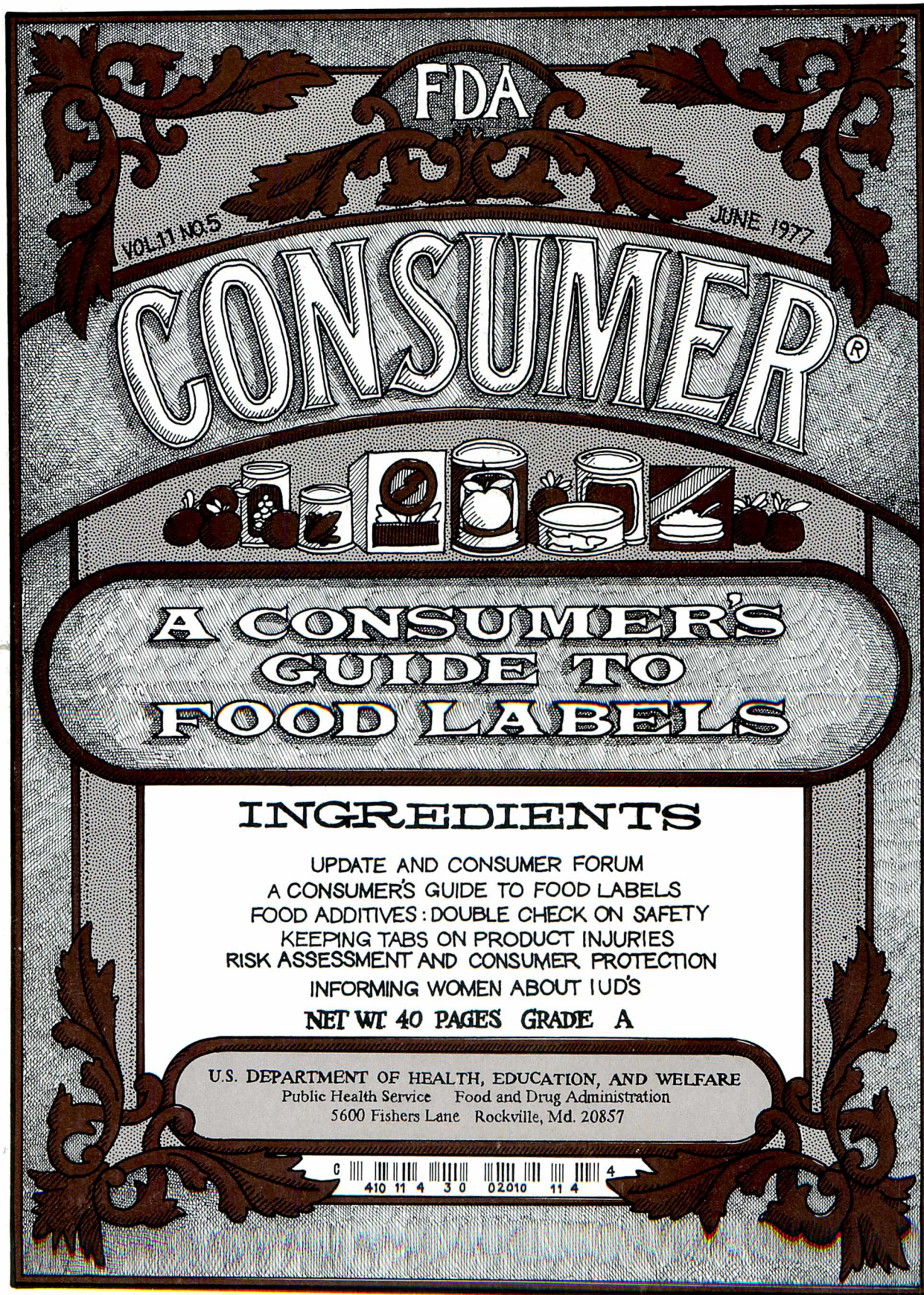


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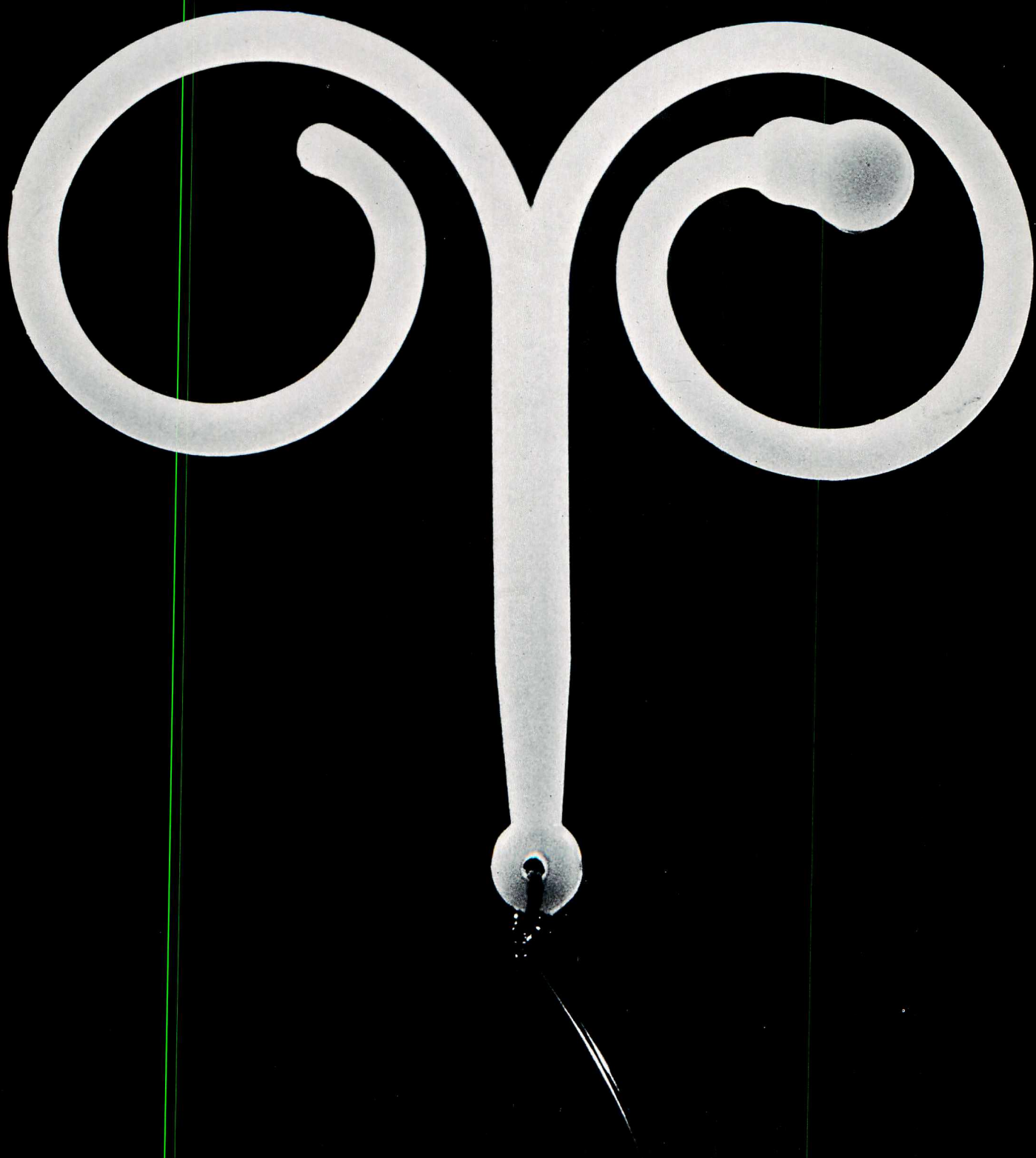
**A CONSUMER'S
GUIDE TO
FOOD LABELS**

INGREDIENTS

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A CONSUMER'S GUIDE TO FOOD LABELS
FOOD ADDITIVES: DOUBLE CHECK ON SAFETY
KEEPING TABS ON PRODUCT INJURIES
RISK ASSESSMENT AND CONSUMER PROTECTION
INFORMING WOMEN ABOUT IUD'S
NET WT 40 PAGES GRADE A

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service Food and Drug Administration
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This Month

When union leader Samuel Gompers once was asked what he wanted for the workers he represented, he is said to have answered with one word: "More." Scientists might give a similar response if asked what they want to know about chemicals that go into the food and drugs and cosmetics we use. This seemingly insatiable hunger to know more sometimes results in the discovery of disturbing information about familiar and trusted substances. Because there are few if any chemicals about which we know everything there is to know, FDA has decided that all approved food additives will be reviewed periodically to assure that they are safe by contemporary scientific standards. An explanation of how this on-going review will be carried out begins on page 8.

Supplying more information to women is the primary purpose of new FDA regulations on the labeling of intrauterine contraceptive devices (IUD's). Beginning this fall, FDA will require that when an IUD is prescribed for a woman she must be given a brochure telling her how the device works and the potential risks associated with its use. The woman must be given the brochure before the device is inserted. There's a report on the new regulations on page 24.

Some consumers undoubtedly feel there ought to be more information on the labels of food products. But food labels already supply quite a bit of material that should be of interest to shoppers who want to know what they are getting for their money. *A Consumer's Guide to Food Labels* tells you what to look for and what it means.

The more FDA knows about the products it regulates the more able the Agency is to protect consumers against potential hazards. But identifying potential hazards is just part of the picture. In order to plan its work and allot its resources, FDA also must establish priorities based on the relative seriousness of the risks posed by regulated products. This process is examined in *Risk Assessment and Consumer Protection*.

One factor in determining risk priorities is the number of actual consumer injuries or illnesses caused by a product or class of products. FDA gets information on product-related injuries from reports on cases treated in hospital emergency rooms. There's more on this reporting system and how it is used in an article entitled *Keeping Tabs on Product Injuries*.

Inside Front Cover Photo: *The Saf-T-Coil is one of five intrauterine contraceptive devices (IUD's) now on the market in the United States. Under a new FDA regulation, when a woman obtains an IUD it will have to be accompanied by a brochure written especially to provide her with important information she should know before using the device. These patient package inserts are described in Informing Women About IUD's.*

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

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

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

Cover Design: Sheldon Cohen and Cameron Gerlach

Update

Raw Materials for Laetrile Seized

Laetrile is a substance made from apricot pits or other plant material that contains the chemical amygdalin. Although there is no scientific evidence that it is effective against cancer, and it is not approved for sale as a drug in the United States, Laetrile is being heavily promoted as a treatment for cancer. The history of Laetrile and the danger to cancer patients who use it is the subject of an article in the December 1976-January 1977 issue of FDA CONSUMER entitled Laetrile: The Making of a Myth. Here's an update.

The Food and Drug Administration has confirmed perhaps the largest enforcement action yet undertaken against commercial producers of the illegal drug Laetrile. Acting under a court order sought by FDA, U.S. marshals in Wisconsin on May 16 seized approximately 12 tons of apricot kernels (amygdalin, the basic ingredient in Laetrile, is usually made from ground apricot kernels); 100,000 unfilled drug capsules; and "several containers" of partially processed apricot kernels. Also discovered were two and one-half 55-gallon drums of ether. Ether, a highly volatile chemical, is used as a solvent in extracting amygdalin from fruit pits.

Much of the raw materials and drug paraphernalia was seized at an old dairy plant in Manitowoc, in eastern Wisconsin. The plant is now occupied by the Mosinee Research Corp. and U.S. Pharmaceuticals, Inc.

FDA Associate Commissioner for Compliance J. Paul Hile said: "The law requires that new drugs be proven effective for their intended use, and it requires us to get remedies off the market if they have not been shown to work. The promoters of Laetrile have been repeatedly urged to come forth with acceptable scientific evidence that it works against cancer. They have never done so. The FDA, therefore, intends to continue to pursue rigorously the legal requirement that it act against the production of this unproven remedy and its movement in interstate commerce."

Laetrile is illegally promoted for the prevention or treatment of cancer or for the alleviation of cancer pain. Despite a decade of scientific testing, according to FDA, the substance has failed to show any promise of effectiveness for any of these claims. At the same time, the FDA has received reports of deaths in treatable cancer patients who rejected proven therapies in preference for Laetrile.

FDA, under Federal law, has judged Laetrile as well as ingredients intended for its manufacture to be an unproved and illegal drug when introduced into interstate commerce.

The FDA further considers Laetrile, when promoted or sold as a food supplement, to be a deceit aimed at circumventing drug regulations, and therefore illegal.

Charges recommended by FDA to the United States Attorney in Milwaukee, William J. Mulligan, were that the products to be seized were:

- Misbranded drugs.
- Drugs manufactured without FDA approval.
- Inadequately labeled to identify relevant hazards, contraindications, side effects, and precautions.
- Adulterated in that apricot kernels contain the poison cyanide.

FDA investigators attempted to inspect the firm's plant in Manitowoc on April 6, 1977. Officials of the firm refused to admit FDA investigators and the Agency obtained an inspection warrant from a U.S. magistrate.

On April 12 company officers again refused inspection and were arrested by U.S. marshals.

After the arrests the manufacturing site was inspected and FDA investigators observed the production of amygdalin from apricot kernels. The finished product was being prepared for shipment as a powder in plastic bags packed in cardboard cartons labeled "amygdalin," "Crude," or "X-1" (for recrystallized amygdalin). The firm's management refused to supply distribution records.

No finished product was found at the time the seizure was carried out.

Consumer Forum

Bust Developers

No wonder the bust developer shown in the upper left hand corner of the bottom photograph on page 10 of the February issue did not work. You have obviously got it hooked up backwards. The metal device is apparently an aspirator designed to be hooked up to a water faucet. When the faucet is turned on, a vacuum would be generated at the side arm and water would come out the end to which you have attached the bust developer. Hooked up the way you have shown, it would be a bust flattener. Try attaching the bust developer to the side arm.

Richard S. Waritz
Wilmington Delaware

Mr. Waritz is correct assuming the purpose of the device is only to create a vacuum. Some devices of this nature have been designed for water massage. Neither type will increase the size of the breast, however, and such devices could be dangerous if used by a woman with a malignant growth in her breast.

A Consumer's Guide To Food Labels

by Margaret Morrison

Food labels provide a great deal of information that can help consumers find out more about what they're getting in the products they buy. Some of this information is required by FDA to be shown on the label; some is included on the label at the option of the manufacturer or processor. Some of the information on food labels may be in the form of symbols or codes or dates.

Here's a rundown of the information most often found on food labels along with a brief explanation of what it means.

BASIC INFORMATION

Certain information must be on all food labels:

- The name of the product.
- The net contents or net weight. The net weight on canned food includes the liquid in which the product is packed, such as water in canned vegetables and syrup in canned fruit.
- The name and place of business of the manufacturer, packer, or distributor.

List of Ingredients

On most foods, the ingredients must be listed on the label. The ingredient present in the largest amount, by weight, must be listed first, followed in descending order of weight by the other ingredients. Any additives used in the product must be listed, but colors and flavors do not have to be listed by name. The list of ingredients may simply say "artificial color" or "artificial flavor" or "natural flavor." If the flavors are artificial, this fact must be stated. Butter, cheese, and ice cream, however, are not required to state the presence of artificial color.

The only foods not required to list all ingredients are so-called standardized foods. FDA has set "standards of identity" for some foods. These standards require that all foods called by a particular name (such as catsup or mayonnaise) contain certain mandatory ingredients. Under the law, the mandatory ingredients in standardized foods need not be listed on the label. Manufacturers may add optional ingredients, however, and FDA is revising the food standards regulations to require that optional ingredients in standardized foods be listed on the product label.

NUTRITION INFORMATION

Under FDA regulations, any food to which a nutrient has been added, or any food for which a nutritional claim is made, must have the nutritional content listed on the label.

In addition, many manufacturers put nutrition information on products when not required to do so.

Nutrition labels tell you how many calories and how much protein, carbohydrate, and fat are in a serving of the product. They also tell the percentage of the U.S. Recommended Daily Allowances (U.S. RDA's) of protein and seven important vitamins and minerals that each serving of the product contains. Nutrition information can help you shop for more nutritious food and plan more nutritionally balanced meals for you and your family.

How to Read Nutrition Labels

Nutrition information is given on a per serving basis. The label tells the size of a serving (for example: one cup, two ounces, 1 tablespoon), the number of servings in the container, the number of calories per serving, and the amounts in grams of protein, carbohydrate, and fat per serving.

Protein is listed twice on the label: in grams and as a percentage of the U.S. Recommended Daily Allowance.

Seven vitamins and minerals must be shown, in a specific order. The listing of 12 other vitamins and minerals, and of cholesterol, fatty acid, and sodium content is optional.

What U.S. RDA Means

The U.S. Recommended Daily Allowances (U.S. RDA's) are the approximate amounts of protein, vitamins, and minerals that an adult should eat every day to keep healthy. Nutrition labels list the U.S. RDA by percentage. For example, the label may state that one serving of the food contains 35 percent of the Recommended Daily Allowance of vitamin A and 25 percent of the Recommended Daily Allowance of iron. The total amount of food an individual eats in a day should supply the U.S. Recommended Daily Allowance of all essential nutrients.

A Key to Metric Units

Nutrition labels show amounts in grams rather than ounces, because grams are a smaller unit of measurement and many food components are present in very small amounts. Here is a guide to help you read nutrition labels:

- 1 pound (lb.) = 454 grams (g)
- 1 ounce (oz.) = 28 grams (g)
- 1 gram (g) = 1,000 milligrams (mg)
- 1 milligram (mg) = 1,000 micrograms (mcg)

Nutrition Quality

Many foods today are manufactured into products that are different from traditional foods. Some classes of these

foods include frozen dinners; breakfast cereals; meal replacements; noncarbonated breakfast beverages fortified with vitamin C; and main dishes such as macaroni and cheese, pizzas, stews, and casseroles.

FDA is establishing voluntary nutritional guidelines for such foods, so consumers can be assured of getting a proper level and range of nutrients when using them. A product that complies with an FDA nutritional quality guideline may include on its label a statement that it meets the U.S. nutritional quality guideline for that particular class of food.

WHAT "IMITATION" MEANS

Some foods are labeled as "imitations" of other foods. Under an FDA regulation, the word "imitation" must be used on the label when the product is not as nutritious as the product which it resembles and for which it is a substitute. If a product is similar to an existing one, and is just as nutritious, a new name can be given to it rather than calling it "imitation." For example, eggless products which are nutritionally equivalent to eggs have been given names such as Eggbeaters and Scramblers.

COMMON OR USUAL NAME

Some foods may look from the label as though they are one thing and actually be another. To prevent deception of consumers, FDA has ruled that such foods must have a "common or usual" name which gives the consumer accurate information about what is in the package or container.

For example, a beverage that looks like orange juice but actually contains very little orange juice must use a name such as "diluted orange juice drink." The product also may be required to state on the label the percentage of the characterizing ingredient it contains. In this case, the common or usual name might be "diluted orange juice beverage, contains 10 percent orange juice."

A noncarbonated beverage that appears to contain a fruit or vegetable juice but does not contain any juice must state on the label that it contains no fruit or vegetable juice.

Another special labeling requirement concerns packaged foods in which the main ingredient or component of a recipe is not included, as in the case of some "main dishes" or "dinners." On such foods, the common or usual name consists of the following:

- The common name of each ingredient in descending order by weight—for example, "noodles and tomato sauce."
- Identification of the food to be prepared from the pack-

age—for example, "for preparation of chicken casserole."

