

# FDA CONSUMER

December 1977-January 1978

Healthful Holiday Fare









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# This Month

**A**lchemists, economists, and efficiency experts have long sought to figure out how to make more out of less. FDA isn't quite ready to teach any alchemists who might still be seeking the secret of instant wealth how to turn lesser metals into gold. But the Agency does have some ideas about how to keep more money in the pockets of the people who foot the bill for the Nation's health care—and that means just about all of us—by making less use of x-ray machines.

More than 240 million x-ray examinations are conducted in this country every year, and it is estimated that as many as 30 percent of these could be eliminated. That would save quite a bit of money, and it would reduce human exposure to the often helpful but always potentially hazardous effects of x radiation. There's more on *Reducing X Rays and Health Costs* on page 16.

There is little doubt that for many people fewer calories would mean better health. That's easier said than done, however, especially during the holiday season when food and drink are thrust upon us at every turn. Still, it is possible to cut down on the richness of holiday food, and it can be done without resorting to a Spartan menu. We offer some ideas in *Healthful Holiday Fare*.

Regardless of the season, much of the food most of us eat contains additives. These additives may be used to preserve the food, to improve its taste, to enhance its color, or for a variety of other purposes. In interviews published in FDA CONSUMER earlier this year a Columbia University nutritionist and a consumer advocate spoke out on additives and other aspects of food and the marketplace. This month we present an industry view on these matters from Richard Hall, vice president for science and technology of McCormick and Company.

Speaking of speaking out, an FDA advisory panel has done just that on ear wax and some of the enduring myths about its causes, effects, and treatment. For a look at what the panel said, see *Now Hear This*.

Modern science and technology have been able to improve on most of the folk remedies that are a part of our medical heritage. That doesn't mean, however, that the plants used for medicine a hundred or even a thousand years ago have been discredited as the source of effective ingredients. To the contrary, many of the most effective drugs used today are traceable to the medical practices of ancient peoples. There's a report on *Our Medical Debt to the Distant Past* beginning on page 12.

**Inside Front Cover Photo:** *The normal, healthy ear has its own protective system. On occasion this natural defense system may need help, but not as much as some people seem determined to give it. For a brief explanation of how the ear protects itself, and some pointers on ear care, turn to page 23.*

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**FDA CONSUMER** was previously known as **FDA PAPERS**. Section 705 [375] of the Food, Drug, and Cosmetic Act:

(a) The Secretary shall cause to be published from time to time reports summarizing all 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.

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**Cover Design:** Helen Vickers and Michael David Brown



# Update

## Quick Action Urged on Saccharin Warning

*In March 1977 the Canadian government announced the results of a test showing that the artificial sweetener saccharin caused bladder tumors in animals. As a result of the Canadian study and other evidence, FDA proposed to discontinue saccharin's use as a general purpose food additive. The legal and scientific reasons for FDA's proposed action were explained in The Saccharin Ban in the May 1977 FDA CONSUMER. Here's an update.*

The Food and Drug Administration has urged manufacturers of saccharin-containing foods to take immediate steps to place a warning on the labels of their products.

The Agency issued tentative guidelines to assist manufacturers in labeling their products and began drafting final guidelines following a public hearing that was held shortly after the President signed legislation requiring a warning label.

The legislation requires that all food containing saccharin that is introduced into interstate commerce 90 days or more after the legislation was signed must carry the warning statement.

The legislation, called the Saccharin Study and Labeling Act, also puts an 18-month moratorium on any regulatory action by FDA to remove saccharin from the market. FDA had proposed a ban on saccharin in foods in April following the receipt of a Canadian study which confirmed earlier evidence that saccharin causes cancer in laboratory animals. The legislation also requires that FDA further study saccharin as well as the relationship between animal studies and humans.

FDA Commissioner Donald Kennedy said: "All the available evidence demonstrates that saccharin can cause cancer in test animals, and we have every reason to believe that it also causes cancer in people. It is essential that the public understand the risks associated with the use of saccharin-containing products so that they can make an informed choice in the marketplace. We urge manufacturers to put this warning label on their products as quickly as possible."

As directed by Congress, the warning label says: "Use of this product may be hazardous to your health. This product contains saccharin which has been determined to cause cancer in laboratory animals."

The tentative guidelines to assist manufacturers in complying with the warning label requirements were published in the November 15 FEDERAL REGISTER.

Under the tentative guidelines, all food containing

saccharin, including saccharin sold in packages as a sugar substitute, must carry the warning label. The only exemption is saccharin packed in bulk form for subsequent use in the manufacture of food.

FDA's tentative guidelines also provide that:

- The warning label must appear in a conspicuous place on the label. It must appear on the principal display panel, parallel to the name of the product.
- Reusable lithographed bottles and bottles that do not have printed labels can have the warning affixed to a tag around the bottle neck.
- Multiunit retail packs such as soft drink cartons must have the warning statement on each principal display panel, though the individual packages do not have to carry the warning.

FDA will be issuing additional notices in the FEDERAL REGISTER to implement other provisions of the Saccharin Study and Labeling Act.

## Pneumonia Vaccine Licensed

*Before any vaccine can be placed on the market in the United States, it must be licensed by the Federal Government. FDA's responsibility for licensing and testing vaccines was covered in an article in the July-August 1977 issue of FDA CONSUMER entitled Making Sure Biologicals Are Safe. Here's an update.*

The Food and Drug Administration has licensed a vaccine against pneumococcal pneumonia, a common form of pneumonia.

There are no other vaccines on the market to prevent this form of bacterial pneumonia, which is a serious and sometimes fatal lung infection.

A similar but less broadly effective pneumonia vaccine was developed in the 1940's under the sponsorship of the Armed Forces, but its use was abandoned and further research ended since it was generally assumed at that time that antibiotics would solve the pneumonia problem.

Despite the wide use of antibiotics, however, pneumonia today is the fifth leading cause of death in the United States, killing an estimated 25,000 Americans annually. The type of pneumonia against which the vaccine protects accounts for a major portion of these deaths. The vaccine is effective in at least 80 percent of the people who receive it.

The company which has been licensed by FDA to sell the vaccine, Merck Sharp & Dohme, West Point, Pennsylvania, expects to begin commercial distribution early in 1978. The brand name of the vaccine is "Pneumovax" (pneumococcal pneumonia vaccine).



The vaccine is expected to be particularly useful for the elderly and for people over the age of 2 with serious chronic diseases, since these groups face an increased risk of dying from pneumonia.

Pneumonia is not generally fatal in healthy young adults and children in the United States, and these groups are not considered prime targets for the vaccine.

The incidence of pneumonia increases under crowded conditions, so the vaccine also is expected to be used in nursing homes and other institutions.

Preliminary studies suggest that the vaccine also is useful in sickle cell anemia patients, since they are at especially high risk from severe pneumonia infections. Studies also are under way to determine the effectiveness of the vaccine in preventing middle ear infection in infants.

Reactions to the vaccine, such as soreness and redness at the injection site, are common, but usually last no longer than 48 hours.

Since the vaccine is entirely derived from inactivated or killed bacteria the vaccine itself cannot cause pneumonia.

## FDA Shapes Medical Device Regulations

*The Medical Device Amendments of 1976 gave FDA authority for the first time to require premarketing approval of medical devices for safety and effectiveness. The legislation also made it easier for FDA to remove hazardous devices from the market and made other important regulatory changes. The new law was described in the October 1976 FDA CONSUMER in an article entitled Medical Devices: Strengthening Consumer Protection. Here's an update.*

FDA has issued a number of proposed or final regulations to implement major provisions of the Medical Device Amendments of 1976. Following is a summary of actions taken by the Agency:

**Registration:** A final rule has been issued setting procedures for manufacturers to register with FDA all establishments in which medical devices are produced. Manufacturers of components and accessories for medical devices and firms that develop device specifications or distribute, repack, or import devices also must register. Firms must tell FDA the names of their products, list each of their facilities, designate an official to be a contact point with FDA, and update the information each year. More than 3,500 firms have registered since regulations were proposed in 1976.

**Premarket notification:** The law requires manufacturers to notify FDA at least 90 days before marketing a new medical device. Final regulations on premarket notifications require manufacturers to supply proposed labels, advertising, directions for use, and a statement about how the device is different from or similar to products already on the market. If

requested, FDA will hold the information confidential for the 90-day period if firms can show that the device is not already on the market, that intentions to market have not been made public, and that plans are known only to the firm and its contractors. The manufacturer must also agree to notify FDA as soon as it intends to sell the product.

Manufacturers must notify FDA of their intention to market any new device. In addition, certain devices must be approved by FDA before they can be marketed. Notification by a manufacturer of intention to market a new device should not be confused with FDA marketing approval for those devices requiring it.

**Classification:** A proposed rule has been published explaining how FDA will classify all medical devices into one of three regulatory categories. The document amplifies definitions in the medical devices amendments. The amendments require that each medical device be placed in one of the following categories:

- **Class I—General Controls:** All devices are subject at a minimum to general controls which include, among other provisions, the registration of manufacturers and recordkeeping requirements. Devices placed in Class I are subject only to these general controls.

- **Class II—Performance Standards:** Devices for which general controls alone are insufficient to assure safety and effectiveness will be required to meet performance standards established by FDA.

- **Class III—Premarket Approval:** All implanted and life-supporting devices will require FDA approval for safety and effectiveness before they can be marketed unless FDA determines that premarket approval is not necessary. Premarket approval can be required for other devices if general controls or a performance standard are insufficient to assure their safety and effectiveness.

Although formal classification procedures have only been proposed, FDA efforts to classify products have been underway for several years. About 90 percent of all medical devices have already been tentatively classified by expert panels. When complete, FDA expects that about half of all medical devices will be in Class I (general controls), 45 percent in Class II (performance standards), and 5 percent in Class III (premarket approval).

**Banned Devices:** FDA has published proposed rules for banning certain medical devices. Under the proposal, medical devices can be banned for being deceptive or for posing unreasonable risk of injury or illness. Before banning a device FDA will review all available data, and will determine whether changes in labeling or instructions alone can remove the risk.

The proposed banning regulations would make it possible for FDA to remove products from the market without having to take individual actions at each point of manufacture or sale.



**Product Listing:** The medical device legislation requires FDA to compile a list of all medical devices in use in the United States. The system for compiling the list proposed by FDA calls for firms that manufacture, assemble, process, or import devices to list with the Agency the common or usual name and the trade name of every medical device produced for human use.

All product listing information supplied by manufacturers will be available for public disclosure. Because provisions in the medical device legislation require product listing, FDA will not wait until the proposed listing regulations are final to initiate listing activities.

**Administrative Detention:** FDA has announced the procedures it will follow to prevent the distribution of devices believed to be adulterated or misbranded. The regulations enable FDA to prevent movement or shipping of possibly defective products for up to 30 days while the Agency gets court orders or carries out other legal or enforcement procedures to remove the products from the market.

### Patient Labeling Now Required for IUD's

*An article in the June 1977 FDA CONSUMER explained FDA's intention to require that women who want to use intrauterine devices for contraception are fully informed on their benefits and risks. The article was entitled Informing Women About IUD's. Here's an update.*

A special brochure now must be supplied to women before intrauterine devices (IUD's) are inserted by their physicians.

The IUD brochure requirement went into effect November 7, 1977. IUD's are used for contraception by about three million women in the United States.

The brochure describes in simple language the uses and possible risks associated with IUD's and is intended to assist women in deciding about using an IUD as a method of birth control.

The new IUD brochure for patients is part of a continuing FDA effort to ensure that full information is available to users of certain prescription drugs and medical devices.

Said FDA Commissioner Donald Kennedy: "I am firmly committed to the general concept that consumers must participate more actively with their physicians in choosing drugs and medical devices such as IUD's."

FDA in 1970 began requiring that benefit and risk information be provided for women who take birth control pills. Regulations requiring that special patient information accompany drugs containing the female sex hormone estrogen became effective October 18, 1977.

In announcing the new IUD patient information requirement, Commissioner Kennedy said: "There are advantages and disadvantages to every method

of contraception and it is up to the individuals or couples to decide which method is best for them. FDA's goal is to make sure that the best information is available on which to base such decisions.

"Our new regulations," said the Commissioner, "require manufacturers to print patient brochures in quantities larger than the number of IUD's produced, so that this information can be readily available in clinics, physicians' offices, and health facilities. We want to be sure people know that these brochures are available. We encourage women to read them carefully and to discuss the information in the brochure with their doctors."

The brochure describes the IUD, how effective it is, what a woman should discuss with her doctor before the IUD is inserted, how to check to see if the IUD is still in place and what to do if it is not, what side effects may occur, what adverse effects to report to the doctor, and what to do if pregnancy occurs with the IUD in place.

The regulations also establish, for the first time, uniform professional labeling for IUD's.

The required information directed to physicians must include instructions about inserting the IUD, under what conditions removal should be considered, what may go wrong during use, and when an IUD should be replaced or not used at all.

### Action Planned on Safety of Eye Cosmetics

*Cosmetics—what they are, what ingredients go into them, and how they are regulated—were the subject of an article in the April 1977 FDA CONSUMER. This primer on a group of products that almost all of us use every day was entitled Cosmetics: The Substances Beneath the Form. Here's an update.*

FDA has announced its intention to propose regulations requiring that mascara and other eye area cosmetics contain an adequate preservative system. The action was prompted by several reports of corneal ulceration associated with the use of contaminated mascara.

The proposal will include not only a requirement for preservation sufficient to protect an eye area cosmetic against contamination during manufacture, processing, packing, or storage, but also a requirement that the cosmetic be adequately preserved to withstand contamination under ordinary conditions of use.

In another action involving the regulation of cosmetics, FDA has issued a rule permitting sellers of cosmetic products distributed by direct mail to list ingredients in the sales catalog, or in a brochure enclosed in the cosmetics package, rather than on the product label. An FDA regulation that went into effect April 14, 1977, requires that labels affixed to all cosmetics must list the ingredients in the product in descending order of predominance.



# Food Additives: An Industry View

*Few subjects generate as many letters to the Food and Drug Administration as food and color additives. Consumers' questions range from why and how additives are used, to what they are made of, to how they are regulated. In this interview, Dr. Richard L. Hall, vice president for science and technology of McCormick and Company, discusses some of the issues often raised about the use of food additives. He was interviewed by Wayne L. Pines, FDA's deputy assistant commissioner for public affairs. This is part of a continuing series of interviews with people outside FDA in an effort to stimulate discussion on important matters of public interest and concern.*

**Q.** *Dr. Hall, one of the subjects most on the public's mind today is food additives. Increasingly, consumers are expressing concern about the need for food additives, and about their safety. What is your view of this problem?*

**A.** The issue of food additives raises three different questions. One is the question of hazard. Are consumers really concerned about the hazards? Second is the question of the usefulness of food additives. Why do we use additives? And third, I think it raises the question of how do we know what we know about them. The thing that many consumers find the most disturbing is the lack of certainty in this area, the fact that we are constantly changing our minds.

**Q.** *Let's take hazard first. Many consumers think food additives pose a real hazard to them. Are these fears justified?*

**A.** I think not. If we look at the real hazards posed by food, food additives are at the absolute lower end of the scale. Without any question, the food hazard that is most important to the public in terms of illness, and certainly high up in terms of food-related cause of death, is microbiological illness, foodborne disease. The second is nutritional hazards and, in terms of contributing to early death, it may well be more important than microbiological hazards. The other hazards are environmental and naturally occurring toxic materials and contaminants in foods and pesticide residues. Then come food additives.

**Q.** *If that's the case, why is it that FDA surveys have shown that the public perceives food additives to be a greater risk than microbiological contamination or nutrition or some of the other problems you have identified?*

**A.** Unquestionably the most important reason is that food additives, like pesticides, are chemicals that ordinary people simply do not feel comfortable with. They don't understand the long, complicated names, and something you don't understand, you naturally fear. A second reason is that people have a false sense of control over the microbiological and nutrition hazards. They tend to think, "Well, I can manage that. I can prevent foodborne illness. I can control my diet." In fact, of course, they don't. Statistics compiled by the Center for Disease Control give evidence of that. We have millions of cases of foodborne illness caused by microbiological contamination. The number of obese people in the population is one evidence of nutritional hazards.

But people do have a feeling of control over these hazards, and indeed, in a sense, these hazards are within their control if they simply choose food properly, and exercise the elements of sanitation in its preparation. Now, people don't have this sense of control over pesticide residues and food additives. They are put there by someone else. And we tend to fear what we cannot control.

**Q.** *Are you saying there is no reason at all to fear the addi-*

*tives in the food supply?*

**A.** People should not fear food additives. Food additives right now are getting enormous amounts of regulatory and scientific attention from FDA, from some other agencies indirectly, and from industry. In fact, in proportion to the actual hazards, they are getting far more than their share of attention. So I think there is no basis for any fear.

It doesn't mean that we should forget all about them, that we shouldn't make any effort to regulate them wisely, that we shouldn't engage in periodic reviews of their safety. Obviously we should do all of these things. That is part of the reason the hazards are low. But we shouldn't live in an almost paranoid fear that we are being poisoned by these additives because in fact we are not.

**Q.** *How do you respond to a consumer who says, "Every day we are finding out new things about old food additives; every day we are finding out new means to detect hazards. The industry has not done the kinds of modern tests which would be required for new food additives, and the consumer therefore should be very cautious about the use of existing additives."*

**A.** You raised several questions there. Let me try to answer them one by one. One of the most unsettling things about safety evaluations is the fact that they are based on a dynamically changing science, a rapidly advancing one. There is no question about it. Analytical chemistry has advanced so rapidly in the last 20 years that we now are able to detect tiny traces of things we never knew were there. Worse than that, we can feed things at high doses to test animals and detect that capacity for harm without being able to say with any assurance what that means for human safety. And this is where the uncertainty and caution arise.



Now, we don't want science to hold still. We must constantly improve methodology. And that inevitably means that the test that was done ten years ago often isn't adequate by modern day standards. The question then becomes, what do you do about it? My response is that we have to look at the margin of safety provided by the testing done ten years or five years ago. If that margin is adequate, then you probably don't need any additional information. But if more modern test methods or later information suggest that you should have additional evidence, then you had better go get it.

**Q.** *And the industry position has been that while that new evidence is being sought, the product or ingredient remains on the market. Why not take it off the market while that new testing is going on?*

**A.** If there were any meaningful hazard involved, then I readily agree it should come off the market while the testing is being done. But in fact we operate with such enormous safety factors in toxicology testing and safety evaluation that that step is seldom necessary. The customary safety factor is at least 100 to 1. That means you take the highest level that causes no apparent adverse effect in test animals, and you let one one-hundredth of that amount into the human diet. In fact, the safety factor usually is much wider than that. It is also much wider than the safety factors with which we consume many of the chemicals nature—more or less sloppily—puts in our food. So we have large safety factors for food additives, and I think therefore we can leave them on the market while new testing is going on, for the most part.

**Q.** *Are you concerned with the synergistic effect of food additives, that is, with how they combine with each other to cause an effect different from that which we can ex-*

*pect from each alone?*

**A.** Yes. And this probably is the most difficult issue of all to deal with. We must consider any substance not in isolation, but in terms of how it reacts in the total environment, in the total diet of the individual, along with everything else, both natural and artificial. We tend to consider the things we put in intentionally as somehow separate and ask how those are going to react with each other. That isn't the real question. The question is how do all chemicals, natural and synthetic, in our food react with each other. The natural chemicals pose a greater hazard partly because the safety factors are smaller, and partly because we don't have much control over them.

**Q.** *What kind of testing has been done on this problem?*

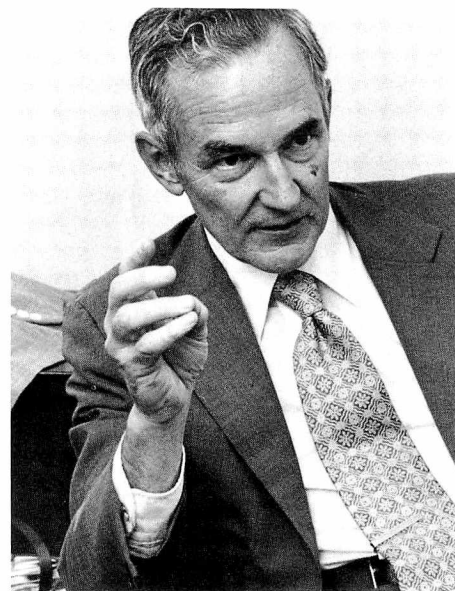
**A.** Some work has been done on this and I'm sure that more will be done. But the task is endless because of the number of substances involved. So it is never going to be completed.

**Q.** *What's been found so far?*

**A.** In general, we're finding a pattern more of antagonism, meaning reduced toxicity, rather than enhanced toxicity. That is, most chemicals do not increase the toxicity of others. But we never will have the complete answer to this problem. We are going to have to fall back on—and it's not a bad fall back—on a very practical way to go, and that is to rely on the relatively wide safety margins we now have.

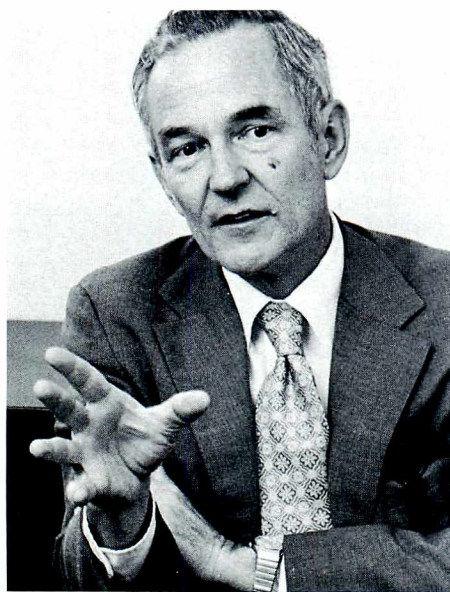
**Q.** *Before we let a new additive on the market, should we require tests to see how it reacts with other chemicals?*

**A.** Which other chemicals? If we have some specific combination to wonder about, then we should



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test. But we can’t do many, or do them randomly. We would then never introduce any new food additive of any sort, because testing each substance against every known possible additive or natural constituent of a food can never be done.

