drugs? Yes, we do, but this should surprise no one, since it is humanly impossible in this less than perfect world to produce tens of billions of doses of a wide variety of drugs each year and not make a mistake.

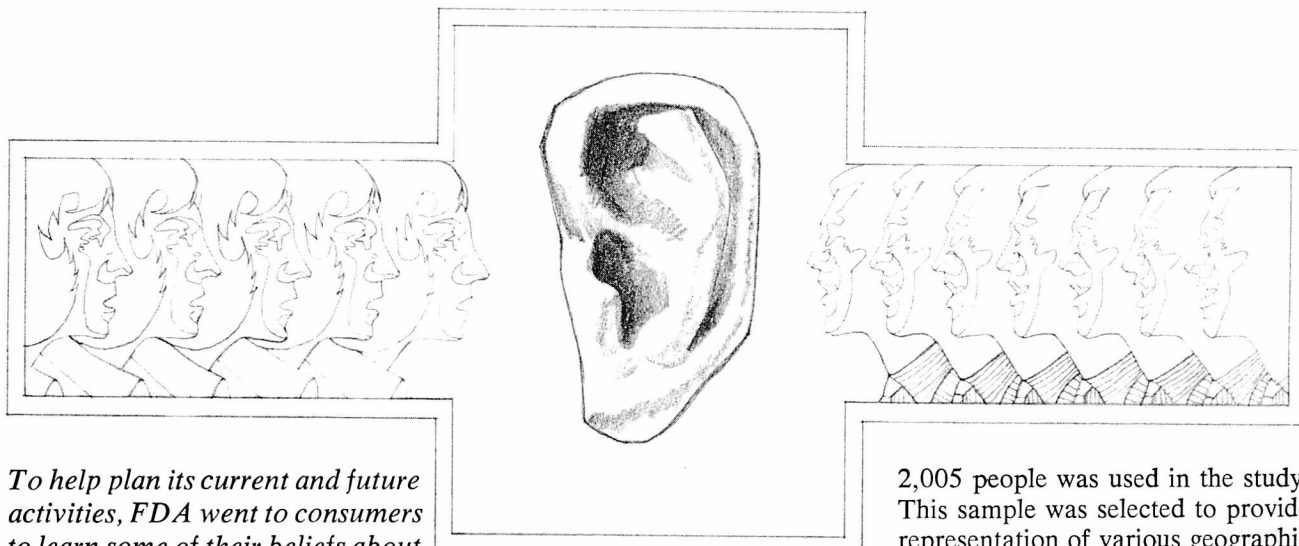
Is a brand name a guarantee that a drug will be good while a generic name is an indication that the drug will be bad? In our experience it is not.

We at FDA plan to take further steps to strengthen our quality assurance program in the months ahead. We know we will find problems in the future. This is to be expected. When found, we will correct them, and thereby raise the standard of quality one more step toward the goal of consistent and uniform high quality drug supply for the American public.



Henry E. Simmons, M.D., M.P.H., has been director of FDA's Bureau of Drugs since April 1970.

# FDA Listens:



*To help plan its current and future activities, FDA went to consumers to learn some of their beliefs about foods, medicines, cosmetics, and toys. The survey revealed some surprising results. Here's what some of the answers were.*

**P**rotecting the consumer—this has been FDA's role since its very beginning, long before the word "consumerism" became a front-page topic. FDA programs and activities have been built around this objective, to assure that American consumers are getting safe foods, drugs, and other products.

In the past few years, with the expanding population, revolutionary changes in technology, and an increasing variety of products on the market, FDA has solicited and encouraged the assistance of individual consumers, consumer organizations, and industry to promote and improve consumer safety.

Consumer opinion and knowledge play an important role in FDA activities, since consumer participation is vital to effective consumer safety. In 1972, FDA sponsored a national survey to learn consumer thinking—*your* thinking—about some of the areas which vitally affect your daily living.

The results of this survey are being used by FDA in planning its long-range programs as well as its

## A Survey of Consumer Opinion

by Philip G. Kuehl, Ph.D.,  
and Mary Ellen Simon

day-to-day activities. The survey information will help the Agency to:

- Design educational materials to supplement the present knowledge of consumers.
- Determine areas requiring increased action by FDA and areas of consumer "self help."
- Develop more effective ways to communicate "self help" information to consumers.

The survey questionnaire was designed to measure public opinion on the safety of five product categories: foods, prescription drugs, over-the-counter drugs, cosmetics and toiletries, and toys. This article deals with general findings on all five, then examines more specifically the opinions on toy safety. Future articles in FDA CONSUMER will discuss the findings on foods, drugs, and cosmetics.

A national probability sample of

2,005 people was used in the study. This sample was selected to provide representation of various geographic areas, types of communities, ages, incomes, and educational levels in such a way that results reflect national public opinion. The questionnaire, which took about 50 minutes to complete, was administered by professional interviewers from Response Analysis Corporation, Princeton, New Jersey, during August and September of 1972.

Since objective, unbiased responses were desired, people interviewed were not given any indication the survey was being conducted for FDA, nor were they told the purpose of the survey. All the findings reported here are preliminary; a final statistical report will be completed later in the year.

The reader should keep in mind that this was a survey of *opinion*. The answers should not be considered as truth on a subject, but merely opinions held by the public.

### All Categories of Products— An Overview

Consumers were found to have a strong concern for the safety of products such as foods, drugs, cosmetics, and toys. In fact, 63 percent of the people are "highly concerned" about the safety of the products they use in and around their homes. At the same time, in

answering a question about the major causes of household injuries, 65 percent said *improper product usage* was the most frequent cause of household accidents.

Two other survey findings provide an insight into the general level of safety concern among consumers. First, consumers believe that toys, drugs, and cosmetics are getting safer, while foods are getting *less safe*. It is important to note that although they believe foods are becoming less safe than in the past, consumers still consider foods the most safe of the five categories.

When respondents were asked which organization in American society did the most to make all types of products “as safe as they are,” they most often mentioned (a) the Government, (b) consumer organizations, and (c) manufacturers of products. (See Table 1)

#### Federal Government's Authority

What do consumers know about the Federal Government's jurisdiction in the regulation of products? FDA attempted to learn the public's understanding of regulatory authority by asking consumers whether they believed the Government can stop the sale of products. The vast majority of consumers (93 percent) recognizes that the Federal Government is empowered to stop the sale of products that are found unsafe.

Consumers were then asked about the Government's authority to stop the sale of specific product categories. The results are in Table 2.

Consumers also were asked about the Federal Government's activity in the area of premarket testing. They were questioned on two specific types of products: medicines and cosmetics. The results show that 30 percent of the public thinks the Government pretests medicines “all the time,” and 34 percent thinks it does this “most of the time.”

These results are surprising, because the Government *pretests* medicines only under certain selected circumstances—for example, it tests

**Table 1**  
**Opinion About Who Does the Most to Make Products Safe**

**Question:** Different groups work to make products safe. Which one of the groups listed do you think does the most to make products used or consumed in the home as safe as they are?

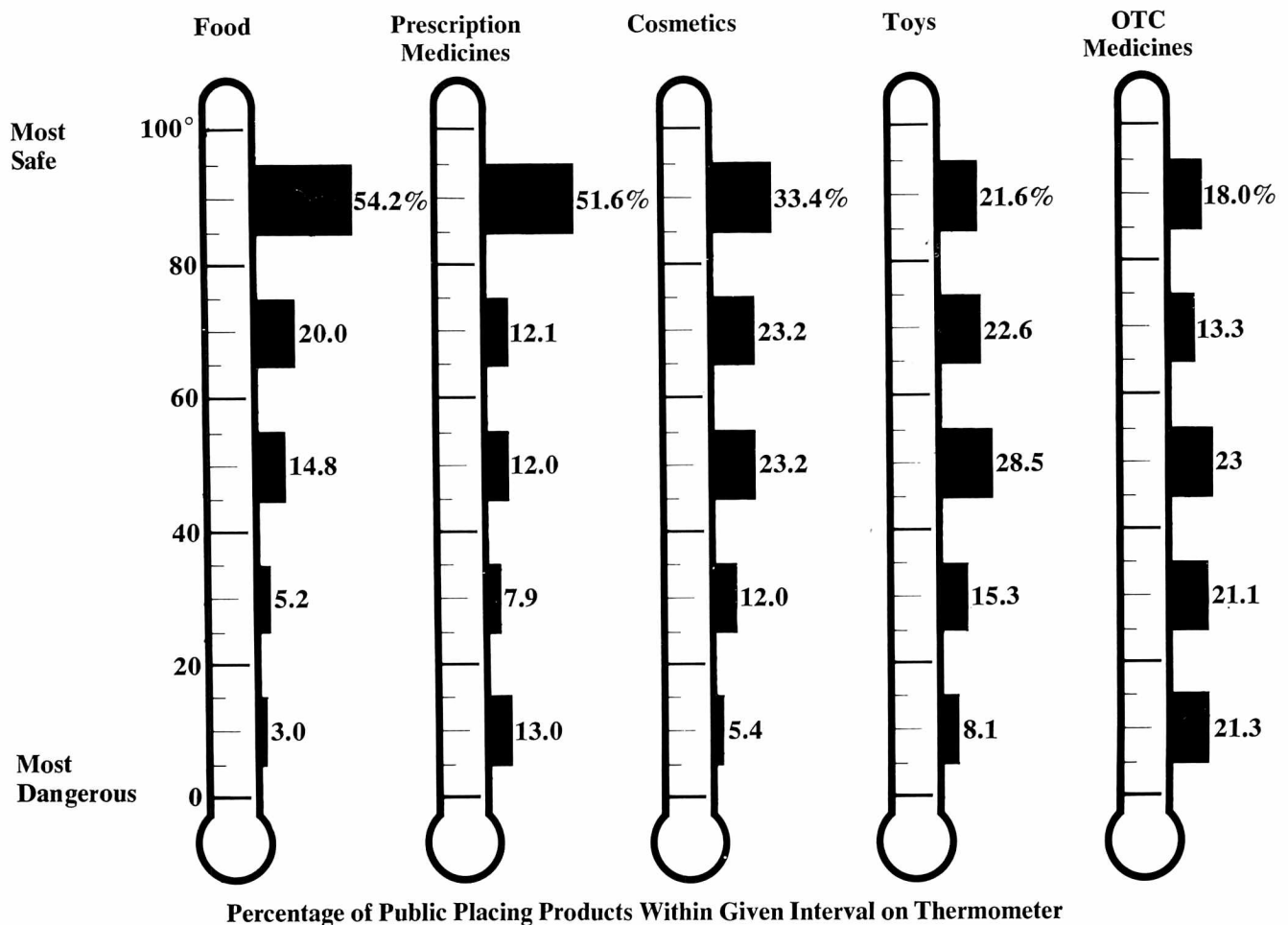
Rank	Group	Percent of Public Making the Choices Indicated
1.	Government	31.0%
2.	Consumer Organizations	27.0
3.	Companies That <i>Make</i> Products	22.1
4.	Individual People	11.0
5.	Companies That <i>Sell</i> Products	4.6
6.	Don't Know	4.3
		100.0%

**Table 2**  
**Beliefs About Government Authority to Stop the Sale of Specific Products**

**Question:** Does the Federal Government have the authority to stop the sale of unsafe products, such as medicines? How about toys? Foods? Cosmetics and toiletries?

Product Category	Percent of Public That Answered:			
	Yes	No	Don't Know	Totals
1. Medicines	94.7%	1.5%	3.7%	99.9%
2. Toys	83.7	4.7	11.4	99.8
3. Food Products	95.3	1.3	3.1	99.7
4. Cosmetics and Toiletries	89.0	2.4	8.5	99.9

**Table 3**  
**Placement of Products on Thermometer Scale**



every batch of antibiotics before marketing. The Government evaluates the safety and efficacy of both prescription medicines and non-prescription medicines before they can be sold—but this evaluation is based on data submitted by manufacturers, not on Government tests. After medicines are on the market, from time to time they are sampled and assayed by the Government.

**Relative Safety of Toys, Prescription Drugs, OTC Drugs, Cosmetics, and Foods**

If you were asked to name the “safest” of these five categories of

products, what would your answer be?

The people questioned in the survey were given the opportunity to rate the products by means of a safety “thermometer.” They were asked to place the products on the temperature scale, in terms of their own opinion of safety, with 100 degrees designating the most safe and 0 degrees the most dangerous. The higher on the scale a product was placed (in terms of degrees of temperature), the *more safe* the product was perceived to be. Results of these rankings are shown in Table 3.

The safety thermometer results



show that people consider food products the safest category, overall, followed closely by prescription drugs. Cosmetics are rated third safest, toys fourth, and over-the-counter drugs fifth safest.

Of particular interest to FDA is the fact that a large number of consumers consider over-the-counter medicines less safe than prescription medicines.

Prescription drugs are, in fact, typically more powerful and considerably more likely to produce side effects than over-the-counter drugs. FDA has initiated additional analysis of the survey findings and will conduct additional surveys as necessary to expand its understanding of consumer beliefs and actions concerning prescription drugs. If necessary, additional educational programs will be implemented to improve consumer understanding of hazards associated with prescription drugs.

### Summary: Opinions About the Safety of Products in General

According to the survey, most consumers are highly concerned about the safety of the products they use—including foods, drugs, cosmetics, and toys—with varying degrees of concern and knowledge about these four categories.

Their concern centers on two aspects of safety: the physical safety of the products themselves, and the *proper use* of products by consumers.

Consumers believe that the Government, manufacturers, consumer groups, and individuals are all contributing to the safety of products.

### In the Public's Opinion, How Safe Are Toys?

What do today's consumers think about the safety of one particular product category—toys? Apparently they feel rather unconcerned about it. Nearly two-thirds of the public was "highly concerned" about the safety of products in general, but only one-third was "highly con-

cerned" about the safety of toys in particular. And when asked "Do you think children's toys are safe or unsafe?" 75 percent of the public indicated they believe toys are safe.

When we look again at the "safety thermometer," which indicates how respondents rated the five categories, we see toys were rated fourth safest. The figures are interpreted to mean that consumers believe toys are safe, but that some other products are even safer.

### Toys and Personal Injury

One explanation for the lack of great concern about the safety of toys evolves from the fact that 82 percent of the public believes personal injuries caused by toys are "minor." Only 9 percent said toy-related injuries are serious. In addition, 95 percent of the public believes toy manufacturers do attempt to make toys safe.

Furthermore, when people were asked whether they thought toy manufacturers were doing an ade-

quate job of removing easy-to-see hazards (such as removing sharp edges and enclosing moving parts), 78 percent said they were. And 63 percent of the public thinks toy manufacturers are doing an adequate job of removing hard-to-see hazards in toys (such as toxic paints and materials).

### What Do Consumers Consider When Purchasing Toys?

Another question in the survey concerned toy purchase. When people were asked what thoughts motivate their purchases, they responded as shown in Table 4.

These results show that only one-fourth of the public thinks of safety first. This lack of great concern about safety when purchasing toys is underscored further by an additional question.

Respondents were asked "When people buy toys for children, do you think they consider the safety of the toy a lot, a little, or not at all?" Only 30 percent of the public considers

**Table 4**

### Most Important Consideration in Toy Buying

**Question:** When people buy toys, they think of a lot of things. Here is a list of some of those things. When you buy a toy, which of these do *you* think of first?

Rank	Factor	Percent of Public Designating Factor as First
1.	Child's Interest	32.3%
2.	Age of Child	29.6
3.	Safety of Toy	25.1
4.	Price	7.8
5.	Manufacturer's Reputation	2.2
6.	No Answer	2.8
		99.8%

**Table 5**  
**Opinions About the Most Important Cause of Toy-Related Injuries**

**Question:** Here is a list of some of the reasons why accidents occur when children play with toys. Which of these five reasons do you think is the *single most important* cause of accidents which happen when children play with toys?

Rank	Reasons	Percent of Public Making the Choices Indicated
1.	Misuse of Toys	39.4%
2.	Directions Not Followed	20.4
3.	Directions Not Read	16.0
4.	Design of Toy	13.4
5.	Accidents Are Bound to Happen	8.5
6.	Don't Know	2.2
		99.9%

safety "a lot"; 52 percent considers it "a little"; 12 percent "not at all"; and 6 percent answered they did not know.

These findings indicate a need for more awareness by adults that safety should be a prime consideration when purchasing toys.

#### **Toy Safety and Usage**

According to consumers' opinions, the single most important cause of toy-related injuries, as shown in Table 5 is (a) misuse of toys by children, (b) not following directions, and (c) not reading directions.

As shown in Table 5, a significant number of people believe the single most important cause of toy-related accidents is failure to follow directions or failure to read directions. When they were asked specifically about their own practices in this regard, it was found that only 23 percent of the people read the directions which accompany toys, all or most of the time; 25 percent hardly ever

read directions; and 46 percent do not read directions any of the time.

It is clear from these findings that, since consumers acknowledge misuse of toys as the primary cause of toy-related accidents, and yet a majority does not even bother to read instructions which accompany toys, additional public education on this subject is needed.

In exploring further the subject of safety and usage, people were asked whether they thought the directions which accompany toys "give enough information" about the safe use of the given product. This question also received a mixed response: 32 percent of the public believes toy directions give enough information; 31 percent believes directions do not give enough information; and 20 percent indicates enough safety information is given "sometimes."

Obviously, the Federal Government can provide a vital service by continuing to work with and encourage manufacturers to produce toy instructions that are complete, clear, and easy to read.

#### **Responsibility for Toy Safety**

Consumers recognize that parents must assume the primary role in insuring that toys are used safely by children—87 percent agreeing with this viewpoint, compared with 13 percent who disagreed or had no opinion.

Consumers also recognize parental responsibility in the *purchase* of toys; 55 percent said adults buy toys "a lot" which are too advanced for the child's age, 32 percent said this happens "a little," while only 4 percent said they did not think this happens at all. In addition, 53 percent felt that when adults purchase toys which are too advanced for the child's age, they definitely create a safety problem.

Two implications emerge from these findings. First, consumers do acknowledge that the final responsibility for safe use of toys in the home lies with parents and other adults. Second, since most consumers are not highly concerned about toy safety, but do assume individual responsibility, it would seem that more needs to be done in alerting consumers to think of safety, to avoid the purchase of improper toys, and to carefully read and follow instructions.

