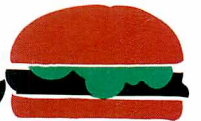


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CONSUMER

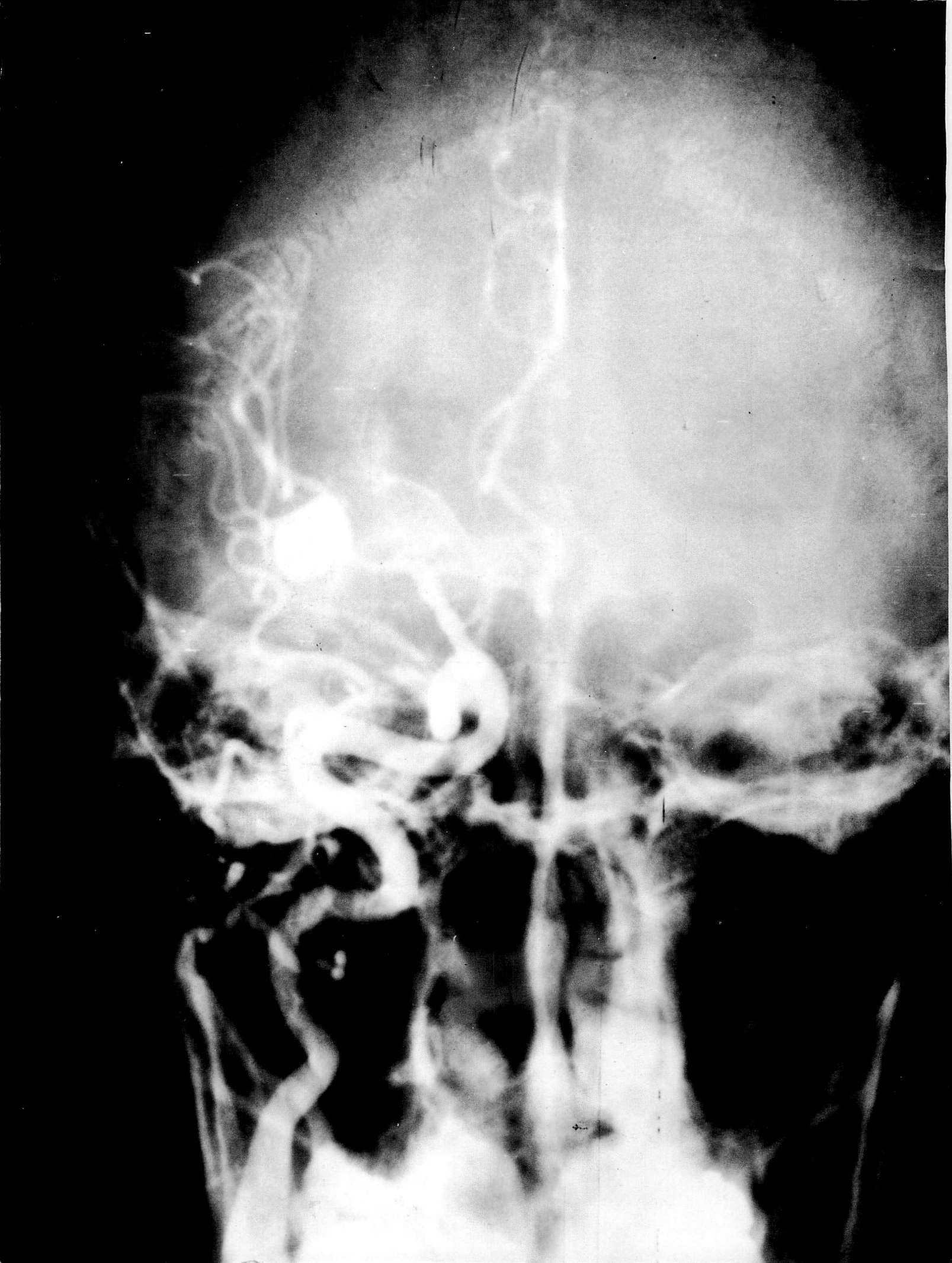
October 1985

**Special
Report:**



**America's
Changing
Diet**

36



Special Report: America's Changing Diet

The past 35 years have seen important changes in what Americans are eating. Health concerns, changing lifestyles, new food products, television advertising—all these forces have come together to rewrite our national menu. This report examines some of the more significant dietary trends and presents the experts' views on why they have occurred.

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For Fruits And Vegetables, Americans Favor 'Fresh'

Economic and health concerns have helped nurture a bumper crop of fruits and vegetables, especially fresh ones, in our diet. Fresh produce is one of the fastest growing categories in U.S. supermarkets.

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Eggs And Dairy Foods: Dietary Mainstays In Decline

Changing lifestyles and worries over fat and cholesterol have helped reduce consumption of eggs and dairy products, although some items—notably yogurt—are bucking the downward trend.

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Fish And Fowl Lure Consumers From Red Meat

Some experts predict that poultry may surpass beef as the preferred entree on the dinner menu. Fish is becoming a favorite, too. Nutritional concerns play a part, but the main reason behind these shifts appears to be price.

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Soft Drinks And Six-Packs Quench Our National Thirst

Nutrition may be playing a bigger role in what we eat, but not when it comes to washing it all down. Soft drinks lead the way in beverage consumption, with beer, wine and liquor not far behind.

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Generic Drugs: Cutting Cost, Not Corners

A new law has streamlined FDA's approval process for generic drugs, offering increased savings to consumers. But these products must still satisfy strict requirements for quality and equivalence to the brand-name drugs with which they compete.

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Because it's difficult to get good X-ray images of soft body tissues, contrast dyes are sometimes given to patients to make the organs of interest stand out more clearly on the X-ray film. These dyes are safe and effective, but not without side effects.

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Even though they are available without prescription, over-the-counter drugs should not be taken lightly. Fortunately, there's a wealth of information on how to use these medications properly—right on the label.

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Margaret M. Heckler
Secretary, U.S. Department of
Health and Human Services

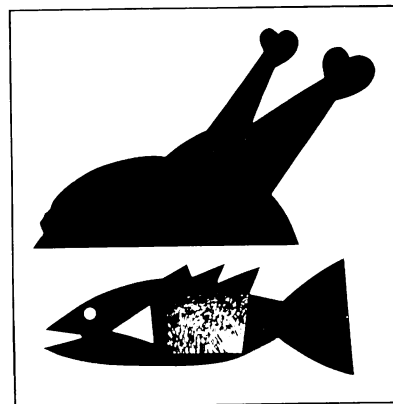
Frank E. Young, M.D.
Commissioner of Food and Drugs

William M. Rados/Editor

Jesse R. Nichols/Art Director

Cover Design: Michael David Brown

America's Changing Diet

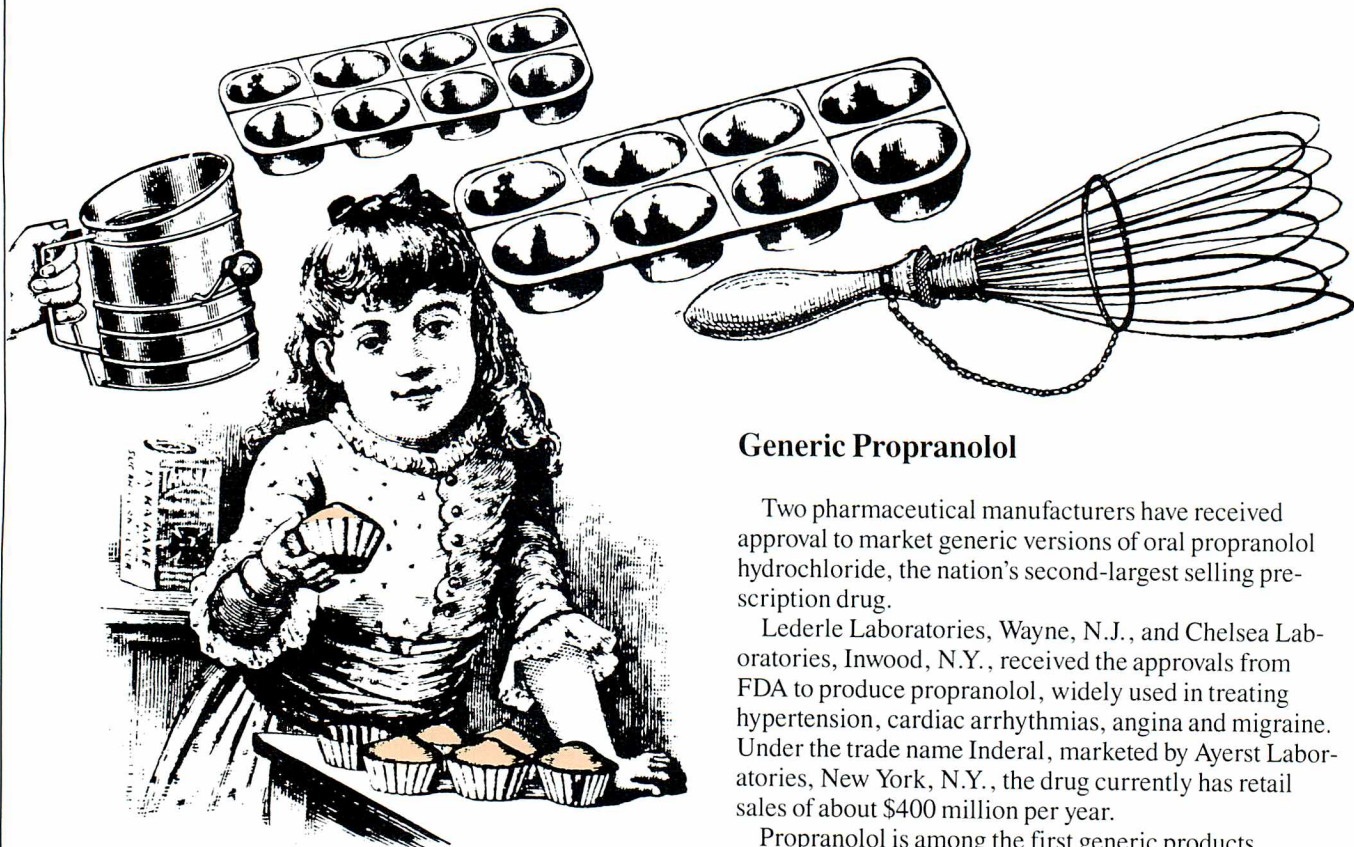


4



Inside Front Cover

In this X-ray taken of the front of the head, an injected contrast dye shows blood vessels (which appear as white lines) on the right side of the head, as well as the location of a lesion, which appears as a squarish patch of white. The left side of the head has a similar pattern of veins and arteries, but, lacking a contrast dye, most of them cannot be seen. For more on how contrast dyes help enhance X-ray pictures, see Dyes Inject Contrast Into X-rays' Shades Of Gray, beginning on page 30.



Recipe Short On Shortening

A recipe for dinner rolls in the article "Low-Sodium Menus Pass School Tests" in the April 1985 *FDA Consumer* came up short on the list of ingredients: A line giving the shortening ingredient was inadvertently omitted. Both the standard and low-sodium formulas call for 1½ cups of shortening (for 100 servings).

Reprints Available

Reprints are available of the following articles that appeared in the July-August 1985 issue of *FDA Consumer*: "On Yeast Infections And Other Female Irritations" and "Speaking Up About FDA Regulations."

Single copies of these reprints can be obtained from the Food and Drug Administration, HFE-88, 5600 Fishers Lane, Rockville, Md. 20857. Requests for up to 100 copies should be addressed to FDA, HFI-40, at the Rockville address. Copies of reprints are also available from FDA's consumer affairs officers, who are located in 29 cities around the country.

Generic Propranolol

Two pharmaceutical manufacturers have received approval to market generic versions of oral propranolol hydrochloride, the nation's second-largest selling prescription drug.

Lederle Laboratories, Wayne, N.J., and Chelsea Laboratories, Inwood, N.Y., received the approvals from FDA to produce propranolol, widely used in treating hypertension, cardiac arrhythmias, angina and migraine. Under the trade name Inderal, marketed by Ayerst Laboratories, New York, N.Y., the drug currently has retail sales of about \$400 million per year.

Propranolol is among the first generic products approved under the Drug Price Competition and Patent Term Restoration Act, which was passed by Congress and signed by President Reagan last year. For more on this law and how it affects generic drugs, see "Generic Drugs: Cutting Cost, Not Corners," beginning on page 26.

No Smoking Deterrents

Smokers who want to quit are out of luck if they are hoping to find an over-the-counter (OTC) product to help them break the cigarette habit. There are no safe and effective OTC drug products that will do the trick, FDA said in a proposed rule to establish a standard for OTC smoking deterrents.

The agency agreed with the findings of an expert advisory panel that the following ingredients are *not* safe and effective smoking deterrents: ground cloves, ground coriander, eucalyptus oil, ground Jamaica ginger, terpeneless lemon oil, licorice root extract, menthol, methyl salicylate, quinine ascorbate, silver nitrate, and thymol. A new ingredient, povidone-silver nitrate, not reviewed by the panel, is also not considered safe and effective.

Further testing was recommended for lobeline, in the

form of lobeline sulfate or its pharmacological equivalent, and silver acetate.

In the proposed labeling, the agency changed the definition of a smoking deterrent to read: "A substance that is used temporarily to help those individuals who want to stop smoking (becoming cigarette free) or to break the cigarette habit."

The proposed smoking deterrent standard was published in the June 3 *Federal Register*.

TSS School Posters

New information to remind young women in junior and senior high school about toxic shock syndrome (TSS) has been sent to secondary schools nationwide by FDA. A poster-format teaching unit alerts students to the symptoms of TSS and reminds them that approximately one in 10,000 menstruating females continues to get TSS every year.

Many young women of 15 to 19 years of age weren't menstruating in 1980 when toxic shock received extensive news coverage and was associated with the use of tampons. Despite alerts on tampon packages, many young women may believe toxic shock has gone away or is less serious.

The teaching unit is designed to be used as part of programs on broader health topics. The poster contains background information, lesson plans, visuals, panels ready for photocopying as handouts, and tests. The unit was developed after field tests with more than 1,300 students in the Washington, D.C., area and Broward County, Fla.

The program is endorsed by the American Academy of Family Physicians and the Association for the Advancement of Health Education and is being distributed in cooperation with the American College of Obstetricians and Gynecologists.

More Sulfites In Dried Fruits

Sulfite-allergic consumers were warned for the fourth time in two months to avoid dried fruit containing undisclosed sulfites. The most recent warning involved Carabee fruit mix products distributed in retail packages and in bulk containers in stores. The products were voluntarily recalled in July. (Earlier warnings were reported in the Updates section in the September 1985 *FDA Consumer*.)

Carabee Food Products, Kent, Wash., sells various combinations of dried apricots, pineapple, papaya and golden seedless raisins in four- and 16-ounce bags and in

15-pound cartons for bulk sale. Retail packages have such names as Deluxe Super Trail Mix, Fruit and Nut Mix, Hawaiian Delight Mix, Tropical Trail Mix, Tropi-Delight Mix, Cascade Trail Mix, Nor'western Trail Mix, Hi-Pro Trail Mix, and Yogurt Pineapple.

Carabee products are sold nationwide but mainly in the Northwest. Distribution includes major chain grocery store distribution centers and wholesale distributors in Washington state, Missouri, New Jersey, Colorado, Minnesota, Vermont, Rhode Island, Oregon, and Alaska.

Because people who are allergic to sulfites can suffer serious reactions, FDA requires manufacturers to disclose the presence of these preservatives on food packages and bulk-food containers. Carabee's recall will result in packages being properly labeled to reflect that sulfites have been used.

FDA "Plan For Action"

Speedier drug approvals, strengthened post-marketing drug surveillance, a broadened nutrition program, and increased public awareness of health fraud are among the goals outlined in FDA's "Plan for Action," made public in July. The plan charts the agency's policy and management directions for the future.

To speed the drug approval process, FDA will take such measures as standardizing application formats, eliminating redundant reviews, and using automated data systems. FDA also will call more often on outside expert reviewers, recruit scientists who can carry out both scientific research and regulatory activities, and develop a fellowship program for academic scientists.

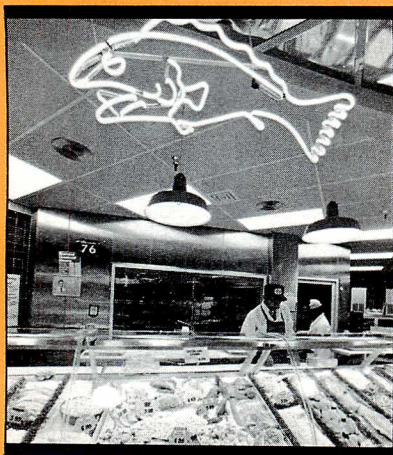
FDA will seek to improve the reporting of adverse reactions to drugs and medical devices by encouraging doctors and other health professionals to report directly to the agency.

Under the action plan, FDA's nutrition program will be broadened to advance the science of nutrition, increase consumer awareness about nutrition, and provide continued assurance of the nutritional quality of the nation's food supply.

In the area of health fraud, the agency expects to increase enforcement efforts against fraudulent products and to expand public awareness of health fraud through consumer information programs.

The action plan also sets priorities in such areas as medical devices, risk assessment and management, and new technologies, such as biotechnology and microelectronics.

America's Changing Diet



More and more Americans are considering their health as they push their carts down the aisles of supermarkets. But they're not forgetting their pleasures or their pocketbooks in making selections to fill their stomachs.

Those are the basic conclusions of a special FDA Consumer report on some broad trends in food consumption since 1950. The report covers five areas: meat, fish and poultry; beverages; fruits and vegetables; eggs and dairy products; and sugar and other sweeteners. These areas represent some of the more significant trends in food consumption in the last 35 years.

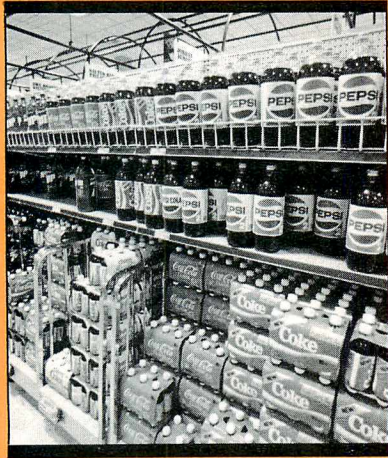
The year 1950 was selected to make the survey long-range enough for trends to be established, although some of the writers delved back to near the turn of the century to uncover even more far-reaching changes. Generally, data from five-year intervals were analyzed to spot the trends, and all of the charts and graphs produced with these articles are based on those intervals.

That Americans overall are more health-conscious in making food selections seemed of little doubt to the experts that FDA Consumer consulted to interpret the trends. For example, Dr. Fredrick J. Stare, professor of nutrition emeritus at Harvard University, said: "Up until a few years ago, nutrition and health were not thought to be major selling points for foods, but this situation has changed dramatically. . . ." He adds that he believes health concerns will continue to be a major influence "for the foreseeable future."

Graham Molitor, president of Public Policy Forecasting, Inc., a Washington, D.C., area food consulting firm, agrees that consumers are increasingly interested in nutrition. "They want to know more about sound nutrition practices and means for preventing poor health and disease," he adds.

Judith Jones Putnam, in an exhaustive study for the U.S. Department of Agriculture on food consumption habits, says that consumers are making new demands on the food industry. She cites a 1980 USDA survey that found that three out of five households had changed their eating habits in the previous three years for health reasons.

The result of this health consciousness has been increases in consumption of poultry, low-fat milk, and fresh fruits and vegetables but declines in eggs, coffee and whole milk. Many people seem to be trying to avoid calories,



cholesterol and some additives, particularly salt.

However, make no mistake about it: We want to have slim figures and six-packs, too. Soft drink sales since 1950 have increased phenomenally. Beer sales have also gone up, and the truth seems to be that Americans today have a greater sweet tooth and taste for brew than ever before.

The soft drink sales success (up 300 percent since 1950) is largely attributed to marketing. But other factors have influenced our taste buds. These include technology, changing lifestyles that bring us more leisure time, two-parent working families, more eating out (most often in fast food restaurants), smaller families and more single-person households, more income, and more education.

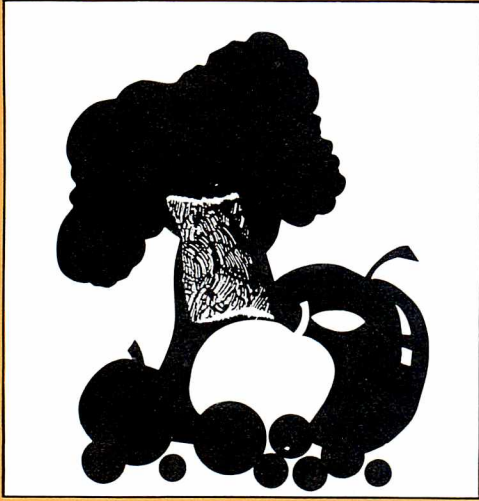
Changes in technology have been rampant and have had an effect on prices. Poultry today is a relatively cheap product because of technological advances in raising chickens and turkeys—advances that the other meat industries haven't been able to match.

A word about the statistics used. Most are from USDA and most are based on per capita "disappearance data." That means that the figures are based on the amount of food available per person, calculated by subtracting exports, year-end inventories, non-food use, and military procurement from total production, imports, and beginning inventories. Included is food that is discarded in processing, lost in spoilage, and thrown away at home. Thus, the statistics do not measure actual consumption. One USDA survey came to the conclusion that up to 35 percent of the food brought home didn't get into anyone's mouth. Nevertheless, these figures are considered useful in spotting trends in consumption and are the only yearly figures compiled for such a broad part of the American diet.