- A statement of ingredients that must be added to complete the recipe—for example, "you must add chicken to complete the recipe."

GRADES

Some food products carry a grade on the label, such as "U.S. Grade A." Grades are set by the U.S. Department of Agriculture, based on the quality levels inherent in a product—its taste, texture, and appearance. U.S. Department of Agriculture grades are not based on nutritional content.

Milk and milk products in most States carry a "Grade A" label. This grade is based on FDA recommended sanitary standards for the production and processing of milk and milk products, which are regulated by the States. The grade is not based on nutritional values. However, FDA has established standards for milk which require certain levels of vitamins A and D when these vitamins are added to milk.

OPEN DATING

To help consumers obtain food that is fresh and wholesome, many manufacturers date their product. Open dating, as this practice often is called, is not regulated by FDA, but the following information may be helpful to you.

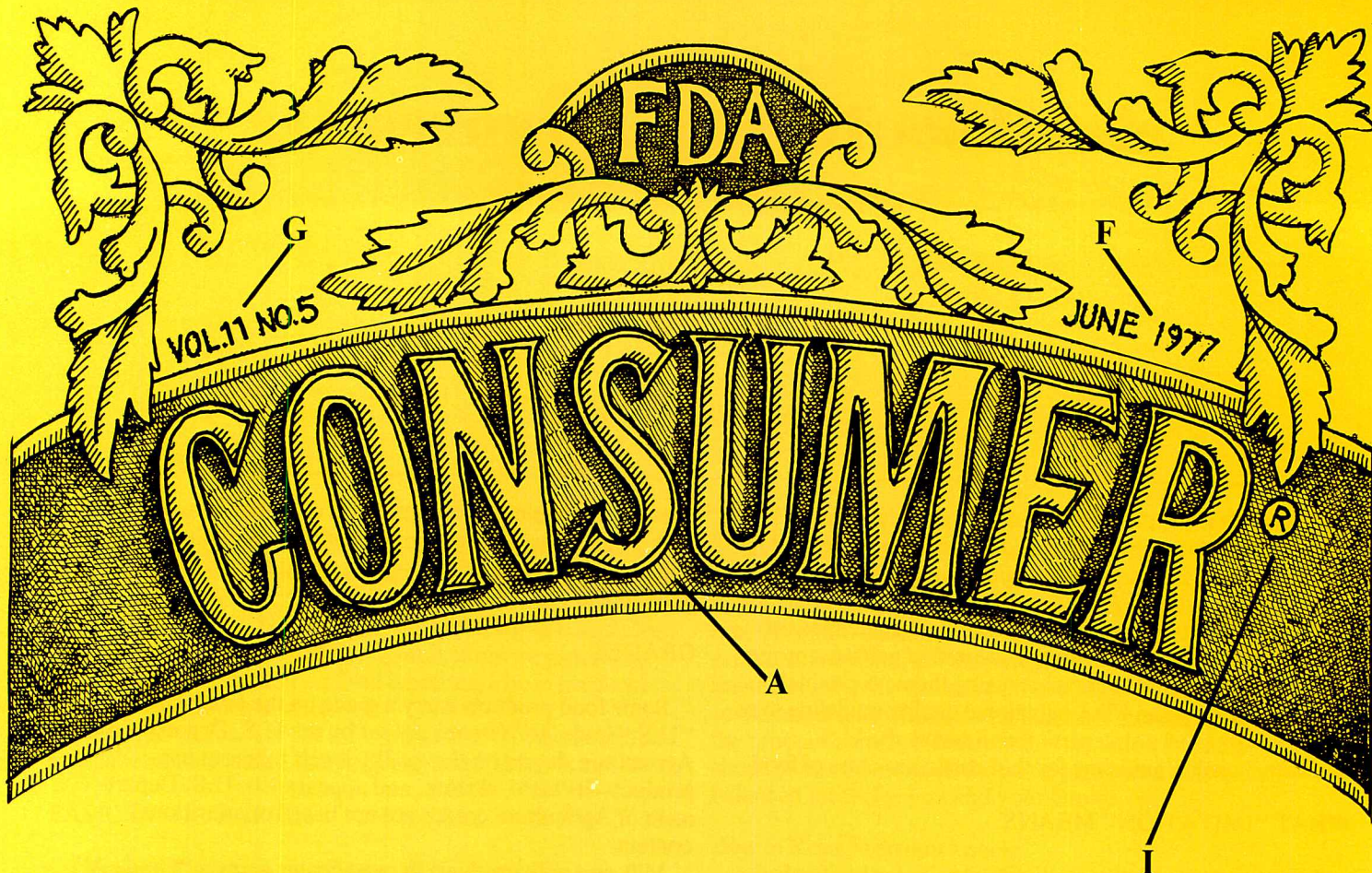
Four kinds of open dating are commonly used. To benefit from open dating, the consumer needs to know what kind of dating is used on the individual product and what it means.

Pack Date—This is the day the food was manufactured or processed or packaged. In other words, it tells how old the food is when you buy it. The importance of this information to consumers depends on how quickly the particular food normally spoils. Most canned and packaged foods have a long shelf life when stored under dry, cool conditions.

Pull or Sell Date—This is the last date the product should be sold, assuming it has been stored and handled properly. The pull date allows for some storage time in the home refrigerator. Cold cuts, ice cream, milk, and refrigerated fresh dough products are examples of foods with pull dates.

Expiration Date—This is the last date the food should be eaten or used. Baby formula and yeast are examples of products that may carry expiration dates.

Freshness Date—This is similar to the expiration date but may allow for normal home storage. Some bakery products that have a freshness date are sold at a reduced price for a short time after the expiration date.



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- A. *The name of the product must be on all food labels.*
- B. *The net contents or net weight must be on all food labels.*
- C. *The name and place of business of the manufacturer, packer or distributor must be on all food labels.*
- D. *On most foods, the ingredients must be listed on the label.*
- E. *Some food products carry a grade on the label.*
- F. *To help consumers obtain fresh and wholesome food, many manufacturers open date their product.*
- G. *Many companies use code dating on products that have a long "shelf life".*
- H. *Many food labels now include a small block of parallel lines of various widths with accompanying numbers for computerized check-outs and inventories.*
- I. *The symbol "®" on a label signifies that the trademark used on the label is registered with the U.S. Patent Office.*

CODE DATING

Many companies use code dating on products that have a long "shelf life". This is usually for the company's information, rather than for the consumer's benefit. The code gives the manufacturer and the store precise information about where and when the product was packaged, so if a recall should be required for any reason the product can be identified quickly and withdrawn from the market.

UNIVERSAL PRODUCT CODE

Many food labels now include a small block of parallel lines of various widths, with accompanying numbers. This is the Universal Product Code (UPC). The code on a label is unique to that product. Some stores are equipped with computerized checkout equipment that can read the code and automatically ring up the sale. In addition to making it possible for stores to automate part of their checkout work, the UPC, when used in conjunction with a computer, also can function as an automated inventory system. The computer can tell management how much of a specific item is on hand, how fast it is being sold, and when and how much to order.

SYMBOLS ON FOOD LABELS

The symbol "R" on a label signifies that the trademark used on the label is registered with the U.S. Patent Office.

The symbol "C" indicates that the literary and artistic content of the label is protected against infringement under the copyright laws of the United States. Copies of such labels have been filed with the Copyright Office of the Library of Congress.

The symbol which consists of the letter "U" inside the letter "O" is one whose use is authorized by the Union of Orthodox Jewish Congregations of America, more familiarly known as the Orthodox Union, for use of foods which comply with Jewish dietary laws. Detailed information regarding the significance and use of this symbol may be obtained from the headquarters of that organization at 116 E. 27th St., New York, New York 10016.

The symbol which consists of the letter "K" inside the letter "O" is used to indicate that the food is "Kosher," that is, it complies with the Jewish dietary laws, and its processing has been under the direction of a rabbi.

None of the symbols referred to above are required by, or are under the authority of, any of the Acts enforced by the Food and Drug Administration.

Margaret Morrison is a staff writer with FDA's Office of Public Affairs.

Food Additives: Double Check On Safety

New scientific knowledge and improved methods of analysis often raise questions about the safety of chemicals that never before were considered a cause for concern. That's why FDA has begun a major new program calling for the periodic review of all additives permitted in food, including those substances that get into food indirectly during growing, processing, or packaging.

by Harold Hopkins

FDA is taking a second look at the safety of all those chemical substances generally known to the public as food additives, and in time will take a third look and a fourth and so on as expanding scientific knowledge lets us probe deeper into the potential food ingredients may have to cause genetic or birth defects, cancer, or other chronic diseases.

The Agency's review of substances now permitted in food is in response to increasing public demand for greater assurance of food safety. The review currently under way amounts to a major re-examination of this substantial segment of the food industry. It will be the most comprehensive look at the gamut of additives since enactment of the Food and Color Additive Amendments of 1958 and 1960 respectively.

The review contemplates not only re-examining three major groupings of substances permitted in food but also establishing or strengthening FDA's in-house competence to deal with them. This aim would be achieved through keeping a close watch on the laboratories which test proposed new food additives for safety and by expanding FDA's staff to reduce the time it takes the Agency to make a decision on industry petitions requesting approval to use new additives.

The purpose of the FDA project is to

look again at additives approved since the additive legislation became effective and determine if they meet the stricter and more sophisticated safety guards imposed in recent years for the newer additives. New advances in analytical capability and toxicology almost automatically raise questions about the safety of many substances approved before these new techniques and findings came along.

FDA said that once the current review is complete it will re-examine all substances periodically in the future. The Agency's announcement of a continuing food additive review was new but the details reflect a philosophy and intent preached by FDA for years: that scientific conclusions can never in fact be "conclusive" but must be tentative; health or safety judgments concerning food additives always will be subject to possible change as new scientific findings make yesterday's knowledge to some degree obsolete.

For some years FDA has been working up plans to re-evaluate all the substances permitted in foods and in fact is well along in its review of several hundred additives. But announcement of its across-the-board review plan had awaited (1) additional manpower, money, and capability, and (2) the drawing up of detailed plans to put the enlarged resources to work and set up examination priorities that promise the best health protection. The wherewithal for FDA to expand its efforts came last year with approval by Congress of the Agency's appropriations for fiscal year 1977 as public concern mounted about the safety of chemical substances used in processing and packaging foods.

Details of the FDA plan were announced January 13 by Sherwin Gardner, then Acting Commissioner of Food and Drugs, in testimony to the Senate Small Business Committee. The

review is thought to be the largest single project ever undertaken by FDA's Bureau of Foods, which is in the process of expanding its food additive staff from 70 to 196 people.

The several parts of the FDA review include the so-called GRAS list of substances used in food; direct food additives, including nonflavor additives, flavors, and color additives; indirect additives; and monitoring of food industry laboratories which provide information to FDA. Pesticides and new animal drugs are regulated under other laws and do not come under the definition of food and color additives. Neither do soil and plant nutrients.

The GRAS list consists of substances considered by qualified experts to be "generally recognized as safe" for use in food. The GRAS list was established after enactment of the Food Additives Amendment of 1958, which set up procedures for approval of food additives. The idea was to place on the list substances that already had been used in food and whose safety generally was accepted by the scientific community. This would free food manufacturers and FDA of the burden of proving the safety of substances already regarded as "safe," permitting them to concentrate their efforts on checking the safety of new additives.

A review of the GRAS list began in October 1969, following FDA's **ban** on the use of a GRAS list substance, cyclamate, as a sweetener after tests had shown that cyclamate produced harmful effects on test animals. The review covers 675 substances, 439 of which are nonflavors. The rest, 236 GRAS flavor ingredients, have been incorporated into another part of the review that has been under way since 1973. This segment of the review covers some 1,700 flavors and spices.

The review of the GRAS list consists



primarily of a search of world scientific literature back as early as 1920 for safety findings on each substance on the list. After this and other relevant information has been evaluated, FDA decides whether to put the substance on an "official" GRAS list, whether to require further testing, or whether to put limitations on its use.

Reviews and evaluations have been completed for about 220 of the 439 nonflavor substances and final regulations on use have been issued on some of them. Evaluation and issuance of the regulations will continue. Searches of scientific literature are now under way on the remaining nonflavor GRAS substances.

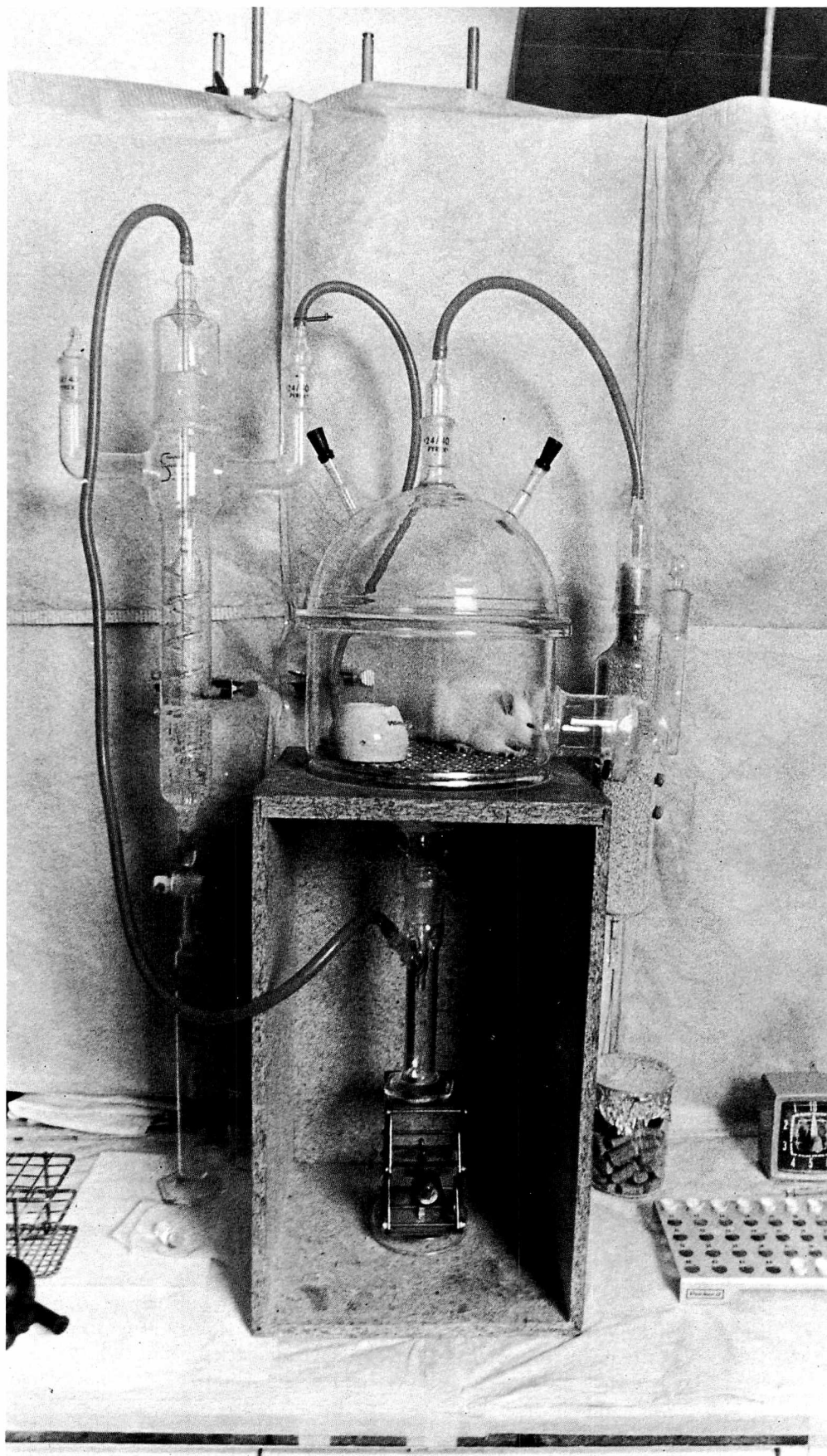
As part of the GRAS review a list of substances selected on a priority basis have undergone laboratory studies to determine if they have the potential to cause genetic or birth defects. As many as possible of the remaining substances, which were assigned no particular priority, have also been studied for such effects.

The Agency's objective in the GRAS review has been to come up with a list of substances whose safety has been re-evaluated under today's scientific standards and which thus figuratively will have an FDA "stamp of approval." The reason is that the law does not precisely define just who are "experts" qualified to determine that a substance is "generally recognized as safe." Since the law doesn't specify that GRAS status be judged solely by FDA, some companies have decided on their own, or on the advice of their trade association, that certain substances are GRAS. These ingredients may be used in food, though they are not included on FDA's "official" GRAS list.

Once FDA has an "official" GRAS list that has been fully reviewed, a food manufacturer who wants to use a substance can check it against this list, and the lists of additives that have been approved under other procedures. If the substance is on none of these lists, the manufacturer will know he should

Before a food additive can be approved, the manufacturer or processor who has requested permission to use it must submit data to FDA on the additive's safety based on tests in animals. FDA does carry out research of its own, however, on various aspects of the safety and use of food additives. Because hogs have many similarities in body systems to humans, they are often used in tests to determine how food additives may affect people. Here, an FDA laboratory group prepares to test a sow to determine if she is pregnant before using her in an additive feeding experiment.

By using a device known as a metabolic cage, FDA researchers can learn what happens to a food additive after it is fed to a rat. An additive that has been made radioactive is fed to the rat and the animal's excreta, urine, and expired carbon dioxide are collected in the cage and examined. The rat is then sacrificed and its tissues examined. The radioactivity that is detected in this series of examinations shows how the additive is broken down in the animal's body and the route it takes.





Piglets a few days old are fed various food additives in FDA experiments to determine how these substances would affect human infants.

submit a petition to FDA requesting approval to use the additive. The petition would have to include data on tests conducted to determine the safety of the additive for its intended uses.

Because the GRAS review project is more than half finished, by far the biggest part of FDA's current review concerns a conglomerate of approximately 2,100 substances, comprising 400 nonflavor direct additives and about 1,700 flavors and spices. In addition, the review will encompass 117 color additives, some used in foods, others used only in drugs and cosmetics. Of the colors, the use of 65 is permitted by regulation and 52 others are currently permitted on a provisional basis pending FDA action to give them regular status or discontinue their use.

As already noted, flavors and spices have been combined for review on the basis that a large number of both categories belong to groups of chemically

related substances.

Because it will take several years to review all food additives, it's important to decide which ones ought to receive attention first to assure the best possible protection of the consumer. FDA accordingly has formed a task group to set priorities by establishing, within one year, a preliminary "toxicological profile" for each of the direct food additives, colors, and flavors. This will be based on so-called medium depth searches of the scientific literature for what has been published on their safety, along with information about when the use of each substance began, the testing requirements for it at the time its use was first permitted, the extent to which it is used in food today, and how much of it is probably being consumed.