#### **What Do People Think Is the Role Of the Federal Government in Toy Safety?**

Consumers were asked to name the groups which make toys "as safe as they are." The results are shown in Table 6.

As seen in this table, consumers believe two other groups—manufacturers and consumer organizations—contribute more to the safety of toys than the Federal Government does.

When respondents were asked whether the Federal Government could stop the sale of unsafe toy products, 84 percent answered affirmatively. But perhaps more significant is the fact that 16 percent answered either "no" or "don't

**Table 6**  
**Contributions of Various Groups to Toy Safety**

**Question:** Different groups work to make products safe. Which of the groups listed do you think does the most to make children's toys as safe as they are?

Rank	Group or Organization	Percent of Public Making the Choices Indicated
1.	Companies that Make Toys	33.8%
2.	Consumer Organizations	26.8
3.	Government	21.3
4.	Individual People	7.3
5.	Companies That Sell Toys	6.8
6.	Don't Know	4.0
		100.0%

know." The Government does have the authority to stop the sale of unsafe toys after they are on the market, but it does not pretest toys before they go on sale.

#### **What Is the Role of the Federal Government?**

At present, the Food and Drug Administration, under the Child Protection and Toy Safety Act, regulates articles intended for use by children—including toys. The law permits FDA to seize or ban a toy only after it has been marketed and tests show it to be unsafe. In many cases, FDA's findings have led manufacturers voluntarily to modify or redesign toys for greater safety.

In addition to its regulatory powers, FDA is engaged in consumer education programs, to help keep consumers informed about toy safety.

In March, the Government's jurisdiction over toys will be assigned to the newly created Consumer Product Safety Commission.

#### **Summarizing the Survey Findings**

What do the responses to the questions in the survey indicate to FDA about its policies and planning?

Many of the answers show that the public's perception of safety in products is quite correct. Others show that there are misconceptions in the minds of many consumers, and it is in these areas that the Government needs to concentrate its efforts.

For example, since most consumers believe the single most important cause of household accidents is *improper product usage*, more should be done to assure that manufacturers include complete, clear, and easy-to-read instructions in all products, and that consumers are encouraged to read and follow these instructions.

Also, since many consumers believe the Federal Government has greater authority to pretest some products than it actually has, they should be informed just how far the Government's jurisdiction extends (or does not extend), so they can

be more aware of their own responsibility in using products safely.

Specifically in the area of toys, it appears the Federal Government should continue its efforts to make parents and others who buy toys more alert to possible dangers, and continue to work with manufacturers in removing hazards from toys.

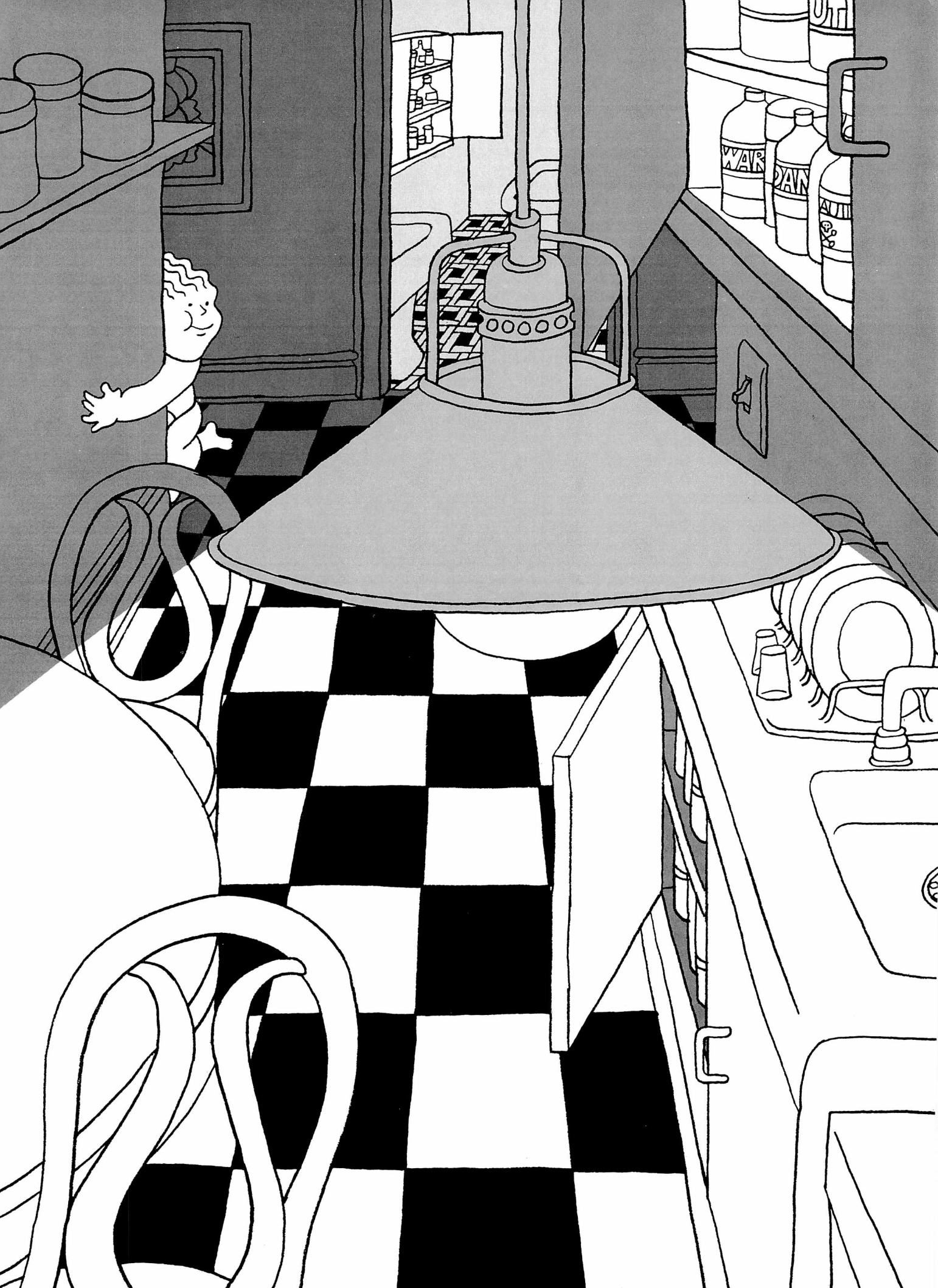
These and other conclusions from the findings will serve as important guidelines for FDA. The survey provides a documented measurement of consumer beliefs—a valuable contribution in the formulation of safety programs that will be most beneficial to all American consumers.



Philip G. Kuehl, Ph.D., is Assistant Professor of Marketing at the College of Business and Public Administration, University of Maryland in College Park. Dr. Kuehl designed the questionnaire for the survey and participated in the analysis of the results.



Mary Ellen Simon, project officer for the survey, is a program analyst in FDA's Office of the Assistant Commissioner for Planning and Evaluation.





Many household products were never intended for human consumption, but that is exactly what curious young children are likely to do when they come across something new. Labeling and packaging laws have been passed to prevent some of the hundreds of thousands of accidental poisonings that occur each year. During National Poison Prevention Week every year in March, parents are advised to keep their children safe from

potential hazards in the home.

In this issue FDA CONSUMER presents two articles on child protection. The first, beginning on the next page, recounts how one man devoted his life to passage of the first in a long series of child protection laws. The second, beginning on page 24, describes the new poison prevention packaging now becoming available and how it can further reduce the accidental poisoning toll.

# **Making The Home Safer For Children**

# Warning: Hazardous to Children

*Efforts to protect children from potential poisons in the home and even the hazards of their own toys have been going on for decades. The story is long—and unfinished.*

by Wallace F. Janssen

In the year 1450 the Court Apothecary of Scotland ruled "that all persons are forbidden under the pain of treason to bring home poisons for any use by which Christian man or woman can take harm."

Doubtless there are even older laws concerning the use, or abuse, of poisons. They illustrate man's effort to deal with an environment that contains a vast number of harmful as well as healthful elements.

From their earliest beginnings the pharmaceutical and medical professions have been concerned about the harm which may be done by the misuse of drugs. Today,

National Poison Prevention Week is proclaimed annually by the President because a Missouri pharmacist, Homer A. George of Cape Girardeau, was concerned enough to lobby almost singlehandedly for the law that established this nationwide educational effort.

In trying to prevent poisonings, we are constantly trying to catch up with experience. The Child Protection Act of 1966, for example, deals, among other things, with the long standing problem of injury from fireworks. This law was an extension of the Hazardous Substances Labeling Act of 1960, which in turn expanded the

protection provided by the original Caustic Poison Act of 1927. All of these laws could have been called "child protection" acts, for that was their primary purpose.

Curiously, unlike other important consumer protective legislation, none of these particular laws resulted from any public outcry or catastrophe reported in the news media. Publicity played almost no part in their enactment. Even though widespread injury to children was the motivating problem, it took the initiative of an individual physician to change callousness into concern, and secure action.

## **A Surgeon Gets Involved**

The story begins not in 1927 but

## The Legacy of Homer George

*In 1937, a Missouri pharmacist had to concoct an antidote for arsenic because he did not have the official antidote on hand when an emergency arose. In 1961, Congress approved a resolution requiring the President to proclaim a National Poison Prevention Week every year. The two events are directly linked through the life of one man whose experience of the first event led him to spend much of his life bringing the second about.*

*Homer A. George of Cape Girardeau was the prime mover behind National Poison Prevention Week. When he realized that poisoning victims were dying because neither the necessary information nor the antidote were*

*always available, he began studying what would be needed for a poison control center. He presented the results first to the president of the county medical society and then to the society itself. Soon Cape Girardeau became the 26th community in the country to establish a poison control center.*

*The next step was to try to prevent accidental poisonings, rather than treat them once they happened. He carried on his personal education program, sending an antidote chart and warning blotter in every delivery and every piece of mail that left his store. But one man can do only so much. He persuaded the county association of insurance agents to sponsor an educational program.*

*Then he got the Cape Girardeau mayor to proclaim a week in October 1958 as Poison Prevention Week. A copy of the mayor's proclamation went to the governor, and soon Missouri became the first State to declare a poison prevention week.*

*Finally, Missouri Congressman Paul Jones introduced a resolution in Congress in 1959. With the backing of the American College of Apothecaries and the American Pharmaceutical Association, the bill was passed in September 1961.*

*Homer A. George has been dead for several years, but he has left a remarkable legacy, National Poison Prevention Week.*

in 1890, when the late Dr. Chevalier Jackson, the Philadelphia surgeon who developed the bronchoscope, devised his first instrument for examining the interior of the esophagus by artificial light. To Dr. Jackson came hundreds of pitiful cases of young children whose throats had been burned by lye and other caustics. As he wrote in his autobiography:



Twelve children, who had been unable to swallow food or water when they came to Dr. Jackson, lie in his bronchoscopic clinic. All had burned their throats by swallowing lye from containers that had no warning labels.

"The development of the (instrument) brought me a series of very sad cases, especially strictures of the esophagus from swallowing lye. These little children of the poor arrived usually in almost dying condition from food and water starvation. If they had not been without water for more than a week,

it was usually possible to save their lives. Some died on the way for want of water . . ."

Lye was used in practically every kitchen in those days, to make soap and as a detergent and drain cleaner. Too often it was kept in the cupboard under the sink where exploring children could find it.

would be kept out of the reach of children."

He went first to the manufacturers, and got replies like this:

"No such thing as a poison label can be put on my preparation unless it is put on every preparation on the market,

Resemblance to sugar contributed to the hazard, and the labels bore no warning signal of the danger.

"Obviously," Dr. Jackson wrote, "these lye burns were preventable accidents. Two things had to be done. A warning label must be on the containers, and a nationwide campaign of education must be inaugurated so that these caustic poisons

## Lye Poisoning—A Case History

Dr. Chevalier Jackson lobbied for cautionary labeling on lye products not because he had read reports but because he had treated the victims of accidental misuse. He also knew how to describe the effects graphically enough to move his readers to action. Here is a case he described in his autobiography, published by the Macmillan Company in 1938.

"A little girl seven years old, emaciated to a skeleton, arrived with the message she had not been able to swallow a drop of water for a week. She looked wistfully at a glass of water, then she tried to swallow some of it; she choked, coughed and all the water came back through the nose and mouth. The two Sisters of Mercy said they had found the child lying on the floor of a coal miner's shanty, where they

had gone to see the mother who was dying of pneumonia. The father was lying on the floor in a drunken stupor. The little girl's ragged dirty clothing was soaking-wet. She was crying for water, and a little three-year-old brother was supplying it with a tin cup from a tin pail. But evidently the water had run out of her mouth and soaked her clothing because she could not swallow it. I put down the esophagoscope between her dry, parched lips and found a tight stricture of the esophagus (the passage from the mouth to the stomach). The scars had not completely closed the passage; in its narrowest part was a corklike plug of grayish material. I removed the plug with delicate forceps passed through the esophagoscope. After removal of the instrument the child was given a glass of water. She took a small

sip expecting it to choke her and come back up. It went slowly down; she took another sip, and it went down. Then she gently moved aside the glass of water in the nurse's hand, took hold of my hand, and kissed it. She took more water and a glass of milk. The nurse put the child to bed, and coming back reported: "She dropped off to sleep. It will be a wonder if she lives: she is just skin and bones." She did live. When she got stronger the Sisters had her admitted to an orphanage and brought her in regularly for treatment. With the esophagoscope the stricture was dilated until at the end of two years she could swallow any kind of food in a perfectly normal way; and she grew well and strong.

No money could give satisfaction equal to that of such an achievement."

because such a label would single out my preparation as dangerous and people would shun it in favor of unlabeled preparations. Even if all packagers now in business agreed, there would be new concerns constantly bringing out unlabeled preparations. If you spent all your time on it, you could not keep up with the new concerns."

It was evident that legislation was the only fair way to solve the problem. But when Dr. Jackson consulted a politician friend, he was advised that getting such a law through the lobby-dominated Pennsylvania legislature would be long, difficult, and expensive. He was told that unless he could find a wealthy philanthropist to back his efforts, he should forget it.

Disheartened but not defeated, Dr. Jackson began securing photographs of the injured children, with a label from the lye container involved in each case. Year after year, he collected this convincing clinical data. In 1910, he summarized his case in the *Journal of the American Medical Association*. The AMA had long been aware of the problem. Indeed, it had gone on record in 1884 in a resolution calling for legislation to require a "poison" label on lye preparations. In 1918, and "better off financially," as he put it, Dr. Jackson went before the AMA Section on Laryngology and Otology with a plan for action. He was promptly made chairman of a new national Committee on Lye Legislation.

Anticipating a long, hard struggle, the Committee first made an extensive study of the problem. Many States already had "poison laws," but the definitions of "poison" were based on lethal quantities. They took no account of the life of misery that could follow constriction of the esophagus nor of the indirect complications which were sometimes fatal. The public was unaware that lye was a dangerous poison. Publicity was needed, but the press

of those days was "afraid to give publicity on this subject." Even a medical journal refused to publish, in connection with a case report, a reproduction of the label of a lye preparation that had caused death. But the *AMA Journal* published the label with its report of the case. The Committee urged every AMA member to report lye burn cases and send in clippings for reprinting and distribution.

The secretary of the AMA's Bureau of Legal Medicine wrote to the manufacturers to inquire what they would be willing to do about labeling. He reported they were unresponsive

"... except one, who pretended to believe that there is no more need for legislation safeguarding the distribution of concentrated lye for household use than for legislation safeguarding the distribution of window glass or of a certain brand of condensed soups. One might cut one's hand opening a can containing such soup, says my correspondent—and, therefore, a danger label is as much needed on a can of soup as on a can of lye."

But the AMA official also pointed out that some of the packers had already acted to "voluntarily and properly label their packages."

Fittingly, Dr. Jackson's legislative campaign plan was first tried out in Pennsylvania. With a reform governor, Gifford Pinchot, the situation in Harrisburg was very different in 1923 from what it had been in 1900, and the AMA bill was quickly passed.

The Committee on Lye Legislation was expanded to include doctors from every State. Campaigns were conducted in each State by means of letters, photographs, interviews, lectures, exhibitions, and clinics, with two main objectives: to educate the public, and to obtain State legislation requiring a poison label on lye and other caustics. Thousands of State legislators were interviewed. Chairmen and members of hundreds of legislative committees were

informed of the need for a law. But over and over the bills died at the close of a session and the process would have to be repeated. By 1925, laws had been enacted in 24 States, but their labeling requirements were far from uniform.

During these years, there had been a great increase in the interstate distribution of lye preparations. Besides the local packers, large firms were now marketing millions of packages through many States. The containers in many instances were misleadingly labeled. Some even bore such statements as "Will not injure the skin or the most delicate fabrics." It was obvious that Federal legislation was needed. Dr. Jackson and his committee then set out to reach more than 90 Senators and 400 Congressmen through interested constituents or in person. He reports they were a "very reasonable and very human audience, but so continuously besieged with self-seeking people that they could not understand why a physician would leave his practice and spend time and money in Washington unless he had some axe to grind." But after nearly two years' work by Dr. Jackson and his Committee, the Federal Caustic Poison Act was passed. On March 4, 1927, President Coolidge gave to Dr. Jackson the pen he used to sign this life-saving law.

The Act required the word "Poison" in 24-point type, plus antidote information, to appear on labels for lye and 11 other caustics and acids. Numerous court actions for failure to label products with the required warnings were needed in the early years of the statute, but after 25 years, these dwindled to only one or two violations each year.

In his final report to the AMA, Dr. Jackson noted that the use of household lye had been greatly reduced, it being replaced in large measure by new and safer detergent substances. He credited the poison label with stimulating research to develop nonpoisonous products. In



1952, after more than 30 years' work, the AMA Committee on Lye Legislation requested its discharge, and it was discharged with thanks.

### Poison Control Centers— A New Approach

The Caustic Poison Act saved thousands of children and adults from serious chemical burns and

fatalities. But it did not solve the problem of accidental poisoning and other types of injury from hazardous products. In fact, the dimensions of the problem had increased greatly. Thousands of new substances and products which could be hazardous in various ways had come into the household.