Sorting out the reasons for changes in food consumption patterns is, of course, difficult at best. Many reasons for the changes remain mysteries. However, presented in these articles are results of surveys and educated judgments from people who are trying to understand how we decide what to have at the next meal.

—Roger W. Miller

Fruit & Vegetables



For Fruits And Vegetables, Americans Favor 'Fresh'



Little Mary and Johnny may spurn the vegetables on their dinner plates, but there are plenty of other people out there who are making up for them. Americans are eating more than they have in the past 25 years, and consumption of fruits and vegetables is keeping pace.

Bountiful supplies, low prices, more disposable income, changing consumer preferences, and increased consumer concerns about health and nutrition have all played a part in increasing the amount of fruits and vegetables, particularly fresh ones, in the nation's diet. In fact, fresh fruits and vegetables have been one of the fastest growing categories in U.S. supermarkets, accounting for \$20 billion in sales in 1984.

Americans ate 209.2 pounds of vegetables per person in 1984. Canned and frozen vegetables accounted for about 59 of these pounds, while the remaining 150 pounds were fresh vegetables, including home-grown produce.

The traditional salad basic—lettuce—topped the 1984 fresh vegetable list, followed by onions (including shallots) and tomatoes. Nearly half of the canned vegetables were tomato products, such as whole tomatoes, pulp and purée, paste, sauce, ketchup, chili sauce, juice and blends. The second-ranking individual food item in the canned category was pickles.

Consumption of fruit in 1984 came to about 142.9 pounds per person; more than half of it was fresh. Bananas ranked first among fresh fruit choices, followed by oranges and apples. Melons—counted separately—accounted for another 26 pounds of fruit per person. An important trend has been the increased consumption of fruit in the form of juice. Fruit juice consumption increased by 50 percent since 1967 and reached a high of 32.4

pounds (7.1 gallons) in 1983.

(Although these figures refer to "consumption," they actually represent produce that "disappeared" from the marketplace rather than what was actually eaten. The portions of vegetables discarded through peeling and spoilage are counted, as well as the servings left on Mary and Johnny's plates.)

Per capita consumption of fruits and vegetables was actually slightly higher in 1950, just as the country was recovering from the austerity imposed by World War II, including rationing of meat and other foods. At that time, Americans were enjoying 214 pounds of vegetables and 151 pounds of fruit per person.

For the next 15 years, consumption of fresh produce declined. At the same time, the nation's cooks were turning to the more convenient processed foods, particularly frozen products.

Frozen food as we know it today didn't come on the scene until 1930. The development of equipment for "quick freezing" made it possible to freeze vegetables, fruits and berries quickly, thus avoiding formation of large ice crystals.

In the post-war years, consumption of frozen vegetables began a steady climb. Between 1950 and 1960, per capita consumption more than doubled to seven pounds. By 1970 it was up to 9.6 pounds. Today Americans are eating about 11 pounds of frozen vegetables per person per year. Some 30 different vegetables, processed singly and in combinations, are available, but corn, broccoli, peas and snap beans account for half of the total consumption.

Since 1950, use of canned vegetables also grew, but at a slower pace, and has actually declined in the last five years. Still, today's grocery store shelves are stocked with more than 130 different vegetable products and mixtures.

In contrast to the increased consumption of frozen vegetables, consumption of both canned and frozen fruit has declined steadily, dropping 40 percent and 20 percent respectively between 1967 and 1983.

But the biggest trend in fruits and vegetables is in the fresh produce department. Thanks to increased consumer demand, supermarkets are providing a greater variety of produce than ever before. The average number of items offered rose from 65 in 1972 to 173 in 1983. Some larger stores may carry as many as 250 items. Foods that were considered "exotic" yesterday are becoming today's staples, according to the 1985 Produce Marketing Almanac. Kiwi fruit, Granny Smith apples, alfalfa sprouts and mangoes are among the "hottest" new items. In many U.S. supermarkets, the produce department has replaced the meat counter as the major drawing card, according to USDA food economist Judith Jones Putnam.

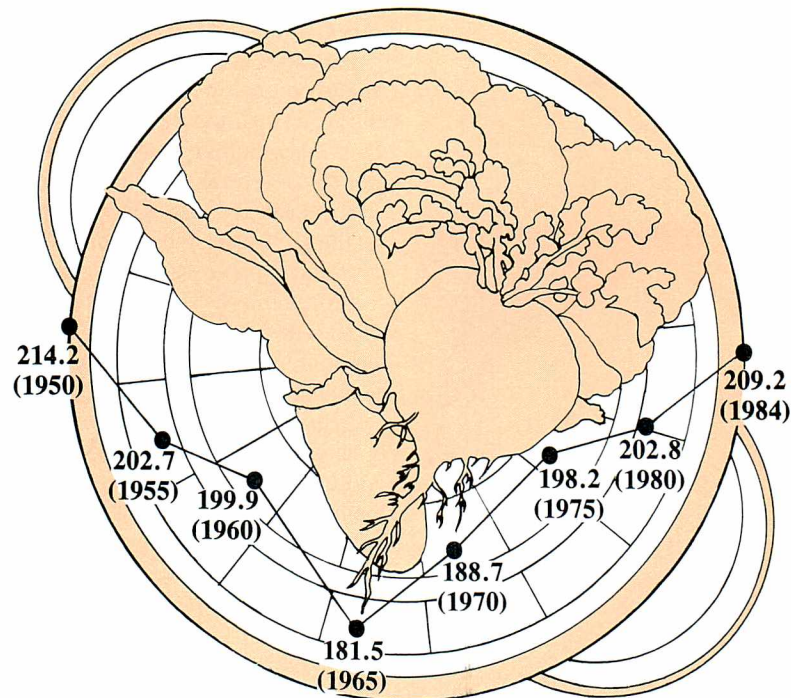
Fresh fruits and vegetables are coming to the market with brand names, and the annual bill for produce advertising is going up. About \$70 million is currently being spent by the fresh fruit and vegetable industry to woo the consumer, according to *The Packer*, an industry trade paper. That compares to \$52 million in 1980. The biggest spenders are Florida citrus growers, who have allocated \$11.9 million to advertise their fruit, up from \$3.7 million in 1980. Washington state apple growers are No. 2, dishing out \$6.2 million.

The switch to fresh is not the result of high-powered advertising alone. This "fresh craze" fits in with consumer concerns about well-balanced diets, nutrition and calories, according to a survey conducted by The Vance Research Services, Prairie View, Ill. Findings of the survey were summarized by *The Packer* magazine in a special issue, "Profile Of The Fresh Consumer," published in early 1985.

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Vegetable Consumption

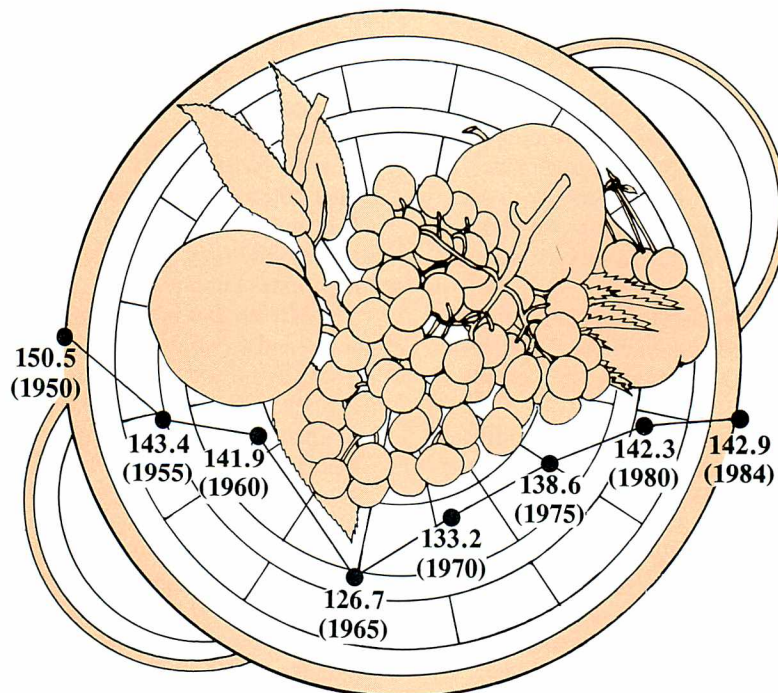
includes home garden produce



pounds per person per year

Fruit Consumption

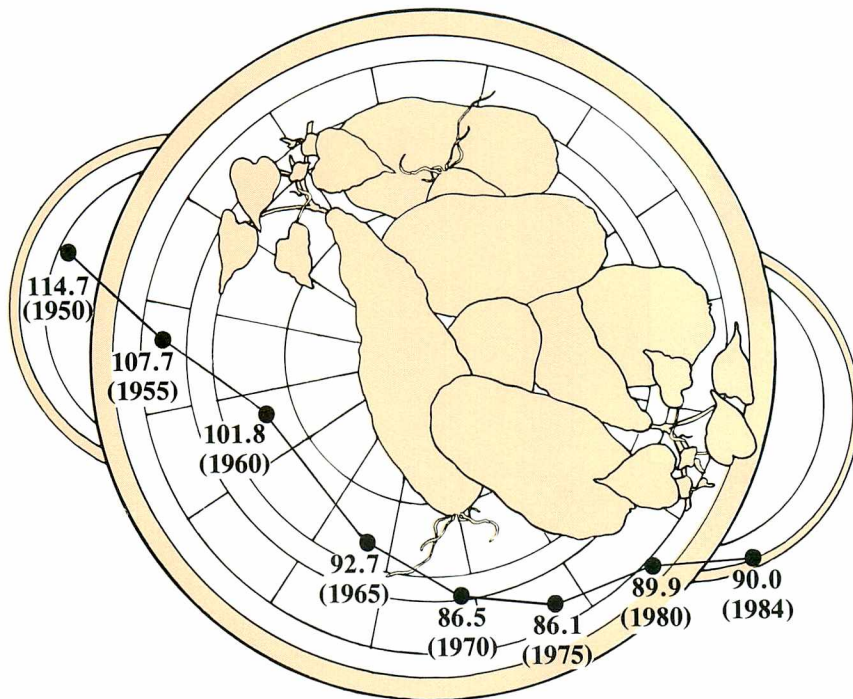
excludes melons



pounds per person per year

Potato Consumption

includes sweet potatoes



pounds per person per year
(retail weight)

(Continued from page 7)

The survey found that nearly half of fresh fruits were eaten as snacks. In contrast, most fresh vegetables are eaten at mealtime.

Consumers who are most concerned about nutrition, who exercise the most, and who are on diets are most likely to eat fresh fruits and vegetables, according to the survey. Fresh produce eaters are also highly interested in cooking, have more modern cooking equipment, own more cookbooks, and clip recipes from newspapers and magazines.

One vegetable not keeping pace with the fresh produce upswing is the old standby, the potato. At the turn of the century, potatoes had a prominent place on the nation's dinner plates and, in fact, provided the principal source of vitamin C in American diets. In 1910, per capita consumption of white and sweet potatoes was 221 pounds per person. But since that time, consumption of potatoes has declined markedly, down to 90 pounds in 1984.

The drop in potato consumption parallels a drop in grain consumption. The reason, it has been suggested, is America's increasing affluence. "With more money to spend, our preferences have shifted away from 'starchy' foods to the higher priced 'protein' foods, such as meat," say USDA food economists Louise Page and Berta Friend in "The Changing United States Diet" (*BioScience*, March 1978).

Well over half of the total 1983 per capita consumption of white potatoes (farm-weight basis) was of processed products, including canned, frozen, chips, shoestrings and dehydrated.

Frozen potatoes take the biggest bite. A staggering 3.9 billion pounds of spuds ended up as frozen french fries in 1984, 3.4 billion pounds of them going to restaurants. An additional 789

million pounds were turned into hash browns and other potato products, including "taters," stew, puffs, O'Brien, and patties.

Consumption of frozen potatoes has jumped more than fourfold over the past two decades, mainly due to greater use of these products in cafeterias, restaurants and other eating places. Chip consumption also rose about one-third.

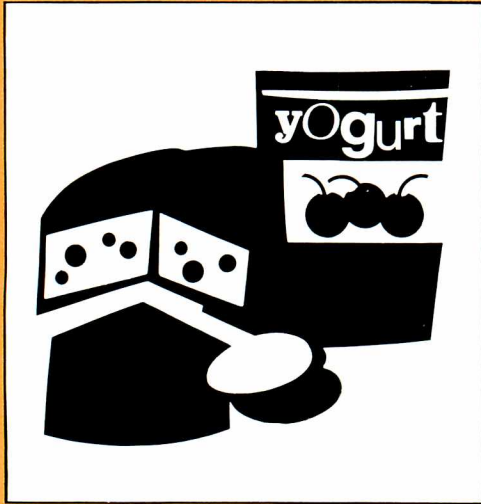
Fresh potatoes may come back into their own, thanks to the recent introduction of baked potatoes in fast food outlets, says USDA's Putnam. Consumption may also get a boost from the increasing home use of microwave ovens that can turn out a baked potato in a matter of minutes instead of an hour. (Microwave oven sales are booming; factory shipments went from 1 million units in 1975 to over 9 million in 1984.)

Although sweet potatoes are included along with white potatoes in USDA data, people in the potato business say they are not related. Sweet potatoes, or yams (as they are sometimes called), are not a universal favorite. Americans ate just over three pounds per capita of fresh sweet potatoes in 1983, about half the amount consumed 20 years earlier. Consumption of processed sweet potatoes—canned and frozen—has stayed at about a pound per person.

As they grow older, Mary and Johnny may never develop a taste for sweet potatoes. *The Packer* survey found only 57 percent of the respondents in the 18-to-29 age group had ever purchased yams. But there is no doubt that our young friends will come around to eating more fresh fruits and vegetables if present concerns about health and nutrition continue to grow. ■

—Annabel Hecht

eGgs & d_AiRy



Eggs And Dairy Foods: Dietary Mainstays In Decline

Eggs and dairy products have traditionally been an important part of the American diet. Milk, butter, cheese, cream and eggs accounted for almost one-fourth of the food the average American ate in 1983, according to the U.S. Department of Agriculture (USDA). In fact, by weight, more dairy products are consumed than any other type of food, providing significant amounts of calcium, riboflavin, phosphorus, vitamin B₁₂, protein and many other nutrients.

Yet, over the past three decades, consumption of eggs and total dairy products has been dropping. In 1983, the average American used 307 pounds of dairy products, down from 384 in 1950. Consumption of eggs showed an even steeper decline during that period, from 378 to 253 eggs per person per year. "Not since the Great Depression of the 1930s have animal products such as milk, butter, lard and eggs made up a smaller share of U.S. diets than

they do now," says Judith Jones Putnam, an economist with USDA's Economic Research Service.

The reasons are many, but the decline is mainly attributed to changing American lifestyles, competition from other foods, and—despite some important nutritional contributions of eggs and dairy products—concerns over health and diet.

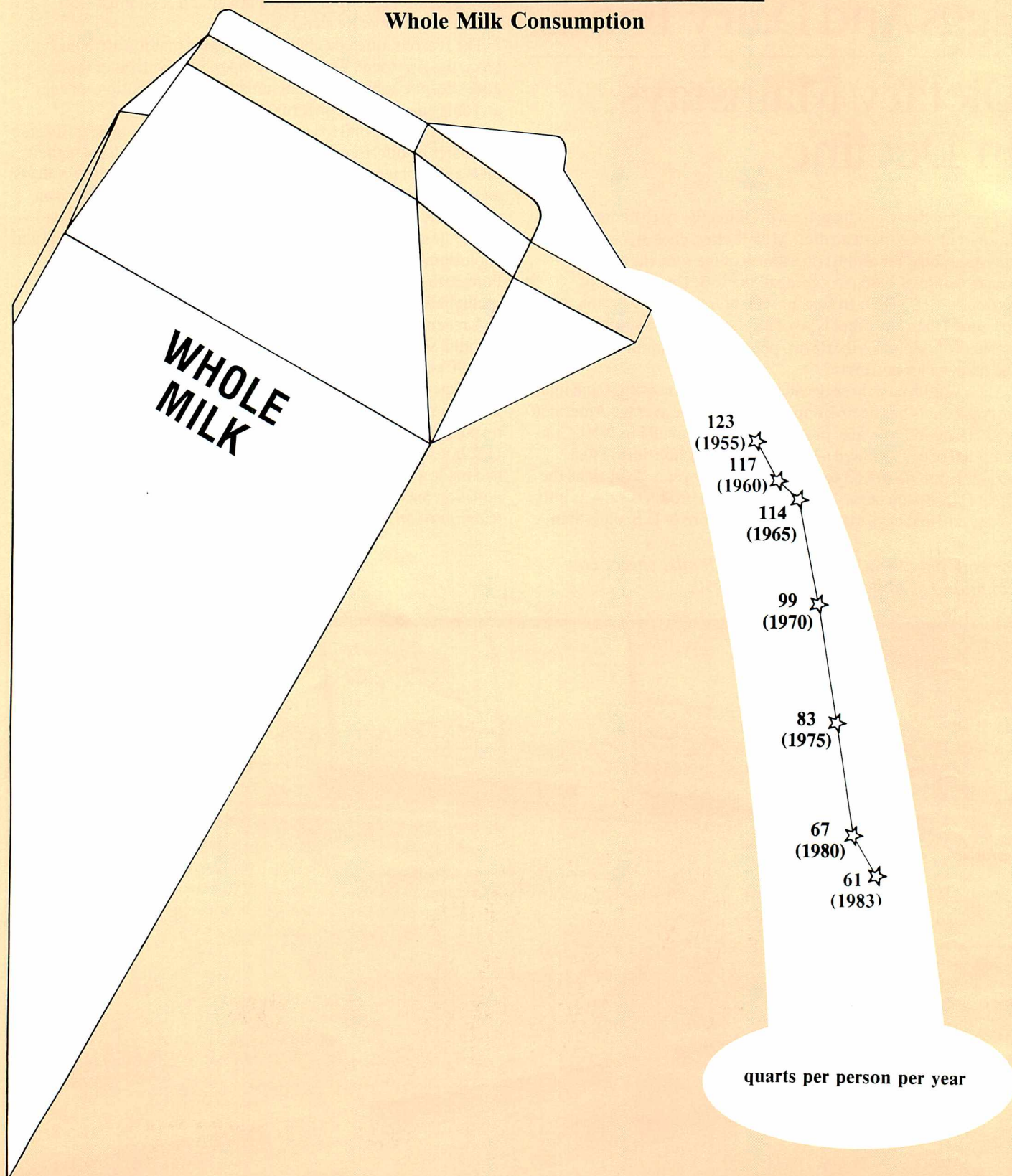
Many experts point to consumers' concerns about heart disease and other health risks from too much fat and cholesterol in their diets as the biggest reason for the swing away from dairy products and eggs, foods generally high in these substances. "American consumers increasingly appreciate the need to cut back or moderate consumption of total fats, animal fats, saturated fats and cholesterol," says Graham Molitor, president of Public Policy Forecasting, Inc., a Washington, D.C., area consulting firm specializing in food issues.

A recent Louis Harris poll conducted for the Food Marketing Institute shows how widespread such health concerns are. More than 90 percent of those surveyed said they are "very concerned" or "somewhat concerned" about nutrition. Cholesterol content of foods was cited as a major dietary worry by 44 percent of the respondents; fat content by 42 percent. A 1980 survey of 1,353 U.S. households by USDA revealed that three in five households had made a diet change in the preceding three years for health or nutrition reasons. One in five respondents reported eating fewer
(Continued on page 13)

Bucking the overall decline in dairy foods, cheese consumption has almost tripled since 1950.



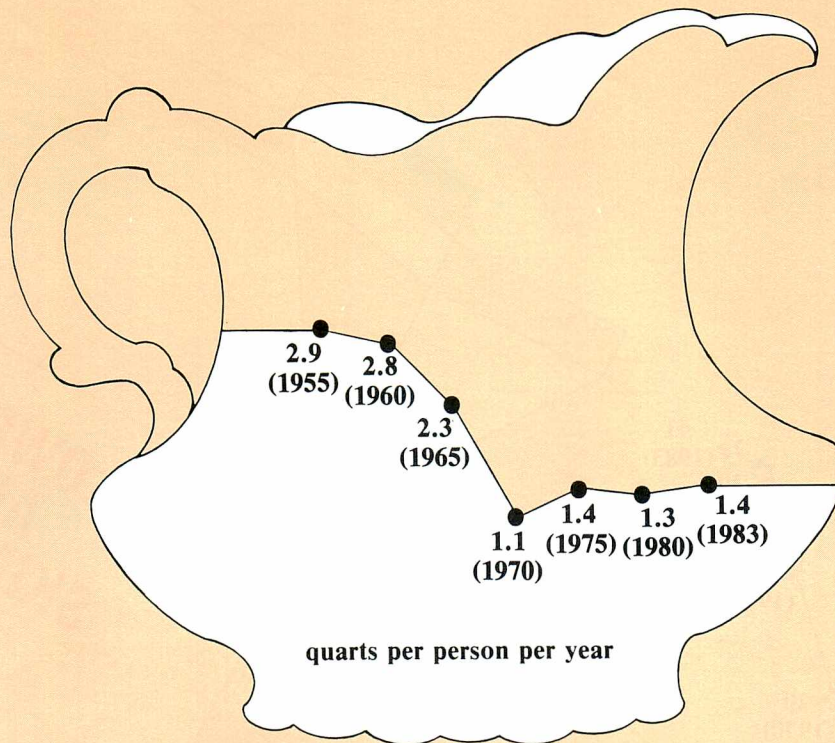
Whole Milk Consumption



Figures from before 1955 are not shown because they were not compiled in the same manner and therefore are not strictly comparable with later figures.
Figures rounded; 1983 figure is preliminary; category does not include chocolate and other flavored milk.
Source: USDA's *Dairy Outlook & Situation*, June 1981 and Sept. 1984

Cream Consumption

Includes half-and-half and light or coffee cream



Figures from before 1955 are not shown because they were not compiled in the same manner and therefore are not strictly comparable with later figures.