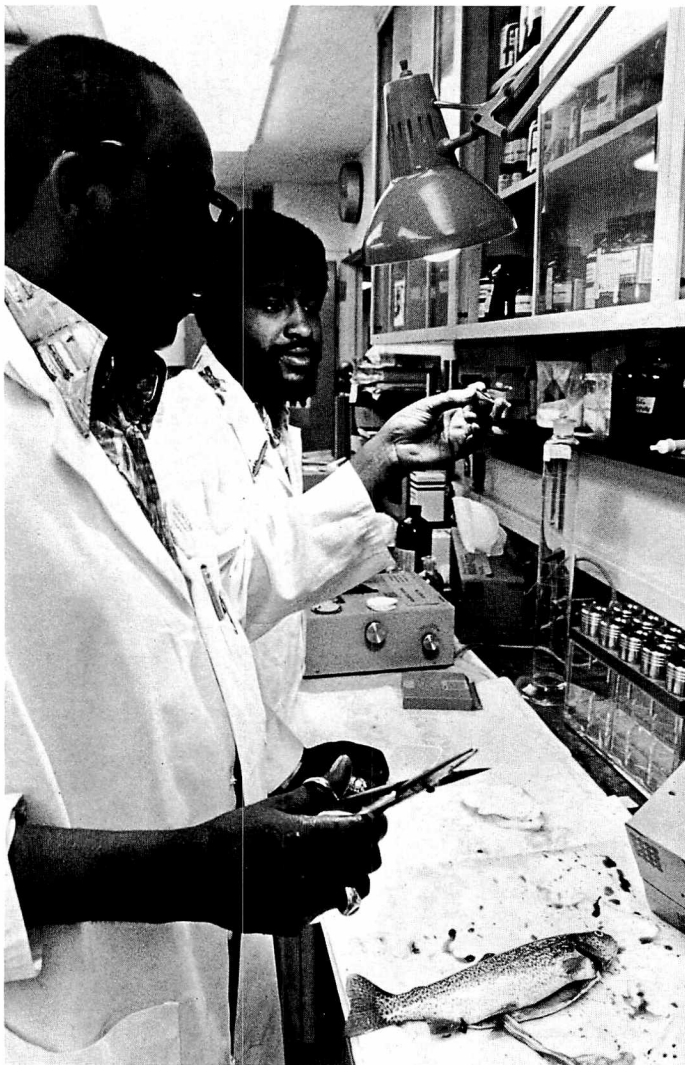
The information thus obtained will be fed into a computer for collation. In 1978 FDA expects to have enough data for printouts on all these ingredients,

showing which have satisfied certain testing requirements and which have not.

The industry sponsors of additives that have not met all test requirements will be notified that they must conduct certain tests within specified time limits. If the sponsor does not conduct the required testing, FDA will move to revoke approval for use of the additive.

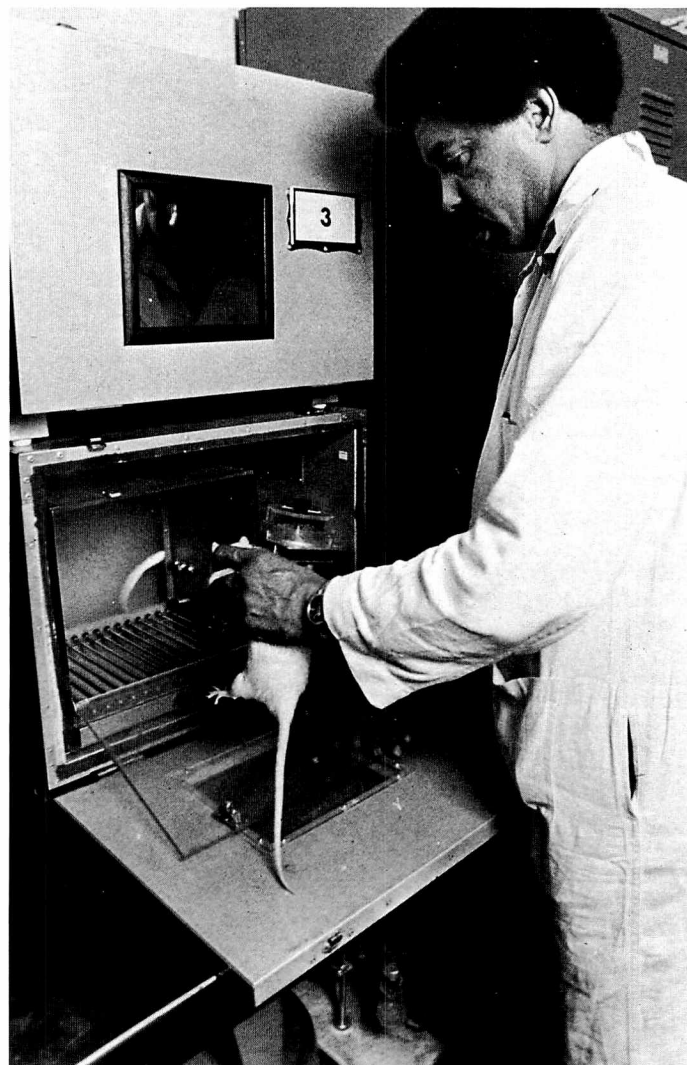
Additives that have satisfied the preliminary requirements will undergo a review in depth by FDA teams of scientists who will evaluate all information collected to determine if these additives still can be considered safe by today's standards.

Lists of substances which require further testing and those eligible for the review in depth will be published in the FEDERAL REGISTER. FDA expects that many substances will require some kind of additional testing, especially the colors, flavors, and older food additives, some of which were approved



FDA is developing a procedure to use rainbow trout for testing food additives. These fish, known to be highly sensitive to many food toxicants, are fed food additives and then are sacrificed and their liver tissues examined.

A Skinner box is used in an FDA test to determine the effects of an additive on an animal's behavior. After being fed an additive, a rat is put into the box, where it must press a lever to obtain food.



ten or more years ago when testing standards were not as comprehensive as today.

The oldest additives will be searched first in the review but the order can be changed as information develops and the situation warrants.

The nationwide industry survey of annual poundage and usage of food additives will be conducted by the National Academy of Sciences under contract with FDA. Another contractor will use this data to calculate the estimated consumer consumption of each substance.

As the review begins, FDA is establishing a Toxicological Evaluation Committee of Agency and other Federal personnel to determine the safety criteria that, by today's standards, should be required for each of the substances.

Unless the Toxicological Evaluation Committee comes up with more com-

prehensive test requirements than those required at present for food additives, it is likely that many of the newer additives—those which were approved in the past few years—will not require additional tests and will go immediately to final evaluation when they clear the preliminary evaluations by 1978.

The review of flavor additives will be handled in the same way as the review of nonflavor substances, except that some of the work is being done on a group basis. Of the 1,700 flavors, many belong to groups of chemically related substances. FDA has previously awarded contracts for literature searches and the development of other information concerning these chemically related flavors. These groups of ingredients are expected to be finished in 1979. For the balance of flavors, those that do not fall into chemically related groups, the literature searches

and development of other information will have to be done on an individual basis and this will probably take several years.

Color additives will be subjected to the same kind of review as other substances added directly to food. Literature searches will be made. The National Academy of Sciences will conduct an industry survey to obtain poundage and food usage information on colors added to food. Safety data already submitted on approved colors will be indexed. Monographs prepared from the information for each color will be reviewed by FDA in fiscal year 1978 and industry will be required to carry out any tests needed. If no additional tests are needed, FDA will publish an order reaffirming the safety of the color additive.

In addition to substances added directly to food, FDA estimates that there are as many as 10,000 indirect food additives. An indirect additive is a substance that can get into food not through direct use but as a result of coming in contact with the food during growing, processing, packaging, storing, or some other stage before the food is consumed. This takes in a great variety of substances and a great many situations, but FDA's primary interest has been in those substances that can migrate to food from its packaging, particularly plastics used for food packaging.

FDA doesn't know as much as it would like to about the characteristics of the many substances involved in packaging manufacture, the adequacy of the Agency's scientific methods for detecting and for predicting expected migrations of such substances into food, and specifications for manufacturing and use that will assure the safety of packaging substances.

The indirect additives review will be conducted differently than the reviews of direct additive substances. The Agency over the next five years will conduct studies to check on the validity of FDA's present migration methods used to assure that no substances that can cause significant harm are

finding their way into food as eaten.

In fiscal 1978 FDA will establish a priority list for its review of indirect additives, putting those substances first which are of the most concern based on their known or suspected toxicity and the extent of their use in food packaging. The priority list will be set by FDA people who are familiar with the composition and technology of food packaging and with food additive regulations.

The list will consist of families of plastics such as vinyl chloride or vinyl acetate. FDA hopes that by using a kind of "class" review it can write one regulation to cover many of the proposed packaging formulations and uses within a family of plastics. Such a regulation, for instance, might specify the kinds of vinyl acetate packaging permissible, as cartons, bottles, film, or bags; the kinds of foods for which each could be used; and the percentage ranges of specific substances that could be used in the formulation of each of these packages or materials.

Over the next few years a study will be conducted to determine what substances are being used—and the proportions—in the manufacture of specific containers in each of the plastic families. For example, the study may find that margarine tubs are being made from vinyl chloride plastic using three different specifications—one calling for 15 percent vinyl chloride, a second using 30 percent vinyl chloride, and a third using 50 percent.

As these specifications are determined for each packaging article in each plastic family, the articles will be manufactured for FDA under contract. Once manufactured, the articles will be subjected to analysis to determine how much of the material might migrate into the specific foods that would be packaged in them.

Data from these contracts will be collated and evaluated to see if it conforms to the safety standards established for indirect additives. Any additional testing would have to be conducted by the industry, with close FDA monitoring.

Over an extended period FDA will then write regulations covering each plastic family, specifying the articles that can be made from this plastic and the substances that can be used, with limits on the amount of each substance that can be used in various formulations. Manufacturers wanting to use new ingredients not covered by regulation or wishing to change the ranges of substances permitted would have to get approval from FDA. In such instances FDA would require the manufacturer to submit information, including data from tests with animals, to show that the new ingredients or new formulations are safe for their intended uses.

FDA now has under way a major new program intended to assure the accuracy and integrity of animal test information submitted to the Agency with requests seeking approval for the use of new food additives. It is part of a large Agency program involving laboratories and investigators who supply information to FDA on studies conducted with animals to determine the safety of various products under FDA jurisdiction. The FDA program was decided upon following investigations in 1975 and 1976 which revealed deficiencies in the operations of many such laboratories and the implications of this for the safety of the product under study.

There are about 130 laboratories which conduct animal tests in support of industry requests for FDA approval to market new food additives. The Agency's program will include regular inspections of these laboratories at least once each two years to assure that they operate in an appropriate scientific manner and that the data from their studies submitted to FDA are accurate, complete, and reliable. The Agency also intends to promulgate regulations setting operating procedures and practices these laboratories must follow to assure that their work meets FDA standards.

Harold Hopkins is editorial director of FDA CONSUMER.

Keeping Tabs On Product Injuries

Reports from selected hospitals help identify products that have been associated with an unusual number of consumer injuries or illnesses. The information might signal the need for FDA to develop new safety guidelines or regulations for certain products.

by James Greene

Ours is a numbered society. Computers have seen to that. Computers bill us by our credit card numbers. They make it possible for the Internal Revenue Service to keep track of our income through our social security numbers. They lump us in statistical categories by age, marital status, and income—to name just a few.

Many people find all this disconcerting. But despite the indignation that often goes with having your personal identity reduced to a statistic, many of the systems that seem to function best by substituting numbers for names produce benefits that can be counted in very human terms. FDA's Medically Oriented Data System (MODS) fits that description.

The MODS program relies for its basic information on six selected hospitals that each night send FDA a summary of cases treated in their emergency rooms involving patients who were injured or became ill through use of foods, drugs, cosmetics, medical devices, or other FDA-regulated products. The reports identify cases by code numbers rather than patients' names and are transmitted via a computer terminal at each hospital to a central computer at FDA headquarters in Rockville, Maryland.

Each injury report includes the age and sex of the patient; diagnosis and part of body injured; where the incident occurred; outcome of the case; and the product involved, including brand name and manufacturer, if available. About 200 reports are received on an average day. FDA pays the

administrative costs of running the operation, and MODS staffers train hospital personnel in the use of the equipment and reporting procedures.

Every week the reports are compiled and analyzed by product category and the findings are submitted to the appropriate FDA bureau. The reports may prompt a bureau to request the collection of additional data on a specific product or group of products through the MODS program. For example, if the Bureau of Drugs finds through MODS' weekly reports that an unusually high number of people have been treated at the six hospitals after suffering adverse reactions to a certain type of drug, the Bureau could request that data collection be expanded to include an additional 36 hospitals that supply information through the system upon special request. This enlarged study would give a much better indication of the real extent of the problem.

Other Government organizations and the medical community also have access to the MODS data. The information can help identify trends in product-related injuries and can be used by hospitals to improve the treatment given to patients who are made sick or are injured by a particular product. MODS studies also are useful in helping FDA develop new safety guidelines or regulations for the products it regulates.

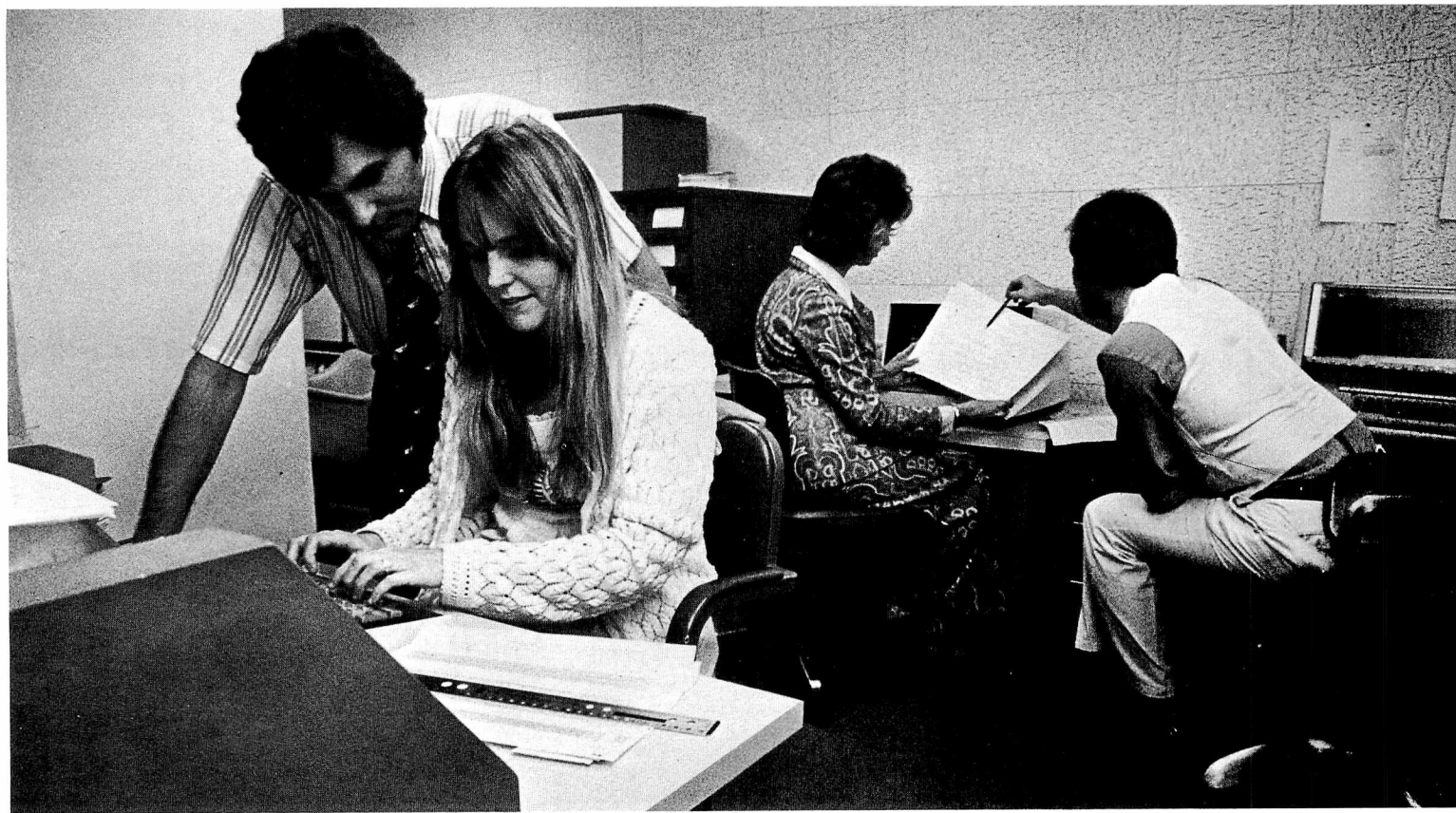
A recent one-year study on sunlamp-related injuries prepared by the MODS staff is a good example of how FDA uses product-associated injury data to point the way to regulatory action. An estimated 12,000 sunlamp injuries were treated by hospitals in 1975, an increase of over 2,000 cases compared with a similar MODS analysis done three years earlier. The sunlamp injury reports were collected by the National Electronic Injury Surveillance System (NEISS), a monitoring setup similar to but considerably larger than FDA's. Some 119 hospitals across the country

report to NEISS, which originally was established by FDA but was transferred to the Consumer Product Safety Commission when that agency was set up and took over regulation of some products formerly handled by FDA. MODS staffers use this network, which is representative of hospitals across the Nation, to collect data that can be used to make national estimates of the number of product-related injuries treated in emergency rooms.

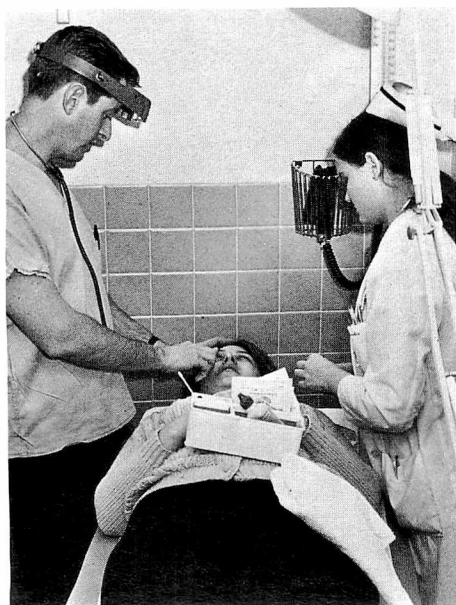
MODS staffers analyzed 513 sunlamp-related injury reports from NEISS. Statistical analysis of the reports identified burns around the face and eyes as the most common type of injury and females between 16 and 20 as the age group most likely to be burned. An FDA followup found that most injuries occurred because users ignored, forgot, or never received directions for safe operations of their lamps. As a result, they stayed under the lamps too long and were burned. One minute under some lamps is equal to one hour in the sun.

These and other findings led FDA to propose regulations requiring labels on sunlamps that would warn of the dangers of overexposure, advise users to protect their eyes, and state the minimum safe distances between lamp and user. Other proposed standards would require sunlamps to have a timer that would shut off the device automatically.

