

# **FDA** **CONSUMER**

FEBRUARY 1975

## Contraception With IUD's

Intrauterine devices (IUD's) have become a popular method for preventing pregnancy. Like other forms of contraception, IUD's present benefits and risks.

PUBLIC HEALTH LIBRARY  
SCHOOL OF PUBLIC HEALTH  
109 OBSERVATORY ST.  
ANN ARBOR, MICHIGAN 48104

# Cream Style White Sweet Corn

Net Weight 17 oz. (1 lb. 1 oz.)  
Metric Weight 482 grams  
Cups Approx. 2



INGREDIENTS: CORN, WATER, SUGAR, SALT,  
STARCH ADDED TO INSURE SMOOTHNESS

NUTRITION INFORMATION—PER ONE CUP SERVING  
SERVINGS PER CONTAINER APPROX. 2  
CALORIES 190  
PROTEIN 4 gm  
CARBOHYDRATE 42 gm  
FAT 0 gm

PERCENTAGE OF U.S. RECOMMENDED ALLOWANCES (U.S. RDA) PER ONE CUP SERVING	
PROTEIN	6
VITAMIN A	•
VITAMIN C	30
THIAMIN (B <sub>1</sub> )	4
RIBOFLAVIN (B <sub>2</sub> )	10
• CONTAINS LESS THAN 2% OF THE U.S. RDA OF THESE NUTRIENTS	
NIACIN	15
CALCIUM	•
IRON	6
PHOSPHORUS	10
MAGNESIUM	8

For good nutrition eat a variety of foods.

DISTRIBUTED BY DEL MONTAGNA CORPORATION  
SAN FRANCISCO, CALIF. 94119, U.S.A.

---

## This Month

---

**I**f you eat, you have a vested interest in this month's article, "A Primer on Four Nutrients: Proteins, Carbohydrates, Fats, Fiber," third of a series on nutrients. If you have forgotten what you learned in grade school or later about these important nutrients, here is a refresher that tells you how they work to provide needed nourishment and keep you in good health and also a few significant things that have been learned about them in more recent years.

If you eat out, you have a vested interest in FDA's proposed Federal food service regulations and the Agency's model ordinance for State and local governments, both intended to assure improved safety and sanitary preparation of the 150 million meals served outside the home daily by some 600,000 food service establishments in this country. "Watching the Pot" discusses the new proposals.

FDA has postponed the effective date of its nutrition labeling regulations for 6 months—until July 1—but the benefits are already accruing as many food manufacturers change over to the new system and consumers learn how to understand it. Read "Time to Bone Up on Nutrition Labeling."

Today's trend toward family planning has created much interest in the newer methods of birth control, of which the best known is The Pill. But several million women have used a less known alternative method, the intrauterine device, called IUD. "Contraception With IUD's" and an accompanying article, "The Dalkon Shield," provide current information about IUD's and discuss questions related to effectiveness and safety.



**FDA**  
**CONSUMER**  
VOL. 9, NO. 1/FEBRUARY 1975

<b>A Primer on Four Nutrients: Proteins, Carbohydrates, Fats, and Fiber</b>	<b>4</b>
<b>Contraception With IUD's</b>	<b>14</b>
<b>Time to Bone Up on Nutrition Labeling</b>	<b>22</b>
<b>Watching the Pot</b>	<b>25</b>
<b>News Highlights</b>	<b>28</b>
<b>Regional Reports</b>	<b>29</b>
<b>State Actions</b>	<b>32</b>
<b>Seizures and Postal Service Cases</b>	<b>33</b>
<b>Notices of Judgment</b>	<b>35</b>

**Caspar W. Weinberger**  
Secretary, U.S. Department of  
Health, Education, and Welfare

**Alexander M. Schmidt, M.D.**  
Commissioner of Food and Drugs

**John T. Walden**  
Assistant Commissioner  
for Public Affairs

**Ellis Rottman**/Editor

**Harold C. Hopkins**/Editorial Director

**Jesse R. Nichols**/Art Director

**Joan M. Galloway**/Managing Editor

**Frederick L. Townshend**/Production Mgr.

**FDA CONSUMER**, the official magazine of the Food and Drug Administration, is published monthly, except for combined July-August and December-January issues. Subscriptions may be ordered from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402, at \$8.55 a year (\$2.15 additional for foreign mailing).

Address for editorial matters: **FDA CONSUMER**, HFI-20, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852.

Text of articles published in **FDA CONSUMER** may be republished without permission. Credit to **FDA CONSUMER** as the source is appreciated. Use of funds for printing this publication approved by the Office of Management and Budget November 1, 1972.

**FDA CONSUMER** was previously known as **FDA PAPERS**.

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

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

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



## Consumer Forum

### Moldy Cheese

The November issue contained an article which I found extremely interesting, and timely. I purchased some cheeses from a company in Madison, Wisconsin. Among my order were several containers of a "processed cold pack" of various flavors of cheese. There was a package insert that advised to keep the cheeses refrigerated, but also stated that if mold should form, it was of little significance. It stated that scraping away the mold would render the product safe to eat.

After reading the article on "mold," I question whether this is a wise practice, since the cheeses were not Bleu or Roquefort, but merely cheddars made into spreads with various flavors added. If this practice is acceptable, then the article is misleading. If not, I feel the company should not include a statement with their products that may cause harm to their clients.

Hopefully, my cheeses will be eaten before mold has a chance to form. However, I would be interested in knowing whether it would be safe to follow the instructions of the company.

Dorothy C. Lochte  
Baltimore, Maryland

*The article on mold advised consumers not to buy cheeses—other than Roquefort, Bleu, and similar varieties that are supposed to be veined with mold—that show signs of mold at the time of purchase. The article did not deal with cheese that develops mold after being refrigerated by the consumer. In the latter situation, there are a number of safeguards that permit the manufacturers to rely on instructions to scrape off mold that forms after refrigeration.*

*Aflatoxin-producing molds, although able to grow on cheese and produce toxins under experimental conditions, are not common on cheese. Furthermore, aflatoxins are not produced under refrigerated conditions. Scraping away the mold will remove toxins if any are produced by the mold. Scraping should be liberal to remove any metabolic mold products that may diffuse.*

*Mycotoxin-producing molds are quite uncommon in cheese; refrigeration is an inhibitor of toxin production; and careful scraping, if necessary, is an added precaution.*

### Changing Food Supply

To answer reader inquiries about "The Changing Food Supply" (FDA CONSUMER, October

1974), several people provided background papers and served as panelists for the FDA meeting on changes in the Nation's eating habits. The changes in nutrient intake indicated in the article represent U.S. Department of Agriculture economic consumption data, not actual food intake. Information on the health aspects of changes in dietary patterns was contributed to the meeting by nutritionists from outside Government.

The following corrections should be noted in the nutrient intake data:

The per capita per day consumption of protein in 1972 was 101 grams (not 95 grams).

Also, in the paragraph on vitamin A and vitamin C, the second sentence should read, "The vitamin C level was 12 percent higher in 1973 than in the earlier period (117 mg vs. 104 mg), and vitamin A value was 7 percent higher than in the earlier period (8,100 IU vs. 7,600 IU). The second sentence in the paragraph on vitamin B-6 should indicate "vegetable sources" instead of just "vegetables." (Vegetable sources include the cereal grains that are good contributors of vitamin B-6.)

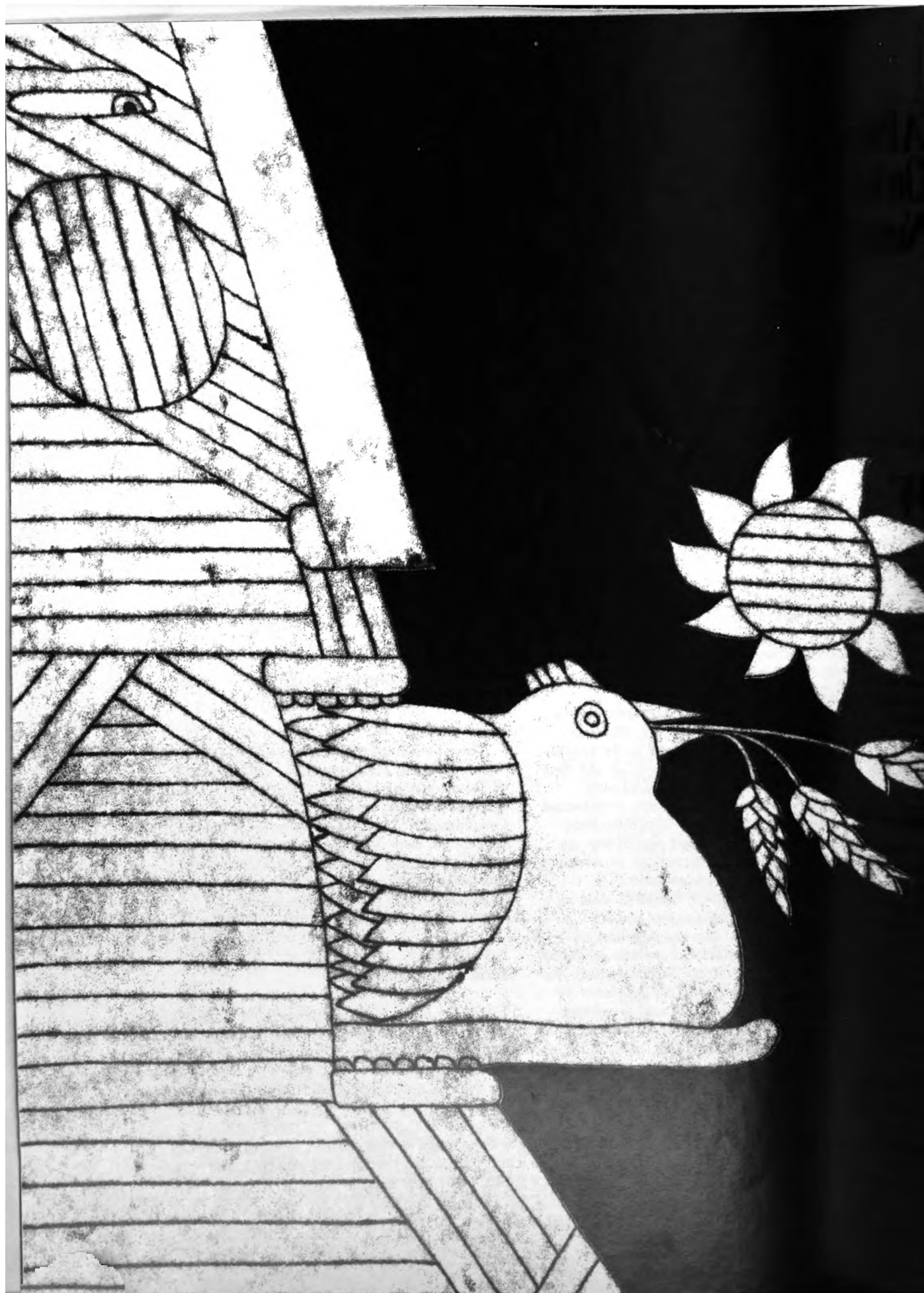
Marilyn G. Stephenson  
Nutritionist, Bureau of Foods, FDA

### Excessive Salt

The article in the October 1974 FDA Consumer, "The Changing Food Supply," overlooked one of the most dangerous aspects of our present day food supply—the amount of salt allowed by the Government in smoked meats such as ham and bacon. Not only does the customer pay a high price for this salt but the fact that excessive salt is responsible for hypertension is well established. How the FDA can permit this dangerous practice to continue, I don't know.

J. P. Oelberg  
Terre Haute, Indiana

*Salt has been used traditionally for hundreds of years in the curing and preservation of meats, and such processing of ham and bacon in this country is regulated by the U.S. Department of Agriculture and State or local governments. Consumers who must limit their intake of salt are advised to avoid these meats or eat them sparingly and choose instead some of the many other nutritious foods on the market that contain little or no salt.*



# A Primer On Four Nutrients:

# Proteins, Carbohydrates, Fats, And Fiber

by G. Edward Damon

**W**e all need good nutrition, and an understanding of what nutrients do in the body is important for anyone who wants to plan a well-balanced diet to meet this need.

Previous stories in FDA CONSUMER have explained the functions of vitamins ("A Primer on Vitamins," May 1974) and minerals ("A Primer on Dietary Minerals," September 1974). This four-part article tells about four nutrients that are also essential for good health—proteins, carbohydrates, fats, and fiber.

Nutrition labels on food are required to include information on three of these nutrients. These labels must list the grams of carbohydrate, protein, and fat per serving as well as the calories and the percentages of the U.S. Recommended Daily Allowances (U.S. RDA) of several vitamins and minerals. Nutrition information already appears on a variety of foods and will be mandatory after June 30, 1975, on foods to which a nutrient is added or for which a nutritional claim is made. Many other products are also being labeled voluntarily by the manufacturers.

## What Are Proteins?

To the average consumer "protein" means "meat." Some would include fish and poultry, and some might add eggs and milk. Thus, most people associate protein with animal products.

In the last year or so, however, vegetable proteins have been widely advertised and sold in supermarkets as meat extenders or meat substitutes, and more consumers are becoming aware that there are both plant and animal proteins.

Consumers interested in good nutrition should know more about how proteins work, for they are, besides water, the most abundant substance in body cells, and they have almost endless functions in the body.

Proteins account for the tough, fibrous nature of hair, nails, and ligaments, and for the structure of muscles. They are a part of hemoglobin, which transports oxygen in the blood; of insulin, which regulates blood sugar; and of the enzymes necessary for digestion of food.

Amino acids—which contain nitrogen that is essential to animal life—are the building blocks of proteins. It is the variations in the composition and arrangement of amino acids in the protein molecule that give protein its remarkable versatility. In protein molecules, hundreds of amino acids are linked into long chains. About 20 amino acids are commonly found in proteins, allowing for an almost infinite

number of combinations and sequences in the amino acid chains, and, therefore, an almost infinite variety of proteins that occur in plant and animal tissues.

## Functions of Proteins

Proteins (actually amino acids) are required by the body for building and maintaining body tissues, and are part of deoxyribonucleic acid (DNA), which controls the genetic code and thus all hereditary characteristics in body cells. The greatest amounts of protein are needed when the body is building new tissue rapidly, such as during infancy, pregnancy, or when a mother is nursing a child. Extra protein also is needed when excess destruction or loss of body protein occurs from hemorrhage, burns, surgery, infections, or other causes. Contrary to popular belief, except for the small amount of protein needed for developing muscles during conditioning, people engaged in sports and other strenuous physical activities do not need increased protein, provided their diets supply enough calories from carbohydrates and fats to meet their energy needs.

Proteins are needed for building the thousands of enzymes which control the speed of chemical reactions in the body, and for making hormones such as insulin and thyroxine, which regulate metabo-



lism (metabolism is a term for the chemical processes occurring in the body). Proteins also are needed for forming antibodies which combine with foreign proteins that enter the body, producing an immunity response that helps ward off harmful infections. They also help regulate the water balance and the acid-base balance in the body.

Proteins, like carbohydrates and fats, can be burned to supply energy, and when the diet does not supply enough calories from the other two nutrients, proteins are used for energy, even at the expense of building body protein. Some protein is needed regularly in the diet because the body has little protein reserve, but if more protein is eaten than is required for the nitrogen needs of the body, the extra protein is used for calories or is converted to body fat. Thus, one can become "fat" from eating excess calories in the form of protein just as much as from too many calories from carbohydrates or fats.

Americans enjoy eating meat and, as incomes have risen since World War II, have increased their consumption of meat and poultry. Most of us today eat more protein than our bodies need. This excess protein consumption is economically wasteful because foods that provide primarily carbohydrates and fats are cheaper sources of calories. It is also biologically wasteful because only part of the protein molecule can be used for energy; the amino groups cannot be used for energy and must be split off and excreted by the kidneys.

### **The Quality of Protein**

To be used in the body, protein in food must be broken down by digestion to amino acids and absorbed into the blood. The body uses the "pool" of amino acids available from foods and metabolism to build the body proteins it needs. The efficient building of body tissues requires a well-balanced mixture of amino acids. Some

amino acids (nonessential) can be made by the human body, but several must be provided preformed from foods, and, therefore, are known as the "essential" amino acids.

The essential amino acids are required in different amounts by the human body. Food proteins providing all of the essential amino acids in the proportions needed by humans are called "complete" or high quality. A protein low in an essential amino acid is said to have a "limiting" amino acid because it limits growth. If the proportions of essential amino acids are too unbalanced, the protein will not support either growth or maintenance. When combined, two proteins, each of which has a different limiting amino acid, may complement one another and provide total protein of high biological value.

Because animal body composition is similar to that of humans, animal products contain more nearly the balance of amino acids required by humans than do plant foods. Meat, fish, poultry, milk, cheese, and eggs are all sources of high quality protein. Vegetable proteins are usually low in one or more of the essential amino acids. Plants also have less protein in their tissues than do animals. Legumes (peas and beans) contain larger amounts and better quality protein than other plant sources.

Combinations of proteins from different vegetable sources (in a meal or in a food product) may complement one another and provide improved total protein quality. Legumes combined with many cereals are nutritious; for example, beans and rice combinations, popular with some ethnic populations, provide both a good quality and quantity of protein. Vegetable sources supplemented with some high quality protein, such as breakfast cereal with milk, or macaroni with cheese, also are nutritious combinations. By adding the essential amino acid which is low in a par-

ticular protein, such as methionine to soy protein, it is possible to prepare meat substitutes equal to animal products in terms of protein quality.

Vegetarians who elect to obtain their diets only from plant sources need to select from a wide variety of plants to ensure that they are getting the amount and quality of protein they need. They also need to take vitamin B<sub>12</sub> as a dietary supplement, because plant foods contain only traces of this vitamin. The inclusion of even small amounts of milk, cheese, and eggs make it simpler to select a diet that is adequate in both quantity and quality of protein.

### **Nutrition Labeling of Protein**

On nutrition labels, the grams of protein in a serving or portion of food are stated in the upper section of the nutrition information panel, and the percentage of the U.S. Recommended Daily Allowance (U.S. RDA) of protein is given in the lower section. The U.S. RDA for protein is based on the protein quality of foods. In effect, food products which contain total protein that is of high biological quality can claim a higher percentage of the U.S. RDA on labels than foods which contain total protein of lower quality. The part of the regulation is intended to protect the consumer from deceptive labeling claims on products which contain large amounts of low quality protein.

Differences in protein quality in foods are typified by comparison of products such as beef and vegetable stew and canned kidney beans. A 1-cup serving of either would contain about the same amount of protein, but the stew would contribute a higher percentage toward the U.S. RDA for protein because beef contains high quality protein. However, the beans are a good and fairly inexpensive source of protein, and when combined with a small amount of cheese, egg, or other animal pro-

tein will provide protein equal in quality to the stew.

### ***What Are Carbohydrates?***

All carbohydrates are made of the chemical elements carbon, hydrogen, and oxygen, and the hydrogen and oxygen are always in the same proportion as in water— $H_2O$ . The name itself indicates the combination: carbo (carbon) hydrate (water).

The carbohydrates which provide nourishment in our foods are the various starches and sugars. The simple sugars — glucose, fructose, galactose — are the foundation of most common carbohydrates. The disaccharides or double sugars—sucrose, maltose, lactose—contain two simple sugars. Complex carbohydrates (polysaccharides) such as starch, are formed by the union of many simple sugars. All carbohydrates must be broken down by digestion into simple sugars before the body can use them. Some complex carbohydrates, for example cellulose, cannot be digested by man but supply roughage needed for proper elimination of solid wastes from the body.

In a very real sense, all animals rely on plants for life. Plants which contain chlorophyll (a green pigment) use the energy from the sun to make carbohydrates from the carbon dioxide in the air and the water in the ground. To survive, humans and other animals eat plants or other animals which subsist on plants.

The major function of carbohydrates in the diet is to provide energy for the work of the body. They also allow the body to manufacture some of the B-complex vitamins and form part of the structure of many biological compounds. In addition, carbohydrates add flavor to our food.

Carbohydrates are economical to produce in abundance—a characteristic that helps a majority of the people in the world to survive. In the United States and Canada, carbohydrates provide 40 to 50 percent



of the total food energy; the entire population of the world obtains about 70 percent of its energy from carbohydrates. The cereal grains (such as wheat, rice, corn, and oats), potatoes, many fruits and vegetables, peas, beans, taro, cassava (tapioca), and sugar cane and sugar beets are major world carbohydrate sources. Many processed foods are rich in carbohydrates, including breads and other baked goods, jams and jellies, molasses, noodles, spaghetti, and dried fruits.

On nutrition labels, the grams of digestible carbohydrates per serving are listed. This includes several types of carbohydrates, the best known of which are starch, glucose, sucrose, and lactose. Starch is the most important carbohydrate food source. Because it is the form in which plants store energy for future use (including nourishment of embryo plants), the seeds of plants such as the cereal grains, legumes, and the roots or tubers such as potatoes, are the richest sources of starch. Cereals contain principally starch, but important vitamins and minerals are present in the outer layer and germ of the grain or kernel. Refinement, as in milling white flour, removes much of the outer layer and the germ. Enrichment of white bread and flour restores three of the B vitamins that are lost in processing and adds iron.

Starchy foods are not very flavorful if eaten raw. Cooking swells the starch granules, breaks them open, makes them taste better, and allows them to be more easily digested. In some vegetables, such as immature corn and peas, a sweet taste is present. This disappears as the plant ripens and the sugar content changes to starch, which has little flavor. In some fruit like bananas, the unripened fruit contains starch which changes to sugar on ripening.

Through digestion, the body changes the starch in foods to glucose, which can be used as a source







of energy by all of the tissues in the body. If the body receives more glucose than it can use as energy, small amounts can be stored as glycogen (sometimes called animal starch) in the liver and muscle tissues, but carbohydrates consumed in excess of the energy needs of the body are rapidly converted to fat. Hence, one can become overweight by consuming excess calories in the form of carbohydrates; however, since this is true of all excess calories, one should not think of carbohydrates as any more fattening than protein or fat.

Sucrose (common table sugar) is mostly produced from sugar cane and sugar beets; the sugars from the two sources are identical chemically. Refined sugar is an unusual food in that it is pure carbohydrate; therefore, it is a source of calories only, that is, it contains no vitamins, minerals, protein, or fat. Almost all other food sources contain some combination of essential nutrients.

The U.S. per capita consumption of sugar at present is over 100 pounds a year, a substantial increase over the consumption prior to this century. The increase is related to our increased consumption of soft drinks, cakes and other bakery products, candies, syrup, jams and jellies, and other sweet manufactured products which have a high sugar content. Many of these foods contribute calories without providing much in the way of other nutrients. These calorie-rich foods should not be consumed at the expense of foods which provide essential vitamins, minerals, and protein, and it should be remembered that an excess of calories from any source leads to overweight.

Lactose, or milk sugar, is produced by mammals where it serves as an energy source for the young. The enzyme lactase must be present to digest lactose. Some people are deficient or lacking in this enzyme after early childhood and may find it difficult or be unable to digest milk

or milk products containing lactose. For most people, however, milk continues to be a good food throughout life, providing a good source of high quality protein, calcium, riboflavin, and vitamin A.