1983 figure is preliminary.

Source: USDA's *Dairy Outlook & Situation*, June 1981 and Sept. 1984

(Continued from page 11)

eggs; one in 10 reported less use of butter, as well as switching to low-fat milk from whole milk.

America's yearning for slimness is also a big part of the switch from certain dairy products. The 1980 USDA survey found that weight control was the leading reason for decreasing the use of whole milk.

As the USDA survey showed, some low-fat dairy products are benefiting from the concerns over health and diet. Consumption of low-fat milk has increased astronomically since 1955, while whole milk, with its higher fat content, has fallen 50 percent. But the growth of low-fat products has not been great enough to offset the overall decline in dairy goods. And eggs have been in steady decline since the peak consumption of 381 per person in 1951, despite prices that have risen far less than food in general (true of dairy products, as well).

Eggs contribute significant amounts of vitamin A, riboflavin, iron, phosphorus, calcium and protein to the American diet. Unfortunately, they also are the No. 1 source of cholesterol, according to a recent article in the *American Journal of Epidemiology* by the National Cancer Institute's Gladys Block and others. Cholesterol is a major component of the atherosclerotic plaque that clogs blood vessels, leading to heart attacks and stroke.

Since the 1960s, the American Heart Association has been urging Americans to eat less fat and cholesterol to reduce their

risk of heart disease, and other health groups have echoed those recommendations. And, in 1984, a panel of experts convened by the National Institutes of Health (NIH) concluded that the blood cholesterol level of most Americans is too high, in large part because of high intake of calories, saturated fat and cholesterol. The panel advised a daily intake of no more than 250 to 300 milligrams of cholesterol. (A single egg yolk contains 270 milligrams.)

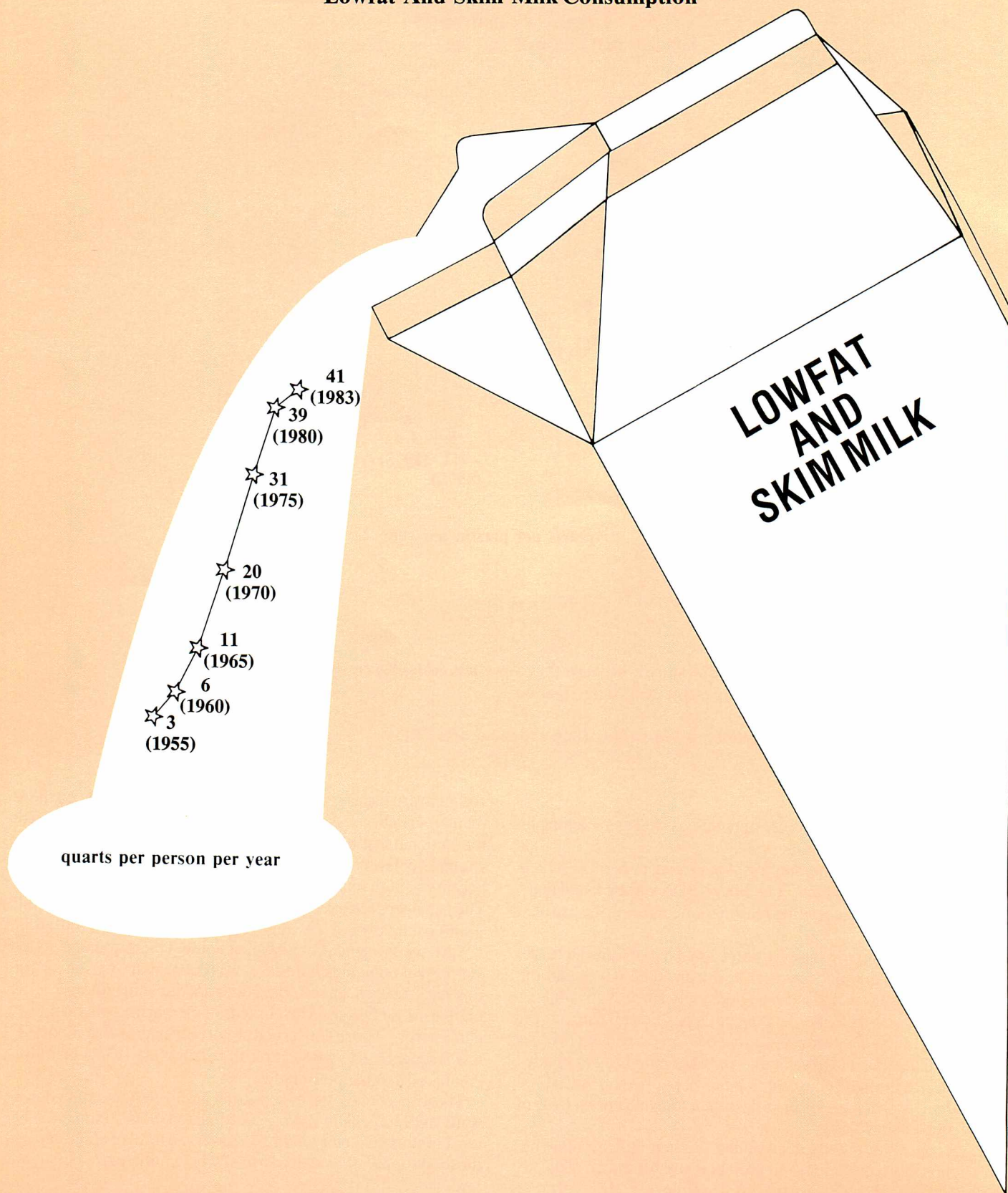
Such recommendations have hit home. USDA found in its 1980 survey that reducing cholesterol was the primary reason for cutting back on eggs, cheese and butter and for substituting margarine for butter. (Most brands of margarine contain no cholesterol.) Those concerned about cholesterol also reported less frequent use of whole milk and greater use of low-fat milk, compared to other households.

The level of cholesterol in the diet has been fluctuating downward since its peak in 1945. According to USDA's Putnam, "The most important factor tending to lower the level of cholesterol in the food supply is decreased use of whole milk, eggs, butter, and lard."

Such dietary changes may, in fact, be having a positive impact on the public health. Coronary heart disease has been declining in this country since the late 1960s, and researchers at the Harvard School of Public Health have estimated that lowered blood cholesterol levels—though still too high—account for about 30 percent of that decrease.

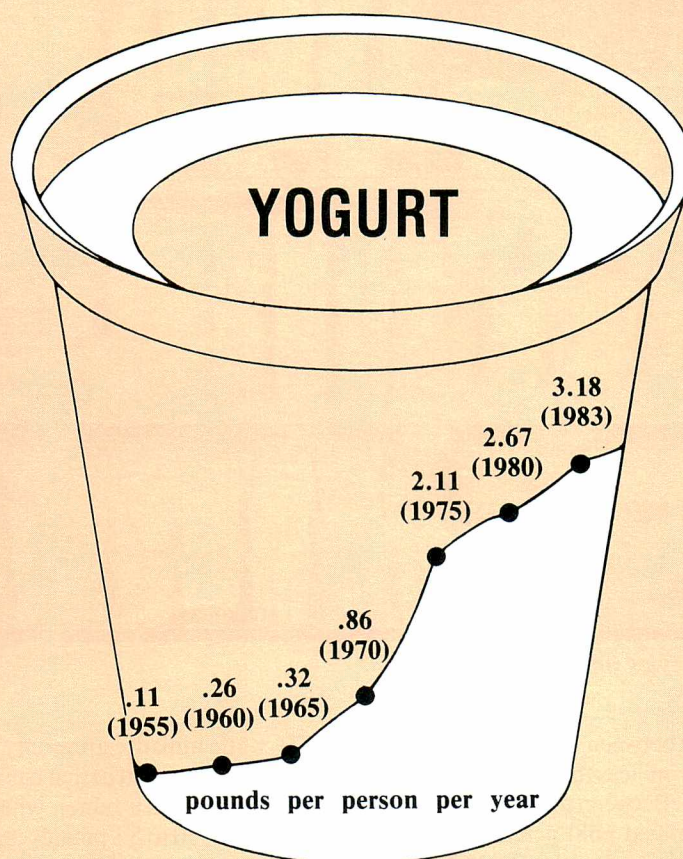
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Lowfat And Skim Milk Consumption



Figures from before 1955 are not shown because they were not compiled in the same manner and therefore are not strictly comparable with later figures.
Figures rounded; 1983 figure is preliminary; category does not include chocolate and other flavored milk.
Source: USDA's *Dairy Outlook & Situation*, June 1981 and Sept. 1984

Yogurt Consumption



Figures from before 1955 are not shown because they were not compiled in the same manner and therefore are not strictly comparable with later figures.

1983 figure is preliminary.

Source: USDA's *Dairy Outlook & Situation*, June 1981 and Sept. 1984

(Continued from page 13)

The egg and dairy industries, however, question the link between dietary cholesterol and heart disease, and whether health concerns are really the main reason for the decline in dairy products. "Fat and cholesterol probably have had some influence," says Bill McDonald, director of marketing and economic research for the United Dairy Industry Association. "But lifestyle changes, such as more eating away from home, are a bigger reason" for the decline. Cathy McCharen, director of the industry-funded Egg Nutrition Center, says that "Consumption [of eggs] probably would have declined whether there was a cholesterol concern or not." Egg use reached high levels during World War II when meat was rationed. During the 1950s, egg consumption began to decline and in subsequent years lifestyle changes—mainly more women entering the workforce and families eating fewer cooked breakfasts—continued that decline to the present day, she says. McCharen also believes that the majority of Americans are not affected by dietary cholesterol. "In general, dietary cholesterol may increase serum [blood] cholesterol in some people. But most people are not 'cholesterol-responders.' They make metabolic adjustments" whereby excess

cholesterol is excreted and otherwise disposed of, she says.

Strongly linked to the concern over cholesterol is a worry about too much fat in the diet, especially saturated fat, a strong contributor to raising blood cholesterol. Among the major sources of saturated fat in the American diet, whole milk ranks second (behind ground beef), cheese third, eggs seventh, and butter ninth, according to the *American Journal of Epidemiology* article by NCI's Block. The same NIH panel that urged Americans to reduce cholesterol intake also recommended that total fat intake be cut from its current level of about 40 percent of calories to 30 percent, with saturated fat no more than 10 percent. Fat in the diet also has been linked to certain forms of cancer, prompting the American Cancer Society in 1984 to say that Americans might reduce their risk of cancer by eating less fat. The federal government's "Dietary Guidelines for Americans" also urges the public to "avoid too much fat, saturated fat, and cholesterol."

Within the dairy category, the shift away from high-fat products has spurred the increase in consumption of milk products with reduced fat at the expense of whole milk. Consumption of whole milk (3.5 percent milk fat) peaked in 1945 at 159 quarts per person; it dropped steadily to 61 quarts in 1983. Meanwhile, per



Yogurt, dished up in countless styles and flavors, has become the health food of the '80s.

capita consumption of low-fat milk (between 2 percent and one-half percent milk fat) has climbed from less than half a pint in 1955 to more than 36 quarts in 1983. Between the 1960s and 1980s, low-fat milk consumption jumped 1,681 percent, making it the fastest growing type of food of all those tracked by USDA during that period. The change in consumption of skim milk (less than one-half percent milk fat) has been less significant; it increased in the 1950s and early '60s but has been relatively stable since, standing at five quarts per person in 1983.

The reasons for this shift to reduced-fat milk are revealed in a 1984 survey by *Dairy Field* magazine: 7 percent of low-fat milk drinkers cited its lower price; 16 percent preferred its taste; 54 percent said they drank it for its lower fat and calories.

Yet the gains in low-fat and skim milk were not enough to offset the decline in whole milk consumption since World War II: Consumption of all three types was 126 quarts per person in 1955, compared to 102 quarts in 1983. According to USDA's Nationwide Food Consumption Survey, between 1965 and 1977 milk consumption dropped in every age group except over-65. The largest decline (22 percent) was for the under-5 age group, according to Karen Bunch of USDA's Economic Research Service.

Another important factor in milk's drop in popularity is competition from other beverages, especially soft drinks, which are now America's favorite type of beverage. But even alcoholic beverages—beer, wine and distilled spirits, combined—have surpassed milk in per capita consumption. Almost a billion dollars in advertising and promotion for beer and soft drinks in 1983 helped propel sales of those drinks.

"It is clear that some of the increase in soft drink consumption has come at the expense of milk," says USDA's Bunch. "Though teenage boys were still drinking more milk than soft drinks in 1977, for teenage girls the opposite was true, with 9.3 ounces of soft drinks consumed per day compared to 8.6 ounces of milk."

Milk also has lagged in the growing dining-out market. Soft drink use by these outlets more than doubled between 1969 and

1979, while milk use grew only 15 percent, Bunch says.

Another major item that has contributed to the overall decline in dairy products is butter, which dropped from 11 pounds per person in 1950 to 5.1 pounds in 1983. Meanwhile, margarine, which came into widespread use as a substitute for scarce butter during World War II, surpassed butter in consumption in the 1950s and is now used twice as much as its dairy counterpart—10.2 pounds per person in 1983.

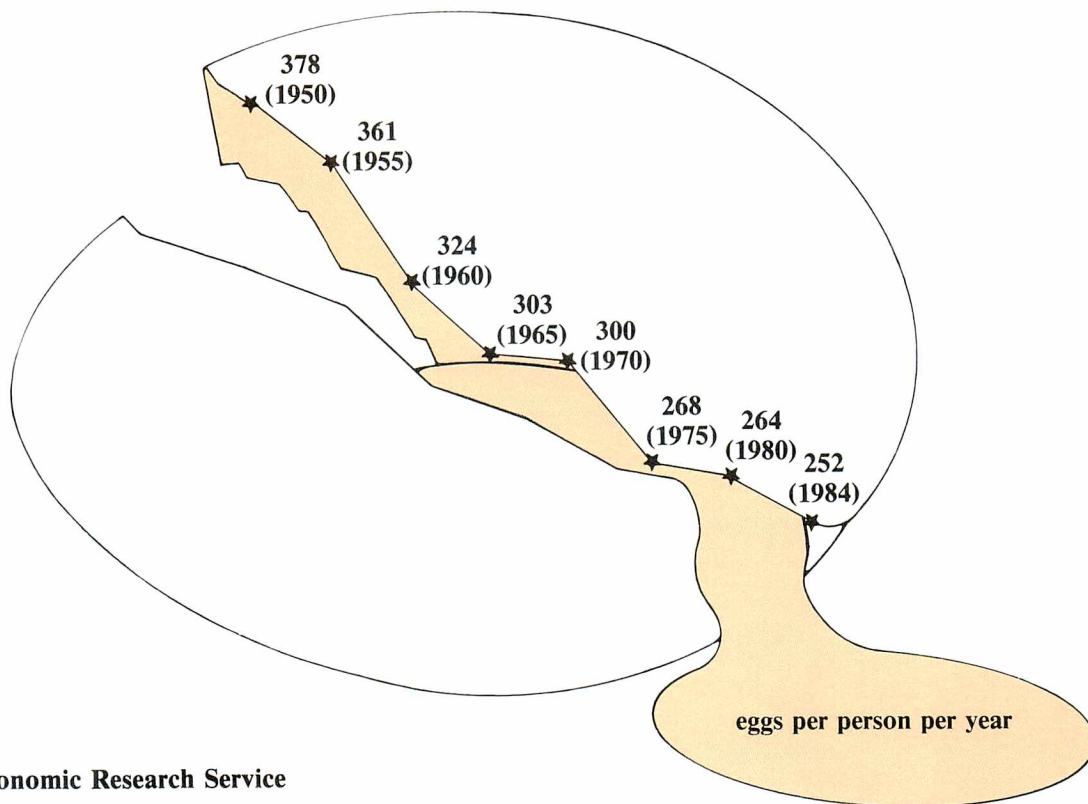
Cream also has suffered from competition, mainly from non-dairy coffee "whiteners" and imitation whipped toppings. Consumption of all forms of cream (half-and-half, light, whipping, sour, and eggnog) fell from about four quarts per person in 1955 to under three quarts in 1983. The decline would have been even greater were it not for a tripling in the use of sour cream during that period, mainly in party dips, due to "increasing affluence, entertaining and snacking," according to Molitor.

Lifestyle changes were also the main force behind the phenomenal growth of two other categories of dairy products: cheese and yogurt. Consumption of all types of cheeses except cottage cheese almost tripled between 1950 and 1984, from 7.7 to 21.7 pounds per person. The dairy industry's McDonald attributes the growth to increasing affluence, the versatility of cheese, with its use in many dishes (especially pizza), and lifestyle trends that made wine-and-cheese parties a substitute for cocktails and chips. Increased advertising budgets—some \$66.2 million in 1983 by leading national manufacturers—have also helped.

Cheese may also be benefiting from its "health food" image among some consumers, according to Molitor. But, while cheese is relatively high in riboflavin, phosphorus, calcium and protein, it has its nutritional drawbacks. "Many cheeses contain over 50 percent fat and are high in saturated fats, cholesterol and sodium—all components that do not stack up well against diet-health recommendations," he says.

Consumption of cottage cheese, on the other hand, has been relatively flat. Its image as *the* diet food of the '50s and '60s spurred a jump in consumption from 3.1 pounds per person in

Egg Consumption



Source: USDA Economic Research Service

1950 to 5.3 pounds by 1970. But then it began to decline, replaced among trend-following weight-watchers by *the* diet food of the '70s and '80s: yogurt.

Thanks to its diet-and-health-food image and heavy advertising (\$29 million in 1984), yogurt was surpassed only by low-fat milk as the biggest food-consumption gainer over the past 20 years. From one-third of a pound per person in 1965, Americans are now gulping down more than three pounds. "Yogurt was initially a curious, small-volume product basically restricted to ethnic enclaves," according to Molitor. "Then along came popularized stories that *really* old folks from far-off places doting on it out-lived everybody else on the planet.

"Yogurt, however, demanded an acquired taste, one that did not meet the liking of most Americans. Stoic-like regular products got left behind in the dust when flavored, smooth-as-velvet versions, low-calorie counterparts, and ice cream substitutes came along."

What does the future hold for egg and dairy product consumption in the United States? Some experts think the downward trend may be halted if low-fat products can gain greater acceptability and— most importantly —if the need for calcium in the diet can be driven home to consumers, particularly women. Sixty-eight percent of the U.S. population fails to meet the Recommended Dietary Allowance for calcium, and about eight out of 10 women

don't get enough of this bone-building nutrient. Lack of calcium can lead to a crippling bone disease known as osteoporosis, which afflicts a fifth of the elderly women in the United States and some elderly men.

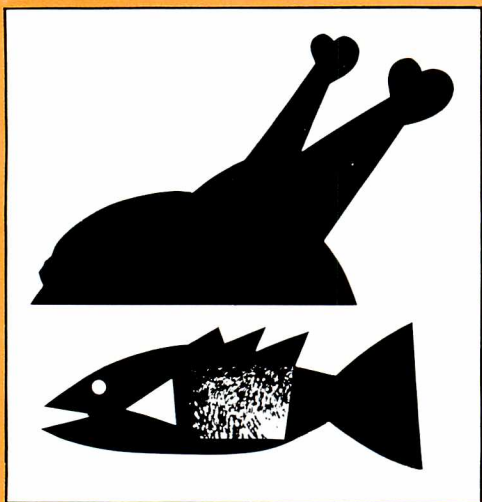
Dairy products are excellent sources of calcium, so the dairy industry is already trying to take advantage of this nutrition issue that, unlike fat and cholesterol, works in its favor. A \$50 million industry promotion effort between September 1984 and April 1985 saw television, radio and magazine ads that stressed the nutritional benefits of calcium.

Beefed-up advertising budgets and the dairy-calcium connection may already be having an effect at the supermarket. Consumption of dairy products in 1983 showed the first gain in eight years, climbing five pounds from 1982. Low-fat milk accounted for about 60 percent of the gain, with yogurt, cheese and frozen desserts making up the remainder. Whole milk consumption continued to drop, although the decline was the smallest in more than 20 years.

The questions for dairy producers are: Will the benefit of calcium overcome the detriments of fat and cholesterol, and can future generations be sold on milk instead of soft drinks and beer?

—Bill Rados

MeAT



Fish And Fowl Lure Consumers From Red Meat

by Chris Lecos

Americans have always displayed a voracious appetite for meat and especially beef. Red meat is a major part of the American diet and has been for most of this century, according to annual food consumption data that the U.S. Department of Agriculture has been compiling since 1909.

But there are some signs that this love affair with red meat is cooling somewhat. USDA figures show that Americans are consuming less red meat, but more poultry and fish than in previous years. Some food experts are even predicting that poultry consumption may surpass that of beef.

Overall, consumption of meat, poultry and fish hit an all-time high in 1984, according to the USDA figures, when per capita consumption reached almost 237 pounds. That was well above the 75-year average of 186 pounds. However, it's fowl and fish—particularly poultry—that have been racking up the big gains in recent years. Red meat (beef, pork, veal, lamb and mutton, and game meat) consumption last year was well below the average of 161 pounds per person per year during the 1970s. The record high for meat consumption was in 1971, when it averaged almost 169 pounds per person. Since 1980, red meat consumption has averaged 154 pounds a year.

