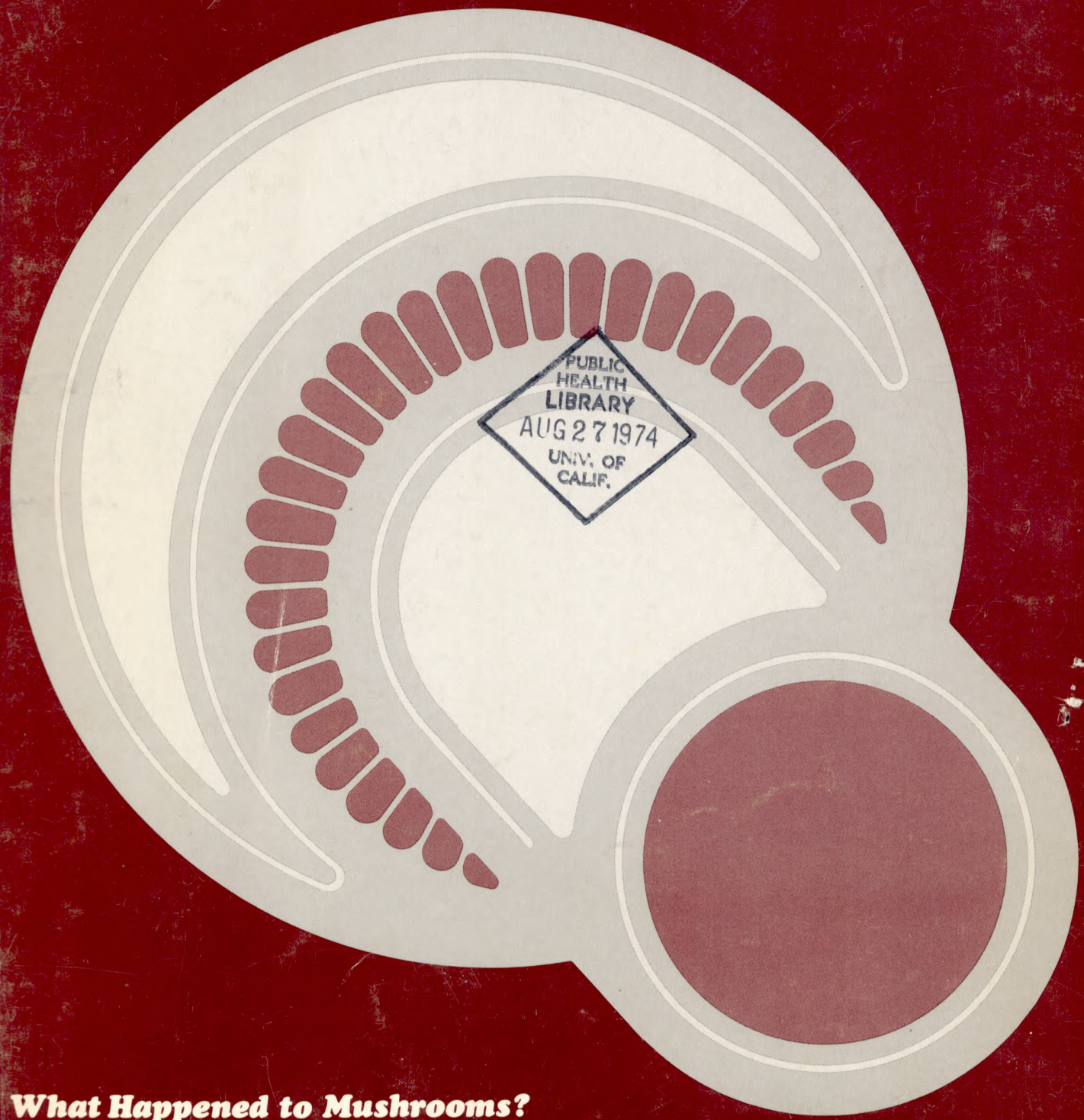


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# CONSUMER



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**What Happened to Mushrooms?**





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## This Month

**Y**es, it is safe to eat canned mushrooms. The great mushroom scare is over. This month, FDA CONSUMER reports on what happened last year and earlier this year to canned mushrooms. The simple answer is that quality control procedures did not keep pace with advancing technology. Our story starts with the Red Alert that brought the problem to FDA's attention, then describes the large-scale inspectional and administrative operation carried out by the Agency to assure the safety of canned mushrooms.

The skyjackings that became commonplace just a few years ago were enough to cause many "Red Alerts" among passengers and airlines alike. Today, skyjackings have been eliminated, thanks in part to new screening devices through which every passenger and all baggage must pass before entering a commercial airliner. To safeguard public health, FDA set standards for the x-ray machines used at airports to detect dangerous objects in baggage. The story of FDA's role in preventing skyjackings is called "X-raying Baggage to Thwart Skyjackers."

Our color story this month is about drug defects and a new system developed by FDA's Bureau of Drugs and the United States Pharmacopeia to uncover them. With the professional assistance of pharmacists across the Nation, FDA and USP are now able to uncover many problems before they pose serious dangers to consumers. You may be surprised at some of the defects found by pharmacists, as illustrated in color photographs.

Another story that emanates this month from FDA's Bureau of Drugs represents an important Agency accomplishment. On June 4, FDA announced that its review and rulemaking for all nonprescription antacid products was completed, and that new standards were being set for antacids. This is the first standard set under FDA's massive review of all nonprescription medicines, on which we've reported before. Our story describes what antacid ingredients can be used, and what changes you'll see in the labeling for these products.

Finally, we present the second in a series of four articles reporting on a national nutrition knowledge survey conducted by FDA in late 1973. Do consumers know what nutrients are contained in milk, meat, peas, and bread? The nutrition knowledge survey concluded that further educational efforts are needed in this important area. Another story this month reports on one such educational effort by FDA concerning nutrition labeling.

# **FDA** **CONSUMER**

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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.



# Consumer Forum

## Tofranil for Children

I am concerned about the marketing of the drug Tofranil by Ciba-Geigy, for the medical treatment of enuresis in children.

Mr. Daniel Zwerdling's article in the "Philadelphia Inquirer" (Oct. 23, 1973) brought out the fact that several side effects of the drug were not being included in promotional literature or on labeling.

Among the omitted side effects were precocious puberty and frequent overdose symptoms — brain damage and death. It does not warn doctors and parents that an overdose is exceptionally difficult to treat due to the speed at which this particular drug is absorbed by the body.

After reading available literature on Tofranil it might appear the FDA has compromised its high standards in allowing Ciba-Geigy to continually promote this drug for enuresis in children.

Before I administer this drug to my daughter, I would like to know the facts regarding the true effectiveness and safety of this drug. Do you really recommend it?

Susan R. Friedman  
State College, Pennsylvania

*Ciba-Geigy's application to market Tofranil for bed-wetting contained the results from 26 controlled clinical trials involving 832 children and, in addition, more than 100 scientific papers describing uncontrolled studies. In 24 of the 26 controlled studies, there was significant reduction in the frequency of bed-wetting in Tofranil-treated patients as compared to an inactive placebo. The effectiveness of the drug was shown to be greater in severely afflicted children, the ones who most need treatment.*

*The adverse reaction rate in 4,243 children reported in the controlled and uncontrolled studies was 5.6 percent. The most frequent reactions are sleepiness, fatigue, irritability, poor appetite, and nausea. Only three cases of breast hypertrophy and one case of precocious puberty have been reported. These reactions all cleared*

*when the drug was discontinued. Death from overdose can occur in children who ingest 10 or more tablets and in suicidal adults who take larger doses. There have been no reported deaths in children taking recommended doses for the treatment of bed-wetting.*

*The data submitted in the Tofranil application were carefully reviewed by the FDA staff, including special reviews by a statistician and a pediatric pharmacologist. The evidence presented was judged to constitute substantial evidence of safety and efficacy under the law, and accordingly the application was approved.*

*The newspaper article by Daniel Zwerdling which appeared in several newspapers contained many inaccuracies. The views of Dr. Elmer Gardner were misrepresented, and the assertion that pressure from the drug industry and the medical profession was involved was false.*

## Chair as Ladder Is Verboten

On page 21, Vol. 8, No. 2/March 1974, the lower left picture shows a man standing on a chair and steadying himself by grasping a shelf. This is decidedly not proper; the chair was not intended for use as an elevated platform. By implication you have condoned one of the leading causes of household injury, at a time when FDA is taking a serious look at product safety. If FDA, experts in product safety, abuses a chair by using it in this manner, the consumer is being told to do as I (FDA) say and not as I (FDA) do.

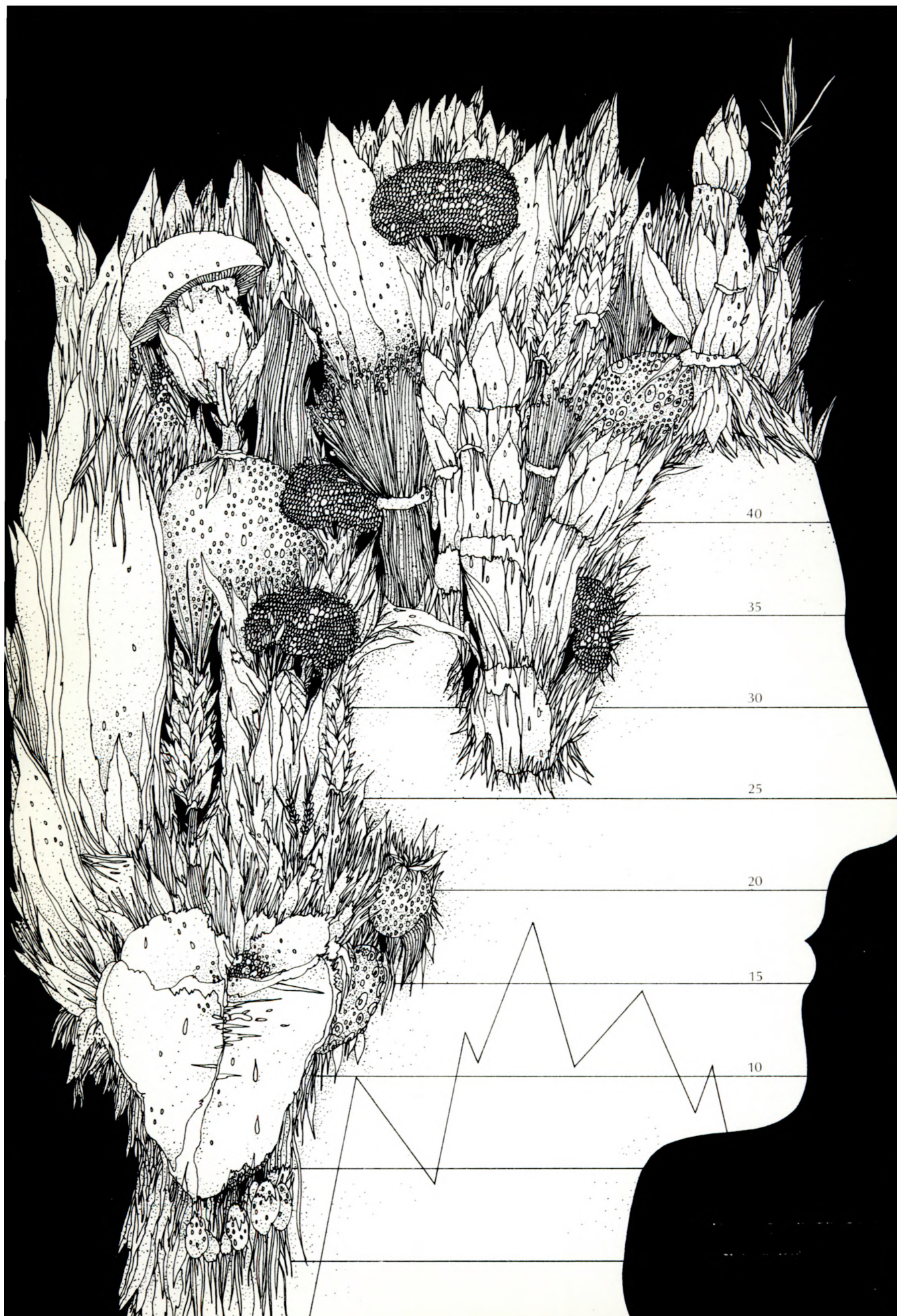
I think you should correct any false impressions this picture might have given by pointing out this unsafe practice in a future issue.

Robert G. Cummisford  
Brookfield, Wisconsin

*We stand corrected.*

*(Just for the record, FDA's responsibility for product safety was transferred in May 1973 to the new Consumer Product Safety Commission. But FDA remains concerned about the safety of all products used by the public.)*







# What Consumers Know About Nutrition

*This is the second in a series on findings from an FDA survey on the state of consumer nutrition knowledge. An overview of the survey results appeared in last month's FDA CONSUMER.*

by Arletta Beloian  
and Diane Schrayner

In the coming months, new shopping aids will become more available in food stores across the country. These aids—such as nutrition labeling on foods, unit pricing for cost comparison, and more widespread use of ingredient labeling—are designed to provide a route to well-balanced diets at the most reasonable prices.

To see how well consumers will be able to follow that route, the FDA survey sought to determine how much they already know about nutrition and what needs to be stressed in information programs. The survey results not only point out what needs to be done now, but also serve as a baseline against which progress in public knowledge can later be measured.

The 1,500 persons questioned in the survey had primary responsibility for family food purchases. They were interviewed personally in a representative sampling throughout the country.

The survey results shattered at least two myths.

First *myth* shattered: That people usually think they know more than they do. The survey showed people were pretty good judges of their level of knowledge—at least of nutrition.

Second *myth* shattered: That the older you get the more you know about everything. Most shoppers

between the ages of 18 and 49 achieved moderate or high scores on nutrition knowledge questions. Shoppers over 50 more often scored low.

## **"The Big Four"**

The survey questioned people about the four food groups—milk and cheese; meat, poultry, and fish; vegetables and fruit; enriched or whole-grain cereal. These have been part of nutrition education since 1956. The intent of these questions was to determine what information is most generally known, what is not known, and what misinformation exists.

A representative food from each group was used in the questions. They were milk, beef, green peas, and enriched bread, chosen on the basis of what would probably have widest recognition throughout the country.

## **Milk**

Milk and milk products are good sources of calcium, high-quality protein, riboflavin, and, if added, vitamin D. Whole milk provides some vitamin A, being bound in the fat; but if milk is skimmed, it provides vitamin A only if it has also been fortified with the vitamin.

When the shoppers were asked to select key nutrients provided by milk, three-fourths mentioned calcium, and less than half mentioned protein and vitamin D. One-third of the respondents said milk provided a lot of fat, but a smaller number, about one-fourth, mentioned vitamin A.

Less than one-tenth of the shoppers mentioned riboflavin (vitamin B<sub>2</sub>) as an element found in milk. About one out of 10 shoppers said milk provides a lot of iron, and

somewhat less than this proportion mentioned vitamin C. Actually, milk supplies little, if any, iron or vitamin C.

Milk's value to the body for 91 percent of the respondents was to build strong teeth and bones. (This is the job for calcium.) Nearly 80 percent also selected "proper growth for children." (Protein's work.) Slightly over a third chose as value to the body milk's contribution to healthy skin (riboflavin) and building of muscle tissue (protein).

When the shoppers were asked to select alternatives to milk, a substantial portion of them, 84 percent, said cottage cheese was a good replacement, and about 50 percent mentioned eggs. Although other food sources do not supply as much calcium as milk does, there are good substitutes for the high quality protein in milk. Some acceptable substitute items, such as peanut butter, fish, chicken, navy beans, and pork and lamb—all good sources of protein—were mentioned by less than 25 percent (one as low as 7 percent) of the shoppers.

It appears that shoppers are able to select alternative products such as cottage cheese in relation to calcium contribution. Alternatives to protein contribution, however, were not as frequently made.

## **Meat**

Meats, as a group, are considered to be good sources of protein and the B vitamins, thiamine, riboflavin, and niacin. Calories and fat may also be present in large amounts. Certain organ meats, liver in particular, are also excellent food sources for iron.

The survey indicated that beef is generally regarded as a good source of protein by eight out of 10 re-



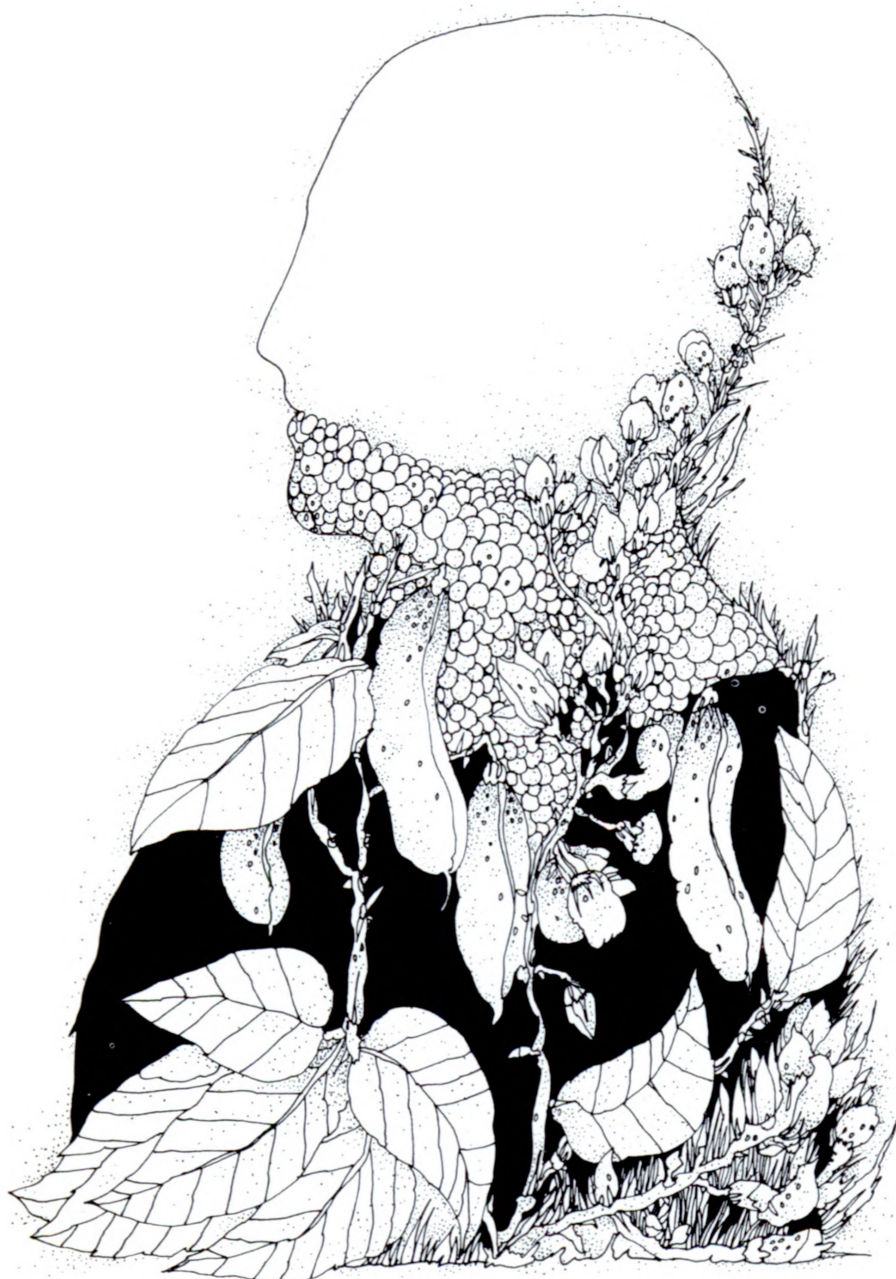
## GREEN PEAS

### Nutrition Information, per serving

Serving Size = 1 cup		Servings Per Container = 2	
Calories	110	Carbohydrate	20 grams
Protein	7 grams	Fat	1 gram

### Percentage Of U.S. Recommended Daily Allowances (U.S. RDA)

Protein	10	Niacin	8
Vitamin A	20	Calcium	4
Vitamin C	35	Iron	10
Thiamine	10	Phosphorus	10
Riboflavin	8	Magnesium	6



spondents. Between a half and a third of those interviewed think beef is also a good source of fat, iron, and calories. Fewer shoppers recognized the vitamin contribution of beef. Only one-tenth or less of the shoppers mentioned any of the B vitamins, riboflavin, thiamine, and niacin.

Seven out of 10 shoppers thought the nutritional value of beef contributes to building blood cells and muscle tissue. A smaller proportion, about four in 10, added that it was necessary for proper growth of children and used in the repair of body tissues. Approximately one out of 10 shoppers select the following as beef's value to the body: fights infection, is good for the nervous system and healthy skin.

For the most part, food substitutes for beef were no problem for the shoppers. Pork and lamb, fish, chicken, eggs, and peanut butter in the food list were chosen by nearly half or more of the food shoppers. Navy beans were selected by less than one-third of the shoppers, and a fifth mentioned cottage cheese.

### Vegetables

Customarily in nutrition education programs, the importance of the vegetable and fruit group in the diet is stressed for the contributions of vitamin A and vitamin C.

Slightly more than a third of the shoppers did not pick any nutrients for green peas, the survey's example of the vegetable/fruit group. This same proportion of shoppers could not select any particular benefit to the body for peas.

At least a fifth of the shoppers, however, did select carbohydrate, vitamin A, and calories as important nutritional elements in peas.

In spite of the lack of certainty among food shoppers as to the nutrients found in green peas, or their value to the body, as many as two-thirds selected string beans as a substitute for peas. Half picked carrots and a third selected navy beans as alternatives to green peas.

Good vegetable sources for vitamin A are dark green leafy vege-



tables, such as kale, turnip greens, and spinach, and deep yellow vegetables and fruits, such as carrots, sweet potatoes, apricots, and peaches. Citrus, such as oranges and grapefruit, supply large amounts of vitamin C. Other vegetables, for example cabbage and white potatoes, can be good sources of vitamin C because they are usually eaten in fairly large amounts. Tomatoes serve a dual purpose by providing vitamin C and vitamin A to the diet.

### Bread

Enriched white bread is a good source of carbohydrates, calories (as are many foods), riboflavin, thiamine, and niacin. It also is a limited source of protein, iron, and calcium, as shown in Figure 2.

Shoppers knew quite a bit about the nutrients in bread.

Nearly half chose it as a source of calories. A slightly smaller proportion chose carbohydrates. Two of the B vitamins—riboflavin and thiamine—were selected by nearly one-third of the shoppers. Niacin and protein were mentioned by a fourth.

Proper growth of children was given by over half of those questioned as to bread's value to the body. Slightly less than this proportion attributed bread's value to building muscle tissue, and close to one-fourth picked out—for strong teeth and bones and to repair body tissues. Substitute foods for bread included macaroni (67 percent), oatmeal (58 percent), potatoes (55 percent), rice (43 percent), navy beans (16 percent), and peanut butter (12 percent).

### Conclusions

According to these answers, then, shoppers do well substituting foods with similar nutrient content. And a large portion also can attribute at least one major nutrient to a food—particularly in regard to milk and beef. Beyond that, however, only a few could select important nutrients.

Younger segments of the shopper population more often answered the questions correctly. Those with

### MEAT (Lean Hamburger, Raw)

#### Nutrition Information, per serving

Serving Size = 4 oz.

Servings in Container = 4

Calories	200	Carbohydrate	0g
Protein	23g	Fat	11g

#### Percentage Of U.S. Recommended Daily Allowances (U.S. RDA)

Protein	50	Riboflavin	10
Vitamin A	0	Niacin	25
Vitamin C	0	Calcium	0
Thiamine	6	Iron	20





## MILK

### Vitamin D Nutrition Information

Serving Size = 8 Fl. Oz. (240 Ml.)

Servings Per Container = 4

	Per Serving (8 fl. oz.)	Per Quart
Calories	160	640
Protein	8 Grams	32 Grams
Carbohydrate	12 Grams	48 Grams
Fat	9 Grams	36 Grams

### Percentage Of U.S. Recommended Daily Allowances (U.S. RDA)

Protein	15	60
Vitamin A	6	25
Vitamin C	4	15
Thiamine	4	15
Riboflavin	25	100
Niacin	0	4
Calcium	25	100
Iron	0	4
Vitamin D	25	100



college education were more frequently high scorers, and those with less than high school responded with substantially more "don't know's."

Shoppers in the West, and to a less extent in the Northeast, had a higher proportion of correct responses than did those in the rest of the country.

Other questions were also used to determine actual nutrition knowledge. For example, shoppers were asked if they believed there was one particular food that's essential in maintaining adult health. Half of the shoppers said "yes," and then they most often mentioned meat and milk as the alleged necessities. Respondents over 50 and those with less than high school education more often followed this one-food line; and meat and milk were selected over any other food regardless of age or education.

On the other side of the coin, when asked if the people can remain healthy without ever eating meat, poultry, or fish, 60 percent of those responding said "yes." Those agreeing tended to fall into the 18-49-year age span and have a higher education. Nearly two-thirds of the western respondents agreed.

### Self-Image vs. Reality

About half the grocery shoppers are pretty fair judges of what they actually know. However, two groups misestimated their knowledge of nutrition: 21 percent of those who think they know a lot actually scored low; and 42 percent of those who feel they know little actually scored in the moderate-to-high range.

Although the more self-confident group had a better feel for good substitute foods, some substitutes were not familiar to them. And while on the whole these consumers displayed more knowledge about specific nutrients than did the other respondents, some areas of knowledge were weak. Most of these highly confident people, for example, did not know that milk provides riboflavin ( $B_2$ ); that beef supplies niacin; or that green peas have thiamine ( $B_1$ ), riboflavin



(B<sub>2</sub>), niacin, and vitamin C. Similarly, bread was not considered a *good* source of either protein or iron by most of this group, while, in fact, enriched bread does provide some of these nutrients.

On the other hand, many of those who were less sure in their own minds about their abilities in the nutrition area, do know some basics about nutrition. Most of this group, for example, know that milk is good for proper growth of children and good for teeth and bones. A majority also know beef builds blood cells and muscle tissue.

A majority of this low self-image group can choose at least one food that provides most of the same things to the body as the example foods do. But naming the actual nutrients found in these foods, again, is often a problem for this group.

Most of the high nutrition scorers, either by self-concept or actual knowledge levels, had at least heard of all the nutrients that are to appear on the new nutrition labels. The nutrients most often selected as being new to the shoppers, particularly among the low scorers, were thiamine, riboflavin, and niacin. The most familiar nutrients among this low scoring group were vitamin C, protein, fat, calories, and iron. Calcium and vitamins D and E were also familiar.