### **What Are Fats?**

People have differing reactions to the word "fat." Many think of fat in terms of being overweight. A nutritionist would be more likely to think about what leads to being "fat," about the fat content of foods, and the basic composition of fats.

Many qualifying terms are associated with fats—such as the nouns lipid and glyceride and the adjectives saturated, unsaturated, and polyunsaturated.

Fats are composed essentially of fatty acids and glycerol. Each fatty acid is made up of carbon atoms joined like links on a chain. The carbon chains vary in length, with most edible fats containing four to 20 carbons.

Each carbon atom has hydrogen atoms attached as the charms might be on a bracelet. When each carbon atom in the chain has attached to it as many hydrogen atoms as it can hold (two), it is called a saturated fatty acid; when a hydrogen atom is missing from two neighboring carbons, a double bond forms between the carbon atoms and the fatty acid is called unsaturated. A fatty acid which contains more than one such double bond in the chain is called polyunsaturated. The polyunsaturated fatty acid called linoleic acid is of particular nutritional importance because the body cannot manufacture it; hence, it is an "essential" fatty acid, because it must be supplied in the food one eats.

Unsaturated fatty acids and fatty acids composed of shorter chains have lower melting points and are liquids (oils) at room temperature. All food fats, animal or vegetable, contain a mixture of saturated and

unsaturated fatty acids, but generally, animal fats are more saturated than the liquid vegetable oils.

Although a rough division can be made in the degree of saturation between fats of animal and vegetable origin, there is variation in saturation within each group, based on the sources. Coconut oil is highly saturated but is liquid because it has short carbon chains. Chocolate also has a higher percentage of saturated fatty acids than most other vegetable oils, and beef has a higher percentage of saturated fatty acids than chicken and fish. Safflower, corn, cottonseed, peanut, and soybean oils are especially rich in linoleic acid, and the labels on products made from these oils often state "high in polyunsaturates," or "high in polyunsaturated fatty acids." When oils have hydrogen added (hydrogenation), they become more solid. Margarine is an example of a food in which vegetable oils are hydrogenated to the consistency of a fat. In the process, the vegetable oil necessarily becomes less unsaturated.

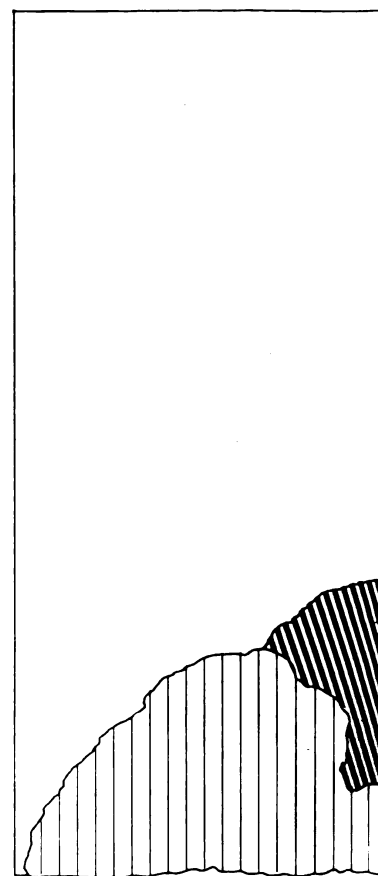
### **Functions of Fat**

The fats in our foods serve a variety of functions. Some fat is essential in the diet to provide linoleic acid, which is necessary for proper growth and a healthy skin. However, only a small amount of linoleic acid is required to meet this need—about 1 to 2 percent of the total calories. Fats also carry fat-soluble vitamins into the body and aid in their absorption. In addition, fats serve as a concentrated source of energy and, because they slow digestion and the emptying of the stomach, delay the onset of hunger. Fats also contribute to our enjoyment of foods because they add flavor and improve the texture.

Fats are called a concentrated source of energy because they have an energy value more than twice that of carbohydrates or proteins; that is, 1 gram of fat provides 9 calories, while 1 gram of protein

or carbohydrate provides only calories. This means that food rich in fats add much to the caloric content of the diet, and all calories in excess of body needs lead to fat deposits in the body. Fat deposits may be good or bad; some fat in the tissues helps to cushion body organs and also helps to prevent heat loss through the body's surface. Too much fat deposited, of course, leads to being overweight. By some estimates, as much as half of the U.S. population is overweight to some degree, and many nutritionists agree that this is the greatest nutritional problem in our country.

A reduction in fat-rich foods is a sensible way to limit calories in the diet for reducing or controlling weight. In judging the amount



it in one's diet, it is very easy to underestimate the total. Most people think about only the visible fats—butter, margarine, lard, cooking and salad oils. But much of the fat in the diet comes from less visible sources—the small fat particles and streaks in meat from well-fed animals; the varied amounts in nuts, meats, and poultry; the fat added in some cooking of foods; and the fat contained in many processed foods.

The following table gives the fat content of several representative types of foods:

Percent Fat	Food
90-100	Salad and cooking oils and fats, lard
80-90	Butter, margarine

70-80 Mayonnaise, pecans, macadamia nuts

50-70 Walnuts, dried unsweetened coconut meat, almonds, bacon, baking chocolate

30-50 Broiled choice T-bone and porterhouse steaks, spareribs, broiled pork chop, goose, cheddar and cream cheeses, potato chips, french dressing, chocolate candy

20-30 Choice beef pot roast, broiled choice lamb chop, frankfurters, ground beef, chocolate chip cookies

10-20 Broiled choice round steak, broiled veal chop,

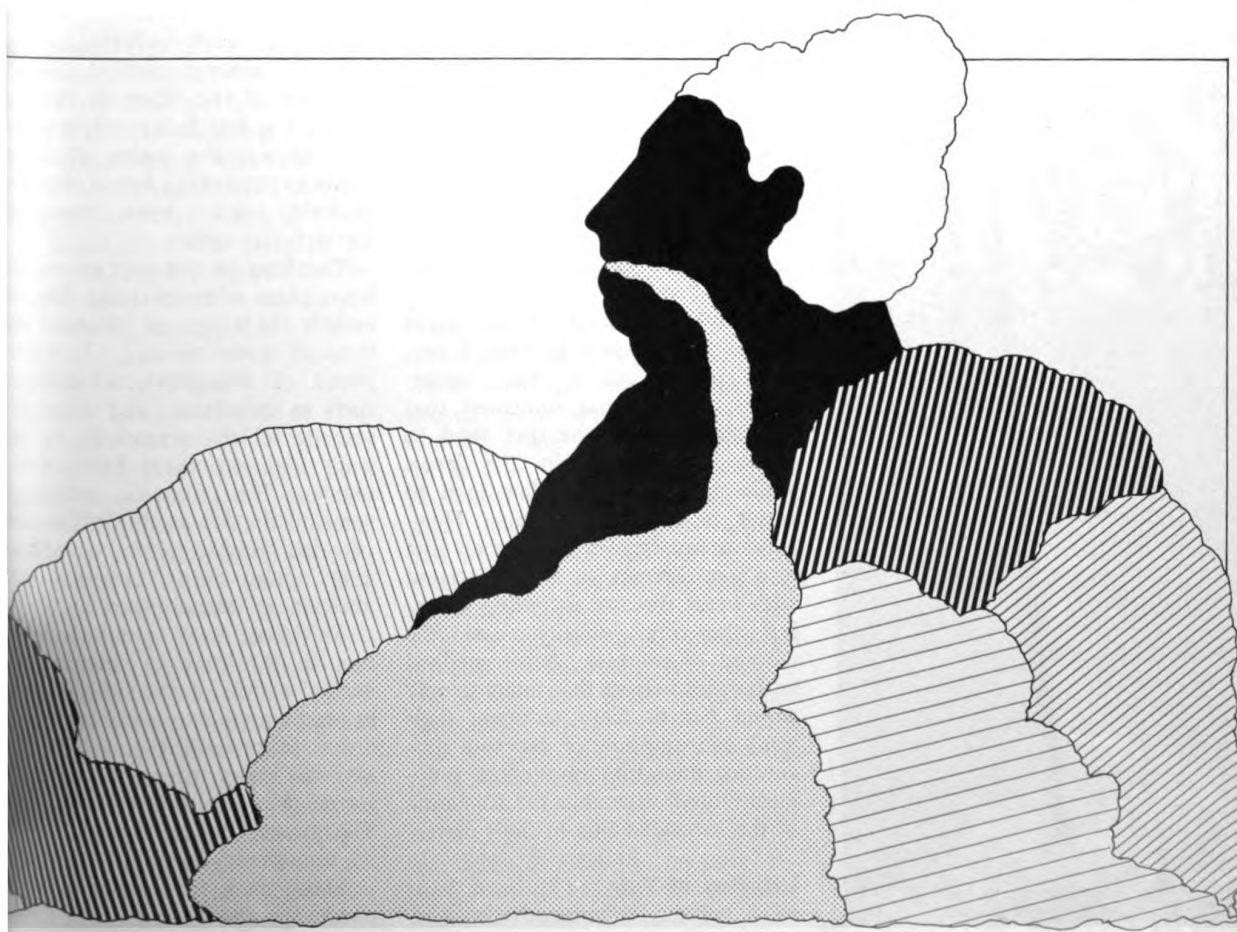
roast turkey, eggs, avocado, olives, chocolate cake with icing, french-fried potatoes, ice cream, apple pie

1-10 Pork and beans, broiled cod, halibut, haddock, and many other fish, broiled chicken, crabmeat, cottage cheese, beef liver, milk, creamed soups, sherbet, most breakfast cereals

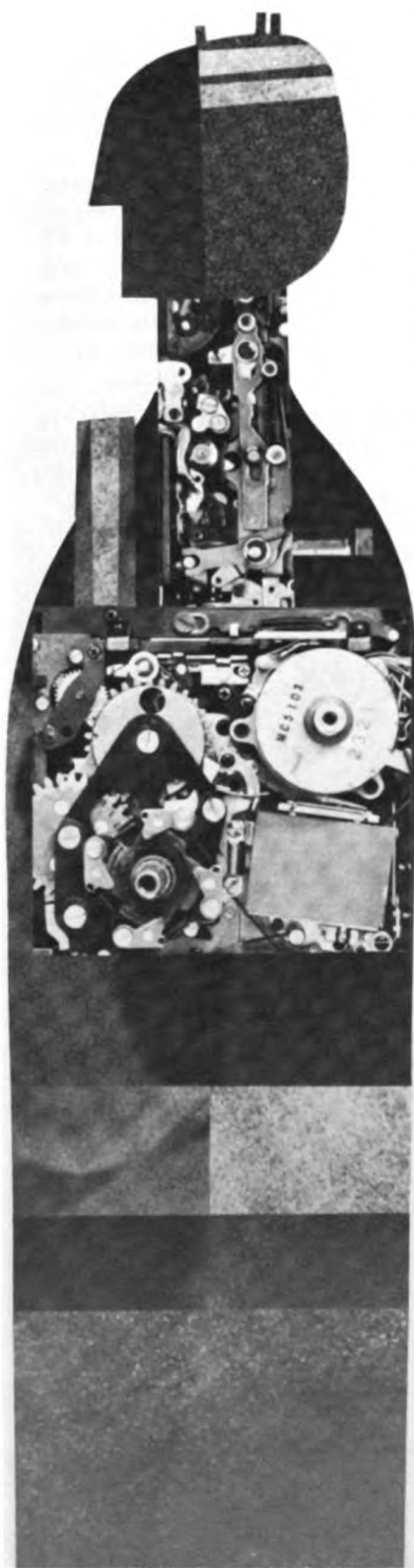
Less than 1 Baked potato, most vegetables and fruits, egg whites, chicken, consommé

#### Consumption of Fats

The amount of fat in the human diet varies greatly in different parts







of the world. In some densely populated or underdeveloped areas, where the land must be used to produce the less expensive high carbohydrate foods such as grains, fat provides as little as 10 percent of the calories. In wealthier societies, where more animal products are consumed, fat may provide almost half of the calories. Fat provides about 42 percent of the calories in the U.S. diet at the present time, an increase of about 10 percent over earlier this century. Many physicians and nutritionists believe that a lower fat intake would be desirable.

In recent years, consumers have read or heard much discussion about the amount of fat they eat (is it too much?), and about the kind of fat they eat (saturated vs unsaturated or polyunsaturated). Most of the controversy involves the relationship of dietary fats and cholesterol to atherosclerosis, a coronary heart disease in which cholesterol and other fatty substances are deposited on the inner walls of arteries. (Cholesterol is a fat-soluble substance which is contained in foods of animal origin. It is also manufactured by nearly all body tissues.)

A high level of blood cholesterol has been identified as one of several risk factors in this disease. Some evidence has indicated that saturated fats in the diet tend to cause an increase in the levels while polyunsaturated fats tend to result in decreased levels. However, many factors other than diet also are known to be associated with heart disease, including smoking, heredity, obesity, and the amount of exercise. Some medical authorities believe that many people would benefit from reducing their total consumption of fat and substituting moderate amounts of polyunsaturated vegetable fat for some of the saturated fats in their diets.

#### **Labeling of Fats**

FDA neither recommends any par-

ticular diet nor takes any part in the dietary fat/coronary heart disease controversy. However, in recognition of some physicians' instructions to their patients regarding fat modification of their diets and consumer interest in the matter, the Agency does permit manufacturers to show the percent of calories from fat, the grams of polyunsaturated and saturated fatty acids, and the cholesterol content of foods in nutrition labeling information. Included must be the statement: "Information on fat and/or cholesterol content is provided for individuals who, on advice of a physician, are modifying their total dietary intake of fat and/or cholesterol."

#### **What Is Dietary Fiber?**

The nutritional qualities of foods are usually described in terms of the protein, carbohydrate, fat, vitamin, and mineral content. The importance of the fiber or roughage in foods is less frequently mentioned, although the value of certain foods in promoting bowel regularity probably has been recognized through the ages.

The fiber in our diet comes only from plant sources (and does not include the tough or "fibrous" portions of some meats). It is composed of complex carbohydrates such as cellulose, and other substances which constitute the cell walls and structural formations of plants. The fibrous sections of some foods, for example, the stems of salad greens, celery, wheat bran and apple skins, contain large amounts of these materials.

This fiber from plants is important in the diet to stimulate the normal action of the intestinal tract in removing waste products. In addition to providing bulk, the fiber absorbs many times its weight in water, thus promoting softer stools. The greater bulk promotes regularity and more frequent elimination.

Many diets for weight reduction encourage the consumption of r

vegetables and fruits. This is often helpful because these foods contain fair amounts of fiber and are generally low in calories. The increased bulk also contributes to satiety through a feeling of fullness.

Recent studies have suggested that dietary fiber may have an additional contribution to our well-being, probably as a result of the greater bulk and more rapid elimination. Some researchers feel that an adequate quantity of dietary fiber may protect against many noninfectious diseases of the large intestine that are prevalent in our society. These conditions include cancer of the colon, hemorrhoids, appendicitis, colitis, and diverticulosis (pouches protruding from the intestinal wall). The incidence of these diseases appears to be lower in less developed societies where the diets contain larger amounts of dietary fiber. Some researchers have also associated increased dietary fiber with reduced blood cholesterol levels, suggesting that a relationship may exist between dietary fiber and freedom from atherosclerosis (fatty deposits on the inner walls of arteries). Based on these research reports, some health authorities believe that an increase in our dietary fiber would be beneficial.

### Consumption of Fiber

Little effort has been made to evaluate the consumption of dietary fiber by Americans because, until recently, there has been little interest in the value of fiber either as roughage or in connection with disease. However, some foods which are major contributors to fiber—whole-grain flour and cereal, potatoes, and fresh fruits and vegetables—have been consumed less in recent years. The consumption of dried beans and peas, which are also good sources of fiber, has also decreased. Increased consumption of meat and poultry, which do not provide fiber, has also been responsible for a lower level of dietary fiber.

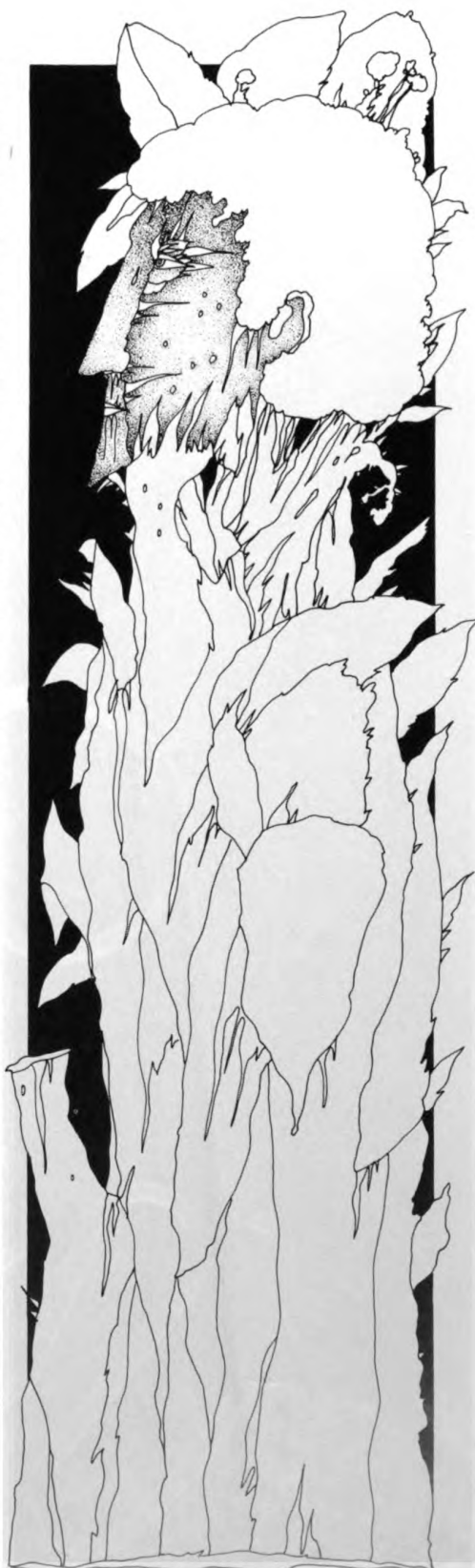
Why can't manufacturers just add fiber to the foods we normally eat? To a certain extent, it could be done; it would be easy to put more fiber in some breakfast cereals, but it wouldn't be acceptable in many other foods. Fiber, to be noticeably beneficial, would have to be in much larger amounts than introduced vitamins, which are added in milligram or microgram quantities. Fiber would have to be added in grams, and this would alter the appearance, taste, chewiness, and mouth-feel of many foods.

At any rate, it is possible to get enough fiber in regular foods by including some foods from a variety of plant sources every day. We need to keep in mind that dietary fiber is made up of many substances, and the composition differs in cereals, vegetables, fruits, and seeds. So a variety of plant foods is needed in our diets. This agrees with the advice often given by nutritionists: "For good nutrition, select your diet from a wide variety of foods."

As a general rule, unrefined foods contain more roughage than refined foods because some fiber is usually removed in processing. For example, breads and breakfast cereals made from whole wheat contain more fiber than products made from wheat that has had the bran removed. Raw apples or other fruits contain some roughage, primarily in the skins, which is not present in processed products. Fruits with seeds, such as strawberries, raspberries, and figs, are high in fiber. Raw and cooked vegetables are excellent sources of fiber.

In the past, we haven't paid much attention to the roughage in our diets, but because of its increasingly recognized importance, the nutrition spotlight is beginning to focus on a newcomer—dietary fiber.

G. Edward Damon, recently retired from FDA, was a consumer writer in the Bureau of Foods.









## Contraception With IUD's

*Intrauterine devices (IUD's) have become a popular method for preventing pregnancy. Like other forms of contraception, IUD's present benefits and risks. Here's what women who are using them or considering using them should know.*

by Margaret Morrison

One of the serious problems confronting many couples today is that of finding a contraceptive method that will prevent pregnancy when it is not wanted, will permit pregnancy at a later date when it is wanted, and will not harm the woman's health in the meantime.

In the past two decades, a number of birth control methods have been developed that have proved superior to previously known ones. For example, The Pill, when taken according to directions, is the most effective means of birth control ever developed.

But no method of contraception is without problems. No method is completely safe or effective. For example, many women suffer adverse effects from The Pill, and have looked for other means to prevent pregnancy. (See "The Pill," FDA CONSUMER, December 1972-January 1973.)

One method now being used by a large number of women—between four and six million in the United States—is the intrauterine (intra-*u*-terine) device, commonly called the IUD. As with The Pill, which refers to various forms of contraceptives taken orally, there is no single item called the IUD. Several IUD's, each a little different in design, have been developed and marketed in the United States by different companies.

The intrauterine device is a small plastic (polyethylene) or metal-containing plastic device that is inserted by a physician through the cervical canal into the uterine cavity. It is kept in place as long as a woman wants to prevent pregnancy. Once it is inserted, there is nothing further the woman must do, except to examine herself about once a month to make sure the device is still in place.

The IUD usually has an appendage (tail or string) which extends through the cervical canal into the vagina. This appendage makes it easy for the patient or physician to verify that the device is in place; it also facilitates removal of the IUD by the physician when called for. Also, most IUD's contain a radiopaque material (usually a barium salt)



*The Saf-T-Coil (left), Dalkon Shield (center), and Lippes Loop account for the overwhelming majority of IUD's now in use in the United States. Although it is not shown, a tail or string is attached to all three of these devices.*

so they can be seen in the body by x ray.

The IUD has several practical advantages over other contraceptive methods. Once inserted, it requires a minimum of attention or supervision—nothing to do “ahead of time,” no schedule of pill-taking to remember, no further decision or concern, except to be sure the device remains in place.

Also, it appears that use of an

IUD has no adverse effect on fertility. When the woman wants to become pregnant, she simply has the IUD removed by her physician.

Women who consider using an IUD usually have such questions as: Will it interfere with sexual intercourse? With douching? With the use of vaginal tampons? The answer to these questions generally is “no.”

Many women may ask how long is the IUD left in place, or how long does it continue to be effective in preventing pregnancy? This varies, but in most cases the IUD remains in place and “works” until it is removed.

IUD's are considered to be approximately 95 percent effective in preventing pregnancy, ranking

just below The Pill, which has an effectiveness rate close to 98 percent.

But how safe are the IUD's? In the past year, serious complaints have been reported among a small percentage of users of IUD's, and the whole subject of IUD safety has come under scrutiny. Present figures show that between one and 10 deaths per million users per year are IUD-related. With oral contraceptives, the rate is 22 to 45 deaths per million users per year. While there is a lower death rate among users of IUD's, the incidence of problems that require hospitalization appears to be about the same for the IUD and The Pill—from .3 to 1.0 per 100 women users per year.

Besides safety and effectiveness

There are other questions most women want answered—and special instructions they should be given—before they decide to use an IUD.

First, insertion of an IUD is a relatively simple procedure performed in the physician's office or clinic, but it must be done by a trained professional.

Before the decision is made to use an IUD, the patient should call to the doctor's attention any special problems she may have, such as heavy menstrual periods, recent pelvic infection, a "tipped" uterus, an allergy to copper (in which case, a copper IUD would be ruled out), or congenital or rheumatic heart disease.