Numerous factors account for the shift from red meat to fish and fowl. Probably the most important influences are pocketbook issues. Poultry has been a better bargain at the supermarket. Prices for meat, poultry and fish have all risen, but red meat prices have climbed higher than poultry.

Poultry's economic advantages have been due in no small part to science and technology. Production efficiency is a major reason many products—including poultry—have become more attractive to consumers and their pocketbooks.

Diet changes are also influenced by beliefs (correct or not) about which foods are healthier to eat. A 1980 USDA survey of 1,353 households disclosed that three out of every five homes had made a diet change in the preceding three years "for health and nutrition reasons." Consumers reported that they were eating less red meat, less processed meat, and more fish and poultry.

Poultry consumption in 1984 was 67.5 pounds per person, a record. What's more, consumption in the 1980s to date is up 139 percent from the early 1950s.

People also ate fish at a record rate in 1984—15.5 pounds per person—although fish consumption has not increased as fast as chicken and turkey consumption.

Per capita consumption of red meats last year was 154 pounds. Beef consumption in the 1970s averaged 86 pounds per person, with a high of 94.4 pounds in 1976. But since then, the USDA figures show decreases almost every year. During the 1980s beef consumption has averaged 77.5 pounds a year.

(It should be noted that USDA derives its data from production and marketing estimates, with adjustments for imports, exports and other factors. Although USDA describes it as food consumption, the agency emphasizes that the data do not tell how much food Americans actually are eating. Rather, the figures represent food that is produced and then goes into commercial channels. Waste, trimming, and spoilage are among the uneaten portions that are included in the per capita "consumption" data. USDA officials point out, however, that the figures still serve as a useful barometer of long-term food trends in the United States.)

One circumstance affecting prices—and therefore consumption—of the different kinds of meat is the ability of producers to react to changing market conditions. And here poultry raisers have an advantage, as noted in an article in USDA's *National Food Review* by Thomas A. Stucker and Karen D. Parham. They wrote: "Differences exist in the ability of livestock producers to respond to a rapidly changing market. Cattlemen have less flexibility than chicken and pork producers because the birth-to-maturing time is 27 to 48 months for cattle; the process is about 10 to 27 months for hogs and even shorter for broilers—3 to 15 months."

Meat and poultry prices are, in part, influenced by the cost of feed grain. When poultry producers are faced with rising feed grain costs, they are in a better position to cut back production, and they can rebuild their production of poultry more quickly when market conditions (read: prices) are more attractive.

Consumption of meat and poultry, Stucker and Parham wrote, also is influenced by comparative prices to consumers. "When beef prices get disproportionately higher than pork or poultry, consumers shift to the lower cost products," they noted. Between 1977 and 1979, for example, retail prices for beef and veal rose 56.4 percent, pork was up 15 percent, and poultry up 16 percent. During that period, beef and veal consumption fell 16 percent while pork and poultry consumption rose 14.3 and 13.6 percent, respectively.

The USDA authors also note the long-term effects of technological advances, production efficiencies, and aggressive marketing on prices and consumption. "The benefit of greater production efficiencies to the consumer is most clearly demonstrated by the poultry industry," they said, which has made its product more attractive to consumers through better feeding practices, disease control, and other production improvements that have kept per-unit production costs of poultry, and thereby prices, considerably below those of beef and other meats.

USDA's 1980 household survey, published this year and authored by Judith Jones Putnam, a USDA economist, cited these trends in America's food choices:

- 21 percent of the 1,353 households surveyed reported using less bacon and sausage, and 4 percent had stopped using these meats.
- 16 percent were eating fewer hot dogs and less luncheon meats, and 3 percent had stopped consuming them.
- 16 percent reported using less beef and pork, while 1 percent had stopped using the two products. Only 3 percent and 2 percent, respectively, said they had increased consumption of beef and pork.
- 17 percent had increased their consumption of poultry, while only 1 percent reported eating less.
- Nearly one out of five households (19 percent) reported consuming more fish and shellfish products, while only 1 percent said they ate less fish.

"Most likely," the study said, "the decline in beef consumption followed changes in the relative prices and supplies of beef, pork and broilers. The change in consumer tastes, preferences, and

Poultry has broadened in popularity, thanks to relatively low prices and health concerns over red meats.



nutritional concerns likely had less impact on beef consumption," George D. Wilson, vice president for science and processed meats at the American Meat Institute in Washington, D.C., said that numerous factors have influenced the "modest decrease" in the consumption of red meats: A changing marketplace that has seen a trend toward smaller family sizes, fewer "eating events" within the family where red meat was once a more common dinner table staple, the difference between meat and poultry prices, the success of the poultry industry in keeping production costs down and its aggressive marketing programs, and diet-health issues.

"There is no question that beef has always sold for more than pork and pork for more than chicken, and that ratio has changed very radically," Wilson said. Years ago, he said, the price ratio between meat and poultry products was much closer. "Chicken was not the value then that it is today," he added.

Diet-health issues also may have had a negative influence on red meat consumption, particularly consumer concerns about the consumption of fat, he continued. "We agree that fat, in excess, is not a desirable food, and we find that beef and pork are perceived as being fatter than chicken. But if you take the skin [off poultry] and equally take the fat off meat, you'll find that the fat content is much closer together than most people think. . . . Meat and fat are not synonymous words."

Dr. Burdette Bredenstein, director of research and nutrition at the National Livestock and Meat Board, contends that fat from red meat represents a considerably smaller proportion of total

dietary fat than is generally recognized. "The fat content of present-day beef and pork cuts is lower because improved genetics and livestock management techniques have produced leaner animals," he said. Wilson argued that the USDA figures do not deal with "consumed weight" and don't take into account the fat that consumers trim and discard from steaks, roasts and other meats.

He estimates that the fat in all the beef, pork, lamb and veal and all processed meats actually consumed contributed 214 calories (24 grams of fat) per capita to the daily diet in 1983. USDA's figures suggest that fat from red meat provides 444 calories (49 grams) per person each day.

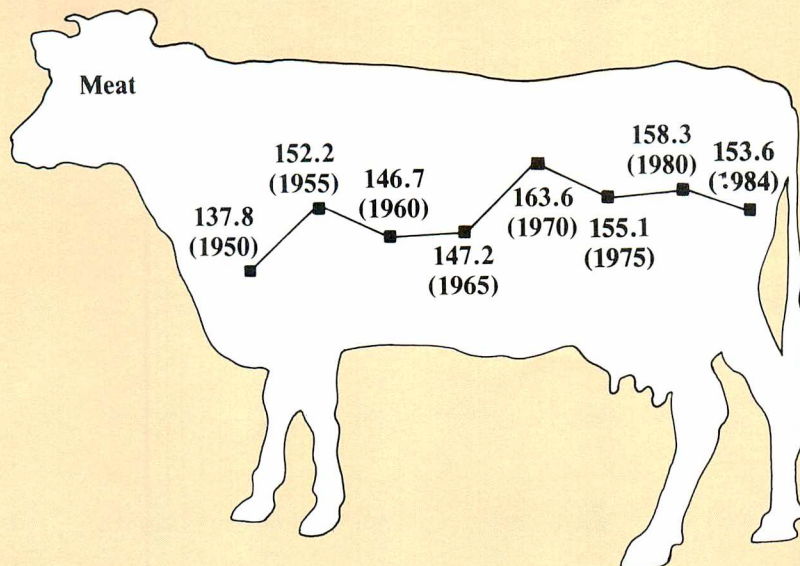
Long-term trends in meat, poultry and fish consumption are hard to predict because of the influence that supply, price and consumer preferences have on demand. For the immediate future, USDA's Parham anticipates continued high demand for poultry products, with red meats, especially beef, remaining at present levels or declining slightly. The demand for seafood is "strong and growing," says Morton Miller of the National Marine Fisheries Service. Development of convenience products and new marketing strategies by supermarket chains have made seafood more attractive to consumers. However, he said, "continued expanded demand for seafood may hinge on the industry's ability to diversify production and slow the rapid increase in prices."

Chris Lecos is a member of FDA's public affairs staff.

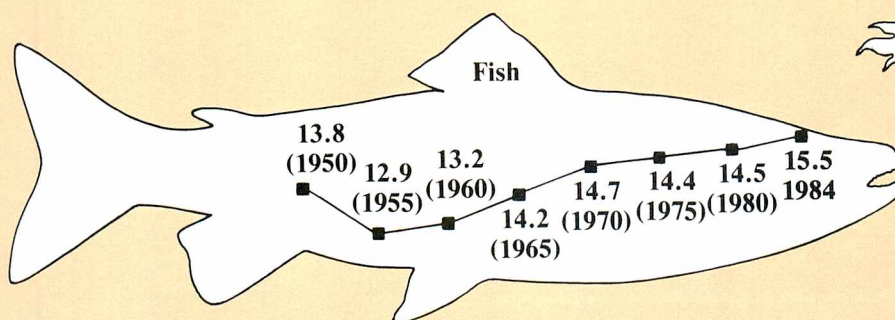
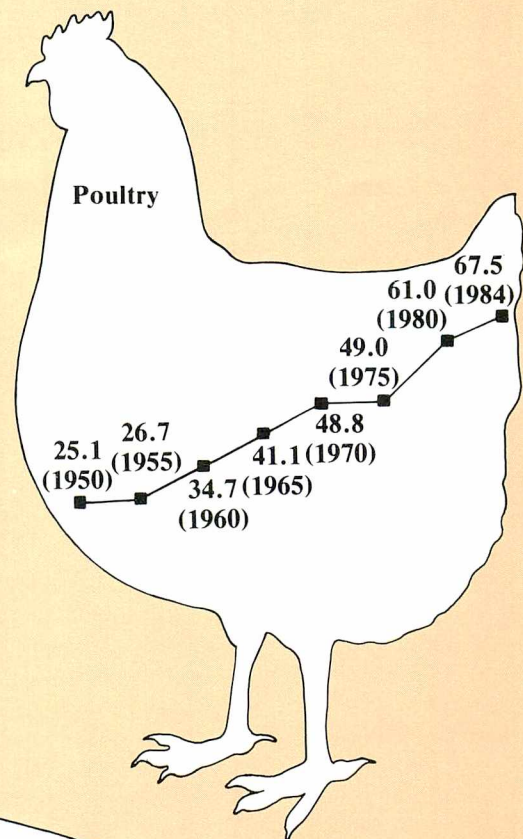
Meat*, Poultry And Fish** Consumption

*Includes beef, pork, veal, lamb/mutton and game meat

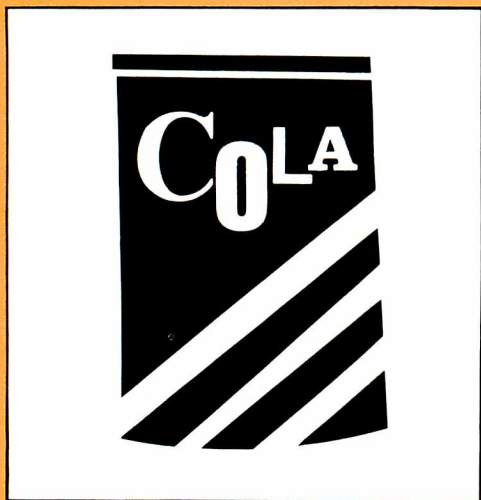
**Includes game fish



pounds per person per year



BEVERAgES



Soft Drinks And Six-Packs Quench Our National Thirst

by Roger W. Miller

If Chairman Gorbachev wants to wean his citizenry off vodka, he might take a few lessons from some capitalist marketing experts—specifically those who have been selling us soft drinks.

For, of all our changes in food consumption since World War II, none has been more startling than the increase in soft drink consumption—up nearly 300 percent since 1950. Sales of some other beverages—notably beer and fruit juices—have shown some sizable increases, particularly since 1965, but nothing like the skyrocketing advances of soda pop.

While we have been popping open more and more cans of soda, we've been drinking far less milk and coffee than we did 35 years ago. Per capita milk consumption in 1983 was half what it was in 1950; coffee consumption also dropped considerably.

The differences in our beverage choices might be best illustrated by this example:

- Offered a choice of milk, coffee, tea, alcoholic beverage, fruit juice or soft drink, one person out of 11 would choose a soft drink in 1950.
- Given the same choice in 1983, three out of 11 would pick a soda.

This marked change occurred as our quaffing quotient, so to speak, for all of those beverages combined went up from 112 gallons per person in 1950 to 136 gallons in 1983.

These trends in beverage consumption can be attributed to a number of factors. The declines in milk and coffee consumption, for example, are generally thought to reflect health concerns. Likewise, the growth in fruit juice sipping. However, the almost geometric increases in soft drink sales seem to belie any general health-consciousness on the part of the public. Soft drinks are largely water and sugar or some other sweetener plus flavoring—hardly the stuff of health food.

The figures suggest that soft drinks have taken the place of milk and coffee in a lot of people's diets. Many experts say that the increase in soft drink sales is mostly a marketing phenomenon. And that's where Chairman Gorbachev should pay attention. If America's advertising industry could increase soft drink consumption by 300 percent, they could do the same thing in Russia and cut down on vodka consumption.

Soft drinks have been pictured in advertising as a recreational drink, in keeping with changes in lifestyles that afford more leisure and outdoor time. Dr. Howard Roberts, vice president of science and technology for the National Soft Drink Association, agrees. Soft drink promotion, he notes, has been "tailored to younger, happier people. It's a fun food." It's also the drink of the fast food franchise, no small matter when considering diet trends.

Roberts says that sales figures indicate that concerns over health—or at least weight—are also reaching soft drink fans. "For years, we always figured artificially sweetened drinks at 10 percent of the market," he says. "Now, they're 20 percent and people are predicting they'll take 30 to 40 percent by 1990." Diet Coke, in fact, is now the No. 3 selling soda, Roberts points out.

Roberts also thinks that competition has helped boost sales, citing a proliferation of different types of soft drinks. "Now you

can get a purple diet drink that tastes like kumquat," he exaggerated.

One of the specialties of the industry has become caffeine-free soft drinks, for those concerned about that additive. Caffeine-containing soft drinks run 30 to 58 milligrams of the stimulant per 12-ounce serving, compared to 40 to 180 milligrams for a five-ounce cup of brewed coffee. Last year, soft drinks without caffeine accounted for 4.6 percent of total sales.

Concern over caffeine is cited as the reason for the decline in coffee sales. Graham Molitor, a Washington, D.C., area food consultant, notes that caffeine "has been indicted as a risk factor" for a number of diseases. However, those are only indictments. The link between most health risks and caffeine is far from established.

Proven risks or not, health concerns are switching people to decaffeinated coffee. The International Coffee Association, which annually surveys U.S. coffee drinking, reported that its 1984 survey showed 17.7 percent of all persons 10 years and older were drinking decaffeinated coffee. That was up a whopping 342 percent from the association's 1962 survey. Better than one out of five cups of coffee Americans drink is now decaffeinated.



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The long-term decline in coffee consumption shows signs of leveling off. Nevertheless, the coffee people have begun a "generic advertising campaign designed to change the image of coffee . . . so that it will appeal to more young people and appear better suited to modern lifestyles," the coffee association reported. Promotions will also be geared "to encourage consumption out of the home, especially in the work place and on university campuses."

Along with soft drinks, alcoholic beverages have also shown a healthy—or unhealthy—increase. From 1962 to 1983, consumption increased by better than 60 percent to 28.4 gallons of beer-wine-spirits per person per year. Part of that increase can be attributed to an older population, as the baby boomers of post-World War II came of drinking age. However, changes in lifestyles and more than \$650 million spent on advertising in 1983 for beer alone contributed to that increase.

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Beer consumption went down between 1950 and 1960 but then started on an upward trend that peaked in 1981 at 24.6 gallons per capita. However, when the 1983 consumption figures of 24.3 gallons are limited to those of beer-drinking age (19 and over), consumption averages 33.75 gallons per adult: one 12-ounce can or bottle per person per day.

Consultant Molitor calls alcohol "a prime target for reduced consumption." He continues: "Alcohol adds very little, if anything, of nutritional value to the diet and actually depletes some nutrients in the body. Alcohol provides the classic example of 'empty calories.'"

The trend in fruit juice consumption shows increased concerns about a healthy diet. Since 1950, we've more than tripled our consumption of fruit juices, from 2.1 to 7.1 gallons a year, with orange juice in the No. 1 spot. In fact, Molitor notes, more frozen orange juice is consumed than any other fruit in any form (beverage, canned, fresh, etc.).

Tea consumption has varied through the years, but generally

we're drinking about 35 cups more a year than we were in 1950 (when per capita consumption was 140 cups). Instant coffee, nonexistent in 1950, is in the same area—about 150 cups a year for each of us.

The situation with milk consumption is covered in "Eggs And Dairy Foods: Dietary Mainstays In Decline" on page 10. The decline in milk drinking is widespread and long-range, and the milk industry is trying to fight its way back with increased promotion and research.

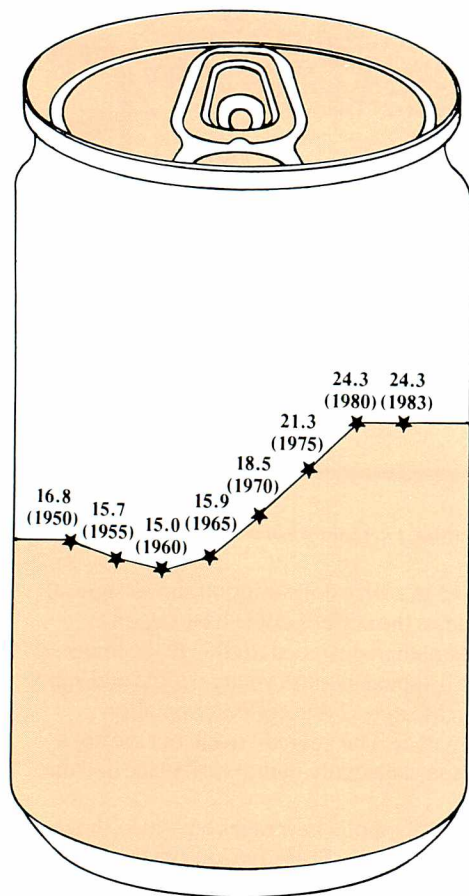
Few would have thought in 1950 that people would be drinking colas for breakfast. But then, maybe fruit juices will be the soft drink of the next generation, or maybe decaffeinated coffee will become the growth drink as the population ages. Or maybe it will be a new, yet-to-be-invented drink.

Who knows? Most crystal balls are cloudy, so there may be hope, Chairman Gorbachev, that you can turn your nation away from vodka to something less spirited. ■

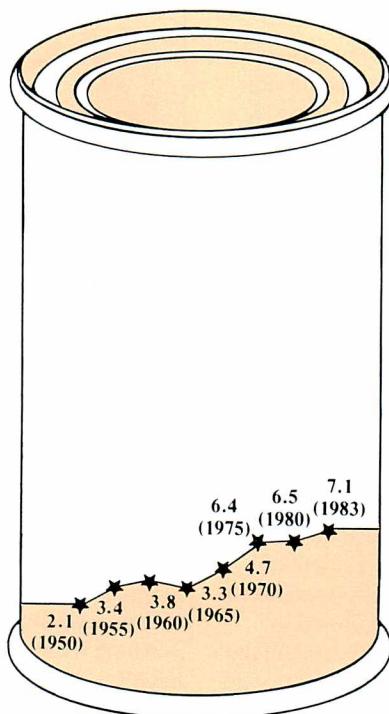
Roger W. Miller is director of FDA's communications staff.

Beverage Consumption

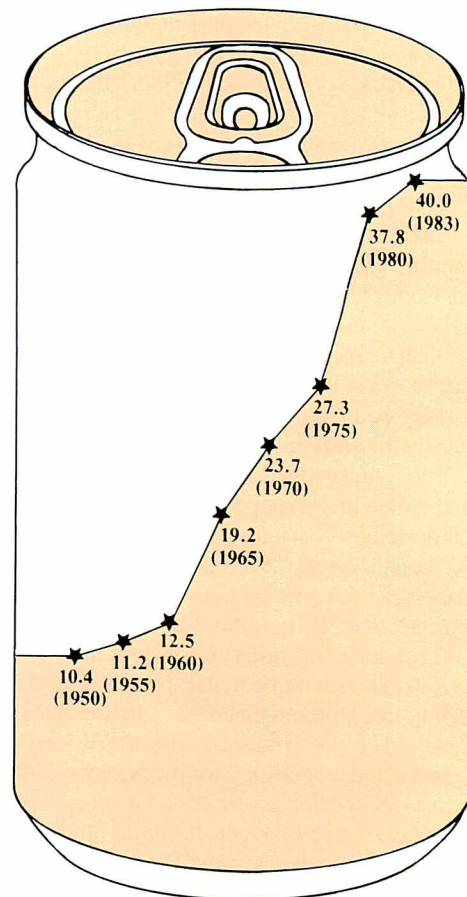
gallons per person per year



Beer



Fruit Juices



Soft Drinks

Source: United States Brewers Association for beer; USDA for fruit juices; National Soft Drink Association for soft drinks.

Our Insatiable Sweet Tooth

Despite the popular belief that Americans today are more diet and calorie-conscious, their appetite for sweetness in foods and beverages continues unabated. In fact, during the 1980s, Americans were consuming sweeteners at a higher rate than at any time in this century, an average of almost 136 pounds a year per person.

The big difference today from previous years is that consumers are appeasing their collective sweet tooth by substituting other kinds of sweeteners for sugar. And this is not always by conscious choice, since most of the sweetening agents used in foods and beverages are put there—before reaching the marketplace—by the manufacturers of the products.