**Q.** *Well, why do we need so many additives?*

**A.** We’ve always used a fairly large number. If you look at the cookbooks of a century ago, you will see additives for most of the purposes for which we use them today. Some—such as the spices—are even the same, though cleaner now. But most of the additives used then were crude, unknown, natural mixtures, unevaluated for safety, like marigold flowers or grass juice for color, or “roach alum” for curing pickles, or a copper kettle for greener pickles. Additives today are defined for identity and purity, and evaluated for safety. We recognize the individual nutrients, and have identified many of the individual chemicals in natural flavors, so it seems like many more. But we ate most of them anyway. Now they’re cleaner and safer.

**Q.** *Industry uses a lot of food additives that are functional, that serve a purpose, such as preservatives. They provide an obvious benefit to the public because they make food last longer. How about the additives that don’t serve functional purposes, such as flavors or colors? Why should we run any risk whatsoever when the benefits are esthetic rather than functional?*

**A.** That is a good question and one frequently asked. The first point I would make is that we ordinarily should not run any definable risk with any additive, considering the type of food supply we have. If we were living without enough food, then we obviously would have to run certain risks. But in the United States and Western countries we don’t have to

run any definable risk. *By that I mean* a demonstrated risk, not a hypothetical one, because you can hypothesize about anything. Any substance is toxic at some level, even water. So I don’t think we should accept any real risk in our food supply, even from functional additives such as preservatives. There are rare cases where—as with nitrite—we have no acceptable alternatives. Then we should simply do the best we can to compare and minimize risks.

The second point I would make is that we differ widely in our tastes. I don’t mean just flavor. What I regard as acceptable and desirable in life another person may not. So some of these additives permit us to satisfy our personal tastes.

A third point is that we usually don’t pick food on the basis only of nutrition and safety. We pick the things we like or that are convenient and that we can afford. And therefore substances which help in those ways, which make food more acceptable or more convenient or less costly, have a utility. We should take advantage of these additives as long as there is no definable, measurable, eliminatable risk.

**Q.** *What is the role of industry in trying to influence the buying and eating habits of the public so that food selection is not based on appearance or convenience, but on nutrition?*

**A.** The desire for flavor and color and texture and mouth feel are not necessarily drummed into us. These are things that are already part of each of us; they make us enjoy food so we will eat. We’ll never select food on a completely functional non-sensory basis. We will always be picking food partly because we like it.

But we can modify those choices, and I think industry does have a role in that, as does Government and every other segment of society. I think it is very difficult to defend some advertisements and promotion which tend to push people into poor food choices.

But beyond that, probably the most intelligent thing industry could do in its own long term best interest would be to do more work in real consumer education and to avoid some of the obvious abuses in advertising and promotion.

**Q.** *To pursue the point further about color additives, why should orange color be added to oranges? Why can't people buy oranges in their natural color, which often is green?*

**A.** Let's get back again to what each of us as an individual considers important. Food is an area where each of us tends to be very cavalier about other people's preferences and defensive about our own. We don't want anyone else telling us what to do, but we are perfectly willing to tell someone else. The obvious answer with oranges is that if oranges were green or brown or some intermediate mixture of color, people may stop eating oranges, which, of course, is of immediate concern to the citrus industry, but it should be of general nutritional interest to everyone. Color does play a role in food selection. There is no point in arguing how much is culturally adapted and how much of it is inherent. The fact is that it exists.

**Q.** *What about the charge that food additives make possible artificial foods that are not as nutritious or healthy as foods are in their natural state? By natural, I don't mean a food grown without pesticides. I mean an orange, compared with an artificially flavored and colored orange drink.*

**A.** I would disagree totally with the notion that "natural foods" in the sense you mean the term, or in the sense that some others use it, that is, foods grown without certain chemicals, are better or safer than processed foods. That doesn't mean that I think we should go the other extreme and eat nothing but highly processed food;

that would be both expensive and stupid. But the notion that "natural" is somehow safer and more nutritious doesn't hold up very well. People tend to forget that many foods have to be processed to be eaten, and can become more nutritious after processing. That's the reason for the processing of soy, for example, to make it edible and digestible.

**Q.** *How concerned are you about the trend towards a society in which more foods are processed or synthetic? Are we going to eventually come to the day when we just pop pills for breakfast, lunch, and supper?*

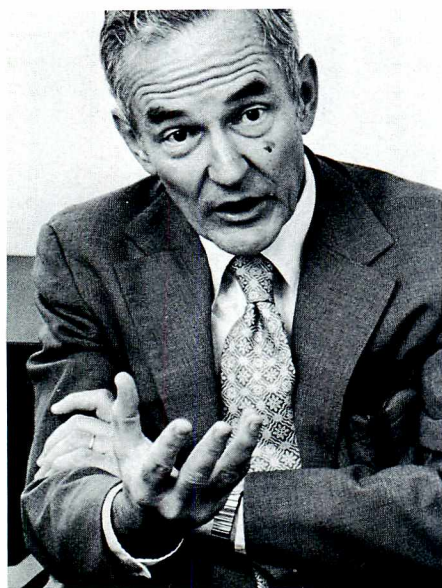
**A.** If the pill weighs about a third of a pound, yes. Seriously, I am not concerned by current trends, so long as people choose wisely and are helped by proper nutrition education and by more thoughtful advertising and promotion. We can do a pretty good job of supporting a person nutritionally on a highly processed diet, but it's very unwise economically. The most sensible thing to do is to eat moderately from a large variety of foods. If we choose from the major food groups and avoid fads, if we prepare food properly, and if we exercise so that we don't have to have too restricted a diet to maintain weight, we'll be fine. By these steps we can hardly miss a diet that is good nutritionally. And we even can include some snack foods that in and of themselves may not be highly nutritious, but that still are good foods. There is nothing really wrong with popcorn, or potato chips, or peanuts, except the quantity consumed and the time when they are eaten. If they are eaten as an occasional snack, or a garnish, or as part of an otherwise very well balanced lunch, fine. If they are the entire lunch, it is terrible.

Most people in industry see us as having to move gradually toward a somewhat more processed total food supply. The pressures in that direction—economic, rising costs of la-



"... we differ widely in our tastes. I don't mean just flavor. What I regard as acceptable and desirable in life another person may not. So some of these additives permit us to satisfy our personal tastes."





“... the notion that ‘natural’ is somehow safer and more nutritious doesn’t hold up very well. People tend to forget that many foods have to be processed to be eaten, and can become more nutritious after processing.”

bor, the need to supply food to other parts of the world—force it. We simply can’t avoid it. Processing necessarily involves the use of additives, and one must mean wise and proper use of additives. But there’s no turning back to the food production and distribution systems and the choice of diet of many years ago.

**Q.** *How well do you think the industry has succeeded in educating the public about nutrition?*

**A.** Pretty poorly, right along with everybody else.

**Q.** *Why so?*

**A.** I wish I knew. I don’t know. One reason though, is that nutrition so often is uninspirationally taught in high schools and colleges. It is usually the least exciting course, yet it can be done very well.

**Q.** *How about nutrition labeling? Is that a good educational device?*

**A.** Present nutrition labeling is well intended but it’s too complex for the people who most need it. Let me get back to that later. I want to make one other point first, and that is that industry just simply has to take a longer term view of its educational responsibility. When industry plays on the latest fear or the latest fad, like saying “contains 40 percent more fiber” when we don’t really know yet what the role of fiber is, then we’ve got a problem. And when products are advertised as having “no preservatives” and “no artificial ingredients”—taking advantage of consumers’ apprehensions in that area—then industry has only itself to blame. And at the same time, many of the same companies are pushing relatively non-nutritious items.

**Q.** *How do we move industry into a more responsible position?*

**A.** One thing that might help would be some relatively minor changes in product labeling, to make labels more informative and a little simpler. We can not swamp people with information they can’t use. And we must highlight some of the more important things. A lot of my industry colleagues don’t agree with me, but I think we should label dietary fat, salt, and sugar. Labeling of those ingredients would go a long way toward helping people select better diets—if we combine it with more attention to nutrition in schools and colleges and with better information in the public media. Much of this educational effort will have to be Government sponsored. I don’t think it is fair to expect industry to advertise products they are not selling. You can’t ask a company to plug a product in which it has no interest. But we do need more public media attention to the necessity of a balanced and restrained diet.

**Q.** *Let’s get back to nutrition labeling...*

**A.** Yes. The present nutrition labeling is too numerical, it’s too detailed. Too much space is taken up with things that are not there. That sort of turns people off. For example, you have to declare nutrients that are there in less than 2 percent of the Recommended Daily Allowance. Let’s use that space to say what’s in the food, not what’s not there. Also, perhaps a graphic rather than a numerical approach would be easier to understand.

**Q.** *A lot of alternatives were tested by FDA in the early 1970’s and the present format was the one that had the best consumer response.*

**A.** This is true. But consumer testing is a difficult area. I had at the time, and I have today, some questions as to how adequate and how valid those test results were. People

tend to give you the answers they think you want. This is what industry runs into all the time during product testing. I am not sure we got the right results then and I am even less sure they are right for now. We could probably take a better look at it.

**Q.** *You said in a speech five years ago that the public has to learn to accept that safety can never be absolute, because “safety” will always change. With all that has gone on in the past five years, with saccharin and Red No. 2 food color, has the public gained some of that understanding?*

**A.** I think it has begun to. The saccharin issue, if it has no other value, has helped us all realize we have to compare risks in the food area. And we also have to look at benefits. And saccharin also shows us, as does nitrite, that we only get into this uncomfortable matter of comparing risks when we are down to our last alternative, our last artificial sweetener. We should encourage more choices.

**Q.** *How do you perceive FDA’s role in food regulation?*

**A.** FDA has an incredibly difficult set of problems. It is buffeted by special interest pressures, by political pressures, and by zealots of every kind. So it isn’t an easy role. I think FDA has devoted too much of its own resources to the relatively remote hazards presented by food additives. On the other hand, of course, these hazards are remote precisely because of some of these efforts. So they have been successful. But we shouldn’t keep pursuing small risks at an ever greater cost and with ever greater zeal. We have reached a point of diminishing returns on food additive regulation. It’s time to emphasize more important hazards.

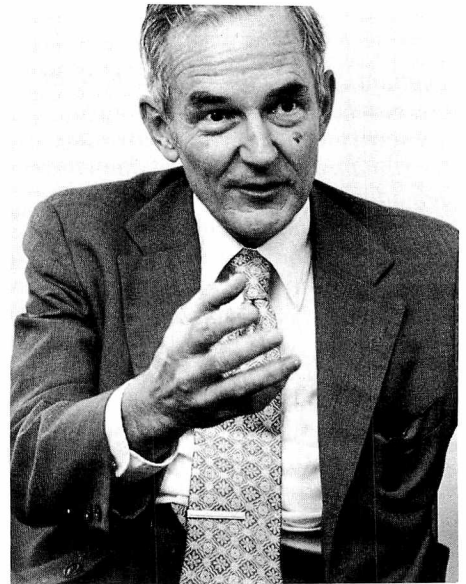
FDA also must recognize that we are approaching a food crisis worldwide, and we will need to develop

better ways of processing foods if we are to meet that crisis. I don’t think FDA should stand in the way by stifling the development of new processes through standards that are unrealistic. We also need to consider how much energy we use in producing foods. These are some of the things FDA must look at, in addition to its concern for food additive safety.

**Q.** *A recent survey found that food manufacturers led the hit parade among industries which the public feels consumer activists should concentrate their efforts on. Forty-five percent of the people surveyed said that the food industry should be a target, while 44 percent said hospitals, 42 percent said the medical profession, 39 percent said the oil industry, and 38 percent said car manufacturers. Why so? Why is the food industry at the top of that list?*

**A.** The top of the list is pretty closely bunched, as you indicated by the figures. The reason the food industry is there is that food is a necessity. It is something we all have to have. We all learn our tastes very early in life. Most of us had a good many of our food tastes well established before we could remember establishing them. Food is therefore a very emotional issue. Any industry that has such a visible role in the economy, and particularly one that touches each of us three times a day, will have that kind of sensitivity. We simply have to get used to it.

Also, due to a variety of reasons, we’ve become accustomed in this country to having food that is relatively cheap compared to the rest of the world. But it isn’t going to be cheap any longer as energy and labor costs rise and as some of the other economic factors increase. So people resent this. They are very concerned about it, they are very suspicious of it, and all this makes the food industry a very likely target.



“... we should label dietary fat, salt, and sugar. Labeling of those ingredients would go a long way toward helping people select better diets. . . .”



# Our Medical Debt To The Distant Past

*The plants and poultices used to treat illness and disease in ancient times may seem unscientific by contemporary standards, but many of them have been adopted by modern medicine. The descendants of remedies known a thousand or more years ago are prescribed today to treat everything from headaches to heart ailments.*

by Robert T. DeVore

Science, in its pursuit of progress, has sometimes been accused of being blind to the merits of primitive and ancient medicine. The charge is partly true.

In some instances it has taken many years, even centuries, for the value of old remedies to be recognized. Sooner or later, however, science either has adopted many of them or used them in creating better remedies. In the process modern man has accumulated an enormous medical debt to the distant past.

The debt may be measured in the annual consumption of millions of pounds of drugs and in millions of dollars in drug business traceable to the medical practices of primitive or ancient peoples. But the extent of mankind's obligation to the healers of old can be understood best by looking at some of the more important of those drugs and what has been done with them to ease human suffering.

One of the best examples of medicine's at times stubborn blindness to the worth of old practices concerns a species of the plant *Rauwolfia*. Yet, as things turned out, the story also represents one of pharmacology's greatest successes.

Western scientists largely ignored *Rauwolfia* (also called snakeroot) until the twentieth century, although for more than 2,000 years medicine men in India had used *Rauwolfia* root, often in a tea, for many diseases, including

cholera, epilepsy, and insanity. To most Western researchers, claims for the plant sounded too extravagant to be credible until, in the late 1940's, Indian scientists isolated some interesting active substances from *Rauwolfia* root. This galvanized Western scientists into action and in 1952 they produced reserpine—the first modern tranquilizer—from *Rauwolfia*.

Reserpine revolutionized the Western World's treatment of mental disease, introducing an era in which psychoanalysis often became supplementary to drug therapy. Newer tranquilizers have largely replaced reserpine, but it still is widely used for high blood pressure. Annual sales of reserpine products in the United States have been estimated at \$80 million.

About a thousand years ago the country people of England used leaves of the purple foxglove for relief from dropsy. It wasn't until 1776, however, that Dr. William Withering, a physician and botanist of Birmingham, England, introduced foxglove to medicine as the world's leading heart stimulant. Dr. Withering had found that leaves from the foxglove, *Digitalis purpurea*, comprised the only active ingredient in an herbal tea used successfully against dropsy by an old farm woman of Shropshire.

Dropsy reflects a failing heart condition. One of its causes is inability of the heart muscles to contract with enough force to drive a sufficient flow of blood through the circulatory system. This leads to inadequate kidney function and causes the tissues and cavities of the body to fill with liquid. *Digitalis* can correct this by causing the heart to beat with a slower and more powerful contraction to prevent fluid accumulation.

During the first century A.D., the Greek physician-botanist Dioscorides wrote that the bitter juice of the white willow was excellent for the pain of

gout. Little did he realize that he was pointing the way to what has become the most widely used painkiller on earth.

The use of willow for pain continued for centuries. Then, in 1860, salicylic acid was synthesized from willow and used by physicians for lowering fever. Salicylic acid, however, was not ideal for internal use. Still sought was a product that would be well tolerated internally and that, like willow, would alleviate pain. Chemists developed what they wanted by synthesizing acetylsalicylic acid in the laboratory. It was introduced to medicine in Germany in 1899 and named aspirin.

Neither aspirin nor any of the salicylates are made today from willow. All are produced synthetically and at greater purity and lower cost than anything derived from natural sources.


For at least 1,500 years, Indians of Peru and Bolivia chewed leaves of the plant *Erythroxylon coca* or rolled them in lime and held them in their mouths during treks across South America's high plateau country. The leaves enabled them to go without food, water, and sleep for many hours.

Coca was discovered by the white man in the 1680's. The active ingredient was isolated by a German organic chemist in 1855. He named it cocaine.

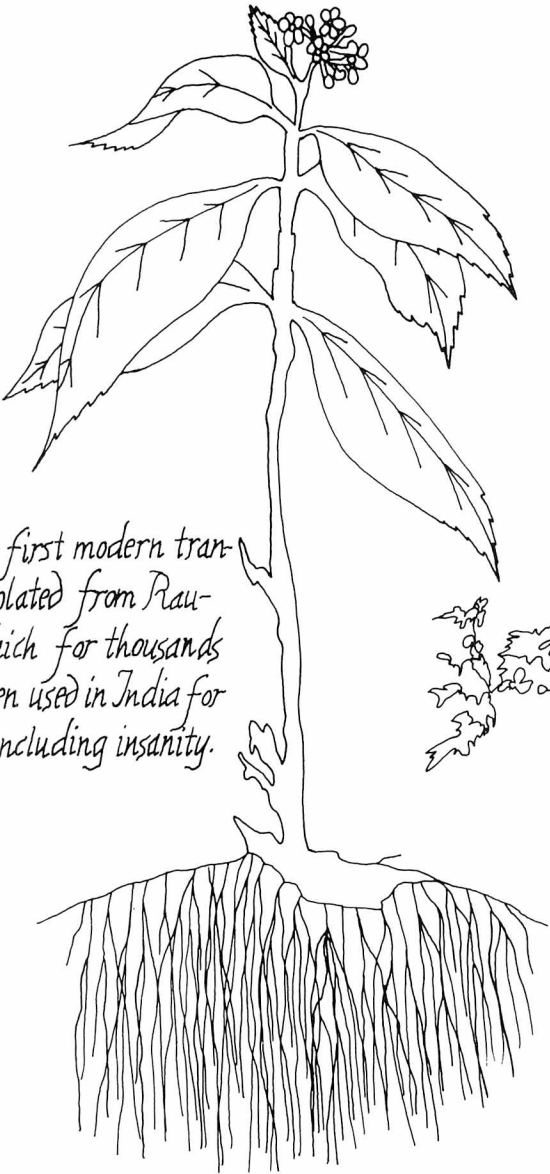
Dr. Carl Koller used the anesthetic properties of cocaine in 1884 to kill the excruciating pain of cataract removal. No general anesthetic then was considered safe for such a delicate procedure.

Because of its toxic and addictive properties, cocaine had to be used carefully and judiciously. Fortunately, in the early 1900's it was possible to synthesize a much safer substitute, procaine hydrochloride, now marketed as novocaine, and widely used as a local anesthetic.


Malaria has ravaged humankind since the earliest times. It has killed



*The heart drug digitalis is so called because it is derived from *Digitalis purpurea*, commonly known as foxglove.*



*Reserpine, the first modern tranquilizer, was isolated from *Rauwolfia* root, which for thousands of years had been used in India for many diseases, including insanity.*



*Use of the juice of the white willow as a painkiller dates to the first century A.D. Its chemical descendant, aspirin, is now our most widely used painkiller.*



*Cinchona* bark was used to treat malaria long before two French pharmacists isolated the substance—quinine—that made the plant effective.



Centuries ago midwives used ergot, a fungus that grows on rye and other grains, to control bleeding in childbirth. Derivatives of ergot are used today for the same purpose.



more people than all the wars in history. To the millions it did not kill it left a legacy of fever, chills, and weakness.

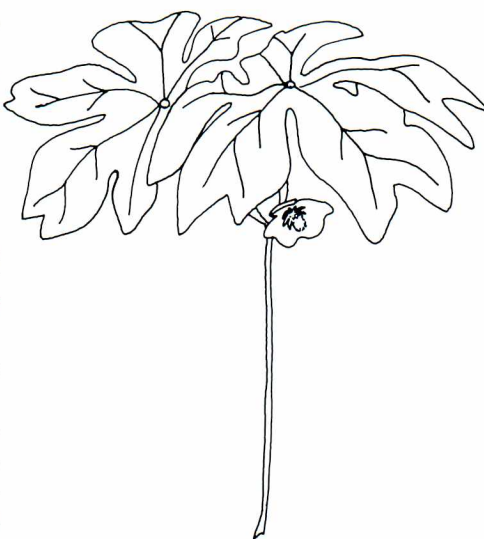
The Collahuya Indians, “druggists of the Amazon,” are believed to have been the first people to discover a treatment for malaria. For years they drank a potion made from the bark of one or more species of *Cinchona*, flowering evergreens found on the eastern slopes of the Andes.

Powder from *Cinchona* bark was used in the treatment of malaria throughout much of the civilized world from about 1645 until 1820. In that year, two French pharmacists, Pierre Joseph Pelletier and Joseph Bienaime Caventou, isolated an essential derivative of *Cinchona* bark. It was named quinine from an old Indian term, *quina-quina*, meaning bark of barks.

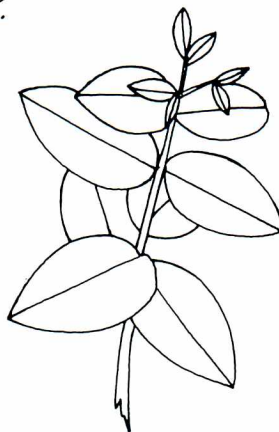
For many years, quinine was pushed into the background by synthetic drugs that many physicians considered superior for malaria. Recently, however, the rise of resistant strains of *Plasmodium*—the mosquito-borne organism that causes malaria—has persuaded many doctors to turn again to quinine. The preferred treatment often is quinine with supportive synthetics.