The physician should be sure the patient has been fully informed about the IUD and has given her consent to have it inserted. The patient should understand that there may be some discomfort or pain at the time of insertion, but usually the procedure does not require any form of sedation or medication for pain.

While the incidence of injury during the insertion procedure is not great, some risk does exist. It is a remote possibility that the walls of the cervical canal or uterus will be perforated during insertion, in which case the patient may require hospitalization so the IUD can be removed surgically. This is why it is important that the device be inserted by a knowledgeable specialist.

Patients should be informed when

they are fitted with an IUD that spontaneous (or accidental) expulsion can occur, especially during the menstrual period. This is more likely to occur within the first few months after insertion. Since this can happen without the patient's being aware of it, she should check regularly to make sure the device is still in place. Obviously, if expulsion occurs, the woman is without protection and should use some other method of contraception until she can have a new IUD inserted.

Many women may have questions about the long-term effects of using an IUD, and may ask—since cancer of the cervix is one of the most common occurrences of cancer in women—whether there is any correlation between cervical cancer and IUD use. So far, there is no known correlation. The long-range effects of IUD use, however, are not yet known.

Bleeding between the menstrual periods, usually in the form of spotting, may occur during the first few weeks after insertion. Also, the first few menstrual periods may be heavier and longer. None of these problems is considered cause for alarm. However, the patient should be cautioned that if her period is late, or she thinks she may be pregnant, she should consult her doctor immediately.

The most serious problem associated with IUD's occurs in the women who become pregnant



*Copper-containing IUD's, such as the CU-7, are classified as drugs because their use involves the extraction of copper into the body.*

while using the device. Cases of septicemia, or blood poisoning, have been reported in the fourth, fifth, or sixth month of pregnancy, and have led to spontaneous abortion and even death of the patient. It is because of these serious complications that women using IUD's are urged to see their doctors if pregnancy is suspected. If pregnancy is confirmed, removal of the IUD is advised.

In the past year, reported deaths and spontaneous abortions associated with one particular IUD,

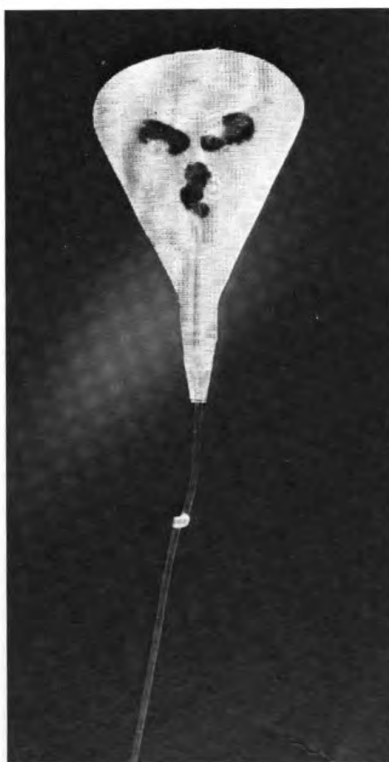


*The Techna (left), an IUD that is filled with a saline solution after it is inserted, and the Ypsilon, a rubber-coated stainless steel IUD, are now being tested.*

the Dalkon Shield, led to an intensive review by FDA. Sales of the Dalkon Shield were voluntarily suspended by the manufacturer in June 1974, and FDA began a study of all available data—a study which is still in progress. Until the study is complete, the Dalkon Shield, with a revised design, will be available only under strict controls that require registration of patients and detailed recordkeeping on each one. (See accompanying story.) The controls will be similar to those imposed on investigational drugs.

Meanwhile, FDA is preparing detailed guidelines for physicians on the management of patients using IUD's, and essential information for patients, including effectiveness data and precautions to be followed.

Whenever a health problem occurs with any product, consumers are apt to ask why FDA allowed the product to be put on the market in the first place. FDA has no authority to require manufacturers to submit data on the safety of medical devices before marketing, as it does with drugs. In the case of medical devices, FDA can take action only



after a product has been marketed and found to be defective or hazardous. Most IUD's are regulated as medical devices.

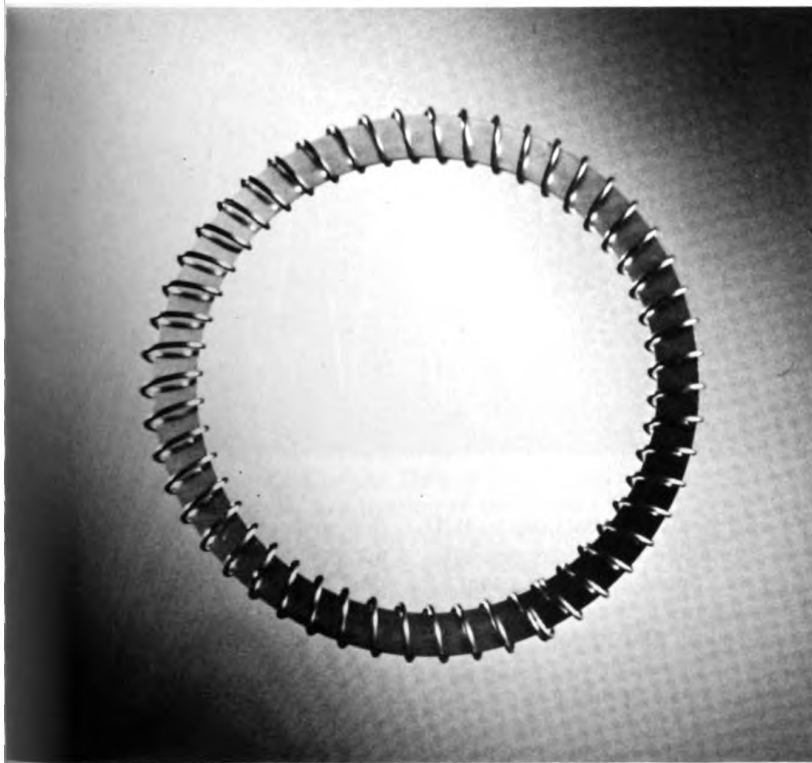
However, there are exceptions. If an IUD contains heavy metals and the use of the product involves the extraction of some of those metals into the body, then the product is considered a drug, and the manufacturer—before marketing the product—must provide FDA with sufficient data to



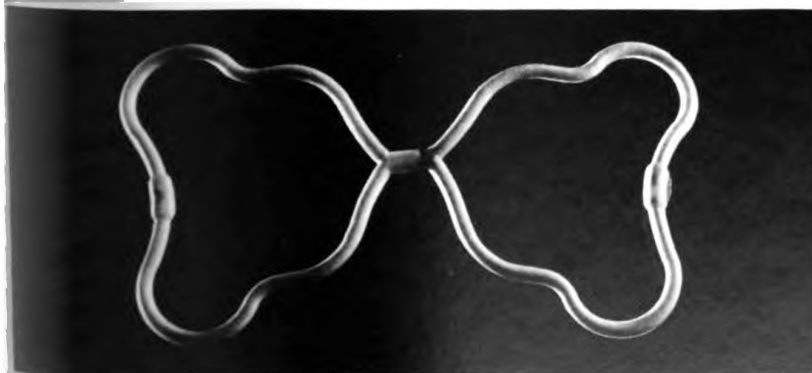
substantiate claims that the product is safe and effective for the uses stated on the labeling.

Several IUD's have been submitted for such approval before marketing because they contain copper. So far, only one IUD containing copper has been approved as a drug product. These IUD's are designed with a thin copper wire wrapped around the major part of the stem. It is not yet known just how the use of





*Because of the possibility of intestinal obstruction, the FDA Advisory Committee on Obstetrics and Gynecology in 1968 recommended discontinuance of "closed" IUD's. Examples of IUD's incorporating a closed design are the circular metal Inhiband, the Butterfly, and the Birenberg Bow, none of which are now on the market in the United States.*





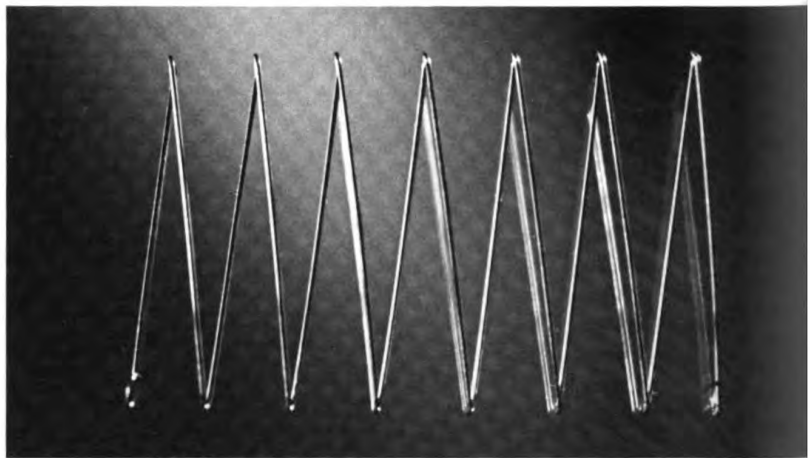
*Evidence of complications among users of the Majzlin Spring IUD caused the FDA to have it withdrawn from the market in 1973.*

copper adds to the contraceptive effect, but it is thought that the copper in some way alters the uterine secretions, making them hostile to sperm.

Since, theoretically, the effectiveness of these IUD's depends on the continued release of copper into the uterine cavity, there has been some question as to how long they can be relied upon to prevent pregnancy. The longest record of use so far is about two and a half years. The manufacturer of the approved copper device recommends replacement at the end of 2 years.

Experimentation and research with new types of IUD's continues, as medicine and industry look for safer and more effective means of birth control. Under study now are several types of IUD's, including medicated IUD's which are designed to release progesterone that can be absorbed by the body. It appears that use of this hormone in conjunction with the IUD increases the effectiveness of the device.

As more scientific evidence becomes available, it will be possible to determine more precisely the safety and effectiveness of IUD's. FDA will continue to study



reports of adverse reactions to IUD use and take action where needed. And, of course, new IUD's that are classified as drugs will be approved by FDA before they are put on the market.

Meanwhile, women who are seeking a birth control method should discuss the subject with their physicians and become informed about the benefits and risks of various methods in relation to their own particular needs. Women already using an IUD should keep in mind these precautions:

- If your menstrual period is late, or you think you may be pregnant, you should be checked by your doctor.
- If you prove to be pregnant, the IUD should be removed, if this can be done easily. Removal of the IUD early in pregnancy

prevents serious complications from occurring and reduces the possibility of miscarriage.

- You should know that if the IUD is not removed, there is an increased risk of infected abortion occurring when the pregnancy is allowed to continue. You and your doctor should discuss whether it best to terminate or to continue the pregnancy.

- If a pregnancy is allowed to continue, whether the IUD is removed or not, you should be followed very closely by your doctor for signs of complication.

- Pregnant or not, if you have any questions about your IUD, talk to your doctor.

Margaret Morrison is a member of the FDA publications staff.

# The Dalkon Shield

**I**n the past year, one intrauterine device, the Dalkon Shield, has focused the attention of the medical community, consumers, and Government agencies on the entire question of IUD's and their safety. It is estimated that the Dalkon Shield may have been worn by as many as two million women in the United States.

In May 1974, the A. H. Robins Company, manufacturers of the Dalkon Shield, sent a letter to 120,000 physicians concerning the Dalkon Shield and septic abortions. This kind of abortion is caused by the entrance of bacteria into the uterus. The letter reported 36 known cases of septic abortion, including four deaths, among women using the Dalkon Shield. All of these had occurred in the mid-trimester (fourth, fifth, and sixth months) of pregnancy. (The figures since have risen to 13 deaths among 219 septic abortions involving users of the Dalkon Shield.)

In the letter, the Robins Company asked that doctors follow certain precautions with patients using the Dalkon Shield. It advised: every patient who misses a menstrual period should have a pregnancy test; as soon as pregnancy is confirmed the device should be removed; if the device cannot readily be removed, serious consideration should be given to therapeutic abortion; patients should be advised, before insertion of the device, that abortion may be recommended in the event of accidental pregnancy.

In June 1974, at FDA's request, the Robins Company suspended sales of the Dalkon Shield, and FDA began an intensive investigation of the safety and effectiveness of all IUD's. An Advisory Committee on Obstetrics and Gynecology was established to review all available data and to recommend appropriate action.

The Advisory Committee's findings were reported in October 1974, and its major conclusions and recommendations were: IUD's are a relatively safe and reliable means of contraception, comparing favorably with the most-used method, oral contraceptives; questions that have been raised about the safety of the Dalkon Shield cannot be answered by the information presently available, and reports of serious problems now accumulating indicate the need to investigate the possible hazards of all IUD's; the moratorium on commercial distribution of the Dalkon Shield should remain in effect pending accumulation of definitive data.

In an action directed toward the accumulation of the kind of data the Committee requested, FDA announced in December 1974 that the Dalkon Shield would be available under a tightly controlled distribution and reporting system similar to that used

for investigational study of new drugs. In conjunction with this decision, the Robins Company decided to modify the design of the Dalkon Shield, changing from a multifilament to a single filament string or tail. Data reviewed by the Advisory Committee indicated that bacteria could accumulate on the many-filament tail and move along it to the uterus. To prevent further distribution of the multifilament devices, the Robins Company retrieved the existing stock from doctors, hospitals, clinics, and suppliers.

Under the controlled distribution system, the new single filament Dalkon Shields—expected to be available later this year—will be distributed only to physicians who have been screened and selected as proper participants and who agree both to register new patients with the company when the device is inserted and to keep detailed records of all registered patients as long as they wear the device. Women who are given the new Dalkon Shield will be fully informed about the purposes of the study and the risks involved. Voluntary consent will be obtained from each woman before a Dalkon Shield is inserted, and each participant in the study will be instructed to inform her physician of any problems or possible pregnancy as soon as possible. Patients will be asked to notify the company of any change in physicians or city of residence. The registry will record such information as expulsion and pregnancy rates, the number and kinds of adverse reactions compared to the number of devices in use, and any other problems encountered.

FDA also has requested two other major manufacturers of IUD's, Ortho Pharmaceutical Corporation (maker of the Lippes Loop) and Julius Schmid Laboratories (maker of the Saf-T-Coil), to consider registry programs for tracing patient experience with their products. These two devices, together with the Dalkon Shield, make up about 91 percent of the IUD market.

In a further effort to find the answers to questions about IUD's and pregnancy, spontaneous abortion and uterine infection, a joint study by FDA and the National Institutes of Child Health and Human Development has begun.

In the meantime, women presently wearing the Dalkon Shield or any other IUD without problems are advised to continue their use, under normal supervision of their physicians. The Advisory Committee on Obstetrics and Gynecology did not recommend removing Dalkon Shields from women now wearing them because there is some risk involved in removing any IUD and because most serious complications are pregnancy-related. Women currently using the Dalkon Shield will not be asked to participate in the registry program. They should, however, follow the precautions recommended for users of any IUD. These precautions are listed at the end of the accompanying article on IUD's.

# Time To Bone Up On Nutrition Labeling

**S**taying the effective date for nutrition labeling is not like postponing Christmas or delaying a pay raise because the program's benefits to the consumer have already been flowing and will continue to be evident in the marketplace.

FDA's nutrition labeling regulations, 5 years in the making, have been published as final orders in the *Federal Register*. The effective date, or the time when compliance would be mandatory, was December 31, 1974. But on November 14, 1974, Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, ordered postponement of the required compliance to June 30, 1975. In announcing the extension, Dr. Schmidt explained that a significant number of companies were having difficulty meeting the deadlines, and if required to do so, would have to destroy food, an action that would result in increased food costs to the consumer.

The reasons for the postponement were described later in more detail by Dr. Howard R. Roberts, acting director of FDA's Bureau of Foods.

"Genuine industry problems revolving around scarcity of ingredients, delays in obtaining equipment and decreased sales resulted in unusual label inventories. In addition, the label changes required by the omnibus food labeling regulations have somewhat overwhelmed label and package suppliers.

"Initially, we felt that we could deal with these problems on a case-by-case basis. However, it soon became apparent that problems were

sufficiently widespread to warrant a blanket extension. If we had not provided this extension in the effective date, thousands of dollars would have been lost because of the need to replace deviating labels and more thousands [of dollars] worth of foodstuffs would have had to be withheld from commerce to be destroyed or at least relabeled, costs which the consumer would ultimately have to bear."

The consumer benefits of nutrition labeling began before the regulations were first proposed by FDA for public comment.

Before the White House Conference on Food and Nutrition made its recommendations on nutrition labeling in 1969, the average food shopper paid little attention to the nutrition value of the food being purchased. The principal considerations then, and even now for many, were how food appealed to the palate and the eye. Most people were attracted to foods they liked to eat and which were cosmetically attractive. That is why processors put heavy emphasis on taste and appearance.

Once the concept of nutrition was emphasized, shoppers gradually began to make this another consideration of their shopping decisions.

The problem then, and even now, was how to recognize nutritionally beneficial food. There was no organized way of making nutrition comparisons between the various food products confronting the shopper in the supermarket. Now, with the rules finalized, there is a system, but it must be learned. That

is why FDA and the food industry have launched a massive educational program.

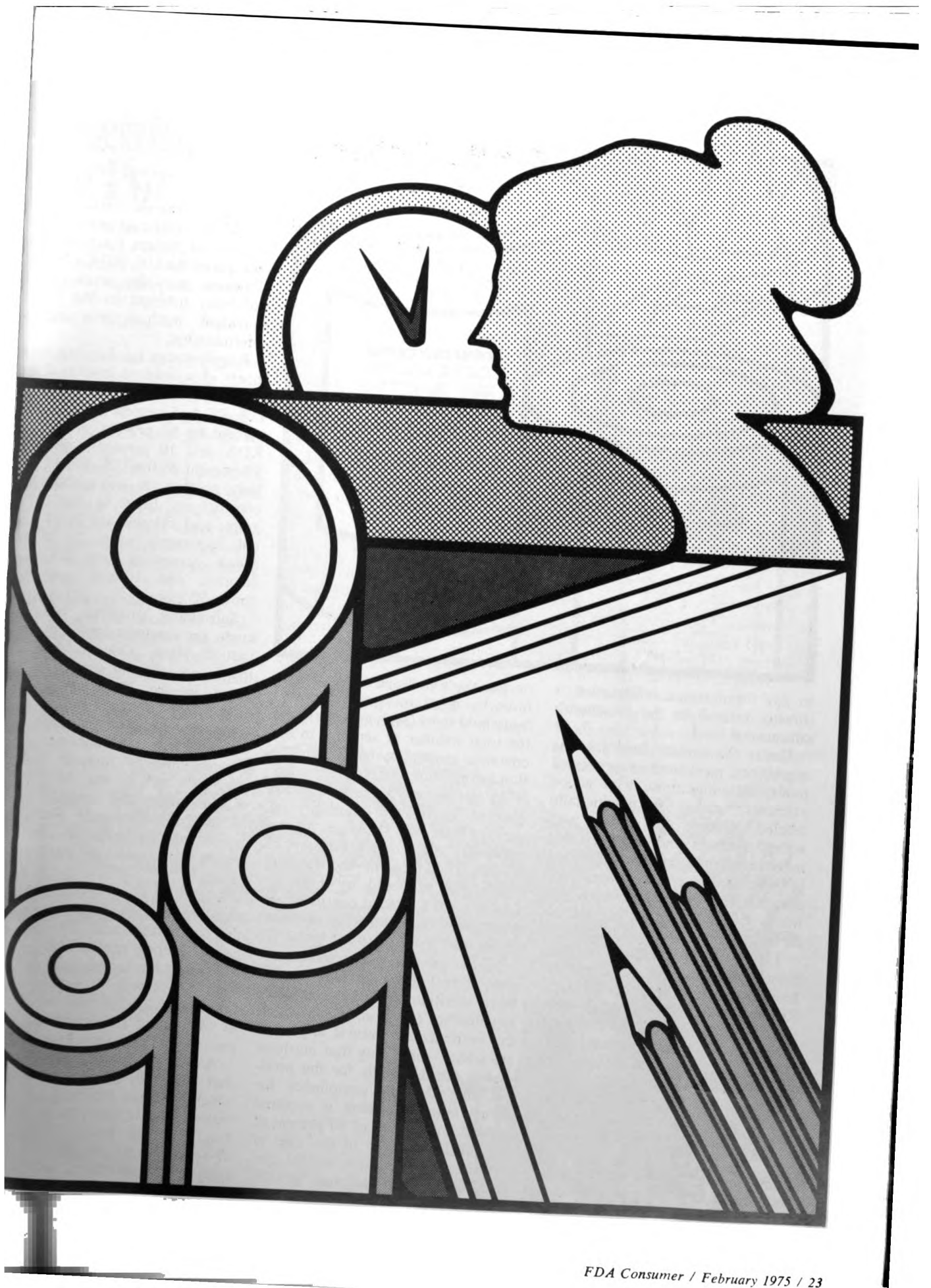
"We found that our current program for relabeling foods with nutritional information has necessarily meant a reeducation of essentially everyone involved with food marketing, and must eventually involve education of the entire public," Commissioner Schmidt said. "Otherwise the full potential of the program will not be realized. We are trying to take on this massive effort step by step. We will be several years at the task."

The basic premise of nutrition labeling is that consumers have a right to information about the minimum levels of protein, vitamins and minerals, and the maximum levels of calories, fats, and carbohydrates in foods. The FDA should not dictate how this information is used, but the consumer has a right to it.

As a minimum, it can be assumed that nutrition labeling will increase consumer awareness and knowledge of nutrition. With the availability of nutrition information and increased nutrition awareness, consumers should be able to do a better job of selecting, comparing, and substituting foods.

How do consumers feel about nutrition labeling? A recent FDA survey of typical consumers showed considerable interest, with 75 percent of those responding indicating a willingness to pay at least a nominal amount for nutrition information. As might be expected, however, the interest in and willingness







to pay for nutrition information is directly related to the consumer's educational level.

Under the present food labeling regulations, most common processed foods, including those with added nutrients, can be nutritionally labeled. Except for foods with added nutrients and those making nutrition claims, nutrition labeling is voluntary. In either voluntary or mandatory situations, however, nutrition information must be presented in a standardized label format.

The labeling format requires presentation of vitamin and mineral levels as percentages of the U.S. Recommended Daily Allowances (U.S. RDA's). U.S. RDA's replace the previously used Minimum Daily Requirements (MDR's) and are established by FDA based on the Recommended Dietary Allowances published by the National Academy of Sciences-National Research Council.

So that consumers may compare food products, nutrition information must be presented on a per serving

or per portion basis. Serving sizes must be listed in commonly used household units (such as a cup), and the total number of servings in the container must appear on the nutrition information panel of the label.

At the outset, there was much concern about the feasibility of nutrition labeling because of the variability in the nutrient content of foods. Therefore, in the labeling regulations proposed by FDA in January 1973, special consideration was given to variability of both added and indigenous nutrients.

In the case of indigenous nutrients, several allowances were made. First, nutrition labeling is completely voluntary for a product in which the nutrients are natural and none are added—providing that nutrition claims are not made for the product. In addition, compliance for actual nutrient content is required only at a minimum of 80 percent of the label claim (or in the case of calories, carbohydrates, and fat content, only at a maximum of 120 percent of the label claim).