With much of the basic information in the area of nutrition already familiar to food shoppers, the availability of nutrition labeling will not only remind them to use the knowledge they have, but will also add to it. For those who think only one food or at most a few foods are essential for good health, there will be evidence before them to prove there are substitutes for almost every food and that very few approach being a "complete" food.

Arletta Beloian is a nutrition analyst for FDA's Division of Consumer Studies in the Bureau of Foods.

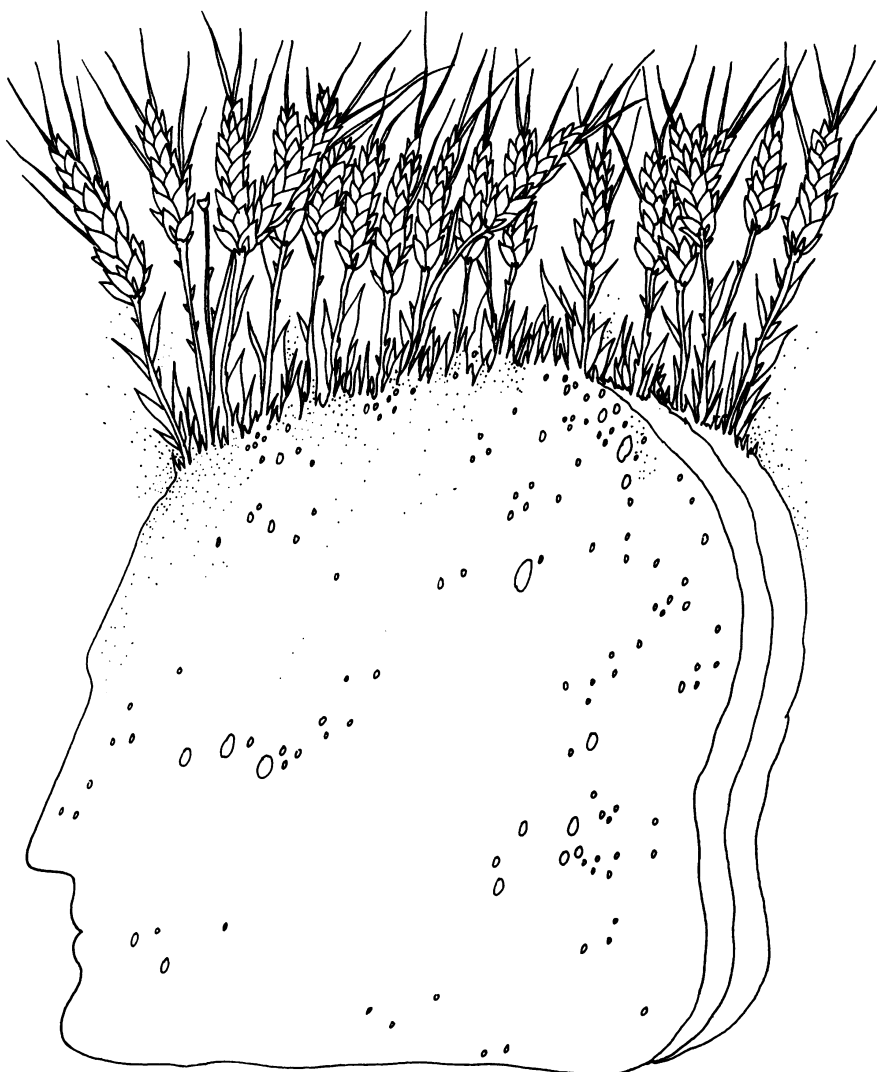
Diane Schraye is a research assistant with Response Analysis Corp., Princeton, New Jersey, which conducted the survey for FDA.

## BREAD

**Nutrition Information, per serving**  
Serving Size = 2 Slices (Approx. 2 oz.)  
Servings Per Container = 8

	2 Slices per serving	6 Slices
Calories	140	420
Protein, grams	4	12
Carbohydrate, grams	27	81
Fat, grams	2	6

Percentage of U.S. Recommended Daily Allowances (U.S. RDA)		
Protein	6	15
Vitamin A	0	0
Vitamin C	0	0
Thiamine	15	45
Riboflavin	10	30
Niacin	10	30
Calcium	6	20
Iron	8	25









# What Happened To Mushrooms?

by Donald Riester

*The mushroom "scare" last year made news headlines across the Nation. Here's what happened.*

**M**id-February 1973. A phone call to FDA headquarters. **BOTULISM!** *Clostridium botulinum* toxin in a can of mushrooms!

**RED ALERT!** And the beginning of a nightmare.

That phone call would be followed by many others. There would be repeated nationwide recalls. And by September 1973 the problem would have grown so serious that an inspection of every warehoused can of mushrooms in the country would be ordered.

There would be nothing in the Agency's history to match this effort, and there would be nothing similar in the last 50 years of canning in this country to so blemish a good record for safety.

There was no indication in the beginning that it would become an industry-wide problem. The week before the call came to FDA, a canner in northern Ohio had found spoilage in his institutional-size cans of sliced mushrooms. He asked the company that supplied the cans to find the cause.

A microbiologist assigned to that task discovered the potent toxin and immediately reported it to the National Canners Association (NCA), which in turn called the Food and Drug Administration.

FDA confirmed the findings and a recall immediately began. At that point there was little chance a consumer would contract botulism. The

reason is that the large cans in which the toxin was found are sold only to institutional and manufacturing users, many of whom inspect their supplies before use.

But no chances could be taken. Since some of the mushrooms are used in remanufacture of such items as frozen pizzas, frozen casseroles, steak sauces, and the like, these secondary products were also recalled where there was any possibility suspect mushrooms could reach the market.

Just getting the products back is not the end of the story for the canner or FDA. In the case of botulism, it never is. The point is to find out how much of the stock was affected, what caused it, and see as far as possible that changes are made to guarantee it won't happen again.

An army of technologists arrived at the plant. They came from FDA, NCA, the Ohio Public Health Service, the can supplier, and even from the maker of control instruments used in the plant. FDA brought in its mobile laboratory and set up shop.

Days later the cause was traced to a new piece of equipment being used to fill the cans. It had been packing the mushrooms so tightly that the subsequent cooking process used at the plant was not sufficient to penetrate and sterilize the product thoroughly. Thus, the spores of *Clostridium botulinum*, present throughout our environment and harmless unless confined in a situation where they can grow and

produce toxin, were not being killed—they were left viable, in the can, in the ideal environment to cause botulism.

No illness had been reported, and an easily correctable cause had been discovered. All the suspect products were retrieved, and people began to relax.

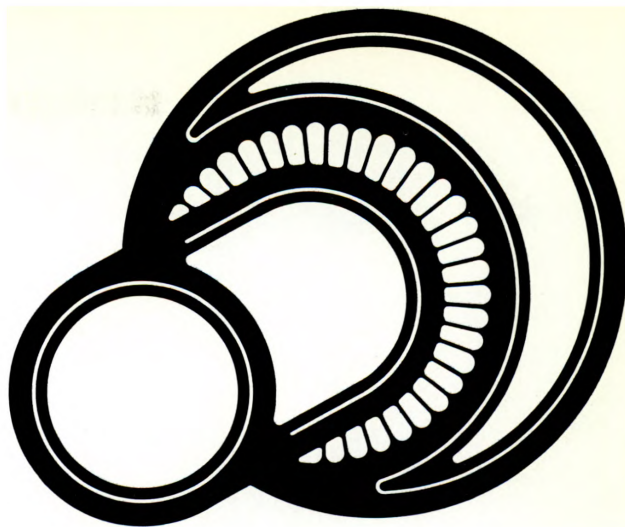
But this was not to last.

During the same month, a consumer of another brand would report to FDA that swollen cans of mushrooms were on grocery store shelves in Mishawaka, Indiana. (Can swelling must be taken as a sign of danger, because it indicates viable organisms, growing and producing gas, which expands the can.)

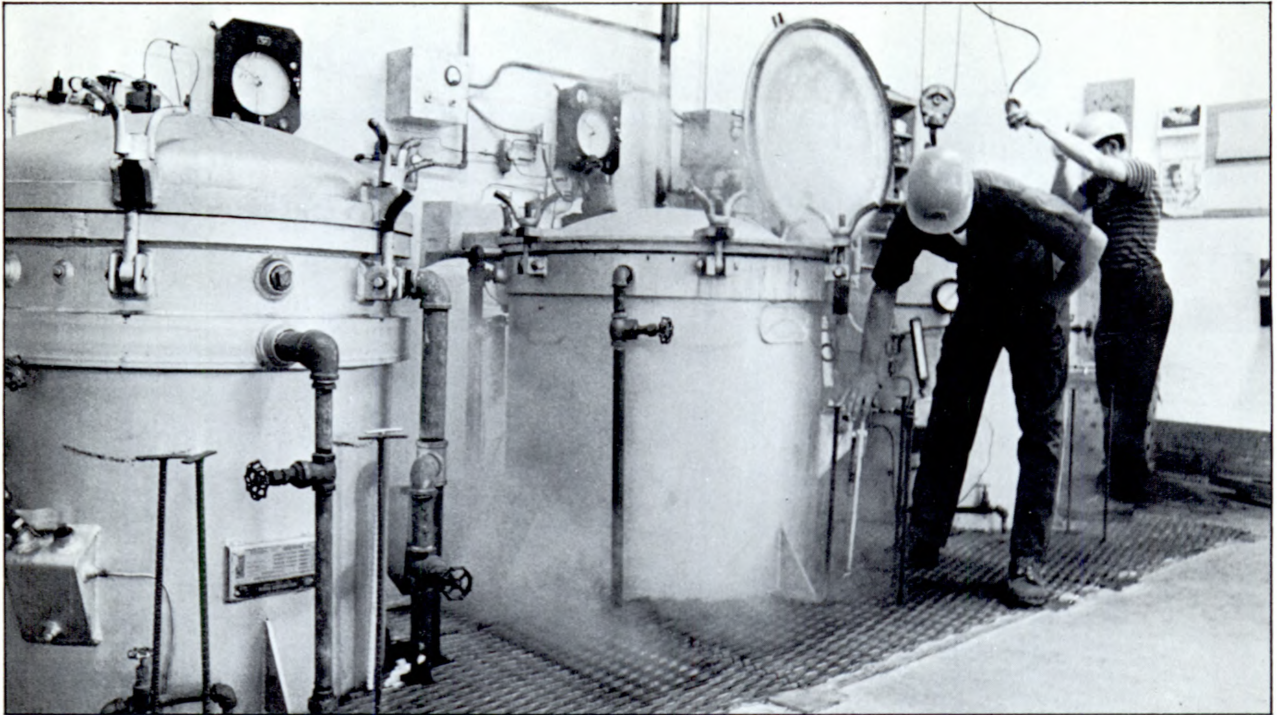
Samples of the small 4-ounce cans were immediately sent to FDA's Cincinnati laboratory, where the same hazard was confirmed! Viable spores of *Clostridium botulinum*!

But for the processor of those cans, the answers would not be as easy to find as they were with his competitor. Despite extensive investigation, the cause for the under-processing couldn't be pinned down. And in this case, although no illnesses had been reported, his TOTAL production had to be recalled. It was an expensive but necessary operation. No one knew how widespread the danger might be.

At this point, particularly because of the good safety record in the past, there was general alarm. Here were two different companies,

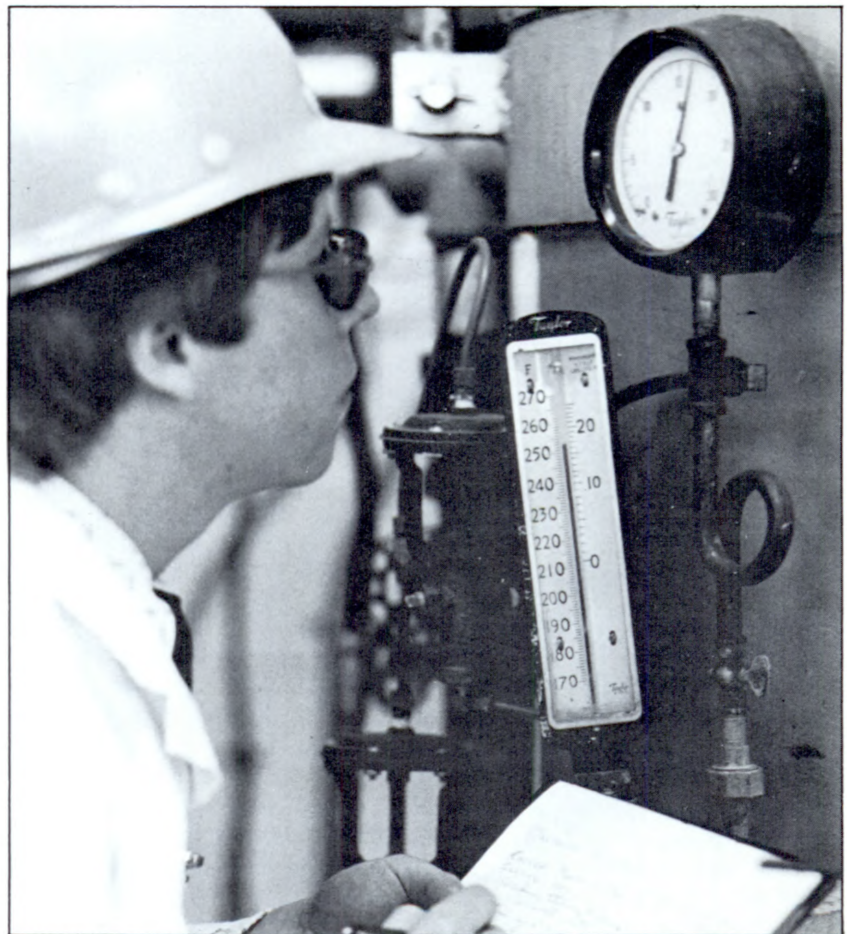






*In a canning operation, the retort area is where the canned product is heated in pressure containers until all dangerous organisms have been killed. These photos are of a retort area in a mushroom canning plant. Upper photo shows the steaming retort units. Photo above shows canned mushrooms being water cooled in retort area.*

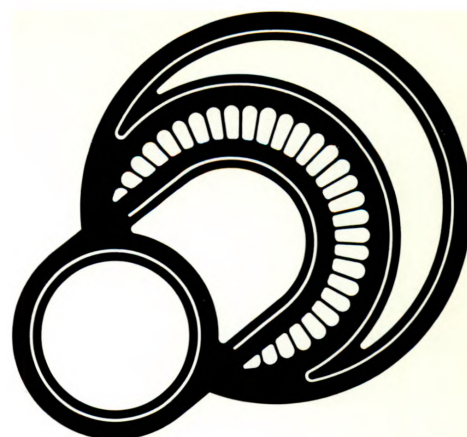
*In photo at right, Consumer Safety Officer Michael B. Falkow checks a retort thermometer and pressure gauge.*





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*"There would be nothing in the Agency's history to match this effort, and there would be nothing similar in the last 50 years of canning in this country to so blemish a good record for safety."*



both with the same rare and serious problem arising within a short period of time.

Would other companies be joining the list?

Instead of waiting for still another shoe to drop, FDA launched an inspection of *all* plants in the country that can mushrooms and mushroom products. The 42 plants are scattered from California and Oregon to New York and Maryland, but are concentrated in Pennsylvania. To cover the concentration in Pennsylvania, it was necessary for FDA to divert experienced inspectors to assist the Philadelphia District Office.

Before the inspections were completed, a third toxic can, produced by a New York State plant, was reported at a military base in Georgia, and another recall began.

The intensive inspection revealed that 20 out of the 42 plants had serious deficiencies in both equipment and operating procedures. When the problems were located and pointed out to management, most plants began immediately to make corrections. Wherever management seemed reluctant, inspectors maintained close surveillance until the needed changes were made.

As a result of this all-out effort, the mushroom canning industry, across the board, is probably in better shape than it *ever* was.

The most critical and widespread problem uncovered was that scheduled heat treatments (cooking times and temperatures once the produce is in the can) had not been properly adjusted to keep pace with the other

changes and innovations in canning over the years.

These changes included revisions in the blanching procedure and adoption of mechanical filling to replace the old system of hand filling. In addition, the product itself had changed in that smaller particles such as chips and thinner slices were being used more frequently.

The process used at mushroom canning plants, however, had not kept pace with these changes. Thermal processes that had formerly been satisfactory were no longer adequate. To say it simply, heat was not sufficiently penetrating to the center of the can and the mushrooms thus were not heated sufficiently to kill the botulinum spores.

Technologists from the National Canners Association and from suppliers to the canning industry began making heat penetration studies under a wide variety of today's operating conditions. And new, safe thermal processes were established to meet modern requirements.

Even after the problems had apparently been cleared up at the manufacturing end of things, that still wasn't the end of the story.

In September, two more toxic cans were found that had been canned before the corrective measures were taken by industry. So FDA launched a massive check of all stocks of canned mushrooms in warehouses throughout the country. FDA inspectors were given 60 days to complete the project.

More than 4,000 warehouses were inspected. The stocks had been produced by the 42 U.S. firms

and by firms of 20 foreign countries. There were approximately 75 million cans, in 25,000 lots.

Abnormal cans were found in more than 2,000 lots and were sampled for microbiological studies. Fourteen of the more than 1,000 lots of foreign-canned mushrooms were held for microbiological study.

During this investigation, FDA looked at literally every lot of canned mushrooms in the United States. Whenever abnormalities were found, the cause was evaluated and the suspect lots removed from the market.

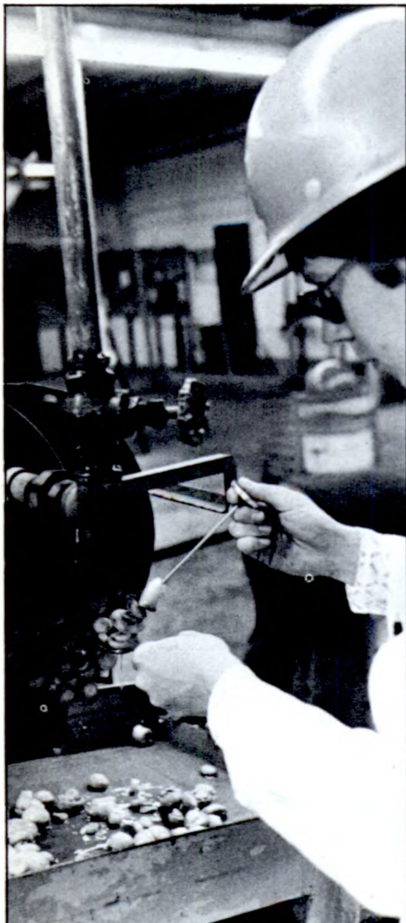
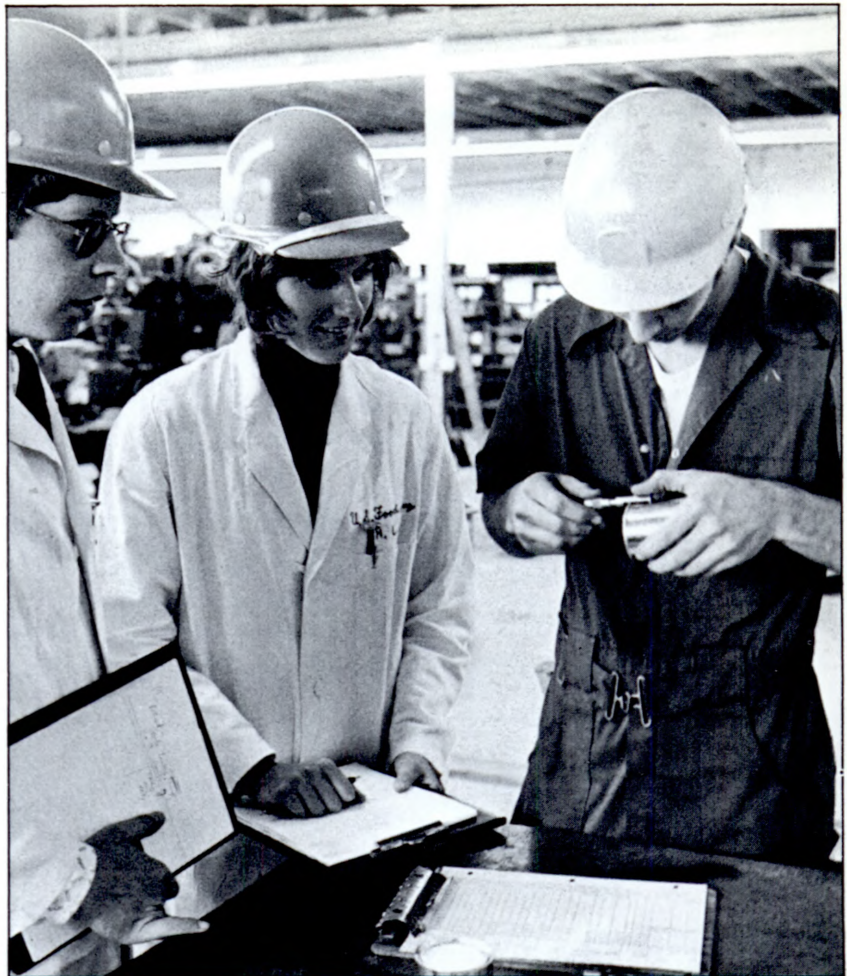
Cost of the survey to the FDA alone was more than \$6.5 million; and there were other costs to State and local public health officials. But as far as can be determined, because of this effort and the corrections made, there were no costs to consumer health.

And judging from the measures taken, there should be far less chance now than at any other time in history of a consumer injury from commercially canned mushrooms.

Throughout the months of investigations into the mushroom problem, 16 public warnings associated with recalls were sent to news media to alert consumers who might possibly have bought the suspect products. Instructions in identifying and returning such products were included with each new warning. The criterion for issuing the warnings was based on FDA policy that these Class I recalls reflect "an emergency situation involving the removal from the market of products in which the



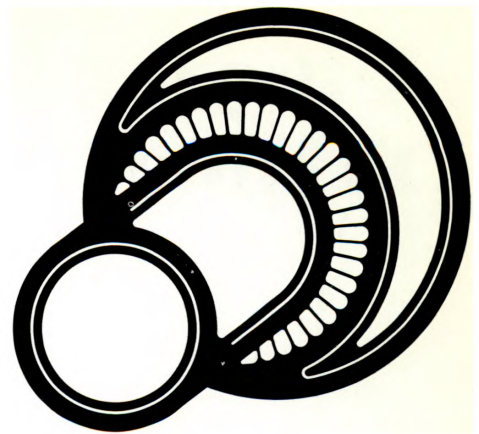
*In inspecting a canning plant, FDA pays special attention to each segment of the processing operation. Photo below shows Consumer Safety Officer Falkow checking mushroom temperature after the blanching operation, during which the product is heated. In photo upper right, CSO's Falkow and Linda J. Robinson watch a plant employee measure the cover-hook area of a can during a "teardown"—a plant inspection that should be made periodically during processing. Photo at lower right shows FDA's Philadelphia District Office staff discussing the massive mushroom survey. From left are Investigations Director Larry E. Ormsbee, Compliance Director Matthew H. Lewis, District Director Loren Y. Johnson, Laboratories Director Coleman R. Seward and Acting Administration Director Richard Hagan.*





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*"The decades of technological improvements in the mushroom industry had not brought uniform progress to every aspect of the processing."*



consequences are immediate or long-range, life-threatening, and involve a direct cause-effect relationship."

Again and again the headlines warned of more problems with mushrooms as the investigation proceeded, and the causes all had the common thread of faulty processing operations and/or equipment.

The decades of technological improvements in the mushroom industry had not brought uniform progress to every aspect of the processing, and finally those aspects that had been "underprivileged" could no longer adequately support the requirements of the other, more sophisticated, steps in canning.

In the mushroom industry, these problems have been addressed and, as far as one can be sure, corrected.

But what about other industries, other types of canned foods? This question can neither be avoided nor answered today.

And even though the experience of the mushroom firms has prompted many other canners to reexamine their operations for similar potential problems, FDA is now following a policy of sustaining—and expanding—its surveillance of the canning industry as a whole until assurances can be made that the nightmares of the continued RED ALERTS will not recur.

Donald Riester is deputy director of the Office of Technology in the Bureau of Foods, in which the technological investigations into the mushroom problem were centered.

#### **A Reminder To Consumers**

Under no circumstances should the contents of a swollen can of any product ever be eaten or even tasted. This applies as well to any food that is foaming or has a bad color. The toxin is so powerful that even a small taste can cause illness or death.

If suspect cans are found in the grocery store, report it to the manager, who should then promptly remove the swollen cans and report the incident back to his supplier.

Swollen cans found in home pantries should be returned at once to the place of purchase *without* opening. If the point of purchase is not known, the consumer should report the matter to the FDA or local public health officials. All information on the can, including code numbers, may be needed by store managers, the canner, and Government officials.

The safety record of commercially canned foods in this country is excellent, blemished only by very infrequent occurrences of botulism in the last 50 years. One author has pointed out that the chance of being killed by lightning is 100 times greater than that of being poisoned by commercially canned foods.

The greater hazard, in fact, comes from home-canned foods. Between 1899 and 1969, for instance, there were 474 recorded outbreaks of botulism from home-canned products, compared with 61 from commercially canned products. No illnesses were reported from last year's mushroom episode, and corrective measures have been taken and new safeguards established to bring industry back in line with its previous record.

#### **What About Uncanned Mushrooms?**

There is not and never has been any reason for being wary of fresh mushrooms on the market, frozen mushrooms, or dehydrated mushrooms.

The organism *Clostridium botulinum* is "anaerobic"—which means it grows only in the absence of oxygen. Such an environment is normally established in the sealed container of any low-acid canned food, and the hazard in such an environment is destroyed only by proper cooking procedures.