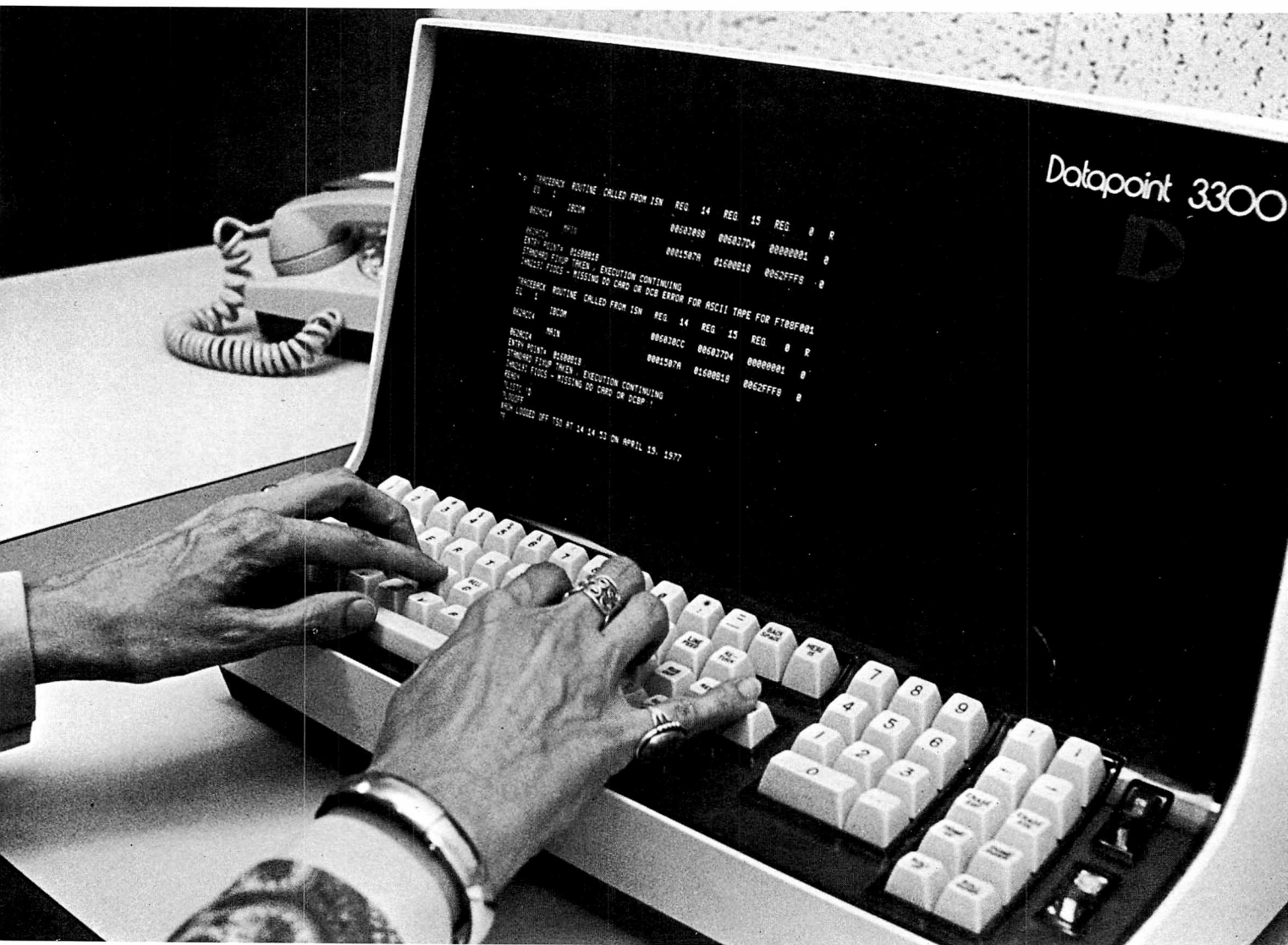
FDA also is in the process of proposing, and in some cases has established regulations that would require certain cosmetics to carry a label statement warning the user of possible adverse reactions if used improperly. Such cautionary statements are based on MODS studies which showed an upward trend in the number of people suffering skin rashes, chemical burns, or foreign particles in the eyes after using hair dyes and shampoos, antiperspirants and deodorants, eye mascaras, and other body and facial preparations.



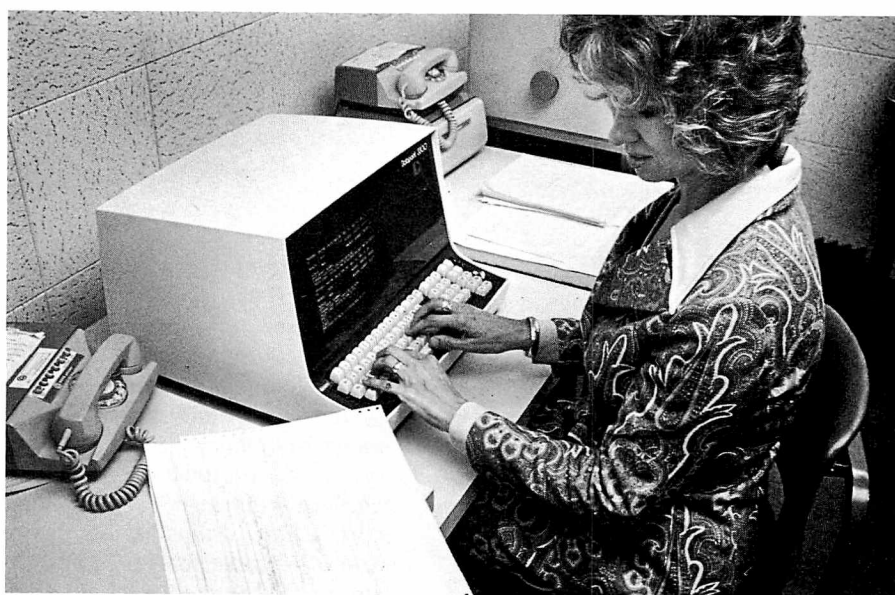
The MODS computer room gives the staff ready access to the information it needs to compile and analyze reports on consumer injuries and illnesses caused by products regulated by FDA.



Reports from hospitals are the raw data on which MODS studies are based. As a result of FDA findings based in part on a MODS study which documented an increase in the number of people suffering eye irritation and injury from hair sprays and deodorants in aerosol containers, FDA issued regulations requiring these products to carry a label statement warning the user of possible adverse effects if sprayed in the eyes.



Program Analyst Carol Vetter uses a computer terminal to retrieve information from the central computer.



02/15/77

AMPHETAMINE-RELATED DRUG INCIDENTS
MEDICALLY ORIENTED DATA SYSTEMS

75

BATCH DATE	SEX	AGE	DIAGNOSIS	NO. D
DRUG NAMES				
1912 PRESCRIPTION DRUGS				
750202	MALE	026	POISONING	2
			AMPHETAMINES/MARIJUANA RED OIL	
750207	MALE	027	OTHER	0
			DRUG ABUSE/ALCOHOL/BENADRYL & BENZEDRINE	
750211	FEMALE	027	POISONING	4
			SUICIDE ATPT/9-10PLACIDYL;6DEXAMYL4PERCODAN;2LIBRIUM/OHSRVE OVERNIGHT	
750317	FEMALE	027	POISONING	2
			ORNADE/SANOREX	
750322	MALE	027	POISONING	6
			ETRAFON/BENTYL PHENOBARBITAL/DHI APRESOLINE/PONDIMIN/IONAMIN/	
750323	FEMALE	027	OTHER	1
			ACUTE ANXIETY/IONAMIN	
750407	MALE	033	OTHER	1
			2 BIPHENAMINE/DRUG REACTION	
750420	FEMALE	018	POISONING	1
			10 SANOREX	
750422	FEMALE	015	POISONING	2
			DIEP/PILLS/ASA	
750502	FEMALE	020	POISONING	0
			SPEED (DIET PILLS)	
750507	FEMALE	031	POISONING	5
			OD:2DARVON;2DIET PILL (AMPH);2APC; 1DIURETIC ;2VALIUM/MED CLEAR-PSY	
750517	FEMALE	020	POISONING	2
			VENTILO/PHENTERMINE	
750604	FEMALE	019	POISONING	1
			OD:AMPHETAMINE (10"WHITES")/PSYC EVA	
750609	MALE	017	OTHER	1
			3 IONAMIN-30 PER DAY/TODAY 6 AT ONE TIME	
750701	FEMALE	037	OTHER	1
			RX TEPANIL (DIET PILL) BY PMD-UNWISEAGGRAVATED PT'S HYPERTENSION/ADMIT	
750713	FEMALE	025	POISONING	1
			OD:10 75MG TENUATE/PSYCH CONSULT	

This is a printout of all amphetamine-related drug incidents reported to FDA by hospitals during a ten-month period. It identifies the age and sex of each patient, the medical problem, and other medical data.

Other cosmetics, including nail polish remover, have caused injuries because they are flammable.

In addition, MODS analysts have completed studies of reports on emergency room treatment of people who had adverse reactions to prescription and nonprescription drugs, or were injured by defective or mislabeled medical devices such as intrauterine contraceptive devices (IUD's), needles and syringes, and contact lenses.

Data also are being collected through

MODS on the use of radioactive drugs (called radiopharmaceuticals) to diagnose certain kinds of cancer and other diseases. These drugs aid in identifying—through radiation—areas of the body that might be diseased. The study seeks to identify trends in the use of these drugs which will benefit patients undergoing nuclear medicine care. Information about the age and sex of patients and the type of radiopharmaceutical equipment is being collected and analyzed.

MODS is expanding its data collection and analysis to include vaccination programs for children in pediatric clinics at the six hospitals comprising its basic reporting network. Adverse reactions to vaccinations children receive for protection against diseases such as

diphtheria, tetanus, and polio are being catalogued. Data on other biological products including adverse reactions to transfused blood also are being fed into the system. These data are submitted to FDA's Bureau of Biologics for evaluation.

Though less than three years old, MODS has proven to be an effective means of gathering and analyzing data on product-related injuries serious enough to require clinical treatment. Translating injury reports into a series of numbers that are fed into a computer may seem an impersonal way to protect consumers and to improve medical treatment—but it works.

James Greene is a staff writer with FDA's Office of Public Affairs.

Risk Assessment And Consumer Protection

To help in planning its work, FDA asks its top managers and consumer groups to rank major regulatory programs in terms of the risks to consumers posed by the products involved. Risk priorities may look quite different from outside the Agency than they do from within.

by Timothy Larkin

Of the products regulated by FDA, which ones pose the greatest risks to consumers?

The way FDA officials answer this question determines to a considerable degree how much time, effort, and money the Agency devotes to each of its consumer protection programs. Put another way, FDA's priorities are determined in large measure by the risk assessments made by Agency officials.

How about consumers? How do they see the risks posed by the products FDA regulates?

To help in planning its work, FDA a number of years ago began asking its top managers to list programs which they believed should receive priority on the basis of consumer risk. More recently, a number of consumer organizations were invited to do the same thing.

Those participating in the process, whether inside or outside FDA, express their views in the same way: through "ballots" specially designed so that the FDA planning office can objectively compare and analyze the results. The participants were asked to choose the seven FDA programs that they believe should have the highest risk priority and the seven that should have the lowest.

One of the more interesting and useful sets of facts to emerge from this year's balloting was that FDA top staff and program managers quite often looked at priorities in a different way than did consumer groups. Sometimes these differences were small; in a few instances they were significant.

As explained in the "ballots," FDA defines risk as the possibility that a consumer will be injured, made ill, or suffer an economic loss. The amount of such risk depends on the *number* of consumers exposed to it and the *sever-*

ity of the potential injury, illness, or economic loss.

The accompanying chart shows how FDA's 29 major program activities were ranked on the basis of risk by 16 consumer groups and by the staff of the Commissioner of Food and Drugs. (Managers in each of FDA's bureaus also rate the risk priorities of their bureau's programs. The ratings of the Commissioner's staff were selected for comparison purposes in this article because this staff rates all the Agency's programs, not just those of one bureau, and thus its views constitute a cross section of opinion.) Almost all consumer groups ranked chemical contaminants as of the highest risk, and drug abuse treatment monitoring as the lowest. The Commissioner's staff also saw chemical contaminants as the top risk and gave drug abuse treatment monitoring relatively low priority.

But although there was considerable agreement, there were also some areas of wide difference. The Commissioner's staff ranked medical devices requiring premarket approval much higher in terms of risk than did consumer groups. Other programs which the Commissioner's staff rated significantly higher than consumers in terms of potential risk were blood and blood products, food sanitation control, ionizing radiation, clinical investigation evaluation, animal drug safety and residues, and shellfish safety.

A comparison of risk ratings by the individual bureaus of the FDA (Foods, Drugs, Medical Devices and Diagnostic Products, Veterinary Medicine, Biologics, and Radiological Health) tends to confirm these differences of perception between what those closest to the problems consider most significant in terms of risk and what consumer groups see as risk.

Why does the Commissioner's staff and the Bureau of Biologics think that blood and blood products involve a degree of risk that entitles this program to a high claim on the Agency's resources? And what about other activities where marked differences exist, such as medical devices, food sanitation control, ionizing radiation, clinical investigation evaluation, animal drug safety and residues? What are FDA's reasons for ranking these so high in terms of risk? Let's take a look at these problems and examine some of the reasons why FDA sees them as involving considerable potential risk.

The Commissioner's staff ranked medical devices requiring premarket approval second (consumer groups placed it twelfth). The staff assigned these devices such priority because they present a high potential hazard to health. Another factor in giving this program high priority is that a new law gives FDA authority to require manufacturers to prove that certain devices, including those implanted in the human body and all life-supporting devices, are safe before they are allowed on the market.

Medical devices are applied, used, or implanted by 4 million nurses, physicians, and allied health professionals, not to mention the millions of consumers who use such devices themselves for treatment or diagnosis.

The medical device industry is one of the most dynamic sectors of our economy. According to an FDA analysis, sales jumped 225 percent between 1958 and 1972, reaching \$3.3 billion. A more recent Commerce Department study sees device sales totaling almost \$12 billion annually by 1980.

More importantly, medical devices increased not only in number but also in complexity and potential contribu-

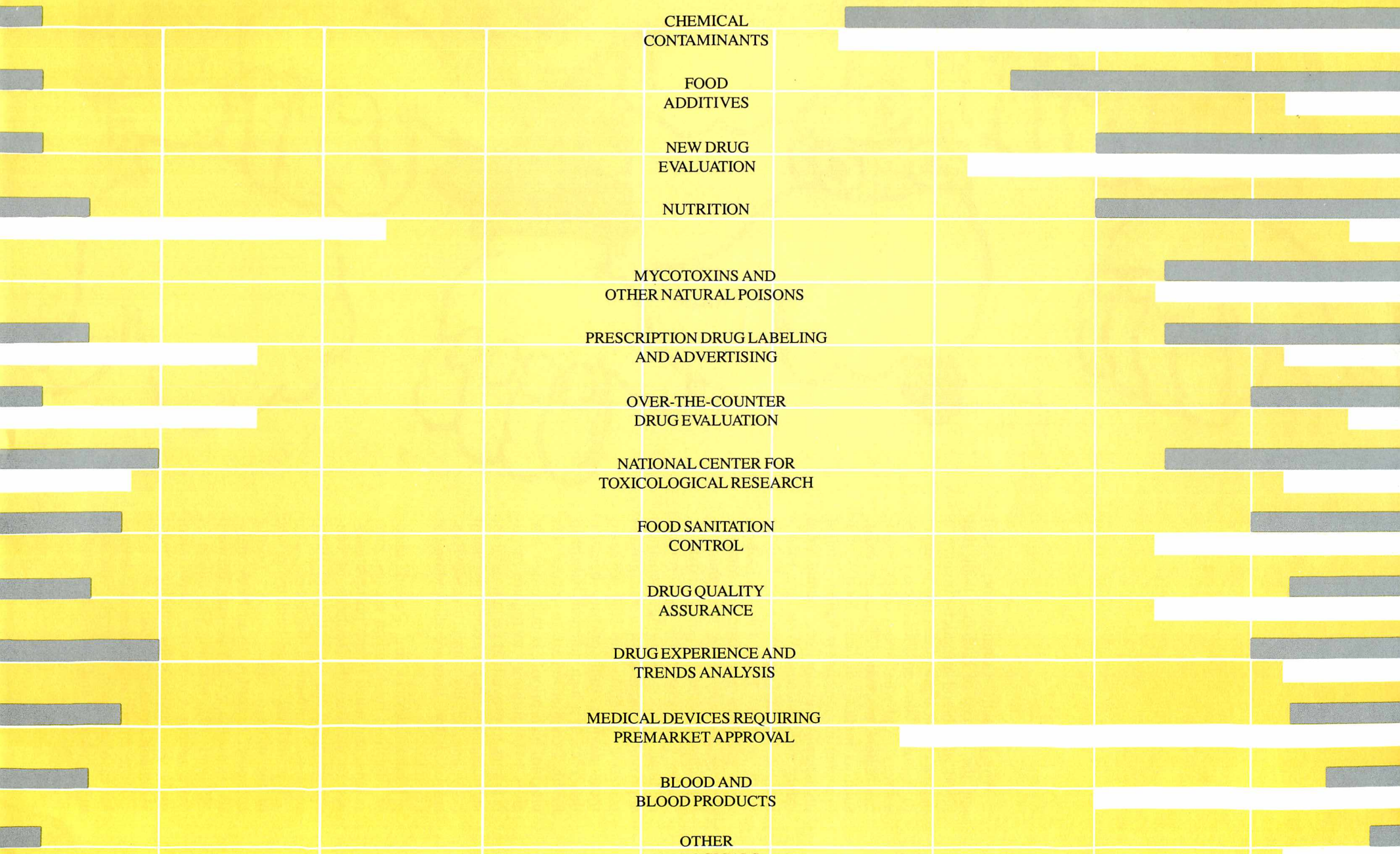


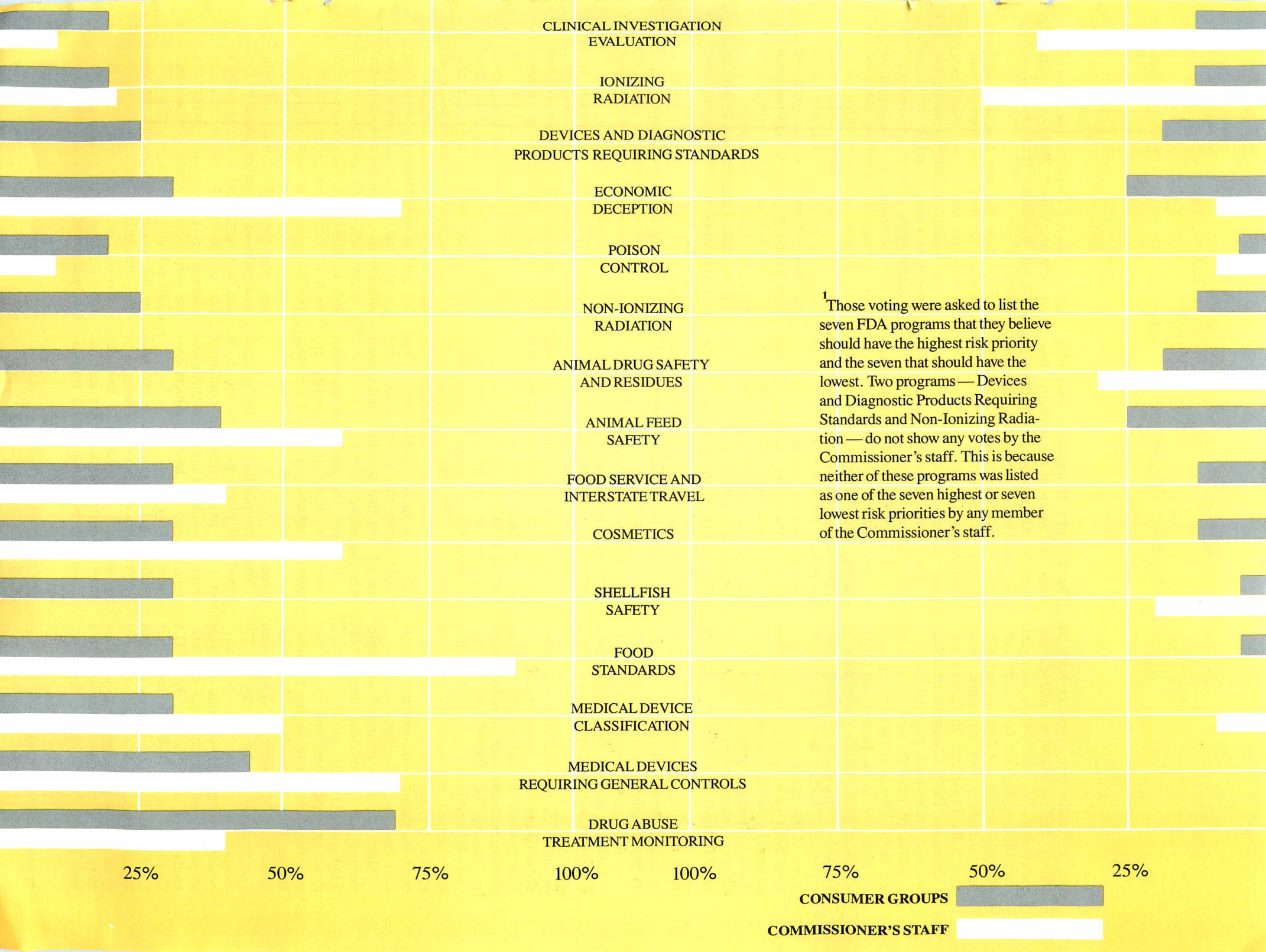
How FDA Commissioner's Staff and Consumer Groups Assess Risk Priorities¹

PERCENT RATING PROGRAM LOW PRIORITY

FDA PROGRAMS

PERCENT RATING PROGRAM HIGH PRIORITY





tion to health care. Devices such as kidney dialysis machines and cardiac pacemakers are now widely accepted, even among those who accept very little else about our form of medicine and society. (For example, both U.S.S.R. President Podgorny and Communist Party Chairman Brezhnev wear American-made pacemakers.)