Other allowances for variability applicable to all types of nutrients include basing compliance checks on the average levels of nutrients in a composite sample (rather than on individual units) and the use of an incremental system for listing percentages of the U.S. RDA's. Finally, allowance was also made for the variability inherent in the present analytical methods for nutrient determination.

Requirements for labeling increments of a nutrient involve 2 percent steps up to 10 percent of the U.S. RDA, 5 percent steps from 10 percent to 50 percent of the U.S. RDA, and 10 percent steps above 50 percent of the U.S. RDA. Similarly, protein, fat, and carbohydrate contents are listed to the nearest gram, and calories are listed in 2-unit increments, up to 20 calories, 5-unit increments from 20 to 50 calories, and 10-unit increments above 50 calories.

Substantial progress has been made on nutrition labeling in the past 2 years. One indication of this is an informal survey of food stores in the Washington, D.C. area which revealed 66 different companies and 361 products using the new nutrition labeling. Other accomplishments include industry programs such as the development of a comprehensive labeling manual by the Milk Industries Foundation which will guide more than 500 member companies in nutrition labeling.

Looking at progress from a slightly different point of view—that of compliance with the proposed labeling regulations—an initial survey conducted by three FDA Districts showed compliance with format and labeled nutrient content in 140 out of 150 products, or 93 percent of those sampled.

As for the future, FDA believes that essentially all the products for which nutrition labeling is mandatory will be in compliance by next July. By that time, it's expected also that the availability of voluntarily labeled products will be commonplace.

# Watching The Pot

*How FDA helps State and local agencies assure the safety and wholesomeness of food served to consumers outside of the home.*

by Enoc P. Waters

**T**here are three ways we get the food we need to sustain ourselves.

We can go to a supermarket, purchase the fixin's and prepare it in our kitchen.

If in a hurry, we can purchase it ready to eat from vending machines.

The third way is to go to a restaurant or cafeteria where the food is already prepared. All we have to do is season it to our liking and eat it.

Regardless of the avenue by which we get our food, the Food and Drug Administration has the responsibility to see that the food we consume is safe—that it contains no substances that might be harmful to our health, that it is free of filth and extraneous matter, and finally,

that it is in good condition, not decomposed or otherwise unfit for human consumption.

That is a herculean task considering there are more than 200 million of us in the United States and that we consume an average of 1,420 pounds of food per person a year.

No mathematical genius is required to comprehend that FDA, with only slightly more than 6,000 employees and an annual budget of less than \$200 million, can't possibly check every place in the United States where food is available, whether ready to eat or not.

Keep in mind that in addition to stationary establishments, food is served on ships, trains, planes, and buses.

And don't forget that food is served in hotels, hospitals, nursing homes, churches, on street corners, in industrial plants, schools, jails, and business establishments. It is catered at dances, weddings, cocktail parties, receptions, picnics, sporting events, and even wakes.

In various stages of preparation, it is sold in supermarkets, corner groceries, open markets, from street

stalls, wagons, and pushcarts.

A minimum of 600 million servings of food are consumed by us every day of the year.

Of all the places where food is available regardless of its state of preparation, there is only one where it is not subject to Federal, State, or local rules and regulations intended to assure its safety—the kitchens in our homes.

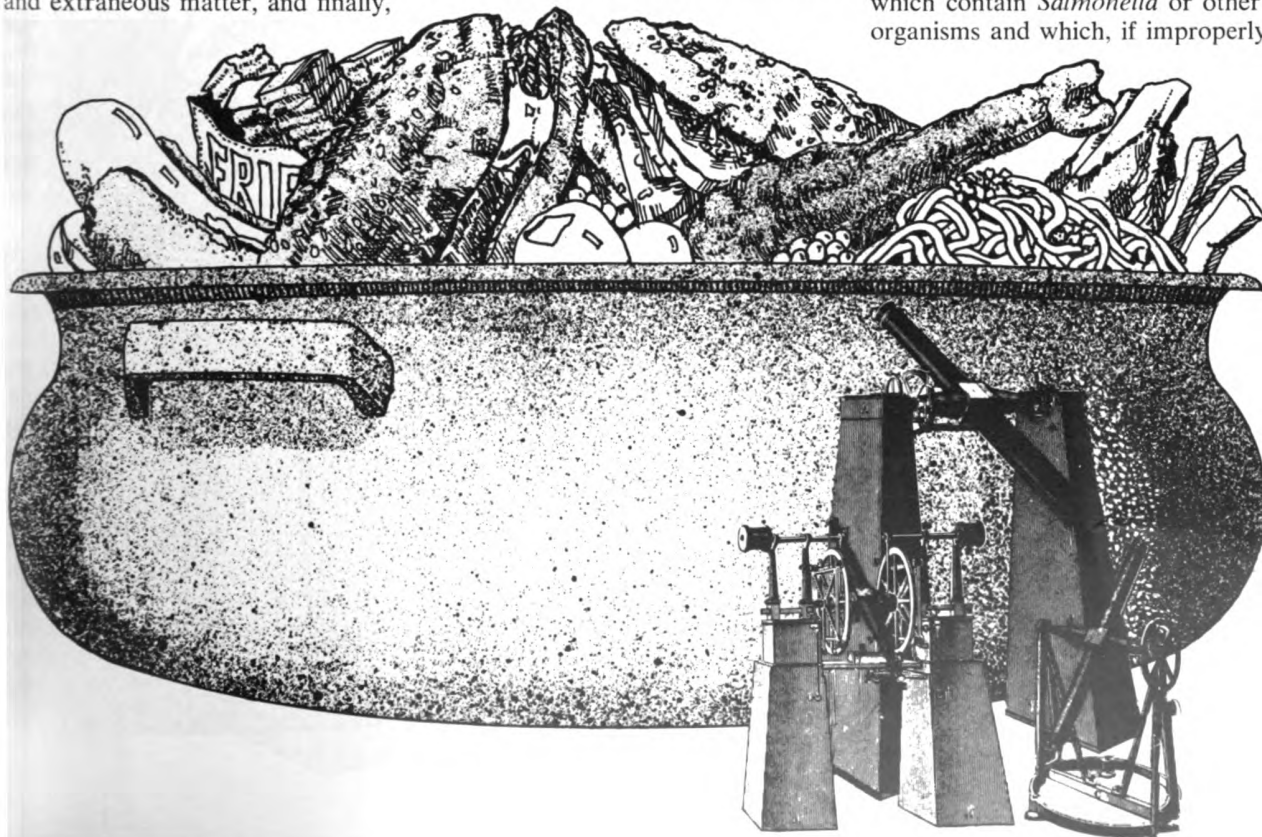
Almost a half century ago the Federal Government realized it had a responsibility concerning food service establishments that it couldn't handle alone.

This was solved through enactment by Congress of the Public Health Service Act, which, among other things, established the Public Health Service.

As vital as food is to sustain life, it can also be, under certain conditions, an instrument of death, and if not death, a hazard to health.

The potential for foodborne illness results from many types of insanitary food-handling practices in food service establishments.

Research indicates that microbiological contamination of foods may occur from raw materials which contain *Salmonella* or other organisms and which, if improperly





handled, cause foodborne illness. The presence of staphylococcal organisms in the throat and on the hands of food handlers contributes to contamination of the environment, and thus can cause illness.

Since foodborne illness can be prevented by following good sanitation practices, it is important to enumerate such practices for the protection of the public health.

To counteract the potential hazard of contaminated food, the Public Health Service in 1934 undertook the development of an ordinance for the sanitary control of food prepared and served in public eating establishments. In 1935, a tentative draft of such an ordinance was published for the guidance of State and municipal health authorities. A tentative code of compliance based upon satisfactory practices and procedures was then developed and published in 1938. After field trials, this ordinance and code was revised and published in 1940 under the title, *Ordinance and Code Regulating Eating and Drinking Establishments—Recommended by the U.S. Public Health Service*. A further revision of this ordinance and code was published in 1943. The model ordinance was revised again in 1962 to incorporate technological changes.

During the next 10 years, 29 States and more than 230 local governments either adopted the 1962 model ordinance or utilized it as a basis for their own regulations.

In June 1969, the responsibility to provide assistance to State and local regulatory agencies in the establishment and maintenance of food service sanitation programs was transferred to the Food and Drug Administration from another unit of the Public Health Service. This was a logical action, since the Federal Food, Drug, and Cosmetic Act provides for FDA to regulate food held for sale after shipment in interstate commerce. In these days, practically all foods or their components have been in

interstate commerce prior to reaching the consumer.

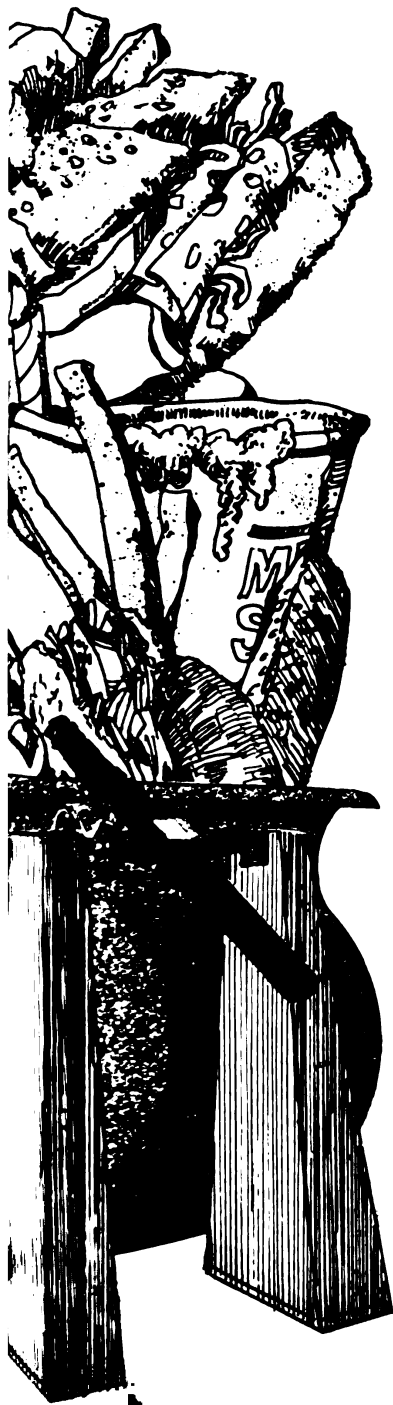
In the meantime, there has also been a phenomenal growth in patronage of food service establishments by the public. There is hardly an American who, on a daily basis or occasionally, does not use the services of such establishments.





The greatest expansion of food service has been in franchise fast-service establishments specializing in a particular food item such as fried chicken, beef or seafood sandwiches, pizzas, and barbecued ribs.

Workers on construction sites and people in their homes are employing the services of caterers to a greater extent than ever before.



It is estimated that there are in existence today more than 600,000 food service establishments in the United States serving 150 million meals daily.

In a number of cases, food service sanitation requirements established by State or local regulatory agencies remain varied. With the trend toward proliferation of national chain and multiunit franchise operators who may have businesses in two or more regulatory jurisdictions, it has become evident that if State and local enforcement agencies adopt uniform requirements known and understood by the regulated industry, and carry out these requirements through strict enforcement, both the consumer and food service industry would benefit.

The food service operator would have a thorough knowledge of what is expected of him, regardless of the location of his business, and could more readily comply with requirements.

To keep abreast of these changes in the food service industry, FDA last October published a proposed updated version of the 1962 model ordinance and, for the first time, proposed corresponding Federal food service sanitation regulations.

The updated model ordinance and new Federal regulations provide State and local governments as before with an up-to-date reference tool which will enhance achievement of the goal of greater uniformity in Federal, State, and local regulation.

In addition to implementing laws prohibiting adulteration of food in interstate commerce, these new Federal regulations will serve the special purpose of establishing criteria for approval of food service operations on interstate conveyances and also of food sources for interstate conveyances.

The model ordinance and Federal regulations must, of course, be identical. Late in 1972, a draft revision of the 1962 model ordinance was developed, and 450

copies were distributed to the States, the organized restaurant industry, and some local regulatory agencies and other interested persons. They were asked to review the draft revision and submit comments. One hundred twenty-five comments were received, including over 1,000 suggestions relating to technical provisions, as well as other suggestions relating to meaning and format.

The final version of the revised model food service establishment ordinance and the new regulations probably will be published later this year.

Meanwhile, FDA is revising the 1965 Recommendations of the Public Health Service for the Vending of Food and Beverages and developing standards for retail food stores. Sometime this year, the Agency will publish for public comment the revision of the model vending ordinance and the recommended sanitary requirements for retail food stores.

With the finalization of all these standards by the end of 1975, the public can be assured that food coming from these sources will continue to be under strict local, State, and/or Federal surveillance and the hoped for result is that the risk of contaminated food reaching the consumer will be considerably reduced.

In addition to these efforts by public agencies, the consumer has a responsibility as well. As was noted earlier, the only source of food not under regulation is the home kitchen.

To assist those responsible for preparing meals in the home, FDA has a number of instructive brochures that can be acquired merely for the asking.

If an FDA office is not readily accessible, write to Consumer Inquiries Office, HFI-10, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.

Enoc P. Waters is an information specialist in FDA.

---

## News Highlights

### **Manufacturer to Correct Potential Radiation Hazard in TV Sets**

More than 400,000 color television sets found to carry a potential radiation hazard will be repaired by the manufacturer at no cost to owners, according to a corrective program submitted to the FDA.

The sets, manufactured by the Matsushita Electric Company of America, are marketed under the trade names Panasonic, Penncrest (J.C. Penney), and Bradford (W. T. Grant Co.). Ranging in picture tube size from 9 to 25 inches, the sets were found by FDA's Bureau of Radiological Health to be capable of emitting 5 to 25 times the maximum limits allowable by the Federal standards for radiation emission.

X rays in excess of FDA limits could be emitted through the front of the picture tube and screen if certain components fail. This problem is made more serious by the fact that the sets can continue to function with an acceptable picture and appear to be operating normally, even with component failure.

Pending correction of the sets, FDA advises that owners who are concerned view their sets from a distance of at least 6 feet or stop using their sets.

The correction plan submitted to FDA by the manufacturer calls for notifying owners and modifying their sets free of charge. Customer notification by the manufacturer will be made as soon as lists of owners can be obtained from dealers and distributors, repair sites established, and parts made available. The action involves about 288,000 Panasonic, 104,000 J.C. Penney, and 15,000 W.T. Grant color receivers. The situation is the first violation of the radiation emission limit established by the Federal performance standard requiring corrective action on television receivers in the homes of consumers.

### **Food, Beverage Manufacturers Cautioned On Substitution of Saccharin for Sugar**

A subcommittee of the National Academy of Sciences/National Research Council (NAS/NRC) has completed a study for FDA on the "Safety of Saccharin and Sodium Saccharin in the Human Diet." The report is being made available to the public by FDA and the Academy through sale by the National Technical Information Service.

Saccharin is marketed at present under an FDA interim order limiting its use. The limitations were imposed by FDA in 1972 after an earlier NAS/NRC panel had concluded: "On the basis of available in-

formation, the present and future usage of saccharin in the United States does not pose a hazard." The previous NAS/NRC panel further concluded that in the interest of safety, saccharin use should be limited while additional safety reviews were conducted. FDA therefore removed saccharin from the GRAS (Generally Recognized as Safe) list and issued an interim food additive order "freezing" uses at then current levels.

The new study now available was undertaken by the Academy at FDA's request in 1972, following reports of bladder tumors in some animals fed saccharin. The study was designed to evaluate the scientific validity of all available laboratory findings. The conclusion of the Academy's subcommittee is:

"The results of toxicity studies thus far reported have not established conclusively whether saccharin is or is not carcinogenic when administered orally to test animals.

"Though the results of the FDA and WARF [Wisconsin Alumni Research Foundation] studies suggest that under the circumstances of these tests the bladder tumors observed were related to the consumption of the saccharin samples used, they cannot be interpreted as showing that saccharin itself was the cause of the tumors.

"At the same time, because the designs of the many reported negative tests were at fault in not involving *in utero* exposure of the test animals, the results of these tests cannot be interpreted as showing that saccharin is not a bladder tumorigen. The additional difficulty in interpreting the negative results in these studies arises from the relatively small number of animals surviving for final examination, a situation that minimizes the possibility of detecting carcinogenic effects of low incidence."

The subcommittee recommended additional studies to resolve the question of carcinogenicity and other safety issues.

FDA is evaluating the report and its recommendations to determine what further tests are needed and how they should be conducted. This evaluation will take several months, and may require consultation with the Academy subcommittee to clarify recommendations in the report. When the evaluation is completed, FDA will define the types of tests to be required. In the interim, saccharin will continue to be marketed under existing limitations.

Copies of the Academy Report, #PB-238137/AS are available from the N.T.I.S., 5285 Port Royal Road, Springfield, Virginia 22151. Single copies are \$4.75 in printed form, and \$2.25 in microfiche.

---

## Regional Reports

---

### REGION I

In a judgment resulting from an investigation by FDA's **Boston Field Office**, Roger Williams Grocery, Inc., Berkley, Rhode Island, was fined a thousand dollars in December by a Federal court sitting at Providence. The company had pleaded guilty to a criminal information charging that it had held six lots of food in a warehouse that was accessible to rodents, causing the food to be infested with live rodents and to be contaminated with rodent filth.

### REGION II

Through an investigation which has the full cooperation of the Long Island District Attorney and the Nassau County Police, FDA's **New York District** hopes to establish the source of a large number of over-the-counter and prescription drugs which the police seized during a recent arrest of six persons charged with conspiracy and with unlicensed practice of medicine and pharmacy. The drugs, Amygdalin/Laetrile, Hoxsey, and unlabeled parenterals, were seized along with a homemade, unlabeled electromagnetic device alleged to be of therapeutic value for cancer. The six individuals are associated with and are local board members of the International Association of Cancer Victims and Friends, Inc., Solana Beach, California.

The Nassau County Laboratory is analyzing all the drugs seized, and has requested FDA laboratory cooperation.

Following up a tip from the U.S. Customs Service, New York District investigated and recommended seizure of canned tropical fruit called Ackees that had been imported with an invoice listing 850 boxes of bananas and 27 miscellaneous boxes which, it was found, contained Ackees. Although they are the national fruit of Jamaica, Ackees have been the center of controversy for many years, for it has been estimated that the fruit has caused over 5,000 deaths since 1886. Ackees contain two toxins, Hypoglycin A & B, which diminish in concentration as the fruit ripens, but is present even in the mature fruit. FDA routinely detains all Ackees offered for import since there are no reliable chemical methods in common use to determine if the toxin is present.

Since New York State is the second largest producer of apples in the country, FDA's **Buffalo District** is

particularly alert to apple processing, and whether rotten apples are being used to make apple juice and cider. In three recent investigations, the District found rot or mold or both in the apple supplies being used for processing, without any inspection by the processor to eliminate the spoiled fruit. Corrective action was taken by the firms involved to prevent consumers from receiving contaminated products.

During a recent 6-week period, Buffalo District detained over \$152,904 worth of TV sets and monitors, microwave ovens, x-ray units and components, and other equipment for failure to comply with the Radiation Control for Health and Safety Act. The articles, as offered for import, were not accompanied by the required certification that they were manufactured according to U.S. Standards. Buffalo District cannot allow the articles to be released for use in the United States until the shipper is able to demonstrate that the articles do comply with such standards.

The District also detained 105 cases of Roman Pecorino cheese, valued at \$8,545, because the Italian-made cheese was adulterated with BHC (benzene hexachloride), an insecticide.

The entire stock of 142 lots of food for human use, valued at approximately \$1.5 million, was seized recently at Harborside Terminal Co., Inc., Jersey City, New Jersey. Request for seizure was filed when investigators from FDA's **Newark District** inspected the public storage warehouse and found massive rodent infestation of its cooler storage area.

Newark District officials witnessed the voluntary destruction of two insect-contaminated lots of ground cocoa cake, totaling 20,000 pounds, at Intercontinental Cocoa Products, Inc., Camden, New Jersey. The District had sampled the two lots in a recent inspection and had found insect activity in the milling area. When management was informed that the lots would be seized, the company elected to destroy the contaminated product.

In three recent separate inspections, FDA's **San Juan District** investigators found insect-infested food, and requested seizures. The investigators later accompanied a Federal marshal in one of the actions to seize 507 hundred-pound bags of starch at Toa Canning Co., Toa Baja, Puerto Rico. In the San Juan actions, Federal marshals seized 3,141 cartons, each containing 24 14-ounce packages of spaghetti at Caribe Storage Co.; and four lots of spices at Agencias Intermares.



### REGION III

FDA's **Philadelphia District** reports that seizure was made recently at Scranton, Pennsylvania, of a railcarload of approximately 77,000 pounds of Oregon russet potatoes the District had found were contaminated by an unsafe quantity of the pesticide chemical chlordane. The potatoes, in 50-pound cartons and 5-pound bags, had been shipped by Desert Magic, Inc., Boardman, Oregon.

Officials from FDA's Philadelphia District, Allegheny County, and the Pennsylvania Department of Agriculture met in Pittsburgh to finalize plans for a triagency inspectional survey of 41 produce warehouses. State and county officials operating independently in the past have found these warehouses to be in poor structural condition, which could lead to the produce being held under insanitary conditions. Since past attempts to bring about correction by the owners have been unsuccessful, the officials feel that combined agency action would work better to achieve compliance. Inspections began in December, and a meeting was planned to review the findings and determine the best regulatory approach.

### REGION IV

The high cost of sugar is of concern to both consumers and industry. The Pine State Creamery in Raleigh, North Carolina, decided to deal with the problem by substituting saccharin for sugar in one of its products without declaring it on the label. In response to an anonymous complaint, Investigator Steven Ziser from FDA's **Raleigh Resident Post** inspected the company premises. He found the company was test-marketing ice pop containing saccharin without declaring the additive on the label. As a result of the inspection, Pine State discontinued the substitution practice and voluntarily destroyed its 150-pound stock of saccharin-based stabilizer.

Atlanta's Hartsfield International Airport, air travel hub of the South, is the first airport in the country where an FDA staffer is exclusively assigned. FDA's Interstate Travel Sanitation Program's conveyance inspection activities are in operation at the airport, and are conducted by Investigator Barbara Loyd.

Gulf Terminal Co., a commercial cold storage facility in Tampa, Florida, which stores large amounts of food products for private firms and for U.S. military and Federal agencies, suffered a break in its liquid ammonia refrigeration system, exposing many products to high concentrations of ammonia gas and thawing. Investiga-

tor Philip DeLisle from FDA's **Orlando District** investigated the problem, and the Hillsborough County Health Department placed under Stop-Sale over 8,000 tons of food valued at over \$35 million. After a discussion with FDA's Bureau of Foods, Gulf Terminal hired an independent research laboratory to determine which products stored in the freezers were safe for human consumption. Sampling and analyses of the foods were monitored by the Florida Department of Agriculture and FDA's Orlando District. Disposition of the foods was monitored by the District in cooperation with USDA, Air Force Veterinary Inspectors, and State and local officials.