For many years, common table sugar—that is, refined sugar made from sugar cane or sugar beets—was the predominant product for sweetening foods and beverages. But last year, consumption of refined sugar amounted to only 67½ pounds per person—the lowest ever recorded by the U.S. Department of Agriculture, which has been compiling food consumption data since the early 1900s.

Over a 25-year period starting in 1950, per capita consumption of refined sugar ranged between 94 pounds in 1951 to a high of 102.3 pounds in 1972. Since then, consumption has declined almost steadily.

According to USDA, the “continuous decline in sugar is largely attributable to increasing use of corn sweeteners—primarily HFCS (high fructose corn sirup)—in place of sugar and the substitution of noncaloric sweeteners, such as saccharin and aspartame.” And the main reason for this shift in sweeteners has been the soft drink industry, once a major user of refined sugar but now a leading user of the less costly corn sweeteners and artificial sweeteners. (High-fructose corn syrup is 30 percent to almost 40 percent cheaper than regular sugar.)

Corn sweetener use has increased rapidly—from 11.6 pounds per person in 1960 to 19.3 pounds in 1970, and 40.2 pounds in 1980. By 1984, corn sweetener consumption reached a record high of almost 58 pounds per person, primarily because of its growing use in soft drinks. High-fructose corn syrup accounts for most of the corn sweetener increase. In 1978, for example, HFCS consumption

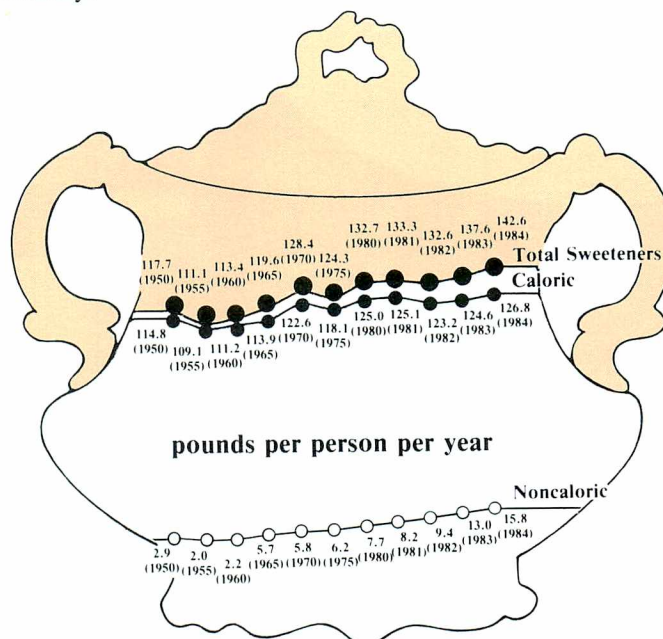
amounted to 12.1 pounds per person. By 1984, it had tripled, hitting 36.3 pounds.

In a speech to the International Sugarworkers Conference last year, Robert D. Barry, of USDA's Economic Research Service, predicted that within the next few years corn sweetener use in the United States would be about equal to that of refined sugar and that high-fructose corn syrup would account for about a third of all caloric sweetener consumption.

Artificial sweetener use was almost negligible in the 1950s when the first diet soft drinks were introduced. Since then, with the growing popularity of diet beverages, per capita consumption of artificial sweeteners has jumped. By 1978, noncaloric sweetener consumption (meaning saccharin, which was the only artificial sweetener in use at that time) was measured by USDA at 7.1 pounds per person. It rose to a record high of 15.8 pounds a person last year, with saccharin accounting for 10 pounds and aspartame 5.8 pounds. Aspartame was introduced in dry

Caloric and Noncaloric Sweeteners Consumption

Caloric sweeteners include refined sugars, corn sweeteners and other calorie-containing sweeteners. Noncaloric sweeteners include artificial sweeteners: saccharin, cyclamate (banned by FDA in 1970), and aspartame, which was approved for dry food use in 1981 and for beverage use in 1983. Saccharin has been used in foods for much of this century.



The weights for noncaloric sweeteners do not represent actual poundage. USDA tabulates artificial sweetener use based on its sweetness equivalency to regular sugar, so the actual poundage is less than the figures shown.

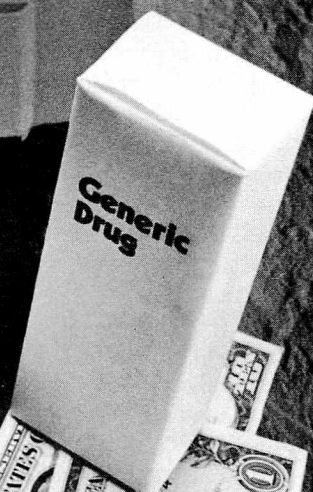
Source: USDA

foods in 1981 and in carbonated beverages in 1983.

(Artificial, or noncaloric, sweetener use is tabulated by USDA according to its sweetness equivalency to regular sugar. In other words, in 1984, American consumption of artificial sweeteners was equivalent to consuming 15.8 pounds of refined sugar. Saccharin is 300 times sweeter than regular sugar and aspartame is about 200 times sweeter. As a result, actual poundage consumed of these artificial sweeteners is much lower.)

The end result is that Americans today are not only consuming more products that are artificially sweetened, but they also are buying foods and beverages where one type of caloric sweetener (corn sweeteners mainly) is being used in growing amounts in place of another type (refined sugars). And, as a result, overall consumption of both caloric and noncaloric sweeteners remains high in the United States. ■

—Chris Lecos



Generic Drugs: Cutting Cost, Not Corners

by Bill Rados

On Sept. 24, 1984, President Reagan signed a law simplifying FDA's approval process for substitute, or "generic," versions of brand-name drugs whose patents have expired. With the law now one year old, newly approved generics are entering the marketplace, offering savings to consumers, but only after satisfying FDA's requirements for quality and equivalence to the brand-name products with which they compete.

Over the past several years consumers have become more and more aware of the money they can save by purchasing generic rather than brand-name drugs. Indeed, the word generic has been added to the public's vocabulary. While generics have the same active ingredient as their brand-name counterparts, they are usually sold at a substantially lower price. In fact, the potential for reducing U.S. health-care costs through wider availability of generic drugs prompted Congress to pass the law last year that streamlined FDA's approval process for generics. When President Reagan signed the law, he noted that "the American people will save money, and yet receive the best medicine that pharmaceutical science can provide."

Since generic drugs must meet the same FDA standards for safety, strength, purity and effectiveness as brand-name drugs, the differences between them are largely economic. All drugs have a generic name, also called the official or proprietary name, which applies to any manufacturer's version of the drug. Newly developed drugs are also given a brand or trade name by the innovator of the drug. Unlike generic names, which usually are contractions of a complex chemical name, brand names generally are short and easy to remember. For example, Darvon is Eli Lilly and Co.'s brand name for propoxyphene hydrochloride—the generic name for this prescription painkiller.

It's a common misconception that brand-name drugs are produced only by large, well-known firms while generics are made by small, unknown companies. A small drug company can put a brand name on its product just as a large company can market a drug under the generic name. And many large drug firms distribute, under their brand names, products that have been manufactured, packaged and labeled by firms that make generic drugs. Some manufacturers may make a drug and sell it under both a trade name and its generic name. In other instances, large firms may make a generic version of a drug product but put their own brand name on it, even though it is not the original version of the product. These "branded generics" usually sell at a price somewhere between the original brand-name drug and "true" generic products. To avoid confusion, FDA prefers to reserve the

term "brand-name drug" for the innovator's product, the one whose brand name has become a synonym for the drug itself (for example, Valium, Darvon, Dyazide) and to call all other duplicate products generic drugs, whether they are sold with a trade name or not.

The savings available when generic drugs are substituted for brand-name products vary widely from drug to drug and store to store. The average saving is between 30 and 40 percent but may be as high as 80 percent in some cases.

Because of the savings they offer consumers, generics have captured a significant share of the prescription drug market over the last decade. For example, generic versions are available for about one-third of the different types of prescription drugs sold as tablets or capsules. Of these generic versions, more than 75 percent have been judged therapeutically equivalent to their brand-name counterparts. The Generic Pharmaceutical Industry Association, a trade group representing generic manufacturers, says that in 1984 generic drugs accounted for 20 percent of total retail sales in the nearly \$20 billion prescription drug market.

Also, public and private hospitals, military installations, and other government health facilities are making it increasingly common practice to dispense generic drugs whenever possible.

Pharmacists are tending toward greater acceptance of generics, according to the trade magazine *American Druggist*. For several years, the periodical has been surveying pharmacists to determine which companies' products they favor when dispensing prescriptions that are written generically or for which state laws allow the pharmacists to choose the product. In 1979, brand-name companies got the highest vote in each of 26 categories. But by 1984, the lead in seven of those categories had passed to a generic firm.

The new law is expected to boost the trend toward greater use of generic drugs. A study reported in May 1985 by SRI International of Menlo Park, Calif., said that the law will help boost annual sales of prescription generics to \$8.5 billion by 1990, giving generics a 35 percent share of the market.

While continuing to ensure the safety and effectiveness of generic drugs, the new law will expedite entry into the marketplace for generic versions of some 160 brand-name drugs whose patents have already expired. These brand-name products, which include six of the 10 top-selling drugs, represent more than \$2 billion a year in sales.

Among the best sellers with patents that have already expired (with their generic names in parentheses) are: Merck, Sharp &

Even though the new law makes it less costly and time-consuming for generic drugs to reach the market, it does not lessen FDA's requirements that they be safe and effective.

Dohme's heart drug Indocin (indomethacin) and high blood pressure drug Aldomet (methyldopa); Hoffman-La Roche's tranquilizer Valium (diazepam) and the sleep-aid Dalmane (flurazepam); American Home Product's heart drug Inderal (propranolol hydrochloride); and Pfizer's diabetes drug Diabinese (chlorpropamide).

The long-term outlook for generics as more patents expire is also rosy: The recent SRI report predicts that by 1991, 81 of the current top 100 revenue-producing compounds and 20 of the 27 compounds that have sales greater than \$100 million will be open to competition from generics under the new law. In all, Rep. Henry Waxman (D-Calif.), who, with Sen. Orrin Hatch (R-Utah), cosponsored the legislation, estimates that the generic provisions of the new law should save consumers about \$1 billion over the next decade.

The new legislation, known as the Drug Price Competition and Patent Term Restoration Act of 1984—or informally as the Hatch-Waxman amendments—is regarded as the most important change to FDA drug laws in 22 years. It also marks the first time Congress has amended the law principally to achieve objectives relating to competitive and commercial forces in the regulated drug industry.

The law is intended to expedite the availability of generic drugs while giving brand-name companies adequate patent protection for the new medicines they develop. The first part of the law permits FDA to approve Abbreviated New Drug Applications (ANDAs) for generic versions of brand-name drugs already found to be safe and effective. The ANDA process has been used for more than a decade for drugs first approved before 1962, when the Food, Drug, and Cosmetic Act was amended to require that drugs be proven effective as well as safe. The Hatch-Waxman amendments permit FDA to apply this streamlined system to drugs first approved since 1962. Many of these newer drugs are among the most widely prescribed; some have sales amounting to hundreds of millions of dollars a year.

The generic drug section of the new law applies to over-the-counter as well as prescription drugs, although the biggest impact on generic availability will be in the prescription area.

The second part of the new law provides for restoring some of the patent time lost while products are going through FDA's approval process. This provision is designed to ensure that manufacturers have the incentive to develop new drugs. Patent protection ordinarily lasts 17 years, but some substantial portion

of this time is often used up before those products obtain marketing approval. According to Joseph Williams, president of brand-name drug manufacturer Warner-Lambert and chairman of the Pharmaceutical Manufacturers Association, the largest brand-name trade group, by the time the average new drug gains approval, it has only eight to nine years of patent protection remaining. The new law allows patent protection to be extended up to five years, provided the total (patent time remaining after FDA approval plus patent extension) is no more than 14 years.

In the words of Sen. Hatch, the new law provides "the best of both worlds—cheaper drugs today; better drugs tomorrow."

Before passage of the Hatch-Waxman amendments, firms that wanted to market generic versions of drugs approved since 1962 had two approval paths they could follow. The first was to do what was required of the pioneer company that developed the drug: conduct studies of the drug in animals and in humans to prove that the drug was safe and effective for its intended use. The firm would then compile the results of those studies and submit them to FDA for review. If all the information was acceptable, the drug would be approved for marketing.

The second path was for the firm to submit what is known as a "paper" NDA. The generic firm would not need to duplicate the research done by the innovator of the drug. It need only supply FDA with copies of journal articles or otherwise publicly available reports of scientific studies showing the safety and effectiveness of the drug. If FDA determined that those studies established the safety and effectiveness of the drug, and that the generic version was therapeutically equivalent to the original, the generic would be approved. While this provided an expeditious way for some generics to reach the market, the scientific literature contained sufficiently detailed reports for only a small percentage of the new drugs approved after 1962. Even in those cases, generic firms frequently had to perform animal studies to supplement the literature reports. The paper NDA path to FDA approval was not adequate to meet the demand for a streamlined system for getting generic versions of post-1962 drugs to market.

The new law allows companies to gain marketing approval at significantly less cost and time than if they had to submit complete NDAs. To develop and fully test a drug for safety and effectiveness and gain FDA approval costs millions of dollars and takes several years. The time spent by FDA reviewing the application averages 2½ years.

But the time from product development to marketing approval

Consumers can save money by asking their doctors to write prescriptions for generic drugs or by asking the pharmacist if a prescription can be filled with a generic version.

through the ANDA process for the first strength and dosage form of a particular generic drug ordinarily takes only one or two years (with an average of eight months of that taken up by FDA review of the application). The average cost is a small fraction of that of a "full NDA" based on clinical trials.

Even compared to the paper NDA route to approval, the ANDA system provided for in the new law is less expensive. Compiling the studies from the scientific literature can be a significant part of the cost of a marketing application for the first version of a particular generic drug. Also, the new law applies to all drugs marketed since 1962 (except antibiotics, which already had a streamlined system in place), not just the small percentage suitable for paper NDAs.

Even though the new law makes it less costly and time-consuming for generic drugs to reach the market, it does not lessen FDA's requirements that they be safe and effective. To be regarded as therapeutically equivalent to an already approved brand-name drug, the products may differ only in such superficial characteristics as color, taste, tablet shape and packaging. A generic must:

- Contain the same active ingredients (inert ingredients may vary).
- Be identical in strength, dosage form (tablet, solution, and so on) and route of administration (for example, taken by mouth or injected).
- Be used generally for the same illnesses, with the same precautions, warnings, and other instructions on the label.
- Be bioequivalent—that is, release the same amount of drug into the body at the same rate and affect the body in the same way as the brand-name drug.

Studies to prove bioequivalence are conducted in humans, generally by measuring the rate and extent of absorption of the drug into the bloodstream.

Along with the results of the bioequivalence studies, the generic drug manufacturer must submit details about its manufacturing plant and personnel, and how it will make the drug. FDA inspectors visit the plant to determine whether it has the capability to produce the drug properly. Samples of the product are tested in an FDA laboratory to make certain they meet appropriate standards.

Not only must each drug meet FDA requirements, so must each drug company. All firms, brand name and generic, must register with FDA; all must inform the agency of any reported adverse

reactions to their products. All are subject to periodic inspection, and all must follow FDA Good Manufacturing Practice (GMP) regulations that touch on every aspect of making drugs, from building maintenance to quality control. These regulations apply to all producers and are intended to ensure that all drugs meet the same standards of safety, strength, purity and effectiveness. These requirements, in fact, were built into the 1962 amendments to the Food, Drug, and Cosmetic Act for the very purpose of encouraging physicians to make wider use of lower-cost generics.

Not only does FDA test samples of the drug submitted by the firm when it files its application, it also collects samples periodically from the manufacturer and the marketplace to test for purity and strength. When trouble is found or suspected, the company is notified immediately and faulty products are removed from the market.

All 50 states now have laws allowing, and in some cases requiring, pharmacists to substitute a generic drug for a brand-name one unless the prescribing physician insists that the brand-name drug be used. Medicare and many private insurers also encourage the use of cost-saving generics. FDA publishes a list of *Approved Prescription Drug Products with Therapeutic Equivalence Evaluations*. The "Orange Book," as it is known, tells state agencies, pharmacists and other purchasers of generic drugs which drugs are therapeutically equivalent to brand-name products and the names of the companies that make them. Currently, more than 4,700 therapeutically equivalent drug products available from more than one manufacturer are listed. Subscriptions for the list and cumulative monthly supplements are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 for \$103.00. (Foreign subscriptions are \$128.75.)

Consumers can help themselves save money by asking their doctors to write prescriptions for generic drugs or by asking the pharmacist if a prescription can be filled with a generic version. Of course, there may be times when a therapeutically equivalent generic drug is not available. But if one is available and if there is no sound medical reason for specifying a brand-name drug, consumers should have the opportunity to save on the cost of their prescriptions while still getting an equally safe and effective product. ■

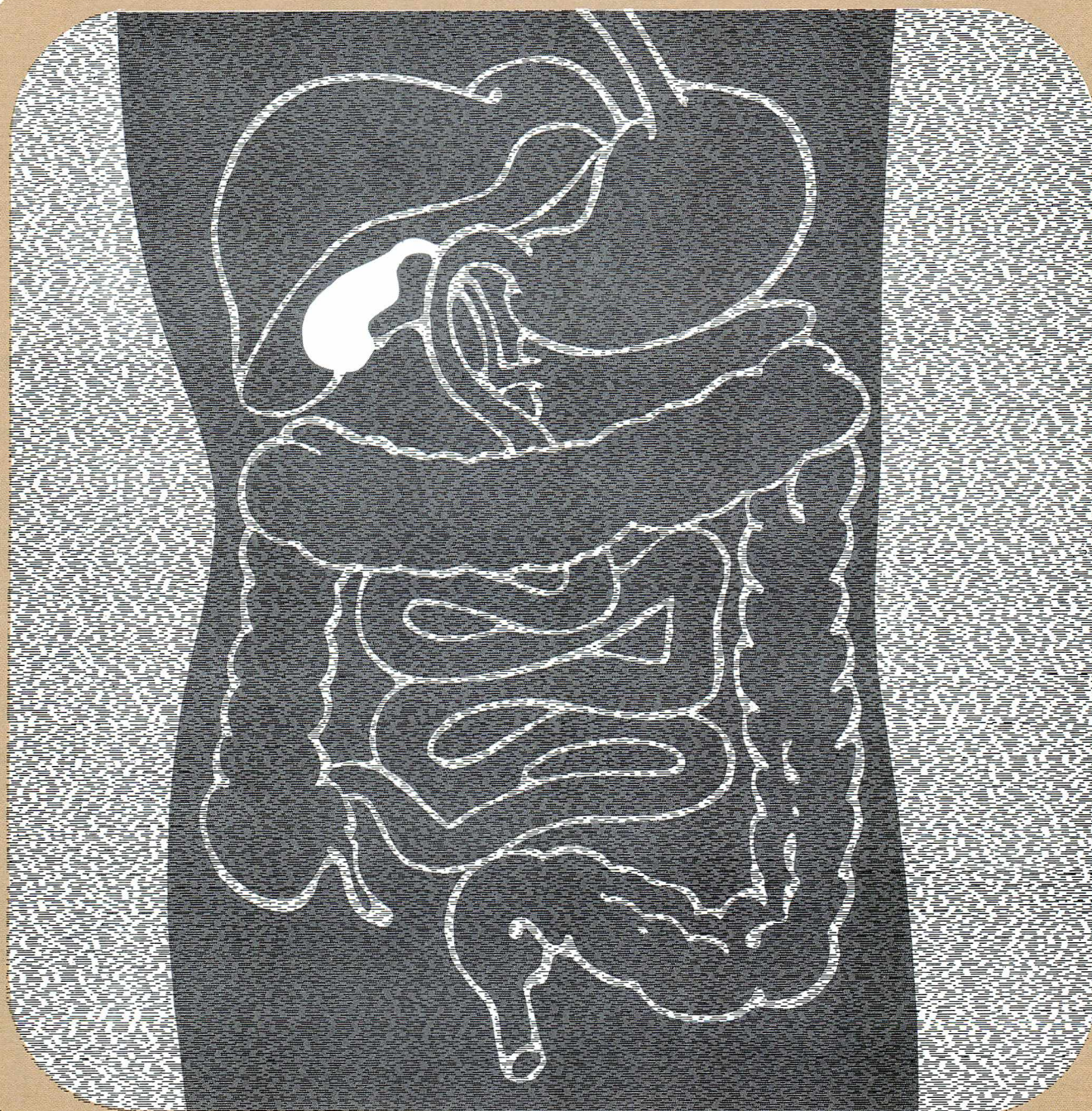
Bill Rados is editor of FDA Consumer.

Dyes Inject Contrast Into X-Rays' Shades Of Gray

by Richard C. Thompson

Diagnostic X-rays show body organs, tissue and structures in varying shades of gray, depending on their density. Since bones are very dense they show up well on X-rays, but softer body tissues do not. It can be difficult to distinguish one from another; to see, for example, the shape and placement of the gallbladder, the location of a possible tumor, or the exact point where a blood vessel narrows.

To overcome this difficulty, patients are sometimes given contrast dyes. These substances, given by mouth, by injection, or rectally—depending on the part of the body being studied—



provide physicians with a sharper image of what they are looking for.

"Dye" may be a misnomer, since the substance does not change the color of any parts of the body. For this reason they are more properly referred to as contrast agents. The agent is usually gone within hours, certainly within days, leaving little evidence that it was there. But while there, it helps the physician diagnose the patient's condition or disease.