Although modern medical devices are highly effective, they may pose a potential risk to the patient. An analysis of medical reports undertaken by the U.S. Department of Health, Education, and Welfare showed there to be some 10,000 injuries and 751 fatalities from faulty or incorrectly used medical devices in one 10-year period. An FDA death certificate study, limited to 10 States, showed 858 deaths directly related to medical devices, also in a 10-year period. The Commission on Professional and Hospital Activities, an independent health group, estimated 36,000 complications from medical devices for a one-year period.

Devices such as heart pacemakers and heart valves can threaten life if improperly designed or implanted. Since 1972, about 25,000 individual pacemakers have been recalled by their producers. Faulty monitoring devices in intensive-care units have been responsible for fatal electric shocks, and defective anesthesia machines have caused explosions in operating rooms. Serious injuries to users have been associated with certain intrauterine contraceptive devices.

Much work is involved in implementing the new medical devices law. FDA must recruit additional staff, draw up regulations, and explain the new requirements to device manufacturers. Thus, in keeping with its view about risk and priority, FDA has asked Congress for enough money for 200 positions to implement the new law.

Consumer groups saw food additives as second only to chemical contaminants as a risk priority. The FDA Commissioner's staff, on the other hand, ranked food additives eleventh because although additives receive a great deal of publicity, as a class they have not been demonstrated to pose a high degree of risk to the consumer.

The difficulty of regulating food additives, and much of the publicity about them, stems from the growth of scientific knowledge. Scientific judgments about food additives tend to be made obsolete as science learns more about the potential for certain substances to cause disease, or as new and more precise studies are made, as happened in the case of saccharin.

FDA is engaged in a massive review of past additive decisions as well as closely scrutinizing all new additive applications. This process of regulating the old and the new according to sound scientific methods is the best way of assuring that food additives do not qualify for a high place on the risk ranking. This point was recently expressed at a congressional hearing by FDA Acting Commissioner Sherwin Gardner, who said:

"The application of contemporary standards to products approved 15 years ago will cause us to revise some old decisions, and undoubtedly produce some public anxiety. New questions always can—and indeed should—be raised about ingredients previously assumed to be safe. Continuing reevaluation, in the light of new evidence and new standards, must become a routine part of FDA's work, and an accepted characteristic of the regulatory process, rather than a cause for accusation and alarm. The time for alarm would come if the safety of approved products were never questioned. That would signify that we were not doing our job and that scientists had ceased to be inquisitive.

"In short, the raising of questions about the safety of previously approved products is a sign of a system that is working, not a signal that it has failed."

The Commissioner's staff placed blood and blood products fourth in terms of risk, while the consumer groups considered nutrition fourth and ranked blood and blood products considerably lower.

Blood and blood products are seen by FDA as a significant risk because of the problem of hepatitis, a liver-destroying inflammation that can be transmitted by human blood transfu-

sions. Evidence indicates that paid donors are much more likely to be carriers of hepatitis than voluntary donors.

FDA now requires that all blood donations be tested for hepatitis and has proposed that donated blood used in transfusions be labeled as having come from a paid or volunteer donor. In recent years, FDA also has substantially strengthened its regulation of firms that collect and process blood for use in plasma and other blood products. These efforts have made blood and blood products safer, but since improper collection or processing of these products poses a high potential risk FDA believes they require a high degree of attention and concern.

FDA ranked nutrition rather low as a risk priority for two reasons. Although the state of nutrition among Americans is not as high as it should or could be, the nutritional situation today does not pose a threat of injury or sickness comparable to that of blood and blood products.

In addition, FDA has already embarked on a major program to support better nutrition. This involves what has been called a food labeling "revolution" designed to make it easier for consumers to identify and select nutritious foods. The backbone of the effort is a requirement that the nutritional content be listed on the label of all foods that make nutritional claims or that contain added nutrients. FDA also is evaluating whether nutrients that are added to foods actually benefit health.

FDA ranks food sanitation control fifth in terms of risk—compared to ninth by consumer groups—because foodborne disease can affect large numbers of persons. Foods that contain even the slightest traces of botulinal toxin—a poison produced by certain bacteria in food—can cause death. The spores of *Clostridium botulinum* bacteria are common everywhere and are harmless, but under certain conditions resulting from improper processing the spores begin growth that produces the deadly toxin.

To deal with such risks, FDA devotes a major part of its inspection and analytical efforts to examining some

70,000 food manufacturing and storage establishments in the United States as well as examining imported foods. A major and continuing effort involves preventing food contamination by developing and enforcing good manufacturing practices. FDA also has undertaken a research effort designed to identify new hazards and develop ways to control them.

FDA sees ionizing radiation as standing eighth in terms of risk, but it was sixteenth on the consumer group's list. Although such radiation has many valuable uses, including medical diagnosis and treatment, it can create serious health problems. For example, the long term effects of low levels of exposure to such forms of radiation as x rays can produce leukemia and other forms of cancer, as well as possible genetic damage that can cause changes or mutations that will show up in later generations.

One reason FDA believes ionizing radiation requires a relatively high risk ranking is that there is no known safe level. Exposure to even very low levels of ionizing radiation must be considered as involving some potential risk. Since we are already unavoidably exposed to a low level of natural radiation from such sources as the sun and radioactive elements in the soil, it is vital that manmade radiation levels be kept as low as possible in relation to the benefits we receive.

Another matter to which FDA assigns a higher risk priority than do consumer groups is the evaluation of data submitted by manufacturers to support applications to market a new drug or food additive. Under the Food, Drug, and Cosmetic Act, manufacturers of drugs and food additives carry out the necessary research to show that the products are safe and submit the research data to FDA. This research data thus plays a crucial role in FDA's decision whether to permit a new drug or food additive on the market.

The policy of FDA has been that unless there is a compelling reason to believe otherwise, it would assume that the evidence submitted to support an application to market a new drug or

food additive was based on research carried out in keeping with high scientific standards.

Based on this assumption, FDA practice has been to examine the *results* of scientific studies as well as the adequacy of the procedures and methods described in written reports of those studies. Only in rare instances, where there was demonstrated cause, did FDA look at work in progress.

To a major degree this was dictated by economic and humane realities: to reproduce everyone's research would be an intolerable drain on FDA's funds and scientific manpower; in the case of drugs, it would also delay therapeutic advances that could save lives.

Unfortunately, recently uncovered evidence of poorly executed laboratory work involving the testing of drugs and food additives in animals has caused FDA to depart from its policy of looking primarily at results and not at work in progress.

The implications of these findings are serious. If the raw data are incorrect so too can be conclusions about drug and food additive safety. This shadow over the approval process could mean pulling drugs and additives off the market and prolonging the evaluation of those not yet approved for marketing. Unless this shadow is removed it will be impossible to have the necessary confidence in our food and drug supply.

It is for these reasons that FDA has launched a major new program to monitor laboratories that test drugs and food additives in animals. And it is for these reasons that FDA ranked clinical investigation comparatively high (ninth) in terms of risk priority out of the total of 29 projects. Consumer groups placed clinical investigations thirteenth. (Clinical investigations usually refer to tests involving people but in this instance the term includes pre-clinical animal tests.)

There was an even greater difference of opinion over animal drug safety and residues. FDA ranked this problem tenth on its list; the consumer groups placed it near the end (21st) of the list. (This difference in perception may be due in part to the fact that when con-

sumer groups cast their ballots the words "and residues" did not appear. These words were added before the Commissioner's staff voted because it was felt they were needed to describe the program adequately.) FDA sees this issue as qualifying for tenth place because about 80 percent of U.S. livestock and poultry receive some animal drugs during their lifespan. Such drugs are used to control or prevent disease and to promote growth. If residues of such drugs occur in meat, eggs, milk, or other products from animals receiving the drugs, consumers can be exposed to serious hazard.

To protect consumers from such residues, FDA and the U.S. Department of Agriculture keep a watchful eye on field, feedlot, and slaughterhouse to assure that prohibited residues of drugs used in animals are not present in food sold to consumers.

One of the difficulties in regulating drugs used in food-producing animals involves drugs that can cause cancer. A key problem has been finding a detection method sensitive enough to detect very small amounts of these drugs in animal products so residues can be kept below the point of potential harm to humans. FDA has proposed test procedures that must be used to assay residues of such drugs in food and will also require that if an adequate detection method cannot be developed for a drug it will either not be approved for use in food-producing animals or approval will be withdrawn if the drug already is being used.

These are some of the programs where FDA and consumer organizations evaluate risk differently, and the reasons behind FDA's risk assessments. That there have been—and probably will continue to be—differences of opinion is not surprising. It is to be expected. But these differences are far less important than the fact that FDA and consumer groups are engaged in a continuing and constructive dialogue on how Government funds should be spent to protect the public.

Timothy Larkin is a special assistant to the Commissioner of Food and Drugs.

Informing Women About IUD's

The things a woman should know about using an intrauterine device—effectiveness in preventing pregnancy, side effects, adverse reactions, and similar information—are contained in new brochures that physicians will be required to give to patients before an IUD is inserted. FDA also is requiring changes in the material physicians receive to inform them about IUD's.

by Annabel Hecht

Coils, loops, "T's"—these are some of the shapes intrauterine devices come in. Such devices, commonly called IUD's, are used by some three million women to keep from getting pregnant. Some are made solely of inactive metal or plastic; others contain heavy metals, such as copper, or drugs or other substances to increase the contraceptive effect.

No matter what they look like or how they do their job, all IUD's soon will be required by FDA to have two types of labeling. Both the physician who prescribes and inserts an IUD and the woman who uses it will be given information on the uses and risks of the device. And, for the first time, physicians will be required to give this important information to their patients before the device is inserted.

The idea of requiring that specific information be given to women who use a certain type of contraceptive is not new. Such information has been required for oral contraceptives (The Pill) since 1970. Although many physicians do discuss with their patients the pros and cons of using oral contraceptives before prescribing them, patients often do not receive this information until after the prescription is filled and they see the printed material that comes with the package.

Under the new IUD labeling requirements a woman planning to use this type of device will get an easy-to-read brochure which has two sections. The first section will tell her what she needs to know about IUD's before the device

is inserted; what an IUD is, how it works, how effective it is. This section also will list medical conditions which might make use of an IUD inadvisable, and possible side effects and adverse reactions.

After her IUD is inserted, there are things a woman should know such as how to check to determine if the device is in place and what to do if she suspects it isn't; side effects that might occur during or shortly after insertion; danger signs that should be reported to her physician; and what happens if she should become pregnant while the IUD is in place. This information is contained in the second part of the brochure.

The new regulations specify that the patient must be given the brochure by a physician, a nurse, or other trained health professional before an IUD is inserted and that the patient should have time to read the material and discuss any questions she has about IUD's and other forms of contraception. FDA says it would be desirable if the patient gets the material on a date earlier than the one set for the actual insertion of the device, although no specific timetable is spelled out in the regulations.

The new labeling for physicians recommends that before prescribing an IUD the physician obtain a complete medical history, and make a thorough physical examination to be certain that the woman can safely wear an IUD. After the device is inserted a re-examination should be scheduled, preferably immediately following the first post-insertion menstrual period, and definitely within the first three months. Annual examinations after that are recommended.

The physician labeling also will include a description of the IUD along with directions for insertion, replacement, and removal; the medical conditions or other circumstances that would indicate a woman should not use an IUD; detailed information on adverse reactions; and suggestions on

what to tell the patient.

The IUD labeling requirements came about after many years of study by FDA of IUD-related problems. Although the device is considered to be a safe and effective means of contraception, certain complications and side effects can develop. FDA felt that many of these problems could be avoided if physicians and patients were adequately informed about the IUD's effectiveness, and circumstances under which it should not be used. A survey of the labeling previously used showed that such information was not uniformly available either to physicians or patients.

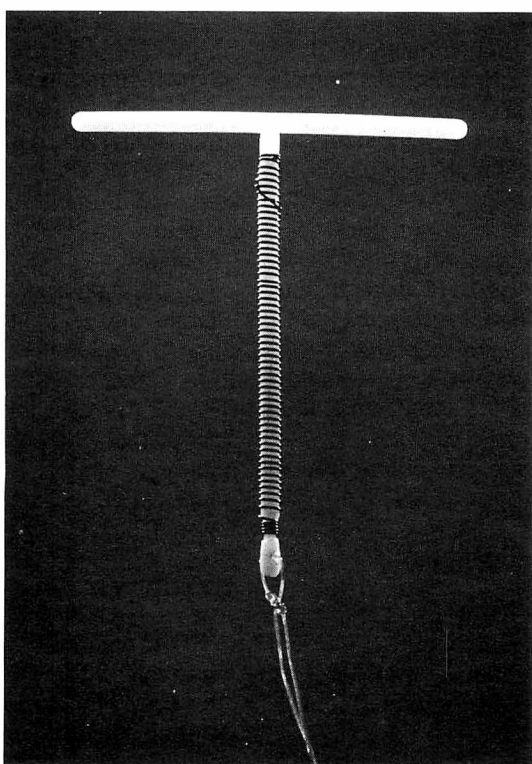
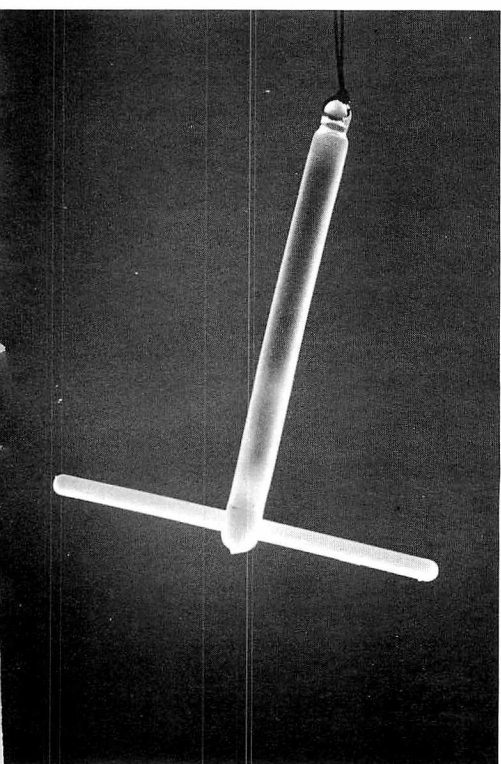
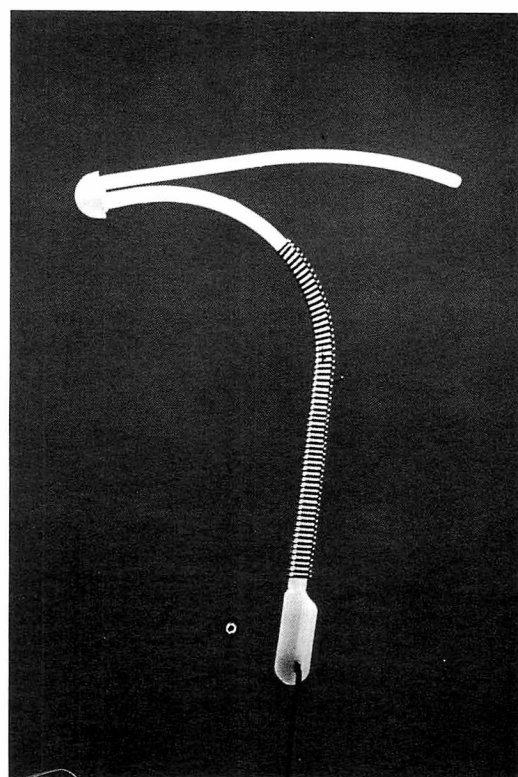
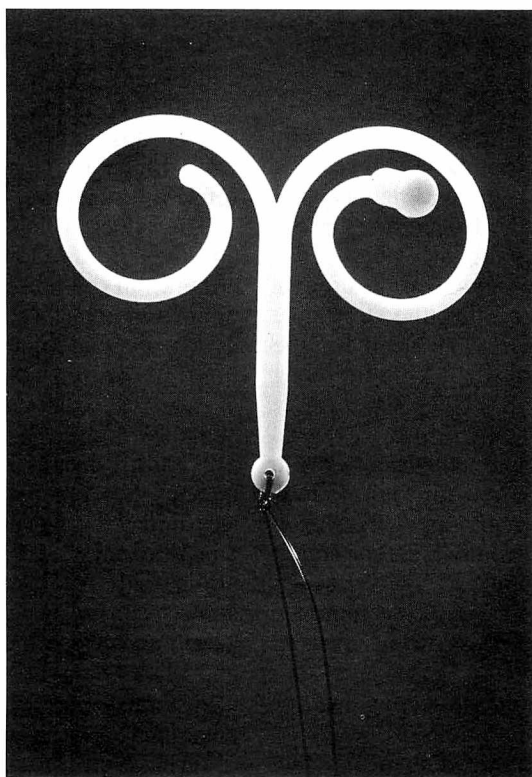
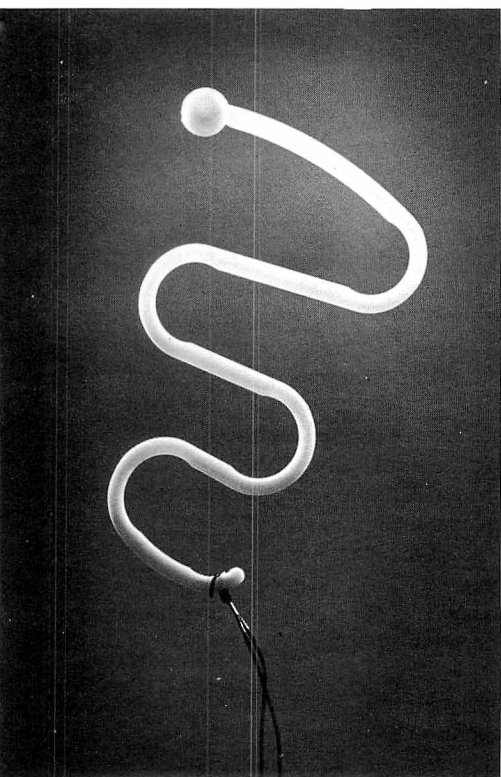
The new regulations were initially proposed July 1, 1975. After careful review of the comments received in response to this proposal, FDA issued the final regulations on May 10. They will become effective November 7.