The Florida State Legislature has enacted a bill requiring that public schools conduct a consumer education program in which each student shall participate. To discuss the new legislation and plan its implementation, a Florida Education Conference on Consumer Education was held in Orlando. The conference drew 450 educators and business and consumer representatives. Its keynote speaker was Virginia Knauer, Special Assistant to the President on Consumer Affairs. Attending from FDA's Orlando District were Adam Trujillo, director, and Wilhelmina Lombardi, Ana Rivera, and Kathy Jones, consumer affairs officers. The District will work with the Florida Department of Education to include FDA information in the curriculum from kindergarten through high school.

### REGION V

The Government seized nearly 50,000 bales of flour valued at approximately \$400,000 at AAA Warehouse in Indianapolis, when FDA's **Detroit District** investigators found during an inspection that the flour was stored under insanitary conditions. They found rodent nests, gnawed bags, and rodent pellets within some of the pallet-loads of flour held in the warehouse.

U.S. marshals in Georgia, North Dakota, Wisconsin, and Michigan have seized lots of tomato catsup with a total value of approximately \$33,000 because of decomposition as evidenced by mold. Detroit District's mobile laboratory had found the catsup, manufactured by NAAS Foods, Portland, Indiana, to be questionable while examining screening samples during the seasonal operation last September.

### REGION VII

Kay-Gee Sales, Inc., a Kansas City, Missouri, wholesale grocery warehouse, and Meyer Gilgus, the company's president, pleaded guilty and nolo contendere respectively before Magistrate Calvin Hamilton in the





U.S. District Court for Western Missouri on two counts of causing food to become adulterated by gross insanitary conditions on the warehouse premises. The magistrate fined the defendants a total of \$4,000, of which he suspended \$2,800, and placed both the company and its president on a 2-year probationary period. The probationary provisions require that the firm retain a qualified pest control operator and establish a sanitation and maintenance program for stored foods so that no future violations of the FD&C Act will occur. FDA's **Kansas City Field Office** inspections and laboratory analysis has confirmed that various foodstuffs in the warehouse were contaminated by rodent hair, excreta pellets, nesting material, gnawed packaging, urine stains on packages, and in one instance, a nest of live baby rodents in a bag of flour.

The **Kansas City Field Office** recently detained, at St. Louis, Missouri, three lots of children's toy plastic sunglasses, imported from Hong Kong and valued at over \$25,800, because they lacked the required impact resistance test data.

## REGION VIII

FDA's **Denver District** reports that Western Research Laboratories, Denver, has consented to a permanent injunction restraining the company from distributing two drugs for human use which FDA has found to be ineffective. Stocks of the two drugs, Cholipan and Zymachol, will be destroyed, and the firm is prohibited from distributing these products and others of similar composition.

A consumer reported to Denver District officials that contents of a jar of pickled peppers sprayed from the container when opened. The product was manufactured by a small company that does a strictly local business—usually out of the FDA's legal jurisdiction. But because it was Election Day and both city and State health departments were closed, a District investigator visited the store where the peppers had been purchased, and found 21 of 23 jars had swollen and leaking lids. The investigator convinced the dealer that the jars should be removed from the shelves.

The District reported the problem to the city and State health departments, and offered assistance in any followup they undertake.

## REGION IX

A Federal court at Los Angeles has completed action in the recent case of U.S. vs. Star-Kist Foods, Inc. et al., with the sentencing of two officials of the company. The court fined John L. Schmidtke and James Baum-

garten each a thousand dollars on one of two counts, dismissed the second count, and placed both men on 2 years' probation. Earlier in the same action, brought by FDA's **San Francisco District**, the court had fined each of the corporate defendants, Star-Kist Foods, Inc., Los Angeles, and Star-Kist Samoa, Inc., Pago Pago, American Samoa, a thousand dollars on each of the two counts. The fines in the case totaled \$6,000.

Star-Kist and the individual defendants, who were operating as manager and plant superintendent respectively, had pleaded guilty to charges of introducing into interstate commerce, over 2 years ago, canned tuna which contained the poisonous and deleterious substance histamine and which consisted in whole or in part of decomposed fish. The violative lots of tuna all have been removed from distribution and destroyed.

For the second time in 4 years, Y. Hata & Co., a food-storage company in Honolulu, and its president, Minoru Hata, were charged in a Federal court in Honolulu in a criminal action with adulterating various foods while held for sale after shipment in interstate commerce. In the 5-day jury trial, FDA charged the company with three counts of holding the stored food under insanitary conditions where it became contaminated with rodent urine, insects, and bird excreta. The case took an unusual turn on the fourth day when both sides presented arguments to an 11-person jury instead of the customary 12 because one of the jurors had flu and was excused. Both had agreed that the 11-person jury would be satisfactory, since no alternates had been selected. After hearing the arguments, the jury the next day returned a verdict of guilty for both defendants on one count and not guilty on the remaining counts. Sentencing was to take place later.

In the previous criminal action against the defendants, which took almost a year to complete, charges against Mr. Hata were dismissed. The company eventually pleaded guilty, was fined one dollar on each of the five counts, and was ordered to pay \$500 court costs.

## REGION X

Investigational coverage by FDA's **Seattle District** of the potato-growing areas of Washington and Oregon last fall, and laboratory testing of newly harvested potatoes, became extensive when laboratory results showed illegal levels of the pesticide chlordane in some that were assayed. Regulatory action by FDA resulted in seizure of 1,444,000 pounds of adulterated potatoes that had been shipped into interstate commerce. Through this action, along with the cooperative efforts of Oregon and Washington Department of Agriculture officials, FDA was able to preclude adulterated potatoes from reaching the retail market.

---

## State Actions

### Soft Drinks/Salmon

The Michigan Department of Agriculture Food Inspection Division reports that it seized over 43,000 cases of soft drinks valued at approximately \$215,000 because the soft drinks were contaminated with foreign material and mold. A division investigation had shown that the detergent being used in the bottle washer was leaving residues in the washer and in the bottles. The products, packed in returnable bottles, were seized at a number of locations within the State and destroyed under the supervision of State personnel.

The Michigan department reports also that 20 samples of coho salmon it had taken recently from Lake Michigan were below FDA's action guidelines for DDT and PCB's. The samples represented fish smaller than 7 pounds in size. The department has data which indicate that larger salmon, particularly the Chinook, still exceed the guidelines.

During 1969, all commercial fishing for coho salmon in Lake Michigan was halted by State and Federal agencies because the fish contained excessive pesticide residues. With the new data, it appears that approximately one-half of the coho harvested in the fall of 1974 will be acceptable for food purposes. This could total over 500,000 pounds of fish.

### Contaminated Food

The Environmental Services Bureau, Montana Department of Health and Environmental Sciences, recently embargoed a large shipment of rice and cornmeal when State officials found that the two railcars in which the food was being shipped were heavily contaminated by rodents and cockroaches, reports Vernon E. Sloulin, bureau

chief. Fumigation of the cars killed the rodents and cockroaches, but the cargo was still contaminated with rodent urine and hairs. State officials have sealed the two railcars, which contain 1,700 bales of rice and 339 bales of cornmeal, and tagged them with embargo notices. The cars will remain under embargo until suitable disposition of their contents is made by the Agricultural Stabilization Conservation Service of the U.S. Department of Agriculture.

### More Sugar Problems

The Colorado Department of Health embargoed almost 100,000 pounds of sugar being transported in a railcar on the Denver and Rio Grande Western Railroad when the railcar was derailed just west of Denver. Harvey Morlan, a department official, said that unbroken bags of 25 pounds or larger totaling 12,173 pounds were released for return to the shippers; smaller unbroken bags were released for sale to salvage dealers; and 1,500 pounds of obviously dirty sugar was sold as bee food. About 14,000 pounds was unsalvageable and was taken to the dump, and over 15,000 pounds was lost at the site of the derailment. In all, said Mr. Morlan, the value of the sugar lost, dumped, and diverted to bee food totaled \$19,493.

### Direct Line

When consumers think they've been had in the purchase of a product, it is much more satisfying to them to have direct communication with the person or persons investigating their complaints. The Oregon Department of Agriculture has taken steps to make this direct contact possible for consumers in the Portland area who have complaints about food products. These con-

sumers now have access to a direct line into the office of the department's consumer officer, Dr. Jane Wyatt, at the Salem headquarters. The number to call for this service is 248-0186, a Portland number. Previously, the calls were taken by the department's branch office and the information relayed to the consumer officer in Salem.

### State Injunction

The State of Connecticut Department of Consumer Protection recently sought and obtained a court injunction against Grocer's Wholesale Outlet, Inc., New Haven, and its president, Anthony N. Zampano, enjoining them from selling or distributing any food in the firm's possession until insanitary conditions at the plant were corrected and all contaminated foods now held were destroyed. The injunction was a result of both Federal and State inspections made in March and again in September, 1974, which revealed several lots of food contaminated by rodent excreta, bird feces, and dead birds. Other insanitary conditions found included crowded storage areas, debris strewn about the warehouse, and birds' nests in fluorescent light fixture.

After initial filing of the injunction, the firm suspended operation for a week and underwent an extensive cleaning and repair program. During this period, several contaminated lots of food were destroyed under the supervision of the State authorities. The injunction will be continued for a period of not less than 6 months, at which time the State agency will report to the court, and the court shall take further action as indicated by the circumstances. Any violation of the terms of the injunction will result in a \$2,000 fine against the firm and individual.

# Seizures and Postal Service Cases

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

A total of 25 actions to remove from the consumer market products charged to be violative was reported in December. These included 20 seizures of foods; 6 involved charges concerning a poisonous and deleterious substance.

14 involved charges concerning contamination. Other seizures included 1 of medical device, and 4 of cosmetics.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>FOOD/Poisonous and Deleterious Substances</b>		
Peanuts, Spanish/Cincinnati, Ohio 11/12/74	Gold Kist Co./Atlanta, Ga. (M,S)	Contain the added poisonous and deleterious substance aflatoxin.
Potatoes/Cincinnati, Ohio 11/14/74	Desert Magic, Inc./Boardman, Oreg. (S)	Contain the added poisonous and deleterious substance chlordane.
Lorain, Ohio 11/13/74	" "	"
Fresh white/Norfolk, Va. 11/29/74	"	"
Tampa, Fla. 11/22/74	"(M,S)	"
Russet/Dallas, Tex. 11/20/74	"	"
<b>Contamination, Spoilage, Insanitary Handling</b>		
Catsup, tomato/Fargo, N.Dak. 11/12/74	Naas Foods, Inc./Portland, Ind. (M,S)	Decomposed.
Lansing, Mich. 11/21/74	"	"
Chestnuts, dried, shelled/San Francisco, Calif. 11/15/74	South End Warehouse Co./San Francisco, Calif. (D)	Held under insanitary conditions; insect contaminated; decomposed.
Cocoa powder, shelled walnuts/Worcester, Mass. 11/8/74	Widoff's Modern Bakery, Inc./Worcester, Mass. (D)	Held under insanitary conditions; insect contaminated.
Corn starch/Toa Baja, P.R. 11/18/74	Toa Canning Co., Inc./Toa Baja, P.R. (D)	"
Syrup, dried; dextrose/East Boston, Mass. 10/31/74	Gum Products, Inc./East Boston, Mass. (D)	Held under insanitary conditions.
Dates/Bufalo, N.Y. 11/18/74	Park Edge Warehouse/Bufalo, N.Y. (D)	Moldy.
Flour, all purpose, enriched, whole wheat, rye, graham, cake and pastry, self-rising/Indianapolis, Ind. 11/27/74	AAA Warehouse Corp./Indianapolis, Ind. (D)	Held under insanitary conditions.
Food, various/Tampa, Fla. 10/24/74	Reina Bros. & Co., Inc./Tampa, Fla. (D)	Held under insanitary conditions; insect and rodent contaminated.
New Orleans, La. 10/18/74	Schwegmann Bros. Giant Supermarkets/New Orleans, La. (D)	"
Laurel leaves, Broiler cinnamon, black pepper, Cumin seed/San Juan, P.R. 11/18/74	Agencias Intermares/San Juan, P.R. (D)	Held under insanitary conditions; insect contaminated
Meat whole/Puerto Nuevo, P.R. 12/5/74	Caribe Storage & Dist. Co./Puerto Nuevo, P.R. (D)	Decomposed.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>Contamination, Spoilage, Insanitary Handling (cont'd)</b>		
Sesame seed, Annato seed/Hato Rey, P.R. and San Juan, P.R. 10/10/74	La Palmita/Hato Rey, P.R.; Nieve Hnos., Inc./San Juan, P.R. (D)	Held under insanitary conditions, insect contaminated.
Spaghetti/San Juan, P.R. 11/18/74	Caribe Storage & Distribution Co./San Juan, P.R. (D)	"
<b>MEDICAL DEVICE</b>		
Adjusting machine/Morehead City, N.C. 11/14/74	Arden D. Zimmerman, D.C./San Jose, Calif. (M,S)	Inadequate directions for safe use by laymen; dangerous to health when used in the dosage, frequency, and duration prescribed.
<b>COSMETICS</b>		
Nail kits/Hialeah, Fla. 9/25/74	House of Barri, Inc./New York, N.Y. (M); Save Way Barber & Beauty Supply/Hialeah, Fla. (S)	Article contains a poisonous and deleterious substance (liquid methyl methacrylate monomer), which may render article injurious to users under such conditions of use as are customary or usual.
Nail lengthener kits/Fort Lauderdale, Fla. 9/26/74	Dark Eyes Co., Inc./Chicago, Ill. (Distributor,S)	"
Austintown, Ohio 9/25/74	C.E.B. Products, Inc./Chicago, Ill. (M,S)	"
Baltimore, Md. 10/30/74	"	"

**U.S. POSTAL SERVICE** actions taken in medical cases as authorized in the Mail Fraud Statute (18 U.S.C. 1341) and/or the False Representation Statute (39 U.S.C. 3005) as reported by the Chief Postal Inspector.

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

September 18, 1974: <b>The Hecht Co.</b> , Dept. 011, Washington, D.C. Sale by mail of appetite depressant to assist in weight loss.	November 7, 1974: <b>Elizabeth St. James Co.</b> , P.O. Box 1264, Pittsfield, Massachusetts 01201. Petition for a mail-stop order based upon breach of former agreement. Firm advertises and sells by mail a bustline developer guaranteed to increase the size of the bustline 1-3 inches in 8 days. Promise total increases of 4-5 or possibly 6 inches.
September 18, 1974: <b>Palafax-Knight Labs</b> , and/or <b>P. Palafax, R.Ph.</b> , Drawer 460, Anthony, Texas 88021. Advertising and sale by mail of a cure for chronic digestive problems.	November 15, 1974: <b>Willpower</b> , 1030 Windsor Parkway, Atlanta, Georgia 30311. Advertising and sale by mail of a reducing method and pill.
October 21, 1974: <b>Katz &amp; Besthoff</b> , 900 Camp Street and One K & B Plaza, Lee Circle, New Orleans, Louisiana 70130. Advertising and sale by mail of Appedrine as a reducing method.	November 21, 1974: <b>Lady Fair Products</b> , Box 1600, Long Island City, New York 11101. Advertising and sale by mail of E-Z Slim Caps, represented to be effective for weight loss.
October 24, 1974: <b>Frontier Shop</b> , Box 9832, Fort Worth, Texas 75107. Advertising and sale by mail of Vitamin E Cream for removing wrinkles.	

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

September 23, 1974: Against <b>Cosmetics Laboratories</b> , 1030 Windsor Parkway, Atlanta, Georgia 30319, and P.O. Box 7040, Atlanta, Georgia 30309, for breach of a Consent Agreement — Etan, Vitamin E Tanning Lotion	October 17, 1974: Against <b>Bio-Alpha</b> , Box 501, Waldorf, Maryland. Advertising and sale by mail of a tape recording that allegedly causes listener to lose weight
September 30, 1974: Against <b>Phase Method</b> , 509 Fifth Avenue, New York, New York 10017. Solicitations and sales by mail of "Phase Method," represented as enabling subscribers to attain rapid and dramatic weight losses by means of a personalized program determined by "Grapho-Therapeutics"	November 4, 1974: Against <b>Joe Weider</b> , 55 Maple Street, Norwood, New Jersey. Advertising and sale by mail of a liquid drink represented to cause weight loss



# Notices of Judgment

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

**Cress greens, canned, Betty Ann**, at Charlotte, W. Dist. N.C.

Charged 7-22-74 when shipped by Monticello Canning Co., Crossville, Tenn., the article contained the deleterious substance cockleburrs. 402(a)(1). Default decree ordered destruction (F.D.C. No. 59872, S. No. 116144 H. N.J. No. 1).

**Frog legs, frozen**, at Chicago, N. Dist. Ill.

Charged 6-28-74 when shipped by Seafood Distributors Corp. and Progressive Sea Products, Brownsville, Tex. the articles, labeled in part "Frozen Frog Legs," packed by Industrias GME Mexico, D.F. and "Blue Dot Quick Frozen Frog Legs Product of Indonesia Processors Conimex Djakarta," contained the added poisonous and deleterious substance viable *Salmonella* organisms. 402(a)(1). Default decree ordered destruction (F.D.C. No. 59832, S. Nos. 96-829/30 H. N.J. No. 2).

**Frog Legs, frozen**, at Chicago, N. Dist. Ill.

Charged 7-17-74 when shipped by E. J. Kozin Co., Inc., Brownsville, Tex., the article, labeled in part "Fresh Frozen Peninsular Frog Legs Processed & Packed by Shrimper, Bombay-22 For India Tobacco Co., Ltd. Product of India," contained the added poisonous and deleterious substance viable *Salmonella* organisms. 402(a)(1). Default decree ordered destruction (F.D.C. No. 59855, S. No. 96-833 H. N.J. No. 3).

**Frog legs, frozen**, at Laredo, S. Dist. Tex.

Charged 7-22-74 while held by Southern Fish Co., Laredo, Tex., who prepared and packed the article from live frogs shipped in interstate commerce, the article contained the added poisonous and deleterious substance viable *Salmonella* organisms, and had been prepared, packed, and held under insanitary conditions. 402(a)(1), 402(a)(4), and the article was offered for sale under the name of another food. 403(a) - 403(b). Default decree ordered destruction (F.D.C. No. 59862, S. No. 89-201 H. N.J. No. 4).

**Buts**, at Cedar Rapids, N. Dist. Iowa

Charged 6-6-74 and amended 6-10-74 when shipped by Walsh Gram Co., Minneapolis, Minn., the article contained a mercurial compound which was a pesticide chemical, and no tolerance or exemption therefrom for such pesticide chemical on oats had been prescribed by regulation. 402(a)(2)(B). Consent decree authorized release to Dalton Gram & Feed Co., Dalton, Minn., for conversion into seed oats (F.D.C. No. 59802, S. No. 74-165 H. N.J. No. 5).

**Tuna fish, canned**, 2 seizure actions at Jackson, S. Dist. Miss., and Hattiesburg, S. Dist. Miss.

Charged 9-27-73 when shipped by Fraering Brokerage Co., Inc., New Orleans, La., the article, labeled in part "Dabon Solid Pack Light Tuna in Water Packed for Dabon Company New Orleans, La.," packed in the "Azores Product of Portugal" contained the poisonous and deleterious substance histamine in such quantity as to ordinarily render the article injurious to health, and the article contained decomposed tuna fish. 402(a)(1), 402(a)(3). The article was claimed by the shipper, who denied the charges. The parties served written interrogatories on each other. Thereafter, the actions were consolidated. As a result of a pretrial conference, the court found that there was no material issue as to any material fact necessary for the ultimate disposition of the consolidated actions. The court said:

The only issue raised by the pleadings is whether or not the defendant property is adulterated within the statutory definition contained in 21 U.S.C. 342(a)(1) or 342(a)(2). Inasmuch as the Court is of the opinion that the primary issue involved is adulteration as defined in 21 U.S.C. 342(a)(1) and that the determination made on that issue will dispose of these actions, no finding is made on the presence of decomposed tuna fish in the defendant property.

The government, in its sworn answers to the claimant's interrogatories, maintains that histamine levels in excess of 25 mg./100 gm. ordinarily render food injurious to human health. Various histamine levels were found in samples of the defendant property by analysts for the claimant and the government. The highest histamine level detected was 96.9 mg./100 gm. found in an analysis conducted on behalf of the claimant and reported by claimant in its sworn answers to the interrogatories propounded by the government. The parties agree and the Court finds that the histamine levels encountered in the defendant property existed at and prior to the time of canning and shipment to the claimant. Both parties also concede that different individuals have varying degrees of tolerance to histamine poisoning depending on age, health and individual sensitivity. In the claimant's sworn answers to the government's interrogatories, the claimant's experts estimate that a minimum level of 100 mg./100 gm. of histamine in a food product would ordinarily render it injurious to human health. Although the claimant's experts are of this opinion they concede that if the histamine level is to be used as a test for determining adulteration of the defendant tuna, a safety factor would have to be built into the 100 mg./100 gm. limit and that with the inclusion of this safety factor the sample found to contain 96.9 mg./100 gm. would in their opinion render the lot to be ordinarily injurious to human health. In view of the foregoing the Court finds that there is no genuine issue as to the adulteration question and that because of the histamine level of 96.9 mg./100 gm. encountered, the defendant property involved in these actions is adulterated within the statutory definition.

The Court accordingly concludes that the plaintiff government is entitled as a matter of law to a judgment

in each of these actions decreeing the forfeiture of the property involved herein and that there is no necessity for a trial as to any issue." (F.D.C. Nos. 59495, 59497, S. Nos. 1-131/2 G. N.J. No. 6).

**Wheat**, at Brownwood, N. Dist. Ga.

Charged 8-16-74 when returned from Kansas City, Mo., to Lee Farm Service, Brownwood, Ga., the article contained the pesticide chemical malathion in excess of the tolerance. 402(a)(2)(B). Consent decree authorized release to shipper for conversion into seed wheat (F.D.C. No. 59884, S. No. 73-971 H. N.J. No. 7).

## FOOD/Contamination, Spoilage, Insanitary Handling

**Black-eyed peas, dried, dried pinto beans, and salt**, at Columbus, N. Dist. Miss.

Charged 7-17-74 while held by Columbus Wholesale, Inc., Columbus, Miss., the articles contained rodent filth and were held under insanitary conditions. 402(a)(3), 402(a)(4). Consent decree ordered destruction (F.D.C. No. 59864, S. No. 59-603 H et al., N.J. No. 8).

**Brown conditioner**, at Buffalo, W. Dist. N.Y.

Charged on or about 7-24-74 while held by Royale Rolls, Inc., Buffalo, N.Y., the article contained live and dead insects and was held under insanitary conditions. 402(a)(3), 402(a)(4). Default decree ordered destruction (F.D.C. No. 59878, S. No. 106-242 H. N.J. No. 9).

**Candy and gum in banks**, at Miami, S. Dist. Fla.

Charged 3-12-74 when shipped by Old Dominion Peanut Corp., Norfolk, Va., the article, labeled in part "Candy Bank," manufactured for National Kidney Foundation by Old Dominion Peanut Corp., was unfit for food, since the candy contained metal fragments approximately 0.5 mm to 2 mm in size. 402(a)(3). Default decree ordered destruction (F.D.C. No. 59692, S. No. 2-410 G. N.J. No. 10).