By 1952, it seemed clear that the existing law did not cover the

situation. In that year FDA contracted with a nationwide newspaper clipping service to collect news reports on accidental poisonings. Deaths were reported from silver polish, aspirin tablets, disinfectants, sleeping pills, radiator cleaner, ant poison, and paint thinners—to name a few. Some of these products had warnings on their labels, but most did not.



Dr. Chevalier Jackson

In the first court case under the Caustic Poison Act, FDA charged that this label did not identify the poison (lye) or tell what to do for eye injury.

**PLEASE READ DIRECTIONS CAREFULLY BEFORE USING.**  
Go-Drain chemically reacts with materials obstructing the flow. Therefore remove all the water possible from the sink, basin, tub, bowl, etc. preparatory to using GO-Drain.

**FOR COMPLETE STOPPAGE**  
Slowly empty the contents of this can in two quarts of water or into the sink, basin, etc., containing two quarts of water. Allow this to work on the drain pipe an hour or preferably, overnight. When obstruction is dissolved, flush pipe with water. When stoppage is beyond trap use two cans of GO-Drain, if necessary.

**REGULAR MONTHLY TREATMENT OF ALL DRAIN PIPES**  
Do not wait for a complete stoppage. Use a half can of GO-Drain to a quart of water and flush pipes within a half an hour after treatment. These applications save money and insure sanitation.

**FROZEN PIPES**  
Empty this can directly into frozen pipes and then flush with one quart boiling water.

**GARBAGE or KITCHEN CANS — CELLAR or GARAGE FLOORS**  
Quickly cleaned by dusting GO-Drain over interior or on surfaces that have first been sprinkled with a little water. Let stand for 20 minutes and then rinse. Be careful of hands and shoes.

**CAUTION-POISON**  
Keep away from bare hands, skin, clothing and open flame. Do not breathe fumes. Keep can tightly closed.

IF TAKEN INTERNALLY, give vinegar, lemon juice followed by lard, olive or cottonseed oil. Summon doctor.

FOR EXTERNAL BURNS, wash freely with water and apply salve, lard or olive oil.

WILL NOT INJURE ENAMEL, PORCELAIN OR PLUMBINGWARE.

Manufactured by  
**GOULARD & OLENA, INC.**  
140 LIBERTY STREET, NEW YORK

**2 LBS.** **NET. WEIGHT**

**for FROZEN PIPE**

Many of the new products for maintaining the home, although hazardous in some way, were not disagreeable in appearance or odor—some were attractively scented, colored, and packaged. The small inquisitive child was the victim in the great majority of cases. In many poisoning cases the label was at hand but failed to inform the physician of the ingredients. The American Academy of Pediatrics surveyed poisoning accidents encountered by its members in their private practices, and established the need for centers that physicians could call for instant information on the ingredients in household products. In 1953, the Illinois Chapter of the Academy set up a pilot project in Chicago called a poison control center. It proved invaluable, and became the model for the more than 583 centers independently established throughout the country, with a National Clearing House in the Public Health Service in Washington. This became an FDA program in 1968.

The centers, however, did not lessen the urgency for putting the vitally needed information on the package. In 1956, the American Medical Association announced that it had authorized its Committee on Toxicology to draft a model law requiring safety labeling for potentially harmful chemicals used in the home and industry. The announcement said that other professional groups, including the National Safety Council, American Academy of Pediatrics, and the American Public Health Association, would be consulted in helping to write a law requiring that harmful ingredients be listed on labels along with their antidotes. Four years later, the Hazardous Substances Labeling Act was passed.

Actually, this law was the product of a long evolution brought about by many individuals, forces, and events.

### Labels and Liability

Use by apothecaries of the pirate

symbol of death, the skull and crossbones, on their labels was common in the early 1700's.

Warning labels on explosives and dangerous chemicals date from the earliest use of such products.

As early as 1857, a bill was introduced in the British Parliament which would have made it compulsory to dispense all liquid poisonous substances in bottles which had the word "poison" molded in the glass. Although the bill was not passed, we can assume that such bottles were being made.

By 1915, the New York City Fire Department had regulations on labeling of bulk chemicals.

Most important, the trend of product liability law made it increasingly desirable for manufacturers to warn the ultimate consumer of inherent dangers in their products. A line of court decisions had overturned the old common-law rule that the injured person could sue only the man who had sold him the product—generally the retail dealer.

One of the important early cases was *Thomas vs. Winchester*, decided in 1852, by the New York Court of Appeals. The plaintiff's physician had prescribed extract of dandelion, but the patient received an almost lethal dose of extract of belladonna through a labeling error by the manufacturer. The defense argued that the druggist was responsible for what he sold, and that a suit could not be brought against a "remote vendor," the manufacturer. Departing from precedent, the court ruled otherwise, and the jury awarded damages. Sustaining the verdict, the Court of Appeals said that if the patient had died, the man who mislabeled the medicine would have been punishable for manslaughter.

In 1916, the New York Court of Appeals, in the case of *MacPherson vs. Buick*, cited *Thomas vs. Winchester* as a "foundation case" in product liability law. Wrote Justice Cardozo: "A poison, falsely labeled, is likely to injure any one

who gets it. Because the danger is to be foreseen, there is a duty to avoid the injury." The court ruled that Buick Motor Company was not absolved from a duty of inspection because it bought wheels, one of which was defective, from another reputable manufacturer. "The obligation to inspect must vary with the nature of the things to be inspected. The more probable the danger, the greater the need of caution," the court said.

Product liability law undoubtedly stimulated both voluntary use of warning labels and the passage of safety labeling laws. And in time, the proliferation of State and local laws began to cause headaches for manufacturers who wanted to label their products for competitive, nationwide distribution.

### From Voluntary Codes to Statute Law

In the late 1930's, the Manufacturing Chemists Association began development of uniform labels for bulk chemicals. In 1945, the association published its first manual titled: "*Warning Labels. A Guide for the Preparation of Warning Labels for Hazardous Chemicals.*"

In the late 1940's and '50's, the Chemical Specialty Manufacturers Association developed recommendations for labeling household products, following the pattern which the manufacturing chemists had worked out in the industrial field.

The chemical industry's labeling code was soon being used by State authorities. Some of the State labor departments adopted it in their safety regulations. In a number of States, the recommendations were enacted into laws, but these varied widely in their coverage and requirements.

In 1958, a model bill drafted by the AMA Committee on Toxicology for both Federal and State enactment was introduced in Congress. A year later, another bill, drafted by four national chemical trade associations, was introduced.

The industry and AMA bills were alike in many respects. Organized labor supported the AMA version because it required safety labeling on industrial chemicals as well as household products, but the union representatives did not insist on this.

The FDA position was more complex. With its hands full regulating foods, drugs, and cosmetics, the Agency was not looking for new business. Yet, here was an industry bill which provided important consumer protection. To get such legislation without industry opposition was an opportunity too good to miss. Accidental drug poisonings, usually of children, were being brought to FDA's attention with tragic frequency. All too often, the label bore no information which could have alerted parents to the danger. The main thing wrong with the industry bill, from the FDA's standpoint, was simply that it exempted foods, drugs, and cosmetics from warnings against accidental misuse—a type of warning not authorized by the Federal Food, Drug, and Cosmetic Act.

Accordingly, FDA proposed the addition of a Title II amending the Food, Drug, and Cosmetic Act to provide legal authority for such warnings as "Keep Out of the Reach of Children," when needed on drugs and cosmetics, and "Do Not Incinerate" on pressure-packed food containers. At first it appeared that the amendment would be accepted. But then a familiar alignment was repeated. Cosmetic and food industry spokesmen joined proprietary drug manufacturers who did not want their products categorized as "hazardous substances." Any amendments of the Food, Drug, and Cosmetic Act should be in a separate bill, they argued. Congress agreed.

### **The Hazardous Substances Labeling Act**

The Hazardous Substances Labeling Act of 1960 was a combination of the chemical industry code and procedures adopted from

the Federal Food, Drug, and Cosmetic Act. These basic ingredients made an effective law. The industry code was a product of expertise and experience. It was based on scientific knowledge in the fields of toxicology, pharmacology, and medicine, applied by the courts in numerous liability cases.

As one commentator put it: "The statutory standard (in the new law) for determining whether a product is hazardous is the standard used by the courts in civil liability cases. The duty to warn is the same under the common-law rule and under the rule of this Act . . ."

Where the common law imposed liability, the Act now added criminal penalties.

The pattern of the law is based on a system of required "signal words" such as DANGER, WARNING, or CAUTION, accompanied by a statement of the hazard and advice on precautionary and first-aid measures. The label must identify the hazardous ingredients for the doctor, in case of an accident, and must give the name and address of the responsible seller. All this must be "located prominently . . . in conspicuous and legible type." If the product is highly toxic, then the word "POISON" is required; it may also be required on a less toxic product which is highly hazardous.

The statement of hazard, such as "harmful or fatal if swallowed," must be appropriate to the hazard. It can be made stronger—"may be fatal if swallowed"—or less strong—"harmful if swallowed"—according to the degree of hazard.

Specific language is likewise provided for products which are corrosive, flammable, or extremely flammable, and these terms are defined both technically and legally.

The Hazardous Substances Labeling Act made a substantial contribution to consumer protection. Compliance was exceptionally good; thousands of consumer products, now bear informative precautionary labeling, which unquestionably has prevented many injuries and

fatalities. Time and experience, however, disclosed several serious shortcomings in this law.

### **Closing Some Loopholes**

The trouble with the Hazardous Substances Labeling Act was it did not provide enough protection for children.

The Act required protective labeling on products packaged for household use. Unlabeled articles were not covered, and experience showed this to be a serious loophole. For example, imported stuffed toy ducklings with the skin and stuffing treated with pesticides and arsenic, some of them further contaminated with infectious bacteria, could not be seized under the Act because they were not packaged.

The question whether the 1960 Act covered fireworks was raised dramatically in 1965, when Commissioner George P. Larrick issued a public warning against "cracker balls," and ordered nationwide seizures on the ground that they did not bear protective labeling. These small, torpedo-like firecrackers closely resembled candy, and also looked like a certain brand of breakfast cereal. Many children mistaking these explosives for food, suffered burns, loosened teeth, and cuts in the mouth. Labeling was impractical as protection from such a hazard: although the courts agreed that cracker balls came under the Act.

The most shocking example of a product too hazardous to be made safe by labeling was X-33, an extremely flammable and explosive water-repellent coating for damp basement walls. It had a flash point of 40 degrees below zero. It caused numerous flash fires and explosions—known to have resulted in death for three persons and injury to 30 others. Yet this product could not be banned from the consumer market. FDA could only make individual seizures on charges that the label warning was not adequate. Over 500 seizures had to be made to take this dangerous product off the market. The court costs were

enormous. Fire departments throughout the Nation aided in rounding up and destroying the seized lots, yet small lots are still occasionally being found.

While these were serious problems, it was accidental poisoning by salicylate drugs, particularly aspirin, that provided the major stimulus for the next legislative effort, the Child Protection Act of 1966. Aspirin had continued to be No. 1 in the statistics on child poisoning. The actual incidence of over-dosage cases was unknown, but the available figures were startling. In 1966, the National Clearing House for Poison Control Centers received 10,859 reports on ingestion of aspirin by children under five who were seen in hospital emergency rooms. Of these, 88 percent were reported to have ingested the candy-flavored children's aspirin. In 1965, the Clearing House received 34,483 reports of accidental ingestion of drugs by children under five, of which 16,328 involved aspirin or other salicylates. In 1964, the Division of Vital Statistics of the Public Health Service reported 125 deaths of children under five attributed to aspirin or salicylate poisoning.

The FDA had not been idle. In 1955, the Agency had called a meeting of pediatric experts and drug industry representatives to consider the problem of accidental poisoning by salicylate drugs in general and aspirin in particular. Adopting a recommendation of the panel, FDA published the now familiar legend: "WARNING: Keep this *and all medications* out of the reach of children" (emphasis added). Industry spokesmen said they would voluntarily use this warning.

The advisory panel made other recommendations:

\*\*\*In lieu of specific dosage, "For children under three consult your physician"—on oral salicylate preparations. This, too, was adopted by FDA.

\*\*\*Voluntary standardization of

dosage of children's aspirin at 1 1/4 grains per tablet.

\*\*\*Development of safety closures and containers (this became law in 1970).

\*\*\*An educational program to inform physicians, pharmacists, and consumers regarding the hazards of accidental ingestion of salicylate drugs.

Some progress was made toward each of these objectives during the next decade. The industry complied with the FDA label regulations; educational messages on poisoning prevention reached millions of parents; a leading producer of children's aspirin adopted a safety closure, and most brands of this product were limited to 50 1 1/4-grain tablets per bottle. Mortality figures, however, showed no improvement. In fact, through 1963 they increased. Many pediatricians felt that the advent of the "baby aspirins" in the 1940's had greatly expanded the hazard. Reports from hospital emergency rooms seemed to confirm their opinions.

### FDA Tries Again

With such a background, it was inevitable that FDA would try again. In legislative recommendations for 1966, the Agency proposed the drafting of a "Child Safety Act" which would provide statutory backing for label warnings and also correct the obvious shortcomings of the Hazardous Substances Labeling Act.

On March 21, 1966, President Lyndon B. Johnson, in a message to Congress on "consumer interests," presented an extensive legislative program which included a Child Safety Act and a Drug Safety Act. In the same message, he supported pending legislation to promote "truth in packaging" and "truth in lending." With the exception of the Drug Safety Act, all of these measures were subsequently enacted.

The Child Safety Act brought all hazardous substances,

regardless of their wrapping, under the safeguards of the Federal Hazardous Substances Act. Deleting the word "Labeling" from its title, the 1966 amendment authorized the banning of household substances that are so hazardous that warning labels are not adequate safeguards. It summarily banned toys and other children's articles containing hazardous substances, regardless of their packaging.

Subsequent events can be recorded only briefly in this article.

It was inevitable that other consumer products besides "hazardous substances" would become a matter of public interest and concern. News stories about young girls burned by flaming sweaters had brought the first Federal flammable fabric legislation in 1953. A Refrigerator Safety Act followed reports of tragic deaths of children who suffocated in abandoned refrigerators. Accident statistics showed that hundreds of thousands of injuries and deaths were related to hazardous features and defects in home appliances and other equipment. Consumers' Union reported in 1966 that in 10 years of its testing activities, 376 products had been found so hazardous as to be unacceptable in the home.

### Presidential Proposal

In his message on February 8, 1967, "To Protect the American Consumer," President Johnson recommended legislation to create a National Commission on Product Safety to make a comprehensive investigation and propose remedial action. Already involved in the matter, the Senate Committee on Commerce held hearings and the Congress enacted the bill and appropriated funds for the Commission which was appointed in 1968.

The Commission on Product Safety held hearings in major cities and made many recommendations. The first legislation to result from its work was the Child Protection and Toy Safety Act, a further amendment to the basic Hazardous

Substances Act. Signed into law by President Nixon on November 6, 1969, it gave FDA the power to take off the market toys which could be injurious because of mechanical, electrical, or thermal hazards. Hundreds of such toys were subsequently removed from sale—569 in the fiscal year 1972. Many more were voluntarily withdrawn or corrected by the manufacturers.

The tendency of young children to ingest poisons which adults leave within their reach is a vexing and persistent problem. Mitigated but unsolved by Chevalier Jackson's Caustic Poison Act, or Homer George's educational Poison Prevention Week, the poisoning of children has continued to challenge parents, the medical profession, manufacturers, and lawmakers. On December 30, 1970, President Nixon approved yet another effort to deal with the problem—The Poison Prevention Packaging Act.

The idea of this legislation was not new—development of so-called safety closures for aspirin was one of the recommendations made by the same FDA medical advisory panel which proposed the label warning to "Keep Out of the Reach of Children." But "combination caps" were then little more than an inventor's dream. Packaging technology has better answers today, and the new law (story, page 24) authorizes FDA to require that hazardous substances be packaged in such a way that adults can open them but most young children cannot. Regulations concerning aspirin tablets, liquid furniture polish, oil of wintergreen, and controlled drugs are in effect already; others will become effective in the months ahead.

The most recent law in this area is the Consumer Product Safety Act, signed into law by the President last October 27. It creates a five-member Product Safety Commission to be appointed by the President with the advice and consent of the Senate. This Commission will be responsible for the administration of the Federal Hazardous

Substances Act (including the Child Protection and Toy Safety Act of 1969), the Poison Prevention Packaging Act, the Flammable Fabrics Act, and the Refrigerator Door Safety Act. Additionally, it will have the authority to set safety standards for all household products not now covered by law. Examples of products already covered by law include: foods, drugs, cosmetics, medical devices, radiological products, motor vehicles, and small boats.

FDA's Bureau of Product Safety will be transferred to the Commission and form the nucleus of the new independent organization. The transfer of personnel, property, and functions is expected to become effective this month (see February 1973 FDA CONSUMER).

The story is not finished. It will never be possible to completely protect people from the hazards around them: to do so would require us to give up too many of the pleasures and conveniences of modern living. But as long as standards and regulations can reduce the hazard to the consumer, it will be the responsibility of Government to be alert to potential hazards and take appropriate action to deal with them.



Wallace F. Janssen is FDA's historian.

Dramatic effects of the Federal Caustic Poison Act are shown in this label change. The label at left, used before the Act was passed, does not say what the content is, that it is dangerous, or what to do if an accident occurs. The label at right does.

**SOLUTION**  
for  
**BALKITE**  
"B" Power Units  
and  
"A" Chargers  
**DIRECTIONS**  
This special Electrolite is for use with Models "K" and "N" Trickle Chargers. Also Balkite "B" 90 and "B" 135 "B" Eliminators. Pour contents as directed. You need add nothing but distilled water to the Model "N" Charger.

**\$1.50**  
**Uncle Sam Products Co.**  
**AKRON, OHIO**

**POISON**  
Solution for  
**BALKITE**  
"B" Power Units & "A" Chargers  
**DIRECTIONS**  
This special Electrolite is for use with Models "K" and "N" Trickle Chargers. Also Balkite "B" 90 and "B" 135 "B" Eliminators. Pour contents as directed. You need add nothing but distilled water to the Model "N" Charger.