Ergot is a fungus with the botanical name *Claviceps purpurea*. It infests rye and other edible grains. Persons who eat bread or other foods prepared from infested grain can suffer horrible disease. Ergot constricts the blood vessels and cuts off the blood supply to the feet and other extremities. These can become gangrenous and sometimes must be amputated.

Epidemics of ergotism, called St.



*Extracts from the Madagascar periwinkle (top) have proved effective against cancer; and mayapple (center) and Maytenus (bottom) have shown promise as sources of anticancer compounds.*



Anthony's Fire, killed thousands of people in France in the tenth and twelfth centuries. There were outbreaks in New York, Kansas, and Ohio in the early 1900's and in the Russian Ukraine in the 1920's. Today, with careful milling operations, ergotism is virtually unknown.

Centuries ago, midwives of many lands employed a crude ergot preparation to aid delivery and control bleeding in childbirth. What they did was to make beneficial use of ergot's power to constrict blood vessels.

It was not until 1808 that ergot was scientifically recognized as an aid to childbirth. The use of derivatives of ergot is now standard in obstetrics to control bleeding, and an ergot derivative also is used to relieve migraine headaches.

U.S. needs for ergot run as high as a million pounds a year.

Some of the most useful plant derivatives modern medicine has borrowed from the distant past are deadly poisons. One is strophanthin, the active ingredient of a species of the plant genus *Strophanthus* that the explorer David Livingstone found southeast African natives using as an arrow poison. The drug is too deadly to be given by mouth. Injected in doses as small as 1/100th of a grain, however, it is a fast-acting heart remedy that can save lives in an emergency.

Curare was used as an arrow poison by South American Indians generations before the white man arrived. The poison caused animals shot with it to lose control of muscles essential to respiration and thus to die of asphyxiation. Curare and synthetics

based upon it now are used as muscle relaxants in abdominal, rectal, and other surgery. Such use frequently makes it possible to employ a relatively low level of anesthesia, thus reducing the risk of postoperative nausea and vomiting.

Drugs derived from old remedies also are being used in the fight against cancer.

The National Cancer Institute has begun to test in cancer patients the effectiveness of a promising new drug called maytansine. Such tests probably would have been conducted much earlier had Institute scientists known that cancer patients had been treated in Africa for many years with an herbal tea using a species of plant closely related to the east African shrub from which maytansine was isolated. Unfortunately, this was not known until after the shrub's tumor-inhibiting properties had been discovered during a massive program sponsored by the Department of Agriculture and the Cancer Institute to screen plants for compounds that might be effective against cancer.

Sources for maytansine include two species of the shrub *Maytenus* found in Ethiopia and Kenya. One of maytansine's most striking characteristics is its low-dose effectiveness in animals. It is indeed fortunate that a very small amount of the drug goes a long way since its concentration in *Maytenus* is so low that 10 tons of plant material are required to produce a teaspoon of maytansine.

Maytansine has been especially effective with mouse leukemias, and available data suggest that its most likely use in humans may be in the treatment of leukemia. Toxicity studies of maytansine in cancer patients have been completed, but effectiveness investigations have just started. Several years of patient testing will be required before scientists will know if the bright promise of maytansine will be fulfilled.

New anticancer compounds characteristically evolve with painful slowness. It was back in 1947, for example, that scientists from the National Institutes of Health reported in separate presentations before the American Society for Pharmacology and Experimental Therapeutics and the American Association for Cancer Research that podophyllin resin from the root of the mayapple, a perennial herb commonly

found in U.S. and Canadian woods, showed promise as an anticancer agent.

Although the point was not made in either presentation, mayapple had been used as a cancer remedy by the Penobscot Indians of Maine, probably long before the white man came to North America. The Penobscots apparently passed their knowledge along to the colonists because private practitioners in the United States are known to have used mayapple in the treatment of cancer during the nineteenth century.

Knowledge of the cancer-destructive properties of mayapple root resin has stimulated the synthesis of a number of derivatives. Two of them have been authorized by the Food and Drug Administration for National Cancer Institute trial in cancer patients. Thus far, they have given encouraging results, particularly showing evidence of activity against various forms of leukemia.

Among other anticancer plant extracts are compounds that first attracted attention as being possibly useful against diabetes. The compounds were obtained from the Madagascar periwinkle, *Catharanthus roseus*, a close relative of the common garden periwinkle. In many parts of the world *Catharanthus roseus* had a reputation in folk medicine as an antidiabetic.

Tests were made by scientists at the University of Western Ontario and Eli Lilly, a U.S. drug manufacturer. Each found *Catharanthus* derivatives worthless against diabetes, but effective against leukemia in research animals. The Canadians discontinued their work, since their major interest was in diabetes. At Eli Lilly, however, cancer research was pursued with a number of *Catharanthus* derivatives, among them vinblastine and vincristine.

Vinblastine has been found especially effective in the treatment of Hodgkin's disease. Vincristine has been described by one authority as "a mainstay" of combination drugs that have been giving impressive long term survival rates in children with leukemia.

The *Catharanthus*, mayapple, and *Maytenus* experiences have persuaded scientists to take folk medicine more seriously. For example, Dr. Robert E. Perdue, Jr., chief of the Agriculture Department's Medicinal Plant Resources Laboratory, now gives priority

in his agency's plant collection activities to plants reported locally to be used for medicinal purposes.

Dr. Perdue says that after 16 years of screening plants and correlating results with information available from folklore, it is "evident" that the search for plants containing substances that are active against tumors would have been considerably more productive "if plant selection had been guided by folk knowledge."

Altogether, more than 70 drugs or their derivatives used by primitive or ancient peoples are in use today for a variety of health problems. The list includes:

- Ephedrine, chiefly valuable for the relief of hay fever and asthma, is obtained from a species of *Ephedra* that the Chinese Emperor, Shen Nung, described as good for a number of ailments 2,700 years ago.

- Juice of the *Aloe* plant, used to treat burns and skin abrasions for at least 2,300 years, is now an ingredient of ointments reported to be more effective than any other preparation for the treatment of radiation burns.

- Rhubarb, valued as a cathartic by the Chinese for more than 5,000 years, is found in laxatives today.

- Castor oil, well known to the ancient Egyptians and Romans, often is prescribed as a purgative. The seeds from which castor oil is obtained are poisonous. But if hulled seeds are crushed between rollers at a temperature not exceeding 50 degrees F., the oil comes out without a trace of poison.

- Cascara, derived from the bark of a tree with the botanical name of *Rhamnus purshiana*, was used as a cathartic by Indians of the U.S. Northwest.

There is little wonder that the number of primitive and ancient plant-derived drugs in use today is large. At one time or another during the long development of civilization virtually every known plant has been tried as a medicine. Mankind still is benefiting from some of these experiments. In many cases, however, the results were disastrous. Uncounted thousands died of poisoning. To these nameless self-experimenters some portion of our medical debt to the distant past is owed.

*Robert DeVore is a freelance writer.*





cherry tomatoes stuffed with minced tunafish, onion, and green pepper also add a splash of color.

**T**he boar's head, once the high point of the traditional Christmas dinner in the homes of English nobles, rarely appears on American tables, but turkey, goose, and other fowl do. Cooks the country over have their favorite stuffing recipes, many of which call for large amounts of bread or breadcrumbs. One way to cut down on calories is to use a stuffing with little or no bread, such as one made of water chestnuts and mushrooms.

Many traditional holiday dinners include several varieties of potato. Why not substitute for one of them another fresh vegetable such as beans seasoned with savory? A type of European mint, savory was once thought to be good for the digestion. Herbs add a delightful touch to many vegetables and can substitute partially for salt. As a change from the usual cranberry sauce try a spicy cranberry relish. If a fresh garden salad is part of the feast, use a low calorie dressing, or one made with tomato juice and herbs.

The piece de resistance of a traditional holiday meal often is the plum pudding, served in a blaze of glory. After months of soaking in brandy, however, this dessert has too many calories to count. The nutrition-minded may prefer a light fruitcake with after dinner coffee. Fresh fruit, nuts in the shell, and cheese also provide a light and nutritious touch after any hearty meal. To strike a happy medium between the high and the low on the calorie scale, try dessert crepes with a fruit sauce. The tiny pancakes can be made in advance and served with a flourish from a chafing dish.

It is hard not to have candy and cookies around during the holiday season, especially where there are children. Dates, with their natural sweetness, offer a nutritious alternative to candy canes and sugarplums. They can be eaten "as is," stuffed with nut meats, or used in sugarless cookies.



**N**o doubt about it, planning "nutritious" holiday fare in the face of the family's demands for the traditional can be a challenge. But a wide range of cookbooks, including those with low calorie recipes, are available in public libraries and bookstores. Voluntary health agencies such as the American Heart Association have printed material on diet and nutrition, including suggested recipes. Some of these organizations have nutritionists on their staffs who can help diet-conscious consumers plan appropriate menus.

And be sure to read the nutrition labels on canned and packaged foods. They contain valuable nutrition information, including calories per serving, which can be a guide in selecting the ingredients you use in your favorite recipes and in planning all your holiday meals.

*Annabel Hecht is a staff writer with FDA's Office of Public Affairs.*



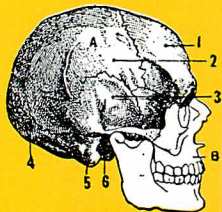
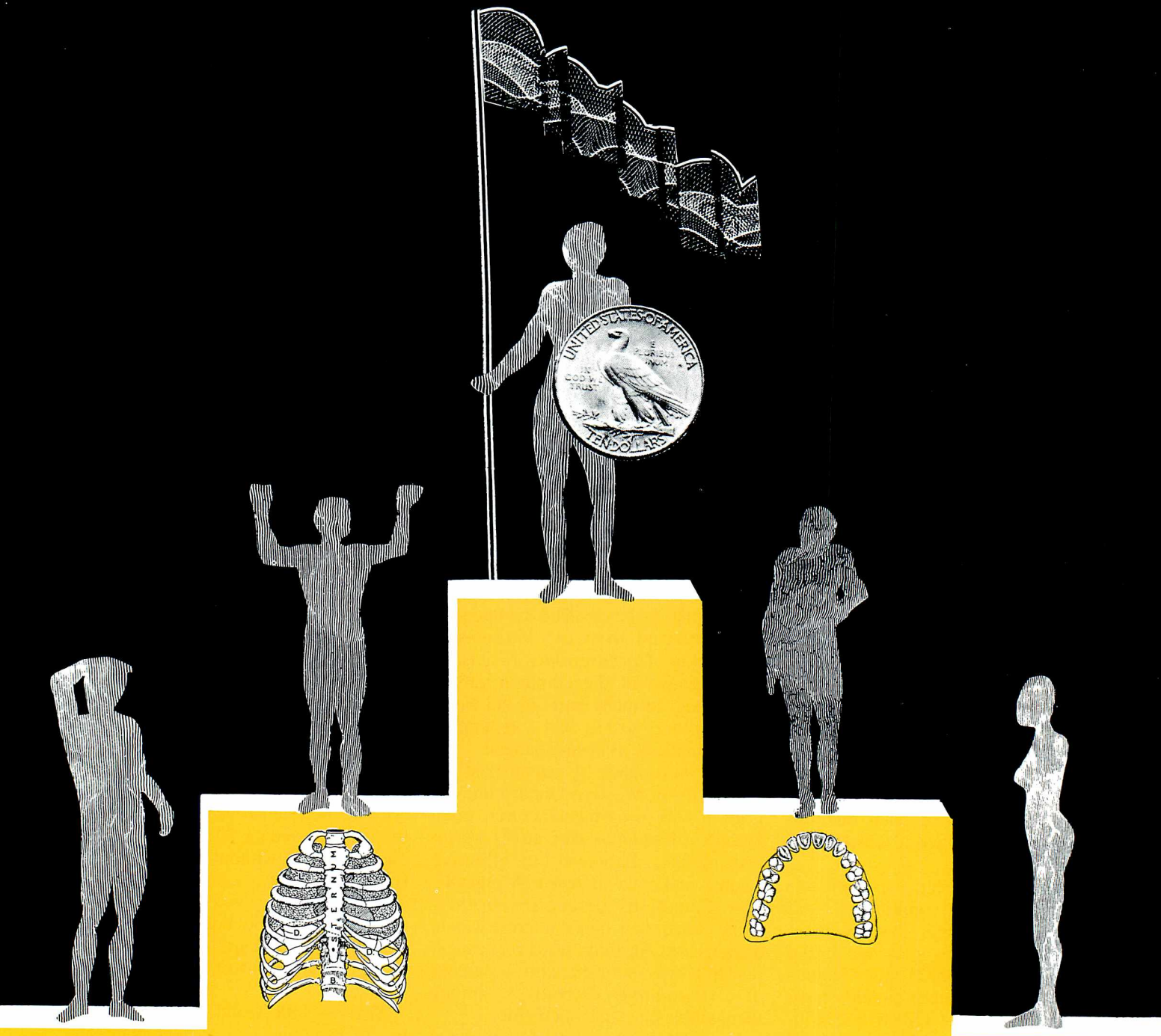


Fig. 16



# Reducing X Rays And Health Costs

*As many as 30 percent of all x rays taken may not be needed. Eliminating unnecessary x rays could cut more than \$2 billion a year from the Nation's total health care bill.*

*by Annabel Hecht*

The Food and Drug Administration estimates that as much as \$2 billion in health care costs might be saved each year by cutting down on the number of unnecessary x-ray examinations people get.

According to FDA's Bureau of Radiological Health, the cost of diagnostic x rays for the Nation is now \$6.3 billion a year. That is nearly 5 percent of all money spent for health care in 1976. If the number of x-ray examinations was cut by only 10 percent, that figure could be reduced by \$630 million a year. Reduce the number of examinations by 30 percent—a figure frequently quoted as the proportion of x-ray examinations that are not needed—and the saving for the Nation would be close to the \$2 billion mark.

That savings are possible has been demonstrated by an FDA-funded pilot project in a Seattle, Washington, hospital where the number of skull x rays taken in injury cases was cut 40 percent by using a list of well-defined criteria to determine the need for such an examination. If all hospitals followed this practice, FDA estimates that \$53 million could be saved annually just in the costs of skull x rays taken after injuries.

As another example of how costs could be cut FDA points out that \$150 million spent each year for film and other materials could be saved if x-ray examinations did not have to be repeated because of poor techniques. It is estimated that 10 percent of all diagnostic x-ray examinations have to be done over and 75 percent of these could be avoided through improved practices in x-ray facilities.

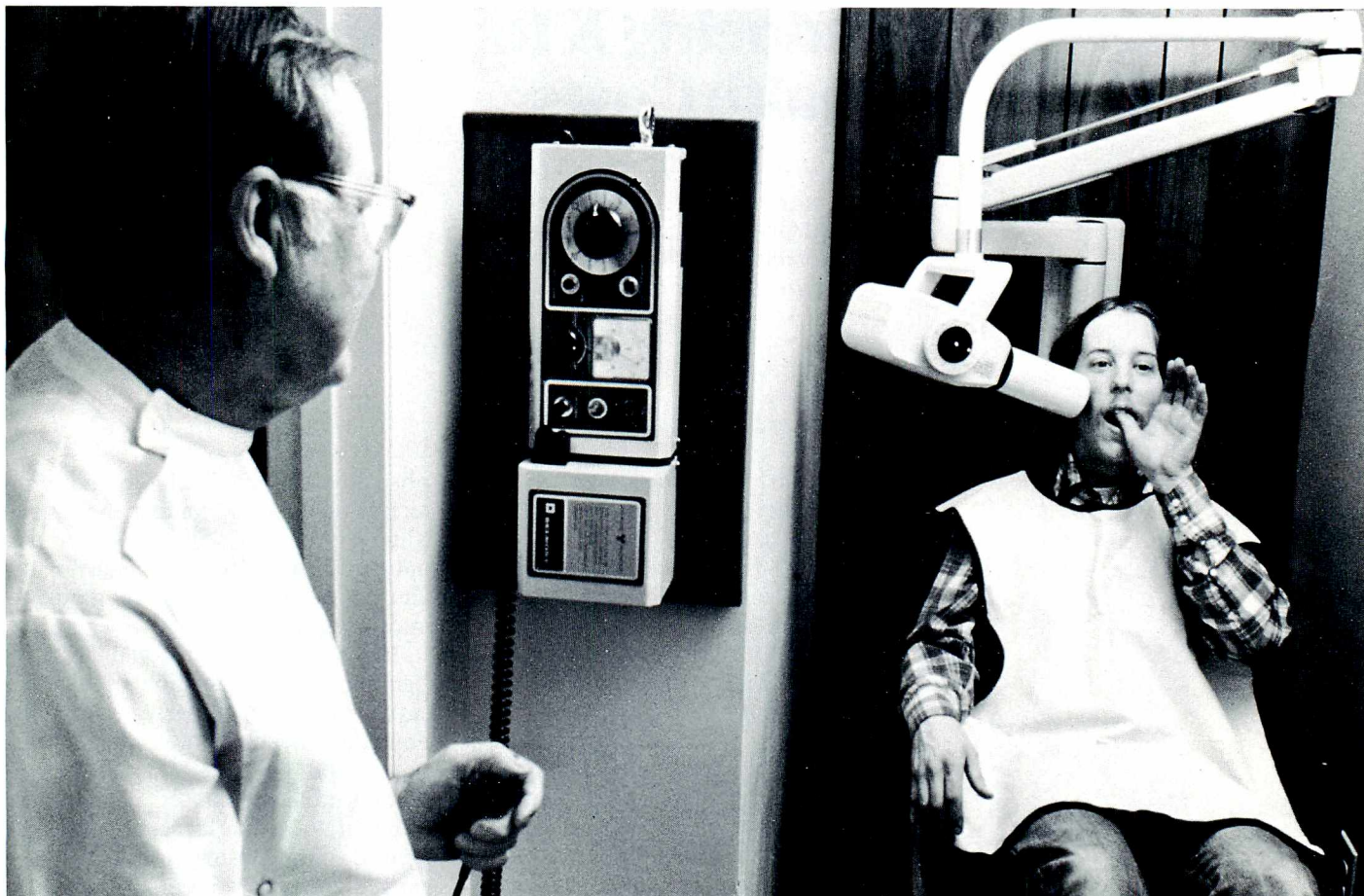
FDA has taken steps to insure that equipment is operating properly through its performance standard for diagnostic x-ray machines which went into effect in 1974. A number of self-help training

programs are available to aid x-ray technologists in upgrading their skills, while a program is under way to find out the reasons for poor quality x rays and to develop simple methods for improving quality.

The \$2 billion that could be saved right now by elimination of unnecessary x-ray examinations is not the total potential savings. More than \$750 million could be saved in the cost of treating radiation-caused illness in the future if the American people can be spared unnecessary exposure to x rays. X rays can cause cancer in people exposed to them. In addition, people exposed to x rays may suffer genetic damage that could cause harm to future generations.

Although the possibility that any individual will suffer long term harm from a single x ray is statistically very small, the problem is of concern for two reasons. One is the large number of x-ray examinations conducted—an estimated 241 million this year. At that rate, even if only one x ray in 100,000 caused damage, more than 2,400 persons could suffer adverse effects. The second cause for concern is that although the incidence of adverse effects from x rays may be very small, the damage (such as cancer) can be serious.

One way to achieve these long term savings in health care costs is by limiting the size of the x-ray beam and protecting patients' reproductive organs by use of specially designed devices known as gonad shields. It is estimated that if physicians and technicians would take these two steps whenever possible the genetic radiation dose from medical x rays might be cut by 50 percent. According to the National Academy of Sciences/National Research Council (NAS/NRC), reducing the x-ray dose by this much would



*An FDA project carried out in cooperation with the radiation control agencies of 28 States has brought about a 40 percent overall reduction in patient exposure to dental x rays. A similar program is under way to reduce radiation exposure in women receiving breast x rays.*

Reducing the number of abdominal x-ray examinations of pregnant women would lead to additional savings in future medical care costs. The developing embryo is particularly sensitive to the cancer-causing effect of radiation. Using National Academy of Sciences' estimates, FDA has calculated that reducing the number of such examinations by one-third would avoid approximately 90 cases of childhood cancer annually. Not only would young lives be spared, but about \$1 million in medical costs would be saved, assuming it costs in the neigh-

borhood of \$10,000 a year to care for a cancer patient.

FDA is moving ahead to reduce unnecessary exposure to x rays through programs conducted in conjunction with State and local radiation control agencies. One such project in 28 States has demonstrated a 40 percent overall reduction in patient exposure from dental x rays and a similar program promises to show equally good results for women receiving breast x rays.

To encourage greater use of gonad shielding, FDA has developed guidelines which were published in the *FEDERAL REGISTER* as a medical recommendation. And to reduce the number of unnecessary x-ray examinations of pregnant women a public information program is planned which will emphasize the collective responsibilities of the referring physician, the patient, and the x-ray technologist.

Getting the act together is not as easy as it seems, however, for there is not enough scientific information that can be used to guide medical practitioners and the legal profession about when x rays are warranted and when they are not. If reliable studies were

available on the clinical value of information obtained from specific x-ray procedures, the potential \$2 billion annual saving could become more of a reality than a statistical estimate.

Even without such studies consumers can avoid unnecessary radiation exposure—thereby protecting their health—by taking a few simple precautions. For instance, women who are pregnant or think they might be should discuss this with their physician if abdominal x rays are ordered. Gonad shielding should be used whenever possible and appropriate.

When an x ray is ordered, patients can ask their physician or dentist whether it is needed. It is possible a previous x ray or another test will serve the purpose. Patients should keep a personal record of all x-ray examinations, including when and where they were taken and who ordered them. This can help eliminate unnecessary radiation exposure.

Asking questions costs nothing; the saving in terms of health alone is well worth the time it takes.

*Annabel Hecht is a staff writer with FDA's Office of Public Affairs.*



# Healthful Holiday Fare

*The parties and family gatherings that traditionally mark the holiday season usually put a strain on the waistline. But these festive occasions don't have to be caloric calamities or nutritional nightmares.*



by Annabel Hecht

President Washington, it is said, once served 20 guests a Christmas dinner consisting of "an elegant variety of veal, turkey, ducks, fowls, hams, etc., puddings, jellies, fruits and nuts and a variety of wines and punch."