**Flour**, at Yauco, Dist. P.R.

Charged 6-26-74 while held by Borniquen Macaroni Corp., Yauco, P.R., the article contained insect filth and was held under insanitary conditions. 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging (F.D.C. No. 59835, S. No. 23-183 H. N.J. No. 11).

**Wheat, buckwheat, caraway seed, poppyseed, and other foods in paper bags and burlap bags**, at Baltimore, Dist. Md.

Charged 9-24-74 while held by Wm. G. Scarlett & Co., Baltimore, Md., the buckwheat contained rodent filth, and the articles had been held under insanitary conditions. 402(a)(3), 402(a)(4). The dealer claimed the articles, denied the charges, alleged that the buckwheat was not an article of food, and alleged that prior to the filing of the complaint the dealer had reconditioned the articles which might have been in violation of 21 U.S.C. 342(a)(3) and had proceeded to eliminate any conditions on its premises which might have created violations under 21 U.S.C. 342(a)(4). Thereafter, a consent decree authorized release of the articles to the dealer for bringing into compliance with the law (F.D.C. No. 59986, S. No. 11-798 H et al., N.J. No. 12).

**Mushroom stems and pieces, canned, Roma, and other brands**, 4 seizure actions, at Bridgeport, Dist. Conn., Suffield, Dist. Conn., Temple, E. Dist. Pa., East Hartford, Dist. Conn.

Charged 4-23-74, 4-25-74, 6-7-73 (amended 8-15-73), 5-8-73 when shipped by Giorgio Foods, Inc., Temple, Pa., and when returned to Temple, Pa. (seizure at Temple, Pa.), the articles, labeled in part "Roma Brand Mushrooms," "Pieces and Stems," packed by Giorgio Foods, Inc., Temple, Pa., "Hy-Top Brand Stems and Pieces Mushrooms," distributed by Hy-Top Products A Division of Federated Foods, Inc., Des Plaines, Ill., and "Richeieu Pieces and Stems Mushrooms," M & R Sales Corporation Dist., Oak Park, Ill., contained decomposed mushrooms. 402(a)(3). The articles were claimed by Capri International, Inc., Rockland, Del. The claimant moved for consolidation of the actions for trial in the Eastern District of Pennsylvania. After the actions were consolidated, consent decrees were entered in the actions authorizing release to the claimant for salvaging. The consent decree also permanently enjoined the claimant from shipping any returned food unless and until such food had been brought into compliance under FDA supervision. (F.D.C. Nos. 59178/9, 59182, 59187, S. Nos. 15-177 G, 14-307 G, 84-084/5 G, 14-306 G. N.J. No. 13).

**Potatoes, dehydrated, and granulated sugar**, at Kansas City, W. Dist. Mo.

Charged 5-13-74 while held by Kay Gee Sales, Inc., Kansas City, Mo., the articles were held under insanitary conditions. 402(a)(4), and when shipped by Surplus City, Wichita, Kans., the labels of some of the potatoes lacked the name and place of business of the manufacturer, packer, or distributor, and lacked an accurate statement of the quantity of contents and the common or usual name of the food. 403(e)(1), 403(e)(2), 403(e)(1). Consent decree authorized release to the dealer for reconditioning (F.D.C. No. 59757, S. Nos. 74-142/3 H. N.J. No. 14).

**Trout**, at New York, S. Dist. N.Y.

Charged 7-30-74 while held for sale, the article contained decomposed trout. 402(a)(3). Default decree ordered destruction (F.D.C. No. 59875, S. No. 41-986 H. N.J. No. 15).



#### FOOD/Economic and Labeling Violations

**Cherries, unpitted, canned, at Kansas City, W. Dist. Mo.**

Charged 5-30-74: when shipped by Northwest Packing Co., Portland, Ore., the article, labeled in part "Lee, Fancy Pitted Light Sweet Royal Anne Cherries Packed in Heavy Syrup . . . . . Lee Foods, Inc., Distributors Kansas City, Mo.," had had another substance (unpitted cherries) substituted for pitted cherries, and the can label statement "Pitted Cherries" was false and misleading for unpitted cherries; 402(b)(2), 403(a). Consent decree authorized release to Lee Foods, Inc., Kansas City, Mo., for relabeling. (F.D.C. No. 59773; S. No. 73-745 H. N.J. No. 16)

**Matzos, at Baltimore, Dist. Md.**

Charged 1-24-72 and amended 12-7-73: when shipped by Provost Warehouse, Inc., East Rutherford, N.J., the labeling of the article (labeled in part "Manschwartz . . . Diet-Thins Matzo Crackers . . . The B. Manschwartz Company, Newark, N.J.") including the name "Diet-Thins" and the label statements "Perfect for Low-Salt, Low-Sugar, Low-Fat Diets" and "No Salt, Sugar, Shortening, Spices, or Artificial Sweeteners Added," falsely and misleadingly represented and suggested that the article was significantly lower in calories than ordinary matzos, and that the article was of significant value in weight control diets as a means of restricting the intake of calories; the label statement "enriched with vitamins and minerals, wheat germ added" falsely and misleadingly represented and suggested that the nutritive value of the article was significantly increased by reason of the presence therein of wheat germ; the label representation that the scored sections of crackers were "bite-size" was false and misleading, since these sections were approximately 2 inches by 2 1/4 inches — 403(a); the article (represented as a food for special dietary use) lacked the required special dietary information as to the minimum daily requirements for a number of specified vitamins and minerals, since the label declared the proportions of the minimum daily requirements which were supplied by consumption of 6 ounces of the article, and 6 ounces of the article was not a quantity which was customarily or usually consumed during a period of one day, or a quantity which is reasonably suitable for and practicable of consumption within such period — 403(j); and the article was also in violation of the Fair Packaging and Labeling Act, since the statement of identity of the article (in type size approximately 3/16 inch high) was not in a type size reasonably related to the most prominent printed matter (i.e., "Diet-Thins" in 1 5/8-inch-high type size) — 15 U.S.C. 1453(a)(1).

The article was claimed by B. Manschwartz Co., Newark, N.J., who denied the charges and moved for a change of venue to the Southern District of New York or to the Eastern District of New York. After a hearing, the court ordered the action removed to the Eastern District of New York. The parties served written interrogatories on each other. The Government moved for summary judgment based upon the grounds that the pleadings, the answers to interrogatories, and the Government's affidavits show that there was no genuine issue of material fact.

The claimant responded with its affidavits and cross-moved for an order directing the Government to comply with certain discovery requests and for an order staying the Government's motion until depositions and further discovery would be had. In granting summary judgment to the Government, the court said:

"Originally the Diet-Thins were thinner than the regular matzos manufactured and marketed by the claimant. Sometime during the mid-60's, however, the thickness of the regular matzos was reduced, so that at the time of the seizure the Diet-Thins were identical with other matzo crackers made by claimant, except that the Diet-Thins were made with enriched flour rather than ordinary flour. The Diet-Thins furnish the same number of calories as plain matzo crackers and have no greater value in weight control diets than claimant's ordinary matzo crackers.

"The words 'Diet-Thins' on the label of the seized article are displayed across the entire front panel in print 1-3/4" high in the corner of the front panel, a sunburst contains the words 'enriched with vitamins and minerals, wheat germ added' in letters approximately 3/16" high. These legends suggest to the consumer that Diet-Thins are useful in a balanced weight control program and are significantly lower in calories than ordinary matzos.

"Although matzos contain less calories than many other crackers on the market, their caloric content is substantially the same as Melba toast, wholewheat crackers, and certain other crackers.

"The side panel also states: 'perfect for low salt, low sugar, no food dyes and No salt, no sugar, shortening, spices or artificial sweeteners added'.

"There is no evidence that claimant has any intention to mislead the public . . . .

"In the *Sudden Change* case, the court said that the test is not the effect of the label on a 'reasonable consumer,' but upon 'the ignorant, the unthinking and the credulous' consumer. Even a technically accurate description of a food or drug's content may violate 21 U.S.C. § 343 if the description is misleading in other respects. *United States v. An Article — Nuclom*, 482 F.2d 581 (8th Cir. 1973). Thus, whether or not the side panel of the Diet-Thins label may accurately describe its virtues for certain special diets which do not appear to involve weight control, the misleading nature of the front panel still justifies condemnation of the seized articles. Moreover, claimant does not assert that the statements on the side panel apply in any different degree to Diet-Thins than to its ordinary matzo crackers.

"Purchasers of diet products are often 'pathetically eager' to obtain a more slender figure . . . .

"There can be no doubt that the weight-conscious consumer may be led to believe that Diet-Thin Matzos are lower in calories than ordinary matzo crackers. The exchange of affidavits, and the depositions and discovery sought by the claimant have no bearing on this basic issue . . . .

"Claimant asserts that the government is bound or estopped by the asserted FDA approval of the label in 1963 or at any rate that the FDA should have given notice before filing a condemnation proceeding. The claimant does not assert, however, that it gave any notice to the FDA when it modified its regular matzos so as to have the same weight and caloric content as the Diet-Thins. The change in the comparative contents of the package may render a label misleading which was truthful when it was first submitted. The asserted defense is inadequate to prevent the award of summary judgment.

"It is ORDERED that the government's motion for summary judgment be granted, and that a decree of condemnation be entered, and that defendants' motions be denied." (F.D.C. No. 57765; S. No. 52-770 E. N.J. No. 17)

#### VITAMINS/SPECIAL DIETARY FOODS

**Geri-Twins vitamin capsules, Organex dietary supplement tablets, and Acerola C vitamin C combination tablets at Cambridge Dist. Mass.**

Charged on or about 3-9-72: while held by Nature Food Centres, Cambridge, Mass., who repacked and labeled the articles, the labeling of the articles contained a number of false and misleading claims such as Geri-Twins capsules — false and misleading claims, including the name of the article, that represented that the needs of older people for dietary supplementation were substantially different from other people and that two capsules of the product, when taken as directed, would adequately serve all the nutritional needs of the elderly; the false and misleading statement "A dietary supplement of high potency vitamins co-

enzymes, enzymes, isotropic factors and amino acids, derived from natural-organic sources in balanced proportions" on the package label, that represented and suggested that co-enzymes, enzymes, isotropic factors, and amino acids were essential in a supplementation to the diet, and that these substances or enzymes, enzymes, isotropic factors, and amino acids, were present in nutritionally significant amounts; Geri-Twins capsules & Organex tablets — false and misleading claims representing that components such as liver, lysine, and wheat germ) would be significantly beneficial in the amount supplied, false and misleading label statements concerning the dosage and vitamin content that represented that from 5 to 11 times the minimum daily requirement of various of the vitamins in the articles would be necessary and useful as dietary supplements; Organex tablets — false and misleading claims, by reason of the labeling of manganese and potassium, that represented that the ordinary diet needed supplementation with minerals, false and misleading claims concerning zinc, magnesium, and copper, when the article's supplementation would not be of significant value in the daily diet, all the articles — false and misleading statements with respect to the composition of the articles as mixtures of nutrients of proven nutritive value (e.g., vitamin C and other vitamins) with nutrients of no proven nutritive value (e.g., citrus bioflavonoid complex, para-aminobenzoic acid, choline, inositol, and/or rutin) which represented that the nutritive value of the article was enhanced by the presence of such ingredients of no proven nutritive value and that such ingredients had proven nutritive value; 403(a). The Geri-Twins capsules were claimed by Freshman Laboratories, Inc., Warren, Mich., the Organex tablets by Dobb Pharmaceutical Co., Inc. (Div. CapuTab, Areola P.R. Yonkers, N.Y., and the Acerola-C tablets by Nutritional Specialties, Inc., Areola, P.R. The claimant Dobb Pharmaceutical Co., Inc., moved for removal of the action to the Eastern District of New York, a district alleged to be of reasonable proximity to such claimant's principal place of business in the Southern District of New York. The other two claimants consented to Dobb's motion and joined in it. In recommending removal of the action, the U.S. magistrate said:

"This is a complaint in rem brought by the United States of America pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq. The complaint alleges that certain articles of food which were branded were shipped in interstate commerce and were seized pursuant to 21 U.S.C. 334(a)(1). Dobb Pharmaceutical Co. of Yonkers, New York, one of the claimants of the articles, filed a motion to remove the action to the Eastern District of New York. The motion was filed pursuant to 21 U.S.C. 334(a)(1). The government opposes. The matter then came to be heard before me on the motion . . . . There are two other claimants located at Areola, Puerto Rico, and Warren, Michigan, however, neither of these claimants objects to removal to the Eastern District of New York. Therefore, good cause to deny removal cannot be found in the fact that other claimants are involved. After hearing and reading the memoranda filed by the government, it would appear that [the] only good cause advanced is the fact that this district, being approximately 216 miles from Yonkers, New York, is in reasonable proximity to claimant's principal place of business in support of its position the government cites the case of *United States v. 81 Packages . . . Nutrilite Food Supplement*, 93 F. Supp. 763 (D.C.N.J. 1950). In *Nutrilite*, the case was removed to a district some 450 miles from the principal place of business of the claimant. The government, therefore, contends, that a distance of 216 miles is not unreasonable, that since the action is already in a district of reasonable proximity there is no need to remove the action to another district.

"While the reasons advanced by the government may be sufficient in some instances to defeat removal they are not sufficient in this case. There does not appear to be any particular reason why the case should be tried here instead of the Eastern District of New York. Inquiry of the Assistant United States Attorney revealed that the witnesses necessary to prove the government's case could be obtained in New York as well as Massachusetts. While this district could be considered in reasonable proximity to the claimant's principal place of business, the Eastern District of New York is more reasonable. And, since the court in its discretion, specifies the district of reasonable proximity, *United States v. United States District Court*, 73 F.2d 238 (8th Cir. 1955), I recommend that the motion for removal be allowed.

The action was thereupon removed to the Eastern District of New York. The claimants thereafter drew the charges, served written interrogatories on the government, and moved for judgment on the pleadings. Subsequently, a consent decree ordered destruction of the articles (F.D.C. No. 57842; S. Nos. 15-462 JF 15-465 F. N.J. No. 18)

#### ANIMAL FEED

**Distiller's dried grain with solubles, at Monticello, N. Dist. Iowa**

Charged 7-10-74: when shipped in a raicar previously used for handling chlordane, the article was held under insanitary conditions whereby it may have been rendered injurious to health because of the presence of the pesticide chemical chlordane; 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 59831; S. No. 74-310 H. N.J. No. 19)

**Feed blocks, medicated with antibiotics, Stockade Anaplas 20 and Stockade Biot, 3 seizure actions at Pittsburg, Dist. Kans., Lubbock, N. Dist. Tex., and Salinas, E. Dist. Okla.**

Charged 1-31-73, 1-31-73, and 2-6-73: while the lot of Stockade Anaplas 20 blocks at Pittsburg, Kans., was held by Harvest Brand (Div. of Harvest Industries, Inc.), Pittsburg, Kans., who had manufactured the article using chlortetracycline shipped in interstate commerce, and when the other articles (Stockade Biot) were at Lubbock, Tex., and another lot of Stockade Anaplas 20 blocks at Salinas, Okla., were shipped by Harvest Brand, Pittsburg, Kans., the articles were new animal drugs, and there was no New Animal Drug Application in effect with respect to the use and intended use of such articles; 501(a)(5).

The articles were claimed by the shipper, who denied the charge. In the Pittsburg, Kans., and Lubbock, Tex., actions, the parties were served written interrogatories on each other. Subsequently, upon motion the claimant, the Lubbock, Tex., action was consolidated for trial with the Pittsburg, Kans., action. A default decree was originally entered in the Salinas, Okla., action, however, upon motion of Harvest Brand the default decree was vacated. The parties served written interrogatories on each other. Thereafter, upon motion of the claimant and with Government's concurrence, the Salinas, Okla., action was transferred to the District of Kansas. Prior to trial, upon motion of the Government, the complaints were withdrawn and the actions were dismissed. Subsequently, the Government issued a notice (21 CFR 135.109) to all marketers such articles to submit data to resolve conclusively the issues of safety to man and animals and the effectiveness of such articles (F.D.C. Nos. 58834/6; S. Nos. 40-138 F. 95-841 F. N.J. No. 20)

#### DRUGS/Human Use

**Acetaminophen, phenopropionolamine HCl and chlorpheniramine maleate combination tablets, at St. Louis Dist. Mo.**

Charged 6-6-74: when shipped by C. M. Bundy Co., Cincinnati, Ohio, the article's strength differed from represented strength since the article contained approximately 80 percent of the declared chlorpheniramine maleate; 501(c). Default decree ordered destruction. (F.D.C. No. 59771; S. No. 107-465 N.J. No. 21)



**Aglian tablets, U.S.P.,** at Muskegon, W. Dist. Mich.

Charged 7-18-74: when returned from Inwood, N.Y., to Generic Drug Co., Muskegon, Mich., the quality of the article, labeled in part "Digloam U.S.P. . . . Manufactured for Rugby Laboratories, Inc., Inwood, L.I. N.Y.," fell below U.S.P. standards, since the article failed the U.S.P. content uniformity requirements. 501(b). Consent decree ordered destruction. (F.D.C. No. 59718; S. No. 42-581 G; N.J. No. 22)

**Golden Seal camphor salve, Honey Cherry cough syrup, Eyedrope solution, Triple Strength No. 18 Holmoet, and No. 35 embrocation,** at Hammond, N. Dist. Ind.

Charged 5-22-74: while held by Indiana Botanic Gardens, Hammond, Ind., who manufactured the articles using components shipped in interstate commerce, the circumstances used for the articles' processing, packing, and holding failed to conform with current good manufacturing practice—501(a)(2)(B); the labeling of the Golden Seal camphor salve lacked adequate directions for use, since it lacked statements of all its intended uses and lacked the frequency and duration of application—502(f)(1); and the Honey Cherry cough syrup lacked adequate warnings against administration for children under 2 years of age except as directed by a physician—502(f)(2). Default decree ordered destruction. (F.D.C. No. 59767; S. No. 39-881 G; N.J. No. 23)

**Diapne enteric-coated urinary antiseptic tablets,** at New Orleans, E. Dist. La.

Charged 7-29-74: when shipped by C. M. Bundy Co., Cincinnati, Ohio, the quality of the article, labeled in part "Pantab URPAN Pan American Laboratories Inc., New Orleans, La. . . . tablets," fell below its purported and represented quality, and the statement "enteric coated red tablets" in the package insert was false and misleading, since the article did not disintegrate after 6 hours in simulated intestinal fluid. 501(c). 502(a). Default decree ordered destruction. (F.D.C. No. 59829; S. Nos. 54-175/6 H; N.J. No. 24)

#### DRUGS/Veterinary

**Medicated feed premix,** at Kewts, N. Dist. Ind.

Charged 8-31-71: when shipped by Walter Henley (Davis Enterprises), Lewisburg, Ohio, the article, labeled in part "Rachelle Super Chloracel 250-Swime . . . Medicated Feed Premix . . . Chlorotetracycline . . . Sulfamethazine . . . Penicillin . . . Manufactured . . . For Rachelle Laboratories, Inc. . . . Long Beach, California," was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to its use or intended use. 501(a)(5). Subsequently, a New Animal Drug Application having become effective for the article, a consent decree authorized release to Rachelle Laboratories, Inc., Long Beach, Calif., for bringing into compliance with the law. (F.D.C. No. 57424; S. No. 93-541 E; N.J. No. 25)

#### MEDICAL DEVICES

**Diapulse electromagnetic energy generator,** at Mocksville, N. Dist. N.C.

Charged 1-22-73: when shipped in interstate commerce after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the accompanying treatment chart contained false and misleading claims for infections, fracture, bone and tissue healing, bursitis, arthritis, low back pain, and blood flow to peripheral areas, and the labeling of the article lacked adequate directions for lay use, and adequate information for use by licensed practitioners could not be prepared. 502(a). 502(f)(1). The article was claimed by Dr. Wilham M. Long, Mocksville, N.C., who denied the charges. The parties served written interrogatories on each other and moved for summary judgment. In finding for the Government and condemning the article, the court said:

"Claimant contends, in substance, that the Diapulse device in his professional judgment based upon his two decades of experience has some value in the treatment of several human ailments, and in any event, is completely safe and harmless. Claimant also contends that the Diapulse device cannot be condemned for failure to be adequately labeled with directions for use pursuant to 21 U.S.C. § 352(f)(1), when in his possession and control, because it is exempted by plaintiff's own regulations, 21 C.F.R. § 1.106(d).

"The Court does not intend to direct much time to a detailed discussion or analysis of this controversy. The Diapulse device is no stranger to condemnation proceedings under 21 U.S.C. § 334. The Diapulse device has been unanimously condemned (1) use that word in both its legal and common vernacular meanings); by the various courts which have had occasion to examine it and pass upon its merits. Indeed, the Diapulse Corporation of America is presently under a federal court injunction prohibiting the shipment of the device in commerce . . . .

"Claimant's answer to plaintiff's interrogatory number 5, admits that the Diapulse device was shipped in interstate commerce. The pleadings, answers to interrogatories and, most particularly, the affidavits of Dr. Joseph B. Davis, Dr. Fred L. Altman and Physician Robert J. Kennedy in support of plaintiff's motion are unrefuted and overwhelming. . . . The Diapulse device has absolutely no useful medical purpose whatsoever. It is concluded, therefore, that the Diapulse device is misbranded within the meaning of 21 U.S.C. § 352(a), and the proper subject of condemnation pursuant to 21 U.S.C. § 334(a).

"Plaintiff also alleges that the Diapulse device should be condemned for misbranding within the meaning of 21 U.S.C. § 352(f)(1). That section of the Act provides that a device shall be deemed to be misbranded unless its labeling bears adequate directions for use. Claimant contends that since he is a licensed practitioner of medicine in the State of North Carolina, he brings the Diapulse within 21 C.F.R. § 1.106(d), a regulation exempting under certain conditions the 'directions for use' requirement of 21 U.S.C. § 352(f)(1). . . .

"Having previously concluded that the Diapulse device should be condemned for misleading labeling under 21 U.S.C. § 352(a), the Court finds it unnecessary to resolve the issue with respect to misbranding under § 352(f)(1). Plaintiff contends that since the treatment chart does not mention any relevant hazards, side effects, contraindications, or precautions under which practitioners can use the device safely and for the purpose for which it is intended it should be condemned for failure to provide adequate directions for use. The trouble with this contention is that the device apparently has no hazards, contraindications, or side effects, and no precautions are necessary. Since the plaintiff has completely satisfied the Court that the device has no purpose, it would appear rather inconsistent to condemn it for failure to provide adequate directions for use. Moreover, a decision of the § 352(f)(1) issue, regardless of who prevailed, would not affect the result of this action, i.e., the device must be condemned under § 352(a) in any event.

"For the foregoing reasons, it is concluded that the defendant's motion for summary judgment should be denied and the plaintiff's motion allowed.

Default decree ordered destruction. (F.D.C. No. 58456; S. No. 1-168 F; N.J. No. 26)

**Diapulse electromagnetic energy generators,** 7 seizure actions, at Franklin, W. Dist. Pa.; Des Moines, S. Dist. Iowa; Des Moines, S. Dist. Iowa; Denver, W. Dist. Colo.; Harrisburg, M. Dist. Pa.; Kaskpell, Dist. Mont.; Clearmont, Dist. Mo.