**ANTIDOTES**  
**EXTERNAL—HANDS** — Ammonia, Lime Water or Milk of Magnesia.  
**INTERNAL—Lime** Water or Milk of Magnesia.  
**EYES—Lime** Water or Milk of Magnesia. Call Physician.

**Contains:**  
**Sulphuric Acid**

Price \$1.50  
**Uncle Sam Products Co.**  
**AKRON, OHIO**



# Poison Prevention Packaging:

# New Protection for Children

by Georg S. Maisel

*Potentially poisonous products are now being marketed in containers that most young children cannot open.*

Every year half a million children or more accidentally poison themselves by drinking turpentine, eating fistfuls of aspirin, or swallowing any of a host of potentially lethal substances found around the house. Several hundred of them die.

Every year, during National Poison Prevention Week, Federal, State, and local groups try to reduce the toll by educating parents in methods of preventing poisoning. This year Poison Prevention Week will begin March 18, and parents will be learning about child-resistant packaging—an important new way to keep their children from swallowing something they should not.

The Poison Prevention Packaging Act became law on December 30, 1970, and now many products are being marketed in packages that adults can open but most young children cannot. If parents make it a point to buy products in the new child-resistant packages, keep the products in these packages, and close them properly after use, a dramatic reduction in the number of accidental poisonings can result.

## It's up to Parents

One of the principal messages during National Poison Prevention Week will be that this packaging is now becoming available; it will be up to parents to buy it and use it properly.

The law authorizes the Food and Drug Administration to identify those substances that should be sold in child-resistant packages and to set standards for the packaging. The first substance identified was aspirin; more children poison themselves accidentally with aspirin than any other product.

The new safety-closure requirement represented a monumental task for the packaging industry; some 750 million packages of aspirin are sold annually in the United States. But as of August 14, 1972, all household packages of aspirin tablets shipped from the manufacturer—with one exception—were required to have safety closures. The law does permit the packing of a single size in each product line in conventional containers for the benefit of the elderly and infirm.

Similar orders became effective last September 13 for liquid furniture polishes containing petroleum distillates, on September 21 for methyl salicylate (oil of wintergreen), and on October 24 for drugs subject to the Narcotics and Dangerous Drugs Act. As more substances are identified as representing a hazard to young children and as standards are set, more packaging orders will be issued.

On April 11 this year, orders covering household substances containing methyl alcohol and turpentine are due to take effect. Another order effective April 11 will cover most household substances containing sodium hydroxide and potassium hydroxide (mostly lye preparations); for those in aerosols

and paste-type oven cleaners, however, the order is effective July 10.

## Next on the List

According to Malcolm W. Jensen, director of FDA's Bureau of Product Safety, the list will be extended to cover these kinds of products:

- paint thinners and removers;
- drain cleaners with both alkaline and acid bases;
- most pesticides;
- auto products such as methyl alcohol deicers and ethylene glycol used in antifreeze preparations;
- over-the-counter drugs that contain iron;
- cigarette lighter fluid and charcoal lighter fluid;
- and practically all prescription drugs in oral dosage form. With these, the manufacturer will not have to ship them in child-resistant containers unless they go into the home in the original containers. Rather, the pharmacist will be required to place the prescriptions in packages with safety closures, unless the physician or patient requests conventional packages.

The key to poison prevention packaging is to design containers that most young children cannot open. Most of those marketed so far involve a cap to which you have to do something, such as squeeze or push down, before it can be released. When a safety closure is designed, it must meet test requirements.

For testing, the regulation requires groups of 200 children, aged 42 to 51 months, both boys and girls. Each child is given a package and

five minutes to open it. Then an adult demonstrates how it is done, and the child is given an additional five minutes.

For a safety closure to pass the test, a minimum of 170 of the 200 children must not be able to open the package in the first five minutes, and a minimum of 160 of the 200 must be unable to open it during the second five minutes. Put another way, at least 80 percent of the children must not be able to open it even after instructions and a second try. The design standard stipulates that 90 out of 100 adults must be able to open and resecure the safety packages within five minutes.

The closures cannot be made completely child-proof. A balance has been struck that will protect most children without making the packaging so cumbersome that adults will refuse to use it and thus

nullify the entire program.

#### **Only a Partial Solution**

As safety closures become available, they should help alleviate the accidental poisoning problem—but they cannot eliminate it. They will not work at all unless parents buy potentially poisonous products in safety packaging, keep the products in them, and properly close the containers after use.

And even if the safety closures are used exactly as intended, they cannot prevent all poisonings. According to the testing protocol, two out of ten children may be able to open them. The same precautions that have always been necessary will still be necessary. These are the precautions that National Poison Prevention Week is specifically designed to bring to public attention.

Poison prevention begins with

consideration of the most frequent potential victim, the young child. Little children have a boundless curiosity. The whole world is new, and they want to look at, touch, handle, and taste everything they come across. They are ingenious; they will pick up something and fiddle around with it until suddenly, unexpectedly, it opens. Then, as likely as not, they will put some of the contents in their mouths.

As they grow, walking and climbing instead of crawling, their range increases. Children at the crawling stage most often poison themselves with cleaners and polishes, petroleum products and paint solvents; these are what they find on the bathroom floor, in cabinets under the kitchen sink, and on low furniture. As they get older, fewer are poisoned from these sources, but more are poisoned from



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medicines and other substances kept on higher shelves.

### What You Can Do

A parent must try to anticipate every possibility and take not one or two, but all possible steps to keep children from poisoning themselves. As safety packages become available, parents should insist on them for hazardous products; at present, about 80 percent of all such products are or will be covered by poison prevention packaging orders. Once the products are in the home, other steps should be taken:

- Keep potentially poisonous substances locked up. If your medicine or cleaning cabinets will not lock, keep your drugs and drain cleaners in another place that can be locked.

- Keep hazardous substances in their original containers; never

transfer them to a cup or soda bottle or anything that might suggest to a child that it is something he can eat or drink.

- Keep internal medicines apart from other household products. Many of the containers look alike.

- Dispose of unused medicines and household products by emptying the residue down the toilet or drain. Then rinse the container before discarding it.

- Get rid of prescription medicines as soon as the illness for which they were prescribed is over. Not only does this remove a potential hazard for children, but over a period of time, chemical changes can take place in the medicine which render it useless or even dangerous.

- Never tell a child medicine is candy or like candy.

- Never take medication in front of a small child. The youngster may

try to imitate you sometime when you are not there.

Progress is being made. In the last three or four years, the number of children's deaths resulting from accidental poisonings has been cut in half. The decrease is attributed, at least in part, to the educational activities of poison prevention programs as well as to the work of the 583 poison control centers across the country, where physicians can get instant information on every kind of poisonous substance that comes into homes.

The ultimate responsibility will always rest with parents, however. The way to prevent accidental poisonings from substances found about the house is to prevent children from getting at them. In the last analysis, for every child accidentally poisoned, there is an adult responsible.



Georg S. Maisel is acting chief of the Poison Prevention Packaging Branch, Division of Chemical Hazards, Bureau of Product Safety.

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# News Highlights

## **FDA Announces New Regulations On Nutrition, Food Labeling**

FDA has announced a 12-part program expected to bring about basic and far-reaching changes in the labeling and promotion of food products in the United States.

Culminating several years of study and preparation, the new program is designed to provide the American consumer with specific and meaningful new information on the identity, quality, and nutritional value of a wide variety of general and special foods available in the Nation's marketplace.

In addition to nutrient and vitamin-mineral labeling, the program provides for identification of fats and cholesterol content, sets standards for vitamins and minerals sold as dietary supplements, and sets new rules for the definition and labeling of imitation food products. The program also consolidates and clarifies existing but piecemeal FDA regulations, affecting food labeling practices.

"The actions we are announcing today will result in the most significant change in food labeling practices since food labeling began," said Charles C. Edwards, M.D., Commissioner of Food and Drugs. "They mark the beginning of a new era in providing consumers with complete, concise, and informative food labeling."

"The regulations will put into practice virtually all of the labeling recommendations of the White House Conference on Food, Nutrition, and Health. They are the result of years of work by FDA, nutritionists, scientists, industry, and consumer representatives. No action in FDA's history has had more broadly based input or been more carefully considered," Dr. Edwards added.

Dr. Edwards stressed the importance of a continuing and major effort by FDA, industry, professional and consumer groups to help consumers understand and utilize the new labeling information.

"As the program gets underway, labels will begin routinely bearing information never before seen by the average consumer. It is important for all of us to make every effort to inform consumers on how to use this new labeling to the benefit of themselves and their families," he concluded.

All of the actions appeared in the *Federal Register* of January 19, 1973. All actions are scheduled to be finalized within six months of that date. Affected manufacturers will then be required to make all appropriate labeling changes for printing of new labels by the end of this year. All foods

shipped in interstate commerce after December 31, 1974, must be in full compliance.

(For a complete description and analysis of the new food labeling regulations, watch future issues of *FDA Consumer*.)

## **FDA Proposes Ingredient-Listing Requirement As Part of Cosmetic Regulation**

FDA has acted to require listing of cosmetic ingredients on product labels.

The action is part of an FDA four-point program of cosmetic regulation begun in August 1971. Already in effect are voluntary registration of cosmetic manufacturing establishments—650 registered to date; filing of product formulas with FDA—802 recorded to date. A system for reporting adverse experience by cosmetic users is planned to begin during 1973.

The proposed FDA ingredient-listing requirement is published concurrently with a petition for such action by the Consumer Federation of America and Professor Joseph A. Page of Georgetown University. The Food, Drug, and Cosmetic Act provides that any citizen or group may petition the Agency for a needed regulation. Public comment is invited on either the FDA proposal or the petition.

Both the FDA proposal and the Page petition require ingredients to be listed in descending order of predominance on labels firmly attached to each product. The FDA proposal specifies details about the label design and language and size of print for ingredients and states that fragrances, coloring, and flavoring may be simply declared as such.

The Page petition provides an exception from ingredient listing where manufacturers can show FDA that a particular ingredient is a trade secret. The ingredient name would be available to a poison control center or a physician.

FDA authority to act is based on the provisions of the Fair Packaging and Labeling Act that allow the Secretary of HEW to issue registrations to facilitate value comparison of products and prevent consumer deception.

Interested persons may, within 60 days, file comments regarding the petition and proposal with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Maryland 20852.

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# Regional Reports

## REGION I

"What you see is what you get" was not necessarily so with a product ordered seized recently at Providence, Rhode Island, in the jurisdictional area of the **Boston Field Office**. The vignette on the label of Snack Mix Deluxe Assortment showed cashew nuts and almonds, neither of which was in the mixture. FDA alleged the article was misbranded not only because of this but because the ingredients statement declared the product to be "Nuts." Under FDA regulations, this is not the common or usual name for each required variety of nut included in the mixture.

Parker Products, Inc., Hollister, Massachusetts, had manufactured and shipped the 444 five-ounce bags of nuts into interstate commerce. The firm did not file a claim to the product within the allotted time following seizure, and the court ordered the nuts distributed to charitable institutions.

## REGION II

**Buffalo District** reports that Bristol Laboratories, Syracuse, New York, is recalling a 21,300-unit lot of its Bristoject Epinephrine Sterile Injection distributed nationwide to 410 hospital accounts. The firm initiated the recall when a doctor at one of the hospitals serviced by the firm reported that a unit failed to operate while he was trying to administer the medication to a patient. Bristol tested the units returned by the complainant and found that 10 percent did not operate. The problem was traced to faulty syringe units that were supplied by a foreign manufacturer. Bristol's quality control tests had not revealed the problem before the units were shipped to its accounts.

The product is used in emergency areas of hospitals, on airport crash carts in use after plane crashes, and in other areas where emergency measures have to be taken. The medication is injected directly into the heart when it has stopped beating to shock it into beating again.

## REGION III

Del Campo Baking Manufacturing Co., Wilmington, Delaware, and an official of the firm, Alfonso Del Campo, pleaded nolo contendere in a U.S. District Court at Wilmington in December to a charge of shipping into interstate commerce bakery rolls infested with insects and insect fragments. Each was fined \$1,000, and Mr. Del Campo was given a three-month suspended sentence.

**Philadelphia District** inspectors first inspected the firm's premises in June 1971. They found bakery products were being produced under insanitary conditions, causing them to become adulterated with insects, and FDA requested legal action. During the ensuing time, the case ran the legal gamut—requests for stays, appeals, etc.

Icelandic Food Products, Camp Hill, Pennsylvania, voluntarily destroyed 131,800 pounds of rodent-contaminated bread crumbs and breeding materials the week of December 18, reports the Pennsylvania Department of Agriculture Division of Food Control. The State officials had embargoed the raw materials, used in preparing precooked foods, in November after Philadelphia District inspectors conducted an establishment inspection of the premises and found extensive rodent contamination of the materials stored at the plant.

Shortly before the FDA inspection, the firm had shipped 5,640 pounds of precooked fish sticks prepared under insanitary conditions to Boston, where FDA's Boston Field Office has requested seizure. In the meantime, Massachusetts State officials have placed the fish sticks under embargo.

## REGION IV

Inspectors from the **Atlanta Field Office** uncovered some cookies recently in routine inspections of the Tasty Cookie Company, Louisville, Kentucky, that because of the added ingredient, rodent hairs, were not very tasty. The cookies had been produced from baking ingredients held under insanitary conditions in the rodent-infested bakery.

The firm and two of its corporate officers, Joseph J. Shapiro, president, and Yandell O'Koon, secretary, pleaded guilty to four of the five charges brought by FDA and nolo contendere to the fifth. U.S. District Judge Charles M. Allen accepted the pleas and fined each defendant and the corporation \$300 per count, totaling \$4,500. In addition, Messrs. Shapiro and O'Koon each received a five-year suspended jail sentence with two years' probation.

When a consumer in Nashville, Tennessee, found that the mineral oil she bought smelled like alcohol, she did what FDA hopes all consumers will do when faced with such a problem—she complained to the Agency. FDA inspectors followed up the complaint with an inspection of the Cumberland Manufacturing Co. in Nashville, where the mineral oil had been produced. They found that the oil possibly had become contaminated due to flushing of pipelines with isopropyl alcohol between



packaging runs. The inspectors examined 17 lots of heavy mineral oil and found that seven of the lots had an odor of alcohol. Sample analysis of two lots showed 0.33 to 0.35 percent isopropyl alcohol. As a result, Cumberland is recalling all stocks of its Swan brand heavy mineral oil in one pint sizes. Inspectors sampled 12 lots of light mineral oil for analysis and it was found to be free of alcohol contamination.

FDA plans to continue its investigation.

## REGION V

**Chicago District's** consumer specialist, Marie Ekvall, spoke to 200 salesmen-members of the Western Confectioner's Association who met in Chicago December 14. They were interested in starting a program of FDA workshops on problems common to their industry and the Agency.

**Cincinnati District** recently completed a successful survey of the use of pesticides on lettuce grown in hot-houses in Ohio, during which time the inspectors uncovered an improper use of the pesticide parathion.

The survey resulted from a consumer's complaint to the District that her two pet canaries had died, possibly from something they had eaten. FDA representatives collected a sample of the lettuce the consumer had been

feeding the birds, and laboratory analysis showed that it contained high levels of parathion.

During the survey, District inspectors collected and analyzed 22 samples of lettuce, thereby identifying the grower who was in violation of FDA regulations for use of pesticides. The Zurowski Greenhouse in Cleveland was found to be using parathion in an unapproved manner, accounting for the high residual level. Follow-up resulted in the successful seizure by FDA's Detroit District of a \$552-lot of lettuce the grower had shipped to that jurisdictional area.

At this time, officials of the Ohio State Department of Agriculture are holding up the firm's harvest of an additional half acre of lettuce that is contaminated with parathion.

The "night people" in Detroit received consumer information from FDA on a person-to-person basis one night recently. **Detroit District's** consumer specialist, Diane Place, appeared on WMUZ-FM radio on an open-line program from 1-4 a.m. to answer questions from listeners whose jobs prevent them from communicating with FDA during normal business hours. The types of questions asked seemed to indicate that the thousands of workers who keep a big city operating while the remainder of the populace sleeps appeared to have as much concern about foods, drugs, medical devices, and cosmetics as do the "daytime" people.

## TV Series on FDA and Consumer Protection

In cooperation with Jack Righeimer, director of public information, University of Illinois Medical Center, Chicago, Region V is producing a series of 30-minute color television programs on the consumer and FDA protection. The programs will be aired on the university's "Consultation" Series.

In the series, Mr. Righeimer discusses FDA programs and common consumer concerns with Agency specialists from the Bureaus of Drugs, Foods, Product Safety, Radiological Health, Veterinary Medicine, and with the Region V director and program consultants. So far, 13 programs have been completed, with Donald C. Healtton, regional director, as FDA advisor, and Dorothy F. Dunn, regional program manager for consumer affairs, as coordinator. The programs cover: X Rays—How Safe; Environmental Contamination of Food; The Consumer Speaks Out; Clean and Safe Food; Use of Drugs With Animals; Cosmetics; Nutrition and Dietary Labeling; Food Additives—How Safe; Electronic Products in the Home; Measuring Drug Safety; Flammable Fabrics; Labels; Toys.

The University of Illinois "Consultation" Series has been on the air for the past five years. It is a public service viewed on over 100 commercial and educational stations in over 40 States. In 1973, the Series will also be used by a number of TV cable systems. Consumers

can check TV schedules to learn if the Series is shown in their local viewing areas.

Additional information about the color television programs can be obtained from the FDA's Region V office.



During filming of the TV series, Mr. Righeimer (left) discusses FDA consumer protection programs with Dr. William Cole, associate director, and John Villforth, director, Bureau of Radiological Health.

The Kroger Co., Indianapolis, pleaded nolo contendere December 11 to an FDA charge of operating a rodent-infested warehouse. U.S. District Judge Cale J. Holder, sitting in the District Court for the Southern District of Indiana, fined the corporation \$750 on each of five counts, a total of \$3,750, plus costs. When the case was filed originally in that court in May 1972, the firm had pleaded not guilty.

The case filed at the same time against the firm's former distribution manager has been continued with no definite date set for trial.