FDA's goal is to make available a variety of contraceptive methods and to make sure that women and their physicians have the information necessary to make an informed decision about which one to use.

"We encourage women to look for and request the new brochure when it becomes available later this year," Donald Kennedy, Commissioner of Food and Drugs said. "We will require manufacturers to print brochures in quantities larger than the number of IUD's produced, so that this information can be readily available in clinics, physicians' offices, and health facilities."

There are five IUD's now on the market. Two of these—the Lippes Loop and the Saf-T-Coil—are classified as medical devices. The other three—the Cu-7, the Progestasert, and the Copper T—are classified as drugs because after insertion each of these devices secretes a substance which is intended to improve its contraceptive effect.

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



The five IUD's now on the market are (from left) the Lippes Loop, Saf-T-Coil, CU-7, Progestasert, and Copper T.

News Highlights

Restrictions Proposed on Use of BHT

The Food and Drug Administration today proposed to restrict the use of butylated hydroxytoluene (BHT), a widely-used food additive, pending the completion of new safety studies.

BHT is a synthetic compound that helps keep fats and oils in foods from becoming rancid. Foods in which it is used include margarines and oils, jams and jellies, nut products, breakfast cereals, snack foods, frozen dairy products, chewing gum, and processed fruits and vegetables.

FDA made clear that the need for additional testing of BHT is not based on any new evidence that the substance may be unsafe at present levels of use. The need for the additional studies was identified as part of FDA's continuing review of all substances that, like BHT, are Generally Recognized As Safe (GRAS) for use in foods. FDA is applying modern scientific criteria to the evaluation of these substances, most of which have been used for long periods and whose safety was determined years ago. FDA will require that all these substances meet today's safety standards. This often requires additional testing.

Under FDA's proposed action, BHT would be removed from the GRAS list and its use restricted to current levels in foods for which it is now approved.

FDA is proposing that this status continue pending the completion of the new studies by manufacturers.

The new studies would resolve such questions as whether BHT can cause changes in the human liver. This effect was found in rats fed BHT but rats do not break down the chemical in the body the same way that humans do. The new studies would be aimed at finding out what test animals are appropriate for a study of how BHT reacts in humans. Then tests using these animals will need to be conducted.

FDA's proposed action is based on a recommendation of the Federation of American Societies for Experimental Biology (FASEB), Rockville, Maryland, which has been evaluating all GRAS substances under contract to FDA. FASEB experts studied scientific data on BHT from 1920 to the present and recommended the additional studies.

Under FDA's proposal, the companies wishing to use BHT must commit to doing the needed studies. If such a commitment is not made then FDA would seek removal of BHT from the market.

Notice of FDA's proposed action on BHT appeared in the May 31, 1977 FEDERAL REGISTER.

Drug Review Panel Submits Final Report

A panel established in February 1975 to study FDA procedures for evaluating new drugs has submitted its final report to Secretary of Health, Education, and Welfare Joseph Califano. The panel reached three principal conclusions:

"The system of new drug evaluation that requires govern-

mental premarket clearance of prescription drugs, based on evidence of safety and effectiveness, is fundamentally sound."

"FDA is neither pro- nor anti-industry in its review and approval of new drugs."

"FDA's implementation of the system of drug regulation needs substantial improvement. The panel has proposed a wide range of legislative, administrative, and procedural reforms to that end."

The panel which was composed of experts from within and outside the Government, identified four principal shortcomings in the present drug regulation system: the system is unnecessarily closed to public review and participation and overly dependent on informal, unreviewable communications between FDA and industry; the Agency's scientific capacity is inadequate; the Bureau of Drugs employs unacceptably imprecise standards and unstructured, inefficient procedures in reviewing new drug submissions; and the Agency has not paid proper attention to, and lacks necessary authority over, approved drugs.

The panel said FDA recognizes many of these problems and already has taken steps to correct them. The panel said some reforms it is suggesting will require congressional action and urged a cooperative approach between Congress and FDA.

Commissioner of Food and Drugs Donald Kennedy issued the following statement on the report:

"The New Drug Panel has produced a comprehensive and useful report; it contains many elements that can lead to important improvements in FDA procedures. Some of the improvements they suggest have already been made, whereas others will be receiving attention in response to the Secretary's request to me that I analyze the recommendations and report to him by year's end.

"Several of the panel's recommendations for congressional action also reflect previous Agency requests, and we certainly agree that they merit careful evaluation by the Congress.

"I am encouraged that the report (1) clears the Agency of charges that it is unduly influenced by the drug industry; (2) finds no evidence of dishonorable or corrupt conduct among FDA management; and (3) endorses the fundamental soundness of the drug regulatory process, including a failure to find evidence that important new drugs available to other people in other countries are denied the American people by an overzealous FDA or by overly restrictive regulatory laws."

Hearing Granted on Use of Animal Drugs

FDA will hold a hearing on its proposal to withdraw approval of three nitrofurans used in food-producing animals. The announcement that the hearing has been granted appeared in the April 8 FEDERAL REGISTER. The announcement did not set a hearing date.

Nitrofurans are synthetic antibacterial drugs used in chickens, turkeys, and swine to fight disease and promote growth. The drugs also are used to treat mammary gland infections in dairy cattle.

The hearing was requested by two manufacturers, Norwich Pharmacal and Hess & Clark, Division of Rhodia, Inc. The three nitrofurantoin drugs on which hearings will be held are furazolidone, nitrofurazone, and furaltadone.

FDA proposed to withdraw approval of these drugs, plus one additional nitrofurantoin drug, nihydrazone, in 1976. The proposed withdrawal of approval is based on a determination that no adequate test exists for detecting residues of the drugs that may remain in edible animal tissue after slaughter. Under the law, a cancer-causing drug may be used in food-producing animals only if it can be shown that no residues will be detected by an adequate test method approved by FDA. Nitrofurans have been found to cause cancer in laboratory animals.

Approval of nihydrazone was withdrawn effective April 8, 1977, since no hearing was requested.

Firm Recalls Defective Diaphragms

The FDA has announced that Holland-Rantos Company, Piscataway, New Jersey, is recalling 86,000 contraceptive diaphragms because some of them may be defective.

Diaphragms are small disc-shaped devices usually made of rubber that, when inserted through the vagina to the opening of the cervix and used with sperm-killing creams, prevent pregnancy. They are available by prescription from physicians, hospitals, or clinics, and are specially fitted to each patient.

The company is asking purchasers to return the diaphragms to the point of purchase for a refund or replacement.

The diaphragms are being recalled because the central disc, which fits over the cervix, may become separated from the rim. The defective diaphragms are ineffective as contraceptives even when used with spermicidal foam or jelly.

Since January 1975 the firm has received over 300 complaints from consumers and clinics of defects in the product.

The diaphragms being recalled are all sizes produced from June through September 1976 and are identified by the name "Koro-Flex Arcing." The firm is asking that any Koro-Flex Arcing diaphragm that appears defective be returned, but is recalling only those with the lot numbers F-6, G-6, H-6, and I-6 printed on the edge.

X-ray Equipment Safety Program Planned

FDA plans to develop standards or recommendations to assure the safety of x-ray equipment used primarily for the treatment of cancer.

To treat a tumor successfully without needlessly exposing surrounding tissue to radiation, the amount of radiation delivered to the tumor must be carefully calculated and the x-ray machine must be capable of delivering the precisely desired dose. Two FDA surveys have shown that although most radiation therapy equipment can deliver a precise dose, unnecessary errors sometimes occur in the calculation or delivery of the proper dose.

The courses of action being considered to reduce such errors include issuing equipment performance standards, developing recommendations for proper use of equipment, establishing training criteria for equipment operators, and developing recommendations for the manufacture or testing of equipment.

To help develop the safety program, FDA has invited comments from interested persons on such questions as whether performance standards are needed for this equipment; what types of performance criteria are needed; what information should be supplied by the manufacturer; and whether recommendations are needed for equipment operation to cover operator training and experience, routine maintenance, and patient and operator protection. FDA also would like information on documented cases of radiation therapy accidents that resulted in injuries to patients or therapy personnel.

The safety program will be developed and administered cooperatively by FDA's Bureau of Radiological Health and Bureau of Medical Devices and Diagnostic Products.

The "Notice of Intent" to develop radiation therapy regulations was published in the March 22, 1977 *FEDERAL REGISTER*. Comments should be sent to the FDA Hearing Clerk, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20857, by July 20.

Overstrength Suppositories Recalled

The Food and Drug Administration has announced that Alcon Laboratories, Inc., Fort Worth, Texas, is recalling one lot (2,300 boxes of 12 units each) of Wans #2 prescription suppositories distributed in 18 States. Some of the suppositories dispensed for use by children may be adult strength. The adult strength suppositories contain twice the dose of an antihistamine and three times the amount of a barbiturate used in the children's suppositories. Giving children, especially small children, an adult dose could result in barbiturate poisoning.

The recall is precautionary. No injuries have been reported.

Wans suppositories are drugs prescribed for treatment of nausea and vomiting.

The States involved in the recall are: Virginia, North Carolina, South Carolina, Georgia, Florida, Alabama, Arkansas, Kentucky, Louisiana, Mississippi, Missouri, Tennessee, Texas, Oklahoma, Kansas, Nebraska, Indiana, and Illinois.

FDA advises consumers in these States with children for whom suppositories were prescribed between approximately April 1 and May 20 to check any unused suppositories or contact their pharmacist to determine if Wans #2 suppositories were dispensed.

The adult suppositories are labeled Wans #2 and are wrapped in a silver foil with the labeling printed in yellow. These suppositories are yellow. Wans children's strength suppositories are labeled with blue printing on the foil and are aqua in color.

Consumers having any of the recalled product in the home should consult their physicians or pharmacists.

The company estimates that the earliest the suppositories could have been dispensed was April. Prescriptions filled before this time are not involved in the recall.

Regional Reports

"Regional Reports" consists of important information on inspections, product seizures, court proceedings, and other regulatory and administrative actions initiated by FDA's regional and district field offices across the country to provide protection to consumers under Federal laws. "State Actions," the section immediately following "Regional Reports," consists of similar information about the consumer protection activities of State and local governments.

REGION I

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

A variety of foods worth more than \$300,000 were detained by FDA's **Boston District** after investigations and laboratory tests of samples collected by FDA inspectors at the Port of Boston confirmed the products were in violation of FDA regulations. The detentions included whiting fish fillets which lacked proper labeling and were offered for import from Japan; *Salmonella*-contaminated frozen shrimp from India; staphylococci-contaminated langostinos from England; and microbiologically-contaminated chopped clams from Canada. In addition, feta cheese from Austria was detained because the label failed to declare net quantity of contents, and mung beans from Thailand were detained because of contamination by the chemical pesticide endrin.

REGION II

New Jersey, New York, Puerto Rico, Virgin Islands

Strato Dine, Inc., Jamaica, New York, a catering firm that supplies prepared food to airlines for in-flight service, is operating again after closing for two days to clean up an active cockroach infestation found by FDA's **New York District** during a routine inspection. The caterer, which supplies food

to Varig Brazilian Airlines and Air Panama, ceased operation for two days after being placed on use-prohibited status by the New York District. Use prohibited means that the supplier is removed from an FDA list of approved sources of food and beverages to be served to travelers on carriers. Under FDA's Interstate Travel Sanitation Program, inspectors regularly examine the methods of preparation, storage, and handling of food that will be served in interstate transit. In this instance, because both airlines were international carriers, they fell under the jurisdiction of the Center for Disease Control. Investigators from the Center cooperated with FDA in advising the airlines of the prohibition. FDA reinstated the firm after reinspecting it following the two-day cleanup.

Ten shipments of mung beans, offered for import from Thailand, and valued at about \$311,000 were detained by FDA's New York District after an analysis at the district laboratory showed that the beans contained residues of the chemical pesticide endrin exceeding the tolerance level for this food. Mung beans are the chief source of the bean sprouts commonly used in Chinese cookery, and sprouts grown from contaminated beans generally have much lower levels of pesticide than the whole beans. Before mung beans that have been detained for pesticide residues can be entered the importer must have an independent laboratory analyze sprouts grown from the beans and submit evidence that the sprouts are under the tolerance level. The importer also must provide an affidavit from each of his customers saying that they were advised that the beans are contaminated with the pesticide involved and can be used only for sprouting.

The Federal Government seized a shipment of over 900 pounds of Italian Boquet Parmesan Flavored Condiment made by Virginia International Sales, at Schenectady, New York, because of labeling violations. The prod-

uct, valued at over \$1,000, contained no parmesan cheese and the label failed to state the common or usual name of the food. The seizure resulted from a routine inspection of the plant by FDA's **Buffalo District**.

A U.S. marshal seized more than 1,300 cases of canned peeled tomatoes at a public storage warehouse in Albany, New York, after investigators from FDA's **Albany Resident Post** found some of the cans had corroded ends and were swollen or leaking, an indication of possible bacteriological contamination. The tomatoes originally were from Italy and Argentina and were canned by Pope Products, Little Ferry, New Jersey, a division of Purex Corporation. FDA declared the shipment, valued at \$20,000, adulterated and otherwise unfit for human consumption.

Braddock Frosted Foods, Inc., a division of Mrs. Paul's Kitchens, Inc., Hammonton, New Jersey, voluntarily destroyed about 15,000 pounds of flour and 10,000 pounds of breadcrumbs under FDA supervision after a routine inspection of the firm by FDA's **Newark District** turned up evidence of rodent defilement.

Representatives of FDA's **San Juan District** witnessed the destruction of over 19,000 cases of canned food by Puerto Rico Food Products, Inc., Bayamon, P.R., because the manufacturer had not complied with FDA's low-acid canned food good manufacturing practice regulations and was underprocessing the canned foods. Low-acid canned foods such as peppers, onions, and pimientos must be heat-treated at a high enough temperature to kill potentially harmful bacteria which can cause botulism. The action resulted from a routine inspection of the firm by FDA's San Juan District which revealed the violations. The food products, which included Puerto Rican specialties such as conch stew with rice, lobster stew, and pigeon peas with salt and water, were destroyed by crushing

the cans with a bulldozer and burying them.

REGION IV

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

One hundred twenty-eight cases of nuts valued at over \$1,000 were seized by U.S. marshals at Roper Pecan Co., Hickman, Kentucky, after an inspection by FDA's **Nashville District** revealed that they were misbranded. The seized nuts, including 121 cases of Kentucky Kernel pecan halves and pieces and seven cases of black walnuts packed by the firm, were short of labeled weights.

The Federal Government seized 860 pounds of dried coconut and 120 boxes of old-fashioned shoe button candy at Krueger-Satin Candy Co., Largo, Florida, after an inspection by FDA's **Orlando District** showed the products were held under insanitary conditions where they could have been contaminated with live insects. Following the seizure the firm, under Orlando District supervision, fumigated the products, removed all insects on the outside, and inspected the packages to make sure no insects had gotten inside the products. The products, valued at about \$600, were then released back to the firm for use in consumer channels.

A complaint from a truck driver to FDA's **Tampa Resident Post** in Florida about insect-contaminated macaroni products led to a seizure by the Federal Government of approximately \$1,600 worth of macaroni and spaghetti products in a warehouse in Tampa. The driver noticed the contamination as the products were being loaded on his truck at the A & H Warehouse. Subsequent inspection of the warehouse by FDA's Tampa Resident Post confirmed the contamination. The macaroni and spaghetti were subsequently denatured, fumigated, and ground up for hog feed.

REGION VI

Arkansas, Louisiana, New Mexico, Oklahoma, Texas

Creamland Dairies, Inc., Farmington, New Mexico, voluntarily recalled 234 cases of a noncarbonated fruit-flavored punch labeled as sweetened

with saccharin because of labeling violations. A routine inspection by FDA's **Dallas District** found that the firm was using sugar instead of saccharin. After FDA discussed these findings with corporate officials in Albuquerque, the firm decided to recall the drinks containing the sugar and either relabel or destroy them. The recall involved over 900 one-gallon jugs with a total value of approximately \$1,000.

M. W. Soloman & Son, Inc., a warehouse in New Orleans, voluntarily destroyed 246 bags of dried beans, corn, flour, sugar, rice, and salt worth approximately \$1,100 after a routine inspection by FDA's **New Orleans District** revealed numerous lots were contaminated by rodents.

Two Mexican shippers of fresh Mexican serrano and poblano peppers, Francisco Del Bosque and Jose Luis Reguena, have been prohibited by FDA's Dallas District from shipping their produce across the U.S. border unless accompanied by a certification of analysis showing the peppers are in compliance with FDA regulations. The action was taken after Dallas District inspectors found that a high percentage of the firms' fresh peppers were contaminated with illegal pesticide residues, primarily Azodrin and Monitor. The U.S. Customs Service is cooperating by not permitting these two shippers to file entries for such peppers unless they contain the certificates proving compliance. Any shipment without the certification will be immediately returned to Mexico.

A deputy U.S. marshal accompanied by an inspector from FDA's **Little Rock Resident Post** in Arkansas seized numerous lots of unpolished rice and the talc used to polish it at Comet Rice Mills, Inc., Stuttgart, Arkansas, because of bird defilement. The seizure resulted from an earlier inspection by the resident post which revealed extensive bird activity in the firm's storage facility. The talc, totaling nearly 2,500 bags and valued at over \$18,000, was seized and destroyed. The unpolished rice was embargoed by the Arkansas State Health Department until the contaminated material could be separated. Under State supervision, approximately 76 bales and boxes of rice were salvaged and 161 (100-pound) bags of rice were destroyed.

REGION VII

Iowa, Kansas, Missouri, Nebraska

Canada Dry Bottling Co., North Kansas City, Missouri, has begun the recall of approximately 47,000 cases of soda after an inspection by FDA's **Kansas City District** revealed glass particles in the bottles. The firm has destroyed about 2,000 of the 4,000 cases so far recovered.