Charged 10-10-72, 10-20-72, 10-24-72, 12-12-72, 1-12-73, 3-9-73, 10-18-73: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' labeling lacked adequate directions for lay use, and adequate information for use by licensed practitioners could not be prepared. 502(f)(1). Claimants to the articles filed answers to the complaints. Based on the pleadings, motions for judgment on the pleadings were granted the Government as to the articles at Franklin, Pa., and at Denver, Colo. In the action at Kaskpell, Mont., the claimant filed a consent to the taking of a default decree against the article. In the remaining actions, the Government filed written interrogatories upon the claimants. In the two actions at Des Moines, Iowa, the court granted the Government's motions for summary judgment based upon the answers to the interrogatories. In the Harrisburg, Pa., and Clearmont, Mo., actions, the court granted the Government's motions for default decrees based upon the failure of the claimants to answer the interrogatories. The decrees in all the actions ordered the articles destroyed. (F.D.C. Nos. 58353, 58400, 58425, 58564, 58705, 58721, 59514; S. Nos. 67-160 F, 41-719 F, 41-720 F, 34-382 F, 66-465 F, 83-761 F, 40-174 F; N.J. No. 27)

**Diapulse electromagnetic energy generators,** 3 seizure actions, at Truth or Consequences, Dist. N. Mex.; Edinburg, S. Dist. Tex.; and La Feria, S. Dist. Tex.

Charged on or about 5-1-74, 6-10-74, 6-10-74: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' labeling lacked adequate directions for lay use, and adequate information for use by licensed practitioners could not be prepared. 502(f)(1). Default decrees ordered destruction. (F.D.C. Nos. 59758, 59793/4; S. Nos. 88-165 H, 88-316 H, 88-307/8 H; N.J. No. 28)

#### NOTICES OF JUDGMENT on Criminal Actions FOOD

**Altman Foods, Inc.,** Max C. Altman, senior vice president, and Sidney Schuman, warehousing director, Atlanta, N. Dist. Ga.

Charged 10-16-72: grits, rice, egg noodles, and flour were held in a building accessible to rodents and were contaminated with rodent filth. 402(a)(3), 402(a)(4). Guilty plea by corporation, fine. Guilty plea by Max Altman, fine, and probation. Guilty plea by Sidney Schuman, probation. (F.D.C. No. 58132; S. No. 3-790 F et al.; N.J. No. 29)

**Martin Blanton Co.,** and Gary E. Dunfee, manager, Ironton, S. Dist. Ohio

Charged 12-3-73: potato slices and diced potatoes were held in a building accessible to rodents and were exposed to contamination by rodents. 402(a)(4). Nolo contendere pleas, fines. (F.D.C. No. 59247; S. No. 29-821 G et al.; N.J. No. 30)

**James W. Booker, Va Hygiene Crab Co.,** Baton, S. Dist. Miss.

Charged 3-13-74: when shipped, four lots of crabmeat, labeled in part, (count 1) "Fresh All Lump Crabmeat Captain Bill's Fresh Crab Meat," (count 2) "All Lump Crabmeat," (count 3) "Special Crabmeat," and (count 4) "Claw Crabmeat. Captain Bill's Fresh Crab Meat," contained coagulase positive *Staphylococci*, *E. coli*, bacterial filth, and/or decomposed crabmeat, and the articles had been prepared and packed under insanitary conditions. 402(a)(3), 402(a)(4). Nolo contendere plea, fine. (F.D.C. No. 59242; S. No. 2-728 E et al.; N.J. No. 31)

**Central Fish & Oyster Co.,** and David E. Marvey, production manager and secretary, Los Angeles, C. Dist. Calif.

Charged 11-21-73: by grand jury, breeding mink was held in a building accessible to rodents and was contaminated with rodent filth. 402(a)(3), 402(a)(4). Guilty plea by corporation, fine. Guilty plea by individual, suspended sentence, and probation. (F.D.C. No. 59302; S. No. 44-963 F; N.J. No. 32)

**Fujiya, Ltd.,** and Yoshihiko Tamada, vice president, Honolulu, Dist. Hawaii

Charged 2-25-74: sweet rice and sweet rice flour were held in a building accessible to insects and were contaminated with insect filth. 402(a)(3), 402(a)(4). Guilty pleas, fines. (F.D.C. No. 59306; S. Nos. 75-885/6 F; N.J. No. 33)

**Jacob Haller Co.,** Robert A. Haller, chief executive officer and chairman of board of directors, and Donald A. Walker, warehouse superintendent, Erie, W. Dist. Pa.

Charged 4-25-74: flour, dog food, and sunflower seed were held in a building accessible to rodents and were contaminated with rodent filth. 402(a)(3), 402(a)(4). Guilty pleas, fines. (F.D.C. No. 59490; S. No. 83-503 G et al.; N.J. No. 34)

**Leader Candies, Inc.,** Jack Kastin, president, and Leon Kastin, vice president, Brooklyn, E. Dist. N.Y.

Charged 9-11-73: against the corporation, and 1-29-74 against individuals: Kastin's raspberry candy, Kastin's assorted filled candies, Kiddie Treats candy, and Kastin's Licorice Pastels candy contained rodent, insect, and/or miscellaneous filth, and had been prepared, packed, and held under insanitary conditions. 402(a)(3), 402(a)(4). Guilty plea by corporation, fine. Guilty plea by individuals, fine, and probation. (F.D.C. No. 59246; S. No. 2-397 E et al.; N.J. No. 35)

**Anthony P. Mackiewicz, V/a Brighton Bakery,** Chicago, N. Dist. Ill.

Charged 4-30-74: flour was held in a building accessible to rodents and insects and was contaminated with rodent filth. 402(a)(3), 402(a)(4). Guilty plea, fine, and probation. (F.D.C. No. 59624; S. No. 23-081 F et al.; N.J. No. 36)

**Radial Warehouse Co.,** Jerry Ink, vice president, and Richard H. Schons, Jr., warehouse manager, North Kansas City, W. Dist. Mo.

Charged 3-7-74: donut mix was held in a building accessible to rodents and was contaminated with rodent filth. 402(a)(3), 402(a)(4). Nolo contendere plea, fines. (F.D.C. No. 59170; S. No. 50-507 G; N.J. No. 37)

**Tabatchnick's Millburn, Inc., V/a Tabatchnick's Smoke House,** Vauxhall, Dist. N.J.

Charged 1-23-74: smoked chubs were prepared, packed, and held under insanitary conditions whereby they may have become contaminated with filth and may have been rendered injurious to health (i.e., botulinum spores) contrary to the regulations relating to good manufacturing practices and safe use of preservatives in the production of smoked chubs. 402(a)(4). Guilty plea, fine.

The defendant also consented to a decree of permanent injunction that permanently enjoined preparing, packing, or holding smoked chubs under insanitary conditions so that they may be rendered injurious to health and may become contaminated with filth and enjoining cooking smoked chubs at temperatures or under conditions other than those specified in the regulations. (F.D.C. No. 58592; S. No. 55-182 E; N.J. No. 38)



**Thurman Co., and Louis S. Epstein, president, and Harry Epstein, treasurer, Boston, Dist. Mass.**

Charged 4-17-74: flour, rye meal, sesame seeds, corn flour, cornmeal, and corn cobs were held in a building accessible to rodents and birds and were exposed to contamination by rodents and birds; and one lot of flour was contaminated with rodent filth, 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Nolo contendere pleas by individuals; fines. (F.D.C. No. 59409; S. No. 13-965 F et al., N.J. No. 39)

**Three Star Smoked Fish Co., and Howard Klein, general manager, Los Angeles, C. Dist. Calif.**

Charged 11-21-73 by grand jury: salmon was prepared and packed as smoked salmon pieces, under insanitary conditions whereby it may have become contaminated with filth, contrary to the regulations relating to current good manufacturing practice (sanitation) in manufacturing, processing, packing, and holding of human foods, 402(a)(4). Nolo contendere pleas; fines suspended, and probation. (F.D.C. No. 59344; S. No. 43-904 F; N.J. No. 40)

**Boris Waters, V/a Waters Seafood, and Clarence L. Waters, plant manager, at Cedar, S. Dist. Ala.**

Charged 7-16-74: when shipped, lump crabmeat and special crabmeat contained E. coli and bacterial filth and had been prepared and packed under insanitary conditions, 402(a)(3), 402(a)(4). Guilty pleas; fines. (F.D.C. No. 59725; S. No. 628 G et al., N.J. No. 41)

**White Villa Grocers, Inc., Harold F. Hall, vice president, and Marion V. Cholecki, plant operations manager, West Carrollton, S. Dist. Ohio.**

Charged 3-13-74 in 2 actions: action involving Sept. '72 FDA inspection—cheese and flour were held in a warehouse accessible to rodents and were exposed to contamination by rodents—402(a)(4); and action involving July '72 FDA inspection—flour and bird seed were held in a warehouse accessible to rodents and were exposed to contamination by rodents, and the bird seed was contaminated with rodent filth—402(a)(3), 402(a)(4). Nolo contendere pleas by corporation; fines. Nolo contendere pleas by individuals; fines suspended. (F.D.C. No. 58666; S. Nos. 27-246/8 F, 30-897 G, 30-899 G; N.J. No. 42)

#### NOTICE OF JUDGMENT on Criminal Action BRIEFS

**Henry J. Isanahigh, V/a RBA Distributor, Wyoming, W. Dist. Mich.**

Charged 8-16-73: the veterinary prescription drug Desamycin solution was delivered to salesmen for subsequent sale to farmers without a prescription or other order of a licensed veterinarian, thereby resulting in the article failing to comply with the conditions for exemption from adequate directions for use due to the possessor not being lawfully engaged in the wholesale and retail distribution of such drug and due to lack of such prescription or order, and the veterinary prescription drugs estradiol suspension and omeprazole synthetic were held for sale to farmers without a prescription or other order of a licensed veterinarian, thereby resulting in a similar failure to comply with the conditions for exemption from adequate directions for use, 502(b)(1). Guilty plea; fine. (F.D.C. No. 59165; S. No. 38-241 F et al., N.J. No. 43)

#### NOTICES OF JUDGMENT on Injunction Actions

**Ferndale Laboratories, Inc., and F. Mertz Cincelli, president, Ferndale, E. Dist. Mich.**

Charged 7-13-72 in complaint for injunction that the defendants were engaged at their Ferndale, Mich., plant in manufacturing, processing, packing, labeling, and holding various articles of drugs for human use (including injectable drugs, such as Aruginous iron acodylate, strychnine sulfate & sodium glycerophosphate injection, and liver injection; drugs in tablet and capsule form, such as phenobarbital tablets, and Gerithene ethinyl estradiol, methyltestosterone, and vitamin combination capsules, and drugs in fluid and semifluid form, such as Special Formula chloral hydrate & tinc. nux vomica combination elixir, and pramoxene hydrochloride acetate & pramoxene hydrochloride lotion), in distributing a number of such drugs in interstate commerce, and in holding for distribution and sale a number of such drugs after shipment of one or more of their components in interstate commerce, that FDA inspections showed that the defendants' production methods, facilities, and controls were inadequate in a number of specified respects, that samples of a number of the defendants' drugs had been collected and a number of specified violations of law had been found with respect to such drugs, that, when shipped in interstate commerce, a number of the defendants' drugs were new drugs without effective approved New Drug Applications, that, when shipped and while held for sale after shipment in interstate commerce, the defendants' drugs were manufactured, processed, packed, and held under circumstances lacking conformity with current good manufacturing practice, that the strength and quality of a number of the defendants' drugs differed from and fell below the drugs' represented strength or quality, or the drugs' official compendium strength and quality, that another substance had been substituted in part for some drugs, that the labeling of some drugs lacked the prescription legend, lacked adequate directions for use, and contained false and misleading statements with respect to the identity, strength, and quality of the article, and the label of some drugs lacked the established name of each active ingredient, 501(a)(2)(B), 501(b), 501(c), 501(d)(2), 502(a), 502(b)(1)(A)(i), 502(f)(1), 503(b)(4), 505(a).

A consent decree of preliminary injunction enjoined the violations complained of, enjoined the interstate shipment of any drugs on hand, and the intrastate distribution of any drugs on hand containing interstate components, unless such drugs had been examined by FDA, necessary recalls had been made, and such drugs brought into compliance with the law, and similarly enjoined the distribution of drugs to be produced by the defendants unless and until a number of specified methods, facilities, and controls conforming to current good manufacturing practice were effected. Following compliance by the defendants with the terms of the injunction, and upon motion of the defendants and without objection by the Government, the court ordered the action dismissed. (Inj. No. 628, S. No. 2-920 F; N.J. No. 44)

**James Ferrera & Sons, Inc., and Harold H. Ferrera, president, Don H. Ferrera, vice president, and William Doherty, warehouse manager, Canton, Dist. Mass.**

Charged 7-12-72 in complaint for injunction that the defendants were engaged in their food storage warehouse at Canton, Mass., in holding food (shipped in interstate commerce) for sale, that the warehouse was accessible to rodents, that the food was contaminated with rodent filth, and that such food was distributed in interstate commerce, that FDA inspections had disclosed the existence of a number of insanitary conditions, and that the defendants had been warned of the existence of insanitary conditions on a number of occasions, 402(a)(3), 402(a)(4).

A consent decree of permanent injunction enjoined the violations complained of, and enjoined the interstate shipment of any food held at the defendants' warehouse or the placing of any food in the warehouse

unless and until a number of specified methods, facilities, and controls were effected, and the food in hand was brought into compliance with the law. (Inj. No. 632, S. No. 13-595 F et al., N.J. No. 45)

**LR Drug Co., Stuart Lazarus, president, Leonard S. Wayne, executive vice president, and Benjamin R. Bessing, production vice president, Union, Dist. N.J.**

Charged 7-27-71 in complaint for injunction that the defendants were engaged in manufacturing, processing, packing, labeling, and holding drugs and in distributing in interstate commerce such drugs and in holding for sale, after shipment in interstate commerce of one or more components, a number of such drugs, that FDA inspections reveal a number of inadequacies in the circumstances used in the production of such drugs, that the strength and/or quality of a number of the defendants' drugs differed from and fell below the strength and/or quality they were represented to possess, or the strength and/or quality set forth in the U.S.P. or N.F., that a number of drugs had had a substance substituted in whole or in part for the drug, that the labeling of a number of drugs contained false and misleading statements with respect to the identity, strength, and quality of the drug, that the labeling lacked adequate warning against unsafe use, and that the defendants were well aware that their activities were in violation of the law, 501(b), 501(c), 501(d)(2), 502(a), 502(f)(2). A temporary restraining order was entered enjoining the violations complained of and imposing a number of other specified conditions. The defendants contended the temporary restraining order and the Government's proposed preliminary injunction exceeded the proper scope of an injunction and in several respects exceeded the FDA's statutory authority. In finding for the Government the court said:

"This Court granted the government's request for a Temporary Restraining Order which enjoined further interstate shipment of drugs by defendant until certain conditions had been fulfilled. First, the methods, facilities and controls for manufacturing, processing, packaging, and labeling of defendants' drugs were to be brought into conformity with the current good manufacturing practices, as defined in 21 C.F.R. §131.14. Specifically, but not exclusively, defendants were directed to correct ten deficient practices in their quality control and record keeping. As a second condition upon future interstate commerce, defendants were required to grant duly authorized Food and Drug Administration inspectors access to defendants' plant for the purpose of inspecting defendants' records, materials, equipment and labeling in order to assure to the satisfaction of the government, that defendants had in fact realigned the operation of the plant in conformity with current good manufacturing practices. Third and finally, all the drugs on hand at defendants' plant site were to be subject to examination by officials of the Food and Drug Administration, assays were to be made in order to assure the safety, identity, purity, strength and quality of these drugs, and recalls were to be made of any line of drug determined to be adulterated or misbranded. These drugs would then have to be examined and, if similarly defective, destroyed or brought into compliance with the law under the supervision of the Food and Drug Administration. The expenses for the inspecting, assaying and recall operations were to be borne by the defendants."

#### THE BREADTH OF THE INJUNCTION

"Defendants vigorously oppose what they regard as a loosely worded order. The complaint is that current good manufacturing practices' presents no ascertainable standard of performance assuming defendants make a good faith effort to cooperate with FDA officials in complying with the sanctions with which has no quarrel. Because they are reputedly without guidelines, the defendants fear they are left 'at the mercy of a summons of contempt'.

"Where, as here, the defendants have been engaged in an overt, long standing, schematic and ongoing thwarting of the law, particularly a law enacted for the protection of an otherwise helpless consumer, the specificity which defendants can respectfully demand under Rule 65(d) can hardly compare to that which might be afforded were there only a single, isolated infraction. None of the cases cited by defendant offer situations in which the public interest in barring adulterated or misbranded drugs from interstate commerce has been sacrificed or attenuated by an overbearing concern for tightly drawn orders bearing only enumerated violations.

"In misbranding cases (e.g. *United States v. Article of Drug, etc.*, 362 F.2d 923, & *United States v. Wiltsie Corp.*, 345 F.2d 864), it is a relatively simple matter for the court to fashion an order which shall proscribe the false or misleading material. *United States v. Lampar Co.*, 293 F. Supp. 147, 155 (D.D. 1968). Supervising compliance is also relatively easy. The facts in this case alone are excellent proof that narrowly worded order enjoining adulteration, on the other hand, can hardly curb the reckless infractor of a highly culpable drug manufacturer, whether his adulterating tactics are ingenious or ingenious. Similarly, consider[ing] the multifaceted imperfections of the LR Drug plant operation, and consider also the innumerable possible defects which may be located in the future, it would be extremely impractical to ask the FDA, which must supervise compliance, to bring a new action for each added infraction detected, no matter how small or no matter how closely incident to past violations. This proposition was not summarized by the court in *United States v. RMI*, 298 F.Supp. 1221 (D. Conn. 1969), in which the Securities and Exchange Commission had asked for and received an injunction closely worded to Section 5(a), (c) and 17(a) of the 1933 Act, with the enumeration of a few additional unlawful practices.

"The danger of overbreadth, which confronted the Third Circuit in *Wiltsie*, is missing in this case. The misbranding, 'current good manufacturing practices' is a term of art within the industry. The drug manufacturer is well aware of what is meant by current good manufacturing practices, and there is every reason to believe that reputable manufacturers have welcomed the efforts of the FDA in defining that phrase. Regulations promulgated by the Secretary of Health, Education and Welfare under the Act, 21 C.F.R. §11 (rev. 1971). Misbranding, on the other hand, is nowhere defined so elaborately in regulations, but is incidentally defined by scattered references or examples. By and large, the metes and bounds of misbranding are delineated by case law.

"The court in *United States v. Lampar Co.*, supra, found that numerous drugs produced by defendant were adulterated within the meaning of 21 U.S.C.A. §351(a)(2)(B). The court granted the government's request for an injunction prohibiting interstate drug commerce.

"Until the method used in and the facilities and controls used for, their manufacture, processing, packaging and holding conform to and are operated and administered in conformity with current good manufacturing practices to assure that such products meet the requirements of the Act as to safety and have the identity and strength and meet the quality and purity characteristics which they purport or are represented to possess.

"Id. at 154. The court suspended the operation of this order for ninety days so that defendants could all plant procedures with current good manufacturing practices by correcting the deficiencies specifically enumerated in the court's finding of facts. However, it cannot be inferred from a fair reading of the opinion that the court intended this reference to specific findings in any way to limit its overall mandate that defendants observe current good manufacturing practices in the future.

"Other courts, in enforcing regulatory legislation, have used little more than a recitation of state language in wording injunctions and have not regarded this practice as offensive to Rule 65(d)."





States v. *INN*, *supra*; *United States v. Schlackman Drug Co.*, 206 F. Supp. 801 (S.D. Ill. 1962); *United States v. Sharnwood*, 175 F. Supp. 480 (S.D.N.Y. 1959). And if there is reason for defendants to fear that borderline activities may violate the injunction, an advisory opinion may be sought from the regulatory agency. *United States v. INN*, *supra*.

A word should also be mentioned about defendants' 'peril of a summons of contempt,' particularly since specific intent is not an element of proof. This Court has already itemized defendants' past Food, Drug and Cosmetic Act transgressions. They are sufficiently severe and close in time together that the Court can only suspect that defendants are either unwilling or unable to comply with the law.

The argument that enforcement of regulatory standards by contempt proceedings, where specific intent was not an element of proof, is an unjustified hardship was emphatically rejected in *United States v. Caster Channel Wing Corp.*, 247 F. Supp. 481 (D. Md. 1965), *aff'd*, 376 F.2d 675, (4th Cir.), *cert. denied*, 389 U.S. 850 (1967).

#### RESTRAINT OF INTERSTATE COMMERCE UNTIL FULL PLANT INSPECTION BY FDA OFFICIALS AND COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICES.

Defendants contest that part of the proposed order which restrains Lit Drug from engaging in interstate commerce until FDA officials have made a thorough plant inspection of all equipment, materials, labels, containers and procedures and are satisfied that such are in compliance with current good manufacturing practices. Defendants attach this as pre-screening not authorized by the Food, Drug and Cosmetic Act, and take the view that this Court under 21 U.S.C.A. §332 may only enjoin illegal activities and leave defendants to risk a contempt citation in the event of noncompliance. This narrow construction of §332 is not only unjustified but plainly hostile to the intent of Congress in enacting the Food, Drug and Cosmetic Act. Effective deterrence as a weightier and more beneficial weapon against drug adulteration than criminal sanctions is a message that pervades the legislative history of this Act. See generally 1962 U.S. Code Cong. & Admin. News 2884. Congressional concern for the manner in which a drug is produced, aside from a consideration of the composition of the drug, is apparent in the new language of 21 U.S.C.A. §351(a)(2) by which a drug is deemed adulterated if it has been processed, packed or held under unsanitary conditions, or if any manufacturing, packing or holding method does not conform to current good manufacturing practice. Thus a drug may be pharmaceutically perfect in content but still be regarded as adulterated under the law. Congress preferred this approach rather than rely upon governmental intervention once the injurious drugs had entered the stream of commerce. The emphasis upon precautionary measures is evident. It is equally apparent that Congress concluded that, as is the case here, such legal machinery would be necessary where the drug manufacturer was either incapable or unwilling to comply with the law.

Because there is no evidence that the restraint upon interstate commerce until adequate inspection has been made is repugnant to the language of 21 U.S.C.A. §332(a), and because there is every reason to believe that it is entirely consistent with congressional intent in preventing drug adulteration, I cannot agree with defendants that the order exceeds the authority enacted in the statute in this respect.

Defendants fear that inspection rights will give the government power of decision, in effect, to interdict future violations, if detected. While this Court does urge defendants to abandon whatever evasive schemes of noncompliance and noncooperation they may have pursued in the past, I can only reiterate that under 21 U.S.C.A. §332(b) defendants are guaranteed a jury trial if any contempt proceedings are brought by the government.