The ingredient that makes many contrast dyes work is iodine, a nonmetallic crystalline element, dark brown to violet in color. Iodine occurs naturally in plants, soil and sea water. It is a heavy, dense substance that cannot be penetrated by X-rays, making it ideal for what it has to do. On an X-ray film, the parts of the body where the dye is present will show up as light areas, in stark contrast to their surroundings. Iodine is nontoxic when properly diluted and is generally well tolerated by the human body. Although few people are allergic to it, it can cause adverse reactions.

One of the many X-ray procedures in which diagnostic agents are used is cholecystography, or examination of the gallbladder. Patients scheduled for gallbladder examination are given a tablet or capsule of the contrast agent (or a prescription for it) by their physicians and are told to take it with water the evening before the test.

Before accepting the prescription or taking the drug, female patients should inform the physician if they are pregnant or nursing, since the contrast agents may cross the placenta into the fetus or enter the mother's milk. Patients should also tell the physician of any allergies to iodine, foods or other substances; of liver or kidney disease; and of other medicines being taken.

Recommendations as to the size and content of the last meal before gallbladder examination can vary, according to the judgment of the physician. After eating that meal and taking the contrast agent, nothing but water or clear liquids should be taken until the test has been completed.

Whatever the particular type, these contrast agents can cause abdominal cramping, nausea, vomiting, diarrhea, skin rashes, itching, heartburn, dizziness or headaches. But these reactions are usually mild and quickly pass.

Of the digestive-type reactions, 12 percent of the patients taking a contrast agent have reported diarrhea, 10 percent have reported nausea, 5 percent nausea and vomiting, and an occasional patient has reported heartburn.

Six percent of the patients have reported headache and 4 percent abdominal cramping. Three percent said they had problems urinating; a few have reported the need to urinate frequently. In reactions affecting the nervous system, 2 percent have reported dizziness. Hives and skin rash have also been reported as rare, minor reactions.

Cholecystographic contrast dyes are absorbed by the lining of the stomach and intestines, then carried by the blood to the liver, and finally concentrated in the gallbladder. They vary in the time it takes them to reach peak concentration in the gallbladder: for one type, iopanoic acid, it is approximately 14 to 19 hours after ingestion; for another type, iocetamic acid, about 10 to 15 hours. This explains the need for the patient to take the dye a certain number of hours before the examination.

Oral contrast agents are eliminated from the body through the urine and feces. Most of the dye is eliminated within a week. However, a minute amount of the iodine may be drawn to the thyroid gland. It has no harmful effect, although it could affect subsequent thyroid tests.

Another diagnostic procedure requiring the use of contrast agents is X-ray examination of the stomach and intestines (the

gastrointestinal tract).

The same cautions to patients apply with these agents as with those used in gallbladder examination. Allergies and other intolerances should be mentioned to the physician; and the dyes should not be used casually with pregnant or nursing women. There may be the side effects mentioned earlier.

The agents are administered orally to visualize the esophagus, stomach, and the portion of the small intestine nearest the stomach. They are administered rectally to visualize the colon or large intestine, with some contrast effect carried up into the small intestine.

The agents are only slightly absorbed as they move through the gastrointestinal tract, and they remain there for a period of time.

For oral administration, the agents can be flavored with vanilla, chocolate or some other preferred taste. If prepared from a powder, they can be diluted with water, milk or a carbonated drink.

Contrast agents can also be injected into veins and arteries of the cardiovascular system.

Cardiovascular injection is a much-used method of improving X-ray images. It can show on X-ray film and fluoroscope screen (which provides a continuous view of internal body parts) the blood vessels serving various body areas; the movement of blood into and through the heart; the blood supply of particular organs; and where blood vessels may be narrowed, blocked or malformed.

Injectable contrast agents are made up as sterile solutions. When injected into a blood vessel, the dye immediately "darkens" the blood so that the vessels in the path of flow "downstream" from the injection are easily seen on an X-ray. Within 10 to 30 minutes, it is diluted in the circulating blood and distributed throughout the body. Since the contrast effect is reduced by this dilution, the physician must work quickly after giving the injection to obtain the best X-rays possible of the areas being studied.

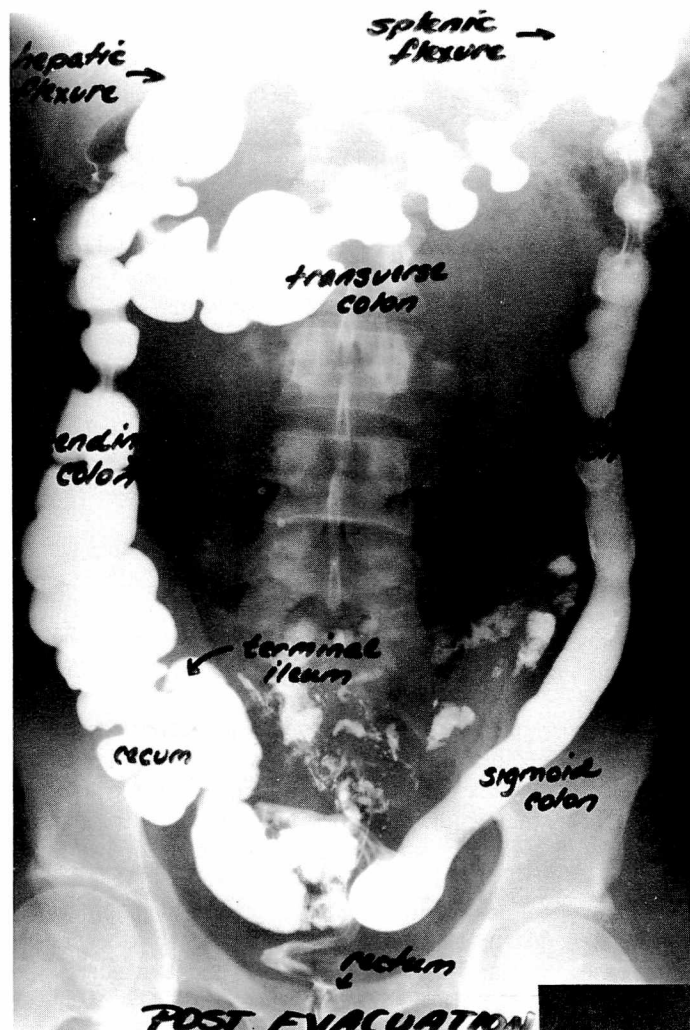
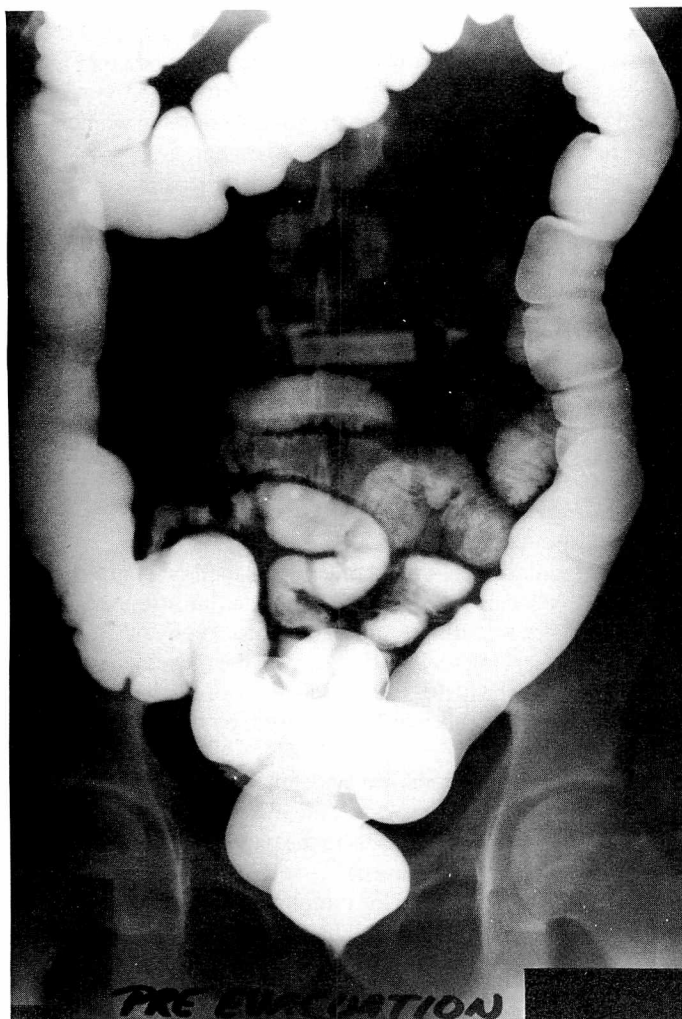
The most frequent reaction to an injected dye (reported by half of all patients) is a feeling of warmth as the solution circulates through the body. This is caused by a relaxing of the blood vessels (vasodilation). About 10 percent of the patients note a brief change in their sense of taste, since the tongue has a rich blood supply and the contrast agent is carried there. A few report some discomfort and swelling at the point of injection. Patients injected in the spinal area will experience pain and may require sedation; and those having injections into bone marrow, which is also painful, may need general anesthesia. Patients with severe medical problems and those with a history of allergy are most likely to experience reactions, no matter how the agent is administered.

Diatrizoate sodium is one type of injectable contrast agent. It is a clear, almost colorless, sterile aqueous (water) solution. Undiluted, it contains about 60 percent iodine.

Diatrizoate has many uses. It can be injected in a vein or infused by intravenous drip to diagnose bladder and urinary problems. It goes quickly to and through the kidneys and within minutes is in the ureters and bladder. Patients having this kind of X-ray diagnosis may be asked to drink no fluids half a day before the examination so that the contrast effect will not be weakened.

Diatrizoate can be injected into appropriate veins or arteries to visualize any portion of the cardiovascular system, including the heart, return of blood from the extremities, and blood flow into and from the lungs and through the aorta, the large vessel that supplies blood to the body.

Injectable agents such as diatrizoate are especially helpful in computerized axial tomography (CAT) scans of the head. They permit precise studies of the brain, a compact, complicated and sensitive organ that must be examined with great care. The agents



These X-rays of a patient's colon (large intestine) show the striking effect of contrast agents in helping to make visible the soft organs and tissue of the body. The X-ray on the left shows the colon soon after the patient was given a contrast agent in the form of a barium sulfate enema. In the X-ray on the right, the intestine appears less distinct since much of the barium has been evacuated, especially from the descending colon.

can show blood vessel injuries and malformations; the presence and extent of benign and malignant tumors; whether and where a stroke has occurred; and a variety of other brain conditions and abnormalities.

Diatrizoate injected intravenously is excreted in the urine after passing through the liver or kidneys. In patients with normal liver and kidney function, elimination can take only a few hours. But if the function of these organs is impaired by illness or injury, the process might take several days.

A non-iodine contrast agent that is much used for examination of the gastrointestinal tract is a liquid suspension of barium sulfate. If taken by mouth, it is known as the barium swallow; if administered rectally, as the barium enema. It may be the contrast agent most people have encountered in the course of medical examination.

Barium sulfate is used to diagnose diseases and abnormalities of the esophagus, stomach, and small and large intestines. It

coats, fills and outlines the shapes and folds of these organs and allows the physician to study them with a fluoroscope as the barium moves along or to take a series of X-ray films for later examination.

Despite the minor nature of most reactions and side effects, the use of contrast agents is not an insignificant procedure and physicians do not administer them casually. Many patients scheduled for X-ray contrast diagnosis have serious illnesses, and their body systems may not be functioning well. Therefore, the procedures must be carried out by specially trained personnel. Equipment must be available to cope with any complication of the procedure, as well as emergency treatment of the occasional severe reaction to the agent itself. Competent personnel and emergency facilities should be available for at least 30 to 60 minutes after administration of an injectable agent, since delayed reactions can occur. ■

Richard C. Thompson is a member of FDA's public affairs staff.

OTC Drug Labels:

'Must' Reading



by Annabel Hecht

“Take charge of your own health” has become a rallying cry of the '80s. A consumer survey on self-medication, reported in 1984, indicated that although Americans have a lot of everyday aches and pains, in nine out of 10 cases they take care of them without professional help, “toughing it out” or using either a home remedy or an over-the-counter (OTC) drug product.

When it comes to minor ailments, it's relatively easy to take care of yourself. There are literally thousands of drug products that can be purchased without a prescription in drugstores, supermarkets, convenience stores, and even snack bars. The various categories of OTC drugs don't quite go from A to Z but they're close—from acne treatments to wart removers. And the list is growing yearly as more prescription drugs are being “switched” to OTC status by FDA because the agency believes they can be used safely and effectively without a doctor's supervision.

Over-the-counter (nonprescription)

drugs should not be regarded lightly. They are often as powerful and can have the same potential for harmful side effects as their prescription counterparts. The difference between prescription and non-prescription drugs is spelled out in the Food, Drug, and Cosmetic Act, which says that drugs that are habit-forming, toxic, or not safe for use except under a doctor's supervision can be dispensed only on prescription. All other drugs are available over the counter.

Unlike prescription drugs, over-the-counter drugs are not usually intended to cure anything. They are used primarily to relieve the symptoms of a particular disease or condition.

The label also sets OTC drugs apart from prescription drugs. Under the FDC Act, the label the pharmacist puts on a prescription product generally tells little more than the name and address of the dispenser, the serial number and date of the prescription, the name of the prescriber, the name of the patient, directions for use, and cautionary statements, if any. If

Overuse of OTC drugs may mask a serious illness.

more information is needed, the consumer can (and should) check with a doctor or pharmacist.

OTC drug product labels are very different. FDA requires more information and very special information because consumers are pretty much on their own when they use the products. Thus, the label must provide the consumer with adequate information for the safe and effective use of the product. This information is important because OTC drugs are often purchased in supermarkets or convenience stores where there may not be a pharmacist to answer questions.

This is the information that should appear on an OTC drug product label:

- The name and address of the manufacturer, packer or distributor and the lot, control or batch number. This means any distinctive combination of letters, symbols or numbers from which the complete manufacturing history of the drug can be determined.
- The name of the product and what type of drug it is—that is, an antacid, nasal decongestant, pain reliever, antiseptic, or so on.
- A statement of the active ingredients. Consumers should read this list carefully when selecting an OTC drug, not only to know what they're taking, but also to avoid ingredients to which they may be sensitive.
- Declaration of the presence of the dye Yellow No. 5. Federal regulations require that the presence of this dye be indicated on the labels of all products—foods and cosmetics as well as drugs. People who are allergic to aspirin will also be allergic to this dye and therefore should be especially careful to look for it on product labels.

Other than Yellow No. 5 and certain other inactive ingredients, such as alcohol, most such ingredients do not have to be declared on OTC drug labels. However, most manufacturers have agreed to voluntarily list inactive ingredients—such as colors, flavors, binders and preservatives—to aid consumers who may be sensitive to them. Under guidelines developed by The Proprietary Association (a trade association of OTC drug manufacturers), the inactive ingredients will be listed alphabetically in type that is legible and visible to consumers at the point of purchase. The voluntary labeling is being implemented now and may be found on some currently marketed OTC drug products.

- The amount of the product in the container—that is, the number of tablets or ounces of liquid, cream or ointment.
- Indications for use—the symptoms or

conditions for which the product should be used.

- Directions for use—(sometimes designated “dosage”)—explain how much of the drug to take (per dose, time between doses, and maximum number of doses) and when to take it. The directions may also tell how to take or use the product: “Tablet should be chewed,” “Take with a glass of water,” and so forth. Directions for ointments and creams will explain how often to apply them, how to apply them (thin layer, for example), and whether to bandage or otherwise cover the area.
- Warnings or cautions—who shouldn't take the drug, when the drug shouldn't be taken, what adverse reactions might develop, and what symptoms signal the need for professional help.

Some OTC drug products should not be given to young children; others should be avoided by people who have conditions such as high blood pressure, glaucoma, kidney disease, or diabetes because the drug's ingredients may adversely affect their existing conditions.

Drugs that have a tendency to make the user drowsy are usually labeled with a warning such as “Do not drive or operate heavy machinery while taking this product.”

While OTC drugs may temporarily relieve symptoms, overuse may mask a serious illness. (The indigestion relieved by an antacid may really be caused by an ulcer, for example.) For this reason, the label may warn that the product shouldn't be taken for more than a specific number of days or that it should be discontinued and a doctor consulted if symptoms persist for more than a specified period of time or if certain other symptoms occur.

The labeling of all OTC drug products that are to be taken internally must include the warning “As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.”

The most important warning on the OTC drug label is “Keep this and all drugs out of the reach of children.” Labeling on most drugs to be taken by mouth must also state “In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.” Most products to be administered rectally or used topically must carry the warning: “In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.”

- Drug interaction precautions—some ingredients in OTC drugs can counteract

Check with a health professional before using any drug if you are pregnant or nursing a baby.

or interfere with the effectiveness of other drugs. Certain antacids, for example, reduce the effectiveness of the antibiotic tetracycline. Taking an OTC product containing phenylpropanolamine (used in some decongestants and weight-control products) with antihypertensive medication containing a monoamine oxidase inhibitor can send blood pressure soaring. Mixing drugs and alcohol is never a good idea, particularly when the drug is one that causes drowsiness.

- **Expiration date**—the month and year beyond which the drug will no longer be effective. Not all OTC drug products will have an expiration date, but when it appears, take it seriously. Taking an out-dated drug may not provide relief and may be harmful.

To assure consumers that they can use nonprescription medications with confidence, FDA initiated a massive review of the safety and effectiveness of the active ingredients in these products and the accuracy of the labeling of all OTC drugs. Because of the enormity of the OTC drug market, the drugs were reviewed by therapeutic class, such as antacids, cough-cold remedies, laxatives, sleep-aids and so forth.

Seventeen panels of non-government experts in the fields of medicine, dentistry, pharmacy and other medical sciences assisted FDA by making the initial evaluation of ingredients and labeling. More than 700 ingredients were studied, some several times because they were used in different kinds of OTC drug products.

As each review was finished, FDA published the panel's findings and recommendations for standards for each class of drugs. Public comment was invited on the panel recommendations. After evaluating the panel's report and the public comments, proposed standards are published. After another opportunity for the public to comment and new data to be submitted, final standards are then published.

Although the OTC review is not yet complete, a number of significant changes in OTC drug product formulation and labeling have already been made. Some ingredients have been taken off the market for reasons of safety, and one entire class of drugs—daytime sedatives—was removed after the review panel and FDA found there was no need for this type of OTC product. Among the ingredients that were switched from prescription to OTC status were hydrocortisone creams and ointments for topical use to relieve itching. (For a rundown of some of the changes

made as a result of the OTC drug review, see "OTC Review Milestone" on page 32 of the February 1984 *FDA Consumer*.)

Changes are also taking place in OTC drug labeling. Most visible are the SPF (sun protection factor) numbers on sunscreen products. Recommended by a panel to help consumers avoid sunburn, the numbering system has been widely adopted by the industry. (See "Tan Now, Pay Later?" in the April 1982 *FDA Consumer*.)

Some of the terminology in OTC labeling has been simplified. For instance, manufacturers can use the word "doctor" instead of "physician" or "dentist" (except in the pregnancy warning). A regulation recently proposed would, if finalized, give manufacturers more latitude in describing the indications for use. More familiar synonyms could be used in addition to or instead of the terminology approved by FDA.

Through its OTC drug review, FDA is making sure that OTC drug products are safe and effective. But it is the consumer's responsibility to see that they are used correctly. Here are some points to remember:

- OTC drugs are to be used primarily for temporary relief of minor symptoms.
- Improper use may aggravate symptoms or cover up a serious condition that needs a doctor's attention. Never take OTC drugs longer than recommended on the label. If symptoms persist or if new symptoms occur, see a doctor.
- Read the label on the drug container carefully before you start to take an OTC drug product. Check it again each time you buy that product. There could be important changes in indications, warnings or directions.
- Consumers who have allergies or chronic health problems should read ingredient, warning and caution statements carefully and check with a doctor or pharmacist if there are questions about taking a product.
- Check the expiration dates on OTC drug products from time to time and destroy, in the safest way possible, any that are out-dated or that have gone bad—for instance, eyedrops or ointments that have become discolored or aspirin tablets that smell like vinegar.
- Keep all drugs out of the reach of children.
- Check with a health professional before using any drug if you are pregnant or nursing a baby. ■

Annabel Hecht is a member of FDA's public affairs staff.

The Notebook: a potpourri of items of interest gathered from FDA news releases, other news sources, and the Federal Register (designated FR, with date of publication). The Federal Register is available in many large public libraries.

■ Information abounds on **FDA's electronic bulletin board**, the agency says. News releases, recalls, drug and device approvals, the *FDA Drug Bulletin*, selected *FDA Consumer* stories, summaries of *Federal Register* notices,



and speeches are offered on the bulletin board, available by subscription through the computer firm ITT-Dialcom (FR July 11).

■ The Drug Enforcement Administration has announced the temporary scheduling of **MPPP and PEPAP**, both chemical variations of meperidine, in Schedule I of the Controlled Substances Act, effective Aug. 12 (FR July 10).

■ **Cytotoxic leukocyte testing** for food allergies will not be covered by Medicare. The Health Care Financing Administration of the Department of Health and Human Services says there is no evidence that such testing is safe and effective (FR July 5).

■ **Gamma radiation** may be used on pork to control *Trichinella spiralis*, effective July 22. The FDA ruling is in response to a petition from Radiation Technology, Inc. (FR July 22).

■ A substance used in **food before 1958** may be generally recognized as safe on the basis of its common use in food outside the United States, FDA has proposed. Information about such use must show the substance is safe and must be documented by published or other information that can be corroborated by information from a second, independent source (FR July 2).

■ The Swiss Federal Office for Foreign Economic Affairs and FDA have signed an agreement which affords reciprocal recognition to each country's **good laboratory practice** program and provides for the mutual acceptance of safety test data collected in either country (FR July 19).