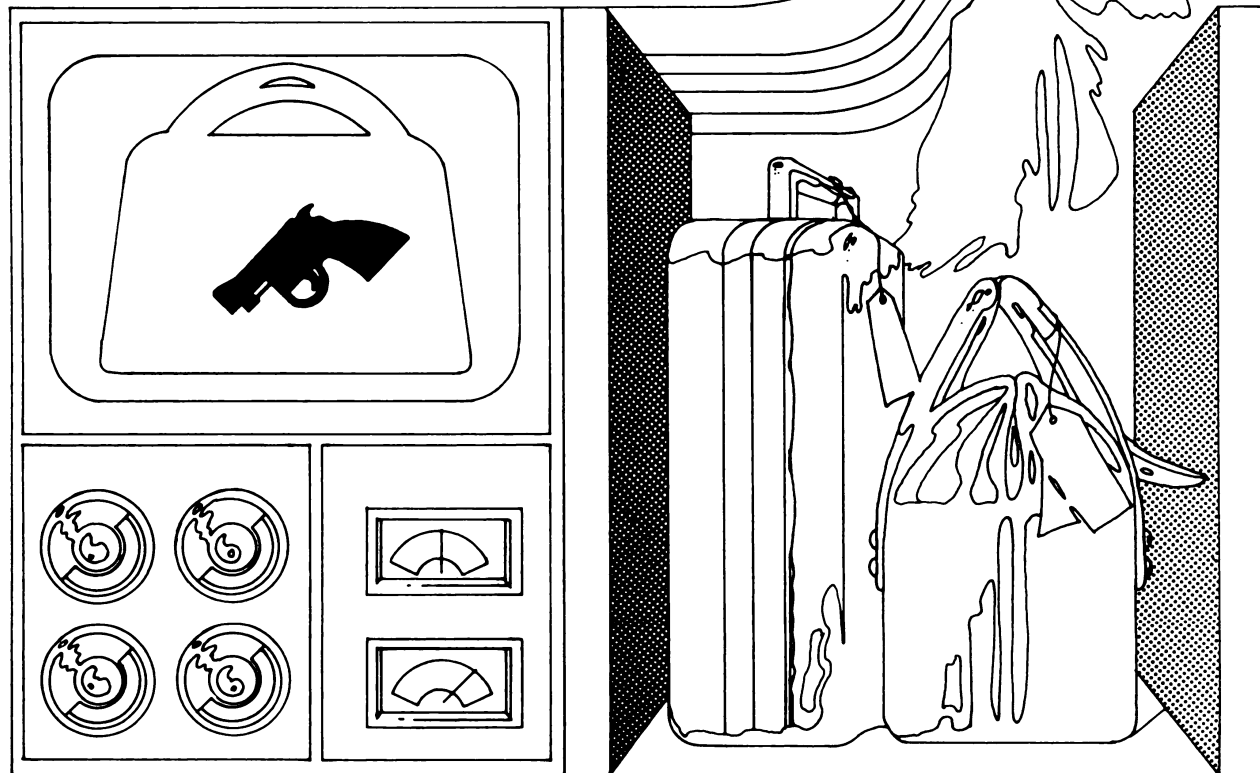
Fresh, fresh frozen, or dehydrated vegetables are normally exposed to air and the organism cannot grow and produce toxin. The organism itself is harmless as long as it is not allowed to grow, because it is during the growth process that it produces toxin.

Whenever we eat fresh vegetables—regardless of the farming method—we are probably consuming *Clostridium botulinum* spores, but there is no hazard.

# X-Raying Baggage To Thwart Skyjackers

*Within the last year, x-ray systems have become the most practical method for conducting baggage inspections at airports. FDA has played a major role in assuring the safe use of x-ray baggage inspection.*

by Michael E. Shaffer



The scenario became common. A skyjacker would conceal a gun or other weapon in a brief case when entering an airplane. Then he would pull it out when the plane was in midair and have the pilot and passengers at his mercy.

During the 5-year period from 1968 to 1972, there were 147 attempts to hijack U.S. aircraft. This was an average of one attempt every 12 days. Ninety-one of these attempts were successful. The worst year was 1969, when there were 40 attempted hijackings and 33 successes.

The last successful hijacking of a

commercial aircraft in the United States occurred November 19, 1972, when three men commandeered a Southern Airlines jet and fled to Cuba after a bizarre flight up and down the East Coast.

Now, since commercial airlines have begun screening passengers and baggage for weapons, air piracy has stopped in the United States.

The program to curtail skyjacking has involved several Federal agencies. The present program began on January 5, 1973, when an Executive Order of the President required the inspection of passengers' luggage for weapons, explosives,

and other dangerous objects.

As a result, the Federal Aviation Administration (FAA), which is responsible for airline security, required airlines to develop programs for inspecting luggage. When inspection programs began, some airlines depended solely on manual searches of bags and luggage and attempted to single out suspicious-looking passengers for more careful scrutiny.

As baggage inspection programs developed, however, it quickly became apparent that the use of x rays was one of the most rapid, economical, and least objectionable meth-



ods for examining luggage—whether the passenger carried the luggage on himself or it was handled by airline personnel.

The use of x-ray equipment to examine baggage of aircraft passengers came on the scene early in 1973. At present, about 190 baggage x-ray inspection systems are used in 52 major U.S. airports. Some manufacturers of x-ray inspection equipment have estimated that several hundred units may be in service within the next year.

The x-ray baggage inspection systems should not be confused with the system used to check passengers themselves. Before entering an airplane, each passenger must pass through a metal detector. This does not involve the use of x rays.

FDA became involved in the anti-skyjacking business after a March 1973 memorandum that FAA sent to its regional directors. The memo spelled out criteria for using x-ray inspection systems. Part of the FAA communique said: "It is required that the x-ray system proposed for use does not derogate the safety of passengers, operator, carry-on items or any person within range of the device. In this regard, the airline should obtain or require that the manufacturer obtain the permission or license from the state in which the device will be used. A document certifying that the device is safe must be furnished along with the amended program before approval for such use will be granted."

FAA's requirement was not expected by most States. Some State radiation control officials, in the absence of any widely held or well-defined criteria for judging the effectiveness and safety of the still developing x-ray inspection systems, turned to FDA for advice and assistance.

Responding quickly, FDA's Bureau of Radiological Health on April 27, 1973, telegraphed radiation safety guidelines to State radiation control program directors in the 50 States. These guidelines had the concurrence of the Conference of Radiation Control Program Directors and the Occupational Safety

and Health Administration. Published in the *Federal Register* August 8, 1973, the guidelines also were intended to serve as a guide to good manufacturing practice for industries.

The main purpose of FDA's radiation safety guidelines was to provide adequate radiation protection for operators, passengers, and others involved in the use of the systems by limiting x-ray emissions to levels sufficiently low to insure that any exposure to persons in the vicinity would be below nationally accepted and recommended limits.

The most significant hazard associated with x-ray baggage inspection systems is possible human exposure to the primary beam of radiation. Many operators are not well trained in the hazards of radiation safety and may not apply enough caution to prevent human exposure. The first of FDA's six-point guidelines recommends safeguards that will prevent direct beam exposure of any part of the body, including legs, arms, and hands.

FDA's underlying philosophy of radiation protection is to keep exposure to persons as low as practicable. The guidelines do not specify how powerful the primary beam may be, but recommend that radiation emitted outside the system not be greater than 0.5 mR (milliroentgens) in any one hour measured at 5 centimeters (2 inches) from any point on the outside surface of the equipment.

This limit is consistent with those applied in the past to other types of x-ray-emitting electronic equipment such as TV sets. In everyday use it is expected that the actual exposure to any individual will be considerably less than the limits generally considered acceptable by even conservative standards.

Since the equipment is used in public areas, it could be hazardous when operated without supervision. The guidelines recommend a key lock to prevent unauthorized use. This is the kind of lock from which the key cannot be removed while the equipment is turned on. This feature will prevent someone from

carrying off or otherwise losing the key while the system is energized.

The guidelines also recommend interlocks that will automatically turn off the x-radiation source if doors or access panels to the system are opened. An "X-ray On" indicator light is recommended to clearly indicate when the system has the potential for producing an x-ray beam.

The guidelines also recommend a switch to assure the presence of an operator at the controls when the x-ray beam is being produced. This may be accomplished, for example, by a switch which must be depressed and held in place by the operator before the x-ray beam can come on, or by using a floor mat switch on which the operator must stand to operate the system. The switch must be situated so that it is necessary for the operator to be able to watch the equipment in use and be able to immediately turn off the beam in an emergency.

The guidelines are recommendations to the States. All but four have adopted them for their own enforcement programs. The four—Alabama, California, Georgia, and Michigan—have imposed more detailed and in some cases more restrictive requirements.

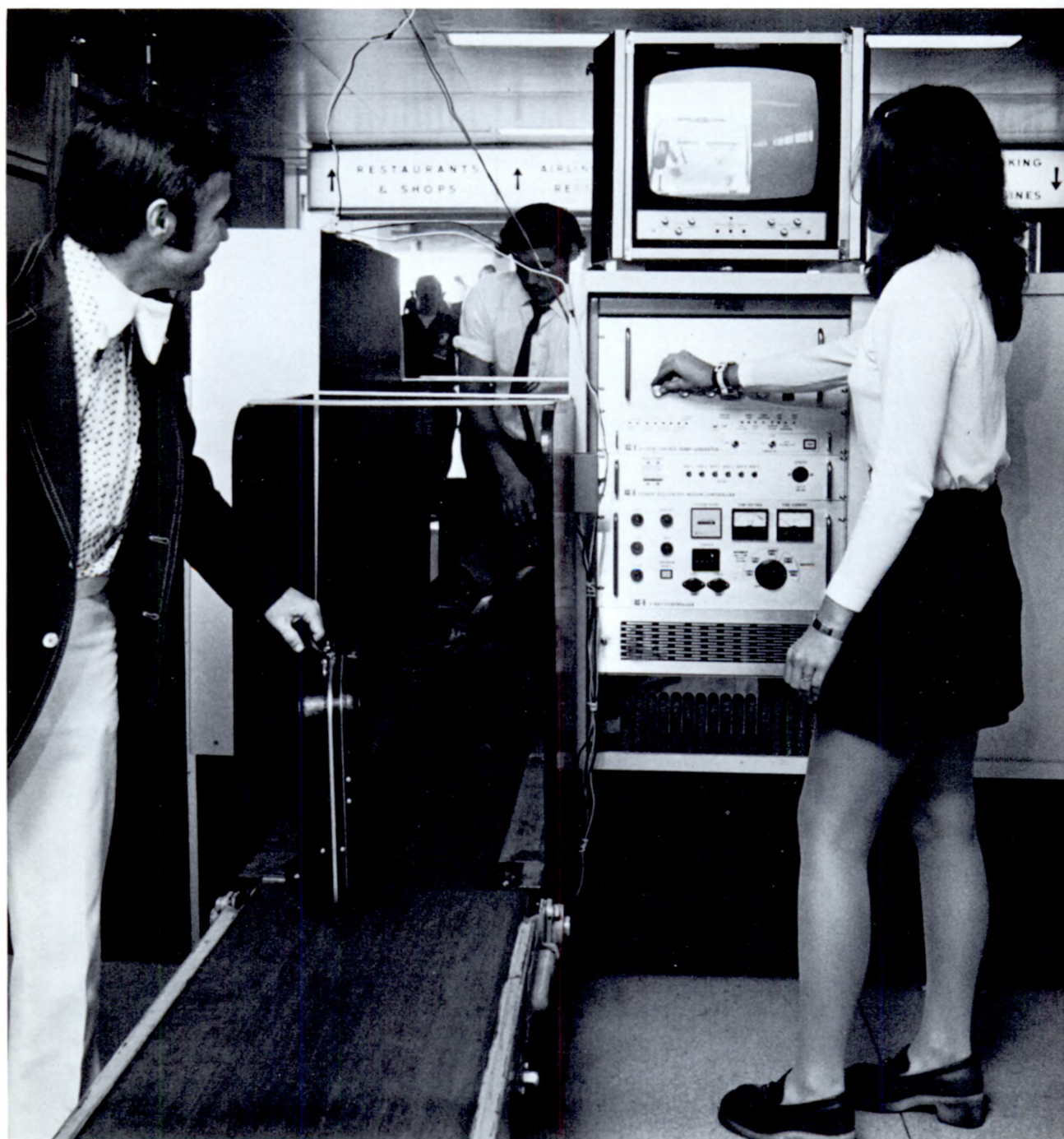
Whereas the guidelines were only recommendations when first issued, the concepts embodied in them are now contained in a recently promulgated performance standard for "cabinet" x-ray systems. This standard applies to baggage inspection devices as well as to other types of x-ray systems used primarily for commercial or industrial purposes.

The units are called "cabinet" x-ray systems to distinguish them from analytical or medical x-ray equipment. The x-ray source is enclosed in a cabinet or shielded enclosure. The standard sets performance requirements for radiation limiting features, safety interlocks, warning devices, and operating instructions.

The standard is effective April 10, 1975, except as it applies to baggage inspection systems. It was effective for baggage systems manu-



*X-ray machines such as this one are used at airports to check passengers' carry-on luggage for dangerous items. FDA's standards protect from x radiation all those who are in the vicinity of the machine.*



factured after April 25, 1974.

Cabinet x-ray systems are used to examine a large variety of materials and objects in factories, museums, laboratories, and medical centers. Electronic components, castings, welds, tires, fossils, food packages, paintings, and microscope specimens are examples of objects routinely examined with cabinet x-ray systems.

The standard for cabinet x-ray systems does not apply to equipment used for medical diagnosis or which cause intentional exposure to humans for medical purposes. Nor does it apply to systems designed exclusively for microscopic examination of materials such as spectrometers or electron microscopes. A separate equipment performance standard for medical and dental diagnostic x-ray systems goes into effect August 1, 1974.

Before the x-ray baggage inspection system guidelines were followed, there were some potential problems with existing systems. For example, some models permitted holding the baggage in the x-ray beam, at the same time exposing the operator's hand to the x-rays with each piece of handled luggage. Good radiological health practices preclude such types of procedures because they result in unnecessary and potentially dangerous x-ray exposure.

Several models of baggage x-ray inspection units were recently declared defective by FDA. Although the products were already in use and manufactured before the effective date of the new standard, the Agency was able to take action under the defect provision of the Radiation Control for Health and Safety Act of 1968.

Manufacturers were informed that the defective models presented unnecessary risks of exposure. Manufacturers of baggage x-ray inspection equipment manufactured after April 25, 1974, are subject to specific provisions of the new standard.

The defective units were cited for radiation leakage in excess of the guidelines. One model also lacked safeguards to prevent an operator's

hands from getting into the x-ray beam. These and other units found defective have appeared or will appear on FDA's weekly recall report.

Corrective action programs submitted by the manufacturers in question were approved by FDA in May. Required modifications to the faulty equipment have been or are being made at the airports where the units are installed. As of June 1, manufacturers reported having modified most of the involved units.

Present law gives FDA authority to require that defects in electronic products, including x-ray equipment, be corrected. But it does not allow the Agency to take the units out of service. Notice of the defects was reported to the Federal Aviation Administration and resulted in that agency ordering the equipment shut down until the defects are corrected.

In communicating its actions to FAA, FDA emphasized that its action was based on issues of public health and safety in keeping with its legal authority and that it did not consider such issues as inconvenience to passengers who might be subjected to delays or the comparative risks of radiation exposure as compared to the risks of hijackings.

Essentially three types of x-ray systems are now in use for inspecting baggage.

One system is derived from conventional devices long used for medical purposes.

The second system is called a pulsed system. This uses a very intense but extremely short (around 40 nanosecond) burst of x-rays.

In the third type, or "flying spot" system, a small spot-like beam scans the baggage as it passed by on a conveyor belt. In each case, an image of the baggage contents is displayed on a viewing screen. Operators are trained to recognize certain patterns which are of a suspicious or questionable nature such as firearms, munitions, blasting caps or wires, knives, or other weaponry. The bag or package is then set aside for a hand search.

According to FAA, 736 persons were arrested during 1973 for at-

tempting to board aircraft with weapons or explosives. Also during 1973, FAA reports that airport security personnel discovered 2,162 guns and rifles, 23,290 knives or similar objects, 3,459 explosive or incendiary devices, and 28,740 other items considered dangerous such as chemicals, Mace, or tear gas.

Early baggage x-ray inspection equipment fogged some types of undeveloped photographic films. When the FAA issued its criteria for using x-ray systems, it also recommended an exposure limit for each item inspected in an effort to encourage systems to be "film safe."

Film manufacturers have said that x-ray exposures of one mR should have no observable effect on film. Systems currently used in the United States operate at beam strengths which produce exposures to baggage in the 0.1 to 0.05 mR range.

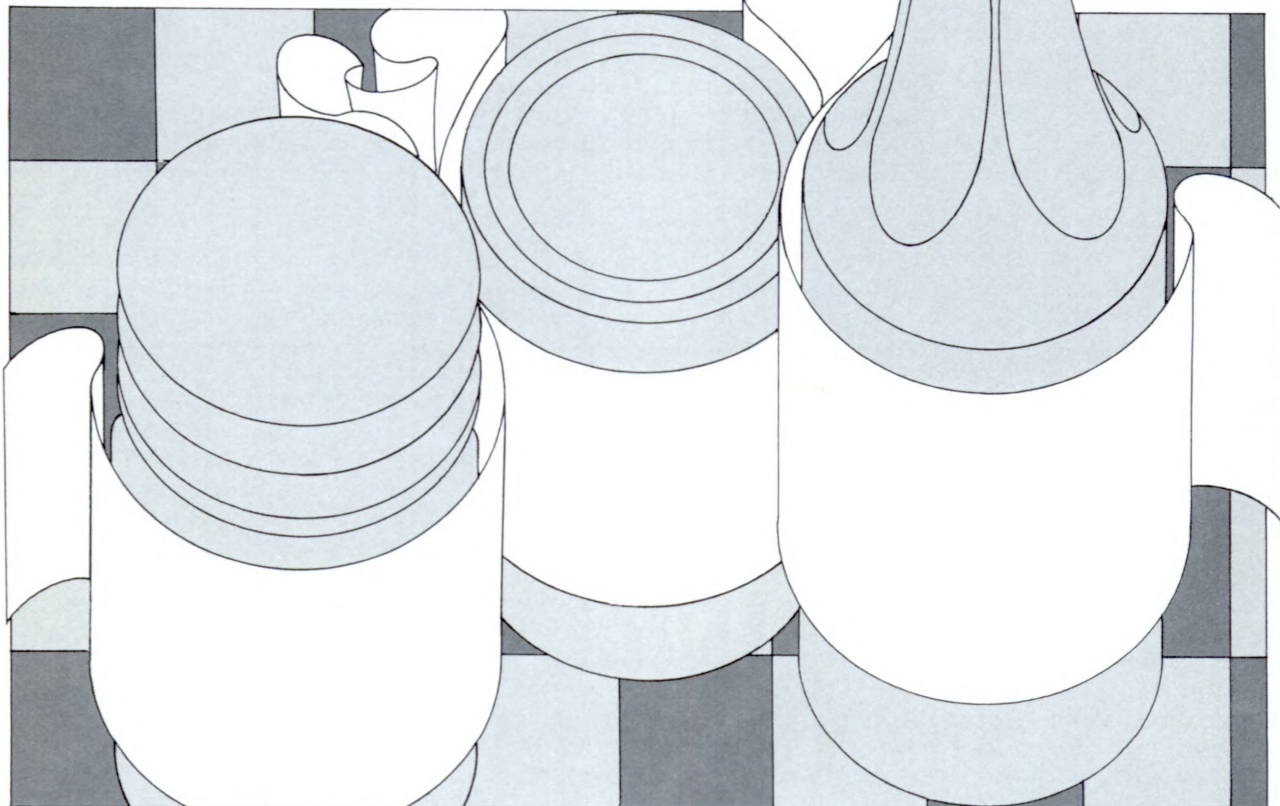
X-ray inspection systems capable of mass screening of articles in and around public places are expected to be more widely used in the near future for examining baggage at travel terminals other than airports, such as ship docks and bus terminals, and for screening packages and briefcases at entrances to courtrooms, political meetings, and government and private buildings. There will also likely be increasing numbers of x-ray scanning devices in use for example by the Department of Defense, the Postal Service, Customs officials, Congress, and the Internal Revenue Service.

It is still too early to predict how effective present screening practices will be over the next few years. As the use of x-ray baggage inspection systems becomes standard operating procedure at main U.S. airports, their presence alone may prove to be deterrent enough for would-be skyjackers. The fact is that skyjacking has virtually stopped since x-ray baggage systems and other types of screening procedures have come into use.

Michael E. Shaffer is public information officer for FDA's Bureau of Radiological Health.



# FDA Launches Nutrition Labeling Education Program



The Food and Drug Administration has launched the most extensive public education campaign in its history, to inform consumers about nutrition labeling.

Nutrition labeling is a program developed by FDA whereby many food labels will carry a standard panel detailing the nutritional content of the product (See "Nutrition Labeling: A Great Leap Forward," FDA CONSUMER, September 1973). Any food which makes a nutritional claim or to which a nutrient is added must carry a complete nutrition information panel, beginning next January 1.

The public education program, launched May 30 at a conference at the Statler-Hilton Hotel, Washington, D.C., has three primary purposes:

- To tell consumers that nutrition labeling is here.
- To tell consumers how to use nutrition labeling.
- To stimulate a greater interest in nutrition.

The education campaign has as its main feature a 14-minute film narrated by TV and movie star Dick Van Dyke. The title of the film is the same as the campaign theme: "Read the Label, Set a Better Table."

The film can be borrowed from any FDA consumer affairs officer, from Modern Talking Pictures, 2323 New Hyde Park Road, New Hyde Park, New York, or from any of Modern's regional offices across the United States.

The film can also be purchased for \$58.25 from the Sales Branch, National Audiovisual Center (GSA), Washington, D.C. 20409. (Make checks payable to the National Archives Trust Fund.)

Other elements of the education program include television and radio public service advertising spots with Dick Van Dyke and Pearl Bailey, a slide show for use by FDA's consumer affairs officers, and a brochure and poster.

FDA is encouraging industry and consumer groups to reproduce the materials themselves. Any company or group that wants to reproduce the materials can get assistance from any FDA consumer affairs officer or from Wayne L. Pines, Food and Drug Administration, HFI-20, 5600 Fishers Lane, Rockville, Maryland 20852.



# Reporting Drug Defects

*A 3-year-old program operated by FDA and the United States Pharmacopeia generates information needed to assure better quality in pharmaceutical products.*

by J. Joseph Belson

**W**hen a pharmacist in a New York hospital received the new shipment of vials of injectable penicillin, she just knew something was wrong.

The labels on the vials said that each contained 5 million units of penicillin. But the label on the box said that the vials each contained

10 million units.

The pharmacist wasted no time in reporting the problem through a new Drug Defect Reporting System. FDA, which the day before had received an identical report from a hospital pharmacist in New Jersey, visited the company and, surprisingly, was told that the company had caught the problem in advance and that no shipments of the mislabeled penicillin had been sent.

As it turned out, the company and FDA investigated further and found that indeed two shipments had been sent out inadvertently—to the two hospitals which had

reported the error.

This was one of many instances in which the Drug Defect Reporting System has provided information to FDA that led to better protection of the public.

Operated jointly by FDA's Bureau of Drugs and the nonprofit standards-setting organization The United States Pharmacopeia (USP), the system has been in existence 3 years now, with pharmacists and other health professionals utilizing their expertise to uncover problems relating to the quality of pharmaceutical products.

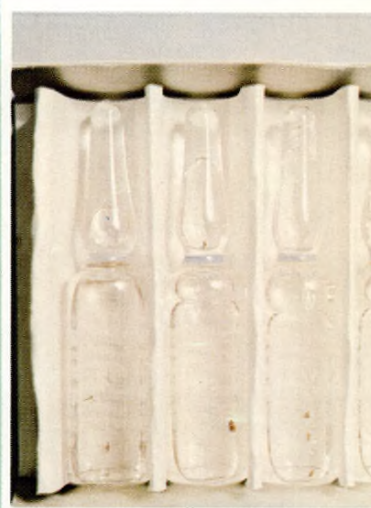
*(continued)*



*A foreign material is shown inside this bottle at the neck. This bottle was intended for use in collecting blood. Discovery of this problem shows the acuteness with which some pharmacists inspect products before use. Problems like this are rare.*



*This barbiturate precipitated out of solution. This pharmacist's report led to the recall of this lot.*



*A pharmacist observed pink crystals which had formed in a solution that was supposed to be clear and colorless. This stability problem was recognized by the firm. Marketed stock was replaced and expiration dating adopted.*



The system is designed to bring to light problems such as mislabeling, poor packaging, poor closures, defects in the drugs themselves, or manufacturing processes which result in inadequately made products.

The program grew out of a recognition by FDA that professionals who regularly handle drugs could provide a valuable service by reporting problems not discovered at the manufacturing plant. No other FDA system provided similar information.

The program also serves as an early-warning surveillance system,

to alert FDA to unusual problems faced by the industry. An example is the penicillin vials which were mislabeled. The company itself honestly believed that no shipments were made.

In addition, the system enables FDA to identify industrywide problems that may not be apparent to any particular company. All the information is put into a computer so that trends can be discerned.

The Drug Defect Reporting System also serves the needs of the cosponsor, USP, which uses the information to revise or develop new standards for the manufacture,

testing, or labeling of drugs.

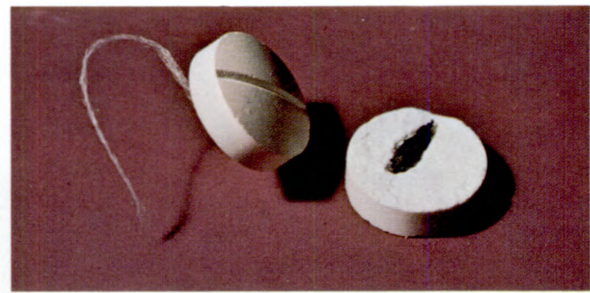
Reports are now coming in at the rate of almost a thousand a month. Each pharmacy in the United States regularly receives forms and postage-paid envelopes.

Thirty-eight State pharmaceutical associations and the American Society of Hospital Pharmacists sponsor the program and encourage participation through their journals. The program is endorsed by the two national pharmacy groups, the American Pharmaceutical Association and the National Association of Retail Druggists.

Pharmacists who see any



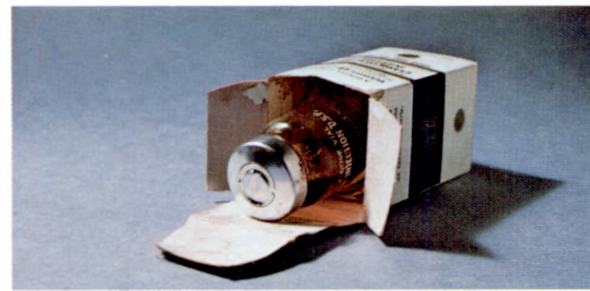
*This problem, FDA discovered, represented a manufacturing fluke. The rubber tip of the plunger was missing when received by a hospital. The disposable syringe cannot be used without the missing part.*



*These are two examples of tablets with foreign matter embedded in them. FDA investigations of this kind of problem usually show that particles such as the black one fall off machinery during processing, and that fibers come from paper or workers' clothing. Problems like this are not unusual.*



*FDA investigated other tablets from this batch after a pharmacist reported that some tablets had formed "lumps" on the surface.*



*A pharmacist discovered that this multidose vitamin injectable drug had a loose stopper which permitted the liquid to leak out, staining the carton. The tamper-proof seal is still in place. FDA discovered that the leak was unique and did not represent a manufacturing problem.*



problems fill out the forms and send them to USP, which forwards copies to FDA and to the drug's manufacturer. The pharmacist may learn later what action has been taken through case histories printed in pharmaceutical journals.