#### RESTRAINT UPON INTERSTATE COMMERCE UNTIL ASSAY OF DRUGS PRESENTLY IN THE LIT DRUG PLANT AND RECALL OF ASSAYED LOTS

Defendants complain against that part of the order which forbids interstate commerce until the FDA has had an opportunity to examine and assay all of the drugs presently being held at the Lit Drug plant and to recall those assayed lots which prove to be adulterated. Defendants do not quarrel with the government demand for a recall of drugs which the plant inspection reveals to be adulterated, but they do argue that this procedure is not related to the future production of drugs, inasmuch as the government has adequate safeguards in those parts of the injunction which direct defendants to make specific corrections. Insofar as the defendants argue that such procedure is not authorized by the Act their argument must fail for the reasons already assigned by this Court in the preceding discussion. Defendants rely chiefly upon *Hygrade Food Products Corp. v. United States*, 160 F.2d 816 (8th Cir. 1947), for the proposition that the order in the instant case is harsh and punitive rather than remedial.

The reviewing court simply held that in light of defendant's evident good faith, the two year restriction, from which defendant could not apply for a modification, was arbitrary and unjustified. Here, however, the time during which interstate commerce is restricted is clearly related to a valid objective.

Hence, it is totally reasonable that the FDA should have an opportunity to examine and assay given lots both within the plant and from those drugs recalled, in order to assure the complete safety of defendants' future operations. Seen in this light, the examination and assay of drugs manufactured already is not so unrelated to the future production of drugs as defendants argue. Nor is there anything harsh or punitive in what the government requests. The Order will reflect this Court's continuing jurisdiction for the purposes of enforcement or modification of the Order.

In accordance with the above opinion, a decree of preliminary injunction was entered against the defendants. Subsequently, the firm was unable to pay its debts as they fell due, and sold its assets. *On*, No. 606; S. No. 56-062 D et al., N.J. No. 46).

<sup>16</sup> *Food Packing Co., Inc.*, Robert E. Wool, president, and Wilbur Wool, production manager, San Jose, N. Dist. Cal.

Charged 6-5-72 in complaint for injunction: that the defendants were engaged in the business of preparing, packing, holding, and distributing in interstate commerce, canned fruit cocktail; that such food contained machinery mold; that such food was prepared and packed under unsanitary conditions; and that the defendants were well aware that their activities were in violation of the law. 402(a)(3), 402(a)(4).

A consent decree of permanent injunction enjoined the violations complained of, enjoined the interstate shipment of the 1971 pack of canned fruit cocktail, ordered the destruction of such 1971 pack unless the defendants exported the article, and ordered the maintenance of an appropriate sanitary control program including a number of specified procedures. *On*, No. 627; S. No. 13-411 E et al., N.J. No. 47).

<sup>17</sup> *Yarn Laboratories, Inc.*, v/a American Chemical & Drug Co., San Francisco, N. Dist. Cal.

Charged 11-24-71 in complaint for injunction: that the defendant was engaged at its plant in Foreign Trade Zone No. 3, San Francisco, Calif., in manufacturing, processing, packing, labeling, and introducing and delivering for introduction into interstate commerce for shipment to Saigon, Vietnam, Pax chloridazepoxide hydrochloride tablets, a new drug without an effective approved New Drug Application, and that the defendant had been previously warned by a seizure action and by an FDA inspection against shipping new

drugs without an approved New Drug Application; 505(a).

The defendant denied the charges, alleging that at all times the shipment of PAX was solely and wholly for foreign commerce only and had not involved any interstate commerce, and that the seizure actions mentioned had not involved PAX and had involved merchandise that had been in interstate commerce. After a hearing before the court, the court concluded that, although "[a]ll steps pertaining to or connected with the arrival of this raw material [the chloridazepoxide hydrochloride basic raw material for PAX tablets], the processing thereof into the finished product of 'PAX,' readying the shipment for export and actually exporting the product to its final destination takes place solely and wholly within the Foreign Trade Zone. . . . [T]he article of drug 'PAX' (Chloridazepoxide Hydrochloride) was introduced or delivered for introduction into interstate commerce from Foreign Trade Zone No. 3," and since PAX was a new drug it was not entitled to export exemption provided in 21 U.S.C. §381(d). A preliminary injunction was issued enjoining the interstate shipment of 'PAX' and any other new drug lacking an effective approved New Drug Application. The defendant moved for reconsideration of the preliminary injunction or, alternatively, for a stay of the preliminary injunction, alleging that the Government had introduced no evidence concerning any other article than PAX, that \$100,000 of products other than PAX had been sold, manufactured, and packed, and would have been shipped to Vietnam prior to the filing of the action but for a dock strike, and that defendant's bond of \$10,000 would be declared forfeit if the orders were not allowed to be shipped. After FDA advised the defendant as to the new drug status of the firm's other products, the court entered an order permanently enjoining the interstate shipment of PAX, without an effective approved New Drug Application, from Foreign Trade Zone No. 3 or from other places in California. *On*, No. 619; S. No. 20-568 E et al., N.J. No. 48).

#### NOTICES OF JUDGMENT on Miscellaneous Actions

Mediatric formulations of methyltestosterone, estrogens, methamphetamine hydrochloride, minerals and vitamins; suit for declaratory judgment, Dist. Md.

Charged 7-5-72 in complaint for declaratory judgment by American Home Products Corp., Ayerst Laboratories Division & Ayerst Laboratories, Inc., subsidiary, a Delaware corporation, against H.E.W. Secretary Elliot L. Richardson, FDA Commissioner Charles C. Edwards, and FDA Director of Bureau of Drugs Henry E. Simmons: that the plaintiff manufactures and distributes Mediatric capsules, liquid, and tablets, which were first marketed in 1952, 1954, and 1956 respectively; that the Drug Amendments of 1962 added the concept of efficacy to the law's definition of "new drug" but contained an exemption commonly referred to as the "grandfather clause"; that the controversy between the plaintiff and the defendants is whether Mediatric products is entitled to such exemption; that the Mediatric products had never been the subject of a New Drug Application, were generally recognized as safe for their suggested use, and were exempt from the efficacy provisions of the Drug Amendments of 1962; that FDA had sent the plaintiff a letter enclosing a Federal Register announcement as to the lack of substantial evidence that a combination (Ritonic) of methyltestosterone, ethinyl estradiol, methylphenidate hydrochloride, and vitamins lacked evidence that it was effective and as to the withdrawal of the 1959 effective New Drug Application of the Ritonic combination; that the FDA letter stated that the plaintiff's Mediatric products were related and were affected by the Ritonic withdrawal announcement, citing notice of proposed rulemaking that applied New Drug Application withdrawal notices to identical, related, or similar drugs not listed in such notice; that the defendants' theory that the withdrawal of NDA approval for one drug was applicable to another drug marketed without an NDA by a different manufacturer was contrary to FDA's past position concerning NDA taken over the years; that Mediatric was distinguishable from Ritonic, and that there was an actual controversy justifiable in character as to whether the efficacy requirement added to the FDCA Act by the Drug Amendments of 1962 applied to plaintiff's Mediatric products.

The Government admitted that Mediatric had never been the subject of a New Drug Application, denied that the controversy was limited to the "grandfather clause" exemption, admitted that the Government's position was that Mediatric was subject to the efficacy requirement of the Act and was a misbranded drug under the Act, and asserted as an affirmative defense (1) that Mediatric was a new drug without an effective approved New Drug Application, and (2) that Mediatric was a misbranded drug. The parties served written interrogatories on each other. Subsequently, with the concurrence of the Government, the plaintiff moved for, and was granted a stay of the proceedings pending decision by the Supreme Court of five specified suits involving FDA upon which certiorari had been granted on January 8, 1973. Subsequently, the Supreme Court decisions in such suits approved the formulation by FDA of procedural regulations for implementation of the Federal Food, Drug, and Cosmetic Act. In light of such decisions, FDA promulgated rules, and documentary evidence submitted by the plaintiff as answers to the Government interrogatories, the plaintiff deemed it appropriate for the new drug status of Mediatric to be determined by the FDA Commissioner in a formal administrative hearing on the record. Accordingly, pursuant to stipulation, the new drug status of the article was referred to the FDA Commissioner and the court action was dismissed. (Misc. No. 194; N.J. No. 49).

Substantial evidence of drug effectiveness, and hearing regulations on refusal or withdrawal of New Drug Applications; suit for declaratory judgment and injunction, Dist. Del.

Charged 7-12-70 in complaint for declaratory judgment and injunctive relief, by Pharmaceutical Manufacturers Association, a Delaware corporation, against H.E.W. Secretary Elliot L. Richardson and FDA Commissioner Charles C. Edwards: that the Pharmaceutical Manufacturers Association (PMA) had a membership which included approximately 120 companies that accounted for the manufacture and sale of approximately 95 percent of the Nation's prescription products; that PMA was filing the complaint on behalf of its affected member companies; that FDA had promulgated on September 19, 1969, regulations entitled "Hearing Procedure for Refusal or Withdrawal of Approval of New Drug Applications and for Issuance, Amendment or Repeal of Antibiotic Drug Regulations, Interpretative Description of Adequate and Well-Controlled Clinical Investigations" which regulations spelled out the criteria to be applied in determining whether clinical investigations were "adequate and well-controlled" and set forth the standards for determining whether a hearing on the issue of effectiveness need be held before a drug was removed from the market; that after such September regulations were declared void because they were issued without notice of proposed rulemaking and opportunity for comment, FDA published on February 17, 1970, proposed regulations entitled "Hearing Requests on Refusal or Withdrawal of New Drug Applications and Issuance, Amendment or Repeal of Antibiotic Regulations," and "Describing Scientific Content of Adequate and Well-Controlled Clinical Investigations"; that extensive comments on the February proposals were made by interested persons, including PMA, that final regulations were published on May 8, 1970; that such May regulations provided that where the FDA Commissioners proposed the withdrawal of approval of a New Drug Application or repeal of an antibiotic regulation, the affected manufacturer must present a "well organized and full factual analysis of the clinical and other investigational data he is prepared to prove" that the regulations authorized the Commissioner to make "findings and conclusions on such data" and to deny a hearing, if he determines, for example that no adequate and well-controlled clinical investigations supporting



the claims of effectiveness have been identified (i.e., the applicant must show a "reasonable likelihood" that he can produce substantial evidence derived from adequate and well-controlled investigations—that the May 8 regulations recognized "uncontrolled" and "partially controlled" studies only as corroborative evidence that could neither substitute for adequate and well-controlled clinical investigations nor be considered in determining whether the requirements of the regulations for such investigations had been met; that the rigid and mandatory definition of "adequate and well-controlled clinical investigations" was arbitrary and capricious and exceeded the defendants' statutory authority, as did the regulations' authorization of the denial or withdrawal of a New Drug Application without a hearing; that the defendants acted arbitrarily and capriciously as to drugs approved for marketing between 1938 and 1962 in failing to provide an interim period in which to conduct clinical investigations required for the first time by the regulations; that the regulations were further arbitrary and capricious in arrogating to the Commissioner the power *ex parte* and *in camera* to resolve disputed and material factual issues; and that the May regulations irreparably injured the plaintiff and its member companies.

In finding for the Government, the court said:

"In this action for declaratory and injunctive relief, the Pharmaceutical Manufacturers Association (PMA), on behalf of its members, seeks a preliminary injunction restraining the Secretary of Health, Education and Welfare (the Secretary) and the Commissioner of Food and Drugs (the Commissioner) from taking any action in reliance upon the regulations promulgated in the Commissioner's Order of May 8, 1970 (the May regulations'), 35 Fed. Reg. 7250. The defendants oppose the issuance of a preliminary injunction and also move for summary judgment of dismissal on the ground that the May regulations are clearly justified.

"Two purely legal questions are raised by the present action: (1) May the Commissioner validly establish criteria for adequate and well-controlled clinical investigations necessary to demonstrate the effectiveness of drug products already on the market and (2) does the summary procedure specified in the May regulations comport with the Act and the requirements of due process?

#### The Issue Of Substantial Evidence

"PMA first challenges the May regulations on the ground that they arbitrarily define 'adequate and well-controlled clinical investigations' so narrowly and rigidly as to be incompatible with the statutory definitions of 'substantial evidence of effectiveness' as elucidated by the legislative history of the 1962 Drug Amendments. Its argument runs that Congress, in adding the new tests of effectiveness, intended no rigid and narrow standard as to the nature of the evidence necessary to establish effectiveness and that the very concept of 'substantial evidence' was designed to reflect and accommodate the fact that clinical experts often disagree as to the effectiveness of a drug. Hence, it is contended that the statutory standard was designed to insure that any drug 'believed by a substantial number of experts' to be effective could be marketed even if the view of the majority of experts was that the drug was ineffective. The Court is unable to agree with this contention.

"First, the legislative history of the drug amendments of 1962 does not support PMA's view. The 1962 amendments were the culmination of an investigation into administered prices in the drug industry by the Subcommittee on Antitrust and Monopoly, Senate Committee on the Judiciary, under the Chairmanship of Senator Kefauver. Beginning in 1960, the Subcommittee heard a succession of witnesses respecting the testing of all drugs.

"Dr. Charles D. May, Professor of Pediatrics, New York University School of Medicine, testified to the fallacy of assuming that 'a collection of impressions' will furnish the truth, pointing out that 'this approach did not prevent doctors from having unbounded faith in the curative powers of leeches for hundreds of years before scientific evaluation became the preferred means of judging efficacy of therapy.' He testified that '[t]he magnitude of sales of a drug after vigorous promotion is no recommendation for its usefulness or efficacy; and recommended that 'the present concept of controlled methods of evaluation of drugs' be employed to determine efficacy.

"Dr. Louis Goodman, Professor of Pharmacology, University of Utah College of Medicine, and co-author of the medical textbook, 'The Pharmacological Basis of Therapeutics,' likewise pointed out the need for controlled clinical testing. He said that those who had seen 'the mass of laboratory and clinical information submitted to the FDA, even by the very best drug houses' . . . are repeatedly dismayed by the welter of anecdotal case reports and uncontrolled clinical studies . . . Dr. Goodman insisted that there must be 'basic, original, clinical evidence that [a] drug is a useful drug and that the claims made by the manufacturer are valid,' stating that 'the individual practicing doctor cannot be the judge.'

"Dr. Harry F. Dowling, Professor and Head of the Department of Medicine, University of Illinois, testified on the need for minimizing patient and investigator bias, on 'the placebo effect,' and on 'double-blinding.' He emphasized that comparative analysis between patient groups is necessary in order to determine that beneficial changes in the patients are due to the drug rather than to mere chance. He said, 'The proposed bill would make sure that the proper tests had been done and that a summary of this information was available to [the individual physician] at the same time that the drug was placed on the market.'

"The concept of a well-controlled clinical investigation also found support from the drug manufacturers. Eugene N. Beesley, President of Eli Lilly & Co., and then Chairman of PMA, said: 'The Pharmaceutical Manufacturers Association believes strongly that a drug should be effective for the uses which the manufacturer claims for it. Therefore, we support the principle that, before introducing a new drug, the manufacturer should be required to submit to the Food and Drug Administration substantial evidence not only that the drug is safe but also that it produces the results claimed.' Mr. Beesley also stated, 'Whenever effectiveness is to be considered in passing on a New Drug Application, the test of effectiveness is to be whether the drug will produce the specific effects asserted by the manufacturer.'

"Summarizing this kind of testimony, the Subcommittee noted that '[t]he experts emphasized the imperative need for an objective determination of efficacy of the drug products placed on the market,' and it was against this background that the 'substantial evidence' rule emerged from the Senate Committee. It was recognized that proof of drug efficacy, as well as safety, would be necessary, and on July 19, 1962, the Senate reported out a bill designed to strengthen the laws designed to keep unfit drugs off the market in the first instance and speed their removal should they reach the market. An amendment to section 505 of the Act authorized the suspension of a new drug application 'upon a finding that there is a lack of substantial evidence . . . that it will have the effect claimed for it' . . .

Among the changes [following proposals to expand coverage] adopted by the Judiciary Committee was the requirement that all claims for effectiveness, whether made initially in a new drug application or at any time thereafter, must be supported by 'substantial evidence' . . . The Committee also reported that the bill had been amended to set forth a new test of effectiveness. . . .

"This legislative history compels the conclusion that the substantial evidence requirement of the Act was to be applied not only to new drugs coming on the market after 1962 but was to be applied also to the drugs approved for marketing between 1938 and 1962. Congress intended no double standard for determining the effectiveness of drug claims. Further, substantial evidence was defined to mean adequate and well-controlled clinical investigations, i.e., an investigation which was as scientifically sound and objective as it was humanly possible to make . . .

"In order to clarify the type of evidence required to support a claim of effectiveness, the May regulations were issued. They definitively spell out the criteria which have developed and been generally recognized by the scientific community, as essentials of adequate and well-controlled clinical investigations.

"Turning to the criteria set forth in the May regulations, the first requirement provides that a clear statement of the objectives of the study be given. It is simply self-evident that in any study the investigator and evaluator must know what is being studied. This requires, regardless of the manner of the study, that its objective be capable of being understood.

"The second requirement provides that (i) the patients selected for study are suitable based on diagnostic criteria of the condition to be treated and, where appropriate, confirmed by laboratory tests; (ii) the subjects are assigned to test groups in such a way as to minimize bias; and (iii) that pertinent variables, such as age, sex, severity, or duration of disease and drugs used are comparable between test groups. The methods used by the investigator to achieve these fundamental objectives are not defined in the May regulations, but are matters of choice left to each investigator to determine depending upon the disease treated, the drug used, and study design chosen.

"Requirement three provides that the study contain an explanation of 'the methods of observation and recording of results' . . . and the steps taken to minimize bias on the part of subject and observer. The fourth requirement provides that the study be comparative with one of four listed known methods of comparison: as to permit quantitative evaluation of the results of the treatment.

"The fifth and final criterion requires 'a summary of the methods of analysis and evaluation of the data derived from the study' . . .

"The May regulations simply require a study to show on its face that an investigation has been complete which meets these standards for adequate and well-controlled clinical investigations. Such required study are designed to afford a greater assurance of objective results and are in contradistinction to the subjective tests of testimonial, random observations and clinical impressions of physicians which have been relied upon in the past to support claims of efficacy for marketed drugs.

"The Court concludes that the criteria of the May regulations are not arbitrarily rigid. On the contrary, they describe broad scientific standards for measuring the adequacy of an investigation of effectiveness while leaving the details of the investigation and study to the evaluator. These criteria appear quite reasonable and certainly are within the Commissioner's power to issue, particularly since the FDA has found it desirable in the interest of the public health to standardize on a scientific basis the kind of efficacy studies which must be made to support claims of effectiveness for drugs. . . .

#### The Issue Of An Evidentiary Hearing

"PMA's second major challenge of the May regulations is based on the contention that they deny hearing rights guaranteed by the Act and the Constitution. The challenge consists of a two-pronged attack.

"First, PMA contends that an order withdrawing approval of a new drug application may not be validly entered without a hearing, if the drug manufacturer so elects. . . .

"PMA concludes that the provisions of the May regulations which require a showing of 'reasonable grounds' in order to obtain a hearing before denial or withdrawal of a new drug application are contrary to the literal language of section 505(d) and (e).

"This contention, however, lacks merit. The 'opportunity for a hearing' provided in section 505(d) and does not mean that an evidentiary hearing must be held in every case, even in the absence of genuine factual issues in dispute. It is an established principle of law that an administrative agency, such as the FDA, may by general regulations condition the holding of an evidentiary hearing upon an applicant's preliminary showing that 'reasonable grounds' exist therefor [e]xcept any unqualified terms of a statute providing a hearing.

"Second, PMA claims that the May regulations illegally authorize the Commissioner to resolve disputed issues of fact to find a basis for denying a hearing. It argues that the summary procedures relating to evidentiary hearing in the May regulations amount to an impermissible 'rule requiring a party to prove case as a condition to getting a hearing or even to demonstrate that there is a substantial likelihood that will prevail on the merits.' PMA has misconceived the import of these procedural regulations. On the contrary, the May regulations simply provide that a request for an evidentiary hearing will be denied where clearly appears that the medical documentation, which the hearing applicant is required to submit, shows on its face that there is no genuine and substantial issue of fact which precludes withdrawal of the drug approval or repeal of the antibiotic certification regulations, i.e., no adequate and well-controlled clinical investigations have been conducted or identified by the applicant.

"If no adequate and well-controlled studies exist to support the applicant's claim of effectiveness as required by the Act and regulations, an evidentiary hearing would be a futile exercise and a waste of time. . . .

"Of course, if a given request for an evidentiary hearing were to raise an issue of genuine fact within regulations, and the Commissioner were to misapply the rules, that would be subject to correction by Courts.

"The Court therefore holds that the hearing procedures of the May regulations are reasonable and valid procedures and that it was within the power of the Commissioner to require that a genuine and substantial issue of fact be raised as a condition for granting an evidentiary hearing—that is a drug firm be required to demonstrate that it had conducted and identified adequate and well-controlled investigations meeting statutory definition of substantial evidence, in support of its claim for the effectiveness of its drugs.

"The Court having found the May regulations to be valid, PMA's motion for a preliminary injunction was denied. The matters herein decided being purely legal in nature and no genuine issue of material fact is in dispute, the defendants' motion for summary judgment of dismissal will be granted." (Misc. No. 149, N.J. 50)

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

Notices of Judgment are prepared by Food and Drug Division, Office of the General Counsel, DHEW. Published by direction of the Secretary of Health, Education, and Welfare.  
Alexander M. Schmidt, M.D., Commissioner of Food and Drugs  
Washington D.C. February 1, 1975



Children ... So Can  
Act Fast ... Poison

# Protect Your Children

National  
Poison  
Prevention  
Week

March 16-22  
1975



Prepared  
by the  
American  
Pharmaceutical  
Association

United States  
Government Printing Office  
DIVISION OF PUBLIC DOCUMENTS  
Washington, D.C. 20402

POSTAGE AND FEES PAID  
U.S. DEPARTMENT OF H.E.W.  
HEW 393



OFFICIAL BUSINESS

FDAP MEDCA420M R 1  
MED CARE REVIEW UNIV OF MICH  
M2030E SCH OF PUB HLTH II  
1420 WASHINGTON HGHTS  
ANN ARBOR MI 48104

**SUBSCRIPTION ORDER FORM**

ENTER MY SUBSCRIPTION TO **FDA CONSUMER** @ \$8.55. Add \$2.15 for foreign mailing. No additional postage is required for mailing within the United States, its possessions, Canada, Mexico, and all Central and South American countries except Argentina, Brazil, British Honduras, French Guiana, Guyana, and Surinam. For shipment to all other foreign countries include additional postage as quoted.

Send Subscription to: \_\_\_\_\_

NAME - FIRST, LAST																													
COMPANY NAME OR ADDITIONAL ADDRESS LINE																													
STREET ADDRESS																													
CITY															STATE					ZIP CODE									

**PLEASE PRINT**

☐ Remittance Enclosed (Make checks payable to Superintendent of Documents)

☐ Charge to my Deposit Account No. \_\_\_\_\_

**MAIL ORDER FORM TO:**  
Superintendent of Documents.  
Government Printing Office.  
Washington, D.C. 20402