REGION VIII

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

The Federal Government seized all stocks of antimicrobial sensitivity testing panels and the antibiotic products used in making the panels at Pasco Laboratories, Inc., Wheat Ridge, Colorado. An investigation by FDA's **Denver District**, prompted by a report from FDA's Bureau of Medical Devices, found that the firm did not hold an antibiotic approval from FDA. In addition, the panels, which are used to determine the proper antibiotic dose level to treat patients who have bacterial infections, were mislabeled in that they failed to bear the common or usual name of the product, indications for use, and an accurate statement of the contents. The diagnostic devices were valued at \$13,000.

A trade complaint to FDA's Kansas City District, forwarded to FDA's Denver District, resulted in the Small Business Administration (SBA) reimbursing a dealer for his losses in the purchase of a stock of veterinary drugs at an auction held by the SBA. The auction was part of foreclosure proceedings of the assets of Seney & Co., a Denver manufacturer of veterinary drugs. Investigators from the Denver District confirmed the complaint that some of the drugs should not have been sold because they were unlabeled and had not been approved by FDA. The SBA witnessed the destruction of two truckloads of the drugs at a dump.

REGION IX

Arizona, California, Guam, Hawaii, Nevada

The Federal Government seized 11 cartons of ground fennel seed in the possession of the Baltimore Spice Co., Sparks, Nevada, after investigators from FDA's **San Francisco District**

confirmed it was adulterated with insect fragments. A portion of the lot originally was shipped to a Denver wholesaler where, during a routine inspection, Denver District investigators discovered the adulteration. They notified the San Francisco District which then checked the Nevada firm where the shipment originated. The 550-pound lot of seed was valued at approximately \$400.

Micro-Media Systems and Micro-Media Laboratories, Inc., Campbell, California, and Raleigh Hansel and Chris Riedel, their two top officers, entered into a consent decree of permanent injunction in the U.S. District Court for Northern California agreeing not to distribute their diagnostic test kits until their antibiotics have been certified by FDA. Investigators from FDA's San Francisco District discovered during a routine inspection that the firms were manufacturing and dis-

tributing kits containing uncertified antibiotic drugs. These diagnostic devices are used to determine the proper antibiotic and dose level to treat patients who have bacterial infections.

Tamayo Bros., a shipper of fresh produce in Culican, Mexico, has voluntarily stopped purchasing green beans from several fields in that area because tests by the California Department of Agriculture, confirmed by FDA, proved the beans were contaminated with the chemical pesticide Monitor. The problem came to light after inspectors from the California Department of Agriculture took a market sample of the beans in Los Angeles. Laboratory tests showed the beans were contaminated. The State agency then notified FDA's **Los Angeles District**, which, in turn, traced the shipment to the Arizona town of Nogales, a major entry point for trucks carrying Mexican produce into this country for sale

throughout the United States. FDA inspectors from the **Phoenix District** collected border samples which were tested for contamination at FDA's mobile laboratory located at Nogales. Tests confirmed the contamination and the shippers agreed not to buy from the fields in question.

REGION X

Alaska, Idaho, Oregon, Washington

A U.S. marshal seized over 4,500 pounds of dried figs in the possession of Starflower Co., Eugene, Oregon, because they were moldy and decomposed. Inspectors from FDA's **Seattle District** collected a sample for laboratory examination after learning that the shipper, Simone Fruit Co., Fresno, California, had violated a California State marketing order by shipping unprocessed low-grade figs. The laboratory examination revealed the presence of moldy and decomposed figs.

State Actions

Food Handlers Trained

A group of 150 terminal restaurant and in-flight service employees at the New Orleans International Airport were given a course on Good Sanitation Practices for Food Handlers. The course was presented by the Louisiana State Health Department in connection with FDA's Interstate Travel Sanitation State Contract Program, under which State sanitarians are trained in the proper method of inspecting catering firms that prepare food for airlines and other passenger carriers.

Inspections Bring Cleanup

Inspections of a bakery and a food salvage warehouse in the St. Louis area by the Missouri Division of Health under an FDA contract resulted in a major cleanup and expenditures in excess of \$25,000 for capital improvements and building repairs. Food products at both firms valued at over

\$10,000 were embargoed and destroyed. Health inspectors found insect and rodent control problems at Theodorow Bakery along with improperly maintained equipment. At Soll-Madden food salvage warehouse inspectors found general insanitary conditions caused by building maintenance problems. The bakery is now under new ownership and the warehouse under different management.

Herbicide Use Restricted

The Oregon Department of Agriculture has placed the controversial herbicide 2,4,5-T on the State's list of restricted-use chemicals. The action comes at a time when the safety of the herbicide is being questioned because it contains minute quantities of a compound called dioxin, a highly toxic substance. Under Oregon law, chemicals for which use is restricted may not be sold or used by the general public. They can be sold to and used only by

licensed or certified chemical applicators who must pass examinations proving their competence in the safe and appropriate uses of the chemicals. For several months the Oregon Department of Agriculture has been in the process of updating its list of restricted-use chemicals.

Damaged Drugs Destroyed

A recent fire at the Co-op Pharmacy in Fairbanks, Alaska, resulted in the voluntary destruction by the pharmacy of \$30,000 worth of fire-damaged drugs. The destruction was witnessed by a Fairbanks city sanitarian. Since there was a substantial amount of controlled drugs involved, including Valium, Benzedrine, Seconal, and Amytal, an Alaska State trooper also was present to witness the destruction. None of the drugs in stock at the pharmacy at the time of the fire was salvaged for consumer use.

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 45 actions to remove from the consumer market products charged to be violative was reported in April. These included 33 seizures of foods: 3 involved charges concerning poisonous and deleterious substances, 21 involved charges concerning contamination, and 9 involved charges concerning economic and labeling violations. Other seizures included 4 of food additives, 6 of drugs (including 2 veterinary), and 2 of medical devices.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD/Poisonous and Deleterious Substances		
Mahi Mahi fish fillets/Los Angeles, Calif. 2/24/77	Inexpac/Ecuador (P)	Contains added poisonous and deleterious histamine-like substances which might render article injurious to health; contains decomposed fish.
Swordfish/Los Angeles, Calif. 10/21/76	Fresh Water Fish Co./Boston, Mass. (S)	Contains the added poisonous and deleterious substance mercury.
San Pedro, Calif. 10/21/76	Garcia Bros. Seafood/Miami, Fla. (S)	
Contamination, Spoilage, Insanitary Handling		
Breeding mix and breadcrumbs/Old Monroe, Mo. 12/6/76	Sun Ring Foods, Div. of Tamara Foods, Inc./Old Monroe, Mo. (D)	Held under insanitary conditions; rodent contaminated.
Chamomile flowers/Boulder, Colo. 3/15/77	Imported from Kashmir.	Insect and bird contaminated.
Cheese/Stanford, Ky. 11/26/76	Shoals Cheese Corp./Florence, Ala. (M,S)	Prepared under insanitary conditions.
Cheeses, Sardo, Blue, & Romano, and dried eels/New York, N.Y. 2/4/77	West Side Cold Storage Co./New York, N.Y. (D)	Held under insanitary conditions; rodent contaminated.
Currants and raisins/Buffalo, N.Y. 12/21/76	Federal Bakers' Supply Corp./Buffalo, N.Y. (D)	Held under insanitary conditions; contain insects and insect filth.
Donut flour/London, Ky. 11/11/76	Henry Nagel & Son/Cincinnati, Ohio (M,S)	Prepared and packed under insanitary conditions.
Fennel seed/Sparks, Nev. 3/11/77	Baltimore Spice Co./Sparks, Nev. (D)	Contains insect filth.
Garrison, Md. 4/6/77	Imported from Kobe, Japan.	Contains bird, rodent, and other filth.
Figs, dried/Eugene, Oreg. 2/24/77	Simone Fruit Co., Inc./Fresno, Calif. (P)	Decomposed and moldy.
Flour/Worcester, Mass. 3/23/77	Yankee Products Co./Worcester, Mass. (D)	Held under insanitary conditions; rodent contaminated.
Tulsa, Okla. 3/29/77	Shipped from Blackwell, Okla.	Held under insanitary conditions.
Halibut, headless, frozen/Los Angeles, Calif. 2/24/77	Shipped from Bellingham, Wash.	Decomposed.
Jujubes/New York, N.Y. 3/1/77	West Side Cold Storage Co./New York, N.Y. (D)	Contains moldy jujubes (red dates).
Mushrooms, canned/Hollywood, Fla. 2/14/77	Imported from Santo Domingo, Dominican Republic.	Unfit for food due to an offensive hydrogen sulfide-like odor; contains decomposed mushrooms.
Poppyseed/Berkeley, Calif. 1/18/77	Brothers' Bagel Factory/Berkeley, Calif. (D)	Held under insanitary conditions.
Prawns, frozen, and frozen shrimp/Ocala, Fla. 11/24/76	LIB International/Savannah, Ga. (S)	Contain decomposed shrimp.
Yams, cut, canned/Centralia, Ill. 3/3/77	Shipped from Springdale, Ark.	Contained in swollen cans.
Talc for coating rice/Crowley, La. 2/28/77	Brown & Cassidy Warehouse, Inc./Crowley, La. (D)	Contains rodent filth; held under insanitary conditions.
Tomatoes, peeled/Albany, N.Y. 3/18/77	Imported from Italy and Argentina.	Decomposed; unfit for food, since is contained in swollen or leaking cans, and in cans having corroding interiors.
Vinegar, cider and white, Little Skipper/Ypsilanti, Mich. 2/1/77	Wiard's Orchards, Inc./Ypsilanti, Mich. (M,S,D)	Contains nematodes (vinegar eels).
Walnuts, unshelled, and currants/Bronx, N.Y. 2/23/77	Becker Storage & Transportation Co./Bronx, N.Y. (D)	Held under insanitary conditions; rodent and/or insect contaminated.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Economic and Labeling Violations		
Cheese, salad dressing & beer/Jefferson- sontown, Ky. 12/21/76	Allen Dairy Foods, Inc./Columbus, Ohio (M); Oak Lake Farms, Inc./ Columbus, Ohio (S)	The term "Beer Cheese" prominently appearing on the label is false and misleading in representing the article (a spread) as cheese.
Honey/Tampa, Fla. 11/12/76	Pakhoed Rotterdam BV/Rotterdam, Holland (S)	Syrup has been substituted in whole or in part for honey.
Nuts, mixed/Grand Rapids, Mich. 2/17/ 77	B & S Produce/Detroit, Mich. (P,S)	Inaccurate quantity of contents statement.
Olive oil, Mamma Mia/Los Angeles, Calif. 10/20/76	Roberts Food Corp./Brooklyn, N.Y. (M,S)	Another oil has been substituted in part for olive oil.
Orange drink/Omaha, Nebr. 12/29/76	Goodrich Dairy Co./Omaha, Nebr. (D)	Label lacks required statement of the percent of orange juice in the food.
"Parmesan" cheese, grated/Indianapo- lis, Ind. 2/23/77	Virginia International Sales (Amity Cheese Co.)/Schenectady, N.Y. (M,S)	A substance other than grated parmesan cheese sub- stituted for the article; label claim "Parmesan cheese" is false and misleading; and article does not meet definition and standard of identity for grated cheese.
"Romano" cheese, grated/Noblesville, Ind. 2/23/77	Virginia International Sales, Ltd./Sche- nectady, N.Y. (M,S)	A substance other than grated Romano cheese substi- tuted for the article; false and misleading label claim "Romano cheese"; and article does not meet definition and standard of identity for grated cheese.
Shrimp, frozen/Grand Prairie, Tex. 4/4/ 77	United Ice Works, Ltd./Malasia (P); G & G Food Sales Co./Phoenix, Ariz. (S)	Article is short weight; the quantity of contents declaration is not separated from other printed information above and below; and the quantity of contents statement was expressed as "Net Wt. 3 LBS." instead of "Net Wt. 48 Oz. (3 Lbs.)".
Shrimp, raw, breaded, frozen/Omaha, Nebr. 2/4/77	Deals' Seafood Co./Miami, Fla. (M,S)	Article does not meet definition and standard of identity for frozen raw breaded shrimp, since arti- cle contains less than 50 percent shrimp material.
FOOD ADDITIVES		
Aangamik 15 calcium pangamate tab- lets/Honolulu, Hawaii 3/1/77	Food Science Labs, Inc./Burlington, Vt. (S)	Contains nonconforming food additive calcium pan- gamate; false and misleading claims about nature, nutritional properties, and usefulness.
Calcium panagamate tablets (Vitamin B- 15)/Des Plaines, Ill. 3/10/77	"	Contains nonconforming food additive calcium pan- gamate; false and misleading claims about nature, nutritional properties, and usefulness; lacks com- mon or usual name of ingredients described as binder and lubricant.
Dallas, Tex. 3/31/77	"	"
Ospor-25 tablets/St. Petersburg, Fla. 2/ 16/77	Alpha Pharmaceutical Co./St. Louis, Mo. (M,S)	Article's label statements "For Special Dietary Use Only" and "Caution: Federal Law Prohibits Dis- pensing Without Prescription" are inconsistent with each other; new drug without an effective approved New Drug Application; contains the non- conforming food additive sodium fluoride.
DRUGS/Human Use		
Aluminum chlorhydrate powder/St. Paul, Minn. 3/11/77	Wickhen Products, Inc./Huguenot, N.Y. (M,S)	Prepared and held under insanitary conditions; cir- cumstances of manufacture, processing, packing, and holding not in conformity with current good manufacturing practice.
Benzthiazide tablets/Miami, Fla. 2/14/77	Lemmon Pharmacal Co., Inc./Sellers- ville, Pa. (M,S)	Article is a new drug without an effective approved New Drug Application.
Mercuric oxide, yellow, U.S.P.; berber- ine neutral sulfate; methyl parasept; and propyl parasept/Bristol, Va. 12/7/ 76	Dickey Drug Co./Bristol, Va. (D)	Circumstances used for the manufacture, processing, packing, and holding of the articles were not in conformity with current good manufacturing prac- tice.
Spirits of camphor, calamine lotion, U.S.P., and wintergreen isopropyl rubbing alcohol, and certain non-Rx drugs/Nitro, W. Va. 1/3 & 4/77	Davis Manufacturing Co., Inc., t/a United Pharmaceuticals, Inc./Knox- ville, Tenn. (M,S)	Circumstances used for the manufacture of the arti- cles were not in conformity with current good manufacturing practice.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
DRUGS/Veterinary		
Chloramphenicol solution/Wakarusa, Ind. 3/23/77	Clare Martin Farm/Wakarusa, Ind. (D)	Article is a new animal drug and no approved New Animal Drug Application was in effect with respect to the use and intended use of the article; article lacked a label and lacked accompanying labeling bearing adequate directions for use.
Sedaspec cough medicine/S. Plainfield, N.J. 3/30/77	Ayerst Labs/S. Plainfield, N.J. (D)	Article is new animal drug and no approved New Animal Drug Application was in effect with respect to the use or intended use of the article.
MEDICAL DEVICES		
Acupuncture needles, patches, tacks, and related items/Dearborn, Mich. 1/17 & 18/77	Grace H. Dohring, t/a Doctor's Supply/Dearborn, Mich. (D)	False and misleading claims for various specified pains, "incurable or hopeless" conditions, colds, stomach conditions, spleen and lymphatics, obesity, addiction, and other specific uses; inadequate directions for use; and (some devices) inadequate directions for veterinary use.
Solarama boards/Lubbock, Tex. 3/5/77	Arden Jones, t/a Solarama of Lubbock/Lubbock, Tex. (D)	False and misleading claims for relaxation of tension; inadequate directions for intended use.

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)

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| <p>March 8, 1977: E-Pill, 447 Merrick Road, Oceanside, New York. Advertising and sale through the mail of the product "E-Pill," representing the ability to increase and rejuvenate sexual drive and potency.</p> <p>March 16, 1977: American Image Industries, Inc., 276 Park Avenue South, New York, New York. Advertising and sale through the mail of the product "Sauna Trim Belt," a device representing the ability to tone, tighten, slim, and firm sagging waist muscles without diet, pills, or exercise.</p> <p>March 22, 1977: Brad Mitchell, 27313 Plymouth Road, Detroit, Michigan. Advertising and sale through the mail of the product "The Amazing Fat Burning System," a diet program representing the ability to cause weight loss.</p> | <p>April 8, 1977: Sunset House, 341 Sunset Building, Beverly Hills, California. Advertising and sale through the mail of the product "Natural Facial Rejuvenation," a facial rejuvenation device representing the ability to "add years of youth to your face."</p> <p>April 12, 1977: Eureka Products, 1246 South La Cienega Blvd., Los Angeles, California. Advertising and sale through the mail of the product "Standard Vacuum Enlarger" representing the ability to cause a longer, thicker penis.</p> <p>April 13, 1977: Lion Products, 13510 Ventura Blvd., Sherman Oaks, California. Advertising and sale through the mail of the product "Spanish Fly Spice" representing the ability to cause an "insistent and compelling need for sexual satisfaction."</p> |
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False Representation Order Issued by Judicial Officer Under 39 U.S.C. 3005

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| <p>March 30, 1977: Against Box 1313, Tupper Lake, New York. Advertising and sale through the mail of literature containing information</p> | <p>representing the ability to cure cancer with the aid of cranberry juice.</p> |
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Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Apricot kernels, at Melrose Park, N. Dist. Ill.

Charged 12-28-76: when shipped by Earth Products, Inc., Marina del Rey, Calif., the article contained the poisonous and deleterious substance hydrocyanic acid (hydrogen cyanide) in such quantity as to render it injurious to health and the article was unfit for food because of the presence of hydrocyanic acid; 402(a)(1), 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61039; S. No. 77-03-610 et al.; N.J. No. 1)

FOOD/Contamination, Spoilage, Insanitary Handling

Beverage, carbonated, 7 Up, at Olathe, Dist. Kans.

Charged 10-13-76: when shipped by the Seven-Up Bottling Co., Kansas City, Mo., the article contained yeast, mold, and nondescript foreign material, and had been prepared, packed, and held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60928; S. No. 77-24-764; N.J. No. 2)

Brazil nuts, at Minneapolis, Dist. Minn.

Charged 1-7-77: when shipped by Braun & Sons, Lake Success, N.Y., the article, labeled in part "Brazil Nuts Product of Brazil Exportadora Mutran Ltda. . . . Belem-Para," contained insects; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61082; S. No. 77-97-603; N.J. No. 3)

Cherries, brined, at Cleveland, N. Dist. Ohio.

Charged 1-19-77: when shipped by Briggs-Aitchison Co., Inc., t/a Northland Products, Inc., Wenatchee, Wash., the article contained insect filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 61064; S. No. 77-13-945; N.J. No. 4)

Fennel seed, at Utica, N. Dist. N.Y.

Charged 7-22-76: when shipped by General Spice Co., Inc., Malden, Mass., the article was unfit for food because of dirt and stones in the food; and dirt and stones had been substituted in part for fennel seed; 402(a)(3), 402(b)(2). Default decree ordered destruction. (F.D.C. No. 60793; S. Nos. 76-58-594/5; N.J. No. 5)

Flour, at Lawrenceburg, M. Dist. Tenn.