Examples of problems detected by the system are numerous. Reports have led to many recalls and changes in manufacturing practices, and to one injunction action.

For example, many reports were received of empty or partly filled ampuls of an injectable pain reliever made by one company. As a result, FDA inspected the manufacturing

plant and found that one of several sealing machines occasionally malfunctioned, making it possible for the drug to leak out of the ampul. The company redesigned the machine.

Another example: A pharmacist reported that tablets of diethylstilbestrol were unusually thick. Assays by FDA revealed that the tablets contained 150 percent of the amount they should have. This led to a recall.

Or: A pharmacist from California reported that the label for a prenatal vitamin preparation was misleading. The quantity of

folic acid present could easily be mistaken for 10 mg instead of 1 mg. The firm thanked the pharmacist for his observation and reported to him that it was redesigning the label to make it clearer.

Probably the most widely known example of how the Drug Defect Reporting System can benefit consumers involved the heart drug nitroglycerin. A pharmacist received a mailing from a company wanting to sell convenient containers for nitroglycerin tablets. The containers, shaped like ball-point pens, were made out of plastic.

The pharmacist questioned the



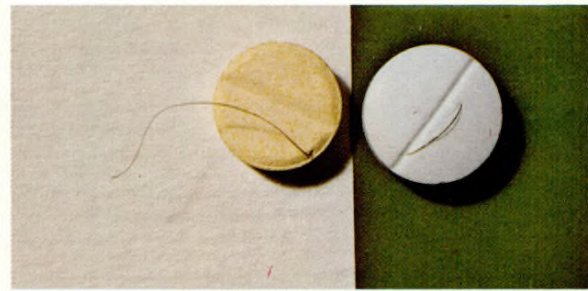
*These tablets should be circular. But small chips and broken tablets had gone through the processing and been coated. Following this report, the company increased its inspection of the tablets before they reached the stage where they are coated.*



*A pharmacist reported that the coating on several tablets like these had shattered. This represents a coating problem which was brought to the attention of the manufacturer.*



*These tablets are fragmenting. This report led to manufacturing changes by the company to prevent similar occurrences.*



*Hairs found in tablets usually indicate that brushes rather than vacuums have been used to clean the equipment. The problem was called to the companies' attention.*



suitability of a plastic container for nitroglycerin, and tests by FDA showed that he was right. The nitroglycerin migrated into the plastic itself, causing the tablets to deteriorate in potency at the rate of almost 50 percent each day. This would render the drug useless in just a few days.

The investigation by FDA later led to new regulations and changes in the USP which required nitroglycerin to be packaged in glass bottles and to be dispensed by pharmacists to patients in the original bottles.

Plans for the Defect Reporting

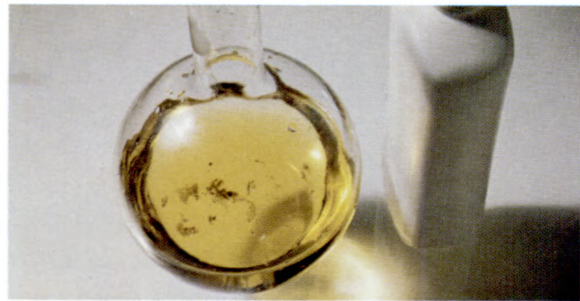
System are to include medical technologists as a reporting element.

As the Drug Defect Reporting System grows and becomes more efficient, consumers can expect additional actions by FDA which will result in better drug quality. The system provides FDA with some of the information it needs to fulfill more efficiently its role as a consumer protection agency.

J. Joseph Belson is director of the Product Research and Surveillance Staff in the Bureau of Drugs. His staff operates FDA's part of the Drug Defect Reporting System.



***A pharmacist discovered that two of the five prefilled cartridges in this package of an injectable antibiotic were discolored, and reported it through the Drug Defect Reporting System. The discoloring indicated that the preservative was coming out of solution.***



***Mold was found in a potassium chloride solution, shown here poured out of the bottle into a flask. At the time of this writing the cause was still being investigated.***

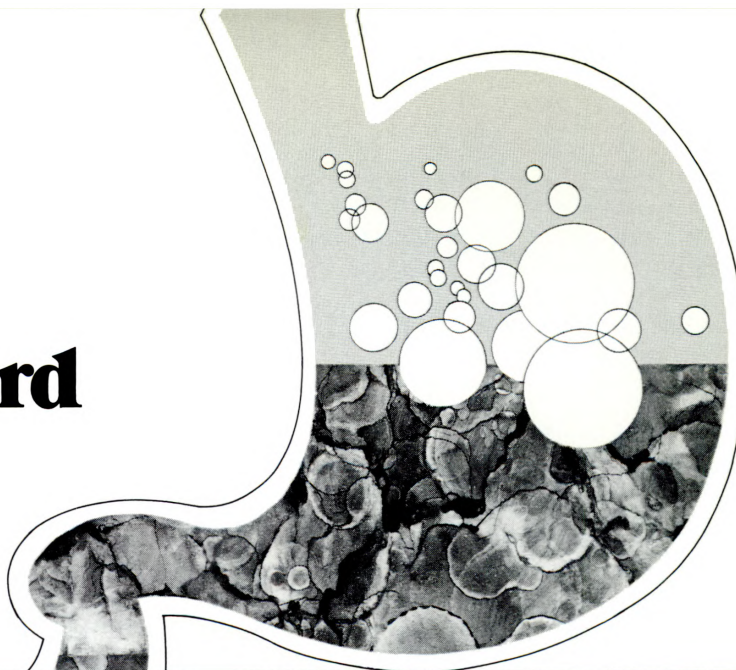


***This yellow antibiotic solution should be clear. One of the bottles also shows a sediment on the bottom.***



# A New Standard For Antacids

*FDA has issued its first standard for a class of OTC drugs. It allows only three labeling claims for antacids, and permits use of 13 ingredients.*



**D**uring the next year, when you pick up an antacid at your neighborhood pharmacy or supermarket, you're going to see some important changes on the label.

Gone will be the claims that the antacid is safe and effective for a multitude of ills, from nervous stomach to hangover.

Gone will be the many confusing formulations, each making its own special claims.

Instead, you will know that every antacid product you see is safe and effective and that all the information you need to use the product correctly is on the label.

For example, you will see only three therapeutic claims on antacid labels: that the product is safe and effective for the symptomatic relief of "heartburn," "sour stomach," and/or acid indigestion.

In addition, many antacids will have special warnings. And any antacid containing aluminum will warn consumers not to take the antacid while they are taking the prescription antibiotic tetracycline. Aluminum can reduce the effectiveness of tetracycline by preventing or reducing its absorption in the body.

More importantly, there will be only 13 acceptable ingredients or groups of ingredients, each of them proved safe and effective.

These important changes will result from an order issued by the Food and Drug Administration June 4, 1974, which requires the

manufacturers of all nonprescription antacid products to meet a new standard. The standard is the first issued under FDA's massive review of all nonprescription drugs.

Few antacids will be removed from the market, predicted Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, in announcing the new standard. Most products probably will remain on the market because they will limit their labeling and promotion to allowable claims, or by changing their dosage and ingredients to meet the new standard.

Antacids will continue to be sold in dosage forms to which consumers have become accustomed: chewable and nonchewable tablets, liquids, effervescent tablets or powder to be dissolved in water, and chewing gum with an antacid coating.

Labeling will provide information so that consumers can make meaningful comparisons between similar products and avoid those containing ingredients which they should not take.

For example, under the heading "Warning," the label must say: "Do not take more than (maximum recommended daily dosage, broken down by age groups if appropriate) in a 24-hour period, or use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a physician."

Certain products must carry special warnings. For example, products that cause constipation in 5 percent or more of persons who take the maximum recommended dosage must warn: "May cause constipation." Also products that may cause laxation in 5 percent or more of the users must warn the consumer of such an effect.

Products containing relatively high amounts of magnesium, sodium, potassium, or lactose must also warn consumers. Magnesium or potassium should not be used by people with kidney disease, except on advice of a physician. Lactose should be avoided by people allergic to milk, and sodium should be avoided by those on a sodium-restricted diet.

Any company that wants to market an antacid that deviates from this standard must seek FDA approval.

The new standard affects about 8,000 currently marketed antacid products. In 1972, antacid sales were estimated at \$117 million.

All products must conform to the new standard by June 4, 1975. New labeling requirements for products promoted only to doctors must be provided by June 4, 1976. This professional labeling must include information about the capacity of the product to neutralize stomach acid.

Publication of the final order setting this new standard for ant-



*This is what a label for an antacid product might look like, under the new standard issued by FDA.*

**DIRECTIONS FOR USE:**

Chew two tablets every four hours or as directed by physician.

**WARNINGS:**

Do not take more than eight tablets daily for more than two weeks, except under the advice and supervision of a physician.  
May cause constipation.

**DRUG INTERACTION PRECAUTION:**

Do not take this product if you are presently taking a prescription antibiotic drug containing any form of tetracycline.

**NDC 0000-0000-00**

**ANTACID TABLETS**

**FOR ACID INDIGESTION, SOUR STOMACH OR HEARTBURN**

**Active Ingredients:**

Aluminum hydroxide	200 mg
Magnesium hydroxide	80 mg

**100 Tablets**

**Manufactured by:**  
PBH Inc.,  
Buffalo, N.Y. 14202

*This drug interaction precaution must appear on any antacid containing aluminum.*

*This is the number which has been assigned to this product by the National Drug Code.*

*These are the only allowable symptoms for relief.*

*Listing of the quantity of ingredients is voluntary.*

acids concluded one of the most intensive scientific reviews ever undertaken by a regulatory agency. For nearly a year, beginning in May 1972, seven of the Nation's leading experts in gastrointestinal therapy, pharmacists, and pharmacologists focused their attention on all available evidence on antacids.

FDA's library performed a search of all recent antacid literature, and more than 50 companies who market antacids provided enough data to fill a shelf 12 feet long. The panel members met six times for 2 or 3 days at a time, and received information at each meeting from any interested party who wished to

appear and present information.

In addition, the panel consisted of two nonvoting members representing consumer groups and industry. They participated in every meeting. Their function was to assure public awareness of and participation in the Government's decision-making process.



This entire process resulted in a report and a proposed new standard to assure the safety and effectiveness of antacids. FDA allowed opportunities at several stages for consumers and industry to comment on the proposed standard, and held a hearing January 21, 1974, to receive further information and comments.

The final order June 4 was the first issued as part of FDA's class-by-class review of all OTC drugs. (The process by which this review is being conducted was described in "OTC Drug Review: An Update," FDA CONSUMER, May 1974.)

Commissioner Schmidt hailed the action as a "significant milestone in FDA's attempt to establish a more manageable system for assuring safe and effective formulas and full labeling for all the hundreds of thousands of nonprescription drugs on the market."

The same process followed by FDA for antacids will be followed for the other 26 classes of OTC drugs. It will be several years before final orders are issued for all the classes.

When they are, the public will have greater assurance that every OTC drug available is not only safe and effective, but is properly labeled and formulated. The new standards also will result in changes in advertising claims, which are regulated by the Federal Trade Commission. Several firms have already modified their television advertising and their product ingredients, even before the official standards were issued.

The day after the antacid standard was published, Dr. Schmidt discussed it in testimony before the Senate Monopoly Subcommittee. Dr. Schmidt cited four significant aspects of the standard:

- That each antacid product must not only be composed of safe and effective ingredients, but that the effectiveness of the finished product must be confirmed by meeting an acid neutralizing test developed by the expert panel.
- That the indications for the use of antacids should be limited to

those conditions clearly related to excess acid in the stomach, and should therefore exclude vague or unsubstantiated claims that now appear on many antacid labels.

- That cautionary and warning statements should be concise and readily understandable.
- That combinations of antacids and other drugs should not be permitted where evidence is lacking that each ingredient contributes to the claimed effect or effects and where there is no specific group of people to which the claims apply.

In testifying before the Senate subcommittee, Dr. Schmidt stated his view that the standard issued by FDA has the force and effect of law. Some people claim that the standard should be only guidelines for industry to follow.

Because antacids were the first class of OTC drugs considered by FDA as part of its overall review, a number of broader issues applying to all OTC drugs were raised which were decided by the Commissioner.

Perhaps the most highly publicized issue was that regarding the combination of an antacid and a salicylate (aspirin). The best example of this is Alka-Seltzer.

Opponents of the combination of an antacid and a salicylate maintained that it is irrational and unsafe because antacids are designed to relieve acid indigestion, while salicylates can cause bleeding in the stomach.

In his testimony June 5, Dr. Schmidt pointed out that the combination is indeed irrational—for use solely as an antacid.

But, the Commissioner added, the combination does conform to FDA's policy regarding combination drugs, "in that both ingredients are indicated and effective for the concurrent symptoms of acid indigestion and headache." The Commissioner agreed there are people who have both symptoms at the same time.

Therefore, the Commissioner concluded that combinations of antacids with salicylates may continue, with proper formulation and labeling.

The Commissioner noted that the use of salicylates is being reviewed by the Panel on Internal Analgesics, which will recommend to the Agency acceptable conditions for use for pain relievers, including their concurrent use with antacids.

In deciding the antacid-salicylate issue, the Commissioner expressed the view that nonprescription drugs composed of two or more ingredients can still be marketed, provided that there is a reason for combining the ingredients, and that the consumer is not exposed to an unreasonable risk.

The Commissioner concluded, however, that adding an anticholinergic ingredient (which decreases stomach activity) to an OTC antacid would not be permitted. Also rejected were products that combine an antacid with a laxative, an enzyme, or an antiemetic (which decreases nausea). None of these uses constitutes rational therapy, the Commissioner found.

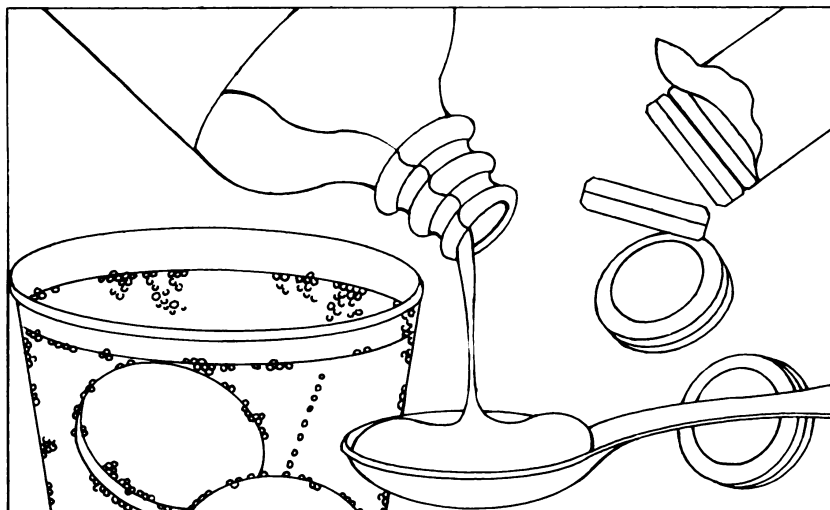
A second issue related to the warning on OTC drug labels to keep drugs out of the reach of children. The Commissioner decided to modify the present warning and require that the following statement appear on drug labels:

*"Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact your poison control center immediately."*

A third issue related to the inclusion on the label of the statement concerning possible drug interactions. Pharmacy groups testified at the January 21 hearing that the label should tell the consumer to consult his pharmacist as well as his physician in case of a possible interaction.

The Commissioner resolved this issue by requiring that the label include a separate section headed "Drug Interaction Precautions," which will state the interaction problem involved with a particular OTC drug. For the first time, the consumer can learn from the label that he should not take the product while also taking a particular pre-





scription drug. The drug interaction precaution for all aluminum-containing OTC antacid products is the first one to be required. Other precautions will be required for other OTC drugs, that may interact with prescription drugs.

In announcing this decision, the Commissioner said:

"The purpose of OTC medication is to permit consumers to engage in self-medication without medical or other professional supervision, or in any event with the least amount of supervision feasible. Directing that consumers consult health professionals of any type would seem appropriate only if it is concluded that this is the only possible method of assuring the safe and effective use of the drug.

"Accordingly, although the Commissioner recognizes the availability of useful drug information through all health professionals, he concluded that it is unnecessary and inappropriate that they be designated on the label in any manner with respect to this particular matter in view of the availability of fully informative labeling which obviates such reference."

The OTC drug review which generated the antacid standard and these more general issues is based on the 1962 Drug Amendments to the Food, Drug, and Cosmetic Act, which required for the first time that all drugs be proven effective as well as safe.

FDA then undertook to review for effectiveness all drugs for which marketing applications had been submitted since 1938, when the safety requirement was added to the drug law. That review disclosed that very few OTC drugs had been the subjects of applications. The initial review, therefore, was limited to prescription drugs.

In 1972, FDA launched the present review to consider 27 categories of OTC drugs and set standards comparable to those now set for antacids.

FDA is using advisory committees as primary sources for this review. In his June 5 testimony, Dr. Schmidt said: "To enable us to make the best possible judgments, we have and will continue to use advisory committees to provide us with information, interpretation, and advice which will supplement that generated internally. . . . The functions of the over-the-counter drug panels demonstrates the increasingly important role of broadly constituted scientific advisory bodies as integral parts of our regulatory process."

In announcing the antacid standard, Dr. Schmidt also reaffirmed FDA's commitment to a system of self-medication in this country. "Self-medication is an essential part of our health care system. Fundamental to self-medication is the requirement that any drug available for use at the purchaser's own ini-

tiative must be safe and effective for its intended purpose.

"It is of equal importance that any such drug must be fully labeled and fairly advertised so that an individual can indeed medicate himself for appropriate conditions safely and effectively, without professional supervision."

"I submit that the publication of our first over-the-counter monograph represents a significant milestone toward this goal."

### Acceptable Ingredients

The new standard for over-the-counter antacid products recognizes 13 acceptable active ingredients. They are:

- Aluminum-containing ingredients
- Bicarbonate-containing ingredients
- Bismuth-containing ingredients
- Calcium-containing ingredients
- Citrate-containing ingredients
- Magnesium-containing ingredients
- Phosphate-containing ingredients
- Potassium-containing ingredients
- Sodium-containing ingredients
- Tartrate-containing ingredients
- Sodium bicarbonate
- Glycine (aminoacetic acid)
- Dried milk solids

In addition, in a different standard for antifatulent products, simethicone with a maximum daily dose of 500 milligrams is permitted in a product labeled "to alleviate or relieve the symptoms of gas."

### Ingredients That Need Further Work

FDA concluded that insufficient evidence exists to determine the role of the following ingredients as antacids, and therefore they can be sold for an additional 2 years if the manufacturer or distributor promptly undertakes testing, and if any product that claims to be an antacid meets the neutralization test.

- Alginic acid
- Attapulgit (activated)
- Charcoal (activated)
- Gastric mucin
- Kaolin
- Methylcellulose
- Pectin
- Carboxymethylcellulose



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# News Highlights

## **Warning Issued For Imported Chinese Herbal Drugs**

FDA warned June 1 against the use of imported Chinese herbal medications that contain a powerful and potentially dangerous drug, phenylbutazone.

One person is known dead and three other persons are hospitalized in the San Francisco Bay area with agranulocytosis (a severe blood condition). All four patients had been taking one or more Chinese herbal medications found by FDA to contain 7 to 30 milligrams per tablet of the drug, phenylbutazone.

The products were described by FDA as hard, round black or brown pills, approximately ¼ inch in diameter, sealed in plastic bags and packaged in glass or plastic jars or bottles.

The Nan Lien Pharmaceutical Company, Ltd. is listed on box labels as the manufacturer of three different brands: (1) Long Life Brand Ginseng Hui Sheng Tsaitsoowan; (2) Sanlungpai Ginseng Hui Sheng Tsaitsoowan; and (3) Chuifong Toukuwan Nan Lien. The pills are black and may be packed in bright colored blue, green, orange, or gold cardboard boxes. Pictures appear on these boxes depicting men and women suffering back and leg pains.

Anyone using these remedies should stop immediately and consult a physician about previous exposure to them.

The other manufacturer is the Ichongtai Pharmaceutical Co., Ltd., Tainan, Taiwan, Republic of China.

The pills are brown and packaged 50 each in translucent amber glass bottles with white screw caps. The label is blue and white. Except for the name and address of the manufacturer, all other labeling information is in Chinese. The bottles may be packed in blue, white, and green boxes, 3 inches in height.

These and similar medications containing phenylbutazone enter the United States illegally, generally in small quantities by mail or in personal baggage. FDA alerted the U.S. Customs Bureau to detain all suspect products at U.S. ports of entry. Although illegal, the products may be available over-the-counter at grocery stores in Chinese communities in the United States. FDA is initiating surveys for the illegal drugs in major U.S. cities.

Ordinarily, herbal preparations are harmless and have no scientifically substantiated curative properties. However, the suspect products contain the potent anti-inflammatory drug, phenylbutazone. This drug is legally available in this country on a prescription basis only and should be used under close supervision of a physician.

FDA announced June 25 that follow-up investigations revealed four additional brands of imported Chinese herbal medications that contain undeclared phenylbutazone.

The additional brands are:

(1) Chihshih-ton, manufactured by Ichongtai Pharmaceutical Co., Ltd.

(2) Favina, manufactured by Baker & Berlin Pharmaceutical Ltd.

(3) Shou Sing Chui Fong Toukuwan, manufactured by Shou Sing Pharmaceutical Co., Ltd.

(4) Hippo Brand Secret Formula Chui Fung Eng, manufactured by Nan Lien Pharmaceutical Co., Ltd.

FDA has also been advised by Canadian authorities that tests on one of the brands involved in FDA's initial warning, "Chuifong Toukuwan Nan Lien," show that the product contains undeclared prednisolone (anti-inflammatory drug), methyltestosterone (male sex hormone), and diazepam (sedative), in addition to phenylbutazone and aminopyrine, both anti-inflammatory drugs. These drugs are all potent and available only by prescription in the United States. They should be taken only under a physician's supervision.

## **FDA Announces Fourth Phase Of Food Labeling Regulations**

FDA announced June 12 the fourth major phase of its long-term program to revise commercial food labeling practices as a means of improving nutrition information to the public.

FDA Commissioner Alexander M. Schmidt, M.D., said the program will produce benefits that "will be visible in the health and vitality of the American people in years to come."

The first three phases of the food labeling program were announced in January, March, and August 1973. The most widely publicized of those regulations set forth the standard for nutrition labeling. The first three phases involved more than 50 regulatory actions.

(The earlier phases were described in FDA CONSUMER. See "Nutrition Labeling: A Great Leap Forward," September 1973, and "The Food Labeling Revolution," April 1974.)

The fourth phase involves 13 new proposals on which FDA is seeking comment, four final orders, and the withdrawal of one previous proposal. This is a brief description of the actions announced June 12 and published in the *Federal Register* June 14:

*General principles governing the addition of nutrients to foods*

In the course of developing earlier regulations, it became apparent to FDA that there was a need to define

and publish principles which would govern the addition of vitamins, minerals, and protein to food. Such a general regulation is necessary because major changes in food consumption, combined with increasing nutritional knowledge, have made it inappropriate to set standards for all food classes to which nutrients are properly added.

The proposed rules would define how and when nutrient additions will be permitted. Such additions would be allowed in five ways:

1. By the traditional procedure of establishing a food standard for a particular class of food. Enrichment of bread to eliminate known nutritional deficiencies is an early example of such a food standard.

2. By establishing a nutritional guideline for a class of food. This procedure can be used when it is not considered necessary to establish all the parameters for a food class that are required for a standard. Proposed nutritional guidelines for five classes of foods were included in actions announced June 12.

3. By adding nutrients to a food to make that food nutritionally equivalent to the food it is designed to replace. The proposal on adding vitamin C to breakfast beverages is an example.

4. By restoring nutrients lost in processing. If 2 percent or more of the U.S. Recommended Daily Allowance for a serving is lost in processing, nutrients can be added to bring the nutrient level back to where it was before the loss occurred.

5. By adding nutrients in proportion to the caloric content of the food. This procedure has been established to govern the addition of nutrients to products which are not nutritionally comparable to any existing food. It is designed to allow "balanced" nutrient addition while providing safeguards against overfortification and exaggerated nutritional claims.

*Fortified ready-to-eat breakfast cereals—proposed nutritional quality guidelines*

This proposal would establish nutritional quality guidelines for ready-to-eat breakfast cereals. Five such proposed guidelines were included in the June 12 package. Such guidelines establish appropriate levels for protein, vitamin, and mineral content and are designed to assure that fortification is neither excessive nor inadequate.

Manufacturers who make products which meet FDA guidelines can use the following statement on their labels:

"This product provides nutrients in amounts appropriate for this class of food as determined by the U.S. Government." Full nutrition labeling information must also be provided.

To discourage over-fortification, the regulation would require a manufacturer who fortifies a product at higher levels to state on the label that the product contains nutrients which are regarded by the Government as unnecessary and inappropriate.

*Fortified hot breakfast cereals—proposed nutritional quality guideline*

This proposal would establish a nutritional quality guideline for fortified hot breakfast cereals. It sets levels for iron and calcium and three B vitamins.

*Cereal, flours, and related products—proposed improvement of nutrient level of enriched farina*

This proposal would amend the existing food standard for farina to make the product's nutritional content consistent with other hot breakfast cereals. A slightly higher level of iron is proposed because the product is more likely to be eaten by children under 12 and adults over 65. Both of these age groups are more vulnerable to dietary inadequacies of iron.

*Main dish products—proposed nutritional quality guideline and common or usual name*

This proposal would establish a nutritional quality guideline for products which are intended as the principal part of a meal. Examples of such products are tuna casseroles and pizza. The guidelines would assure that these products are nutritionally adequate as a main dish. They specify the kind and amount of protein and vitamins and minerals which must be included. In addition, as part of the common name of the product, the components must be listed in the order of descending predominance by weight.