New Year's celebrations in colonial America were no less elaborate. Early New Yorkers put forth "splendid ornamented and iced plum cakes," along with confections and fruits, wines and cordials. Even the Quakers were reported to have punch bowls large enough to have "swimm'd half a dozen young geese." Two favorite drinks were Floating Island and Syllabub, both equally caloric as well as alcoholic for they consisted of large amounts of sugar and cream in addition to wines and spices.

Every national and ethnic group that has come to this country has brought its culinary customs. It is little wonder that an abundance of food, a good deal of it rich and sweet, is as much a part of today's holiday tradition as decorated evergreens, Santa Claus, Rudolph the Red-Nosed Reindeer, and the singing of "Auld Lang Syne" on New Year's Eve.

Many people consider any holiday incomplete without a groaning board for

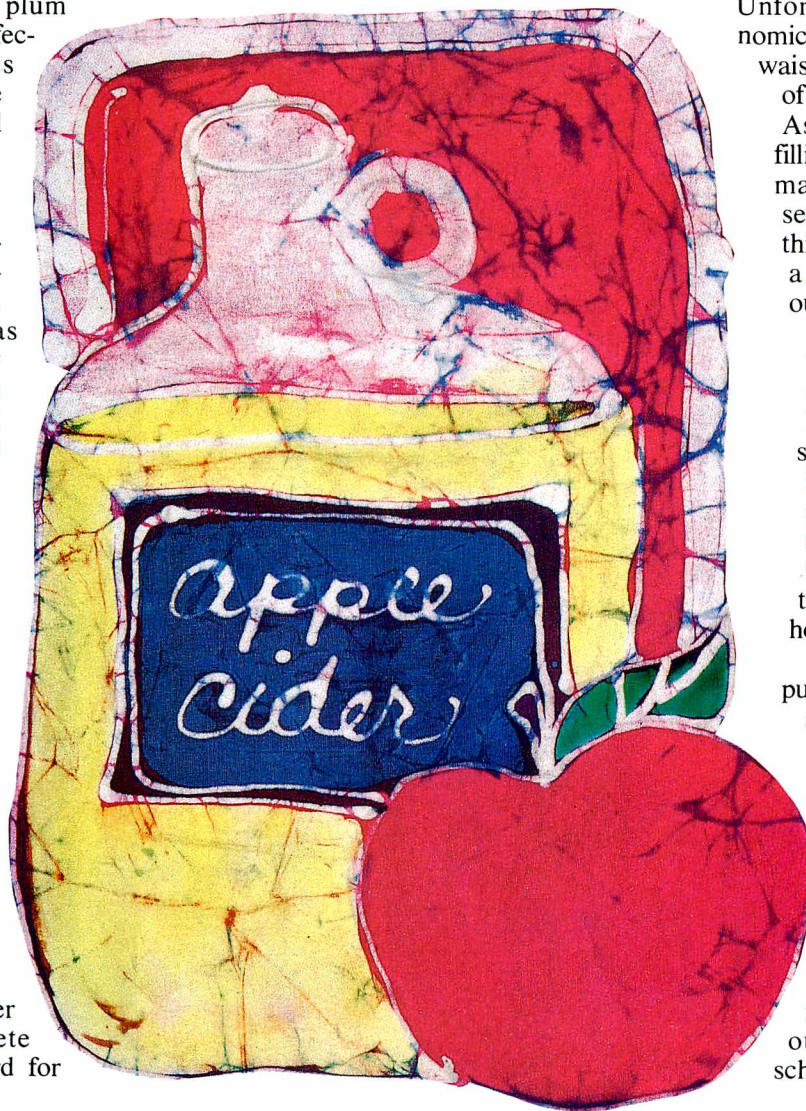
the family dinner. The visions that dance through youngsters' heads are no longer limited to sugarplums, but include candy canes, chocolate Santas, and gaily iced cookies in symbolic shapes. If adults dream at all of the delights of the season it is more likely that they see plum pudding and eggnog followed by antacid tablets plopped into a glass of water.

Unfortunately, such gastro-nomic traditions tend to increase waistlines and lengthen the list of New Year's Resolutions.

As a once-a-year activity, filling up on holiday goodies may not be more than a seasonal indulgence. But if this style of eating becomes a habit, it can lead to serious health problems.

Good eating habits and weight-watching diets need not go completely by the board during the holidays, say Food and Drug Administration nutritionists. With a little imagination, any cook can prepare nutritious, lower calorie foods that are in keeping with the holiday spirit.

For instance, serve a fruit punch or mulled cider as an alternative to eggnog. For a refreshing change in party hors d'oeuvres include carrot and celery sticks, cucumber strips, radishes, peeled broccoli stems, or cauliflower florets along with a low calorie "confetti" cheese dip. Green pepper and pimientos in the dip carry out the holiday color scheme. If they are available,





## Holiday Recipes

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### Spiced Cranberry Relish

1 pound fresh cranberries  
2 apples, peeled and cored  
1 cup crushed pineapple, drained  
¼ teaspoon ginger  
¼ teaspoon cloves

Chop or blenderize cranberries and apples. Add drained pineapple and spices, and blend. Chill before serving.



### Sugarless Freezer Date Cookies

½ cup butter or margarine  
1 egg  
2 teaspoons vanilla  
1 cup flour  
1 teaspoon baking powder  
¼ teaspoon salt  
1 cup pitted dates, chopped  
1 cup shredded coconut  
1 cup chopped walnuts

Cream butter, egg, and vanilla. Mix dry ingredients. Blend both mixtures thoroughly. Mix dates, coconut, and walnuts until blended. Form dough into two 1½-inch rolls and wrap in waxed paper or foil; chill in freezer 2 hours or up to 1 month. Slice with sharp knife into ⅜-inch slices. Place on lightly greased cookie sheet and bake at 350 degrees for 12 minutes. Cool on rack. Makes 5 dozen.

### Mulled Apple Cider

2 sticks of cinnamon  
A few cloves  
2 jugs of apple cider (1 gallon and 1 quart)

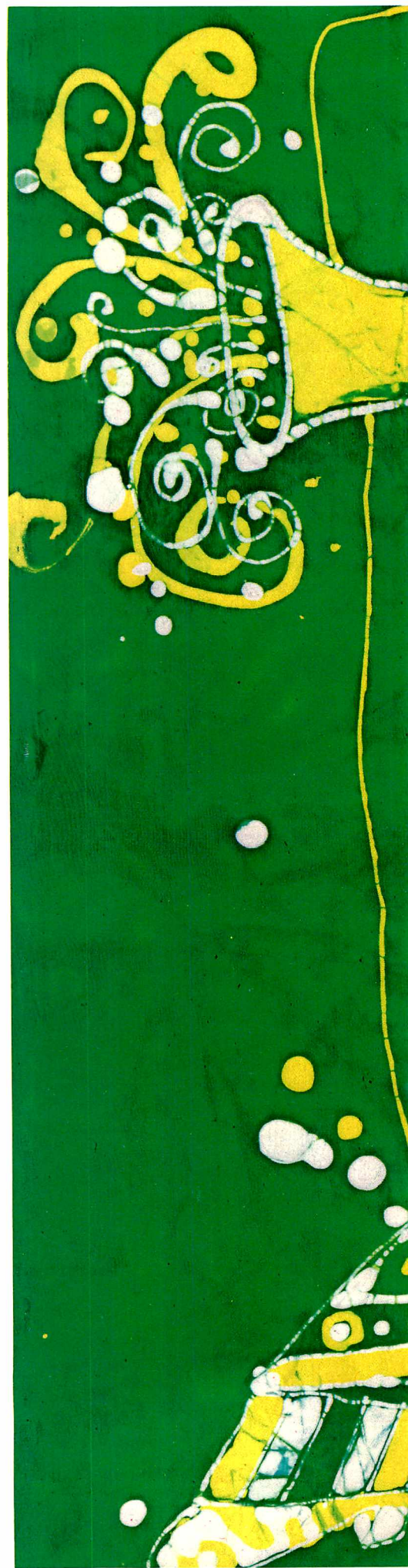
Put all of the ingredients in a saucepan, heat until bubbles form on the bottom of the pan. Cool and serve.



### Confetti Cheese Dip

1 pint cottage cheese  
¼ cup milk  
1 tablespoon mayonnaise or salad dressing  
2 tablespoons finely chopped green pepper  
1 tablespoon chopped pimiento  
Dash of Tabasco sauce

Blenderize ingredients and chill. Serve with raw vegetables such as carrot and celery sticks, cucumber strips, radishes, peeled broccoli stems, cauliflower florets.











cherry tomatoes stuffed with minced tunafish, onion, and green pepper also add a splash of color.

**T**he boar's head, once the high point of the traditional Christmas dinner in the homes of English nobles, rarely appears on American tables, but turkey, goose, and other fowl do. Cooks the country over have their favorite stuffing recipes, many of which call for large amounts of bread or breadcrumbs. One way to cut down on calories is to use a stuffing with little or no bread, such as one made of water chestnuts and mushrooms.

Many traditional holiday dinners include several varieties of potato. Why not substitute for one of them another fresh vegetable such as beans seasoned with savory? A type of European mint, savory was once thought to be good for the digestion. Herbs add a delightful touch to many vegetables and can substitute partially for salt. As a change from the usual cranberry sauce try a spicy cranberry relish. If a fresh garden salad is part of the feast, use a low calorie dressing, or one made with tomato juice and herbs.

The piece de resistance of a traditional holiday meal often is the plum pudding, served in a blaze of glory. After months of soaking in brandy, however, this dessert has too many calories to count. The nutrition-minded may prefer a light fruitcake with after dinner coffee. Fresh fruit, nuts in the shell, and cheese also provide a light and nutritious touch after any hearty meal. To strike a happy medium between the high and the low on the calorie scale, try dessert crepes with a fruit sauce. The tiny pancakes can be made in advance and served with a flourish from a chafing dish.

It is hard not to have candy and cookies around during the holiday season, especially where there are children. Dates, with their natural sweetness, offer a nutritious alternative to candy canes and sugarplums. They can be eaten "as is," stuffed with nut meats, or used in sugarless cookies.



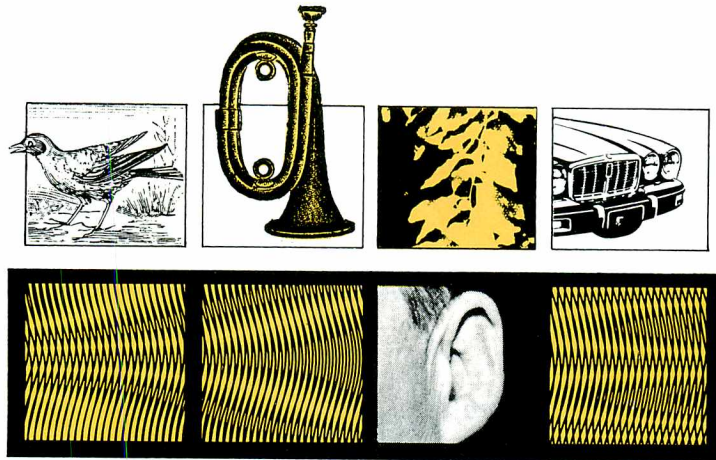
**N**o doubt about it, planning "nutritious" holiday fare in the face of the family's demands for the traditional can be a challenge. But a wide range of cookbooks, including those with low calorie recipes, are available in public libraries and bookstores. Voluntary health agencies such as the American Heart Association have printed material on diet and nutrition, including suggested recipes. Some of these organizations have nutritionists on their staffs who can help diet-conscious consumers plan appropriate menus.

And be sure to read the nutrition labels on canned and packaged foods. They contain valuable nutrition information, including calories per serving, which can be a guide in selecting the ingredients you use in your favorite recipes and in planning all your holiday meals.

*Annabel Hecht is a staff writer with FDA's Office of Public Affairs.*



# Now Hear This



*The buildup of wax in the ear is not a sign of "poor hygiene," an FDA advisory panel has pointed out. Wax or cerumen is, in fact, part of the ear's natural defense against infection and many of the ways people remove it can do far more harm than good.*

by Annabel Hecht

As long as people have had ears, they have had ear aches. In pursuit of something to relieve those aches they have turned most often to heat—heat in the form of hot salt applied on the outside of the ear, a hot roasted onion held against the ear, or warm liquids, including the juice from the kidney of a bald duck, poured into the ear. For severe throbbing pain, an 1894 home treatment guide recommended two leeches, one to be placed in front, the other immediately behind the ear. In keeping with good pediatric practice, the guide indicated that one leech would be sufficient for children!

While most people today would be reluctant to try such bizarre treatments, many folklore remedies and

superstitions about the ear still persist, according to a panel of experts which has been studying nonprescription topical otics—drugs that can be applied directly to the ear for treatment of ear conditions.

The panel is one of 17 advisory groups called together by the Food and Drug Administration to evaluate the safety and effectiveness of the hundreds of thousands of drugs American consumers can buy "over the counter," or without a doctor's prescription. Topical otics were one of four types of ingredients reviewed by this panel. The three others, to be reported on at a later date, are painkillers used to relieve the pain of rheumatism (topical analgesics); drugs for the treatment of burns (skin protectants); and products to prevent sunburn (topical sunscreens).

Information about ear products is often misleading, the panel noted. What consumers really need, it said, is more information on how to care for their ears. The group wanted the record to be clear on these points:

- Deafness is not caused by ear wax.

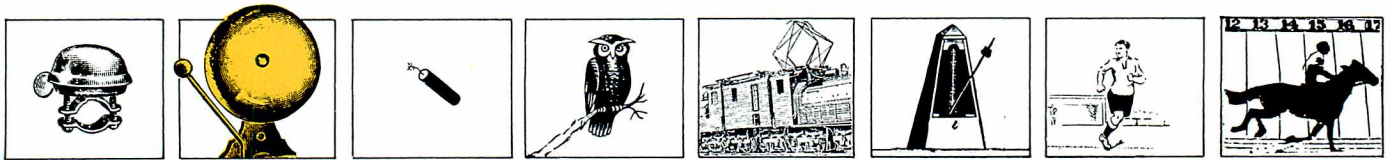
- The normal loss of hearing due to advancing age cannot be relieved by removing ear wax.

- The presence of ear wax does not imply "poor hygiene."

The normal, healthy ear has its own protective system. There are hairs at the entrance to the ear canal which prevent foreign material from entering. In addition, the skin of the ear canal has a relatively high acid content. This "acid mantle," as it is called, defends the ear against bacterial and fungal invasion. Further protection comes from the combined secretions of the various glands in the ear which form a waxy, water—repellant coating called cerumen, or ear wax.

Accumulated wax, along with cast-off skin cells, is continuously being moved outward along the ear canal by the movement of the jaw in the process of chewing. It is unfortunate, the panel report said, that "cerumen has a color reminiscent of an unkempt child." Many people think they have to remove this wax every day and they use a variety of tools, from the tip of the finger to the business end of a match. Poking anything into the ear can break





the acid mantle, the panel pointed out, paving the way for infection.

The panel particularly warned against use of cotton-tipped sticks. Daily cleaning of the ear canal with these devices not only damages the protective skin barrier, but can push the wax deeper into the ear canal where it can become impacted.

The only condition of the ear that consumers should treat themselves is the accumulation of ear wax in the external ear canal, the panel said, and the only product suitable for this purpose is an ear wax softening agent. Two ingredients reviewed by the panel—glycerin and carbamide peroxide in glycerine—were considered safe and effective as ear wax softening agents. Ingredients that soften wax are not the same as those that dissolve it, the panel stressed. Dissolving agents, called cerumenolytics, should be used only by a physician for removing hard, impacted wax from the inner ear.

Two other ingredients evaluated by the panel were deemed neither safe nor effective for self treatment. These are antipyrine and benzocaine used in ear drops to relieve pain. The panel concurred with FDA's action, taken in

1973, requiring that ear drop preparations containing these drugs be sold by prescription only. It is better to take aspirin or an aspirin substitute for pain than to use ear drops, said the panel, since topical painkillers placed in the ear are not absorbed from the skin of the ear canal or ear drum well enough to do any good.

The panel stressed that ear aches can result from a variety of conditions, such as infections, foreign material pressing against the ear drum, or can be "referred pain" from diseases of the teeth, jaws, tongue, or nasal sinuses. Thus, symptoms such as earache, running ear, itching, a sensation of fullness as if the ear were blocked, hearing impairment, and fungal infections such as "swimmer's ear" should be diagnosed and treated by a physician.

The panel recommended that labels for ear wax softening agents be permitted to claim only that the product is "to aid in the softening and removal of obstructive ear wax." Labels should not be permitted to claim that the product is for ear hygiene, wax prevention, wax dissolving, deafness, itching or other discomforts, pain, raw or

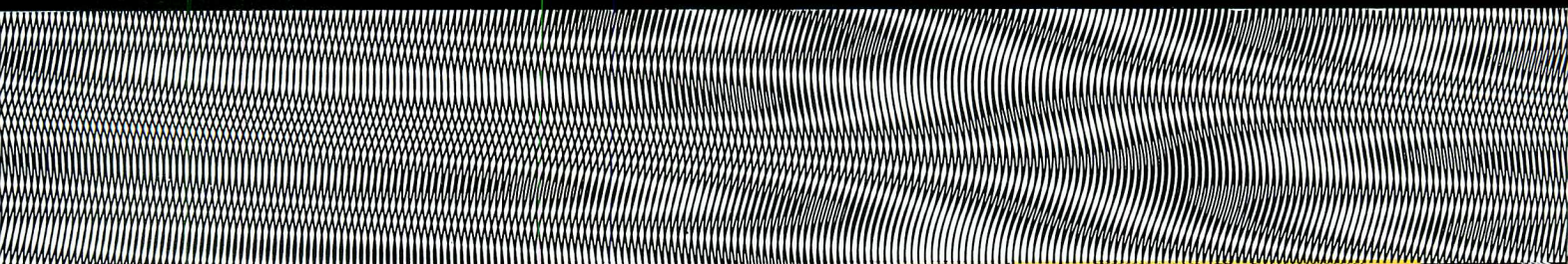
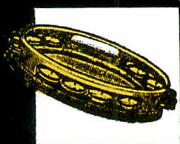
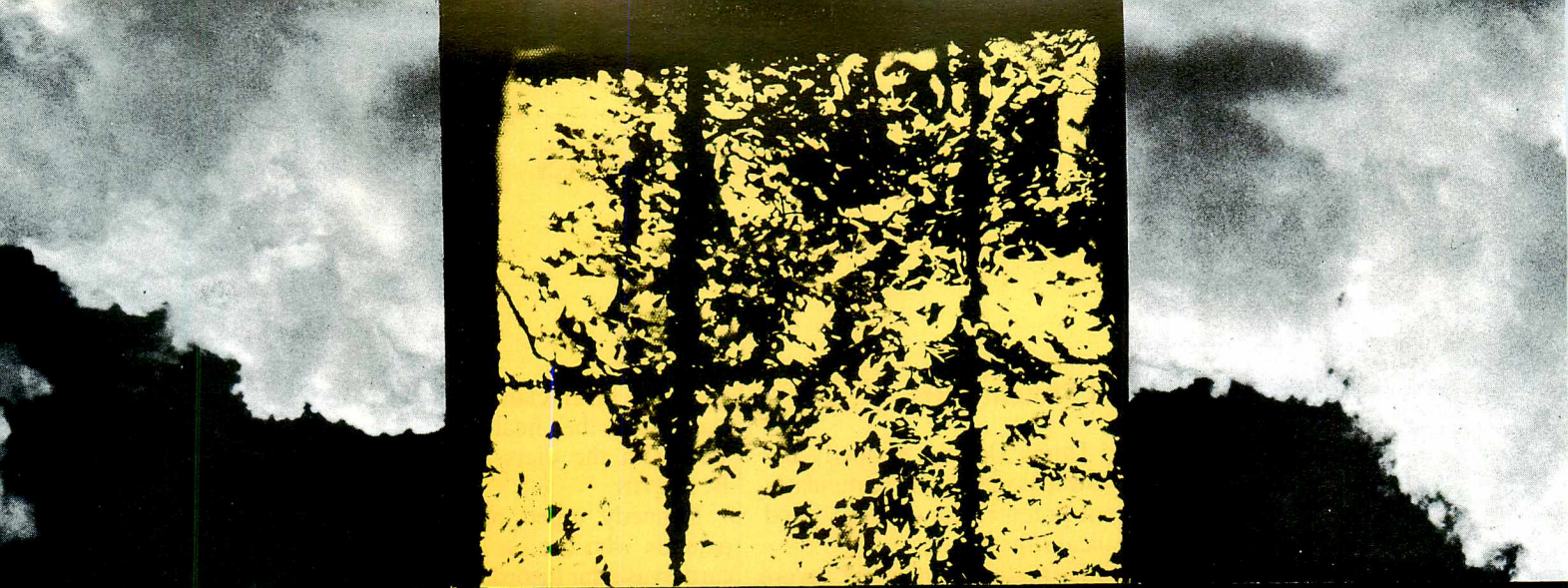
inflamed tissues, "swimmer's ear," or ringing in the ears, the panel said. It also called for a label statement advising consumers to consult a physician if "symptoms of fullness" persist, or if there is pain or dizziness. To alert individuals who may have a disease condition, the panel said the label should caution that the product should not be used if there is ear drainage, pain, or known eardrum perforation.

The panel also advised that ear wax softening agents should not be used in children under 12 without consulting a physician.

The topical otic report is the eighth panel report to be completed in FDA's continuing review of nonprescription drugs. Recommendations of the panels are advisory and FDA publishes them in the FEDERAL REGISTER to give interested persons an opportunity to comment before the Agency issues final regulations on acceptable ingredients and labeling claims. The topical otic report was being prepared for publication as this issue of FDA CONSUMER went to press.