■ The National Council on Patient Information and Education has begun distributing 250,000 Spanish-language "Get The Answers" **medical data wallet cards**. FDA, the National Coalition of Hispanic Mental Health and Human Services Organizations, the American Red Cross, the National Council of La Raza, and the National Association of Community Health Centers, Inc., are helping in the distribution of the "Obtenga las Respuestas" cards.

■ FDA says **vitamin D**, when added to food as crystalline vitamin D₂, crystalline vitamin D₃, vitamin D₂ resin, and vitamin D₃ resin, is generally recognized as safe. It may be used as the sole source of added vitamin D, within certain limitations, in breakfast cereals, grain products and pasta, milk and milk products, infant formula, and margarine (FR July 24).

■ An FDA proposal would allow metered-dose **nitroglycerin** and metered-dose **cromolyn sodium** to be sold in pressurized cans containing a chlorofluorocarbon propellant (FR July 24).

■ **Surimi-based** products represented as a specific type of natural seafood must be labeled as imitation, according to an FDA policy guide. Labels must also list the common names of seafood in the product in descending order of predominance (FR July 26).

■ Temporary permits to market-test **canned green beans** with added zinc chloride to keep the beans green have been issued by FDA to Continental Can Co., Stamford, Conn.; The Larsen Co., Green Bay, Wis.; Green Giant Co., Minneapolis; Comstock Foods, Inc., Rochester, N.Y.; Agripac, Inc., Salem, Ore.; Stokely USA, Inc., Scottsville, Mich.; and Furman Foods, Inc., Northumberland, Pa. (FR July 30).

■ **FDA Guidelines:** Available from FDA's Documents Management Branch (HFA-305), 5600 Fishers Lane, Rockville, Md. 20857: "Guidelines for Anti-Infective Bovine Mastitis Product Development" and "Guideline for Efficacy Evaluation of Canine/Feline Anthelmintics." (FR July 18). Available from the Center for Devices and Radiological Health at the Rockville address are: "The Selection of Patients for Dental X-Ray Examinations: Routine Dental X-Ray Examinations" (send request to HFZ-250) and "Embryo, Fetus, Infant . . . Recommendations to Minimize Diagnostic Nuclear Medicine Exposure" (send request to HFZ-240) (FR July 19 and July 11).

Available from the Shellfish Sanitation Branch (HFF-344), 200 C St., S.W., Washington, D.C. 20204 is "National Shellfish Sanitation Program Manual of Operations, Part I, Sanitation of Shellfish Growing Areas" (FR July 8).

Human blood is donated for transfusions, through Red Cross and hospital blood banks, for example. But it is also a marketable commodity, bought and sold for a variety of medical uses. To meet the demand for blood and its components, an entire industry of commercial blood centers has been developed nationally.

lin, albumin, clotting proteins, etc.) and in clinical chemistry.

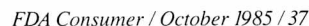
There are some 400 of these centers throughout the country, where donors can get \$10 or \$15 for their blood, and considerably more if it contains certain antibodies or disease-fighting substances. Since the body replaces the lost serum within two days, it is possible for donors to give plasma as often as twice a week.

FDA regulates plasma centers and plasma products to protect public health and safety. Centers that significantly or repeatedly violate FDA regulations can have their licenses suspended or revoked, and center owners and operators can be prosecuted. This happened recently with centers in Richmond, Va., Buffalo, N.Y., and San Antonio, Texas.

Charges involving the now-closed Richmond center included overbleeding donors and then falsifying whole blood logs to conceal that overbleeding; making false entries to show that equipment had been sterilized when it had not; using false red blood cell figures that made donors appear to be healthier than they were; and making false entries that showed quality control tests had been done with blood and plasma when they had not.

Employees said the center accepted donors who were pregnant, intoxicated, feverish, underweight, or donating too frequently. Also, instead of doing required tests, the center used information from previous visits when regular donors came in to sell their plasma.

The employees testified that they were



instructed by various managers to falsify whole blood weights and fabricate test results. One employee testified that she was given an entire log book to copy at home because it showed too many over-bleedings. Realizing this was wrong, she kept the original, which was introduced as evidence at the trial.

The Richmond center was one of seven plasma centers around the country operated by Automated Medical Laboratories (AML). Hugo Partucci, a long-time AML employee, had been "responsible head" at Richmond and also regional manager for the others. He could not be located at the time of the trial and is believed to have returned to his native Argentina.

Defense attorneys contended that his absence greatly weakened their case, but the judge pointed out that the violations continued long after Partucci left in 1979.

The attorneys also attempted to show that there had been "prejudicial delay" in bringing the case to trial in 1984, since the investigation began in 1980 and indictments were not returned until late 1983. Although Judge D. Dortch Warriner was critical of the Department of Justice and FDA, he did not agree the delay was totally prejudicial, saying that he would reconsider its effect after hearing the case.

Pedro Ramos, a manager of the center, was found guilty of falsifying records and fined \$500 and sentenced to one year's probation. He was acquitted of a conspiracy charge.

Norberto Queris, another manager, had earlier pleaded guilty to falsifying records. With other charges dropped, he testified on behalf of the government. He was fined \$1,000 and placed on three years' probation.

The center itself was fined \$1,000 on one count of conspiracy, with sentence suspended on additional counts of falsifying records. AML, the parent firm, was fined \$1,000 for making false statements and conspiracy. AML closed the Richmond facility on East Broad Street but has since opened another one a few blocks away.

Employees of the Buffalo Plasma Center in Buffalo, N.Y., had a story much like that

in Richmond.

They told FDA investigators they were required to falsify donor records to conceal overbleeding. They also said they falsified freezer charts to conceal the thawing of frozen plasma (thawing reduces quality); used saline solution left over from one donor to infuse the next; and altered donor records so that the center's blood products would be acceptable to laboratories purchasing those products.

The firm's licenses to produce and ship products were suspended by FDA. The agency then referred its findings to the U.S. attorney for grand jury investigation.

The grand jury indicted Dr. Guillermo Lesassier, the firm's president and manager of one center, on 11 felony counts; his wife, Maritza, manager of another center, on four counts; the firm itself on 11 counts; and company official and principal stockholder Pedro Diaz of Miami on six counts.

The Lesassiers had fled to the Dominican Republic after the firm's licenses were suspended. The Dominican government expelled Dr. Lesassier, an American citizen, into the custody of a U.S. marshal. His wife, a Dominican national, was arrested in Puerto Rico when she arrived there to post bond for her husband.

Dr. Lesassier pleaded guilty to three of the felony counts and was sentenced to a year and a day in prison. The judge noted that the prison term was intended to deter others who might be considering similar schemes. Mrs. Lesassier pleaded guilty to one count and was given four months' probation. Diaz had already pleaded guilty to all counts. He received a sentence of five years, with 4½ years suspended, 10 years' probation, and a fine of \$10,000.

In a separate but related action, Fred J. Lighte, operator of a Miami plasma center, was found guilty of perjury for telling a grand jury investigating the Buffalo center that he knew nothing of a certain Miami bank account that came into question in the case. Testimony revealed that \$50,000 had been deposited in the Miami bank by Lighte's plasma center in Miami, by Lesassier's center in Buffalo, and by a center in West Palm Beach to bribe an employee of a processing firm to purchase

plasma from these three suppliers. Lighte attributed his forgetfulness to an illness he had in 1977. He appealed his conviction but lost that appeal in January 1985.

In the case involving the San Antonio center, a donor whose blood contained a rare antibody was deliberately inoculated to increase her body's production of the valuable component. She was then overbled at the Plasma Derivatives Center in San Antonio, Texas, and records were falsified to conceal both the dangerous inoculations and overbleeding.

Robert J. Dratnol, center director, was indicted on six felony counts. He pleaded guilty to one and was fined \$7,000 and given a suspended prison term of three years.

Dratnol's indictment developed from testimony by the center's former manager, George Freeman, who had earlier been charged with 19 felony counts of violating FDA regulations. He pleaded guilty to one count of conspiracy and one of making and using false documents. He was sentenced to four years in prison—with all but six months suspended—and fined \$3,000.

Two other employees charged in the same indictments implicated Dratnol. They were Deborah Villafranco, who pleaded no contest to one count and received a suspended sentence; and Jose Gomez, who pleaded guilty to a conspiracy count and was fined and sentenced to six months in prison.

The centers cited here are not typical of the national plasma industry. Since the first plasmapheresis regulations were published in 1973, there has been a concerted effort by FDA and the American Blood Resources Association, the industry's nonprofit trade association, to upgrade and maintain standards that protect the health and safety of donors and the quality and safety of plasma products. Much of the success in accomplishing this is due to the educational efforts of the American Blood Resources Association, which has encouraged and promoted FDA enforcement of licensing and production regulations.

—Richard C. Thompson

A Change Of Attitude

Some people have a hard time facing up to the truth. A case in point is the Empire Seed Co. of Othello, Wash.

Empire operates a complex of six warehouses in which Washington-grown beans and peas are stored and, to some extent, processed before being distributed throughout the United States and abroad.

Norman L. Eilert is president and manager of the family-owned business.

In March 1985, an inspection of Empire Seed Co. by FDA's Seattle district office found many serious problems, not the

least of which were moldy and decomposed beans in bins and on the floor; extensive rodent and insect infestation (including many live mice); poor-fitting and damaged loading doors; and unbaited and unarmed rodent traps.

When presented with FDA's findings, Eilert expressed surprise that there were so many live rodents, but he also admitted that no fumigation work had been undertaken for five or six years. He indicated he would arrange for a pest control service to eliminate the rodents and insects.

An investigation in May revealed that conditions at the company had not improved and were actually worse.

Because Empire Seed Co. had a history of failing to correct insanitary conditions dating back to 1973, FDA felt the voluntary approach to cleaning up the warehouses would not work. Consequently, the Seattle office asked the Department of Justice for a temporary restraining order to prevent the moldy and defiled products from getting into interstate commerce.

At a June 10 hearing in the U.S. District court in Spokane, Eilert presented statements and documents to the effect that all vermin in the warehouse had been cleared out and the food was free of contamination. At his insistence and at the request of the court, three people from the Seattle district office, accompanied by attorneys from the Department of Justice and FDA headquarters in Rockville, Md., journeyed to Othello the next day to inspect the Empire Seed Co.

The inspection began at 10 a.m. as the entourage progressed through the warehouses.

By 1 p.m. the confidence previously demonstrated by Eilert appeared to be waning as the investigators encountered the very problems that were supposed to have been corrected: construction defects through which rodents could get into the warehouses; rodent nests; dead and live mice; bins of moldy and decomposed beans; and birds flying over unprotected bulk piles of beans.

By 2 p.m. Eilert and his attorneys began to discuss a consent decree of permanent injunction with the government. At 3:30, they asked FDA to stop its inspection.

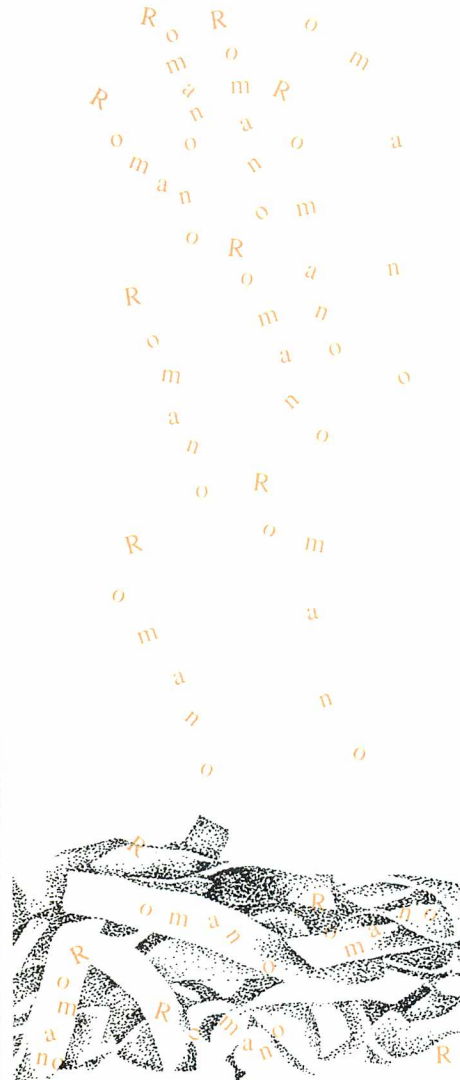
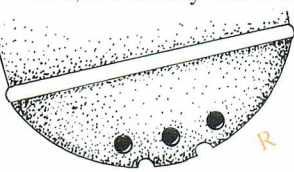
On June 12, the defendants entered into a consent decree of permanent injunction under which Empire Seed couldn't introduce any food into interstate commerce until the warehouses were cleaned up and measures taken to prevent vermin and

insects from getting in. The firm also agreed to establish a written sanitation control program and report in writing to FDA the actions they are taking.

FDA will be looking in on Empire Seed Co. from time to time to see that all this will be done.

Fettucine Á La Nausea

It was the beginning of a three-day weekend, and investigator Otto Vitillo of FDA's Brooklyn district office was just beginning to relax at home when the phone rang. It was his supervisor with news of a reported food poisoning that needed immediate investigation. For Vitillo, the holiday was over almost before it had begun.



Early the next morning, the investigator visited the woman in Northport, N.Y., who had made the complaint. She explained that she and her children had experienced nausea, flushing and some numbness about 30 minutes after eating her home-prepared Fettucine Alfredo. She had examined all the ingredients and noticed a peculiar odor in the Romano cheese. Vitillo took some of the cheese for laboratory analysis.

He then went to the supermarket where the cheese had been purchased. The cheese there also had a peculiar odor, and he collected another sample. The store manager removed the remaining stock from the shelves.

The cheese had been packaged by a Long Island firm, Habco Sales, Inc. Habco officials said they received grated cheese in bulk from a Wisconsin manufacturer and repacked it into smaller containers. The officials said they, too, had received a report of an illness. Vitillo took another sample of cheese, which had the same peculiar smell as the other samples, and delivered his collection to the New York regional laboratory.

Analysis showed that the odor seemed to be caused by a chemical in the plastic bags that the cheese was shipped in. The chemical, pentadiene, is added to plastic to keep it soft. Brooklyn district staff concluded that contamination of the cheese by this chemical was possibly the cause of the illnesses and asked FDA's Minneapolis district office to collect a sample bag from the cheese manufacturer, Park Cheese Co., Fond Du Lac, Wis., for further analysis.

Habco Sales, Inc., recalled the cheese. Almost 10,000 pounds, worth over \$33,000, was eventually destroyed.

No Cure for Psoriasis

For many years he had suffered from a severe case of psoriasis, Vittorio Tosti claimed. But when he started taking multivitamin tablets, he said, his skin condition cleared up. Inspired by his "cure," Tosti decided to go into the business of selling a vitamin-mineral product. With two friends, one a physician, he formed Vita-Skin Ltd. International, applied for and received a trademark for the product name, Vita-Skin, and began marketing the product nationwide and in Canada and Italy. The firm is headquartered in Patchogue, N.Y.

(Continued on next page)

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Claims for a "revolutionary new discovery in the treatment of Psoriasis and Eczema" were touted in brochures, advertisements on television, in local newspapers, and in display cards in retail stores. Consumers could also obtain Vita-Skin through the mail.

For all the sophisticated-sounding, "scientific" explanations in the advertising, there was one basic problem with the product. Vitamins and minerals won't cure psoriasis. In fact, there is no known cure for this chronic itchy skin condition, although there are medical treatments that can control it. (See "PUVA's Double Whammy On Psoriasis" in the September 1982 *FDA Consumer*.)

In early 1983, FDA's Brooklyn office sent a letter to the firm pointing out, among other things, that the Vita-Skin label falsely represented the product to be effective for psoriasis and eczema. In response, Tosti sent a collection of testimonials from satisfied customers and medical references he claimed supported the use of vitamins in psoriasis treatment. The firm, however, did not take any action to stop its medical claims.

In July 1984, Tosti again submitted testimonial letters and the results of an uncontrolled clinical study to FDA. Although he said Vita-Skin was a food supplement, Tosti sought FDA approval to market his product as a nonprescription drug.

In the exchange of letters that followed, Tosti was reminded that therapeutic claims on the label made Vita-Skin an unapproved new drug and that if he wanted to market the product simply as a vitamin-mineral combination such claims would have to go. Tosti agreed to take the words "For Psoriasis and Eczema" out of the container label, but he said that he would continue to promote and advertise the product with drug claims.

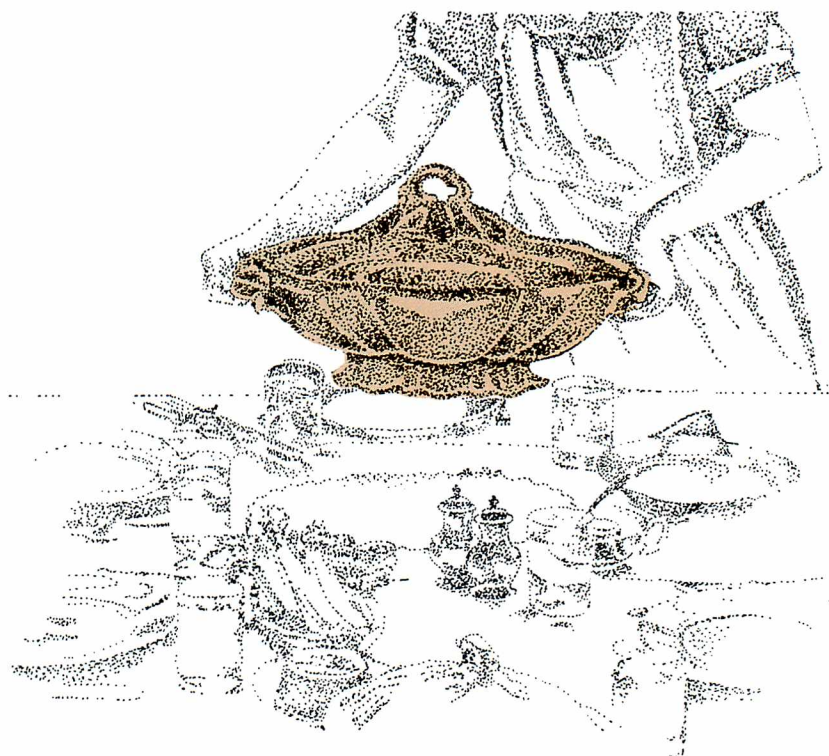
A January 1985 inspection revealed that the firm was continuing to market Vita-Skin as a drug. Furthermore, even though references to psoriasis and eczema were dropped from the container label, such words as "therapeutic program" remained.

Since it was obvious Tosti did not intend to voluntarily comply with the Food, Drug, and Cosmetic Act, FDA requested and received court approval for a seizure of Vita-Skin products. A deputy U.S. marshal seized all of the product on the firm's premises as well as product labels and promotional literature. Brooklyn dis-

trict investigator Lawrence Farina witnessed the seizure, which involved items with a retail value of \$8,000.

Vichyssoise II

'Twas the night before Thanksgiving 1984. But at the FDA Newark district office in East Orange, N.J., cold potato soup was replacing all visions of cranberries and turkey. They had just learned from headquarters that a Jersey City firm, S. Gumpert Co., Inc., was voluntarily recalling four underprocessed lots of canned vichyssoise.



Thirteen years ago, a similar situation involving a national recall of underprocessed vichyssoise had resulted in a consumer's death. This time, the Newark district saw to it that the entire investigation, recall implementation, and recommendation for agency action were completed within two weeks without any reported illnesses.

FDA obtained distribution records of the four lots from the firm's technical director at his home on Thanksgiving Day, and an intensive inspection of the firm was initiated the next day.

The inspection revealed that records were confusing and contradictory and that manufacturing practices were seriously

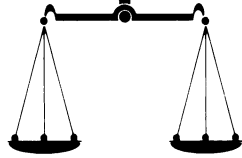
deficient. For example, the operator of the retort (pressurized cooking equipment) routinely applied incorrect and inadequate thermal processes to products not on his official time-and-temperature list. He routinely measured initial temperatures incorrectly, taking the temperature of can contents up to 10 minutes before the steam was even turned on. Only one retort was used for two different can sizes, and the process applied was the one designed for the smaller can. (FDA learned that it was only by chance the firm's technical director had noticed the erroneous mixing of can sizes.) Moreover, these fundamental

errors went unnoticed during the daily record review conducted by a second employee. Previous lists of objectionable conditions showed that many of the processing problems were recurrent ones.

On the basis of the district's recommendation, FDA approved an Emergency Permit Control notification and hand-delivered a letter informing the firm. Under this action, all subsequent lots are to be inspected by the Continental Can Co. and FDA before distribution.

— This small sample of reports from the field was prepared by Annabel Hecht, Carol Ballentine, Dixie Farley and Herman Janiger.

Summaries of Court Actions



Summaries of Court Actions are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act. Summaries of Court Actions 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.

Summaries of Court Actions are prepared by Food and Drug Division, Office of the General Counsel, HHS.

Published by direction of the Secretary of Health and Human Services.

SEIZURE ACTIONS

Foods/Contamination, Spoilage, Insanitary Handling

PRODUCT: **Cake flour and pie-dough mix**, at Memphis, W. Dist. Tenn.; Civil No. 82-2078-M.

CHARGED 2-4-82: While held by Progressive Foods Inc., Memphis, W. Dist. Tenn., the articles had been held under insanitary conditions—402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 63646; S. Nos. 82-276-242/3; S.J. No.1)

PRODUCT: **Flour**, at Rockville, Dist. Md.; Civil No. M-84-3313.

CHARGED 8-28-84: When shipped by Piedmont Mills Inc., Lynchburg, Va., the article contained insect filth—402(a)(3).