*Formulated meal replacements—proposed nutritional quality guideline and common or usual name*

This proposal would establish a nutritional quality guideline for products used as meal replacements. Such products are presently sold as convenience foods, aids in weight control, meal adjuncts or snacks. They are unique in that they are promoted as providing a complete and balanced meal.

This proposal details the nutrients which must be included in such products. It would establish "formulated meal replacement" as the common name for products which are complete in themselves. When it is necessary to add milk or other food to the product to make it equivalent to the meal it is replacing, the common name would be "formulated meal base," along with a listing of the food which must be added.

*Breakfast beverage products—proposed nutritional quality guideline*

Breakfast beverages constitute the major source of vitamin C for most people in this country. Many beverages promoted for breakfast use are now fortified with vitamin C at various levels. This proposed nutritional guideline would set the level of vitamin C at 60 mg per 6-oz. serving—approximately the level that occurs naturally in orange juice. The guidelines are designed to assure that when vitamin C is added to such a product, it will provide a nutritionally adequate level of the vitamin, but will not be in excess of nutritional requirements. All noncarbonated beverages represented as breakfast juice beverages are covered by the guideline.

*Tomato juice—amendment of identity standard*

This action amends the food standard for tomato juice to allow the optional addition of vitamin C and to



make the standard consistent with the nutritional quality guideline for breakfast beverage products.

*Common or usual name for plant protein products*

In recent years, food technology has developed protein products from cereal and vegetable sources. These products are sold as extenders or replacements for traditional protein sources such as meat, seafood, poultry, eggs, or cheese. Such products look and taste the same as the more familiar protein products.

This proposal would define the nutritional qualities which must be present in such products to assure that they have the same nutritional value as the products they replace. It would specify the quantity of protein, the quality of the protein, and the amount of vitamins and minerals. Three common names would be established, based on the ratio of protein to other material in the product. The common names would be:

1. "Soy flour" or "soy granules" for those products which have less than 65 percent protein and retain most of the chemical properties of the source plant.
2. "Protein concentrate" for those products with a protein content of 65 to 90 percent. Such products are manufactured by eliminating part of the fiber, carbohydrate, or mineral from the original product, thus "concentrating" the protein. The source of the protein would precede "protein concentrate" in the name.
3. "Protein isolate" for those products with a protein content exceeding 90 percent. Such products are prepared by dissolving protein from the plant material and recovering the protein in essentially pure form. The source of the protein would precede "protein isolate" in the common name.

*Diluted fruit or vegetable juice beverages—proposed common or usual name for nonstandardized foods*

Regulations presently require that all diluted orange juice beverages list the percentage of juice present in the product. This proposal would extend this requirement to all other diluted fruit and vegetable juice beverages.

*Table sirups—establishment of standards of identity*

This regulation establishes a food standard for table sirup, maple sirup, cane sirup, and sorghum sirup. Included in the standard is a requirement that the percentage of each type of sirup be included on the label.

*Use of international units for vitamins A and D*

This notice confirms the effective date for using "International Units" instead of "U.S.P. Units" for vitamins A and D.

*U.S. Recommended Daily Allowance for infants*

This final order establishes procedures for use of U.S. RDA's for nutritional labeling on infant, baby, and junior-type foods. A separate labeling category for infants has been established in response to a request from the American Academy of Pediatrics.

*Food labeling: Label declaration of ingredients; misleading vignettes: Common or usual name for food*

This proposal would clarify labels by establishing a

uniform procedure for listing ingredients on food labels. New rules would govern the listing of standardized foods which are used as ingredients in other foods. Procedures are also clarified for listing ingredients which come in various forms such as liquid, dry, or frozen.

The proposal would require that each individual fat or oil ingredient be identified on a food label. Current regulations require such ingredients to be listed as being of animal, vegetable, or marine origin, or in some cases, simply as shortening.

Another part of this proposal is designed to eliminate possible consumer deception from vignettes which depict food ingredients which are not included in the package. It would require label declarations to advise the consumer that he must add an ingredient such as meat, to complete the meal. Presently, this requirement exists only for the "heat and serve dinner" class of food.

*Proposed serving and portion sizes and daily consumption amounts*

Nutrition labeling is based on the average "serving" or "portion" size of a given product. When the nutrition labeling regulation was published, FDA called on industry and consumers to work together to devise uniform serving and portion sizes so that consumers could make meaningful comparisons.

A recent survey revealed that the serving and portion sizes are not reasonable or uniform within some product classes. In some cases, the serving size has doubled since the advent of nutrition labeling.

This proposal would establish a procedure for setting appropriate serving and portion sizes. It also proposes specific serving sizes for five classes of foods—non-carbonated breakfast beverage products, formulated meal replacements, ready-to-eat breakfast cereals, hot breakfast cereals, and fluid milk beverages.

*Uniform method of declaring the percentage of an ingredient in foods*

Percentage labeling of ingredients is not now required for most classes of food products. Some manufacturers and grocery chains have voluntarily initiated percentage labeling. This proposal would prevent confusion and possible deception by establishing a uniform method to be used whenever such labeling is offered. It is in response to a petition by Giant Foods, a Washington-based grocery chain.

*Multiunit and multicomponent food packages—proposed exception from required label statements*

This technical proposal would allow manufacturers to eliminate ingredient listing on internal packages which are not designed to be sold separately and the ingredients are listed on the external package.

*Ingredient statement regarding fats and oils in food for human consumption*

This action withdraws an earlier proposal on labeling of fats and oils. Labeling requirements for such products are included in another of the proposals.

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# Regional Reports

## REGION I

A fine of \$4,000 was imposed on the Thurman Co., Boston, and \$1,000 each on Louis S. Epstein, president, and Harry Epstein, treasurer, on charges that flour on the company premises was contaminated by rodents and that the flour and seven other lots of foods were held under insanitary conditions whereby they may have become contaminated by bird or rodent filth. The sentences were imposed by U.S. Magistrate Willie Davis in the U.S. District Court at Boston, the corporation pleading guilty to eight counts and the individuals nolo contendere to four counts. The charges resulted from investigations by FDA's **Boston Field Office**.

After several court hearings, a default decree has been entered in the U.S. District Court for New Hampshire, Concord, for forfeiture of a lot of 146 cases (2,752 one-pound packages) of diced onions misbranded as onion rings, and the lot has been donated to a New Hampshire hospital. The lot was seized by the Government last year at Buy Rite Foods, Salem, New Hampshire. It had been shipped by Boston Bonnie, Inc., Boston. The seizure was made based on charges by FDA's Boston Field Office.

In a recent month, FDA's Boston Field Office detained 13 lots of crabmeat offered for import from Taiwan, and valued at \$130,000, because of contamination with insect filth. Other detentions included 12 lots of decomposed cheese from France valued at \$5,000, \$20,000 worth of decomposed whiting fish from Argentina, \$40,000 worth of decomposed shrimp from Indonesia, and \$40,000 worth of fish meal and dry milk from Canada found to be contaminated by *Salmonella*.

## REGION II

FDA's **New York District**, in cooperation with the Agency's Office of International Affairs, held a briefing in New York attended by more than a hundred commercial attachés of foreign consulates, representatives of import trade associations, and brokers handling imports concerning recent changes in FDA regulations that affect imported products.

The recent changes affect biologic and other drugs, food additives, and food contaminants, canned low-acid foods, food labeling, and import clearance procedures. After distribution of information packets, John J. Zaic of FDA's Office of International Affairs urged participants to relay the information to those concerned both in this country and abroad.

The Government has seized 30 cartons totaling 2,000 pounds of broken brazil nuts, imported from Brazil, in New York on charges by FDA's New York District of contamination by live insects and gross misbranding, including the label claim that they are "the world's highest source of vitamins."

Deadly botulinum toxin was found in a can of tuna and possible injury to health of others averted through the alertness and concern of a consumer in Buffalo, New York. Offended by the odor and appearance of the spoiled contents of the can when she opened it, she gave it to a friend who worked at a Veterans Administration hospital in Buffalo. The hospital laboratory's analysis revealed contamination by *Clostridium botulinum*. FDA's **Buffalo District** forwarded the can and the rest of the contents, along with several unopened cans from the same code, Star-Kist code 921G1 over EE489, to FDA's New York District, whose laboratory confirmed findings of botulinum toxin in the opened can, and tiny leaks in the side seam of the opened can and other cans of that code. The lot of tuna, distributed only in Western New York State, was recalled. Consumers were alerted in the area by local newspapers, radio, and TV, and asked to return any cans of the code unopened to the place of purchase. Seven other codes packed in the Star-Kist plant in American Samoa at the same time have been withheld from the market for checks by FDA, which is continuing to investigate.

The Government seized 46 drums, each containing 50 gallons of frozen whole cherries, at Clermont, New York, after FDA's Detroit District alerted Buffalo District that the cherries, shipped in September 1973 by Musselman Division of Pet, Inc., St. Joseph, Michigan, contained rotten fruit. Laboratory analysis revealed an average rot content of 13.7 percent.

A consent decree of permanent injunction to prevent further violations of the Food, Drug, and Cosmetic Act has been signed by General Trading Co., Inc., a food warehouse at Carlstadt, New Jersey, after four inspections by FDA's **Newark District** in the past year revealed the continuing presence of rodent infestation and rodent-defiled foodstuffs. The decree prohibits the company from receiving or shipping foods in interstate commerce until the warehouse is free of rodents, and methods have been established to keep it that way. The action followed repeated warnings to the company and its failure to remedy the situation.

FDA's Newark District is monitoring a nationwide



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recall by Bonat, Inc., West Paterson, New Jersey, of 14 brands of hair spray manufactured by the company because the aerosol products contain vinyl chloride monomer, a suspected carcinogen, as a propellant agent, and may subject the user to exposure by inhalation. The company mailed recall letters to 1,000 beauty supply outlets requesting subrecalls to the beauty salon level.

FDA's **San Juan District** assisted in the Government seizure of a lot of 50 cases of a rice cereal infested with insects at Celestino Perez & Co., Inc., a warehouse in Caguas, Puerto Rico, after District inspection revealed insect and rodent problems.

A lot of 36 100-pound bags of insect-infested peanuts was seized by the Government at Caribbean Snacks, Inc., a peanut processor and snack manufacturer in Rio Piedras, Puerto Rico, after investigation by FDA's San Juan District disclosed the product was stored in a plant infested by moths and cockroaches.

### REGION III

FDA's **Philadelphia District** is monitoring the disposition of antibiotics damaged in a fire at A.M. Uhrig Drug Co., Philadelphia. The drug material, five batches of bulk tetracycline powder, was embargoed by the State of Pennsylvania, and FDA notified the owner, Richlyn Labs, Inc., Philadelphia, that the Agency's previous certification of the five batches is no longer valid. The Pennsylvania State Department of Health's Division of Drug Control embargoed the damaged antibiotics after being notified of the damage by FDA's Philadelphia District.

Mary Groome, consumer affairs officer, FDA's Philadelphia District, has assumed full-time duties at Pittsburgh to serve consumers of western Pennsylvania.

FDA's Philadelphia District is working with two groups in consumer education: the Philadelphia Association of Retail Druggists in FDA's upcoming consumer education campaign on over-the-counter drugs, and the Philadelphia Dietetics Association in FDA's current campaign on nutrition labeling.

Giant Foods has arranged to provide identification to FDA's **Baltimore District** of manufacturers of products sold in the company's grocery stores to assist FDA in following up complaints. Both the company and the District are cooperating in identifying trends in consumer complaints.

FDA's Baltimore District is conducting a pilot test in using four volunteers to extend the work of the District's Consumer Affairs Section. The project is being promoted by announcements on the "Call for Action" program on radio station WBAL in that city. The sta-

tion also helps train the volunteers in the techniques of dealing with the public. Each of the four volunteers will work 1 day a week answering consumer inquiries on the District's "Consumer Phone" from 11 a.m. to 1 p.m. (Monday through Thursday), the telephone reverting to dispensing recorded messages of interest to consumers the rest of the time. The volunteers will also assist the District's consumer affairs officers in a variety of assignments calling for contact with the public.

### REGION IV

The Government seized 155 cases of canned "creecy" greens at a warehouse in Kernersville, North Carolina, after analysis by FDA's Atlanta laboratory of samples taken by Frank Williams, consumer safety officer at **FDA Atlanta Section's Greensboro Resident Post**, confirmed a consumer's complaint that the greens were adulterated by cocklebur. Creecy greens are similar to watercress but are grown in drier soil. The canned greens were packed and distributed by Monticello Canning Co., Crossville, Tennessee.

The new consumer affairs officer in the **Nashville Section** of FDA's Region IV is Barbara Ann Banks, who will be consulting with consumers and professionals throughout Tennessee, Kentucky, and Mississippi on FDA regulatory programs and other functions. Her business address: FDA, 297 Plus Park Boulevard, Nashville, Tennessee 37217. Telephone: 615-749-7127.

### REGION V

The services of the FDA were described by Marguerite Robinson, consumer affairs officer, FDA's **Chicago District**, and the services of the Federal Trade Commission by Jerome Lamet, assistant FTC regional director, at a session during the fifth annual Statewide Conference on Consumer Education at Springfield, Illinois. About 500 consumer education specialists and teachers attended. The conference also represented the first meeting of the newly formed Illinois Consumer Education Association.

FDA's **Cincinnati District** checked out a number of health problems that arose after a series of tornadoes struck seven cities and towns in Ohio on April 3, causing 40 deaths and more than 1,200 injuries and over \$100 million in property damage. There was little damage to commercial stocks of foods, drugs, and cosmetics, the tornadoes mainly affecting residential areas.

The Government seized all finished drugs and raw materials in possession of Detroit Professional Labs, Warren, Michigan, after investigations by FDA's **Detroit District** showed a long history of noncompliance with the Agency's Current Good Manufacturing Prac-

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tice Regulations.

The Professional Equipment Co., Detroit, and its owner, Robert Bruesh, have entered into a consent decree of permanent injunction in which the company agrees to comply with FDA requirements for notifying customers of defects in x-ray machines and other requirements. The injunction grew out of an investigation by FDA's Detroit District of the company's failure to make the required notification and its failure to submit plans for repair, replacement, or refund of purchase price as required under the Radiation Control for Health and Safety Act of 1968.

Eagle Baking Co., Detroit, after pleading guilty to operation of an insanitary bakery, was fined \$1,500 on two counts by Magistrate Paul J. Kormives of the U.S. District Court for Eastern Michigan in a case resulting from investigation by FDA's Detroit District.

About 6,000 cosmetologists and beauticians kept FDA's **Minneapolis District** busy answering questions about FDA's new cosmetic labeling regulations at the FDA exhibit during the National World of Beauty Show held in Minneapolis. Those attending reported that the exhibit and materials available were both useful and timely.

## REGION VI

Brown Miller Co., Texarkana, Texas, pleaded guilty to seven counts and was fined \$1,000 for storing foods under insanitary conditions under which they became contaminated by insect filth and for preparing and packing foods under insanitary conditions under which they may have become contaminated by filth. The charges, brought in the U.S. District Court for Eastern Texas, Texarkana Division, resulted from recommendations by FDA's **Dallas District**. Charges against two officials who had left the company were dropped.

FDA's **Dallas District** detained 148,960 pounds of coffee worth \$83,256 from Brazil because of live insect infestation and 95,000 pounds of coffee worth \$55,500 from Indonesia because of infestation by live insects and insect-damaged beans. Both detentions were made at the port of Houston.

Charles Dennergy Co., New Orleans, a wholesale food storage division of DCA Food Industries, Inc., New York, pleaded guilty and was fined \$4,000 on four counts of allowing food to become defiled by rodents and holding food under conditions whereby it might have become contaminated by rodents. The charges resulted from investigations by FDA's **New Orleans District**. Magistrate Morey L. Sear of the U.S. District Court for Eastern Louisiana, New Orleans, also fined Lazare Levy, president and general manager, and Benjamin C. Mauthe, plant manager, \$500 each on

two counts to which they had pleaded nolo contendere, two additional counts against each being dismissed.

Inspection by FDA's New Orleans District resulted in Government seizure of 530,270 pounds of green coffee valued at \$264,000 on the New Orleans docks in possession of the Retla Steamship Co., Inc., because it was contaminated by pigeon excreta while stored there after release from import status. The Government also seized 195,500 pounds of flour that had become moldy on a New Orleans wharf while awaiting export to Dubai in the Middle East. FDA's New Orleans District ascertained from the Ambassador of Dubai in New York that his country did not want to import the moldy flour.

## REGION VII

Two Missouri companies and their presidents entered guilty pleas and were fined as a result of prosecutions brought in the U.S. District Court for Western Missouri, Kansas City, based on recommendations by FDA's **Kansas City Field Office**. Dell's Potato Co., Kansas City, was charged with two counts of manufacturing diced potatoes under insanitary conditions whereby bacterial contamination occurred and shipping the adulterated potatoes into interstate commerce. The company was fined a total of \$1,000 on two counts and its president, Dell E. Johnson, \$100 on one count. Zidell Sales Co., St. Joseph, a wholesale grocery warehouse, was fined \$750 and its president, Elliott Zidell, \$500, on one count against each which charged storage of food under insanitary conditions whereby it became contaminated. Four other counts against each were dismissed.

Adulterated food valued at a total of \$28,000 was seized by the Government upon recommendations by FDA's Kansas City Field Office. Three were based on insanitary conditions of warehouses wherein the products were exposed to contamination by rodent or insect filth, including coconut at St. Louis, whey powder at St. Louis, and several lots of crackers at Bluff City, Missouri. The Government seized a railcar of flour in Kansas City after rodent contamination was discovered upon delivery in another State to a consignee (who refused delivery), and the flour was returned to Kansas City.

A lot of amygdalin, a substance widely promoted as a treatment for cancer, was refused entry by FDA's Kansas City Field Office when offered for import at St. Louis because no approved New Drug Application for it exists. The lot of 100 kilograms was valued at \$28,000 and was offered for import from Monaco. Amygdalin is derived from peach or apricot kernels and sometimes is known under the brand name "Laetrile." To date no acceptable evidence of its safety or efficacy as an anticancer agent has been established. Refusal



of the lot followed detention and lengthy correspondence with the importer, who claimed it was intended to be used as a food product but who failed to produce adequate evidence to that effect.

## REGION VIII

Associated Grocers of Colorado, Inc., Denver, was fined \$3,500 on a criminal charge of allowing cheese and other foods in the company's warehouse to become contaminated by rodents. The charges were brought upon recommendations by FDA's **Denver District**. The conviction in the U.S. District Court for Colorado, Denver, followed a plea of guilty by the company. Jack B. Kennedy, vice president, and Menno R. Duden, general manager, pleaded guilty and were fined \$300 each on misdemeanor charges. Both retired from the company before the court trial. Both the company and the two former executives were convicted of violations of the Food, Drug, and Cosmetic Act in 1964.

## REGION IX

FDA's **San Francisco District** added to its reasons for detaining three lots of fishcake offered for import from Japan when a microbiological analysis method showed that a chemical substance in the product induced mutation (genetic changes), as demonstrated in tests with a strain of *Escherichia coli* bacteria. The District detained two lots of the fishcake because of the undeclared presence of artificial color and another lot because of short weight. But samples sent to the Environmental Mutagenesis Branch of the National Institute of Environmental Health Service in Research Triangle Park, North Carolina, were reported by EMB to contain furylfuramide, a nitrofurantimicrobial agent that is mutagenic (produces genetic changes) and is not approved for use in food in the United States. The Japanese labeling declared the presence of the substance but the English labeling did not. The District amended its detentions to reflect the findings. Since there is no established method in this country for identifying furylfuramide in this type of product, the District has asked that the San Francisco importer, Nishimoto Trading Co., not only provide proper identity in the required English labeling but also obtain an analytical method from the Japanese supplier.

Grocers Wholesale Co., Inc., San Francisco, and two officers were fined \$1,000 each by Magistrate David E. Urdan in the U.S. District Court for Northern California, San Francisco, upon pleas of nolo contendere to charges of storing foods under insanitary conditions, brought by FDA's San Francisco District. The officers were Joseph L. Girimonte, corporate vice president, and Ernest L. Cappai, secretary.

A lot of sesame seeds valued at \$800 was seized by the

Government at Stockton, California, after consumer safety officers of FDA's San Francisco District, supervising reconditioning of some large lots of other imported foodstuffs, noted rodents in and around the lot of sesame seeds. The District later made a complete inspection of the port facility and presented a lengthy report of findings to the port authority, which has undertaken to make corrections.

FDA's San Francisco District detained more than 170,000 cartons of canned Tropical Fruit Salad offered for entry by Del Monte Corp. from its plant in the Philippines and consigned to a company plant in the Bay Area of San Francisco. The District's examination showed that 20-25 percent of the cans were damaged because of a rough ocean crossing.

A Hawaiian company and a company officer have been convicted in the U.S. District Court for Hawaii on charges of storing food under insanitary conditions, following investigation by FDA **San Francisco District's Honolulu Resident Post**. Hawaii Grocers, Ltd., Hilo, and its executive secretary and manager, Tomiji Yamamoto, pleaded guilty and were fined \$300 and \$50 respectively on one count; another against each being dismissed.

## REGION X

The Government seized virtually all foodstuffs of an interstate origin, valued at approximately a million dollars, stored in a large grocery warehouse in Seattle after an inspection by FDA's **Seattle District** disclosed that a large quantity of chocolate-flavored baking chips, flour, dextrose, salt, and potatoes was grossly contaminated by rodents, and that an undetermined quantity of various types of foods in packages, susceptible to rodent contamination, was being held in the warehouse under insanitary conditions whereby it may have become adulterated with rodent filth.

U.S. Attorney Stan Pitkin filed charges against the food being held at Associated Grocers, Inc., Seattle, upon FDA's request, in the U.S. Court for the Western District of Washington, and the court ordered seizures on March 1. The warehouse has a floor space of about 12 acres under one roof. The action was one of the largest multiproduct warehouse seizures made by FDA.

In a consent decree entered into with the court, the company posted a million dollar bond as an assurance that the warehouse would properly salvage the contaminated foods. Under the terms of the consent decree, the company checked each food unit in the warehouse under FDA supervision and corrected every condition deemed to be objectionable by FDA. The salvaging operation was carried out from March 4 to March 18. Approximately 122,000 pounds of adulterated food was destroyed under FDA supervision by burial in a landfill.

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## State Actions

### Shellfish Waters Closed

A major rupture in a new \$55 million sewage system outfall—built to carry wastewater effluent from the Wantagh Sewer District's sewage treatment system in Nassau County, Long Island, New York, for 7 miles through South Oyster Bay out to the Atlantic—has resulted in closing of 6,000 acres of the bay to shellfish harvesting to prevent contaminated shellfish from reaching the market.

Since the break in the line was a complete one, all the 4 million gallons a day fed into the system at present was leaking into the bay. The rupture was discovered by the Nassau County Department of Public Works during testing of the underwater pipeline for leaks. Such tests are made by feeding dye into the wastewater effluent and then checking the waters above the pipeline area for signs of escaping dye. The finding of a leak or rupture in the South Oyster Bay section of the outfall, instead of the ocean section, was unexpected. The cause of the break has not yet been determined.

The emergency closure of the 6,000-acre section of the bay to shellfish harvesting was ordered by the Commissioner of the New York Department of Environmental Conservation, and this and other areas along the outfall will remain closed until the break has been repaired and the integrity of the outfall assured. The rupture of the pipeline, which was installed in part to protect shellfish from contamination, served as a warning to other health and environmental officials that approved shellfish waters along all new outfall lines must be temporarily closed to harvesting until the lines are tested and found to be leakproof before the effluent is pumped through.

New York authorities and

George Meyer, shellfish consultant for FDA's Region II, cooperated closely in determining whether any shellfish contaminated by the rupture had been harvested and in removing suspect shellfish products from the market.

### Contaminated Wheat

The Washington State Department of Agriculture has embargoed approximately 30 carloads of wheat because of the presence of high levels of calcium cyanide. Calcium cyanide is manufactured by American Cyanamid and has been registered since 1947 for use as a fumigant for insects.

The high levels are thought to be due to an unusual combination of climate conditions, including cold temperatures at Midwest loading points and extremely dry wheat. These conditions may have prevented the normal volatilization of the calcium cyanide crystals.

The Environmental Protection Agency has been notified and is gathering information to determine if the use of calcium cyanide should be temporarily discontinued until the climate conditions change.

All of the wheat in question is reportedly intended for export.

### Water Problem

Illness of more than 200 children after drinking orange juice that was part of a supplemental foods program at an elementary school in Locust, North Carolina, resulted in investigations by the county health and State health departments and the Federal Communicable Disease Center, Atlanta. The problem was traced to a faulty water fluoridation system at the school and use of the water to reconstitute the frozen orange juice concentrate. A sample analysis revealed 275 parts per million of fluorine in the unused

orange juice and 120 ppm in the water at the school. Daniel Sitko, supervisory consumer safety officer at the Raleigh Resident Post of FDA's Atlanta Section, determined that the orange juice concentrate was not contaminated after being notified of the incident by the State Department of Agriculture.

### Bad Eggs

About 3,000 dozen eggs were placed under seizure at an egg farm in Washtenaw County, Michigan, by action of Michigan Department of Agriculture food inspectors after FDA's Detroit District reported samples of shell eggs from the farm contained residues of the pesticide chlordane in excess of FDA action level guidelines.

Not waiting for laboratory results, the farmer voluntarily destroyed both the eggs and chickens by burial. The analysis had revealed high levels of chlordane in both the eggs and the fat of the chickens. The farm's owner had been advised to discontinue sale of the eggs and chickens for either human or animal food while the analysis pended.

### Contaminated Peas

A consumer complaint about insect contamination of Old El Paso brand chickpeas to the Food Section of the Virginia Department of Agriculture and Commerce and subsequent investigation resulted in voluntary recall of the two lots affected by the problem. FDA's Dallas District, notified of the complaint, inspected the manufacturer, Mountain Pass Canning Co., Anthony, Texas. Of a distribution nationwide and in Canada of 7,500 cases of 27 15-ounce cans, the company estimated that only about 500 cases were not recovered by the recall.