*Annabel Hecht is a staff writer with FDA's Office of Public Affairs.*

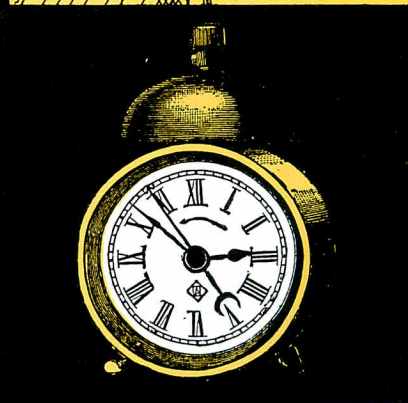
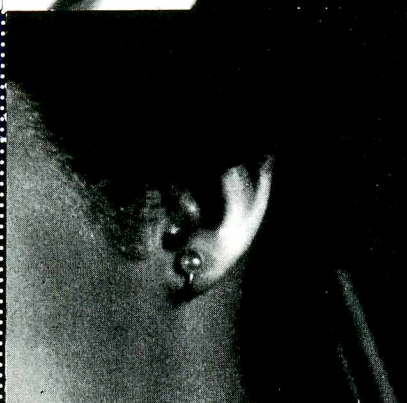
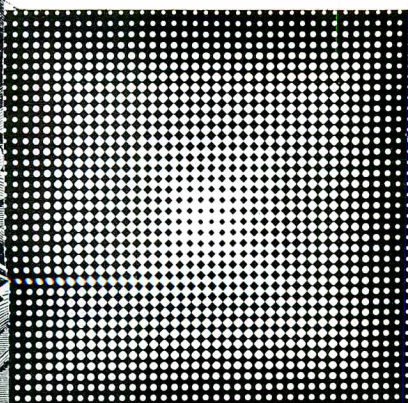
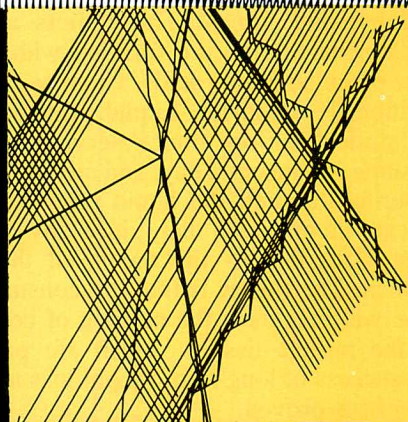




Ch. Clarinet

Sw. Vox celeste

coupled to Sw.





# News Highlights

## Public Cautioned on Liquid Protein Diets

Commissioner of Food and Drugs Donald Kennedy has warned the public that very low calorie diets, particularly liquid protein diets, "have great potential for damage" and should not be used without medical supervision.

FDA has reports of 16 deaths and a number of severe illnesses that may be associated with the use of predigested liquid protein diets, Kennedy said. All of these cases involve people who subsisted on this type of diet without other nourishment for weeks or months.

Ten of the reports of death have been investigated by the Federal Center for Disease Control (CDC). CDC reported that all 10 of these people were obese women between the ages of 25 and 44 who lost an average of 90 pounds of weight after being on liquid predigested protein diets for extended periods. None had a history of heart disease and all died suddenly, without previous symptoms, of heart irregularities—either while on the diet or shortly after going off it. CDC said that in all eight patients on whom complete autopsy reports were available, the coronary arteries were free of disease which could account for sudden death.

Commissioner Kennedy said that on the basis of the CDC findings there was "every reason to believe that the liquid protein diet was at least a contributing factor or cause of the deaths," although further study would be needed to establish a firm cause and effect relationship.

Liquid protein diets are made from hydrolized (predigested) collagen or gelatin obtained from animal hides, tendons, and bones. These diets are basically protein supplements. Some are fortified with a limited number of other essential amino acids, vitamins, and minerals. None is nutritionally complete. Liquid protein drinks contain about 60 calories per one-ounce serving. Women on the diets consume 3-5 ounces a day, and men 4-7 ounces.

During the diet, the liquid protein is intended to be the principal item in the diet, since any carbohydrate eaten in other foods defeats the theory of the "modified fasting" regimen. The theory is that the consumption of this protein alone will maximize the burning of body fat while conserving the muscle tissues, which are predominantly protein. The success of long term weight loss under this regimen has never been proved.

Commissioner Kennedy said FDA is developing a mandatory warning label for liquid protein diet products that will say:

"Do not use for weight reduction or maintenance without medical supervision. Do not use without medical advice if you are taking prescription medications. Not for use by infants, children, or pregnant or nursing women."

Manufacturers have been asked by FDA to supply such warnings immediately on a voluntary basis.

In addition to developing a warning label, Kennedy said FDA is inspecting plants and testing liquid protein products to find out how they are made and what they consist of,

checking label claims for accuracy, and informing physicians and other health professionals about the risks associated with the diets through an article in the FDA DRUG BULLETIN.

Kennedy urged physicians who prescribe the diet and patients who are on it to be alert for any warning signs of cardiovascular disorders.

"None of the liquid protein diets is nutritionally complete," Kennedy emphasized, "and use of the diet alone can, and often does, lead to serious nutritional deficiencies, including potassium imbalance, which can cause fatal heart irregularities; rapid drops in blood pressure on standing up; or muscle weakness and cramps, dry skin, or hair loss."

He strongly recommended that people on the diet receive close medical supervision, pointing out that vitamin and mineral supplements, and especially potassium supplements, might be required and that these must be carefully prescribed. "Too much potassium, as well as too little, can be extremely harmful," he said.

People coming off the diet and re-introducing their bodies to solid food should be especially careful, Kennedy said, and the diet should not be used by the elderly; people with kidney, liver, or heart disease or high blood pressure; or by pregnant women or nursing mothers.

Research is now going on at several medical centers to see whether there may be merit to the theory behind the liquid protein concept. The research is designed to see whether the protein-type low-calorie diets have merit over other low-calorie diets; that is, if a person consuming 500 calories on the protein diet will lose less lean body mass (muscle) than a person on another type of 500-calorie diet. The research is focused on extremely obese people who use the diet under strict medical supervision as part of a total program to achieve weight reduction. If the protein diet regimen proves to have value, it most likely will be for some people who are extremely obese.

## Aerosol Warning Label Now Required

Food, drug, and cosmetic containers propelled with chlorofluorocarbon gases now must carry this label: "Warning: Contains a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere."

The warning label is required under a new regulation issued by the Food and Drug Administration and is part of a government-wide effort to end the use of aerosol products propelled by chlorofluorocarbons.

Under FDA's regulation, the warning label must appear on deodorants, antiperspirants, hair sprays, colognes and fragrances, and other FDA-regulated products propelled with chlorofluorocarbons and shipped in interstate commerce on or after October 31. Of the self-pressurized containers sold in this country each year, about 360 million will be affected by this FDA order.



In the case of cosmetic fragrances and gift packages, the warning statement will not be required until December 31, 1977. FDA granted the extension to avoid disruption and increased production costs for certain seasonal products.

The Consumer Product Safety Commission (CPSC) has issued a final regulation to require the same warning label on household cleaners, air fresheners, and other products it regulates. CPSC's regulation will go into effect February 20, 1978. Since April 15, the Environmental Protection Agency (EPA) has required that chlorofluorocarbons be identified on the labels of all pesticides containing the chemical.

The labeling actions are intended to encourage voluntary cutbacks by consumers in the use of aerosol products propelled by chlorofluorocarbons until a mandatory phase-out of these products can be completed. Earlier this year, FDA, EPA, and CPSC proposed a timetable for this phaseout to start in October 1978 and to be completed by April 1979. Final regulations ordering the phaseout will be issued by FDA and EPA after public comment received on the proposed timetable is evaluated.

The FDA-required warning label will not apply to products in which the use of chlorofluorocarbons is essential. These include over-the-counter drugs intended for inhalation therapy for bronchial asthma; contraceptive vaginal foams; and cytology fixatives, a medical device used in a diagnostic procedure for cancer.

The Government actions on chlorofluorocarbons follow through on regulatory commitments made by the agencies in response to a National Academy of Sciences report issued in September 1976. The NAS report affirmed that chlorofluorocarbons rise into the stratosphere and may deplete the ozone layer which shields the earth from certain harmful rays of the sun. The theory was first advanced by scientists in 1974.

Chlorofluorocarbons are members of a family of chemicals known as halocarbons; they are composed of chlorine, fluorine, and carbon.

FDA regulates about 85 percent of all products using chlorofluorocarbons as propellants in the United States. CPSC and EPA regulate the remaining 15 percent.

## Rules Proposed for Product Tests on People

FDA has proposed new standards spelling out the obligations of drug, food, medical device, and other firms in monitoring product testing performed on people.

The proposed regulations provide for greater protection for the rights and safety of volunteer subjects, and will help assure the quality and integrity of test data submitted to FDA, according to the proposal published in the *FEDERAL REGISTER* September 27.

Recent investigations by FDA and other Federal agencies have raised questions about the validity and reliability of scientific data used to support marketing applications.

Last year, FDA took the first step in setting national standards for product testing by proposing mandatory rules to be followed by companies conducting animal testing. Comments on this regulation, called Good Laboratory Practices (GLP's), have been evaluated and a final regulation is being drafted.

The new proposal focuses on the responsibilities of firms which sponsor human testing and the responsibilities of persons who monitor the conduct of these tests. Such testing is performed after animal tests have been completed and the safety of the product has been measured.

Examples of the types of requirements which the new regulations would impose on sponsors and monitors include:

- Visits to the investigator before the study on humans begins to make sure the investigator understands the status of the product to be tested and the test plan.
- Periodic visits to the investigator during the study to assure adherence to the test plan and maintenance of adequate records.
- Assurance that the investigator has adequate facilities for the proper conduct of the test and for the protection of the human subjects.

• Evaluation of all new data from the investigator on the safety and effectiveness of the product being tested.

Under the proposed rule, a company or individual that does not adhere to these regulations may be disqualified.

FDA established a 90-day period beginning September 27 (the date of publication in the *FEDERAL REGISTER*) for submission of comments on the proposal. Comments should be submitted to the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20857.

## Consumer Groups Seek Action on Cigarettes

A number of consumer groups and a consumer representative on an FDA advisory committee have taken actions aimed at involving FDA in the regulation of cigarettes.

Two of the actions involve petitions. The first, filed in May 1977, calls for FDA to take jurisdiction over the regulation of cigarettes on the grounds that they are drugs or medical devices. The petition asks FDA to regulate cigarettes "no less strictly than saccharin" and to restrict the sale of cigarettes containing nicotine to pharmacies. The petition was filed by Action on Smoking and Health (ASH) together with 13 other State and national organizations and prominent individuals including two former surgeon generals, Drs. Luther Terry and Jesse Steinfeld.

FDA officials met with ASH Executive Director John Banzhaf and Dr. Terry in July. ASH has said it will supply FDA with additional data in support of its petition.

In August the National Interagency Council on Smoking and Health also asked FDA to regulate cigarettes containing nicotine and supported ASH's petition.

A second petition was received in October from a citizen's group concerned about the effects of smoking on women who take birth control pills. This group wants FDA to reopen the comment period for the Agency's regulation requiring that women who purchase oral contraceptives be given a special brochure that explains the side effects associated with the use of these drugs. There have been reports that smokers who use oral contraceptives are more likely to suffer adverse side effects than non-smokers.

All the petitions are being carefully studied and FDA will respond to each.

In another action, FDA's Anesthesiology Device Classification Panel decided that cigarette filters are medical



devices and voted unanimously to advise the Agency to regulate them. The issue was raised by the consumer representative to one of the panel's subcommittees because this panel advises FDA on how to regulate medical devices involving respiration and functions of the lungs. The panel recommended that FDA classify cigarette filters as Class III devices under the medical device law enacted in 1976. A device placed in Class III must be approved by FDA for safety and effectiveness before it can be sold.

Acting solely on the scientific merits of the issue, the panel reasoned that cigarette filters sold separately and those attached to cigarettes are medical devices because of implied claims made by manufacturers that they can relieve symptoms of ill health caused by smoking. The panel said the filters should be placed in Class III because more data are needed to evaluate their safety and effectiveness. The panel's classification recommendations along with FDA's views will be published in the *FEDERAL REGISTER* within the next few months.

Tobacco products are not specifically excluded from regulation under the Food, Drug, and Cosmetic Act. In the past, however, the Act has been interpreted to exclude jurisdiction over these items unless health claims (such as for weight reduction) are made for them. The warning that appears on cigarette labels and advertising was required specifically by the Congress following the Surgeon General's Report on Smoking and Health in 1964, and is enforced by the Federal Trade Commission.

### **Safeguards Set for Intraocular Lenses**

The Food and Drug Administration has established new safeguards for the use of intraocular lenses.

Intraocular lenses are plastic lenses surgically implanted in the eye following removal of the natural lens, most frequently because of cataracts. About 400,000 people are operated on annually for cataracts. About 50,000 Americans have received lens implants over the past 20 years, with most being in the past few years.

Until now, intraocular lenses have been generally available for use by eye surgeons. However, last year Congress passed the Medical Devices Law, which gave FDA increased authority over devices such as intraocular lenses.

The new requirements, which were published November 11 in the *FEDERAL REGISTER*, limit intraocular lenses, including those now on the market, to investigational use only.

This means that physicians who want to implant lenses must participate in a formal investigation. The results of their findings must be submitted to FDA.

It also means that patients must be informed in writing about the risks and benefits of intraocular lenses before implantation and sign a form stating that they understand the terms of the investigation in which they are participating.

On the basis of these investigations, manufacturers will accumulate information to apply to FDA for permission to make their lenses available generally to eye surgeons. Only lenses that are adequately tested and proved safe and effective will be approved by FDA for general marketing.

Under the regulation, manufacturers have 90 days to

submit proposed plans for manufacturing, sterilization, and testing of their products.

These restrictions are needed because there have been reports of more than 100 serious injuries, including five eye losses, after intraocular lens implantation. The injuries appear related to inadequate quality control and manufacturing practices.

FDA in July 1977 ordered one manufacturer to notify 650 physicians and hospitals that had received shipments of 7,700 lenses that could cause irritation and infection. About 1,200 of these lenses already had been implanted. Ninety-four patients experienced adverse reactions and some required surgical removal of the lenses.

The regulation became effective upon publication in the *FEDERAL REGISTER*.

### **Curb Sought on Tetracycline Use in Feed**

The Food and Drug Administration has proposed to severely restrict the routine use in animal feeds of the antibiotics chlortetracycline and oxytetracycline.

These tetracyclines have been routinely added to animal feeds for over 25 years to help animals gain weight faster and to prevent and control disease.

The tetracycline proposal is FDA's second step toward halting the routine long term, low-level use in animal feed of antibiotics that are important in treating diseases in people or animals. The tetracyclines used in animal feed are the same drugs used to treat infections in humans.

FDA took the first step to restrict antibiotic use August 30 by proposing to prohibit the addition of penicillin to animal feeds.

The Agency is proposing these actions because with the continuous long term use of small amounts of penicillin and the tetracyclines in animal feed, the bacteria in the animals develop resistance to the antibiotics being fed and often to other drugs as well. It is possible for this drug resistance to be transferred to bacteria in people.

When bacteria that have become resistant to an antibiotic cause disease in people or animals, that antibiotic is less effective as a medical treatment.

The goal of the proposed regulations is to preserve these antibiotics' effectiveness as medical treatments.

Under FDA's proposal, tetracyclines could still be used in animal feed to control outbreaks of five diseases that affect poultry, sheep, and beef cattle because there are no effective substitutes. FDA believes that when such outbreaks occur the addition of tetracyclines to feed to protect healthy animals outweighs the potential risk.

FDA's proposal will not affect the availability of the tetracyclines to treat diseased animals.

The proposed action on the tetracyclines mainly affects feed for hogs and cattle and, to a lesser extent, poultry. Other antibiotics that are less likely to produce bacterial resistance can be substituted for the tetracyclines in feed for these animals.

Dr. C. D. Van Houweling, director of FDA's Bureau of Veterinary Medicine, said: "As the use of the tetracyclines and other antibiotics in animal feed has increased over the years, drug resistant bacteria in people and animals also have increased. Studies in chicken, swine, and cattle show



that the routine use of tetracyclines even in small doses will cause a marked increase in resistant bacteria.

"We have concluded that the benefit to the livestock industry and consuming public from the routine and continuous use of tetracyclines in animal feeds does not outweigh the potential long term risk to the public health since this use increases bacterial resistance to important antibiotics. This action is designed to help preserve the effectiveness of the tetracyclines in treating disease in people and animals."

The tetracycline proposal was published in the October 21 *FEDERAL REGISTER*. FDA allowed 90 days from that date for public comment on the proposal and 30 days for industry to request a hearing on the proposed action. Comments should be sent to the Hearing Clerk, Food and Drug Administration (HFC-20), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

## **FDA to Revoke Licenses of 11 Biologicals**

The Food and Drug Administration has announced its intention to revoke the licenses of 11 biological products used to diagnose, treat, or prevent certain respiratory, allergic, arthritic, and skin ailments.

The action is based on an evaluation of 31 bacterial vaccines and antigens (an antigen is a substance—usually a protein—that elicits an immune response in humans) by a nongovernment expert advisory panel. The products, virtually all given by injection, are used by a small number of physicians, mostly for treating chronic conditions.

The products reviewed by the panel were, for the most part, licensed before 1940, when acceptable evidence of safety and effectiveness often consisted of clinical impressions, testimonial evidence or other anecdotal information. The panel review was based on a judgment of the safety and effectiveness of these products according to current scientific standards.

FDA has published formal notices to revoke the licenses for the 11 products. Manufacturers may request a hearing.

The panel found that 12 additional vaccines and antigens lacked evidence of safety and effectiveness, but their licenses already have been revoked at the request of the manufacturers.

For the remaining eight products in the total of 31 reviewed, the panel recommended that FDA require additional studies. FDA intends to provide time for manufacturers to conduct the needed studies if they comply with a specific study schedule.

If these eight products continue to be used, FDA is proposing that they be labeled with a prominent statement saying that further studies are needed to establish effectiveness. FDA also is proposing to require that lay-language information be provided to patients to make clear that the products have not been proven effective.

The panel report, along with the announcement of FDA's proposed actions, was published in the *FEDERAL REGISTER*, November 8, 1977. The *FEDERAL REGISTER* announcement said that the Agency intends to revoke the licenses of 17 bacterial vaccines and antigens but, just prior to publication of the announcement, one manufacturer requested that six of these licenses be revoked. Therefore, only 11 licenses remain to be revoked.

Sixty days from the date of publication in the *FEDERAL REGISTER* were allowed for public comment on the report and announcement.

The panel spent four years evaluating all data available on the 31 vaccines and antigens. It was chaired by Dr. Richard S. Farr, director, Department of Medicine of the National Jewish Hospital and Research Center, Denver, Colorado.

The panel had the option of placing each of the products in one of four categories. Category I products are deemed safe and effective. None of the 31 products was rated in this category. Category II products are determined to be unsafe or ineffective and should be removed from the market. Three products were in this category. Category IIIA products require further study but may remain on the market in the interim. Eight were placed in this category. Category IIIB products are those for which available data are not sufficient to classify them as safe and effective and which the panel believes should be removed from the market. Twenty products were assigned to this category.

The panel report is the second in a series of six reports in FDA's safety and effectiveness review of all licensed biological products. The first report, published in the *FEDERAL REGISTER*, September 30, 1977, covered skin test products used to detect a variety of medical conditions. Based on that report, FDA is planning to revoke the licenses for eight such tests and require additional studies on six others.

Four panels are still reviewing products. These products are: bacterial vaccines and toxoids with potency standards; viral and rickettsial vaccines; allergenic extracts; and blood and blood derivatives.

Comments on the report may be sent to the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20857.

## **Cooper Named FDA General Counsel**

Richard M. Cooper is the new General Counsel of the Food and Drug Administration. He succeeds Richard A. Merrill, who resigned effective last August to return to the law faculty at the University of Virginia.

Cooper served earlier this year with the Energy Policy and Planning Office, forerunner to the Department of Energy, where he worked on President Carter's national energy plan.

As FDA General Counsel, Cooper will serve as the principal legal counselor and adviser to the Secretary of Health, Education, and Welfare (FDA is a constituent agency of the U.S. Department of Health, Education, and Welfare) and to the Commissioner of Food and Drugs in the interpretation, application, and enforcement of all laws and regulations administered by FDA.

Cooper practiced law in Washington, D.C., from 1971 to early 1977 with the firm of Williams, Connolly and Califano. For a year before he joined this firm, he worked in Uganda with the chief adviser to the attorney general of that nation.

Cooper served as a law clerk to Supreme Court Justice William J. Brennan, Jr., following his graduation, summa cum laude, from Harvard Law School in 1969. He was president of the law review at Harvard.



# Regional Reports

*"Regional Reports" consists of important information on inspections, product seizures, court proceedings, and other regulatory and administrative actions initiated by FDA's regional and district field offices across the country to provide protection to consumers under Federal laws.*

## REGION I

*Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont*

Various lots of foods including rice, flour, cookies, and beans, valued at \$230,000, were seized by a U.S. marshal at Samuel Kurr and Co., Westwood, Massachusetts, because of insect contamination. The seizure resulted from a routine inspection by FDA's **Boston District** which revealed insect infestation throughout the warehouse. All foods in nonrigid containers were seized.

## REGION II

*New Jersey, New York, Puerto Rico, Virgin Islands*

A 110-pound lot of swordfish, valued at \$350, was seized by U.S. marshals at the Fulton Fish Market, New York, because of mercury contamination. Tests on samples of the swordfish collected by FDA's **New York District** revealed mercury levels in excess of the 0.5 parts per million allowable under FDA regulations. The swordfish was held under embargo by the New York City Health Department until Federal seizure. FDA monitors swordfish for possible mercury contamination under a routine surveillance program.