The six fisheries in the **Minneapolis District** area that were permanently enjoined in November from shipping DDT-adulterated fish in interstate commerce (see February 1973 FDA CONSUMER) have filed a notice of appeal with the court in Milwaukee, Wisconsin. The fisheries are all based in Wisconsin and include Goodman Fish Co., Kenosha; Ewig Bros. Fish Co., Inc., Port Washington; Strege & Rousar Fish Co., Racine; Ray's Fish Co., Racine; Robert Strege Co., Racine; and G and M Fisheries, Racine.

The immediate result of the appeal is that the injunctions are not in effect so long as the appellants actively pursue their case. This means then that the fisheries can ship DDT-adulterated fish in interstate commerce until the circuit court renders a decision. It will be up to the court of appeals to determine whether or not the public will be offered fish that possibly will contain DDT in an amount over the 5 parts per million interim tolerance established by the Secretary of Health, Education, and Welfare.

## REGION VI

**Dallas District** personnel recently participated in a two-day workshop at Brownsville, Texas, held entirely in Spanish for the line-workers of the shrimp industry there. Brownsville has a mixed cultural environment—people speak both English and Spanish, with some speaking Spanish only.

When the workshop started at 8 a.m. on December 5, nearly 1,000 line-workers sat in the town's civic center waiting to learn about plant and personnel sanitation. All shrimp plants in the area had stopped production for as long as the workshop would last. "You have to admire the interest that the shrimp industry has shown by shutting down production so the workers can attend this workshop," said John Bittenbender, Dallas District's resident inspector in Brownsville. Mr. Bittenbender was on the program later in the day, talking about what he looks for as an inspector when he visits the shrimp plants.

Those on the program from Dallas District were Philip B. White, Region V food and drug director; Joe P. Durham, deputy regional food and drug director; James B. Hyndman, supervisory bacteriologist; John Krakosky, supervisory inspector; Roman E. Longoria,

Jr., import manager; Humberto Guerrero, chemist; and Juan Tijerina, consumer specialist. Dr. Joseph C. Olson, director of the Division of Microbiology, Bureau of Foods; and John Kedzior, Industry Guidance Branch, Bureau of Foods, came from FDA headquarters in Washington to be part of the program.

Those coming from industry to participate were Dr. Rafael Pedraja, vice president of research, development and quality control, Booth Fisheries, Chicago; Placido Gonzales, bacteriologist, National Shrimp Processors, Inc., Brownsville; and Donald Toloday, Singleton Packing Co., Tampa, Florida.

Alfred Basler, Jr., U.S. Department of Commerce, spoke on that department's inspection and sanitation program.

Representatives from the Mexican Government attended a number of sessions. Later they held several discussions with Messrs. Longoria, White, and Durham.

The workshop was considered quite successful, for the shrimp industry and the FDA now know what each expects of the other. If the industry produces a cleaner and safer product and if fewer compliance problems are encountered, then the time and money spent on a workshop of this type has to be considered a sound investment.

The national tradition of celebrating by shooting off fireworks, not only on the Fourth of July but in certain parts of the country on Christmas as well, keeps FDA busy tracking down violative distributors. A legal action on December 21 was the result of sales made to FDA inspectors from the **New Orleans District** by L. L. Stonebraker. The distributor was arrested in the East Baton Rouge Parish by deputy sheriffs for illegal possession of Class B fireworks—nine ½-gross bags of M-80's. Mr. Stonebraker is now free on \$500 bond pending further action.

According to statistics recently released by the port statistician for the Board of Commissioners of the port of New Orleans, the city continues to be the second largest seaport in the United States. The statistics, for the year 1971, revealed that of about 8.5 million tons of articles imported, two million tons—or 28 percent—were articles regulated by FDA. Expressed in money value, the total for the year was \$1.3 billion, of which about \$0.5 billion—or 35 percent—fell under the jurisdiction of FDA. The port of New Orleans business continues to grow rapidly. During calendar year 1972, the District alone detained \$2.5 million worth of articles. Also, as compared to 12 million pounds of tea imported in 1968, over 37 million pounds was imported in 1972.

## REGION VII

The **Kansas City Field Office** has an ongoing toy safety program, inspecting 109 retail outlets in Region VII

and comparing stocks of toys against the banned-toy list. Inspection of 11 toy manufacturers for banned toys, as well as other children's articles, continues in the Region's toy safety activities. In a special follow-up program to visits from Public Information Research Groups (P.I.R.G.), Field Office personnel inspected 22 retail outlets recently in Missouri and Iowa.

The Consumer Protection Association of Lawrence, Kansas, surveyed 15 stores there and found over 300 banned toys. Through the cooperation of the store managers, these toys were removed on the association's first visit, and no followup by FDA was required.

## REGION VIII

Julia Hewgley, **Denver Field Office** consumer specialist based in Laramie, Wyoming, has completed a series of 24 video tapes concerning the consumer education activities of the FDA. The tapes are each 15 minutes long and will be used on educational television throughout Wyoming. They will be available also for use by the State Extension Service. The tapes were produced by the Broadcast Services of the University of Wyoming in conjunction with the FDA under a grant from the Department of Health, Education, and Welfare.

## REGION IX

Twice in a two-month period a local firm found itself in trouble with the **San Francisco District** because of insanitary conditions in its warehouse. On December 12, a U.S. marshal went for the second time to the warehouse where large lots of cocoa beans and green coffee beans were being held under insanitary conditions and seized approximately \$145,000 worth of the merchandise.

The previous seizure, in October, was of over \$54,000 worth of green coffee beans which were also being held under insanitary conditions.

In January, Marbo Quality Foods, Inc., Fresno, and its president, Martin N. Berberian, pleaded nolo contendere in the U.S. District Court of the Eastern District of California to a charge of holding rice under insanitary conditions in the company packaging plant. They were fined a total of \$750.

The **Los Angeles District** effected seizure of 728 cases of decomposed frozen cuttlefish filets, valued at \$4,000, as the result of a recent trade complaint to the District by the firm holding the fish in storage. Frosty Fish Co. reported it had received numerous complaints of a bad odor coming from the stored fish. Although the firm was aware that the fish might be seized, it requested that the District sample the lot.

The District initiated seizure in Los Angeles several months ago of a food supplement called "Bee-(picture of a bee) Seventeen," labeled as containing amygdalin,

a nonapproved drug intended for use in the treatment of cancer. The Institute of Nutritional Research, Los Angeles, a nonprofit foundation, was distributing the new product.

When California officials investigated the Foundation in July 1972, they learned that the new product had been launched at the International Association of Cancer Victims & Friends Convention the same month, and that distribution was to have started in health food stores and possibly in regular food markets.

## REGION X

The **Seattle Field Office** has been participating in consumer education workshops for Indians as one of its ongoing programs (see February 1973 FDA CONSUMER). The need for such a program was evident recently in the Klamath Falls, Oregon, area.

The Indians there are receiving a per capita payment of approximately \$12,000 from the Federal Government for lands turned over to the Government. Since the Indians were subjected to several incidents of fraudulent business practices about 10 years ago when they received \$43,000 per capita, it is important that they be taught how to recognize such practices to protect themselves.

Workshops were held in Klamath Falls December 14 and in nearby Chiloquin December 15. They were sponsored jointly by the Organization of Forgotten Americans, the Federal Trade Commission, the FDA, and State and local consumer protection agencies. Twenty representatives of the various Indian tribes attended the workshop in Klamath Falls and 30 attended in Chiloquin. Included in the program topics were: How to Shop for a Car; Advertising; Door-to-Door Sales; Health Frauds; Trust Funds and Guardianships; Buying Meats and Convenience Foods; Shopping for Credit; Your Rights as a Consumer; and Where to Go for Help.

It doesn't pay to try to fool the Federal Government, one fish importer found out recently, least of all the U.S. Customs. In this case, the importer was the one who paid—and quite heavily.

At Bellingham, Washington, Seattle Field Office officials sampled the import entry from Japan of 5½ million pounds of frozen pollock in 18½-pound blocks. The fish was labeled as being skinned and boned, but upon analysis FDA found it actually was a ground fish product. No decomposition was found, and FDA released the entry with the comment that future entries of the product would be detained if not properly labeled as "ground or minced."

When the U.S. Custom officials at the port of entry read FDA's comment, they levied a 2½-cents-per-pound duty on the entry of "ground fish product," a total of \$138,715. If the fish had been skinned and boned as labeled, it would have been considered an unprocessed product and thus duty free.

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# State Actions

## Misbranding Violation

The Pennsylvania Department of Health, Division of Drug Control, issued a violation notice at a department store in Springfield, Pennsylvania, charging that the Max Factor line of Pure Magic medicated products was misbranded, under the State law, in that the labeling failed to declare the active ingredients. The products were Super Cover Stick (medicated "instant cover up"), Super Cover Medicated Cake Make-up, Super Lip Gloss, Super Gel, and Super Pure Medicated Shiny Lip Gloss (lipstick).

State officials contacted the Max Factor Company officials and, after a series of discussions with the firm's attorney, obtained a voluntary agreement from the company to re-label its products to try to bring them into compliance. The agreement was confirmed by a letter to the department indicating that the firm's distribution center in Chicago would provide stick-on labels to all Pennsylvania sellers and would request that the labels be placed on the products involved. The company said its supply company salesmen would check shelf stock during routine visits and apply the stick-on labels where needed.

## Consumer Publication

Oregon consumers will be kept up to date on what the Oregon Department of Agriculture is doing to protect their food supply through a new department publication, *Consumer Protection*.

The newsletter will be published monthly. It will carry informational articles on foods, current news items related to consumer protection, dates of hearings and meetings of interest to the consumer, and reports of any action on consumer legislation relating to food.

Through this publication the consumer will also be kept informed of violations of food standards, since

it lists food products not meeting those standards set either by law or department regulations, plus any seizures of food items, arrests, and court cases resulting from violation of standards. The newsletter will also carry information on any temporary suspensions of business firm operations due to failure to meet sanitation requirements.

*Consumer Protection* is directed at the consumer and does not replace the department's quarterly publication, the *Agri-Record*. The latter publication will continue and will concentrate on matters of interest to the agricultural community, and on those statistics and violations not listed in the new publication.

Persons interested in receiving *Consumer Protection* will be placed on a mailing list by writing to Dr. Jane Wyatt, Consumer Officer, Oregon Department of Agriculture, Agriculture Building, Salem, Oregon 97310.

## Pesticide Contamination

Dieldrin contamination on a chicken farm in Iowa recently involved eventually not only the Iowa Department of Agriculture's Consumer Protection Division, but also FDA's Minneapolis District, the District's resident post at Des Moines, and the U.S. Department of Agriculture—but not necessarily in that order.

The FDA inspector at the Des Moines post reported to the Minneapolis office that the USDA had been informed of a 63-case lot of eggs being detained at a firm in New Richland, Minnesota, because of dieldrin contamination. Investigation determined that the eggs had come from a farm in Iowa. FDA sampled the eggs, and when the analysis showed 0.64 parts per million of the pesticide, a USDA inspector supervised destruction of the lot.

The information, with sample

results, was then forwarded to Everett Hart, director of the Iowa Consumer Protection Division. State inspectors were sent to the farm to collect samples of food, water, and other materials for pesticide analysis. Samples of the birds were collected also, and analysis of the meat revealed more than 3 parts per million of dieldrin in the fatty tissues. The owner voluntarily destroyed the entire flock of approximately 5,000 chickens.

## Embargo Lifted

The Pennsylvania Department of Agriculture's Division of Food Control on December 26 lifted its embargo of all flour stocks stored at Hawk Flour Mills in Allentown. The company had voluntarily destroyed 50,000 pounds of bagged flour valued at \$7,000 and had made extensive improvements costing approximately \$20,000 to bring the warehouse into compliance.

State officials had placed the embargo at the request of FDA's Philadelphia District following an establishment inspection by District inspectors during which they had found an active, extensive rodent problem.

## Insanitary Bakery

The Ohio Department of Agriculture's Division of Foods, Dairies and Drugs recently issued a 24-hour notice to a local bakery to clean up or cease operations. After the bakery's all-night cleanup, the division found the premises in satisfactory condition. The State then gave the bakery a 30-day notice to repair walls, floors, and ceiling. The company planned to make these repairs or move to new quarters within the allotted time.

The State action was a followup to a report from FDA's Cincinnati District that its inspectors had found the bakery operating under insanitary conditions.

# Seizures and 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 72 actions to remove from the consumer market products charged to be violative was reported in November/December. These included 26 seizures of foods: 12 involved charges concerning contamination, and 14 involved charges

concerning economic and labeling violations. Other seizures included 4 of drugs (including 3 of veterinary and medicated feed), 35 of medical devices, 3 of cosmetics, and 4 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>FOOD/Contamination, Spoilage, Insanitary Handling</b>		
Bakers Gem coconut flakes/New Orleans, La. 11/13/72	Chas. Denney Div. of DCA Food Industries, Inc./New Orleans, La. (D)	Held under insanitary conditions; rodent contaminated.
Bread, frozen, demi white, and Italian/Landover, Md. 11/24/72	New York Frozen Foods, Inc./Bedford Heights, Ohio (M, S)	Prepared under insanitary conditions.
Cocoa beans—Gmirandag, cocoa beans—Marchan, green coffee beans—Cameroon, cocoa beans—Brasil Bahia, cocoa beans—Angoo/San Francisco, Calif. 12/12/72	Thompson Bros., Inc./San Francisco, Calif. (D)	Held under insanitary conditions.
Bottlers pure sugar, granulated sugar/Cedar City, Utah 11/2/72	Seven-Up Bottling Co./Cedar City, Utah (D)	Held under insanitary conditions.
Donut mix/Charlotte, N.C. 11/2/72	Con Agra, Inc./Martel, Ohio (M, S)	Prepared, packed, and held under insanitary conditions.
Flour/Nampa, Idaho 11/17/72	Salt Lake Flour Mills/Salt Lake City, Utah (M, S)	Held under insanitary conditions.
Sharpsville, Pa. 11/6/72	Lock Two Grain & Milling Co./New Bremen, Ohio (M, S)	"
inst-pup mix/Union City, Calif. 12/12/72	Cheney Bros. Food Products, Inc./Union City, Calif. (D)	"; (flour) rodent contaminated.
Kipper snacks, fillets of kipper herring/New Orleans, La. 12/12/72	Norbest Co. A.S./Bergen, Norway (P,S)	Decomposed; faulty can seams.
Milk, nonfat, dry, low fat soy grits/Walnut Creek, Calif. 11/21/72	Debco Manufacturing Co./Walnut Creek, Calif. (D)	Held under insanitary conditions.
Peanuts/Greenville, N.C. 11/8/72	Keel Peanut Co./Greenville, N.C. (S)	Smoky, sour odor; scorched nuts, empty shells, miscellaneous debris.
Potato flakes/Ironton, Ohio 11/14/72	Markin-Blanton Co./Ironton, Ohio (D)	Held under insanitary conditions; rodent contaminated.
<b>Economic and Labeling Violations</b>		
Abalone/Denver, Colo. 11/8/72	Imported from Australia. American Rainbow Sales/Los Angeles, Calif. (S)	Not in conformity with the Fair Packaging and Labeling Act; no net quantity of contents statement on principal display panel; false and misleading claims.
Banana wafers/Raleigh, N.C. 11/13/72	Oven Krisp Cookie Co./Norfolk, Va. (M, S)	Quantity of contents statement not conspicuously placed on label and without sufficient contrast with background.
Cherries, canned/Lima, Ohio 12/7/72	Diamond Fruit Growers, Inc./Vancouver, Wash. (S)	Decomposed and moldy; leaky cans with holes; not in conformity with definition and standard of identity for canned cherries.
Gefilte fish, d'oeuvre fish bits/Denver, Colo. 11/8/72	I. Rokeach & Sons, Inc./Farmingdale, N.J. (M, S) Shipped from New York.	Not in conformity with the Fair Packaging and Labeling Act; no dual declaration of quantity of contents; label fails to bear common or usual name of each ingredient.
Ginger ale, root beer/Concord, N.H. 11/3/72	Canada Dry Corp./Waltham, Mass. (M, S)	Not in conformity with the Fair Packaging and Labeling Act.
Honey, raw, repacked/New Haven, Conn. 11/16/72	Cliff Jackson, partner Rawgenic Foods/New Haven, Conn. (D and Repacker)	"; contains Indian meal moths, insect and metal fragments.
Old Germany, wild blossom, linden/Chicago, Ill. 12/4/72	Kuhn's Imports, Inc./Chicago, Ill. (D)	Not in conformity with the Fair Packaging and Labeling Act; no dual declaration of quantity of contents.
Kangaroo-tail soup/Denver, Colo. 11/8/72	Imported from Australia. Liberty Import Corp./Carlstadt, N.J. (S)	Not in conformity with the Fair Packaging and Labeling Act; quantity of contents statement not in proper type size; not in bottom 30% of principal display panel; no "Net Weight" statement.



PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>Economic and Labeling Violations (cont'd)</b>		
Lemon crystals/Cornwells Heights, Pa. 11/30/72	John Lecroy & Son, Inc./Camden, N.J. (M, S)	Misleading label statement "Contains No Sugar"; contains dextrose and corn syrup solids.
Old-Fashioned sugar jumbles cookies, oat-meal cookies/Oklahoma City, Okla. 11/14/72	Mrs. Allison's National Sales Co./St. Louis, Mo. (S)	Not in conformity with the Fair Packaging and Labeling Act; net quantity of contents statement not in required type size.
Shawnee red raspberry muffin mix, blueberry mix/Joplin, Mo. 11/22/72	Shawnee Milling Co./Shawnee, Okla. (M, S)	False and misleading labeling, since there are no raspberries or blueberries in the mixes; no declaration of chemical preservative; quantity of contents statement lacks conspicuousness.
Snack Mix DeLuxe assortment/Providence, R.I. 11/24/72	Parker Products, Inc./Holliston, Mass. (M, S)	False and misleading label vignette, since no cashew nuts or almonds are in the assortment as depicted; label fails to name ingredients, just bears "Nuts."
Top Flight cockles clams in brine/Denver, Colo. 11/29/72	Seattle Fish Co./ Denver, Colo. (D)	Inaccurate label statement "net drained weight 3 oz"; article is short weight.
Weight Watchers onion broth/Smyrna, Ga. 11/6/72	Weight Watchers International, Inc./Great Neck, N.Y. (M); Foodways National, Inc./Valhalla, N.Y. (S)	Inaccurate label statement "Net Wt. 1¼ Oz."
<b>DRUGS/Human Use</b>		
Saliplex tablets/Miami, Fla. 11/10/72	Warner-Davis National Ltd./Miami, Fla. (D)	New drug without effective approved New Drug Application; false and misleading claims to be effective "for relief of pains associated with arthritis, sciatica, rheumatism, neuritis, bursitis, lumbago and other similar conditions."
<b>Veterinary/Medicated Feed</b>		
Dexamycin injection, vitamin E injection, Oxytocin injection, sterile estradiol suspension N.F., sterile prednisolone acetate suspension, prednisolone boluses/Wyoming, Mich. 11/6/72	Henry Jansingh/Wyoming, Mich. (D)	No adequate directions for use.
DMSO—Pure (dimethyl sulfoxide)/Louisville, Ky. 11/28/72	Aldrich Chemical Co., Inc./Milwaukee, Wis. (M, S)	New animal drug without effective approved New Animal Drug Application.
Stilbestrol repository/Brush, Colo. 11/13/72	Veterinary Laboratories, Inc./Lenexa, Kans. (M, S)	New animal drug without effective approved New Animal Drug Application.
<b>MEDICAL DEVICES</b>		
Diapulse/Sylacauga, Ala. 12/7/72	Diapulse Corp. of America/New Hyde Park, N.Y. (M, S)	Inadequate directions for safe use by laymen.
Phoenix, Ariz. 11/30/72	"	"
Hot Springs, Ark. 11/27/72	"	"
Lake City, Fla. 11/17/72	"	"
Palm Beach, Fla. 11/3/72	"	"
Rockford, Ill. 11/17/72	"	"
Streamwood, Ill. 11/20/72	"	"
Cresco, Iowa 11/15/72	"	"
Kansas City, Kans. 12/5/72	"	"
Bastrop, La. 11/6/72	"	"
Church Point, La. 11/6/72	"	"
Thibodaux, La. 12/6/72	"	"
Ash Grove, Mo. 11/17/72	"	"
Aurora, Mo. 11/17/72	"	"
Elmo, Mo. 11/14/72	"	"
Garden City, Mo. 11/7/72	"	"
Kansas City, Mo. 11/8/72	"	"
St. Louis, Mo. 11/30/72	"	"
Omaha, Nebr. 11/10/72	"	"
Columbus, Ohio 11/1/72	"	"
Harrisburg, Pa. 11/24/72	"	"
E. Peoria, Ill. 11/14/72	"	"
Paris, Ky. 11/9/72	"	Inadequate directions for safe use by laymen; false and misleading claims to be effective as treatment for infections, fractures, bone and tissue healing, bursitis, arthritis.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>MEDICAL DEVICES (cont'd)</b>		
Venice, Fla. 11/13/72	Bloch Equipment Co./Miami, Fla. (S)	Inadequate directions for safe use by laymen; false and misleading claims to be effective as treatment for infections, fractures, bone and tissue healing, bursitis, arthritis.
Hollywood, Fla. 11/3/72	Professional Medical Specialties/Orlando, Fla. (S)	"
De Land, Fla. 11/28/72	M and S unknown	"
Holly Hill, Fla. 11/8/72	Diapulse Corp. of America/New Hyde Park, N.Y. (S)	"
Ormond Beach, Fla. 11/8/72	Remington Rand Div. Sperry Rand Corp. (M); Diapulse Corp. of America/New Hyde Park, N.Y. (S)	Inadequate directions for safe use by laymen; false and misleading claims to be effective as treatment for infections, fractures, bone and tissue healing, bursitis, arthritis, low back pain.
Flagler Beach, Fla. 11/28/72	"	"
Daytona Beach, Fla. 11/3/72	"	"
Hot Springs, Ark. 11/15/72	"	"
Alma, Mich. 11/1/72	"	Inadequate directions for use.
Ann Arbor, Mich. 11/14/72	"	"
Detroit, Mich. 11/1/72	"	"
Owosso, Mich. 11/1/72	"	"
<b>COSMETICS</b>		
Baby shampoo/Denver, Colo. 11/8/72	Abolition Products/Chicago, Ill. (M); Topco Associates, Inc./Skokie, Ill. (S)	Moldy.
Tame creme rinse, Tame creme rinse with lemon, Tame creme rinse with body/Denver, Colo. 10/18/72	The Gillette Co. Personal Care Div./Chicago, Ill. (M, S)	Not in conformity with the Fair Packaging and Labeling Act; no dual declaration of quantity of contents.
"Touch of Sweden" hand lotion/Denver, Colo. 11/3/72	Dow Chemical Co./Midland, Mich. (M,S). Shipped from Los Angeles, Calif., and Danville, Ill.	"
<b>HAZARDOUS SUBSTANCES</b>		
Clacker balls/Mableton, Ga. 11/24/72	Plymouth Novelties, Inc./Apopka, Fla. (M); Port of Miami/Miami, Fla. (S)	Banned hazardous toy; mechanical hazard.
Re-Silvering polish/Omaha, Nebr. 11/10/72	Ag Bond International, Inc./Batavia, N.Y. (M, S)	Banned hazardous substance; contains soluble cyanide salts.
Chicago, Ill. 11/14/72	NIMM, Inc./Chicago, Ill. (D)	"
Windshield washer/Cincinnati, Ohio 12/2/72	M. J. Daly Co./Ludlow, Ky. (M, S)	Banned hazardous substance; contains methyl alcohol; no warnings as required by regulations.

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

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

October 2, 1972: Against **Dyna Power, Ltd.**, P.O. Box 239, Gary, Indiana 46401. Advertising and sale by mail of "Dynamite" and "Prolong Tablets," represented to be effective as sex stimulants.

October 2, 1972: Against **Gwendolyn**, 152 West 42nd Street, Suite 536, New York, New York 10036. Advertising and sale by mail of "French Love Powder," represented to be an effective aphrodisiac or sexual stimulant.

October 2, 1972: Against **Hernandez**, 324 S. First Street, Alhambra, California 91802. Advertising and sale by mail of "Pseudo Spanish Fly Chewing Gum," represented to be an effective aphrodisiac or sexual stimulant.

October 2, 1972: Against **Natural Products**, P.O. Box 10047, Newark, New Jersey 07101, and 266 Middle Street, Portsmouth, New Hampshire 03801. Solicitations of orders and sales through the mails of "Seacreme," represented as enabling users to wipe away ugly fat instantly from any area of their bodies without dieting, pills, or exercising.

October 3, 1972: Against **Health Activators** and **Arnold King Distributors**, 7008 SW 4th Street, Miami, Florida 33144, and **Personal Professional Products**, P.O. Box 493, Miami, Florida 33142. Advertising and sale by mail of "I Q.U.I.T.," represented to be an effective aid to stop smoking.

#### False Representation Orders Issued by Judicial Officer Under 39 U.S.C. 3005 (cont'd)

- October 3, 1972: Against **Health Activators and Arnold King Distributors**, 7008 SW 4th Street, Miami, Florida 33144, and **Personal Professional Products**, P.O. Box 493, Miami, Florida 33142. Advertising and sale by mail of "Lbs Off Plan," represented to be an effective diet pill and regimen for losing weight.
- October 3, 1972: Against **Products of Ann Lee**, 9864 Bird Road, Miami, Florida 33165. Advertising and sale by mail of "Dynamic Kaps," represented to be effective as a sex stimulant.
- October 4, 1972: Against **Nina of Germany**, 152 West 42nd Street, New York, New York 10036. Advertising and sale by mail of "Super Nature Tablets," or "Spark Pills," represented to be an effective aphrodisiac or sexual stimulant.
- October 4, 1972: Against **Products of Ann Lee**, 9864 Bird Road, Miami, Florida 33165. Advertising and sale by mail of "Up and Atom," represented to be effective as a sex stimulant.
- October 4, 1972: Against **Sauna Belt, Inc.**, P.O. Box 3984, San Francisco, California 94119. Advertising and sale by mail of "Sauna Belt," represented to be effective as a waistline reducer.
- October 4, 1972: Against **Thornton and Thornton Lab**, 152 West 42nd Street, Suite 536, New York, New York 10036. Advertising and sale by mail of "Mad Dog Weed," represented to be an effective aphrodisiac or sexual stimulant.
- October 5, 1972: Against **Royjel, Inc.**, 144 Mason Street, Greenwich, Connecticut 06830. Solicitations of orders and sales through the mails of "Royjel" tablets, represented as an effective aphrodisiac or sexual stimulant for both men and women.
- October 12, 1972: Against **United Distributors**, 152 West 42nd Street, Suite 536, New York, New York 10036, and 6915, 6919, and 6921 S. Vernon Avenue, Chicago, Illinois 60637. Advertising and sale by mail of "Frenchie's Spanish Fly Chewing Gum," "Knockout Drops," "Pussy Gum," "Spanish Fly," and "Spanish Fly Candy," represented to be effective as sex stimulants.
- October 12, 1972: Against **United Distributors**, 152 West 42nd Street, Suite 536, New York, New York 10036. Advertising and sale by mail of "Frenchie's Spanish Fly Chewing Gum," represented to be an effective aphrodisiac or sexual stimulant.
- October 13, 1972: Against **John Mortimer**, P.O. Box 1353, Winnipeg, Canada, for advertising and sale by mail of a method guaranteed to cure asthma.
- October 18, 1972: Against **Trim-Tights**, 6311 Yucca Street, Hollywood, California 90028. Advertising and sale by mail of "Sauna Girdle," represented to be effective as a spot reducer.
- October 19, 1972: Against **See-Well Company**, Box 1010 CW3, Postal Station A, Toronto, Canada, for advertising and sale by mail of a system of eye exercise guaranteed to correct various eyesight deficiencies.
- October 31, 1972: Against **Alpine Ski Diet**, P.O. Box 284, Alpine, California 92001. Advertising and sale by mail of a diet plan represented to be effective in causing a weight loss of 20 pounds in two weeks.
- October 31, 1972: Against **Diversified Products Co.**, P.O. Box 7218, San Diego, California 92107. Advertising and sale by mail of a diet plan represented to be effective in causing a weight loss of 20 pounds in two weeks.
- October 31, 1972: Against **Ski Team Diet**, P.O. Box 15493, San Diego, California 92115. Advertising and sale by mail of a diet plan represented to be effective in causing a weight loss of 20 pounds in two weeks.
- November 6, 1972: Against **Berringer & Berringer, Active 8 Division**, and P.O. Box 1386, North Miami, Florida 33161. Advertising and sale by mail of "Active 8," represented to be effective as a sex stimulant.
- November 6, 1972: Against **Vigor Tone**, Room 256, Department (NIC), 35 NE 17th Street, Miami, Florida 33132. Advertising and sale by mail of "Magic Muscle Cream," represented as a muscle developer.
- November 8, 1972: Against **Lockwood Distributors**, P.O. Box 798, Miami, Florida 33144, and **How To Co.**, 7008 SW 4th Street, Miami, Florida 33144. Advertising and sale by mail of "Instant Erecto Cream," represented to be effective as a sex stimulant.
- November 8, 1972: Against **Lockwood Distributors**, P.O. Box 798, Miami, Florida 33144, and **How To Co.**, 7008 SW 4th Street, Miami, Florida 33144. Advertising and sale by mail of "La Fem Climax Cream," represented to be effective as a sex stimulant.
- November 8, 1972: Against **Lockwood Distributors**, P.O. Box 798, Miami, Florida 33144, and **How To Co.**, 7008 SW 4th Street, Miami, Florida 33144. Advertising and sale by mail of "P.E.P.P.," represented to be effective as a sex stimulant, wrinkle remover, and bust developer.
- November 9, 1972: Against **Lockwood Distributors**, P.O. Box 798, Miami, Florida 33144, and **How To Co.**, 7008 SW 4th Street, Miami, Florida 33144. Advertising and sale by mail of "Lbs Off Plan," represented to be an effective method to lose weight.
- November 9, 1972: Against **Lockwood Distributors**, P.O. Box 798, Miami, Florida, and **How To Co.**, 7008 SW 4th Street, Miami, Florida. Advertising and sale by mail of "I.Q.U.I.T.," represented to be an effective aid to stop smoking.
- November 10, 1972: Against **Amar North, Adansh Ayurvedic Pharmacy**, Post Box 27, Chandigarh, India. Advertising the sale by mail of remedies represented as a guaranteed cure for any number of incurable diseases and serious maladies.
- November 14, 1972: Against **Marion Johnson Products, Health Aid Distributors, Exclusive Home Products, and Products "4" Health Co.**, 9864 Bird Road, Miami, Florida 33165. Advertising and sale by mail of "Up and Atom," represented to be effective as a sex stimulant.
- November 14, 1972: Against **Marion Johnson Products, Health Aid Distributors, Exclusive Home Products, and Products "4" Health Co.**, 9864 Bird Road, Miami, Florida 33165. Advertising and sale by mail of "Dynamic Kaps," represented to be effective as a sex stimulant.
- November 20, 1972: Against **Products of Discretion**, 9864 Bird Road, Miami, Florida 33165. Advertising and sale by mail of "Up and Atom," represented to be effective as a sex stimulant.
- November 20, 1972: Against **Products of Discretion**, 9864 Bird Road, Miami, Florida 33165. Advertising and sale by mail of "Dynamic Kaps," represented to be effective as a sex stimulant.

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

- September 27, 1972: **Stark Research Corporation**, Cedarburg, Wisconsin 53012. Advertising and sale by mail of "Catalyte," a product represented to speed up the fat-burning process in the body.
- September 28, 1972: **Natural Vitamin Research Council**, P.O. Box 1367, Studio City, California 91604. Advertising and sale by mail of a vitamin E product represented to be an effective treatment for wrinkles, scars, cuts, and other skin problems.
- September 29, 1972: **Scott House Division**, 2425 Colee Station, Fort Lauderdale, Florida 33303. Advertising and sale by mail of "Eternal Youth Wrinkle Remover," a product represented to be effective as a wrinkle remover.

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

- October 4, 1972: **B-Beautiful Method**, P.O. Box 1231, Radio City Station, New York, New York 10019. Advertising and sale of "the first ALL NEW approach to bosom development in years," a set of exercises which allegedly will promote bosom growth.
- October 4, 1972: **Berringer & Berringer, Active 8 Division**, and P.O. Box 1386, North Miami, Florida 33161. Advertising and sale by mail of "Active 8," a product represented to be effective as a sex stimulant.
- October 4, 1972: **Stim-U-Lar Research Corp.**, 5999 NW 18th Court, Sunrise, Florida 33313. Advertising and sale by mail of "Magic Mate Oil," a product represented to be effective as a sex stimulant.
- October 6, 1972: **Lockwood Distributors** and P.O. Box 798, Miami, Florida, and **The How To Co.**, 7008 SW 4th Street, Miami, Florida. Advertising and sale by mail of "Lbs Off Plan," a product represented to be an effective diet pill and regimen for losing weight.
- October 6, 1972: **Lockwood Distributors** and P.O. Box 798, Miami, Florida 33144, and **The How To Co.**, 7008 SW 4th Street, Miami, Florida. Advertising and sale by mail of "I Q.U.I.T.," a product represented to be an effective aid to stop smoking.
- October 6, 1972: **Marion Johnson Products, Health Aid Distributors, Exclusive Home Products, and Products "4" Health Co.**, 9864 Bird Road, Miami, Florida 33165. Advertising and sale by mail of "Dynamic Kaps," a product represented to be effective as a sex stimulant.
- October 6, 1972: **Marion Johnson Products, Health Aid Distributors, Exclusive Home Products, and Products "4" Health Co.**, 9864 Bird Road, Miami, Florida 33165. Advertising and sale by mail of "Up and Atom," a product represented to be effective as a sex stimulant.
- October 10, 1972: **Health Aids Co.**, Box 1, Rugby Station, Brooklyn, New York 11203. Advertising and sale of diet tablets, KAL-X TABLETS, as a vehicle for effecting loss of weight.
- October 10, 1972: **The How To Co.**, 7008 SW 4th Street, Miami, Florida 33144. Advertising and sale by mail of "Instant Erecto Cream," a product represented to be effective as a sex stimulant.
- October 10, 1972: **The How To Co.**, 7008 SW 4th Street, Miami, Florida 33144. Advertising and sale by mail of "La Fem Climax Cream," a product represented to be effective as a sex stimulant.
- October 10, 1972: **The How To Co.**, 7008 SW 4th Street, Miami, Florida 33144. Advertising and sale by mail of "P.E.P.P.," a product represented to be effective as a sex stimulant.
- October 11, 1972: **Greenland Books, a/k/a Gift House Books**, 4500 NW 135th Street, Miami, Florida 33054. Advertising and sale by mail of a book titled "Miracle Diet for the Fast Weight Loss." Presale advertising representations differ from the representations made in the book.
- October 11, 1972: **Windsor House, Inc.**, 3947 Austin Blvd., Island Park, New York, New York 11558. Advertising and sale through the mails of "Spot-Wrap" system, guaranteed to enable subscribers to reduce inches from waist, abdomen, buttocks, hips, thighs, flabby arms, calves, and ankles 90 minutes after using as directed.
- October 12, 1972: **Health Aids Co.**, Box 1, Rugby Station, Brooklyn, New York 11203. Advertising and sale of HEALTH AIDS TABLETS as a "NEW SCIENTIFIC DISCOVERY" that will produce an increase in weight for persons desiring same.
- October 18, 1972: **Oak Products**, P.O. Box 15, Ellicott Station, Buffalo, New York 14205. Advertising and sale of "Famous U.S. Women's Ski Team Diet" that allegedly will produce a weight loss of as much as 20 pounds in two weeks.
- October 27, 1972: **Fannie**, P.O. Box 239, Gary, Indiana. Advertising and sale by mail of "Mimic Love Sugar," represented to be effective as a sex stimulant.
- October 30, 1972: **The Wilbanks Company**, 1635 Commercial Drive, Naples, Florida 33940. Advertising and sale by mail of "Chin Strap," represented to eliminate double chins.
- October 31, 1972: **Products of Discretion**, 9864 Bird Road, Miami, Florida 33165. Advertising and sale by mail of "Up and Atom," represented to be effective as a sex stimulant.
- October 31, 1972: **Products of Discretion**, 9864 Bird Road, Miami, Florida 33165. Advertising and sale by mail of "Dynamic Kaps," represented to be effective as a sex stimulant.
- November 2, 1972: **Lydia Feldman**, 8228 Sunset Boulevard, Los Angeles, California 90046. Advertising and sale by mail of a tonic represented to be effective in weight reduction.
- November 3, 1972: **Beauty Research Co.**, P.O. Box 2142, Palm Springs, California 92262. Advertising and sale by mail of a method represented to be effective for the removal of facial wrinkles.
- November 3, 1972: **Better Health Products**, 218 Cortelyou Road, Brooklyn, New York 11218. Advertising and sale through the mails of "End-Smoke" tablets, represented to be effective as an aid to stop smoking.
- November 3, 1972: **Eat-Well**, 283 Greenwich Avenue, Greenwich, Connecticut 06830. Advertising and sale through the mails of "Eat-Well" tablets, represented as enabling an obese person to reduce without dieting.
- November 3, 1972: **Vel-X-Gum Co.**, Box 98, Cedarhurst, New York 11516. Advertising and sale through the mails of "Vel-X-Gum," represented as a means of controlling and preparing an obese person to lose weight.
- November 6, 1972: **Sutton's Specialties**, 4252 Fremont Avenue, No., Seattle, Washington 98103. Advertising and sale by mail of an herb tea represented to be effective in dissolving gallstones, kidney stones, and bladder crystals.
- November 7, 1972: **Ana Maher, Inc.**, 19 West 44th Street, New York, New York 10036. Advertising and sale through the mails of "Cucumbre Frost," represented as effective to eradicate facial lines, wrinkles, and puffiness.
- November 16, 1972: **Vitamin Blends**, 7224 Melrose Avenue, Los Angeles, California 90046. Advertising and sale by mail of a vitamin E product represented to be an effective treatment for wrinkles, scars, cuts, and other skin problems.
- November 16, 1972: **Vitamin E**, 7224 Melrose Avenue, Los Angeles, California 90046. Advertising and sale by mail of a vitamin E product represented to be an effective treatment for wrinkles, scars, cuts, and other skin problems.
- November 21, 1972: **Height Department, Royal London Imports**, P.O. Box 29119, Ecorse, Michigan 48229. Advertising and sale of an exercise course that allegedly will produce a substantial increase in height for those who desire same.
- November 24, 1972: **Elan Cosmetics Corporation International**, 200 E. Ontario Street, Chicago, Illinois 60611. Advertising and sale by mail of "Peel N Smoothe," a product represented to be effective as a wrinkle remover.