# Seizures and Postal Service Cases

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

A total of 15 actions to remove from the consumer market products charged to be violative was reported in May. These included 10 seizures of foods: 7 involved charges concerning contamination, and 3 involved charges concerning economic

and labeling violations. Other seizures included 4 of drugs (including 1 of veterinary and medicated feed), and 1 of prophylactics.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>FOOD/Contamination, Spoilage, Insanitary Handling</b>		
Articles of food/Seattle, Wash. 3/1/74	Associated Grocers, Inc./Seattle, Wash. (D)	Held under insanitary conditions; rodent gnawed and contaminated.
Beans, dark red kidney/Edmore, Mich. 4/30/74	Edmore Grain & Lumber Co./Edmore, Mich. (M, S)	"
Cereal, Instant/Caguas, P.R. 4/25/74	Celestino Perez & Co., Inc./Caguas, P.R. (D)	Held under insanitary conditions; insect contaminated.
Oysters, boiled/Seattle, Wash. 11/26/73	Esperanto Imports/Seattle, Wash. (D)	Decomposed.
Rice, soybeans, white hominy grits/Chicago, Ill. 5/13/74	Grocerland Co-operative, Inc./Chicago, Ill. (D)	Held under insanitary conditions; filth contaminated.
Sea Shells, Sunrise Midget/Salt Lake City, Utah 4/24/74	Porter-Scarpelli Macaroni Co./Portland, Ore. (M, S)	Held under insanitary conditions; label fails to bear name and place of business of the manufacturer, packer, or distributor.
Sesame seed/Stockton, Calif. 5/28/74	Stockton Port District (Warehouse Storage)/Stockton, Calif. (D)	Held under insanitary conditions; rodent contaminated.
<b>Economic and Labeling Violations</b>		
Brazil nuts, broken/New York, N.Y. 4/15/74	Baker & Williams/New York, N.Y. (D)	False and misleading labeling "Brazil Nuts World's Highest Source of Vitamins" and "Best Source of Vitamins"; no accurate statement of quantity of contents; insect contaminated.
Flour Mix, Soya Carob/Portland, Ore. 3/22/74	Sterling Food Co./Seattle, Wash. (M, S)	False and misleading labeling "Soyacaroba Flour Mix," which consists mainly of wheat flour.
Rice/Canton, Mass. 5/24/74	Liberty Rice Mill, Inc./Kaplan, La. (M, S)	Lacks name and place of business of the manufacturer, packer, or distributor; lacks the common or usual name of the food; no accurate statement of quantity of contents; insect contaminated.
<b>DRUGS/Human Use</b>		
Aspirin tablets, throat troches, Dextyl tablets, Red tablets E.C., Sali-Sal tablets, Boric Acid 4%, Ascorbic Acid tablets, high potency caps. 250, Maline tablets/Warren, Mich. 5/28/74	U.S. First Aid Co./Warren, Mich. (D)	Not in conformity with good manufacturing practice.
Digoxin/Muncie, Ind. 4/22/74	Cord Laboratories, Inc./Detroit, Mich. (M, S)	Quality below U.S.P. standard.
Various drug products/Warren, Mich. 4/23/74	Detroit Professional Labs/Warren, Mich. (D)	Not in conformity with good manufacturing practice.
<b>Veterinary/Medicated Feed</b>		
Repository DES/Denver, Colo. 4/30/74	Seney & Co., Inc./Denver, Colo. (M); Recordati Industria Chimica E. Farmaceutica, S.A.S./Milan, Italy (S)	New animal drug without effective New Animal Drug Application.
<b>Prophylactics</b>		
Prophylactics, rubber/Tulsa, Okla. 5/3/74	Dean Rubber Co./North Kansas City, Mo. (M, S)	Contained holes.

**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 Chief Postal Inspector.

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

- February 15, 1974: **Harvey Steider, d/b/a The World of Solarama**, P.O. Box 5083, Sarasota, Florida 33579. Advertising and sales through the mail of an electronic healing board.
- February 19, 1974: **Wayne Research Laboratory**, Box 5753, Detroit, Michigan 48239. Advertising and sale through the mail for a treatment to eliminate psoriasis.
- February 22, 1974: **M-M Enterprises**, P.O. Box 4146, Roanoke, Virginia. Sale and advertisements by mail of alleged aphrodisiac, Spanish fly love potion.
- March 5, 1974: **Diet**, 309 N. King Rd., Los Angeles, California 90048. Advertisement and sale by mail of the Vitamin "E" Plus "C" Diet, represented to be effective for fast weight loss.
- March 5, 1974: **Lakewood Neurophen Co.**, 1942 West 65th Street, Cleveland, Ohio 44102. Advertising and sale through the mail of a treatment for epilepsy.
- March 5, 1974: **Solarama of Miami, Inc.**, P.O. Box 366, Coral Gables, Florida 33134. Advertising and sale through the mail of an electronic healing board.
- March 11, 1974: **Hanover House**, Hanover, Pennsylvania. Sale and advertisements by mail of an Electric Vibrator Belt to cause waistline measurement reduction up to 3 inches in 1 week.
- March 13, 1974: **Dagmar of Copenhagen**, 9601 Wilshire Boulevard, Suite 22, Beverly Hills, California 90210. Advertising and sale by mail of Bosom Building Cream represented to be effective for enlargement of the breasts.
- March 13, 1974: **S.C.A.**, P.O. Box 246, Ridgecrest, California 93555. Advertising and sale by mail of a diet method represented to bring about a weight loss of 25 pounds in 2 weeks.
- March 20, 1974: **Bio-Cell**, P.O. Box 48950, Los Angeles, California 90048. Advertising and sale by mail of an RNA formula represented to be effective for elimination of wrinkles, improve blood circulation, and other maladies associated with aging.
- March 27, 1974: **Joe Weider**, 55 Maple Street, Norwood, New Jersey. Sale and advertisement by mail of Supreme E Wheat Germ Oil Capsules to build endurance and hasten muscle gains.
- March 29, 1974: **National Health Institute**, P.O. Box 39, Durham, California 95938. Advertising and sale by mail of a ski team diet which represented to produce a weight loss of 20 pounds in 2 weeks.
- March 29, 1974: **Joe Weider**, 55 Maple Street, Norwood, New Jersey. Sale and advertisement by mail of Slimmer Shake to assist in weight loss up to a pound a day.
- April 2, 1974: **Brenda Hardy**, 11848 Vose Street, North Hollywood, California 91605. Advertising and sale by mail of directions for preparing a tonic represented to be effective for weight reduction.
- April 2, 1974: **Louise Nettleton**, 114823/4 Oxnard Street, North Hollywood, California 91606. Advertising and sale by mail of directions for preparing a tonic represented to be effective for weight reduction.
- April 19, 1974: **15-Minute Beauty Renewal Plan**, 21100 Erwin Street, Woodland Hills, California 91364. Advertising and sale by mail of a product represented to be effective for the rejuvenation of the user's face.
- April 9, 1974: **Iso-Tensor Plan**, 21100 Erwin Street, Woodland Hills, California 91364. Advertising and sale by mail of an exerciser represented to be effective for increasing the user's breast size.

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

- February 21, 1974: Against **Vital-E**, P.O. Box 742, Encino, California 91316. Advertisement and sale by mail of a vitamin E oil represented to be effective for treatment of wrinkles.
- March 5, 1974: Against **James Allen**, P.O. Box 80834, Atlanta, Georgia 30341. Advertising and sale through the mail of a "Magic Plan" reducing method.
- March 6, 1974: Against **E-Diet**, Box 376, Encino, California 91316. Advertising and sale by mail of the Vitamin E Diet representing that vitamin E is an integral part of a weight loss plan.
- March 7, 1974: Against **Slim and Trim**, Box 376, Encino, California 91316. Advertisement and sale by mail of the Vitamin E Diet representing that vitamin E is an integral part of a weight loss plan.
- March 18, 1974: Against **Harvey Steider, d/b/a The World of Solarama**, P.O. Box 5083, Sarasota, Florida 33579. Advertising and sale through the mail of an electronic healing board.
- April 4, 1974: Against **Good Drugs**, P.O. Box 549, Oak Park, Illinois 60303, and **Good Pharmaceutical Co., Merchandise Mart Building**, P.O. Box 3042, Chicago, Illinois 60654. Advertising and sale through the mail of a sex stimulant.
- April 8, 1974: Against **Diet**, 309 N. King Rd., Los Angeles, California 90048. Advertising and sale by mail of a diet plan in which it is represented that vitamins E and C tablets play an essential part in the weight reduction program.
- April 10, 1974: Against **Diet-E**, 309 N. King Rd., Los Angeles, California 90048. Advertising and sale by mail of a diet plan in which it is represented that vitamin E tablets play an essential part in the weight reduction program.
- April 11, 1974: Against **Dan N. Myers**, 7150 21st Ct., NW Fort Lauderdale, Florida 33313. Advertising and sale through the mail of a cream to remove wrinkles.
- April 11, 1974: Against **Mr. D. N. Myers**, 7150 NW 21st Ct., Sunrise, Florida 33313. Advertising and sale through the mail of a bust developer.
- April 12, 1974: Against **Dagmar of Copenhagen**, 9601 Wilshire Blvd., Beverly Hills, California 90210. Advertising and sale by mail of a bosom building cream.



# Notices of Judgment

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

### Alfalfa hay, at Chino, C. Dist. Calif.

Charged 10-9-73: when shipped by Manuel Romo, Parker, Ariz., the article contained the added pesticide chemical toxaphene in excess of the prescribed tolerance; 402(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 59509; S. No. 53-897 G; N.J. No. 1)

### FOOD/Contamination, Spoilage, Insanitary Handling

#### Artichoke hearts, canned, at Chicago, N. Dist. Ill.

Charged 3-1-72: while held for sale, the article contained a decomposed substance; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 57844; S. No. 20-402 F; N.J. No. 2)

#### Basil leaves, at Countryside (La Grange), N. Dist. Ill.

Charged 10-18-73: while held by Sokol & Co., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59516; S. No. 26-603 G; N.J. No. 3)

#### Candy bars, sugar, dog food, and gelatin dessert mixes, at Nashville, M. Dist. Tenn.

Charged on or about 1-11-74: while held by Bi-Rite Food Stores, Inc., Nashville, Tenn., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59609; S. Nos. 6-721/6 G; N.J. No. 4)

#### Chili peppers, at Chicago, N. Dist. Ill.

Charged 1-2-74: while held by Hammond Columbia Refrigerated Warehouse, Chicago, Ill., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59596; S. No. 26-613 G; N.J. No. 5)

#### Cookies and flour, at Lawrence, Dist. Mass.

Charged 5-9-73: while held by Maroun Bros., Inc., Lawrence, Mass., the flour contained rodent filth, and both articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59161; S. Nos. 15-283/4 G; N.J. No. 6)

#### Corn, white, shelled, at Phoenix, Dist. Ariz.

Charged 11-5-73: while held by R & S Mexican Foods, Inc., Phoenix, Ariz., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59461; S. No. 54-578 G; N.J. No. 7)

#### Cornmeal and hominy grits, at Dorchester, Dist. Mass.

Charged 7-23-73: while held by Manhattan Stores, Inc., Dorchester, Mass., the articles were held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59359; S. Nos. 15-324/5 G; N.J. No. 8)

#### Catsup, at Grand Rapids, W. Dist. Mich.

Charged 12-27-73: when shipped by Fettig Canning Corp., Elwood, Ind., the article, labeled in part "Spartan Tomato Catsup . . . Distributed by Spartan Stores, Inc., Grand Rapids, Mich.," contained decomposed tomato material; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 59575; S. No. 108-614 G; N.J. No. 9)

#### Catsup, at Wichita, Dist. Kans.

Charged 11-28-73: when shipped by Fettig Canning Corp., Elwood, Ind., the article, labeled in part "Shurfine Tomato Catsup . . . Distributed by Shurfine-Central Corporation, Northlake, Ill.," contained decomposed material; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59563; S. No. 49-551 G; N.J. No. 10)

#### Flour, at Jeanerette, W. Dist. La.

Charged 8-16-73: while held by Le Jeune Bakery, Inc., Jeanerette, La., 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. 59418; S. Nos. 67-789/90 G; N.J. No. 11)

#### Flour, at Kansas City, Dist. Kans.

Charged 3-1-74: while held for sale, the article contained rodent filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59677; S. No. 35-835 G; N.J. No. 12)

#### Flour and donut mixes, at Detroit, E. Dist. Mich.

Charged on or about 3-20-73: while held by D.S.M. Food Products, Inc., Detroit, Mich., the articles were held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for reconditioning. (F.D.C. No. 58951; S. Nos. 98-553/9 F; N.J. No. 13)

#### Flour and dried lima beans, at Churchpoint, W. Dist. La.

Charged 6-6-73: while held by Churchpoint Wholesale Grocery Co., Inc., Churchpoint, La., the lima beans contained rodent filth, and both articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 59221; S. Nos. 67-563/5 G; N.J. No. 14)

#### Flour and salt, at Charlotte, W. Dist. N.C.

Charged 9-18-73: while held by Statesville Flour Mills Co., Charlotte, N.C., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree authorized donation to a charitable institution for use as animal feed. (F.D.C. No. 59454; S. Nos. 1-298/300 G; N.J. No. 15)

#### Mushroom stems and pieces, canned, Sno Top, at E. Palestine, N. Dist. Ohio.

Charged 7-21-70: when returned to United Canning Corp., E. Palestine, Ohio, from Pennsylvania, the article contained decomposed mushrooms; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 56386; S. No. 19-580 D; N.J. No. 16)

#### Mustard seed, at Denver, Dist. Colo.

Charged 5-18-73: while held by Brown's Food Products, Inc., Denver, Colo., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for reconditioning. (F.D.C. No. 59214; S. No. 45-193 G; N.J. No. 17)

#### Peanuts, at Alexandria, W. Dist. La.

Charged 12-13-73: while held by Noah's Potato Chip Co., Inc., Alexandria, La., 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. 59572; S. No. 67-736 G; N.J. No. 18)

#### Peanuts, at Detroit, E. Dist. Mich.

Charged 12-28-73: while held by Raynard A. Miller, t/a Rocky Peanut Co., Detroit, Mich., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Rocky Produce, Inc., Detroit, Mich., for salvaging. (F.D.C. No. 59573; S. No. 108-529 G; N.J. No. 19)

#### Peanuts, Spanish, at Arvada, Dist. Colo.

Charged 12-28-73: while held by Doran Nut Co., Arvada, Colo., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59603; S. No. 45-970 G; N.J. No. 20)

#### Poppy seed, at Lawrence, Dist. Mass.

Charged 1-7-74: while held by Vitamine Health Products Manufacturers, t/a V. H. Better Baking, Lawrence, Mass., 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. 59602; S. No. 17-311 G; N.J. No. 21)

#### Rice, at Miami, S. Dist. Fla.

Charged on or about 12-5-73: while held for sale, the article contained decomposed rice; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59560; S. No. 3-149 G; N.J. No. 22)

#### Rice and kidney beans, at Miami, S. Dist. Fla.

Charged 7-20-73: while held by Miavana Wholesale Co., Inc., Miami, Fla., the articles contained rodent and insect filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree authorized destruction. (F.D.C. No. 59365; S. Nos. 2-910/11 G, 2-913/14 G; N.J. No. 23)

#### Sauerkraut, canned, at Sacramento, E. Dist. Calif.

Charged 2-22-73 and amended on or about 8-20-73: while held for sale, the article contained decomposed sauerkraut and was unfit for food, since some cans were defective and abnormal; 402(a)(3). The article was claimed by Libby, McNeill & Libby, Chicago, Ill. Postseizure samples were collected by both the claimant and the Government. Written interrogatories were served by both parties. Subsequently, the claimant withdrew its claim, and a default decree ordered destruction. (F.D.C. No. 58926; S. No. 91-041 G; N.J. No. 24)

#### Sesame seed, at Buffalo, W. Dist. N.Y.

Charged 1-9-74: while held by Royale Rolls, Inc., Buffalo, N.Y., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59612; S. No. 21-512 G; N.J. No. 25)

#### Shortening, at Hato Rey, Dist. P.R.

Charged on or about 10-18-72: while held by Caceres-Johnson Corp., Hato Rey, P.R., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 58447; S. No. 92-152 F; N.J. No. 26)

#### Shrimp, cleaned, canned, at Elizabeth, Dist. N.J.

Charged 12-5-73: while held for sale, the article contained decomposed shrimp and was held in swollen, leaking cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59564; S. No. 64-735 G; N.J. No. 27)

#### Soups of various kinds, 3 seizure actions, at Bronx, S. Dist. N.Y.; Dobbs Ferry, Pelham, and New York, S. Dist. N.Y.; and Bronx, S. Dist. N.Y.

Charged 1-13-72, 1-13-72, and 2-7-72: when shipped by Bon Vivant Soups, Inc., Newark, N.J., the articles (some of which were labeled in part "Bon Vivant Vichyssoise Soup [or 'Consomme Madrilene'] . . . Packed by Bon Vivant Soups, Inc., Newark, N.J.," "Ancora . . . Turtle Soup . . . Bon Vivant Soups, Inc., Newark, N.J.," "White Rose Consomme Madrilene . . . White Rose Foods Corp. Distributors Farmingdale, N.J.," "S.S. Pierce

... Black Bean Soup with Sherry . . . Packed for S.S. Pierce Company, Boston, Mass., or "Bradens Concentrated Cream Vichyssoise Soup or "Fancy Grade A Black Bean Soup with Sherry Wine") . . . California Products, Inc., Distributors, New York 13, N.Y.") were unfit for food in that some cans of these foods had been found to be defective and abnormal, and in that the manufacturing procedures used did not assure proper sealing of the cans or adequate heat treatment of the sealed cans to prevent contamination and spoilage; and the articles had been prepared and packed under conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health; 402(a)(3), 402(a)(4). Default decrees ordered destruction. (F.D.C. Nos. 57664, 57673, 57761; S. Nos. 9-581 E, 9-582 E, 83-014 E; N.J. No. 28)

**Soy product pieces, salted**, at Monroe, W. Dist. N.C.  
Charged 11-12-73: while held by Trophy Brands, Inc., Monroe, N.C., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59547; S. No. 1-241 G; N.J. No. 29)

**Soybean protein powder**, at Chelsea, Dist. Mass.  
Charged 5-9-73: while held by William H. Driscoll Warehouse, Inc., Chelsea, Mass., the article had been held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59162; S. No. 15-030 G; N.J. No. 30)

**Sugar**, at Denver, Dist. Colo.  
Charged 12-28-73: while held by Rocky Mountain Mercantile Co., Denver, Colo., the article was held under insanitary conditions; 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 59601; S. No. 45-922 G; N.J. No. 31)

**Sugar**, at Memphis, W. Dist. Tenn.  
Charged 5-25-73: while held by Patterson Warehouse, Inc., Memphis, Tenn., 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. 59265; S. Nos. 3-630 Z G; N.J. No. 32)

**Sugar and flour**, at Des Moines, S. Dist. Iowa.  
Charged on or about 11-23-73: while held by Acri Wholesale Grocery Co., Inc., Des Moines, Iowa, the articles contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59559; S. Nos. 48-950/1 G; N.J. No. 33)

**Tomatoes, canned**, at Cincinnati, S. Dist. Ohio.  
Charged 11-27-73: when shipped by Milroy Canning Co., Inc., Milroy, Ind., the article, labeled in part "Little Skipper Quality Brand Solid Pack Tomatoes . . . Distributed by Pilot Stores, Inc., Cincinnati, Ohio," contained decomposed material; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59562; S. No. 32-122 G; N.J. No. 34)

**Tomato sauce, canned**, Del Monte, at Pauline, Dist. Kans.  
Charged 11-21-73: when shipped by Del Monte Corp., Sacramento, Calif., the article contained machinery mold and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59555; S. No. 107-364 G; N.J. No. 35)

**Wheat**, at Boston, Dist. Mass.  
Charged 3-22-73: while held by C. Pappas Co., Inc., Boston, Mass., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 58979; S. No. 14-828 G; N.J. No. 36)

#### FOOD/Economic and Labeling Violations

**Candy, caramel cream, and Tootsie Roll Midgee candy**, at Lowell, Dist. Mass.  
Charged 6-23-73: when shipped by Tootsie Roll Industries, Inc., Chicago, Ill., the Tootsie Roll Midgee candy's ingredient statement was not prominently placed on the label with the required conspicuousness, since the ingredient statement was printed on the end of the candy wrapper which was twisted so that the names of the ingredients were not legible at the time of purchase—403(i)(2); and while held by Quin-Pak Candies, Inc., Lowell, Mass., who had repacked the individually wrapped bulk candies into plastic bags, labeled in part "De Moulas Markets . . . Family Treats . . . Tootsie Rolls (or "Caramel Creams")," the articles were in violation of the Fair Packaging and Labeling Act, since the statement of identity of the articles failed to appear on an alternate principal display panel, and was not presented in bold type and was not in a size reasonably related to the most prominent printed matter on such panel; the quantity of contents statement failed to appear on an alternate principal display panel; and the quantity of contents statements, appearing on principal display panel area of more than 25 square inches, were in a type size less than 3/16 inch high—15 U.S.C. 1453(a)(1), 1453(a)(2), 1453(a)(3)(C)(i). Default decree authorized donation to a charitable institution. (F.D.C. No. 59259; S. Nos. 14-342/3 G; N.J. No. 37)

**Concentrate for orange juice drink, frozen**, Sunny Orange, at East Hartford, Dist. Conn.  
Charged on or about 7-8-72: when shipped by Sunny Orange, Inc., Orlando, Fla., the article was in violation of the Fair Packaging and Labeling Act, since the statement of identity of the article was not in bold type in a reasonably related size and was not in lines generally parallel to the base of the article; and the statement of identity of the article was not duplicated on the alternate display panel; and the quantity of contents declaration did not appear on either the can's front or back principal display panels: 15 U.S.C. 1453(a)(1), 1453(a)(2). The article was claimed by the shipper, and the action was transferred to the Northern District of Florida. The Government moved for summary judgment. The court granted the Government's motion and condemned the article. The court authorized the claimant the option of bringing the article into compliance or having the article donated to a government institution. The claimant requested reconsideration and, in the alternative, for the court to find the facts specifically and set out separately its conclusions of law; this was denied. Subsequently, the claimant appealed. The Government moved to dismiss the appeal on the grounds that it was not filed within the required 60-day period. The court of appeals granted the Government's motion and dismissed the claimant's appeal. (F.D.C. No. 58010; S. No. 14-425 F; N.J. No. 38)

**Cookies, gingerbread figure**, at Houston, S. Dist. Tex.  
Charged 6-26-73: when shipped by Crystal Cookie Corp., San Fernando, Calif., the article was in violation of the Fair Packaging and Labeling Act, since the principal display panel areas of the article lacked a statement

of identity of the article, and the quantity of contents declaration did not appear upon the principal display panel area: 15 U.S.C. 1453(a)(1), 1453(a)(2). Consent decree authorized release to the shipper for relabeling. (F.D.C. No. 59258; S. No. 35-339 G; N.J. No. 39)

#### Popcorn, at Worcester and Northboro, Dist. Mass.

Charged 5-15-73: when shipped by Consolidated Popcorn, Inc., Schaller, Iowa, the article, labeled in part "Sweetlife . . . Popcorn . . . Distributed by Sweet Life Products Corp., Suffield, Conn.," was in violation of the Fair Packaging and Labeling Act, since 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: 15 U.S.C. 1453(a)(3)-(C)(i). Consent decree ordered destruction. (F.D.C. No. 59195; S. No. 14-806 G; N.J. No. 40)

#### VITAMINS/SPECIAL DIETARY FOODS

##### Food nutrient powder, at Jackson, S. Dist. Miss.

Charged 4-23-73 and amended 6-22-73: while held by Health Aids, Inc., Jackson, Miss., the article, labeled in part "O.N.E. Nutritional Balance Food Powder . . . Optimum Nutrition Essentials Made under License of Research Nutrition Foundation For: Health Aids, Inc. . . . Jackson, Miss.," the dealer's labeling contained a number of false and misleading claims, such as: to make you feel better, regardless of your state of health; to supply all essential nutrients in amounts sufficient to satisfy dietary needs; to maintain perfect health from the cradle to the grave; to produce the highest state of nutrition; to make you as young as you feel and lengthen life by 10 to 27 percent by well-balanced diets; to provide more than 60 chemicals required to build new tissue and bone needed by the body each day, and to prevent some parts of the body from getting a little weaker or less active; to prevent aging and becoming handicapped; to enable the body to rebuild each cell stronger and healthier year after year; to prevent many ills that should never happen and can be corrected; to promote health and prevent infectious diseases; to promote normal growth, development, appearance, personality, and ability to work; to supply higher quality foods necessary in modern living; to supply protective foods, that is, proteins, vitamins, and minerals; to prevent malnutrition and efficiency diseases; to provide essential nutrients lacking in many American diets due to the use of refined foods and an insufficient intake of mineral and vitamin-rich natural foods; to prevent malnutrition in all age groups and at all economic and social levels caused by four decades of consumption of empty calorie foods lacking adequate protein, vitamins, and minerals; to prevent digestive symptoms, lack of appetite, pallor, frequent infections, tiring quickly, night restlessness, and crossness, which are signs of malnutrition; to provide certain essential nutrients to which most ailments and illnesses that afflict man respond in an almost miraculous way; to provide optimum nutrition and all essential nutrients required by man for complete metabolism; to reduce or eliminate aches and pains, promote an increased feeling of well-being, eliminate the need for medication, and reverse severe conditions in many diseases common to man; to rebuild the cells of the body; to improve health and appearance, and to stop or reverse the aging process; to make the body its own healer; and that the article was formulated on the basis of 20 years of scientific research; that scientific experts had bestowed a special award on the article because of its nutritive contents; that minimum daily requirements had been established for amino acids; that 2 milligrams of thiamine, 2 milligrams of riboflavin, 50 milligrams of ascorbic acid, and 2 micrograms of vitamin B<sub>12</sub> were the Recommended Daily Dietary Allowances established by the National Academy of Sciences, National Research Council, and that Recommended Daily Dietary Allowances had not been established for calcium, phosphorus, iron, iodine, and magnesium—403(a); and the article was also in violation of the Fair Packaging and Labeling Act, since the quantity of contents was expressed as "Net Weight 2 Lbs. 5-1/2 Oz. (37-1/2 Ozs.," instead of "Net Wt. 37-1/2 Ozs. (2 Lbs. 5-1/2 Ozs.)," and 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—15 U.S.C. 1453(a)(3)(A)(i), 1453(a)(3)(C)(i). Default decree ordered destruction. (F.D.C. No. 59147; S. No. 1-922 F; N.J. No. 41)

##### Nutri-Bio dietary supplement wafers, Nutri-Bio Protein instant mix, and Nutri-Bio vitamin and mineral tablets, at Dunedin, M. Dist. Fla.