U.S. marshals seized 3,400 cases of margarine, valued at nearly \$52,000, at Wylie Distribution and Warehouse,

Buffalo, after an inspector from FDA's **Buffalo District** discovered pools of oil beneath pallets of the margarine during a routine inspection. The oil proved to be melted margarine. The firm, despite warnings on the cases to keep the product refrigerated, had stored the margarine at room temperature. The margarine, which was labeled under three different brands, was seized after samples were analyzed by the Buffalo District and found to be short in weight from 0.5 to 3 percent.

Lyons Canning Co., North Rose, New York, voluntarily destroyed 7.5 tons of chickpeas imported from Morocco after an investigator from the Buffalo District found they were contaminated with insects. During a routine inspection, the investigator observed what looked like a black sheen on the water in a bin of soaking chickpeas. Closer inspection revealed that the film was actually a layer of drowned insects. The chickpeas, valued at about \$6,000, were buried at the town landfill.

Roche Laboratories, a division of Hoffmann-LaRoche, Inc., Nutley, New Jersey, voluntarily recalled more than 100,000 ampoules of a drug for newborn babies after it found variations in potency ranging from 10 to 200 percent of the labeled strength. The product, Konakion Injectable, is a clear, liquid injection of vitamin K<sub>1</sub>, which is used primarily in the treatment of hemorrhaging in newborns. The firm notified FDA's **Newark District**, which then inspected the plant to determine the cause of the problem. Preliminary findings point to a breakdown in the drug's emulsifying agent which caused the variation in the drug's strength. Roche Laboratories has written to all 188 direct accounts that purchased the drug, directing them to return ampoules with the lot number 0164-11116

to the plant.

A truckload of about 6,800 pounds of fish and oysters, valued at \$10,000, was destroyed by burial in a landfill at Kearny, New Jersey, because of decomposition. The seafood had been shipped from Rupert's Inc., Los Angeles, to the Bayonne Military Ocean Terminal in New Jersey. Upon arriving at the terminal the truckdriver told officials that he had been on the road for three weeks with a malfunctioning cooler. FDA's Newark District was notified and subsequent laboratory analysis of haddock, catfish, and oysters collected by Newark District investigators confirmed the decomposition.

A lot of 2,600 50-pound bags of dried milk, valued at \$130,000, was seized by a U.S. marshal at a food warehouse in San Juan, Puerto Rico, because of heavy insect infestation. The seizure at Industria Lechera de Puerto Rico resulted from a routine inspection by FDA's **San Juan District**.

## REGION IV

*Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee*

Reina Bros. and Co., Inc., Tampa, was fined \$3,000 in the U.S. District Court for the Middle District of Florida for storing food in an insect- and rodent-contaminated warehouse. In addition, Domenico Reina, Jr., the president of the firm, was fined \$1,000. The legal action resulted after several inspections by FDA's **Orlando District** revealed insanitary conditions in the warehouse.

A shipment of over 4,000 pounds of whole red snapper fish, offered for import from Oceanica, Ltd., in Colombia, South America, was detained





by the Orlando District at the Port of Miami because of decomposition. The fish, valued at over \$12,000, was destroyed. The detention resulted from a routine wharf inspection by Orlando District investigators.

## REGION V

*Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin*

A mass seizure of falsely labeled devices, which supposedly reduced the swelling of body tissues, soothed aching joints, and assisted blood flow for people who wore them, was made by the Federal Government at the manufacturer, Jung Products, Inc., Cincinnati, Ohio. The product, labeled Future Thermolastic, was made of elastic material in the shape of a glove, toeless sock, or tube for application to the hand, ankle, knee, or elbow. The seizure resulted from a lengthy investigation by FDA's **Cincinnati District** into labeling claims made by the manufacturer, which indicated to FDA it was conducting studies to support the therapeutic claims. After the company failed to provide FDA with such studies, the misbranded products, valued at \$200,000 were seized to stop further distribution to consumers. The firm originally had contacted the Cincinnati District to find out how it could properly label its products to market them in California. California earlier had refused to allow the firm to market the products because of mislabeling.

H. W. Martin and Sons, owner of Quality Farm Seeds and Chemicals, Hebron, Ohio, has agreed in court not to distribute products until adequate processing controls have been established in its seed treating plant. The firm entered into a consent decree of permanent injunction in the U.S. District Court for the Southern District of Ohio as the result of cooperative inves-

tigations by the United States Department of Agriculture (USDA) and FDA's Cincinnati District. The investigations showed that 45 hogs and 5 head of cattle in a slaughterhouse in Columbus, Ohio, were contaminated by mercury after being fed mercury-treated grain seeds at Quality Farm Seeds' farm at Hebron. The Cincinnati District was informed of the situation by USDA inspectors who discovered the contaminated meat during surveillance of the slaughterhouse. Cincinnati District investigators inspected the farm and found that the owner inadvertently allowed grain eventually intended for human and animal food to be mixed with chemically-treated seeds. Seeds intended for planting are sprayed with fungicides including captan and phenylmercuric ammonium acetate and are required to be dyed pink or red as a warning against their use in food or feeds.

## REGION VI

*Arkansas, Louisiana, New Mexico, Oklahoma, Texas*

Omicon Medical Corp., Dallas, a manufacturer of devices that are used to administer anesthetics which are inhaled, has revised the labeling on its machines to caution against use of the devices in conjunction with a humidifier. The danger is that humid air can cause filters in the inhalation devices to become clogged and obstruct the flow of the anesthetic gas to the patient. Such a condition could result in improper anesthesia and thus threaten the patient's health. The firm sent letters to its 16 medical wholesalers in 13 States warning them of the potential hazard. The wholesalers, in turn, notified their clients, mostly hospitals, of the potential problem. The warning letter resulted from an investigation by FDA based on information from a private physician who had done re-

search on the device and noted the potential hazard. **Dallas District** investigators then visited the manufacturer at which time the firm agreed to contact its wholesalers.

For the fifth year in a row FDA's resident post in San Antonio, Texas, participated in the Mexican Trade Fair held in San Antonio. The fair, sponsored by the Mexican government, gave nearly 400 Mexican manufacturers and wholesalers the chance to display products they sell to American companies. The items displayed included a number of products FDA regulates as well as building materials, textiles, home furnishings and appliances, jewelry, leather goods, and arts and crafts. FDA consumer affairs officers and investigators from the resident post tended an information booth and provided pamphlets and brochures in English and Spanish on the Agency's consumer mission. In addition, they informally surveyed new and unusual foods, pharmaceuticals, cosmetics, and other products which fall under FDA's jurisdiction once they are shipped across the border.

FDA's **New Orleans District** monitored the reconditioning of more than \$654,000 worth of green coffee beans imported from El Salvador by Jan C. Uytterwyck Co., New Orleans. An investigator from the New Orleans District found the beans were stored in an open shed on the wharf at the Port of New Orleans where they were defiled by birds, rodents, and even dogs. The firm, which operates the dock, undertook the reconditioning after the State placed an embargo on the coffee pending regulatory action by FDA. The beans were contained in nearly 2,000 150-pound bags.

FDA's New Orleans District completed an investigation of damage





caused by Hurricane Babe to firms in its district which produce, distribute, or sell food, drugs, and other products that are under the Agency's jurisdiction. The hurricane struck southern Louisiana last September. Damage was relatively light with most problems caused by high water rather than wind. A tornado generated by the hurricane caused slight structural damage to Elmers Candy Co., Ponchatoula, Louisiana. Hardest hit was the Acli Seafood Co., Chauvin, Louisiana, where floodwaters reached the plant's freezer causing loss of more than \$50,000 in food products and an additional \$12,000 in packaging materials.

## REGION VII

*Iowa, Kansas, Missouri, Nebraska*

U.S. marshals seized about 8,100 pounds of various food products, including mung beans, sweet rice, and rice flour at King's Trading, Inc., Kansas City, Missouri, because of rodent contamination. The seizure resulted from a routine inspection by FDA's **Kansas City District** of the wholesale company, which distributes imported oriental foods. The products were valued at over \$2,700.

## REGION VIII

*Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming*

The Tri-County District Health Department of Englewood, Colorado, has discontinued the repackaging of bulk prescription and nonprescription drugs which were dispensed through its clinical care program. Inspections by FDA's **Denver District** over the past two years have turned up numerous and significant deficiencies in the repackaging procedures. This led to the health department's decision to close down the repackaging operations and use prepackaged individual dosages instead.

A U.S. marshal seized a lot of chamomile, valued at \$100,000, at Ce-

lestial Seasonings, Inc., Boulder, Colorado, because the bitter herb was contaminated with live and dead insects. The seizure resulted from an inspection of the firm by FDA's **Denver District**. The firm is a repacker of various teas. The chamomile tea was labeled as originating from Argentina.

Two lots of animal drugs, valued at nearly \$6,000, were seized by a deputy U.S. marshal at Triple Crown Pharmaceutical, Inc., Fort Collins, Colorado, because the drugs had not been approved by FDA. The seizure resulted from an inspection of the firm by FDA's **Denver District**. The drugs, Prednisone Suspension and Adrenal Cortex Injection, were manufactured by Chromalloy Pharmaceuticals, Inc., Carter-Glougau Laboratories Division, Glendale, Arizona.

## REGION IX

*Arizona, California, Guam, Hawaii, Nevada*

U.S. marshals, accompanied by an inspector from FDA's **Phoenix Resident Post**, seized the entire inventory of media plates and tubes at Bolin Laboratory, Phoenix, Arizona, because of mislabeling violations. The materials, used in diagnosing bacterial diseases, failed to contain package inserts containing information about the product as required by Federal regulations. The seizure of over 4,000 plates and tubes, valued at over \$3,200, resulted from a routine inspection of the firm by the Phoenix Resident Post.

## REGION X

*Alaska, Idaho, Oregon, Washington*

A U.S. marshal in Seattle seized approximately 2,300 pounds of canned salmon after examination by FDA's **Seattle District** revealed decomposition in the lot. The salmon, valued at about \$7,500, was shipped by St. Elias Ocean Products, Cordova, Alaska, to a storage warehouse in Seattle where investigators using the district's mobile lab-

oratory collected samples.

A U.S. marshal in Boise, Idaho, seized nearly 2,500 40-pound bags of potato flakes at Magic Valley Foods, Inc., Rupert, Idaho, following an inspection of the firm by the **Seattle District**, which indicated the product had been manufactured under insanitary conditions. Subsequent laboratory analysis by FDA of samples collected during the inspection found that the potato flakes contained *Escherichia coli* and excessive coliform bacteria, whose presence in food indicates insanitary food handling practices by employees. The lot originally was shipped to a company in Ontario, Oregon, but later was recalled by the manufacturer.

J. B. Gottstein and Co., Inc., Anchorage, Alaska, and its responsible officials, have agreed to an order issued by the U.S. District Court for the District of Alaska, to bring its food service operation into compliance with FDA regulations. The action resulted from an inspection of the firm by the **Seattle District** which revealed the firm was holding rodent-contaminated food including cracker meal, rice, pepperoni, and lentils in a rodent-infested warehouse. Under the order, FDA inspectors will supervise the examination of each lot of food for filth before it is allowed into distribution channels. Any food found contaminated must be destroyed or brought into compliance with the Federal Food, Drug, and Cosmetic Act. If the firm fails to comply with the order, it could be subject to closure or whatever additional remedies the court deems necessary. In addition, the firm must eliminate vermin, renovate its facilities and equipment, and select a qualified person to be responsible for maintaining the facilities, equipment, and operations in a sanitary manner. The corporation is a wholesale distributor of various foods to the retail trade and military installations in the Anchorage area.



# 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 21 actions to remove from the consumer market products charged to be violative was reported in October. These included 11 seizures of foods: 1 involved charges concerning poisonous and deleterious substances, 8 involved charges concerning contamination, and 2 involved charges concerning economic and labeling violations. Other seizures included 7 of drugs (including 3 of veterinary/medicated feed), 2 of medical devices, and 1 of cosmetics.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>FOOD/Poisonous and Deleterious Substances</b>		
Almonds, shelled/South Boston, Mass. 9/12/77	Kane International Corp./Larchmont, N.Y. (S)	Contains the added poisonous and deleterious substance aflatoxin. Label lacks name and place of business of manufacturer, packer, or distributor, and lacks common or usual name of food.
<b>Contamination, Spoilage, Insanitary Handling</b>		
Coffee beans/Savannah, Ga. 8/16/77	Ocean Terminal Office/Savannah, Ga. (D)	Unfit for food since article contains dirt, stones, sticks, and other extraneous material; and such materials were substituted in part for article.
Flour/Sikeston, Mo. 7/27/77	Shipped in two railcars from Arkansas City, Kans.	Held under insanitary conditions; contains insects and flakes of foreign material.
Potato granules, dehydrated/Clearfield, Utah 7/22/77	R. T. French Co./Shelley, Idaho (M,S)	Prepared and packed under insanitary conditions; contains <i>E. coli</i> , and bacterial filth.
Rice/Idaho Falls, Idaho 7/26/77	Norton Fruit Co./Idaho Falls, Idaho (D)	Held under insanitary conditions; rodent contaminated.
Rice and other warehouse stocks/West- wood, Mass. 8/19/77	Samuel Kurr & Co./Westwood, Mass. (D)	Held under insanitary conditions; some lots of rice contain insect filth.
Sesame seeds/Brooklyn, N.Y. 8/26/77	Gel Spice Co., Inc./Brooklyn, N.Y. (D)	Held under insanitary conditions.
Shrimp, frozen/San Francisco, Calif. 7/ 21/77	Orient Marine Products/Madras, India (P); Shore Lobster Shrimp Corp./New York, N.Y. (S)	Contains decomposed shrimp.
Spearmint leaves/Kenosha, Wis. 7/20/77	Herbarium, Inc./Kenosha, Wis. (D)	Contains insects and insect fragments.
<b>Economic and Labeling Violations</b>		
Dairy powder, chocolate-flavored/Can- ton, Ill. 7/5/77	Consolidated Flavor Corp./St. Louis, Mo. (M,S)	Chocolate-flavored dairy powder made with cocoa and carob was substituted for chocolate-flavored dairy powder made with cocoa.
Fruit cocktail, canned/Lomira, Wis. 7/ 20/77	California Cannery & Growers/San Jose, Calif. (M,S)	Fails to conform to the definition and standard of identity for canned fruit cocktail, since the peach content exceeds and pear and pineapple contents are below the prescribed amounts.
<b>DRUGS/Human Use</b>		
Athlete's foot spray and first aid spray/ West Seneca, N.Y. 9/6/77	Pelorex Corp./West Seneca, N.Y. (M)	Circumstances of manufacture, processing, packing, and holding not in conformity with current good manufacturing practice.
Ephedrine tablets/Denver, Colo. 7/27/77	William C. Petty/San Diego, Calif. (S)	Label lacks name and place of business of manufacturer, packer, or distributor; lacks quantity of contents statement; lacks established name of drug; and labeling lacks adequate directions for use and is not exempted.
Lidocaine HCl injection and Dicyclo- mine (Pasmin) injection/Peñuelas, P.R. 8/4/77	D-M Pharmaceuticals/Rockville, Md. (M,S)	Circumstances of products' manufacture, processing, packing, and holding not in conformity with current good manufacturing practice.
Zinc undecylenate/Buffalo, N.Y. 7/15/77	Lucidol, Div. of Penwalt Corp./Buffalo, N.Y. (M,D)	Fails to meet U.S.P. standard, since it exceeds the 1 percent residue limit for alkalis and alkaline earths.



PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>Veterinary/Medicated Feed</b>		
Medicated animal feeds, in-process medicated feeds, and drug components for feeds/Fredericktown, Mo. 7/28/77	Paul Skaggs & Sons, Inc./Fredericktown, Mo. (D,M)	Circumstances of manufacture, processing, packing, and holding, not in conformity with current good manufacturing practice.
NF-180 Concentrate furazolidone medicated premix/Evansville, Ind. 7/6/77	Rhodia, Inc. (Hess & Clark Div.)/Ashland, Ohio (D)	New animal drug and fails to conform to approved New Animal Drug Application, since furazolidone not from an approved source.
Penicillin & dihydrostreptomycin injectable, and procaine penicillin injectable/Comanche, Tex. 7/6/77	Gore Bros. Agri-Service Center/Comanche, Tex. (D)	Circumstances of products' holding, not in conformity with current good manufacturing practice, since products were stored at room temperature.
<b>MEDICAL DEVICES</b>		
Comforters, hand, elbow, knee, and ankle/Cincinnati, Ohio 8/4/77	Jung Products, Inc./Cincinnati, Ohio (D)	False and misleading claims for edema in rheumatoid arthritis, for swelling, and for easing, relieving, or alleviating stiffness, aching, sore, painful, or tender body and limb joints, and false and misleading claims concerning findings of effectiveness and being tested at U.C.L.A. Medical Center, and concerning derivation of effect through warmth plus compression; labeling fails to bear adequate directions for lay use and were not exempted therefrom.
Vital Air replacement oxygen spheres/Cambridge, Mass. 8/19/77	Vital Air Oxygen Co./Cleveland, Ohio (M,S)	Labeling lacks accurate quantity of contents statement in terms of measure of oxygen gas contained; labeling lacks adequate directions for intended use since cannot be written and article not exempt; and the article is dangerous to health when used as recommended or suggested since article is intended for emergency use and lacks a sufficient supply of oxygen for emergency medical purposes for the claimed time.
<b>COSMETICS</b>		
Glow Goop novelty cosmetic/Temple, Ariz. 8/8/77	Creative Images, Inc./Temple, Ariz. (M); Hannon Products Corp./Corona, Calif. (S)	Contains the nonconforming color additive zinc sulfide.

**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.

No information available for this issue.



# Notices of Judgment

## NOTICES OF JUDGMENT on Seizure Actions

### FOOD/Poisonous and Deleterious Substances

#### **Swordfish pieces**, at Manchester, Dist. N.H.

Charged 5-19-77: when shipped by Great Atlantic Fish Corp., Boston, Mass., the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 61212; S. No. 77-91-555; N.J. No. 1)

### FOOD/Contamination, Spoilage, Insanitary Handling

#### **Butter, anhydrous milk fat, and pasteurized process American cheese**, at Seattle, W. Dist. Wash.

Charged 7-29-75: while held by Consolidated Dairy Products Co., Seattle, Wash., who manufactured the anhydrous milk fat and pasteurized process American cheese (using interstate cheddar and some of the butter which had been returned to the manufacturer from Los Angeles, Calif.), the butter contained decomposed butter, and the anhydrous milk fat and pasteurized process American cheese contained decomposed anhydrous milk fat; 402(a)(3). The articles were claimed by the manufacturer who denied the charges. The claimant and Government served written interrogatories on each other. Ultimately a consent decree of condemnation authorized release to the claimant for conversion into animal food. (F.D.C. No. 60417; S. Nos. 19-883/5 H; N.J. No. 2)

#### **Coffee beans**, at Dale City, N. Dist. Calif.

Charged 1-20-77: while held by Alexander-Balart Co., Dale City, Calif., 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. 62008; S. Nos. 77-75-289/93; N.J. No. 3)

#### **Coffee beans**, at San Jose, N. Dist. Calif.

Charged 1-13-77: while held for sale, one of the four lots of the article contained rodent filth, and all lots of the article had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Keystone Co., San Jose, Calif., for salvaging. (F.D.C. No. 61072; S. Nos. 77-523/7; N.J. No. 4)

#### **Corn husks**, at Denver, Dist. Colo.

Charged 8-20-75: while held by El Molino Foods, Inc., Denver, Colo., the article contained insects, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 60426; S. No. 76-17-703; N.J. No. 5)

#### **Cornmeal, cereals, baking mixes, flour, and other warehouse stocks**, at Dallas, N. Dist. Tex.

Charged 5-14-76: while held by T. L. Jeffrey Distributing Co., Inc., Dallas, Tex., a number of the articles contained rodent and/or insect filth, and all the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized destruction of selected foods and authorized release to dealer of remaining foods for salvaging. (F.D.C. No. 60740; S. No. 76-14-143 et al.; N.J. No. 6)

#### **Dextrose and ammonium sulphate**, at San Jose, N. Dist. Calif.

Charged 4-5-77: while held by Harold Freund Baking Co., San Jose, Calif., the articles were held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61158; S. Nos. 77-75-299/300; N.J. No. 7)

#### **Flour, salt, cracker meal, rice, crackers, and other warehouse stocks**, at Yuma, Dist. Ariz.

Charged 1-5-76: while held by Yuma Wholesale Produce & Grocery Co. (L. W. Gordon), Yuma, Ariz., the flour, salt, cracker meal, and rice contained rodent filth, and all the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 60592; S. No. 76-28-507 et al.; N.J. No. 8)

#### **Grits**, at Yonkers, S. Dist. N.Y.

Charged 2-22-77: while held for sale, the article contained insects; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61092;

S. No. 77-88-816; N.J. No. 9)

#### **Macaroni products, egg noodles, spaghetti, popcorn, oat cereal, rice, cake mixes, and other grocery stocks**, at Tucson, Dist. Ariz.

Charged 11-23-76: while held by Southwestern Grocery, Inc., Tucson, Ariz., some of the articles contained insect filth, and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 60987; S. No. 77-28-544 et al.; N.J. No. 10)

#### **Peanut cake, oriental noodles, ginger, rice powder, dried bean curd, dried shark fins, and other oriental retail and warehouse grocery stocks**, at San Francisco, N. Dist. Calif.