# Notices of Judgment

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

- Animal by-product meat and bone cracklings**, at Jersey City, Dist. N.J.  
Charged 4-7-72: when shipped by Granite State Rendering Co., Manchester, N.H., the article contained the added poisonous and deleterious substance *Salmonella* micro-organisms; 402(a)(1). Consent decree authorized release to shipper for reconditioning. (F.D.C. No. 57923; S. No. 14-336 F; N.J. No. 1)
- Copra meal pellets**, at Waipahu, Dist. Hawaii.  
Charged 11-26-71: while held for sale, the article contained the added poisonous and deleterious substance aflatoxin; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 57656; S. No. 17-575 E; N.J. No. 2)
- Lettuce, Singh's**, at Syracuse, N. Dist. N.Y.  
Charged 11-25-70: when shipped by Rala Singh Farms, Glendale, Ariz., the article contained the pesticide chemical parathion in excess of the prescribed tolerance; 402(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 56841; S. No. 21-321 D; N.J. No. 3)
- Oats**, at Davenport, S. Dist. Iowa.  
Charged 8-13-71: when shipped by Benson Quinn Co., Minneapolis, Minn., the article contained a pesticide chemical, a mercurial compound, for which no tolerance or exemption therefrom had been prescribed; 402(a)(2)(B). Consent decree authorized release to Hawley Cooperative Elevator Co., Hawley, Minn., for decharacterization of the article into seed oats. (F.D.C. No. 57364; S. Nos. 65-418/20 B; N.J. No. 4)
- Swordfish chunks, frozen**, at Brooklyn, E. Dist. N.Y.  
Charged 5-3-71: when shipped by Frigid Express, Jersey City, N.J., the article, labeled in part "Monani Fish . . . Frozen Swordfish Chunks . . . REM CIA Distribuionda de Pesca Lucas S.A. Frigorifico Atlantico . . . Santa Cruz de Tenerife Canary Islands," contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 57155; S. No. 66-218 D; N.J. No. 5)
- Swordfish fillets, frozen, and swordfish pieces, frozen**, at Seattle, W. Dist. Wash.  
Charged 2-22-71: when shipped by Washington Fish & Oyster Co. of California, San Francisco, Calif., the articles, labeled in part "Frozen Swordfish Fillet (Skinless) . . . Product of Taiwan, Republic of China" and "Frozen Swordfish Product of Japan WAFICO Seattle," contained the added poisonous and deleterious substance mercury; 402(a)(1). Consent decree authorized release of the swordfish fillets to Seattle Seafoods, Inc., Seattle, Wash., for export to original foreign supplier, and ordered destruction of the other fish. (F.D.C. No. 56992; S. Nos. 73-935 D, 76-847 D; N.J. No. 6)
- FOOD/Contamination, Spoilage, Insanitary Handling**
- Almonds, unshelled**, at Fairhope, S. Dist. Ala.  
Charged 12-1-70: while held by Schermer Pecan Co., Inc., Fairhope, Ala., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for reconditioning. (F.D.C. No. 56858; S. No. 84-584 D; N.J. No. 7)
- Barley flour, malted**, at Catano, Dist. P.R.  
Charged 12-8-70: while held by Molinos De Puerto Rico, Inc., Catano, P.R., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for conversion into stock feed. (F.D.C. No. 56859; S. No. 65-338 D; N.J. No. 8)
- Beans, kidney, canned**, at Grimes, S. Dist. Iowa.  
Charged 4-14-72: when returned to Beaver Valley Canning Co., Grimes, Iowa, the article, labeled in part "Shurfine . . . Dark Red Kidney Beans . . . Distributed by Shurfine-Central Corporation, Northlake, Ill.," contained moldy beans; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 57940; S. Nos. 42-041/2 F; N.J. No. 9)
- Clams, Alaskan Razor**, at Everett, W. Dist. Wash.  
Charged 8-20-71: when shipped by Certified Alaskan Clams, Kodiak, Alaska, the article had been prepared and packed under insanitary conditions whereby it may have been rendered injurious to health, since the clams were obtained from an uncertified source in Alaskan waters; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 57359; S. No. 39-552 E; N.J. No. 10)
- Cocoa powder**, at Chicago, N. Dist. Ill.  
Charged 4-17-72: while held by Howich, Inc., Chicago, Ill., the article contained insects and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 57946; S. Nos. 19-947/55 F; N.J. No. 11)
- Coffee beans**, at St. Louis, E. Dist. Mo.  
Charged 4-13-72: while in transit, the article contained rodent filth and was held under insanitary conditions in a rodent-infested railroad car; 402(a)(3), 402(a)(4). Consent decree authorized release to Missouri Pacific Railroad Co., St. Louis, Mo., for reconditioning. (F.D.C. No. 57937; S. No. 43-446 F; N.J. No. 12)
- Fish cakes, frozen**, at Bronx, S. Dist. N.Y.  
Charged 4-8-69: when shipped by Commodore Foods, Lowell, Mass., the article, labeled in part "Carnation Golden Fried 6 Fish Cakes . . . Distributed by Oceans of the World, Inc., Los Angeles, Calif.," contained bacterial filth, and the article had been prepared and packed

under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 55694; S. No. 189-877 C; N.J. No. 13)

- Lima beans, dried**, at Americus, M. Dist. Ga.  
Charged 2-16-71: while held by Glover Wholesale Co., Americus, Ga., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 56995; S. No. 1-302 E; N.J. No. 14)
- Lobster tails, frozen**, at Seattle, W. Dist. Wash.  
Charged 4-27-72: when shipped by S. I. Greene Co., Chicago, Ill., the article, labeled in part "F. R. New York U.S.A. Distributed by E. J. Kozin Co. Lobster Rock," consisted in part of decomposed lobster tails; 402(a)(3). Consent decree authorized release to E. J. Kozin, t/a E. J. Kozin Co., Chicago, Ill., for salvaging. (F.D.C. No. 57933; S. Nos. 43-164 E & 78-392 F; N.J. No. 15)
- Peanuts, shelled**, at Charlotte, W. Dist. N.C.  
Charged 4-19-72: when shipped by Columbian Peanut Co., Bainbridge, Ga., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the shipper for reconditioning. (F.D.C. No. 57947; S. No. 301 F et al; N.J. No. 16)
- Pecans, shelled, Mansura**, at Sharon, W. Dist. Pa.  
Charged 4-13-72: when shipped by Central Pecan Shelling Co., Mansura, La., the article contained *E. coli* and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 57935; S. No. 66-554 F; N.J. No. 17)
- Rice**, at Mobile, S. Dist. Ala.  
Charged 9-12-68: when shipped by Delta Rice, Inc., Hollandale, Miss., both lots of the article which were labeled "Jocko" and labeled in part "100 lbs. Jocko Long Grain Rice . . . China Doll, Inc., Mobile, Ala.," contained insects and had been prepared and packed under insanitary conditions; and the lot labeled "Jocko" lacked a label containing the name and place of business of the manufacturer, packer, or distributor and lacked an accurate statement of the quantity of contents; 402(a)(3), 402(a)(4), 403(e)(1), 403(e)(2). Consent decree authorized release to shipper for reconditioning. (F.D.C. No. 55537; S. Nos. 178-713/4 C; N.J. No. 18)
- Wheat germ**, at Fargo, Dist. N. Dak.  
Charged 11-18-71: while held by General Nutrition Mills, Inc., Fargo, N. Dak., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to the dealer for reconditioning. (F.D.C. No. 57648; S. No. 76-410 E; N.J. No. 19)
- FOOD/Economic and Labeling Violations**
- Lollipops**, at Lynwood, C. Dist. Calif.  
Charged 4-21-72: when shipped by Teddy's Candy, Phoenix, Ariz., certain required information (i.e. the name and place of business of the manufacturer, packer, or distributor, the quantity of contents statement, and the common or usual name of each ingredient) was not prominently placed in the label with such conspicuousness as to render it likely to be read and understood, since such information appeared on the rolled paper stick of the lollipop which was overwrapped with cellophane—403(f); and the article was in violation of the Fair Packaging and Labeling Act, since the net quantity of contents declaration failed to appear upon the principal display panel; 15 U.S.C. 1453(a)(2). Default decree ordered destruction. (F.D.C. No. 57942; S. No. 44-989 F; N.J. No. 20)
- Smoke flavor, Sutton's**, at Carson, C. Dist. Calif.  
Charged 8-9-71: when shipped by Sutton Smo-King Products, Inc., Dallas, Tex., the article lacked a quantity of contents statement and lacked a statement of its ingredients; 403(e)(2), 403(i)(2). Consent decree authorized release to the shipper for relabeling. (F.D.C. No. 57360; S. No. 66-616 E; N.J. No. 21)
- Sorghum molasses, cane juice, and citric acid mix**, at Jasper, W. Dist. Ark.  
Charged 4-7-72: when shipped by Roy McClain, Joplin, Mo., the article had been substituted for sorghum molasses, which the article was represented to be; and the label statement "Sorghum Molasses" was false and misleading as applied to the article; 402(b)(2), 403(a). The article was also in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not separated from other printed label information appearing above and below the declaration; the quantity of contents was expressed as "Minimum Weight 4½ Pounds (Net 70 Fluid Ounces)" instead of "70 Fl. Oz. (2 Quarts, 6 Fl. Oz.)"; the quantity of contents statement, appearing on the principal display panel area of more than 25 square inches, was in a type size less than 3/16 inch high; and the quantity of contents declaration on the principal display panel was qualified by the word "minimum" appearing in conjunction with the declaration; 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(3)(C)(i), 1453(b). Default decree authorized donation to a charitable institution. (F.D.C. No. 57926; S. No. 53-290 F; N.J. No. 22)
- Strawberries, frozen**, at Buffalo, W. Dist. N.Y.  
Charged 5-28-71: when shipped by Delta Packing Co., Humboldt, Tenn., the article, labeled in part "Delta Brand Select Whole Strawberries . . . In Heavy Syrup . . . Packed by Humboldt Canning Co., Inc., Humboldt, Tenn.," was in violation of the Fair Packaging and Labeling Act, since the name and place of business of the packer was on the inner lip of the package lid and was not specified conspicuously on the label; the

quantity of contents declaration was not within the bottom 30 percent of the principal display panel area, and the quantity of contents was expressed as "Net Wt. 1 Lb." instead of "Net Wt. 16 Oz. (1 Lb.)"; 15 U.S.C. 1453(a)(1), 1453(a)(2), 1453(a)(3)(A)(i). Consent decree authorized release to Humboldt Canning Co.—Delta Packing Co., Humboldt, Tenn., for relabeling. (F.D.C. No. 57229; S. No. 37-341 E; N.J. No. 23)

**Strawberries, sliced, sugared, frozen, at South Bend, N. Dist. Ind.**

Charged on or about 8-6-71: when shipped by Pearl Grange Fruit Exchange, Inc., Benton Harbor, Mich., the article, labeled in part "Scotland Sliced Fresh Frozen Strawberries with Sugar . . . Distributed by Redi-Froz Division of Scot Lad Foods, Inc., South Bend, Ind.," was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration on the principal, and alternate principal, display panel area of more than 5 square inches, was in type size less than 1/8 inch high; 15 U.S.C. 1453(a)(3)(C)(i). Consent decree authorized release to Redi-Froz Distributing Co., South Bend, Ind., for relabeling. (F.D.C. No. 57363; S. No. 93-539 E; N.J. No. 24)

**VITAMINS/SPECIAL DIETARY FOODS**

**Brewer's yeast, Dynavit, at Compton, C. Dist. Calif.**

Charged 4-11-72: when shipped by Dyna S. A., Fribourg, Switzerland, required information (i.e., the name and place of business of the manufacturer, packer, or distributor, an accurate statement of the quantity of contents, the common or usual name of the food, and the common or usual name of the ingredients) failed to appear on the label in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since such information was not in English; 403(f). Default decree ordered destruction. (F.D.C. No. 57932; S. No. 44-955 F; N.J. No. 25)

**Nutrition booster powder, Tiger's Milk, at Tulsa, N. Dist. Okla.**

Charged 10-14-70 and amended 3-31-71: when shipped by Plus Products, Los Angeles, Calif., the article's label statement "The need in human nutrition has not been established" in reference to biotin and pantothenic acid was false and misleading; the listing of amino acids on the label was false and misleading in representing and suggesting that those amino acids had unique and special nutritional values, when amino acids are ordinary constituents of protein; the listing on the label of such nonessential amino acids as alanine, aspartic acid, cystine, glutamic acid, glycine, proline, serine, and tyrosine was false and misleading in representing and suggesting that such acids were of vital importance and essential to nutrient intake needs; and the label statement "Each serving of four heaping tablespoons supplies over 15 grams of protein" was misleading where other label statements indicated the ordinary serving consisted of one or two tablespoons of the article—403(a); and the label lacked the common or usual name of each ingredient, since "High-Protein Concentrates from soybeans," "an exclusive primary grown yeast," and "High-Protein Concentrate from milk" were not the common or usual names of ingredients—403(i)(2); and two of the four lots of the article failed to bear statements required for special dietary foods in order to inform purchasers as to the article's value for special dietary use—403(j). Three lots of the article were in violation of the Fair Packaging and Labeling Act, since the three lots lacked the quantity of contents declaration in the bottom 30 percent of the principal display area—15 U.S.C. 1453(a)(2); and one lot of the article declared the net quantity of contents as "Net Wt. 20 Oz." instead of "Net Wt. 20 Oz. (1 Lb. 4 Oz.)," and the quantity of contents declaration on the principal display panel area of more than 25 square inches, was in a type size less than 3/16 inch high—15 U.S.C. 1453(a)(3)(A)(1), 1453(a)(3)(C)(i). Default decree ordered destruction. (F.D.C. No. 56747; S. No. 37-217 D; N.J. No. 26)

**Vitamin capsules, Dwarfies Daily Dozen Thirteen Vitamins All-In-One Daily Capsule Plus Lemon Bioflavonoid Complex, at St. Joseph, W. Dist. Mo.**

Charged 8-27-71: while held by Dwarfies Corp., St. Joseph, Mo., who was repacking the article from bulk capsules shipped in interstate commerce, the name of the article and the label statements "For Use As A Dietary Supplement Each Capsule Contains: Thirteen Different Vitamins Plus Lemon Bioflavonoid Complex" and "Lemon Bioflavonoid Complex 10 mg." were false and misleading in representing and suggesting that lemon bioflavonoids are nutrients with special dietary properties; and the article which was represented as a special dietary food by reason of its lemon bioflavonoid complex content lacked required information concerning its dietary properties upon which such use was based in whole or in part; 403(a), 403(j). Default decree ordered destruction. (F.D.C. No. 57371; S. No. 27-815 E; N.J. No. 27)

**FOOD ADDITIVES**

**Cracker meal, Sunshine, at Oakland, N. Dist. Calif.**

Charged 4-11-72: when shipped by Sunshine Biscuits, Inc., Dayton, Ohio, the article contained the nonconforming food additive Ronnel (a pesticide chemical); and the article had been prepared, packed, and held under insanitary conditions whereby it may have been rendered injurious to health, since inspection showed the manufacturer using a Ronnel-containing spray for floor/wall junctions throughout the plant, and a compound contaminated with Ronnel was used for fogging the production area; 402(a)(2)(C), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 57924; S. No. 74-476 F; N.J. No. 28)