DISPOSITION: Consent—authorized release to the shipper for salvaging (conversion into animal food). (F.D.C. No. 64365; S. No. 84-469-342; S.J. No. 2)

PRODUCT: **Flours and cornmeal**, at Decatur, N. Dist. Ala.; Civil No. 80-L-5129NE.

CHARGED 5-21-80: While held by BMB Specialty Co. Inc., Decatur, Ala., some of the articles contained rodent filth, and all of the articles had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 63004; S. No. 80-163-268 et al.; S.J. No. 3)

PRODUCT: **Flour for chapatis**, at Berkeley, N. Dist. Calif.; Civil No. C 81-3244-WHO.

CHARGED 8-6-81: While held by Bombay Bazar Wholesale Distributors, Berkeley, Calif., the articles contained insects and had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—authorized release to Harry V. Parmar t/a Bombay Wholesale Distributors, Berkeley, Calif., for salvaging. The claimant failed to bring the article into compliance within the specified time; and the government moved for forfeiture of the claimant's bond. However, the claimant subsequently submitted an acceptable plan to convert the article into animal food. (F.D.C. No. 63525; S. No. 81-247-349; S.J. No. 4)

PRODUCT: **Garlic bulbs, dried**, at Ponce, Dist. Puerto Rico; Civil No. 81-1821.

CHARGED 9-22-81: While held for sale, the article was partially decomposed and contained insect filth—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63533; S. No. 81-173-849; S.J. No. 5)

PRODUCT: **Maraschino cherries**, at Gloucester, Dist. N.J.; Civil No. 81-0947(SSB).

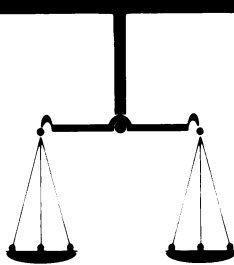
CHARGED 3-31-81: When shipped by Lansmith Inc., Ripley, N.Y., the article (labeled "Red Rose Brand . . . Maraschino Cherries . . . Packed by Lansmith, Inc., Ripley, New York" and "Acme Ideal . . . Maraschino Cherries . . . Distributed by Acme Markets, Inc., Phila.. Pa.") contained insect filth—402(a)(3).

DISPOSITION: The article was claimed by the shipper, who denied the charge. Subsequently, the claimant consented, without an admission of any facts, to a consent decree condemning the article. (F.D.C. No. 63429; S. No. 81-244-114 et al.; S.J. No. 6)

PRODUCT: **Maraschino cherries**, two seizure actions, at Montgomery, M. Dist. Ala.; Civil Nos. 81-145-N and 81-199-N.

CHARGED 3-11-81 and 4-1-81: When shipped by Lansmith Inc., Ripley, N.Y., the article (labeled "Whitfield Maraschino Cherries . . . Whitfield Olive Co., Inc., Montgomery, Alabama") contained insect filth—402(a)(3).

DISPOSITION: The article was claimed by the shipper, who con-



sented to a decree of condemnation without an admission of any facts. (F.D.C. Nos. 63402 and 63424; S. Nos. 81-252-154 and 81-288-649 et al.; S.J. No. 7)

PRODUCT: Mung beans, at New York, S. Dist. N.Y.; Civil No. 82-Civ-2452(MEL).

CHARGED 4-16-82: While held by Mayline Co. Inc., New York, N.Y., the article contained rodent filth and had been held under insanitary conditions—402(a)(3), 402(a)(4); and the dealer had repackaged some of the mung beans (from damaged bags) into bags with rice labels, so that the labeling of such mung beans was false and misleading as to the identity of the food, as to the name and place of business of the manufacturer, and as to the nutritional information about the food—403(a)(1).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 63678; S. No. 82-375-647; S.J. No. 8)

PRODUCT: Pepper, black, ground, at Lynchburg, W. Dist. Va.; Civil No. 84-0236-L.

CHARGED 12-28-84: While held for sale, the article contained animal filth—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64448; S. No. 85-464-536; S.J. No. 9)

PRODUCT: Rice, garbanzos, and cornmeal, at Mayaguez, Dist. Puerto Rico; Civil No. 81-2158.

CHARGED 11-5-81: While held by Mr. Special Supermarkets Inc., Mayaguez, Puerto Rico, the articles contained rodent filth and had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 63585; S. No. 82-281-771 et al.; S.J. No. 10)

PRODUCT: Sardines in mustard sauce, canned, Admiral Brand, at Little Rock, E. Dist. Ark.; Civil No. LR-C-84-955.

CHARGED 11-14-84: When shipped by R. J. Peacock Canning Co., Lubec, Maine, the article had been packed and held under insanitary conditions whereby it might have been rendered injurious to health (because of an excessive number of critical and major can seam defects)—402(a)(4).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64415; S. No. 84-335-558; S.J. No. 11)

PRODUCT: Sesame seed and sesame seed syrup, at San German, Dist. Puerto Rico; Civil No. 81-1969.

CHARGED 10-16-81: While held by Tropical Fruit Products Co. Inc., San German, Puerto Rico, the sesame seeds contained rodent filth and had been held under insanitary conditions—402(a)(3), 402(a)(4); and the sesame seed syrup had been prepared under insanitary conditions—402(a)(4).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63572; S. No. 81-281-664; S.J. No. 12)

PRODUCT: Sunflower seeds, at St. Louis, E. Dist. Mo.; Civil No. 82-0589-C.

CHARGED 4-19-82: While held by Red River Commodities, Fargo, N.D., the article contained insect filth and had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63692; S. No. 82-236-097; S.J. No. 13)

Foods/Economic and Labeling Violations

PRODUCT: "Sorghum" syrup, two actions, at Muskogee, E. Dist. Okla., and Van Buren, W. Dist. Ark.; Civil Nos. 81-349-C and 81-2212.

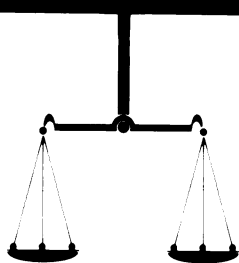
CHARGED 9-9-81 and 9-18-81: When the initial shipment was made by Tom Royce (t/a Lemuel's Pride Co.), Warner, Okla., from Anthony's Syrup Co., Philadelphia, Miss., and when the subsequent shipment (articles seized in Arkansas) was made by Griffin Grocery Co., Muskogee, Okla., the articles (labeled (40-ounce jars, with other size containers being similarly labeled) "Lemuel's Pride Old Fashion—Home Made Pure Sorghum, Lemuel Royce Farms, Stigler, Oklahoma Net Weight 40 Oz.") had had glucose syrup substituted for sorghum—402(b)(2); the articles' labels were false and misleading as to who had manufactured the articles, and were also false and misleading in representing that the articles consisted wholly of syrup from sorghum—403(a)(1); the articles failed to conform to the definition and standard of identity for sorghum syrup, since the articles were made with syrup from a source other than sorghum cane—403(g)(1); and the articles were also in violation of the Fair Packaging and Labeling Act as follows: the quantity of contents statements of some jars and cans of the article were not expressed in fluid ounces followed in parentheses by the largest whole unit of net quantity of contents, as required by regulation—15 U.S.C.1453(a)(3)(A)(i); the quantity of contents statements of some articles contained letters and numerals in a type size less than the type size established by regulation—15 U.S.C.1453(a)(3)(C)(i); and the quantity of contents declaration of some articles was not separated, as required, from other printed label information appearing above or below the declaration—15 U.S.C.1453(a)(2).

DISPOSITION: Default decrees ordered destruction. (F.D.C. Nos. 63530/1; S. Nos. 81-267-151/2 and 81-221-978 et al.; S.J. No. 14)

Foods/Color Additives

PRODUCT: Brassware (pitcher sets for coffee), at Hanahan, Dist. S.C.; Civil No. 2:84-2791-1.

CHARGED 11-19-84: When shipped by Khoslos, New Delhi,



India, the article (labeled "Hi artistic brassware . . . Coffee Set . . . Made in India") contained the nonconforming food additive lead (approximately 66-102 parts per million leachable lead)—402(a)(2)(C).

DISPOSITION: Default—ordered disposed according to law (melting at Charleston Naval Shipyard). (F.D.C. No. 64416; S. No. 85-302-321; S.J. No. 15)

PRODUCT: **Jimmy Cones (ice cream cones of vanilla ice cream with chocolate jimmies)**, at Charlestown, Dist. Mass.; Civil No. 85-409-G.

CHARGED 1-28-85: When shipped by Ellsworth Ice Cream Co. Inc., Saratoga Springs, N.Y., the article contained the nonconforming color additive FD&C Yellow No. 5 (i.e., the presence of FD&C Yellow No. 5 in the vanilla ice cream had not been declared on the article's label)—402(c); and the article's label failed to specifically declare the presence of FD&C Yellow No. 5 (which declaration is required for the protection of allergic persons)—403(a)(1).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64499; S. No. 85-389-054; S.J. No. 16)

Vitamins/Special Dietary Foods

PRODUCT: **Spirulina tablets**, at Tulsa, N. Dist. Okla.; Civil No. 84-C-887E.

CHARGED 11-2-84: When shipped by Akin Southwest Distributors Inc., Tulsa, Okla., the article contained insect filth—402(a)(3); and the labeling of the article contained false and misleading claims, as follows: that the product was "one of nature's best sources of protein" when the product serving size of six tablets failed to supply protein in amounts to significantly supplement the diet; that the product supplied five micrograms or 170 percent of the U.S. RDA of vitamin B₁₂, when five micrograms was not equivalent to 170 percent of that U.S. RDA; and the nutrition labeling claim of caloric content was not expressed as required by regulation—403(a)(1).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64405; S. No. 84-466-281; S.J. No. 17)

Drugs/Human Use

PRODUCT: **Sodium borate & boric acid solution**, at Rio Piedras, Dist. Puerto Rico; Civil No. 81-0584CC.

CHARGED 4-21-81: While held by Sein Mendez Laboratories, Rio Piedras, Puerto Rico, who had manufactured the article using interstate components, the circumstances of the article's manufacture, processing, packing and holding failed to conform with current good manufacturing practice—501(a)(2)(B); and the article's labeling lacked adequate directions for its intended use in the

eyes—502(f)(1).

DISPOSITION: The manufacturer filed a set of comments objecting to the action. The government opposed such comments and asserted that, in order to question a seizure action, the property owner should file a verified claim first and then file an answer. The manufacturer wrote that it would not contest the seizure and that this should not be interpreted as an admission as to the charges. Default—ordered destroyed. (F.D.C. No. 63417; S. No. 81-274-486; S.J. No. 18)

Drugs/Veterinary Use

PRODUCT: **Flea Tabs yeast combination tablets for dogs and cats**, at Canton, N. Dist. Ohio; Civil No. C-79-2090A.

CHARGED 11-7-79: While held by Bowman Pharmaceuticals Inc., Canton, Ohio, who manufactured the article using interstate brewer's yeast, the article (labeled "Flea-Tabs . . . causing the animal's skin to emit a strong odor that fleas dislike . . . Flea-Tabs, Inc., Bowling Green, OH") 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)(5).

DISPOSITION: The article was claimed by the manufacturer, who denied the charge and denied that the article was a drug. Subsequently, a consent decree authorized release of the article to the claimant for bringing into compliance. (F.D.C. No. 62671; S. Nos. 79-112-672/8; S.J. No. 19)

Medical Devices

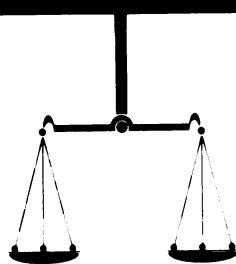
PRODUCT: **Adhesive patches with magnets, Acu-Dot**, two seizure actions, at Valley View and Wickliffe, N. Dist. Ohio; Civil Nos. C-79-2332 and C-79-2331.

CHARGED 12-20-79 and 12-20-79: The article (labeled "Acu-Dot Magnetic Analgesic Patch Acu-Dot Corp. . . . Akron, Ohio"), which had been prepared and packaged at Huntington Beach, Calif., for Acu-Dot Corp., Akron, Ohio, had false and misleading labeling claims for temporary relief of occasional minor aches and pains of muscles and joints—502(a); and the article's labeling lacked adequate directions for lay use for its intended purposes—502(f)(1).

DISPOSITION: Pursuant to stipulation between the government and the distributor, the parties agreed to trial of the issues in a similar seizure action at Cleveland, Ohio. After trial of the issue before the court, the court found for the government and condemned the articles. (F.D.C. Nos. 62709/10; S. Nos. 80-114-047 and 80-112-679; S.J. No. 20)

Cosmetics

PRODUCT: **Washing grains**, two lots, at Lynchburg, W. Dist. Va.; Civil No. 85-0017-L.



CHARGED 1-31-85: While held by Frances Denney, Lynchburg, Va., who manufactured the article using interstate talc, the article (labeled "Bio-Clear Washing Grains . . . MedTech Laboratories Inc., Dist. Cody, Wy. . . Lic. Dist. of Helena Rubenstein, Inc.") contained insect filth (one lot only)—601(b); and both lots had been prepared, packed and held under insanitary conditions—601(c).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64504; S. Nos. 85-360-757/8; S.J. No. 21)

CRIMINAL ACTIONS

DEFENDANT: **Marshall Pharmacal Corp.**, and **Gustave A. Godinez**, president, South Hackensack, Dist. N.J.; Criminal No. 84-0076B-01.

CHARGED 5-22-84: When shipped to Stamford, Conn., reserpine alkaloid tablets, 0.25 mg., U.S.P., lot 8297, differed from U.S.P. standards because the tablets failed to meet the specifications for content uniformity—501(b).

DISPOSITION: Guilty pleas: corporation—\$1,000 fine; and individual—30 days' imprisonment and \$1,000 fine. (F.D.C. No. 63757; S. No. 79-189-086; S.J. No. 22)

INJUNCTION ACTIONS

DEFENDANT: **Farm Rite, Inc.**, and **Roger J. Lamoureux**, president, Attica, W. Dist. N.Y.; Civil No. 84-0508-E.

CHARGED 5-3-84 in a complaint for injunction: That the defendants were selling interstate veterinary prescription drugs directly to lay persons without the benefit of a prescription and were thereby causing such drugs to be misbranded due to failure to bear adequate directions for use—502(f)(1); that FDA inspections established that a number of such violative sales had been made and that various specified veterinary prescription drugs were found on the defendants' premises; and that the defendants were well aware that their actions were in violation of the law.

DISPOSITION: Pursuant to stipulation of the parties, a consent decree of permanent injunction enjoined the sale of any interstate veterinary prescription drug, prescribed specified FDA inspections of the defendants' facilities, inventory and records, and required the defendants to give notice of the injunction to persons who then or in the future might act with the defendants in the sale or distribution of veterinary drugs. (Inj. No. 1065; S. No. 82-285-433 et al.; S.J. No. 23)

MISCELLANEOUS ACTIONS

SUBJECT: **Proteolytic enzymes and megavitamins added to food and drink**, and suit to compel FDA action, New York, S.

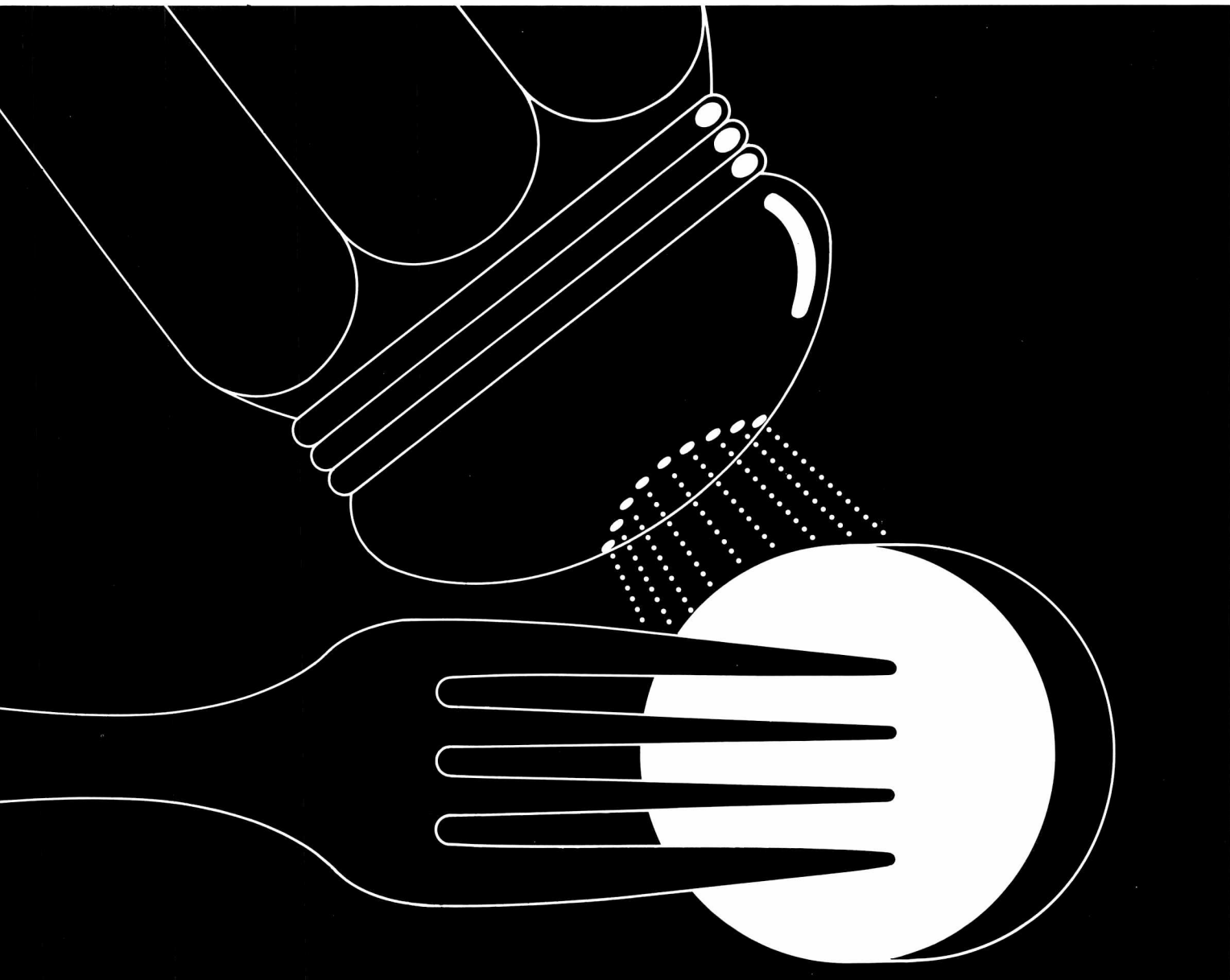
Dist. N.Y.; Civil No. 82-Civ-5586(EW).

PETITIONED 8-23-82 by Stanley Solomon, Kew Gardens, N.Y., against the Food and Drug Administration in a complaint for injunction and other relief: That, for approximately 12 years, canned, packaged and bottled food and drink sold in the plaintiff's area have had certain specified substances added to such food and drink; that plaintiff was allergic or hypersensitive to such substances; that a named individual, or some other individual, was pretending to add megavitamins but was actually adding proteolytic enzymes and megavitamins in a powder or liquid to the cans and bottles of the plaintiff's food and drink; that such individual pretended to be adding megavitamins to gain the cooperation of the manufacturers or packers of the food and drink; that the cans and bottles containing the proteolytic enzymes did not list them as ingredients on their labels as required by law; that plaintiff was unable to avoid such food and drink since it was distributed to all the supermarkets in the areas where plaintiff lived and traveled and was also added to his food and drink if plaintiff ate in a restaurant; that plaintiff knew from physical effects of the allergic or hypersensitive reaction that such adulterated cans and bottles were continuing to be used in food establishments and markets; that this use of adulterated food had been brought to the attention of FDA four months earlier and FDA's failure to stop this constituted an intolerable delay; that plaintiff had no adequate remedy at law; and that plaintiff sought action by FDA to prevent such violative action by food and drink manufacturers where the purpose of such addition was to cause the plaintiff to involuntarily and unknowingly ingest such proteolytic enzymes or megavitamins, and to prevent any stockpiled violative products from being placed in food establishments or markets in the communities where plaintiff usually purchased his food.

DISPOSITION: The government opposed the plaintiff's motion for a preliminary injunction and moved to dismiss the action. The court denied the plaintiff's motion for a preliminary injunction because the plaintiff had not shown a likelihood of success on the merits, since FDA's authority to enforce section 331 of the Food, Drug, and Cosmetic Act was discretionary, and since the public interest would not be served by the removal, from the shelves of supermarkets in plaintiff's neighborhood, of all the products challenged by the plaintiff.

The plaintiff moved for reconsideration of his motion for a preliminary injunction. Subsequently, the court dismissed the action, saying that determinations made by FDA to demands for actions such as that of the plaintiff rested in the sole discretion of FDA and were not reviewable by the court. Since the government's motion to dismiss the action for a failure to state a claim was granted, this necessarily disposed of the plaintiff's motion for reconsideration of the application for a preliminary injunction. (Misc. No. 688; S.J. No. 24)

NO MATTER HOW YOU SHAKE IT... ...OUT COMES THE SODIUM.



Sodium is in almost every food we eat.
But if we get too much of it, high blood pressure and
other diseases may develop.

We need only 1,100 to 3,300 milligrams a day.

Be sensible about sodium.

Check food labels to see how much you're getting.

Single copies of this poster (actual size 17 by 22 inches)
are available free from: Food and Drug Administration
(HFE-88), 5600 Fishers Lane, Rockville, Md. 20857. Re-
quest HHS Publication No. (FDA) 85-2207.