Charged 10-22-76: while held by Chuck Lee's Market (at that partnership's warehouse and retail store), San Francisco, Calif., some of the articles contained rodent filth; and all the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 60967; S. No. 77-74-205 et al.; N.J. No. 11)

#### **Rice**, at Phoenix, Dist. Ariz.

Charged 10-22-76: while held by Union Seafoods, Inc., Phoenix, Ariz., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60527; S. No. 76-28-406; N.J. No. 12)

#### **Sodium acid pyrophosphate**, at Monte Vista, Dist. Colo.

Charged 7-11-74: while held by Nonpareil Processing, Monte Vista, Colo., the article was held under insanitary conditions; 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 59866; S. No. 80-841 H; N.J. No. 13)

#### **Talc for use for coated rice**, at Crowley, W. Dist. La.

Charged 2-10-77: while held by Brown & Cassidy Warehouse, Inc., Crowley, La., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Eagle Rice & Feed Mills, Inc., Crowley, La., for salvaging. (F.D.C. No. 62051; S. No. 77-78-628; N.J. No. 14)

## FOOD/Economic and Labeling Violations

#### **Syrup and honey mixture**, at Tampa, M. Dist. Fla.

Charged 11-10-76: when shipped by Pakhoed Rotterdam BV, Rotterdam, Holland, the article, labeled in part "Pure Honey Net Weight 650 Lbs. Rotterdam," had had syrup substituted in part for honey; 402(b)(2). Consent decree authorized release to National Papaya Co., Tampa, Fla., for export to original supplier. (F.D.C. No. 60966; S. No. 77-64-019; N.J. No. 15)

## FOOD ADDITIVES

#### **Selenium, chromium, yeast & vitamin combination tablets**, at San Juan Capistrano, C. Dist. Calif.

Charged 6-20-77: while held by Rajar Enterprises, Inc., San Juan Capistrano, Calif., who manufactured the article using vitamin E powder which had been shipped in interstate commerce, the article labeled in part "Super Sel-E-Chrome III," contained the nonconforming food additives selenium, *DL*-methionine and aspartic acid; 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 61290; S. No. 77-77-115; N.J. No. 16)

#### **Sodium pangamate combination tablets**, at Passaic, Dist. N.J.

Charged 9-22-76: while held for sale, the article (all lots) contained nonconforming food additives due to its content of sodium pangamate and of (19 bottle lot and 112 bottle lot) glycine—402(a)(2)(C); the article's labels contained false and misleading claims about the article, and its vitamin B-15 and pangamate content, when sodium pangamate was not an identifiable substance, was not a vitamin or pro-vitamin, and there was no accepted scientific evidence establishing nutritional properties, identifying a deficiency, or demonstrating safety—403(a); and the article failed to declare the common or usual name of each ingredient—403(i)(2). Default decree ordered destruction. (F.D.C. No. 60913; S. No. 76-87-331 et al.; N.J. No. 17)





## VITAMINS/SPECIAL DIETARY FOODS

### **Vitamin B<sub>12</sub> and ribonucleic acid (RNA) combination tablets**, at Compton, C. Dist. Calif.

Charged 5-27-77: while held by I. D. Co., Compton, Calif., after manufacture by Cosmo-Pharm., Inc., North Hollywood, Calif., using imported RNA powder, the article, labeled in part "RNA 325 mg./Vit. B-12 400 mcg . . . Each Tablet Contains: . . . in a base of yeast containing DNA . . . Suggested Use: As a dietary supplement," contained the nonconforming food additives ribonucleic acid (RNA) and deoxyribonucleic acid (DNA); 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 61243; S. No. 77-10-300; N.J. No. 18)

## DRUGS/Human Use

### **Glucose tolerance test cola**, at Baltimore, Dist. Md.

Charged 11-8-76: while held by Custom Laboratories, Inc., Baltimore, Md., who manufactured the article using dextrose which had been shipped in interstate commerce, the article, labeled in part "glucose tolerance test cola—100 gm. abco-dex Mfd. for Abco Dealers, Inc. Milwaukee, Wisconsin," had been manufactured, processed, packed, and held under circumstances that failed to conform with current good manufacturing practice; 501(a)(2)(B). Consent decree authorized release to the manufacturer for bringing into compliance with the law. (F.D.C. No. 60965; S. No. 77-59-777; N.J. No. 19)

### **Lidocaine HCl injection, Hepviron injection, pyridoxine HCl injection, liver injection, sodium heparin injection, and triamcinolone diacetate injection**, at Cincinnati, S. Dist. Ohio.

Charged 5-12-77: when shipped by Bel-Mar Laboratories, Inc., Inwood, N.Y., the circumstances used for 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. 61222; S. Nos. 77-18-602/7; N.J. No. 20)

### **Thiamine hydrochloride tablets; and phenobarbital tablets and other drug stocks**, two seizure actions, at Broomfield, Dist. Colo.

Charged 3-9-76 and 3-24-76: while the thiamine hydrochloride tablets were held by Cord Laboratories, Inc., Broomfield, Colo. (who had manufactured that article and the other articles, using components shipped in interstate commerce), and while the other articles were held by the manufacturer or the manufacturer's repackaging and labeling subsidiaries at Broomfield, Colo., the circumstances used in the manufacture, processing, packing, and holding of the thiamine hydrochloride tablets, the phenobarbital tablets, and the other drug stocks failed to conform to current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction of the thiamine hydrochloride tablets. The other articles were claimed by the manufacturer who denied the charges. The claimant petitioned the court to receive representative samples of various lots of chlorpromazine hydrochloride tablets, aspirin tablets, meprobamate tablets, Taloidin tablets, Bacarate tablets, Tora tablets, and Theo Cord tablets. The court authorized the claimant and the Government to obtain those samples in accordance with the claimant's petition. Subsequently, a consent decree of condemnation authorized release of the remaining articles for bringing them into compliance with the law in accordance with an agreed upon sampling and testing program. (F.D.C. No. 60676; S. No. 76-17-503 et al.; N.J. No. 21)

## DRUGS/Veterinary

### **Brophen atropine methyl nitrate tablets and injections**, at Covina, C. Dist. Calif.

Charged 9-14-76: while held for sale after manufacture from interstate atropine methyl nitrate (tablets) by ICN Pharmaceuticals, Inc., Covina, Calif., and (injections) by Titan Pharmacal Co., Los Angeles, Calif., the articles labeled in part "Brophen Tablets [or "Injection"] . . . Manufactured for Hall Veterinary Drug Co. . . . Garden Grove Ca.," were new animal drugs and no approval of a New Animal Drug Application was in effect with respect to their use and intended use; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 60732; S. Nos. 76-27-758/9; N.J. No. 22)

### **Cardiac digitalin german, strophanthin, sparteine sulfate & nitroglycerin tablets, and Cardiac Toytabs digitalin german, strophanthin, sparteine sulfate & nitroglycerin tablets**, at Kansas City, W. Dist. Mo.

Charged 7-1-77: when shipped by Haver-Lockhart Laboratories, Div. Bayvet Corp., Shawnee, Kans., the articles were new animal drugs and no approval of a New Animal Drug Application was in

effect with respect to the articles' use or intended use; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 61267; S. Nos. 77-16-328/9; N.J. No. 23)

### **Comfrey Leg Gel salve with allantoin**, at Canby, Dist. Oreg.

Charged 6-16-77: while held for sale after manufacture by Highland Laboratories, Inc., Portland, Oreg., using allantoin shipped in interstate commerce, the article was a new animal drug, and no New Animal Drug Application was in effect with respect to the article's use or intended use; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 61263; S. No. 77-07-026; N.J. No. 24)

### **Dimethylsulfoxide fluid**, at Hallandale, S. Dist. Fla.

Charged 4-4-77: when shipped by Vet Aid Laboratories, Inc., Aiken, S.C., in an unlabeled drum, the article was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to the use or intended use of such drug as a veterinary liniment—501(a)(5); the article lacked the name and place of business of the manufacturer, packer, or distributor, lacked a quantity of contents statement, and lacked the established name of the drug—502(b)(1), 502(b)(2), 502(e); and the labeling of the article lacked adequate directions for use and was not exempted due to failure to conform to the requirements of the exempting regulations—502(f)(1). Default decree ordered destruction. (F.D.C. No. 62055; S. No. 77-43-539; N.J. No. 25)

### **Esmopal implants**, at Indianapolis, S. Dist. Ind.

Charged 6-10-77: while held by Mattox & Moore, Inc., Indianapolis, Ind., who manufactured the article using imported estradiol-17 beta monopalmitate, the article was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to the use or intended use of the article for growth promotion or feed efficiency; 501(a)(5). The article was claimed by the manufacturer who entered into a consent decree condemning the article. The decree authorized release to the manufacturer for bringing into compliance with the law by means of specified changed labeling and also ordered that the claimant not in the future cause the adulteration of any new drug through employment of labeling not approved in an effective New Animal Drug Application. (F.D.C. No. 61254; S. No. 77-67-010; N.J. No. 26)

### **Furazolidone-60 medicated premix**, at Omaha, Dist. Nebr.

Charged 5-31-77: while held by International Nutrition, Inc., Omaha, Nebr., who manufactured the article using bulk furazolidone 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 its use or intended use; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 61238; S. No. 77-16-307; N.J. No. 27)

### **NF-180 Concentrate furazolidone medicated premix**, at Evansville, S. Dist. Ind.

Charged 6-29-77: while held for sale by the local dealer who used furazolidone shipped in interstate commerce by Rhodia, Inc. (Hess & Clark Div.), Ashland, Ohio, the article was a new animal drug and failed to conform to an approved New Animal Drug Application, since the article contained furazolidone which was not from a source approved in the application; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 61284; S. No. 77-66-990; N.J. No. 28)

### **Nitrofurazone veterinary powder**, at Charlotte, W. Dist. N.C.

Charged 4-22-77: when shipped by Performance Products, Inc., St. Louis, Mo., the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to its use and intended use; 501(a)(4). Default decree ordered destruction. (F.D.C. No. 61181; S. No. 77-61-452; N.J. No. 29)

## MEDICAL DEVICE

### **Cathioderm ozone producer and electric current introducer for head and facial treatment**, at Southfield, E. Dist. Mich.

Charged 4-19-76: while held by Esthetics of Mira Linder, Inc., Southfield, Mich., who had imported the article from Paris, France, the article's label lacked adequate directions for lay use for its intended purposes, since such directions could not be written, and it was not exempted since adequate information for use by licensed practitioners could not be furnished; 502(f)(1). The article was claimed by the dealer who entered into a consent decree of condemnation. The decree also authorized the article to be exported to the original foreign supplier upon payment by the claimant of court costs and fees, and storage and other proper





expenses. (F.D.C. No. 60659; S. No. 86-073 H; N.J. No.30)

#### COSMETICS/BEAUTY PRODUCTS

**Roux Lash & Brow Tint kits (Bottle No. 1—pyrogallol solution; Bottle No. 2—silver salt solution; and Bottle No. 3—stain remover) for black tint, and similar kits for brown tint, at San Dimas, C. Dist. Calif.**

Charged 5-13-74: when shipped by Roux Laboratories, Inc., Jacksonville, Fla., the articles were cosmetics which were not hair dyes and the articles contained a nonconforming color additive composed of pyrogallol and silver lactate, because such color additive was not a provisionally or permanently listed, or an exempt, color additive; 601(e). The articles were claimed by the shipper who denied the Government's allegations, except for admitting that the articles were not hair dyes. The claimant asserted: (1) that the complaint failed to state a claim upon which relief could be granted; (2) that the seizure action was in violation of the court's order in *The Toilet Goods Assn., Inc., et al. v. Finch* (63 Civ. 3349) (the "TGA case"), because pyrogallol and silver lactate were not color additives, but were diluents intentionally mixed in the seized cosmetic to facilitate the use of the cosmetic in coloring, and because the TGA order prohibited FDA from enforcing regulations requiring the listing and premarket clearance of diluents; (3) FDA had failed to complete required administrative procedures, since no regulations for separately listing a color additive for use in or on the seized cosmetic had been promulgated; and (4) the seizure was in violation of FDA regulations.

The claimant also moved for discovery of evidence concerning FDA's determination to effect the seizure and FDA handling of a petition for color additive listing. Pursuant to stipulation, the parties each took representative postseizure samples of the articles. The Government served written interrogatories on the claimant.

The claimant subsequently moved for permission to file an amended answer to the complaint, asserting additionally: (5) that the seizure action constituted a deprivation of property without due process of law, and (6) that the action was barred by *res judicata* and collateral estoppel due to an April 14, 1942, Eastern District of New York seizure of Roux Lash & Brow Tint.

The Government moved to strike the claimant's affirmative defenses and for protective orders concerning the discovery. The claimant filed a cross-motion for summary judgment. After a hearing on such motions, the court ruled as follows:

"This matter is before the Court on motions filed by both parties during the past several months and heard together pursuant to stipulation of the parties on January 20, 1975.

"Claimant's motion for summary judgment dismissing the complaint is denied. Genuine issues of material fact exist which cannot be resolved on this motion. See *United States v. Roux Laboratories, Inc.*, 437 F.2d 209 (9th Cir. 1971).

"Claimant's motion for leave to file an amended answer adding fifth and sixth affirmative defenses is granted. See *Foman v. Davis*, 371 U.S. 178 (1962) and *Howey v. United States*, 481 F.2d 1187 (9th Cir. 1973). We decline to speculate as to whether the affirmative defenses newly offered in claimant's amended answer are legally sufficient and have not considered such sufficiency on this motion to amend. *Breier v. Northern Calif. Bowling Proprietors Assoc.*, 316 F.2d 787 (9th Cir. 1963).

"Plaintiff's motion to strike affirmative defenses asserted in claimant's Answer of July 18, 1974 is denied without prejudice.

"Plaintiff's motion for a protective order regarding discovery and arising out of claimant's notice of taking deposition filed on October 21, 1974 is denied without prejudice. While the notice in issue indirectly states in general terms possible subject matters of the noticed deposition, we are reluctant to determine the propriety of deposition questions before any examination commences, particularly where as here the moving party can be protected adequately by motion under F.R.Civ.P. Rule 30(d).

"Plaintiff's motion filed November 26, 1974 for a protective order regarding claimant's Request for Production of Documents is granted. The request seeks all documents (documents being defined in some sixteen lines of the request) contained in plaintiff's files relating to its 1938 seizure of Roux Lash and Brow Tint, and the litigation relating thereto (emphasis added). On the record before us, such documents appear irrelevant to any issue in this action and not likely to lead to discovery of any evidence admissible herein.

"Plaintiff's motion for a protective order regarding claimant's Notice to Admit is also granted."

At a subsequent hearing, the court heard the matter based on the claimant's fourth affirmative defense and the Government's motion for summary judgment on that defense. In ordering such summary judgment on that defense for the Government, the court said:

#### Findings of Fact

"1. On December 10, 1963, the United States Food and Drug Administration issued an order appearing at 28 F.R. 13374 entitled 'Color Additives: Metallic Salt and Vegetable Hair Colors' which stated that the United States Food and Drug Administration would not take regulatory action against hair colorings whose ability to alter the color of the hair was due basically to their metallic salt ingredients solely because they are not permanently or provisionally listed as color additives pending a further announcement in the FEDERAL REGISTER.

"2. On January 31, 1973, the United States Food and Drug Administration issued an order appearing at 38 F.R. 2996 which stated that the order appearing at 28 F.R. 13374 was rescinded effective immediately. An exemption from regulatory action for hair dyes whose coloring ability was based upon components consisting of metallic salts was continued in effect until July 30, 1973.\*\*\*"

#### ORDER

\*\*\*

"The issue presented by these motions is to what extent the 1963 FDA notice entitled 'Color Additives: Metallic Salt and Vegetable Hair Colors,' . . . was rescinded by the subsequent notice entitled 'Color Additives, Metallic Salts and Vegetable Substances in Hair Dyes,' . . .

"In our view the 1973 notice rescinded the earlier notice entirely. The later notice was in response to the FDA's amendments to 21 C.F.R. §§ 8.1(f), 8.1(u) and 8.35, published at 36 F.R. 16902 (August 26, 1971), which were promulgated to conform the Color Additive Regulations to the holding in *Toilet Goods Association v. Finch*, 419 F.2d 21 (2d Cir. 1962). Whatever the scope of the 1963 notice, it was rescinded in 1973. Claimant's ingenious interpretation of the 1973 notice is not reasonable when the two notices are read in conjunction with *Toilet Goods Association v. Finch, supra*.

"Plaintiff's motion for summary judgment on claimant's Fourth Affirmative Defense is granted, and claimant's cross-motion for summary judgment is denied."

Thereafter the case came on for trial by jury. The jury returned a verdict for the claimant and the seizure action was accordingly dismissed. (F.D.C. No. 59766; S. No. 67-434/5 H; N.J. No. 31)

#### NOTICE OF JUDGMENT on Criminal Action FOOD

**Lighthouse Wholesale Distributors, Inc., and David Feinsilver, president, and Charles Markusfeld, vice president, Miami, S. Dist. Fla.**

Charged 5-19-77 by grand jury: rice, hominy grits, macaroni, flour, food starch, and spice cake mix were held in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation to all counts; fine. Guilty pleas by individuals to counts involving the rice and macaroni; fine and probation. (F.D.C. No. 60902; S. No. 76-44-101 et al.; N.J. No.32)

#### NOTICE OF JUDGMENT on Injunction Action

**City Smoked Fish Co., and Sam Cohen, vice president & treasurer, Detroit, E. Dist. Mich.**

Charged 12-2-69 in a complaint for injunction (Civil Action No. 33989): that the defendants were engaged in receiving, after shipment in interstate commerce, fish known as chubs which contained the chemical substances DDT and its derivative DDE, were engaged in preparing such chubs as smoked chubs, and were engaged in packing and distributing in interstate commerce such smoked chubs for human consumption; that such smoked chubs contained nonconforming food additives (DDT and DDE), since the total amount of such food additives present in such smoked chubs exceeded the interim limit of 5 ppm (parts per million) established by the FDA announcement of April 22, 1969; that causing the interstate shipment of such smoked chubs and causing chubs, which were held for sale after interstate shipment, to be prepared, packed, and distributed resulted in violations of the law; and that the defendants were well aware that their activities were in violation of the law; 402(a)(2)(C). (Note that prior to the filing by the Government of this injunction action, the defendant firm had initiated an injunction action against FDA (Civil Action No.





33669) complaining of related matters as reported in Notice of Judgment No. 34 of this issue of FDA CONSUMER.)

City Smoked Fish Co. and Sam Cohen admitted to receiving chubs which contained DDT and/or DDE, asserted that the fish ingested such substances in the waters of the Great Lakes and that their presence could not be avoided in the manufacturing process. The defendants also asserted that there was no scientific evidence to show that smoked chubs containing even up to 10 ppm of DDT and its derivatives would adversely affect humans and would not be safe for human consumption, that the Government was required to adopt a tolerance level regulation, that FDA analyses included in the tests of chubs interfering substances so that the reports of analysis were erroneous; that the Governors of all five Great Lakes States had petitioned for the adoption of a 10 ppm tolerance for chubs and a 15 ppm tolerance for coho salmon; and that FDA flagrantly discriminated against City Smoked Fish Co. by applying double standards of administrative justice. The defendants moved to dismiss the action.

The Government's suit and the earlier suit by City Smoked Fish Co. were consolidated for the purposes of a hearing. At the conclusion of six days of trial before the court, the court said that it would not issue a temporary restraining order at that time or hold the firm to its verbal commitment not to ship any chubs in interstate commerce. The case was taken under advisement and the parties were permitted additional time to submit written post-trial briefs. Subsequently, the court ruled for the Government, saying:

"In Civil Action 33989, the United States filed a complaint alleging that City Smoked Fish Company and Sam Cohen were shipping smoked chubs in interstate commerce which were adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C), in that they contained more than five parts per million (p.p.m.) of DDT and its derivatives and sought a permanent injunction prohibiting such conduct. Defendants alleged that the five parts per million guideline was arbitrary and discriminatorily enforced and that the United States was proceeding under the wrong statute.\*\*\*

"Six basic issues are presented to this court for its determination: (1) the reasonableness or unreasonableness of the five parts per million guideline; (2) the statutory authority under which the guideline was promulgated; (3) the constitutional validity of 21 U.S.C. §§ 342(a)(2)(C) and 348 as applied to this case; (4) the presence and amount of DDT in the samples of defendants' fish taken by the FDA; (5) whether DDT found in raw chubs and smoked chubs is a 'food additive' within the meaning of the Act; and (6) the alleged discriminatory enforcement of plaintiff's guideline.

### I

"It appears to be one of defendants' contentions that the five part per million guideline adopted by the Food and Drug Administration is arbitrary and unreasonable because there is not sufficient scientific evidence to indicate that more than five parts per million of DDT in fish is harmful to man.

"In evaluating this position, it is important to determine what standards should be used in judging the Secretary's selection of five parts per million of DDT in fish as the upper allowable limit. Congress has determined in Section 346(a) (dealing with pesticide chemicals), 348(a) (dealing with food additives), and Section 321(s) (defining a food additive), that a substance, whether it be a food additive or pesticide chemical, shall be deemed unsafe for the purposes of Section 342(a)(2) if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures to be safe for use or unless it is used pursuant to a tolerance or exemption issued by the Secretary. It is established here that there is no such tolerance or exemption. Thus, under the terms of the statute, any amount of DDT in fish causes such fish to be adulterated. It is difficult for this court to understand how an interim enforcement guideline permitting up to five parts per million of DDT in fish can be considered unreasonable or arbitrary because the limit thus set does not permit more DDT to be present when the statute permits none.

"Also, this court was favored with substantial testimony as to how the five parts per million limit was selected by the Secretary. Dr. Coulston, a highly respected and eminent toxicologist, testified that the Joint Committee on Pesticide Residues of the Food and Agriculture Organization and World Health Organization, Specialized Agencies of the United Nations, had adopted a recommendation that an average daily intake (a.d.i.) of DDT in man of .01 milligrams per kilogram of body weight was probably safe and

should not be exceeded. He further testified, as a member of this committee, how this figure was selected. In late 1969, after the five part per million guideline had been adopted by the FDA, Dr. Coulston testified that the Joint Committee reduced the a.d.i. to .005 milligrams per kilogram of body weight, half of its previous level.