**Crackers, saltines, Sunshine, and cracker meal, Sunshine, at Columbus, M. Dist. Ga.**

Charged 4-14-72: when shipped by Sunshine Biscuits, Inc., Dayton, Ohio, the articles contained the nonconforming food additive Ronnel (a pesticide chemical); and the articles had been prepared, packed, and held under insanitary conditions whereby they may have been rendered injurious to health, since inspection showed the manufacturer using a Ronnel-containing spray for floor/wall junctions throughout the plant, and a compound contaminated with Ronnel was used for fogging the production area; 402(a)(2)(C), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 57936; S. Nos. 4-103/6 F; N.J. No. 29)

**ANIMAL FEEDS**

**Animal feed liquid, at Dubuque, N. Dist. Iowa.**

Charged 2-18-72: when returned from Lanark, Ill., to Dubuque Tank Terminal Co., Dubuque, Iowa, the article, labeled in part "Liqui-Plus . . . Manufactured for FS Services, Inc. . . . Bloomington, Illinois," contained the new animal drug diethylstilbestrol, and there was no approval of a New Animal Drug Application in effect with respect to the use and intended use of the drug; 402(a)(2)(D). Consent decree authorized release to the shipper for salvaging. (F.D.C. No. 57814; S. No. 42-066 F; N.J. No. 30)

**Medicated feed, Cooper Life-Gro, at South Sioux City, Dist. Nebr.**

Charged 4-13-72: while held by O. A. Cooper Co., Inc., South Sioux City, Nebr., who had manufactured the article using ethylene diamine dihydriodide which had been shipped in interstate commerce, the article was an animal feed containing the drugs ethylene diamine dihydriodide and diethylstilbestrol, which in combination with each other in the article were new animal drugs, and there was no approval of a New Animal Drug Application in effect with respect to such animal feed; 501(a)(6). Default decree ordered destruction. (F.D.C. No. 57931; S. No. 41-677 F; N.J. No. 31)

**DRUGS/Human Use**

**Chorionic gonadotropin injectable, at Plainview, E. Dist. N.Y.**

Charged on or about 9-18-70: when shipped by Glogau & Co., Inc., Chicago, Ill., the article, labeled in part "Multiple Dose Unival Chorionic Gonadotropin . . . Manufactured for Interstate Drug Exchange, Inc., Plainview, L.I., New York," the article's strength was approximately 28 percent deficient; 501(c). Default decree ordered destruction. (F.D.C. No. 56599; S. No. 66-770 D; N.J. No. 32)

**Digoxin tablets, U.S.P., at Columbus, S. Dist. Ohio.**

Charged 11-19-71: while held by Philips Roxane Laboratories, Inc., Columbus, Ohio, who manufactured the article from digoxin powder shipped in interstate commerce, the strength of the individual tablets of the article differed from the U.S.P. standard; 501(b). The article was claimed by the dealer who denied the charge. Thereafter, for economic reasons, since the expense of litigation was disproportionate to the value of the drug seized, and without admitting that the article did not meet U.S.P. standards, the dealer withdrew his claim. Thereafter, default decree ordered destruction except for 10 bottles released to FDA for further studies. (F.D.C. No. 57650; S. No. 61-903 E; N.J. No. 33)

**Lady Curvaceous and Mr. Trim boric acid, sodium bicarbonate, aluminum potassium sulfate, and magnesium sulfate powder, at Pittsburgh, W. Dist. Pa.**

Charged 7-7-71: when shipped by Sterns Athletic Equipment Co., San Diego, Calif., the article was a new drug without an effective approved New Drug Application; and the accompanying pamphlets entitled "Lady Curvaceous" and "Men! Try the all new Mr. Trim" contained false and misleading claims for spot reducing, removing unwanted inches, making unwanted inches vanish quickly, molding user to desired proportions, contouring the body, losing adipose tissue, and improving health, and false and misleading claims that the article was approved by the medical profession; 505(a), 502(a). Default decree ordered destruction. (F.D.C. No. 57301; S. No. 10-157 E; N.J. No. 34)

**Mepharmosin mephenesin, amobarbital & guayanesin tablets, at Oxford, E. Dist. Mich.**

Charged 2-1-71: while held by Oxford Pharmacal Co., who manufactured the article using mephenesin shipped in interstate commerce, the circumstances of the article's manufacture, processing, packing, and holding failed to conform to current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 56880; S. No. 37-874 D; N.J. No. 35)

**Reserpine combination tablets, at Glendale, C. Dist. Calif.**

Charged 3-7-72: while held for sale, the strength of the article, which had been manufactured by Linden Laboratories, Inc., Los Angeles, Calif., and labeled in part "Tablets Elserpine—Prab Canright Corporation Glendale . . . Calif.," was deficient and the labeling false and misleading, since the article contained approximately 84.2 percent of the declared reserpine; 501(c), 502(a). Consent decree authorized release to the manufacturer for salvaging. (F.D.C. No. 57857; S. No. 92-378 E; N.J. No. 36)

**Scalp treatment kit, at Pensacola, N. Dist. Fla.**

Charged on or about 5-25-70: when shipped by Eckerd Drugs, Inc., Mobile, Ala., the article, labeled in part "Mallard Scalp Treatment . . . Castor oil, olive oil, sulphur, sarcoptic mange medicine, petrolatum. Mallard Beauty Products . . . Mobile, Ala.," was a new drug without an effective approved New Drug Application; and the jar and bottle labels of the article and an accompanying placard reading in part "Guaranteed to Grow The Hair 1/4 Inch Per Week" contained false and misleading claims about falling hair, dandruff, itchy scalp, bald spots, thinning around the edges, and growing hair; and the article's label lacked the established name of each active ingredient, specifically "sarcoptic mange medicine"; 505(a), 502(a), 502(e)(1)(A)(ii). Default decree ordered destruction. (F.D.C. No. 56437; S. Nos. 78-208 D; N.J. No. 37)

**Vice Spice capsicum annuum (red pepper) capsules, at Detroit, E. Dist. Mich.**

Charged 1-8-71: when shipped by Product Promotions, Los Angeles, Calif., the article was a new drug without an effective approved New Drug Application—505(a); and while held by Crown Industries & Supply Co., Detroit, Mich., who had repacked the article from bulk, the article was in violation of the Fair Packaging and Labeling Act, since the article lacked a statement of identity of the commodity on the principal display panel, the quantity of contents was not expressed in terms of numerical count on the principal display panel and was not separated from the label information appearing above and below the quantity of contents declaration—15 U.S.C. 1453(a)(1), 1453(a)(2). The repacker claimed the article and denied the charges. The Government served written interrogatories upon the claimant. Thereafter, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 56928; S. No. 40-544 D; N.J. No. 38)



#### VETERINARY/Medicated Feed

##### Dr. Brittner's Tonic tablets, at Pennsauken, Dist. N.J.

Charged 3-20-72: while held by Animal Specialties, Inc., Pennsauken, N.J., who had packed and labeled the article from bulk tablets, the article was a new animal drug without an effective approved New Animal Drug Application; and the bottle label and the accompanying catalog of the packer contained statements (including the name of the article "Tonic tablets") which were false and misleading in claiming that the article was a general "tonic," stimulated and improved the appetite of dogs that were finicky eaters, and was a treatment for nonspecific skin disorders; 501(a)(5), 502(a). Default decree ordered destruction. (F.D.C. No. 57858; S. No. 54-964 F; N.J. No. 39)

##### Dimethyltoluthionine coagulant veterinary solution, at Tulia, N. Dist. Tex.

Charged 5-18-72: when shipped by Wittney & Co., Inc., Denver, Colo., the article, labeled in part "AVC Hemo-Stop Veterinary . . . Manufactured For Affiliated Supply Company Tulia, Texas," was a new animal drug for which no approval of a New Animal Drug Application was effective; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 57948; S. No. 32-523 F; N.J. No. 40)

##### Trisulite sulfonamides, potassium iodide, and sodium arsanilate combination drug for swine, at Wichita, Dist. Kans.

Charged on or about 5-3-72: when shipped by Diamond Laboratories, Inc., Des Moines, Iowa, the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to the use and intended use of the drug; and the labeling contained false and misleading claims for eliminating acute and chronic infection in the bowel and lungs of swine of all ages; 501(a)(5), 502(a). Default decree ordered destruction. (F.D.C. No. 57943; S. No. 41-845 F; N.J. No. 41)

#### MEDICAL DEVICES

##### Diapulse electromagnetic energy generators, at Columbus, S. Dist. Ohio.

Charged 7-13-72: when shipped by Diapulse Corp. of America, New Hyde Park, N.Y., the labeling of the articles contained false and misleading claims for infections, fractures, bone and tissue healing, bursitis, arthritis, low back pain, increasing blood flow to peripheral areas, accelerating wound healing, sinusitis, herpes zoster, and foot lesions; 502(a). Default decree ordered destruction. (F.D.C. No. 58101; S. No. 32-335 F; N.J. No. 42)

##### Sterilizer, electric, Renewal, at Dayton, S. Dist. Ohio.

Charged 5-15-72: when shipped by American Sundries Co., Roslyn Heights, N.Y., the article was dangerous to health when used as directed, since the leakage of electrical current on the exposed metal cover of the device was sufficient to be lethal; 502(j). Default decree ordered destruction. (F.D.C. No. 58002; S. No. 26-042 F; N.J. No. 43)

#### COSMETICS/BEAUTY PRODUCTS

##### Hair brushes, at Albany, N. Dist. N.Y.

Charged 12-23-71: when shipped by Wagman-Wolfe, Inc., and Samuel Zeithin & Sons, Philadelphia, Pa., the article, labeled in part "100% Pure Boar Bristle Mohawk U.S.A.," contained nits and nit fragments; 601(b). Consent decree authorized release to Fuller Brush Co., E. Hartford, Conn., for reconditioning. (F.D.C. No. 57654; S. Nos. 78-389/91 E; N.J. No. 44)

##### Stink Stop pressurized detergent product, at Fort Smith, W. Dist. Ark.

Charged 4-17-72: when shipped by Texas Industrial Chemicals, Inc., Beaumont, Tex., the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration failed to appear on the principal display panel; 15 U.S.C. 1453(a)(2). Default decree ordered destruction. (F.D.C. No. 57949; S. No. 53-291 F; N.J. No. 45)

#### HAZARDOUS SUBSTANCES

##### Cherry bombs, at Grenada, N. Dist. Miss.

Charged on or about 6-4-71: while held at Jack's Place Pit Bar-B-Que, Grenada, Miss., the article was a banned hazardous substance intended to produce audible effects by a charge of more than 2 grains of pyrotechnic composition; 2(q)(1)(B). Default decree ordered destruction. (H.S.L. No. 1109; S. No. 22-824 E; N.J. No. 46)

##### Cherry bombs, at Holly Springs, N. Dist. Miss.

Charged on or about 6-4-71: while held at Colonial Inn Restaurant, Holly Springs, Miss., the article was a banned hazardous substance intended to produce audible effects by a charge of more than 2 grains of pyrotechnic composition; 2(q)(1)(B). Default decree ordered destruction. (H.S.L. No. 1108; S. No. 22-823 E; N.J. No. 47)

##### Cherry salutes, silver salutes, and M-80 fireworks, at Charleston, E. Dist. Mo.

Charged 7-1-71: while held at Ronnie's Trading Post, Charleston, Mo., the articles were banned hazardous substances intended to produce audible effects by a charge of more than 2 grains of pyrotechnic composition; 2(q)(1)(B). Default decree ordered destruction. (H.S.L. No. 1148; S. No. 27-837 E; N.J. No. 48)

##### Gold spray paint, at St. Louis, E. Dist. Mo.

Charged 4-16-70: when shipped by Morris Paint & Varnish Co., E. St. Louis, Ill., the article was a flammable substance and presented a special hazard by reason of its toluene and xylene content, and the article lacked a number of required conspicuous label statements—2(p)(1)(B&E); the label lacked the statement "Vapor Harmful," as required by regulations—3(b); and the label statement "Non-Toxic" negated and disclaimed required label statements—2(p)(1). Consent decree authorized release to Morris Paint & Varnish Co., St. Louis, Mo., for relabeling. (H.S.L. No. 1079; S. Nos. 23-604/5 D; N.J. No. 49)

##### Silver salutes and repeating bomb fireworks, at Mount Pleasant, N. Dist. Miss.

Charged on or about 1-4-71: while held at Mackey's Grocery & Service Station, Mount Pleasant, Miss., the article was a banned hazardous substance intended to produce audible effects by a charge of more than 2 grains of pyrotechnic composition; 2(q)(1)(B). Default decree ordered destruction. (H.S.L. No. 1097; S. Nos. 80-324/6 D; N.J. No. 50)

##### Toy animals, assorted stuffed, at Chicago, N. Dist. Ill.

Charged 6-27-72: when shipped by R & R Toy Manufacturing Co., Inc., Pen Argyl, Pa., the article which contained commingled multicolor scotty dogs, orange blobs, and long snouted animals, and which was labeled in part "SCOTTY ROSS ASSORTMENT BAGGED/PREPRICED SCOTTY ROSS TOYS," was a banned hazardous substance presenting mechanical hazards because of the readily removable eyes which had the potential for causing puncture or laceration wound injury; 2(q)(1)(A). Consent decree authorized release to Division Sales, Inc., Chicago, Ill., for salvaging. (H.S.L. No. 1258; S. No. 20-597 F; N.J. No. 51)

##### Toy electric automobile powered by sulfuric acid battery, at Ontario, Dist. Ore.

Charged 6-14-72: when shipped by Universal Specialties, Boise, Idaho, the article, labeled in part (carton) "Appollo Minicar Made in Taiwan Republic of China" and (plastic bottle) "Dilute Sulfuric Acid," was a banned hazardous substance which contained sulfuric acid susceptible of access by the child to whom the toy was entrusted, since the battery of the toy, when filled with the accompanying acid, leaked under reasonably foreseeable conditions; 2(q)(1)(A). Consent decree authorized release to John L. Estrano, Ontario, Ore., for salvaging. (H.S.L. No. 1253; S. No. 77-335 F; N.J. No. 52)

#### NOTICES OF JUDGMENT on Criminal Actions

##### FOOD

##### Easy Eggs Corp., and Robert Wheeler Muller, president, Whitesboro, N. Dist. N.Y.

Charged 12-14-71: when shipped, frozen whole eggs were decomposed (count 1) and contained the added poisonous and deleterious substance *Salmonella* micro-organisms (counts 2 & 3); 402(a)(3), 402(a)(1). Guilty plea by corporation to counts 1, 2 & 3; fine. Guilty plea by individual to count 2; fine. (F.D.C. No. 57322; S. No. 4-990 E et al; N.J. No. 53)

##### General Grocer Co., t/a Pick-N-Save Division, Donald Felker, general manager, and Frank Blair, Jr., warehouse manager, E. St. Louis, E. Dist. Ill.

Charged 12-9-71: crackers, breakfast cereals, and noodle mixes were held in a building accessible to rodents and insects and were contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (F.D.C. No. 57380; S. No. 8-028 E et al; N.J. No. 54)

##### Litchfield Grocery Co., Inc., Litchfield, S. Dist. Ill.

Charged 6-15-72: flour, chocolate candy bars, peanut butter cup candy, egg noodles, and macaroni were held in a building infested with insects and were contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty plea; fine plus costs. (F.D.C. No. 57905; S. No. 74-314 E et al; N.J. No. 55)

##### Merchants Co., and Donald B. Suber, vice president and general manager (grocery division), Jackson, S. Dist. Miss.

Charged 3-27-72 by grand jury: rice was held in a building accessible to rodents and was contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty pleas by corporation; fine. Nolo contendere plea by individual; fine and probation. (F.D.C. No. 57319; S. Nos. 1-622/4 E; N.J. No. 56)

##### Peavey Co., Buffalo, W. Dist. N.Y.

Charged 10-13-71: when shipped, American Beauty cake donut mix and American Beauty raised donut base contained insect filth and had been held under insanitary conditions—402(a)(3), 402(a)(4); and American Beauty yeast-raised potato donut & roll mix, King Midas flour, and rye flakes were held in a building accessible to rodents and insects, and the mix and flour were contaminated with insect filth—402(a)(3), 402(a)(4). Guilty plea; probation. (F.D.C. No. 57178; S. No. 14-255 D et al; N.J. No. 57)

##### Robinson Public Warehouse Co., and Arthur G. Robinson, president, Houston, S. Dist. Tex.

Charged 11-19-70 by grand jury: dried potato flakes (counts 1 & 2) and peppermint sticks (count 3) were held in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea to all counts by corporation; fine. Guilty plea to count 1 by individual; fine. (F.D.C. No. 56490; S. Nos. 35-504 D, 35-507/8 D; N.J. No. 58)

##### Standard Importing Co., Inc., and Costas Pailles, president, New York, S. Dist. N.Y.

Charged 1-4-72: when shipped, Hungarian feta cheese contained the food additive benzene hexachloride, the use and intended use of which failed to conform to any exemption or regulation; 402(a)(2)(C). Guilty pleas; fines. (F.D.C. No. 57182; S. No. 15-761 D; N.J. No. 59)

#### HAZARDOUS SUBSTANCES

##### Theodore O. Perlenfein, t/a Ted's Tobacco & Grocery Store, and Mrs. Theodore O. Perlenfein, Tarkio, W. Dist. Mo.

Charged 1-7-72: cherry bombs were sold (count 1) and M-80 firecrackers (count 2) were offered for sale; and such fireworks were banned hazardous substances intended to produce audible effects by a charge of more than 2 grains of pyrotechnic composition, were not intended for use solely for bona fide crop protection, and complete records of the receipt and distribution of such fireworks had not been maintained; 2(q)(1)(B). Guilty pleas by Mrs. Perlenfein to count 2 and by Mr. Perlenfein to both counts; fines. (H.S.L. No. 1191; S. Nos. 27-953 E, 43-997 E; N.J. No. 60)

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, Drugs, and Product Safety 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. March 1, 1973

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anything  
he can  
get his  
hands on . . .



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- *Children will imitate. Take your own medicine out of their sight.*
- *Children love sweets. Never tell them medicine is "candy." They'll eat it when you're not around.*
- *Small children can't read warning labels. Store hazardous household products and medicines in separate cabinets. Keep these substances locked up when not in use. Clean out cabinets periodically.*
- *Children get hungry and thirsty. Keep hazardous products in original containers, never in cups, soft-drink bottles or other food utensils.*



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