Charged 4-25-72: when shipped by Nutri-Bio Corp., Beverly Hills, Calif., the labeling of the instant mix and the wafers contained false and misleading claims, as follows: wafers—the label declarations of arginine, histidine, tyrosine, cystine, serine, glutamic acid, glycine, proline, aspartic acid, and alanine, in the setting in which they were used, represented and suggested that these amino acids were essential to the diet, which representations and suggestions were false and misleading, since they were contrary to fact; and wafers and instant mix—the listing of 18 amino acids on the label represented and suggested that these products were of better and greater value than ordinary protein foods, which representation and suggestion was false and misleading, since it was contrary to fact—403(a); all the articles were in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration failed to appear on the principal display panels—15 U.S.C. 1453(a)(2); and while held for sale, valuable constituents of the vitamin and mineral tablets had been omitted or abstracted, and the label statements as to the declared amounts of vitamin A, vitamin C, vitamin B<sub>12</sub>, vitamin E, and pantothenic acid were false and misleading, since the vitamin and mineral tablets were subpotent in those constituents—402(b)(1), 403(a). Default decree ordered destruction. (F.D.C. No. 57934; S. Nos. 1-109/11 E; N.J. No. 42)

##### Protein supplement, instant, Special Formula With Fructose, at Los Angeles, C. Dist. Calif.

Charged 7-31-72: while held by Rho H. Blair & Co., Los Angeles, Calif., who repacked the article from bulk protein supplement shipped in interstate commerce, the labeling of the article contained the following false and misleading claims: in that the name, "Instant Protein Supplement," on the can label of the article represented and suggested that the protein in the article was immediately available, which representation and suggestion was false and misleading, since protein must be broken down by the body to be utilized; false and misleading claims that fructose contributed a special dietary property to a protein supplement, that fructose and protein consumed together enhanced each other, that fruit sugar helped spare protein for tissue building and repair, that fructose potenti-



ated the utilization of certain vitamins, that some fruit sugar was not 100 percent fructose, that fructose was superior nutritionally in the human diet to other sugars, that fructose was safe for diabetics, and that ordinary sugar was dextrose; false and misleading claims that the article was of special value to athletes, movie stars, and entertainers, and was adequate and effective to build a healthy, attractive, well-formed body; false and misleading claims that the article was of special dietary value by reason of its lysine-tryptophan ratio; false and misleading claims with respect to the article's composition as a mixture of nutrients of proven nutrient value with an ingredient of no nutritional significance (i.e., potassium) in a protein supplement; false and misleading claims that the nutritional value of the article as a protein supplement was significantly enhanced by the presence of 15 percent fructose and 9 percent lactose; false and misleading claims that the daily protein requirements were 2.5 to 3 grams for children 1-12 years old, 1.5 to 2 grams for persons 13 to 20 years, 80 grams for pregnant females, and 100 grams for lactating females; false and misleading claims with respect to amino acids and "minimal daily requirements," that represented and suggested that amino acids were necessary and useful in dietary supplementation, and that minimum daily requirements had been established for individual amino acids; false and misleading claims in the accompanying leaflets that the nutritive value of the article was enhanced by the presence of fructose in place of sugar; that protein was more important than other nutrients; that the human body consisted chiefly of protein; that fruit sugar and protein, when eaten together, complemented each other; that fructose was not a refined sugar; that fructose spared protein for tissue building and repair, enhanced the utilization of certain vitamins, and was safe for diabetics; that 70 percent of the population suffered from protein malnutrition; that most diets in the United States provided insufficient high quality protein; that most people in the United States would benefit from protein supplementation; that the biological value of protein was determined by the amounts of percentages of the eight essential amino acids; that protein obtained from soybeans was poor quality and would not support life; that the odor and flavor of the article induced enzyme secretion and more efficient absorption and utilization of the article; that the article was produced by a unique process which preserved nutritive values and made it the only undenatured protein supplement in the world; that undenatured protein was superior nutritionally to denatured protein; that the article was the first concentrated protein supplement; that the protein value of the article was enhanced by the addition of fructose and vanilla, and the absence of refined sugars, artificial sweeteners, artificial flavorings, and synthetic ingredients; that the article was adequate and effective to build a well-formed healthy body and was of special value to athletes, movie stars, and entertainers; that the article has been more extensively tested than any other protein supplement; that the article was adequate and effective for body weight loss, body weight gain, to maintain firmness of the body tissues, skin, and muscle; and that regular use of the article would transform a sickly youth into a vigorous, healthy adult; that the article, when taken as directed, was adequate and effective for the prevention and treatment of restlessness, overwrought and overstimulated conditions, general inability to relax, anxiety, sleeplessness, stress, irritability, emotional strain, tension, crankiness, desire for candy, coffee, liquor, and smoking, frustration, underweight, poor choice of foods, sensitive nervous system, phosphorus jitters, to promote peace of mind, calmness, tranquility, inner peace, happier, healthier, longer life, proper chemical balance in the body, friendliness, improved disposition and behavior in children, improved personality and elation, calmness and serenity, comfortable state of mind, normalization of the taste buds, a better you, and to maintain correct nutritional balance; the false and misleading statement "Phosphorus is abundant in every single food we eat!" and the false and misleading representation that to obtain a proper calcium to phosphorus ratio in the diet it was necessary to take food concentrates and supplements—403(a).

The article was also in violation of the Fair Packaging and Labeling Act, since the quantity of contents statement of the 10-ounce cans of the article, appearing in the principal display panel area of more than 5 square inches, was in a type size less than 1/8 inch high, the quantity of contents statements of the 1 1/2-lb. and 3-lb. cans of the article, appearing on the principal display panel areas of more than 25 square inches, was in a type size less than 3/16 inch high; such 1 1/2-lb. and 3-lb. cans of the article had quantity of contents statements that were not fully expressed as required, e.g., "Net Weight 24 Oz. (1 1/2 Lbs.)," and "Net Weight 48 Oz. (3 Lbs.)."—15 U.S.C. 1453(a)(3)(C)(i), 1453(a)(3)(A)(i).

The article was claimed by H. B. Hadley (an incorporator and director of the repacking firm) who filed a motion to dismiss the complaint. Thereafter, the repacker and Rheo H. Blair also claimed the article, and the motion for dismissal was withdrawn. The claimants moved for partial summary judgment in favor of the claimant on some of the charges. The Government also moved for partial summary judgment. Thereafter, a consent decree authorized release to the claimants for salvaging. (F.D.C. No. 58069; S. No. 44-990 F; N.J. No. 43)

#### FOOD/COLOR ADDITIVES

##### Candy of various types, at Los Angeles, C. Dist. Calif.

Charged 8-1-73: when shipped by Mazetti AB, Malmo, Sweden, the articles contained nonconforming color additives represented to be Patent Blue and nykocinkin; and the label statement "U.S. Certified Colors" was false and misleading. 402(c), 403(a). Consent decree authorized release to Robert Younzer, Los Angeles, Calif., for export to original foreign supplier. (F.D.C. No. 59376; S. Nos. 53-294/5 G; N.J. No. 44)

##### Oil for feed use, vegetable, Ultra-Fat, at Tony, W. Dist. Wis.

Charged 1-22-74: when shipped by Ultra-Life Laboratories, Inc., East St. Louis, Ill., the article contained the nonconforming food additive dieldrin; 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 59632; S. No. 61-480 G; N.J. No. 45)

#### DRUGS/Human Use

##### Afrodex methyltestosterone, yohimbine HCl, and nux vomica extract capsules, at Covina, C. Dist. Calif.

Charged 8-1-73: while held by ICN Pharmaceuticals, Inc., Covina, Calif., who manufactured the article using drug components shipped in interstate commerce, the article's labeling lacked adequate directions for use, and the article was not exempted therefrom, since the article was a new drug without an effective approved New Drug Application; 502(f)(1). De-

fault decree ordered destruction. (F.D.C. No. 59391; S. No. 54-185 G; N.J. No. 46)

##### Beef neptones injection, at Anaheim, C. Dist. Calif.

Charged 5-31-73: when shipped by Myers-Carter, Glendale, Ariz., the article, labeled in part "Pepto-B Fellows Medical Mfg. Co., Inc. . . . Oak Park, Mich.," was a new drug without an effective approved New Drug Application; and the article's package insert contained false and misleading claims for "relief of pains associated with herpes zoster, relief of pain in neuritis (facial, sciatic, or intercostal) of inflammatory nature, not arising from traumatic or mechanical etiology, and for relief of pains associated with tabes dorsalis (lomotor ataxia)"; 505(a), 502(f)(1). Default decree ordered destruction. (F.D.C. No. 59272; S. No. 52-656 G; N.J. No. 47)

##### Catalyte kelp tablets, at Lenexa, Dist. Kans.

Charged 7-24-73: while held by Park Research, Lenexa, Kans., the dealer's accompanying printed promotional material contained false and misleading claims for the article to cause a reduction in body weight and to "take off excess pounds without starvation diets, drugs," and that "These easy to take, chewable tablets gently nudge your body to turn calories into energy more completely instead of letting them be stored as fat"; and the article's labeling failed to bear adequate directions for use and was not exempted, since the article was a new drug without an effective approved New Drug Application; 502(a), 502(f)(1). Default decree ordered destruction. (F.D.C. No. 59373; S. No. 49-233 G; N.J. No. 48)

##### Chlordiazepoxide HCl capsules and diazepam tablets, at Columbus, M. Dist. Ga.

Charged 8-9-73 and amended 1-16-74: when shipped by Poda Trading Co., Ltd., London, England, the articles, labeled in part "Librium . . . Chlordiazepoxide hydrochloride B.P. . . . Roche Products Limited Welwyn Garden City England" and "Valium . . . diazepam B.P. . . . Roche Products Limited Welwyn Garden City England," were new drugs without effective approved New Drug Applications [i.e., articles manufactured in plant other than plant specified by New Drug Application]; the labeling failed to bear adequate directions for use; 505(a), 502(f)(1). The article was claimed by Lee Drug Co. of Georgia, Inc., Columbus, Ga. Thereafter, consent decree authorized release to claimant for export to original foreign supplier. (F.D.C. No. 59395; S. Nos. 4-616/18 G; N.J. No. 49)

##### Citrate of Magnesia solution, at Northville, E. Dist. Mich.

Charged 6-13-73: while held by Northville Lab., Inc., Northville, Mich., who manufactured the article using magnesium carbonate shipped in interstate commerce, the article, labeled in part "Paul Newman's Pasteurized Solution Citrate of Magnesia . . . Children in proportion to age . . . Northville Lab., Inc., Northville, Mich." or "Cunningham Pasteurized Solution Citrate of Magnesia . . . Children in proportion to age . . . Dist. by Cunningham Drug Stores, Detroit, Mich.," had been manufactured, processed, packed, and held under circumstances lacking current good manufacturing practice; and the article lacked adequate directions for use, since its labeling indicated it was intended for children, and the dosage statement for children was inadequate; 501(a)(2)(B), 502(f)(1). Default decree ordered destruction. (F.D.C. No. 59266; S. No. 40-528 G; N.J. No. 50)

##### Dextro-amphetamine sulfate and amobarbital timed-release capsules, at Brazil, S. Dist. Ind.

Charged 7-24-73: while held for sale, the listing of amobarbital in the labeling of the article, and the statement "Indications: Exogenous obesity, as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction," falsely and misleadingly represented and suggested that amobarbital in the total formulation of the article was of value for the article's intended use, when the presence of amobarbital in the article did not contribute to the claimed effects of the drug and did not alter the incidence of adverse side effects of the drug; and the article's labeling lacked adequate directions for use and was not exempted therefrom, since the article was a new drug without an effective approved New Drug Application; 502(a), 502(f)(1). Default decree ordered destruction. (F.D.C. No. 59375; S. No. 40-255 G; N.J. No. 51)

##### Dextro-amphetamine sulfate with amobarbital capsules, at Connersville, S. Dist. Ind.

Charged 6-26-73: while held for sale, the listing of amobarbital in the labeling of the article, and the statement "Indications: Exogenous obesity, as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restrictions," falsely and misleadingly represented and suggested that amobarbital in the total formulation of the article was of value for the article's intended use, when the presence of amobarbital in the article did not contribute to the claimed effect of the drug and did not alter the incidence of adverse side effects of the drug; and the article's labeling lacked adequate directions for use and was not exempted therefrom, since the article was a new drug without an effective approved New Drug Application; 502(a), 502(f)(1). Default decree ordered destruction. (F.D.C. No. 59312; S. No. 40-181 G; N.J. No. 52)

##### Diazepam tablets, at Monroe, W. Dist. La.

Charged 8-14-73: when shipped by Poda Trading Co., Ltd., London, England, the article, labeled in part "Valium . . . diazepam B.P. Roche Products Limited Welwyn Garden City England," was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 59419; S. No. 67-374 G; N.J. No. 53)

##### Drug component stocks and finished drug stocks of a manufacturer, at Chicago, N. Dist. Ill.

Charged 3-10-72: while held by Maizel Laboratories Division of Myers-Carter Laboratories, Inc., Chicago, Ill., who had purchased the articles from the predecessor firm Maizel Laboratories, Inc., Chicago, Ill., the circumstances of the articles' manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; 501(a)(2)(B). The articles were claimed by Benhill Corp., formerly known as Maizel Laboratories, Inc., Chicago, Ill. Subsequently, the Government moved for a default decree of condemnation on the grounds that no answer to the charges had been filed. After a hearing, the court directed the claimant to file an answer. In the claimant's answer subsequently filed, the claimant denied the charges and additionally defended on the grounds that the good manufacturing regulations were vague and indefinite. Subsequently, the claimant withdrew its claim and answer, and a default decree ordered the articles destroyed. (F.D.C. No. 57868; S. No. 19-751 F; N.J. No. 54)

##### Hexaset hexachlorophene skin cleanser, at Oak Forest, N. Dist. Ill.

Charged 6-28-73: while held for sale after manufacture by Medwick Laboratories (formerly Medical Chemicals), Melrose Park, Ill., using hexa-

chlorophene shipped in interstate commerce, the labeling of the article lacked adequate directions for use and was not exempted as an Rx drug, since the labeling lacked adequate information for use by licensed practitioners, and since the article was a new drug without an effective approved New Drug Application; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 59297; S. No. 22-372 G; N.J. No. 55)

**Levamisole succinate capsules**, at Inglewood, C. Dist. Calif.

Charged 7-16-73: when shipped by S. J. Tutag & Co., Detroit, Mich., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 59313; S. No. 54-221 G; N.J. No. 56)

**Methyltestosterone (buccal) tablets, N.F.**, at Los Angeles, C. Dist. Calif.

Charged 6-21-73: while held for sale after manufacture by Linden Laboratories, Inc., Los Angeles, Calif., using methyltestosterone shipped in interstate commerce, the strength and quality of the article, labeled in part "Android 5 (Mugets) Methyltestosterone N.F. Buccal Tablets . . . The Brown Pharmaceutical Co., Los Angeles, Calif.," differed from and fell below the N.F. standards, since the article contained approximately 84 percent of the declared methyltestosterone, and failed the N.F. test for content uniformity; 501(b). Default decree ordered destruction. (F.D.C. No. 59296; S. No. 52-643 G; N.J. No. 57)

**Ner-Vita tonic**, at San Juan, Dist. P.R.

Charged 6-28-72: when shipped by Etna Chemical Co., Inc., Madison, Conn., the circumstances of the article's manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 58098; S. No. 59-418 F; N.J. No. 58)

**Potassium chloride injection for pediatric use**, at South El Monte, C. Dist. Calif.

Charged 5-18-72: while held by International Medication Systems, Ltd., South El Monte, Calif., who had manufactured the article using potassium chloride shipped in interstate commerce, the circumstances of the article's manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; the quality and purity of the article fell below the U.S.P. standard; the required information in the package insert under which licensed practitioners can use the drug safely for its intended purposes lacked the required prominence and conspicuousness due to the smallness of the type in which the information appeared; the labeling lacked adequate directions for lay use and was not exempted therefrom, since the package insert lacked adequate information for licensed practitioners concerning safe dosages for its intended pediatric use and since the article was a new drug without an effective approved New Drug Application; 501(a)(2)(B), 501(b), 502(c), 502(f)(1). The article was claimed by the dealer, who denied the charges. The parties served written interrogatories on each other. The claimant also served requests for admissions on the Government. Thereafter, pursuant to stipulation, the claimant withdrew its claim and answer, and a default decree ordered the article destroyed. (F.D.C. No. 58023; S. No. 44-876 F; N.J. No. 59)

**Prescription and nonprescription drug stocks of a pharmacy**, at North Little Rock, E. Dist. Ark.

Charged 10-18-71: while held by Spriggs Drug Store, North Little Rock, Ark., the articles had been held under insanitary conditions, since they had been subjected to intense heat, dust, and debris during a fire; and the circumstances for the holding of the articles lacked conformity with current good manufacturing practice; 501(a)(2)(A), 501(a)(2)(B). The dealer claimed the articles and denied the charges. The Government served requests for admissions and written interrogatories. The claimant initially failed to answer the Government's requests for admission, and the Government moved for summary judgment based in part upon such failure to answer. The court allowed the claimant additional time to answer, and the claimant abandoned its claim to the prescription drugs. Subsequently, a consent decree ordered all the articles destroyed. (F.D.C. No. 57569; S. No. 35-383 E; N.J. No. 60)

**Quinidine sulfate tablets, U.S.P., Cherasulfa sodium citrate and sulfa combination tablets, Eponal theophylline, phenobarbital, and ephedrine sulfate tablets**, at Fresno, E. Dist. Calif.

Charged 5-3-73: while held by H. R. Cenci Pharmacal Co., Inc., who manufactured the articles using ingredients shipped in interstate commerce, the circumstances of the articles' manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 59183; S. Nos. 91-901/3 G; N.J. No. 61)

**Thyralis thyroid and digitalis tablets of various dosage units and colors, Parloid thyroid tablets of various dosage units and colors, digitalis tablets of various dosage units and colors, and powdered digitalis leaves**, at Dallas, N. Dist. Tex.

Charged 1-22-68: while held by Lanpar Co., Dallas, Tex., who was manufacturing the articles in tablet form from ingredients such as the powdered digitalis leaves and raw pork thyroid glands, the manufacturer's accompanying labeling for all the articles contained false and misleading claims as follows: for hypothyroidism, amenorrhea, and hypomenorrhea, for safely bringing about weight loss without benefit of rigid dieting; that obesity was a disorder of metabolism; that disturbances of digestion, assimilation, and the faulty use of foods might cause obesity in the male; that obesity was most commonly due to a "derangement and disturbance of gland system synchronous function, since each gland must work in harmonious collaboration with its fellow endocrine glands in order to produce perfect functional balance"; that obesity resulted when faulty secretions interfered with the proper utilization of stored fats; that if the gastrointestinal and glandular balance were perfect, weight would be normal; that use of the articles would cause a change toward the normal in metabolism; and that the articles were safe and effective adjuncts in the treatment of obesity—502(a); the labeling for the digitalis contained false and misleading claims that moderate doses of digitalis leaves safely and satisfactorily curtailed hunger and appetite, and were practically devoid of untoward results; and that the article was a safe and effective adjunct in the treatment of obesity—502(a); that the labeling of the Thyralis tablets, Parloid tablets, and digitalis tablets lacked adequate directions for use and were not exempted therefrom, since the labeling lacked adequate information for safe use by licensed practitioners for their intended purposes—502(f)(1); the Thyralis tablets, Parloid tablets, and digitalis tablets were dangerous to health when used as directed in their labeling—502(j); and the Thyralis

tablets, Parloid tablets, and the digitalis tablets in cartons of 1,008, 5,012, 10,024, 15,008, 20,020, 25,004, and 30,016 tablets (which were packaged in plastic bags of 28 tablets each) lacked a label on the plastic bags containing the name and place of business of the manufacturer, packer, or distributor, lacked a quantity of contents statement, lacked the established name of the drug and the established name and quantity of each active ingredient, and lacked the prescription legend—502(b)(1 & 2), 502(e)(1)(A)(i & ii), 502(b)(4). Consent decree authorized release to the manufacturer for the purpose of destroying or bringing into compliance. (F.D.C. No. 55145; S. No. 18-121 C et al.; N.J. No. 62)

**Thyroid and digitalis tablets of various strengths and colors, 5-grain thyroid tablets, liothyronin thyroid, iodized calcium, and peptone tablets, and Thyrogid thyroid & digitalis with anterior pituitary tablets**, at Las Vegas, Dist. Nev.

Charged 1-24-68 and amended 5-13-68: when shipped by Western Research Laboratories, Inc., Denver, Colo., and (one lot only of thyroid digitalis tablets) Leo Linden Laboratories, Inc., Culver City, Calif., and while held by Associated Researchers, Inc., Las Vegas, Nev., who was repacking the articles (which had been shipped in bulk), all of the articles except the liothyronin tablets were new drugs without an effective approved New Drug Application—505(a); all the 5-grain thyroid tablets and all of the tablets containing both thyroid and digitalis were dangerous to health when used as directed in the labeling—502(j); the labeling of all of the articles lacked adequate directions for use and were not exempted therefrom, since their labeling lacked adequate information for use by licensed practitioners for the articles' intended purposes—502(f)(1); the labeling of all the articles containing both thyroid and digitalis, and shipped by Western Research Laboratories, contained the following false and misleading claims: that thyroid safely accelerated cellular metabolic processes, increasing the basal metabolic rate; that Western Research Laboratories, Inc., had overcome many of the thyroid disadvantages (rapidly increased metabolic rate resulting in nervous irritability, palpitation, tachycardia, along with a fast but weak pulse) by properly balancing the thyroid dosage with digitalis; and that Western Research Laboratories' Thyrogid preparations were safe and effective adjuncts in the treatment of obesity—502(a); the labeling of the 5-grain thyroid tablets contained the following false and misleading claims: that the articles safely accelerated cellular metabolic processes, increasing the basal metabolic rate, that the articles were safe and effective adjuncts to the dietary treatment of obesity and were safe and effective in the treatment of menstrual disorders, infertility, threatened abortion, and in certain skin diseases, and the labeling of the articles was misleading due to failure to reveal the following material facts: that the articles were not safe and effective in the treatment of obesity, menstrual disorders, infertility, threatened abortion, and skin diseases, unless those conditions were associated with hypothyroidism; and that the overwhelming number of persons who suffer from such conditions were not afflicted with hypothyroidism—502(a); and the labeling of the liothyronin tablets contained the false and misleading claim that the article was an effective adjunct in the treatment of obesity—502(a). The articles were claimed by the dealer, who denied the charges. The claimant subsequently withdrew its claim and answers with respect to the lot of thyroid digitalis tablets shipped by Leo Linden Laboratories, Inc. Subsequently, the case was held in abeyance pending litigation in the District of Colorado between the Government and Western Research Laboratories, Inc., which involved the principal issues of this case. Thereafter, a default decree ordered destruction of the lot shipped by Leo Linden Laboratories, Inc.; and a consent decree ordered destruction of the rest of the articles. (F.D.C. No. 55160; S. No. 32-418 C et al.; N.J. No. 63)

#### DRUGS/Veterinary

**Ideal Calf Booster medicated rumen boluses and Ideal Cattle Booster medicated rumen boluses**, at Nampa, Dist. Idaho.

Charged 5-31-72: when shipped by Ideal Laboratory, Modesto, Calif., the articles were new animal drugs, and no approval of a New Animal Drug Application was in effect with respect to the use and intended use of the articles, and their labeling contained false and misleading claims as follows: Calf Booster boluses—to reestablish the rumen microflora, to stimulate rumen activity in unthrifty animals, to promote faster rumination, and to restore appetite; and Cattle Booster boluses—as an aid in the treatment of ketosis (acetoneemia) and milk fever, and because of its dried rumen bacteria content, to stimulate rumen activity; 501(a)(5), 502(a). Default decree ordered destruction. (F.D.C. No. 58051; S. No. 77-341 F; N.J. No. 64)

**Korum Improved Formula 3-nitro-4-hydroxyphenylarsonic acid solution for poultry**, at Kansas City, W. Dist. Mo.

Charged 6-4-73: while held for sale by I. D. Russell Co. Laboratories, Kansas City, Mo., who manufactured the article using 3-nitro-4-hydroxyphenylarsonic acid shipped in interstate commerce, the article was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to the drug's use and intended use: 501(a)(5). Default decree ordered destruction. (F.D.C. No. 59199; S. No. 48-927 G; N.J. No. 65)

**Theralin prenatal vitamin-mineral supplement and Theralin prenatal and puppy tablets**, at Temple, W. Dist. Tex.

Charged 5-24-72: when shipped by Lambert-Kay, Div. Carter-Wallace, Inc., Los Angeles, Calif., the articles were new animal drugs, and no approval of a New Animal Drug Application was in effect with respect to the article's use or intended use; and the bottle labels contained false and misleading claims that the articles were adequate and effective in dogs and cats to promote optimum growth and development of the fetus and adequate lactation, to promote good bones, tissue, and general development in newborns and during the early critical growth periods; and that each article was a conditioner generally—501(a)(5), 502(a); and while held by VETS Co., Temple, Tex., the dealer's accompanying catalog contained false and misleading claims that the articles were adequate and effective in dogs and cats (prenatal and puppy tablets) to condition females for breeding and preparing for shows and field trials, to provide for adequate lactation and accelerated nutrition needs, to promote optimum growth of the fetus, and to provide maximum protection against abortions, and (vitamin-mineral supplement) to promote good health and development generally, to prevent vitamin-mineral deficiency diseases generally, to produce "show coats," and to promote stronger bones, sound nervous systems, and better resistance to disease generally—502(a). Consent decree ordered destruction. (F.D.C. No. 58035; S. Nos. 32-242/3 F; N.J. No. 66)



## MEDICAL DEVICES

### Biofeedback galvanic skin response apparatus, at Linn, W. Dist. Mo.

Charged 6-28-73: when shipped by Mind Machine Co., Inc., El Segundo, Calif., the accompanying letters and reprint contained false and misleading claims for migraine headaches, ulcers, hypertension, various muscular disorders, tension headaches, and Reynard's disease; and the article's labeling lacked adequate directions for use for its intended purposes, since such directions cannot be written; 502(a), 502(f)(1). Default decree authorized donation to FDA for education and exhibit purposes. (F.D.C. No. 59327; S. No. 46-925 G; N.J. No. 67)

### Diapulse electromagnetic energy generator, at Latta, Dist. S.C.

Charged 9-1-72: when shipped by Diapulse Corp. of America, New Hyde Park, N.Y., the accompanying treatment chart contained false and misleading claims for tissue and bone healing, infections, bursitis, arthritis, and blood flow to peripheral areas; 502(a). Default decree ordered destruction. (F.D.C. No. 58180; S. No. 1-084 F; N.J. No. 68)

### Diapulse electromagnetic energy generators, 17 seizure actions, at Wichita, Dist. Kans.; Houston, W. Dist. Mo.; Chester, Dist. Conn.; Phoenix, Dist. Ariz.; Wichita, Dist. Kans.; College Park, N. Dist. Ga.; Fullerton, C. Dist. Calif.; Joplin, W. Dist. Mo.; Albany, M. Dist. Ga.; Monroe, W. Dist. N.C.; Miami, S. Dist. Fla.; Seymour, S. Dist. Ind.; Lubbock, N. Dist. Tex.; Clovis, Dist. N.M.; Dallas, N. Dist. Tex.; Beaumont, C. Dist. Calif.; Opportunity E. Dist. Wash.