"Dr. Fitzhugh, toxicological advisor to the Bureau of Sciences of the Food and Drug Administration, testified that in recommending a temporary enforcement guideline for fish, he utilized the .01 a.d.i. limit suggested by the Joint Committee as the *maximum* exposure to DDT to which a man should be subjected in any one day. He pointed out that this exposure takes place primarily through food and water which are ingested. He attempted to determine how much fish a person, who might be termed a fish eater, would eat since this is the only way that all persons could be adequately protected rather than only those who consume average and below-average amounts. He determined, based on Department of Agriculture studies, that fish constitutes about twelve per cent of the total daily diet of those persons who eat fish in significant amounts. On this basis, he recommended a limit of 3.5 parts per million in fish. The Secretary, however, when he promulgated his guideline, set the limit at five parts per million in fish.

"It is true that Dr. Zavon, a very highly qualified and respected toxicologist, presently Public Health Officer for Cincinnati, who testified for defendants, felt that it would be quite safe to permit a twenty part per million DDT residue level in fish. His opinion appears to be well considered and based on a careful evaluation of all relevant data. Dr. Wilcox, a physician and defendants' other expert witness, felt that a ten part per million limit on DDT in fish would be appropriate.

"At most, this testimony by defendants' witnesses shows that reasonable minds can differ as to a proper level of DDT residues which should be permitted in fish. It does not prove that the Secretary's determination of a five p.p.m. limit was arbitrary or unreasonable. Moreover, the statute does not require that the Secretary select the highest possible limit of DDT which a qualified scientist might support. The statute requires, rather, that the Secretary select a limit which is generally recognized among qualified experts as safe. There is no evidence in this record that qualified experts generally recognize any amount of DDT in excess of five parts per million to be safe. Therefore, it cannot be said that the Secretary's determination is unreasonable or arbitrary.

### II

"The second issue that arises in any proper consideration of this case, although not raised by defendants, is the statutory basis for authority of the Food and Drug Administration to issue its interim enforcement guideline. Plaintiff concedes that this guideline is neither a 'regulation' which the Act empowers it to issue, nor any other species of administrative rule recognized by any relevant or pleaded statute. This guideline is not published in the Code of Federal Regulations, nor apparently in any other published compilation of administrative rules.

"Since there is no statutory authority to issue such an interim enforcement guideline, it follows that defendants' violation of law, if any, must be of the statute itself, in this case, the Food, Drug and Cosmetic Act. As previously noted, the Act would forbid any DDT residue in fish unless it is generally recognized by qualified experts that it is safe for man. The evidence in this record establishes clearly that there is no such general recognition. Consequently, this court concludes that any amount of DDT in fish is prohibited under 21 U.S.C. § 342.

### III

"In view of the uncontradicted testimony in this record that some amount of DDT is found in every food, a serious constitutional question may be raised in an attempt to enforce this statute with respect to DDT. The enforcement of the statute, in the absence of any regulations by the Secretary, would virtually forbid the sale of any food in this country. However, the Secretary has issued regulations governing the amount of DDT residues which may be present in almost all varieties of foods. See 21 C.F.R. § 120.147. There is no regulation, however, determining how much DDT may be permitted in fish. In the absence of such a regulation, the effect of this statute is to remove all fish and fish products from the dealers' shelves.

"Since this question of the constitutionality of the statute, as applied to fish, has not been raised, briefed, or argued by counsel, this court will not determine the question at this time.

### IV

"Much of the evidence at trial was directed to proving the





methods used by plaintiff in determining the amount of DDT contained in defendants' smoked chubs and establishing the accuracy or inaccuracy of those methods. It is defendants' position that the tests used by plaintiff gave spurious values as to DDT content because of the possible presence of undetected interfering substances, particularly chlorinated nap[h]thalenes. \* \* \*

"While it is not necessary to describe these tests in detail in this Memorandum Opinion, it should be noted that the primary method for determining both the presence and amount of DDT in the samples was gas chromatography. In testing each sample, this procedure was run more than once to verify the results. Also, the presence of DDT was further established through thin-layer chromatography on all samples and alkaline hydrolysis on most samples.

"Defendants suggested that polychlorinated biphenyl (p.c.b.) could cause a spurious reading if present and undetected. Plaintiff established, without contradiction, that a method had been devised to separate any p.c.b. present from DDT and that this method was followed in analyzing all the samples introduced into evidence. This test was known as the salicylic acid separation procedure.

"Defendants then suggested that chlorinated nap[h]thalenes could give spurious values. However, the Government's witness, Jerry Burke, an expert in chemistry who is familiar with chlorinated pesticides (a term which includes DDT and chlorinated nap[h]thalenes), stated that the salicylic acid separation procedure would also separate chlorinated nap[h]thalenes from DDT. No other witness disputed or in any way questioned this statement.

"The only evidence which might support defendants' position concerning interfering substances were statements by various witnesses to the effect that there was a theoretical possibility that some unidentified substance could cause spurious results in a manner unknown at present. These statements appear to this court to be no more than a scientist's way of saying that neither he nor science knows everything and, therefore, that it is conceivable that someday a substance will be found which produces spurious readings as to the amount of DDT present in a substance when measured by the methods used here. Absent any other and more probative evidence, the court finds that the Government has met its burden of proving that the ten samples of defendants' chubs each contained more than five parts per million of DDT.

#### V

"Although the court has determined that more than five parts per million of DDT were present in all the samples introduced into evidence by the Government, it is still necessary to determine whether the presence of this DDT violates the statute. . . .

"The important phrases in this statute [21 U.S.C. § 342(a)(2)(C)] which require further definition are: (1) 'food additive,' (2) 'pesticide chemical,' and (3) 'raw agricultural commodity.' 21 U.S.C. § 321 defines each of these terms. . . .

"It appears to this court that DDT is a pesticide chemical within the meaning of the Act when it is found in or on a raw agricultural commodity. It further appears that DDT found in *raw* chubs is a pesticide chemical and not a food additive within the meaning of the Act. However, the court concludes that DDT found in *smoked* chubs is a 'food additive,' since the chubs are no longer in their raw or natural state as required by the Act. Clearly, the Government has established that the City Smoked Fish Company violated Section 331(a) of the Act when it shipped smoked chubs containing DDT in interstate commerce. . . . The court also concludes that defendant violated the Act when it processed raw chubs into smoked chubs after the raw chubs had been shipped in interstate commerce because the processing caused the chubs to be adulterated within the meaning of Section 342(a)(2)(C). . . .

#### VI

"Finally, defendant alleges that the United States has discriminated against it in the enforcement of its five parts per million guideline. The undisputed testimony does establish that chubs come almost exclusively from the Great Lakes and that Union Fish Company, Joline Fisheries, and Olsen Brothers, all of Chicago, Illinois, are the major suppliers of raw chubs in this country. The court also finds that defendant, along with its major competitors, Vita Foods, Montrose and Acme, receive most or all of their supply of raw chubs from the above-mentioned distributors and that the distributors purchased these chubs from fishermen in the Great Lakes, particularly Lake Michigan.

"Defendant alleges further that the Food and Drug Administration in its enforcement of the guideline has applied unlawful double standards of conduct, one favorable to defendant's competitors, and the other adverse to defendant, and that the conduct of the FDA reflects a pattern of discrimination against the City Smoked

Fish Company. The record does establish, in the court's view, that the Food and Drug Administration did focus on the activities of defendant and instituted a program of acquiring evidence against defendant in the form of samples of its products taken both from the premises of defendant and from its customers in other states. However, the record does not establish that the Food and Drug Administration was unconcerned with the activities of defendants' competitors or the suppliers of raw chubs.

"With respect to the suppliers of raw chubs, it is the uncontradicted testimony of Mr. Beebe, acting director of the Detroit District of the Food and Drug Administration and formerly stationed in Chicago, that the FDA was collecting two to three samples of fish from Union Fisheries and Joline Fisheries per week in 1969 and that about fifty per cent of these samples exceeded the guideline of five parts per million of DDT in the fish. He also testified without contradiction that the Chicago Regional Office of the Food and Drug Administration has recommended the initiation of further suits for injunction, such as that before this court, against at least one of the suppliers of raw chubs and also against the Vita Foods Corporation, one of defendants' competitors.

"Since the court has determined that the five parts per million guideline has not been discriminatorily enforced, it is not necessary to consider defendants' contention that a discriminatory enforcement of the guideline against defendant would deprive it of the equal protection of the laws. . . .

#### VII

"In Civil Action No. 33669, *City Smoked Fish Company*, as plaintiff, asked injunctive relief against the Food and Drug Administration and its Commissioner, Dr. Ley, alleging that the five parts per million guideline was unreasonable and arbitrary and that the guideline was being enforced against City Smoked Fish Company in a discriminatory manner. The Food and Drug Administration and Dr. Ley responded by filing a Motion to Dismiss, or, in the alternative, for Summary Judgment. The hearing on this motion was combined with the hearing on the Motion for Preliminary Injunction in No. 33989 filed by the United States against City Smoked Fish Company and Sam Cohen.

"Since all parties have submitted all available evidence on the issues of discriminatory enforcement and unreasonableness of the guideline, and inasmuch as the court has determined that the guideline was not enforced in a discriminatory manner against City Smoked Fish Company and that the guideline is reasonable, it follows that the prayer of City Smoked Fish Company for injunction against the Food and Drug Administration and its Commissioner must be denied. Also, there is no allegation in the complaint setting forth the statutory basis of this court's jurisdiction as required by Rule 8 of the Federal Rules of Civil Procedure.

#### VIII

"For the reasons set forth above, this court finds that the limit of five parts per million promulgated by the Secretary is reasonable and not contrary to the due process clause of the fifth amendment. The court also finds that more than five parts per million of DDT were present in all the samples introduced into evidence before this court and that the guideline has not been enforced discriminatorily against City Smoked Fish Company.

"The court concludes that DDT in smoked chubs is a 'food additive' within the meaning of the Act and that any amount of DDT in fish violates the Act.

"For these reasons, and in view of the public interest involved, although there is a possible question of constitutional validity of the statute as applied to fish containing DDT, the court will issue a preliminary injunction as requested by the Food and Drug Administration, prohibiting the City Smoked Fish Company from introducing or causing to be introduced, and delivering or causing to be delivered, for introduction into interstate commerce smoked chubs and other smoked fish and preparing, packing, and distributing chubs and other fish as smoked chubs and as smoked fish while held for sale after shipment in interstate commerce unless such smoked chubs and smoked fish contain less than five parts per million of DDT, including its derivatives."

In accordance with the court's opinion, City Smoked Fish Co. and Sam Cohen were, pending the final determination of the action, enjoined from causing any of the violations complained of. In addition, the suit by City Smoked Fish Co. was dismissed. City Smoked Fish Co. and its vice president moved to reopen the hearing in both cases for further proceedings and for a new trial. In denying such motions, the court said:

"Civil Action No. 33989 involved a request for a permanent





injunction against City Smoked Fish and Sam Cohen to prevent them from shipping smoked chubs containing more than five parts per million of DDT in interstate commerce in violation of 21 U.S.C. § 342. This court after extensive hearings issued a preliminary injunction restraining City Smoked Fish and Sam Cohen from delivering in interstate commerce any chub unless it contained less than five parts per million of DDT. Civil Action No. 33669 involved a counter suit by City Smoked Fish against the United States for an injunction.

"The only remaining issue in these cases as set forth by the parties at the last pretrial is the constitutionality of the statute underlying the regulation. At the pretrial, counsel for City Smoked Fish contended that the statute was unreasonable and arbitrary. Both parties agreed to rely upon their briefs previously filed in this matter. In reviewing these briefs, the only portions dealing with the constitutionality of 21 U.S.C. § 342 appear in briefs filed on the motion to re-open hearing for further proceedings and for new trial. Despite the insistence of counsel for City in that brief that the constitutionality of the statute had been raised in the brief first filed with this Court . . . , we find that the constitutionality of the statute as opposed to the constitutionality of the regulation was not raised until the motion for rehearing or new trial was made.

"Be that as it may, City has challenged the statute on the following grounds: (1) '21 U.S.C. § 342 was enacted in 1938, and DDT was first used in 1944, so that it was not within the contemplation of Congress when the Food, Drug and Cosmetic Act was first enacted,' and (2) in its strict enforcement the statute creates substantial injustice in that it strangles the economy of the fish industry in the United States and that this was not . . . within the contemplation of the Congress.' These are the only allegations made in City's brief concerning the validity of the statute. These two arguments, however, do not bear on the constitutionality of Section 342, but go to the intent of Congress to include substances like DDT within the scope of the statute. We find no allegations that the statute is unreasonable or arbitrary. Nor has plaintiff supplied us with any authority from which to determine the intent of the Congress in enacting Section 342.

"Moreover, this court has determined as set forth in its memorandum opinion that 'DDT in smoked chubs is a "food additive" within the meaning of the Act and that any amount of DDT in fish violates the Act.' . . . Therefore, this Court has ruled upon the objections which City has raised in its brief. We find no reason to sally forth into an area such as the constitutionality of this statute without an adequate brief from the party attacking the validity of the statute as applied to DDT.

"Civil Action No. 33669 was dismissed by order of this Court on June 18, 1970. On that same date this court issued a temporary injunction in case no. 33989. Subsequently City Smoked Fish filed motions in both cases to 'Re-open Hearing for Further Proceedings and for New Trial.' The question of the constitutionality of the statute was raised for the first time in those motions. For the reasons set forth above those motions are denied. Thus the order of dismissal stands in Action No. 33669 and a permanent injunction shall issue in Action No. 33989."

Ultimately, the court issued a permanent injunction enjoining City Smoked Fish Co. and Sam Cohen from causing any of the violations complained of. (Inj. No. 584; S. No. 196-148 C; N.J. No. 33)

#### NOTICE OF JUDGMENT on Miscellaneous Action

##### **Chubs, processed as smoked chubs, and injunction against enforcement of 5 ppm DDT tolerance level against a single processor, Detroit, E. Dist. Mich.**

Charged 10-13-69 by City Smoked Fish Co., Detroit, Mich., against the Food and Drug Administration and FDA Commissioner Herbert L. Ley, Jr., in a complaint for injunction (Civil Action No. 33669): that the plaintiff was in the business of processing fish, was established in 1945, was the largest processor of smoked fish in Michigan (with annual sales in excess of \$3,000,000), and employed 20 full-time employees and other part-time employees (with an annual payroll in excess of \$250,000); that the plaintiff had the right to maintain and operate its business within the law without discriminatory action through unlawful double standards of administrative justice; that the plaintiff's chubs come from the Great Lakes and are sold by commercial fishermen principally to two Chicago distributors, who are the prime suppliers of chubs to all major U.S. fish processors and who supply plaintiff's principal competitors; that plaintiff obtains its chubs from one of those two Chicago distributors; that plaintiff had previously never been

charged with processing smoked fish which were not fit for human consumption; that plaintiff had taken the highest precautions to insure that its smoked fish were clean, wholesome, and fit for human consumption; that a New York shipment of the plaintiff's chubs had been embargoed on allegations of 6 to 7 ppm of DDT; that within minutes of the placing of the embargo, a competitor's representative solicited plaintiff's customer, advising that smoked chubs could not be obtained from the plaintiff and that the competitor would like to supply such customer's needs; that no charges had been filed against the chubs of the plaintiff's competitors (which came from identical waters as plaintiff's chubs); that the defendants showed favoritism to plaintiff's competitors and discriminated against the plaintiff; that plaintiff had written the defendant setting forth its position and demanding equal justice and stating that a large shipment of smoked chubs processed by a competitor had been observed being delivered that very morning to a Detroit supermarket warehouse; that, if plaintiff's chubs were contaminated with an excess of DDT, the same must be true of its competitors' smoked chubs; that plaintiff expressed deep concern over all consumers of smoked chubs and offered to stop processing smoked chubs containing DDT over a reasonable tolerance level, if its competitors agreed to do likewise and if FDA discontinued its discrimination against the plaintiff pending a full scientific review of the effect of DDT on human beings and the establishment of reasonable tolerance levels; that the seizure of plaintiff's smoked chubs and the ensuing newspaper notoriety caused great loss and damage to the plaintiff; that plaintiff was fearful the defendants would discriminate against plaintiff by other seizures and would cause plaintiff to defend a multiplicity of suits; that the plaintiff therefore prayed: that the 5 ppm DDT tolerance be judged unreasonable, arbitrary, and confiscatory and, therefore, unconstitutional and void; that the defendants be permanently enjoined from enforcing the 5 ppm DDT tolerance against the plaintiff unless it pursued a constitutional course of conduct and applied the same standards to all processors of smoked chubs; and that, in the meantime, the defendants be likewise temporarily restrained; and that, pending the final hearing on the matter, the defendants be enjoined from an unconstitutional course of conduct in the enforcement of the temporary tolerance, unless defendants adopt a single standard of administrative justice and apply it to all smoked chub processors.

The court temporarily restrained the defendants and issued an order that the defendants show cause why an injunction should not issue in the meantime and during the pendency of the suit. Subsequently, the Government instituted a number of suits to enjoin the shipment of chubs which exceeded the 5 ppm DDT tolerance, including a suit (Civil Action No. 33989) against the plaintiff in this action. Both City Smoked Fish Co. actions were consolidated for a hearing. After extensive hearings an injunction was issued against City Smoked Fish in the action brought by the Government, and that firm's action against FDA and its Commissioner (i.e. this action—Civil Action No. 33669) was dismissed. The court's determination that FDA's guideline was reasonable and was not enforced in a discriminatory manner is set forth above in Notice of Judgment No. 33, in part VII of the court's opinion, together with the subsequent opinion denying City Smoked Fish Co.'s motion to "Re-open Hearing for Further Proceedings and for New Trial." (Misc. No. 132; N.J. No. 34)

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

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

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

Donald Kennedy, *Commissioner of Food and Drugs*

Washington, D.C., December 1, 1977



# If it's hot, keep it hot!

At room temperature, bacteria can multiply in food.

These bacteria can cause upset stomach. Or other illness.

To prevent food contamination—

**Keep hot foods hot. Keep cold foods cold.**

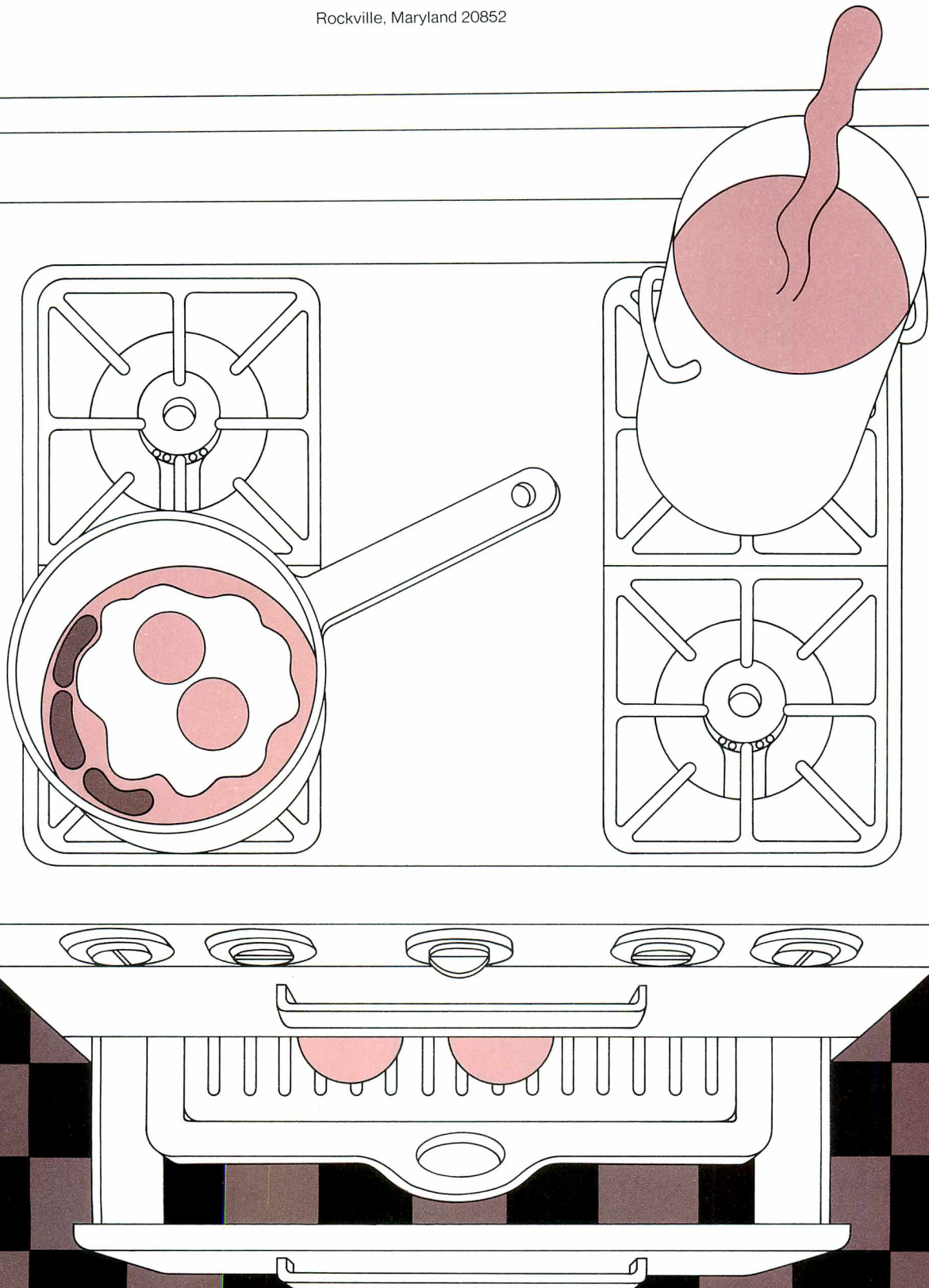
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