Charged on or about 1-24-73, 2-2-73, 2-20-73, 2-9-73, 1-30-73, 2-16-73, 2-22-73, 3-8-73, 3-20-73, 3-6-73, 4-17-73, 3-5-73, 5-14-73, 4-11-73, 5-21-73, 4-4-73, 3-30-73: when shipped by Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' accompanying treatment charts and leaflets contained false and misleading claims, such as claims for bone and tissue healing, infections, bursitis, arthritis, and blood flow to peripheral areas; and the articles lacked adequate directions for use for their intended purposes, and neither adequate directions for lay use nor adequate information for use by licensed practitioners for the articles' intended use could be written; 502(a), 502(f)(1). Default decrees authorized destruction or, in the Kansas seizure actions, rendering inoperable and donation to an educational institution. (F.D.C. Nos. 58788/9, 58795, 58822, 58832, 58853, 58857, 58865, 58902, 58943, 58965/6, 58975, 58981, 59024, 59048, 59088, S. Nos. 39-805 F, 39-781 F, 12-753 F, 48-301 F, 48-504 F, 87-129 F, 47-692 F, 39-550 F, 84-034 F, 1-261 G, 523 G, 40-264 G, 35-708 G, 35-709 G, 36-355 G, 52-583 G, 99-322 G; N.J. No. 69)

### Diapulse electromagnetic energy generators, 12 seizure actions, at Washington, Dist. Columbia; Naples, S. Dist. Fla.; Pittsboro, S. Dist. Ind.; Indianapolis, S. Dist. Ind.; Etowah, W. Dist. N.C.; Tampa, M. Dist. Fla.; Swainsboro, S. Dist. Ga.; Norfolk, E. Dist. Va.; Zionsville, S. Dist. Ind.; Salt Lake City, Dist. Utah; Hoyt Lakes, Dist. Minn.; St. Petersburg, M. Dist. Fla.

Charged 3-21-73, 4-17-73, 4-6-73, 4-6-73, 4-6-73, 4-4-73, 4-4-73, 4-16-73, 5-16-73, 5-25-73, 5-2-73, 5-25-73: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' labeling lacked adequate directions for lay use for the articles' intended purposes, and adequate information for use by licensed practitioners could not be prepared; 502(f)(1). Consent decrees in the actions at Pittsboro, Ind., and Norfolk, Va., authorized destruction. In the other actions, default decrees authorized destruction or donation to FDA for educational purposes. (F.D.C. Nos. 58945, 58982, 59022/3, 59050/1, 59106, 59134, 59180, 59184, 59188, 59234; S. Nos. 10-405 G, 84-250 F, 40-265 G, 40-266/7 G, 1-269 G, 921 G, 4-948 G, 10-361 G, 35-118 F, 44-523 G, 60-109 G, 927 G; N.J. No. 70)

### Majzlin intrauterine contraceptive springs with inserter tubes and rods, at Jamaica, E. Dist. N.Y.

Charged 5-25-73: while held by Anka Research Ltd., Jamaica, N.Y., who was assembling the devices using springs and tubes shipped in interstate commerce, the articles' labeling lacked adequate warnings against unsafe use, and the articles were dangerous to health when used as directed; 502(f)(2), 502(j). Default decree ordered destruction. (F.D.C. No. 59277; S. No. 70-888 G; N.J. No. 71)

### Solarama therapeutic 2' x 2' bed-board square, at Harrisburg, M. Dist. Pa.

Charged 6-22-73: when shipped by Nolt Enterprises, Harrisburg, Pa., from Hyattsville, Md., the accompanying promotional material shipped by Solarama of Washington, Hyattsville, Md., contained false and misleading claims for arthritis, tension, nerves, virus infections, bursitis, headache, in blood-pressure control, sleeplessness, anxiety, depression, burns, skin ulcers, frostbite, postoperative healing, paralysis, hemorrhoids, cancer, leukemia, and kidney infection; and that the article was adequate and effective for the purpose of regenerating lost limbs, heart muscle, and body organs, and in bone mending; 502(a). Default decree ordered destruction. (F.D.C. No. 59328; S. No. 84-212 G; N.J. No. 72)

### Sportron electric muscle stimulators, at Indianapolis, S. Dist. Ind.

Charged 6-18-73: when shipped by Sportron, Inc., Fullerton, Calif., and while held for sale, the articles' labels lacked the name and place of the business of the manufacturer, packer, or distributor; the labeling lacked adequate directions for use for the articles' intended purposes; and the labeling lacked adequate warnings against unsafe use; 502(b)(1), 502(f)(1), 502(f)(2). Consent decree ordered destruction. (F.D.C. No. 59292; S. No. 40-285 G; N.J. No. 73)

### Prophylactics, rubber, Fiesta, at Denver, Dist. Colo.

Charged 8-2-73: when shipped by Julius Schmid Pharmaceuticals, West Paterson, N.J., the quality of the article fell below its purported quality, and the label statements "Prophylactic" were false and misleading, since the article contained holes; 501(c), 502(a). Default decree ordered destruction. (F.D.C. No. 59397; S. Nos. 43-954 G, 44-408 G; N.J. No. 74)

## NOTICES OF JUDGMENT ON Criminal Actions

### FOOD

### Midland Milling & Feed Co., and Raymond Schewe, president, Millstadt, E. Dist. Ill.

Charged 2-12-73: when shipped, white cornmeal, yellow cornmeal, and Baltz's Best white cornmeal mix had been prepared, packed, and held under insanitary conditions; 402(a)(4). Nolo contendere pleas; fines. (F.D.C. No. 58583; S. No. 20-129 F et al.; N.J. No. 75)

### Safeway Stores, Inc., Garland, N. Dist. Tex.

Charged 3-13-73 by grand jury: walnuts, sugar, tortilla chips, and popcorn were held in a building accessible to rodents and were contaminated with

rodent filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (F.D.C. No. 58588; S. No. 31-514 F et al.; N.J. No. 76)

### Switzer's, Inc., East St. Louis, E. Dist. Ill.

Charged 10-18-72: macaroni shells, long macaroni, vermicelli, cut spaghetti, lasagne noodles, macaroni, and donut mix were held in a building accessible to insects and were contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (F.D.C. No. 58134; S. Nos. 50-944/51 E; N.J. No. 77)

### Statesville Flour Mills Co., and J. Wesley Jones, Jr., secretary-treasurer and general manager, Statesville, W. Dist. N.C.

Charged 12-29-72: salt was held in a building accessible to rodents and insects and was contaminated with rodent filth, and bulk wheat was held in a grain elevator accessible to insects and was contaminated with insects; 402(a)(3), 402(a)(4). Nolo contendere pleas; fines. (F.D.C. No. 58086; S. Nos. 3-056 E, 16-554 E; N.J. No. 78)

### Wingold Macaroni Manufacturing Co., Inc. (formerly Viva Macaroni Manufacturing Co., Inc.), Richard D. McGoldrick, vice president, and Thomas Cosco, plant manager, Lawrence, Dist. Mass.

Charged 1-15-73: when shipped, spaghetti (count 1) and rigatoni (count 2) labeled in part "Thin Spaghetti [or 'Rigatoni'] David's Brand Semolina Product . . . Dist. By S. Vogel Sons East Hartford, Conn.," egg noodles (count 3) labeled in part "Shopwell Enriched Egg Noodles . . . Dist. By Daich Crystal Dairies, Inc. New York, N.Y.," shell macaroni (count 4) labeled in part "Viva Brand Macaroni Products Lawrence, Mass. . . . Medium Shell," and egg noodles (count 5) labeled in part "Pathmark Egg Noodles Enriched . . . Dist. by Supermarkets General Corp., Woodbridge, N.J.," had been prepared, packed, and held under insanitary conditions, and all such articles except the count 5 egg noodles contained insect filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Nolo contendere pleas by individuals; fines. (F.D.C. No. 57909; S. No. 29-107 E et al.; N.J. No. 79)

## NOTICE OF JUDGMENT ON Criminal Action

### DRUG

### Vernon L. Cockerill, D.V.M., t/a Schuyler Laboratories, Rushville, S. Dist. Ill.

Charged 4-9-73: when shipped, animal drugs, labeled in part "Pig Neo Nitroville . . . Nitrofurazone . . . Neomycin Sulfate . . . Neomycin Base equivalent . . . Schuyler Animal Hospital Rushville, Illinois . . . Manufactured by Schuyler Laboratories Rushville, Illinois" (counts 1 & 2); "90 gms. Bismuth per lb. For 1 ton of feed . . . Manufactured by Schuyler Laboratories" (counts 3 & 4); Pigiron Fortified . . . 100 cc. . . Each 2 cc. contains: Elemental iron . . . Benthazine penicillin G . . . Procaine penicillin G . . . Dihydrostreptomycin base . . . Neomycin base . . . Schuyler Animal Hospital Rushville, Illinois" (counts 5 & 6); and "Custom Vitamin Premix Medicated . . . Pig Pusher #3 . . . Chloret, Sulfamet, Lysine, Methionine, Vitamins, Flavoring, Iodine Thera . . . Manufactured by Schuyler Laboratories, Rushville, Illinois" (counts 7 & 8); were new animal drugs, and no approvals of New Animal Drug Applications were in effect with respect to their intended uses, and the circumstances of the manufacture, processing, and packing of such drugs failed to conform to current good manufacturing practice—501(a)(5), 501(a)(2)(B) [charged in the odd-numbered counts]; and the labeling of the articles failed to bear adequate directions for use and were not exempted as veterinary prescription drugs—502(f)(1) [charged in the even numbered counts]. The defendant filed a motion for a bill or particulars and filed a motion to dismiss on the grounds that 21 U.S.C. 351(a)(2)(B) was unconstitutionally vague. The Government supplied a bill of particulars and came on for trial before court and jury. At the conclusion of the Government's case, the court acquitted the defendant on all counts except counts 3 and 4. At the conclusion of the presentation of all the evidence, the court reserved its ruling on the renewed motion for acquittal. The jury returned a verdict of guilty. Subsequently, the court acquitted the defendant of the remaining charges saying:

"On a Motion for a Judgment of Acquittal, the sole duty of the trial judge is to determine whether substantial evidence taken in the light most favorable to the Government tends to show the Defendant is guilty beyond a reasonable doubt. *United States v. McCall*, 460 F. 2d 952 (D.C. Cir. 1972). *United States v. Andrews*, 431 F2d 952 (5th Cir. 1970).

"The relevant instruction given in the present case, No. 20, is as follows:

"In order to find the defendant guilty on either count, you must find beyond a reasonable doubt for that count."

"6. That the defendant, Vernon L. Cockerill, D.V.M., was not acting within the scope of his licensed practice as a veterinarian, when he shipped the drug in interstate commerce.

"In addition, Instruction No. 21 was given as follows:

"You are instructed that, although not licensed in Georgia, the defendant did not violate that state's law if you find that the drug was shipped there for bona fide research.

"Both of these instructions were given without objection by the Government. The second instruction leaves the matter of veterinary practice incomplete. There were no objections made by the Government to any of the instructions as given nor did the Government object to any instructions offered by the Government and not given. All instructions given or not given met with the approval of both parties. The instructions quoted above were the standard by which the jury was required to weigh the case against the Defendant on the element of veterinary practice. There was, in fact, no proof whatsoever on this one essential element; what constituted the practice of veterinary medicine in Georgia or Illinois? For present purposes there is no need to determine whether the law of Georgia or Illinois applies to the present situation since there was no proof as to the law of either state. If there is a failure to prove an essential element, the Defendant is entitled to an acquittal. *United States v. Blattel*, 340 F. Supp 1140 (ND Iowa 1972).

"In its memorandum in opposition, the Government asserts:

"There is no need to dwell at length on the various facets of veterinary medicine that constitute the practice of veterinary medicine since the acts performed by Dr. Cockerill in Georgia are so universally within the scope of the practice of veterinary medicine that the jury was afforded a full factual basis for making a determination as to whether defendant was or was not engaged in the licensed practice of veterinary medicine in connection with the Bismuth Premix referred to in Counts III and IV." (p. 3)

"The Government's contention is not well taken. The practice of veterinary medicine in the States of Illinois and Georgia is defined by the statutes of these states. *Collins v. Texas*, 273 U.S. 288, 296 (1912) (opinion of Holmes, J.). There was no request by either party to take judicial notice of the applicable statutes and none was taken. An attempt by the Government to have the Court take judicial notice of the applicable statutes after the verdict is inappropriate, nor do discussions during the trial with counsel in chambers about the law on this subject serve to instruct the jury in its deliberations.

"It is clear that the jury received no evidence as to the law of Georgia or Illinois nor was the jury instructed by the Court as to the law in either jurisdiction except to the limited extent noted above. The jury received no evidence as to this essential element of the offense.

**"Conclusion:**

"The Government has failed to prove all the elements of the offense charged in both Count III and IV of the information in that it failed to prove what constituted the practice of veterinary medicine in Illinois or Georgia." (F.D.C. No. 57983; S. No. 43-847 E et al.; N.J. No. 80)

**NOTICES OF JUDGMENT on Injunction Actions**

**Pratt Equity Exchange, Inc.,** a cooperative association, **Donald L. Finchan,** president, and **Curtis E. Huit,** general manager, **Pratt, Kans.** Charged on or about 5-27-71 in complaint for injunction: that the defendants were engaged in the operation at Pratt, Kans., of a grain-storage facility which included a flat storage building, that the defendants were shipping wheat in interstate commerce which contained rodent filth and which had been held under insanitary conditions in the flat storage building; and that the defendants were well aware that their activities were in violation of the law; 402(a)(3), 402(a)(4). The court issued a temporary restraining order enjoining such violations. Subsequently, a consent decree of permanent injunction was issued enjoining the violations complained of, enjoining the interstate shipment of wheat for human consumption held at the defendants' flat storage building unless and until the flat storage building was thoroughly cleaned, renovated, and rendered suitable for wheat storage, the insanitary conditions were eliminated, and all of the wheat on hand in the flat storage building was destroyed, brought into compliance with the law, or diverted into use as animal feed. (Inj. No. 610; S. Nos. 27-439/41 E; N.J. No. 81)

**Hortense Spier, Inc., and Bing Spier,** president, **Palisades Park, Dist. N.J.** Charged 12-22-69 in complaint for injunction: that defendants were engaged at their plant at Palisades Park, N.J., in preparing, packing, holding, and distributing in interstate commerce frozen cream-type pies, which contained *E. coli* and which had been prepared, packed, and held under insanitary conditions; and that the defendants were well aware that their activities were in violation of the law; 402(a)(3), 402(a)(4). A consent decree of preliminary injunction was filed which enjoined the violations complained of, which enjoined the continued interstate distribution of such foods unless and until a number of specified methods, facilities, and controls concerning sanitation were effected and the pies on hand were destroyed or found to be free of filth. Subsequently, the defendants ceased to be involved in the baking business and, pursuant to stipulation of the parties, the injunction was dismissed. (Inj. No. 587; S. No. 222-021 C et al.; N.J. No. 82)

**NOTICES OF JUDGMENT on Miscellaneous Actions**

**Cyclamates in soft drinks, foods, and nonprescription medicines, San Francisco, N. Dist. Calif.**

Charged 11-5-69 in complaint for injunction by **Leo Rudolph Rossi, Robert Haxton, George Velis, Louis Mosconi, Joanne Rossi, Paul Stathis, and Patricia Champlain** (as representatives of a class so numerous that joinder was impossible), against **H.E.W. Secretary Robert H. Finch** and **FDA Commissioner Herbert L. Ley, Jr.**, to restrain enforcement of an Act of Congress: that this action challenged the section of the Federal Food, Drug, and Cosmetic Act known as the "Delaney Clause" (21 U.S.C. 348(c)(3)(A)), as being in violation of the due process clause of the 5th Amendment to the U.S. Constitution, that, by virtue of the Commissioner's order deleting cyclamates from substances generally recognized as safe, the plaintiffs would be deprived of the free and nonrestricted consumption of noncaloric soft drinks, foods, and nonprescription medicines containing cyclamates; that the Commission's order itself was not challenged as being unconstitutional per se, but the Delaney Clause authorizing the issuance of the order was contested as being unconstitutional; that plaintiff would suffer irreparable damages; and that there was no adequate remedy in the ordinary course of law. The plaintiffs also requested that a three-judge court be convened.

The Government moved to dismiss the action on the grounds that the plaintiffs had not been irreparably injured, there was no jurisdictional basis to convene the requested three-judge district court, and the Delaney Clause, 21 U.S.C. 348(c)(3)(A), did not violate constitutional rights.

The three-judge court ordered the action dismissed, saying:

"The complaint is accompanied with a request that a three-judge court be convened under the provisions of 28 U.S.C. §§ 2282, 2284. The single judge who heard this request concluded that an injunction was being sought which would restrain the enforcement and operation of an Act of Congress and accordingly a three-judge court was convened to hear and determine the cause.

"The defendants filed a motion to dismiss the action for failing to meet the jurisdictional requirements of a three-judge district court. This Court concludes that the motion should be granted.

"Plaintiffs contend that the Commissioner's orders deleting all cyclamates from the list of substances that are generally recognized as safe for their intended use and restricting the use and sale of foods containing cyclamates were made under authority found in the Delaney Amendment. In this way plaintiffs claim standing to attack the constitutionality of the Delaney Amendment because they are aggrieved by the administrative orders in question. However, the Delaney Amendment is operative only upon petitions which are filed to determine the safety of new food additives or those that were not exempted at the time the Delaney Amendment was enacted in 1958. See 21 U.S.C. §§ 321 (s), 348. The cyclamates are among those food additives which were exempted by inclusion in the list of additives generally recognized as safe at the time Section 409 was added to the Federal Food, Drug, and Cosmetic Act. 24 Fed. Reg. 9368 (1959). The recent orders of the Commissioner removed cyclamates from

the list and imposed restrictions on its use. See 34 Fed. Reg. 17063 (1969). Such action by the Commissioner, under properly delegated authority by the Secretary, is authorized under 21 U.S.C. § 371, without any reliance on the provisions of 21 U.S.C. § 348. The validity of such orders is reviewable by the Courts of Appeals of the United States and not by the District Courts. 21 U.S.C. § 371(f).

"Since plaintiffs' standing to contest the constitutionality of the Delaney Amendment depends upon the relationship of this Act of Congress to the administrative orders of the Commissioner restricting the use of cyclamates, and there being no such relationship, the action must be dismissed as one which fails to state a claim for relief within the jurisdiction of this court." (Misc. No. 137; N.J. No. 83)

**Cyclamate-containing soft drinks, action for judicial review in U.S. Court of Appeals for Sixth Circuit.**

Petitioned 11-10-69 by **Nehi-Royal Crown Beverage Co., Inc., Grand Rapids, Mich.,** (Sixth Circuit), against **H.E.W. Secretary Robert H. Finch** for review of order removing the artificial sweetener, cyclamate, from list of substances generally recognized as safe for use in foods: that petitioner was engaged in bottling and distributing a variety of soft drinks including Diet-Rite Cola and Gatorade, that these beverages contained cyclamate in minimal amounts; that petitioner had in its Grand Rapids warehouse \$250,000 worth of cans and returnable bottles, which cans and bottles bore the imprinted word "cyclamate"; that the October 18, 1969, order was illegal, unjustifiable, and not based upon reasonable scientific findings; that the order had the effect of confiscating and making worthless all of such cans and bottles; that the H.E.W. Secretary be ordered to file with the court the record of proceedings upon which the cyclamate removal order was based; that petitioners be permitted to adduce additional evidence supporting petitioner's claim that such order was not based upon reasonable medical facts; and that such order be stayed.

Thereafter, pursuant to Rule 17(b) of the Federal Rules of Appellate Procedure, the Government filed a certified list of the record upon which the order was based together with copies of the listed documents. The Government served its brief on the petitioners, setting forth the historical background of development, testing, and unprecedented use and consumption of artificial sweeteners such as cyclamates, and arguing that there was evidence that cyclamates were not generally recognized as safe, and that removal from the GRAS (Generally Recognized As Safe) list of substances was warranted by the Delaney Amendment. The petitioner thereupon withdrew its petition on the grounds that the record underlying the cyclamate removal order had been furnished to the petitioner, and that the record revealed that additional medical testimony could not change the order so long as the Delaney Amendment remained the law. (Misc. No. 138; N.J. No. 84)

**Trisulfaminic trisulfapyrimidines, phenylpropanolamine hydrochloride and pheniramine-pyrimidine maleates combination tablets, and Trisulfaminic suspension, Wilmington, Dist. Del.**

Charged 11-3-69 by **Sandoz-Wander, Inc.,** a Delaware corporation, successor to **Wander Co.'s Dorsey Laboratories Division, Lincoln, Neb.,** against **H.E.W. Secretary Robert H. Finch** and **FDA Commissioner Herbert L. Ley, Jr.,** in complaint for declaratory judgment: that Trisulfaminic tablets and suspension were not new drugs, and the Drug Amendments Act of 1962 did not apply to such products; that such products were not misbranded; that FDA had advised plaintiff on July 11, 1957, that the products were not "new drugs"; that, on March 18, 1966, the FDA Commissioner had written the plaintiff that the products were not generally recognized as safe and effective for the conditions for which they were currently offered, and FDA formally withdrew any previously offered opinion that the products were not new drugs, and that FDA regarded the products as new drugs; that the plaintiff submitted New Drug Applications, but was advised that the information presented was inadequate; that action on the products was deferred until implementation of the NAS/NRC review; that the NAS/NRC review concluded that the products were new drugs without effective approved New Drug Applications; that, because of plaintiff's continued belief that its products were not "new drugs" under the statute, plaintiff withdrew its New Drug Applications on October 31, 1969; and that the defendants had taken the position that there was a lack of "substantial evidence" that short-acting systemic sulfonamides, including the plaintiff's product, were effective in respiratory infections.

The defendant's answer to the complaint denied that this was an actual justifiable controversy and asserted that the plaintiff's products were "new drugs," and asserted that the product's labeling contained false and misleading claims for infection of the upper respiratory tract. The plaintiff served written interrogatories on the defendants. Thereafter, plaintiff stated that it no longer manufactured the products, that the pipeline of distribution of the products was now clear of the products, and that plaintiff had no intention of resuming the manufacture of the products. Upon such facts, the parties agreed that the action was moot; and, upon stipulation, the action was dismissed. (Misc. No. 136; N.J. No. 85)

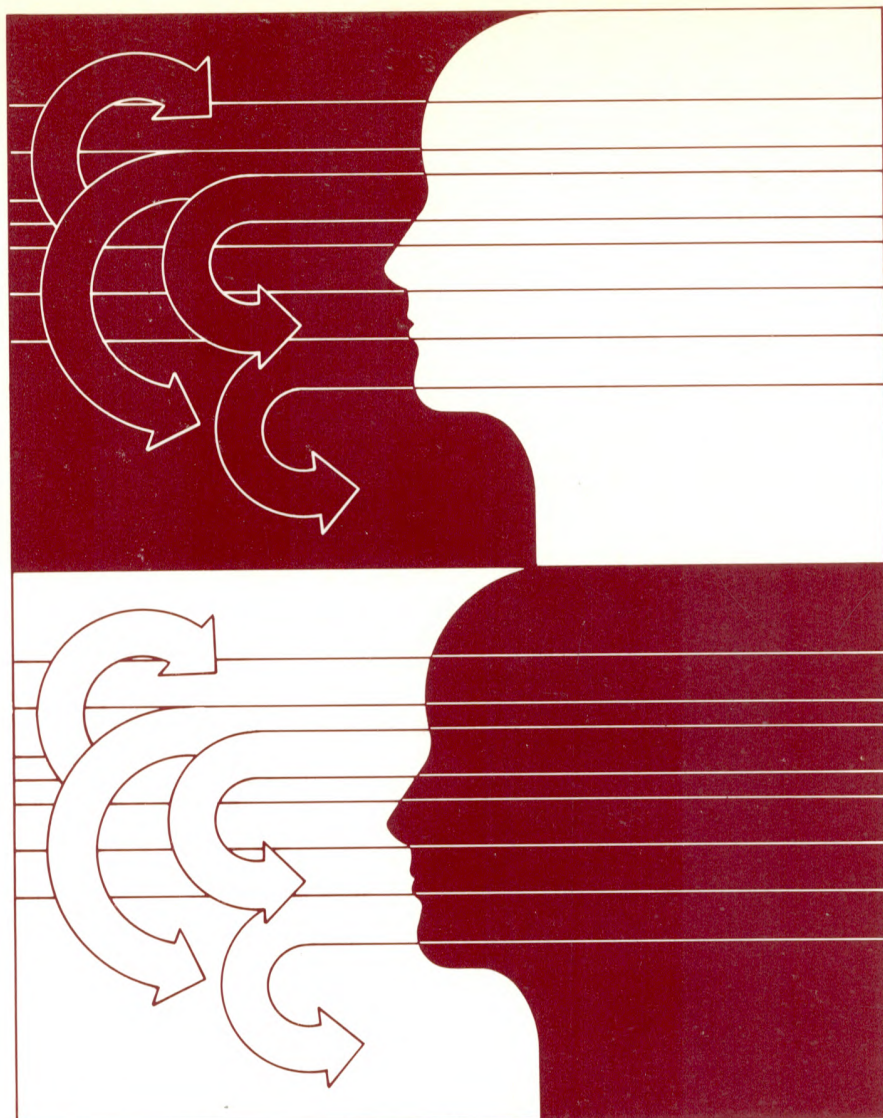
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Notices of Judgment are prepared by Food and Drug Division, Office of the General Counsel, DHEW.

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

Alexander M. Schmidt, M.D., *Commissioner of Food and Drugs*  
Washington, D.C., July 1, 1974





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