Charged 1-5-76: while held by M.G.H. Wholesale Grocery, Inc., Lawrenceburg, Tenn., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 60609; S. Nos. 76-34-226, 76-34-228; N.J. No. 6)

Flour, at Virginia Beach, E. Dist. Va.

Charged 12-3-76: while held for sale, the article contained insects; 402(a)(3). Consent decree authorized release to Norfolk Southern Railway Co., Virginia Beach, Va., for conversion into feed for nonhuman use. (F.D.C. No. 60802; S. Nos. 77-60-234/5; N.J. No. 7)

Flour, high gluten, at Cambridge, Dist. Mass.

Charged 7-16-76: while held for sale, the article had been held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60713; S. No. 76-57-380; N.J. No. 8)

Flour and textured vegetable protein, at Kansas City, W. Dist. Mo.

Charged 2-1-77: while held by Isis Foods, Inc., Kansas City, Mo., the textured vegetable protein contained rodent filth, and the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61074; S. Nos. 77-84-521, 77-84-523; N.J. No. 9)

Lentil soup, canned, at Brooklyn, E. Dist. N.Y.

Charged 11-22-76: when shipped by Florio & Co., Salerno, Italy, the article, labeled in part "Florio . . . Lentils soup . . . Florio & C. S.p.A. Salerno—Italy . . . Imported By D. Coluccio & Sons" Brooklyn, N.Y., contained insect filth—402(a)(3); and the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not within the bottom 30 percent of the principal display panel area; 15 U.S.C. 1453(a)(2). Default decree ordered destruction. (F.D.C. No. 60871; S. No. 77-41-900; N.J. No. 10)

Lobster tail meat, frozen, at Hopkins, Dist. Minn.

Charged 1-7-77: while held for sale, the article contained decomposed slipper lobster tail meat; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61062; S. No. 77-30-576 et al.; N.J. No. 11)

Macaroni products, rice, textured protein and other retail food stocks, at Grand Prairie, N. Dist. Tex.

Charged 9-21-76: while held by Basic Needs, Inc., Grand Prairie, Tex., the articles were held under insanitary conditions, and some of the articles contained insect filth; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. However, the dealer neither posted bond nor brought the articles into compliance. Accordingly, the Government moved for, and was granted a default decree. The default decree ordered the articles destroyed. (F.D.C. No. 60918; S. No. 77-65-722 et al.; N.J. No. 12)

Mushrooms, breaded, Chef Edward, at Old Monroe, E. Dist. Mo.

Charged 1-7-77: while held by Sun Ring Foods, Div. Tamara Foods, Inc., Old Monroe, Mo., who manufactured the article using mushrooms and breading mix shipped in interstate commerce, the article had been prepared under insanitary conditions; 402(a)(4). Default decree authorized donation to governmental department for animal feed and not for human consumption. (F.D.C. No. 61073; S. No. 77-24-098; N.J. No. 13)

Oat cereal, barley, macaroni products, sugar, cake mixes, and other grocery stocks, at Kenosha, E. Dist. Wis.

Charged 11-5-76: while held by Kenosha Wholesale Grocery Co., Kenosha, Wis., the articles were held under insanitary conditions, and some of the articles contained insect filth; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60978; S. No. 77-30-983 et al.; N.J. No. 14)

Squash, canned, One-Pie, and canned pumpkin, One-Pie, at Andover, Dist. Mass.

Charged 1-3-77: when shipped by Medomak Canning Co., Winslow's Mills, Maine, the articles contained decomposed squash and decomposed pumpkin, respectively; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61043; S. Nos. 77-57-546, 77-57-548/9; N.J. No. 15)

Wheat (triticale), at New York, S. Dist. N.Y.

Charged 10-13-76: while held by Mattel Health Foods, Inc., New York, N.Y., the article contained insect filth, and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60895; S. No. 77-89-082; N.J. No. 16)

Whiskies, Scotch, Canadian, and Kentucky Bourbon, at Superior, W. Dist. Wis.

Charged 11-14-73: while held by Exports, Inc., Superior, Wis. (when the floor of the Customs Bonded warehouse collapsed and the articles fell into the waters of the Duluth-Superior harbor), the articles were held under insanitary conditions; 402(a)(4). The articles were claimed by the dealer, who denied the charge and denied that the articles were either in interstate commerce or were held for sale after shipment in interstate commerce. Subsequently, a consent decree of condemnation was entered which authorized release under bond for salvaging by redistillation. (F.D.C. No. 59496; S. No. 59-938 G; N.J. No. 17)

FOOD/Economic and Labeling Violations

Candy bars, at Irvine, C. Dist. Calif.

Charged 9-20-76: while held for sale after manufacture by Natural Protein Products, Hayward, Calif., using peanut butter shipped in interstate commerce, the labeling of the article (labeled in part "Tigers Milk Calorie Watcher's Snack . . . Extra Low in Calories and Carbohydrates No Sugar . . . Plus Products, Irvine, Ca. . . . Distr.") was false and misleading, since specified label statements represented that the article contained no sugar and that the article was for use in calorie-restricted diets, although the article contained brown sugar, corn syrup, sorbitol, and honey, and supplied 175 calories per 1.5 ounce bar; the article's labeling was also false and misleading as to the list of ingredients, since such list, which was required to appear in descending order of predominance by weight, was in a different order on the carton label than on the bar wrapper label; and the article's label lacked the common or usual name of each ingredient, since the "carob coating" and "special Tiger's Milk blend" declared as ingredients on the carton label were not common or usual names of ingredients; 403(a), 403(i)(2). Consent decree authorized release to Plus Products, Inc., Irvine, Calif., for salvaging. Subsequently, the article was found to be infested with insect matter, and pursuant to stipulation of the parties, the article was ordered destroyed. (F.D.C. No. 60897; S. No. 77-77-971; N.J. No. 18)



Cheese, grated, Dante, at Cincinnati, S. Dist. Ohio.

Charged 2-14-77: when shipped by Virginia International Sales, Ltd., t/a Amity Cheese Co., Schenectady, N.Y., the article, labeled in part "Dante Italian Caccio-Parmesan-Bianco Grated Superior . . . Packed By Virginia International Sales, Ltd., Schenectady, N.Y.," had had a food other than parmesan cheese substituted wholly or in part for the article; label claims of consisting wholly of parmesan cheese were false and misleading; and the article failed to conform to the definition and standard of identity for grated cheese, since the fat content of the solids of the grated cheese was less than 31 percent (fat content of product in 1-lb. jars—approx. 9 percent; fat content of product in 5-lb. buckets—approx. 12 percent); 402(b)(2), 403(a), 403(g)(1). Default decree ordered destruction. (F.D.C. No. 60234; S. Nos. 77-81-002/3; N.J. No. 19)

Pepperoncini, Gloria, at Boston, Dist. Mass.

Charged 6-24-76: while held by Gloria Packing Corp., Boston, Mass., who repacked article from bulk pepperoncini shipped from Greece, the article was approximately 9 percent short in volume; 403(e)(2). Consent decree authorized release to dealer for reconditioning. (F.D.C. No. 60782; S. No. 76-07-047; N.J. No. 20)

Sugar, citric acid, dehydrated lemon juice, egg white, and sodium saccharin combinations, at New York, S. Dist. N.Y.

Charged on or about 10-18-76: while held for sale, the articles (which were manufactured by the Lemon Corp. of America, New York, N.Y., using sodium saccharin shipped in interstate commerce and which were labeled in part "L.C. Mix Sweetened . . . Prepared For The Mixologist To Be Used In Alcoholic Drinks . . . Lemon Corporation of America New York, N.Y.," and "Juice Right Lemon Juice Mixer . . . Made Professionally For Professionals . . . The Juice Right Company . . . Farmingdale, N.Y.") contained the food additive saccharin which was not in conformity with regulations providing for its use or intended use as a sweetening agent only in special dietary foods—402(a)(2)(C); saccharin had been substituted in part for sugar in the articles—402(b)(2); and the label vignettes of a person holding a cocktail shaker and certain other label statements were false and misleading in representing that the articles might legally be added to alcoholic beverages, since due to the lack of a valid special dietary use for saccharin for naturally high calorie alcoholic beverages—403(a). The articles were claimed by Stanley R. Scheftel, t/a The Juice-Right Co., Farmingdale, N.Y., and the Lemon Corp. of America, Inc., New York, N.Y. Subsequently, a consent decree was entered condemning the articles, ordering the destruction of the violative labeling, authorizing the retention of the organic contents of the articles, and permanently enjoining the printing, manufacturing, using, or distributing of packaging and labels which represented that the articles might be legally added to alcoholic beverages. (F.D.C. No. 60875; S. Nos. 77-42-396/7; N.J. No. 21)

FOOD ADDITIVES

Vita Life calcium gluconate & dimethyl glycine tablets, at Tulsa, N. Dist. Okla.

Charged 12-8-76: when shipped by Belvedere Laboratories, Hayward, Calif., the article contained the nonconforming food additives calcium pangamate and dimethyl glycine; the article's label lacked the common or usual name of each ingredient; and label statements, such as "a formula for Calcium Pangamate, a salt of pangamic acid," "Vitamin B₁₅," and "Suggested use: as a dietary supplement" were false and misleading, since, among other reasons, calcium pangamate was not an identifiable substance and was not a vitamin or provitamin, and since no medical, nutritional, or other usefulness for calcium pangamate had been established; 402(a)(2)(C), 403(a), 403(i)(2). Default decree ordered destruction. (F.D.C. No. 60997; S. Nos. 77-16-181/2; N.J. No. 22)

Sodium pangamate tablets, at Hollywood, S. Dist. Fla.

Charged 7-19-76: while held by Generix Drug Corp., Hollywood, Fla., who was repacking the article into bottles labeled in part "Gold Line . . . Vitamin B-15 (Sodium pangamate) . . . Tablets Distributed by Generix Drug Sales Co., Hollywood, Fla.," the article contained the nonconforming food additive sodium pangamate; the article's labels lacked the common or usual name of each ingredient; and bottle label statements, such as "Vitamin B-15," "50 mg.," "As a dietary supplement . . . or as prescribed by a physician," "Vitamin B-15 is not intended for . . . treatment or prevention of disease . . ." were false and misleading, (1) since

sodium pangamate was not an identifiable substance and was not a vitamin or provitamin, (2) since there was no accepted evidence which had established any nutritional properties of the substance or had identified a deficiency of sodium pangamate in man or animals, (3) since physicians generally did not prescribe sodium pangamate, and (4) since no medical, nutritional, or other usefulness for sodium pangamate had been established; 402(a)(2)(C), 403(a), 403(i)(2). Default decree ordered destruction. (F.D.C. No. 60784; S. Nos. 76-43-398/400; N.J. No. 23)

ANIMAL FEED

Beef, raw, frozen, for greyhounds, at Avondale, Dist. Ariz.

Charged 1-18-77: when shipped by Hi-Plains Processing, Wildorado, Tex., the article was wholly, or partly, the product of diseased animals or animals which had died otherwise than by slaughter; 402(a)(5). Default decree ordered destruction. (F.D.C. No. 61061; S. No. 77-65-876; N.J. No. 24)

Skim milk, refined tallow and lecithin combination feed mixes, at Kenosha, E. Dist. Wis.

Charged 1-10-77: while held by Morelli's Overseas Export Service of Wisconsin, Inc., Kenosha, Wis., the articles contained rodent filth, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release of one lot to Berns and Koppstein, New York, N.Y., and the other lot jointly to M. E. Franks, Inc., New York, N.Y., and Mulligan's Sales, Inc., City of Industry, Calif., for salvaging. (F.D.C. No. 61086; S. No. 77-30-916; N.J. No. 25)

DRUGS/Human Use

Ether, U.S.P., at Cincinnati, S. Dist. Ohio.

Charged 12-23-76: when shipped by Mallinckrodt Inc., St. Louis, Mo., the quality and purity of the article fell below U.S. Pharmacopeia standards, since the article contained excessive aldehydes and peroxides; 501(b). Default decree ordered destruction. (F.D.C. No. 61055; S. Nos. 77-81-857/8; N.J. No. 26)

Trisulfapyrimidines tablets, U.S.P., at Columbus, S. Dist. Ohio.

Charged 10-18-76: when shipped by Cord Laboratories, Inc., Bloomfield, Colo., the article, labeled in part "Triple Sulfa (Trisulfapyrimidines Tablets, U.S.P.) 500 mg. . . . Distributed By Standex Laboratories, Inc. Columbus, Ohio," was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 60890; S. No. 77-81-124; N.J. No. 27)

DRUGS/Veterinary

Digitoxin treat-type chewable tablets for animals, at Garden Grove, C. Dist. Calif.

Charged 2-19-75: while held for sale after manufacture by Linden Laboratories, Inc., Los Angeles, Calif., from digitoxin shipped in interstate commerce, both the 0.2 mg and 0.05 mg dosages of the article labeled in part "Aric-A-Tab Digitoxin 0.2 mg [or "Digitoxin 0.05 mg"] . . . Dangerous Drug . . . Made Expressly For Hall Veterinary Drug Co. . . . Garden Grove, Calif.," were new animal drugs, and no approval of a New Animal Drug Application was in effect for the use or intended use of such drugs; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 60221; S. Nos. 55-796/7 G; N.J. No. 28)

Pet-Tabs Gee diethylstilbestrol, methyltestosterone, vitamins, and minerals combination tablets, in-process material, and diethylstilbestrol raw material, at Bristol, E. Dist. Tenn.

Charged 1-20-75: while held by Beecham-Massengill Pharmaceuticals Div. of Beecham, Inc., Bristol, Tenn., who was manufacturing the tablets using diethylstilbestrol shipped in interstate commerce, the articles were new animal drugs and no approval of a New Animal Drug Application was in effect with respect to the use and intended use of the articles; 501(a)(5). The article was claimed by Beecham Laboratories (formerly Beecham-Massengill Pharmaceuticals) Division of Beecham, Inc., Bristol, Tenn. The claimant admitted that there was no approval of a New Animal Drug Application for the Pet-Tabs Gee tablets, denied that any of the articles were new animal drugs, and asserted that in 1970 and 1971 FDA had advised the claimant in writing that the Pet-Tabs Gee tablets was not a new animal drug, and that, prior to this action, FDA had never modified its advice to the claimant. The Government filed requests for admissions. The claimant moved for a stay



pending an FDA administrative determination by the FDA Commissioner that Pet-Tabs Gee was a new animal drug. The Government opposed such a stay. The court referred the new animal drug status to the FDA Commissioner for such an initial administrative determination. The FDA Commissioner responded to the order of the court, respectfully declining to accept the referral of the issue of new animal drug status for the following reasons:

1. FDA's administrative determination that the Pet-Tabs Gee tablets was a new animal drug had already been made in preparation for the seizure action, was implicit in the FDA request for filing the action, and was explicitly alleged in the complaint for forfeiture;
2. Although the promulgated, but not yet effective [40 F.R. 23046] regulations cited by the claimant did provide for the option of intralitigation referral of a matter within the FDA primary jurisdiction on which the Agency had not yet taken a position, such regulations were not intended to retract, from the district court's consideration, any issue raised in FDA enforcement proceedings, and properly tendered to the court for judicial decision;
3. Having invoked this court's jurisdiction to consider this case, directly raising the new animal drug issue, the Commissioner of Food and Drugs must decline the opportunity to interrupt the proceedings brought at the Agency's instigation to make again a jurisdictional determination that must, in any event, be subject to judicial review;
4. Referral of such cases back to FDA for re-determination of new drug status will delay the condemnation of the drug seized here if found to be adulterated as alleged, and will provide a disincentive to other manufacturers to submit the New Animal Drug Applications required by the Federal Food, Drug, and Cosmetic Act.

Based on the FDA Commissioner's response, the court denied the stay requested by the claimant. The court found that adjudication of the new animal drug issue was necessary as a predicate to any enforcement in this action and accordingly assigned for trial such issue. The court denied the claimant's motion for reconsideration of its motion for a stay. The parties served written interrogatories on each other. Both parties also moved for summary judgment in their own favor. The court denied such motions on the ground that summary judgment was proper only where there was no genuine issue of material fact and that whether the seized drug was or was not recognized as safe generally, among qualified experts, was a genuine issue of material fact.

The case came on for trial by the court. The court found that the articles were new animal drugs and no approvals of New Animal Drug Applications were in effect for the drugs; that there had been no FDA administrative determination of new drug status for Pet-Tabs Gee until about December 4, 1974; that such determination of new drug status was not based upon any evidence of known safety or lack of effect of the drug as labeled and formulated; and that Pet-Tabs Gee tablets were not exempted by the grandfather clause. The Government moved that the court order the claimant pay all the costs of the trial of the action. In denying such motion, the court said:

"The plaintiff moved the Court for an order requiring the claimant to pay its reasonable expenses incurred in proving that the articles of drug involved herein were 'new animal drugs' within the meaning of 21 U.S.C. § 321(w)(1), which the claimant refused to admit when requested to do so by the plaintiff pursuant to Rule 36(a), Federal Rules of Civil Procedure; Rule 37(c), Federal Rules of Civil Procedure; 21 U.S.C. § 334(e). After trial herein, the Court made a finding of fact that *** [t]he articles of drug, 'PET-TABS-GEE,' constituted new animal drugs *** within the meaning of such statute. . . .

"Rule 37(c), Federal Rules of [Civil] Procedure *** requires the Court to award expenses including reasonable attorney's fees to a party whose request for the admission of the truth of any matter under Rule 36 is denied and who thereafter proves the truth of the matter, unless any one of four conditions is found to exist. *** . . . One such condition is that *** the party failing to admit had reasonable ground to believe that he might prevail on the matter. *** Rule 37(c)(3), Federal Rules of Civil Procedure. The true test is not whether such party actually prevailed at trial but whether he acted reasonably in believing that he might prevail. . . .

"Whether such articles of drug were 'new animal drugs' involved complex issues of both fact and law. Such determination required not only a consideration of the general recognition of safety and effectiveness of such items, but also a legal conclusion

as to whether or not such drug was entitled to 'the grandfather protection' from the new drug definition of 21 U.S.C. § 321(w)(1) by virtue of Public Law 90-399, § 108(b)(3). As a conclusion of law the Court held that such 'grandfather clause' was not applicable hereto. . . . Under such circumstances, the Court finds that the claimant had reasonable ground to believe that it might prevail on the matter which the plaintiff requested it to admit. . . .

"The plaintiff also bases its motion on 21 U.S.C. § 334(e). Such provision provides that *** [w]hen a decree of condemnation is entered against the article [of drug], court costs and fees, and storage and other proper expenses, shall be awarded against the person *** intervening as claimant of the article. *** Such statute is not applicable to the type of costs and expenses sought herein, since the Government's expenses in proving the aforementioned matter do not fall within its scope of coverage. Expenses of presenting proof at trial do not appear to be either 'court costs and fees' or 'storage and other proper expenses' within the meaning of such statute."

Meanwhile the clerk of the court taxed the routine witness and court costs. The claimant moved for review of the cost assessed by the clerk so as to reduce the costs from \$2,588.76 to \$647.68. The court found that the mileage fees for witnesses was not limited to fees for no more than 100 miles, but disallowed witness fees for individuals who came to the courthouse but did not testify. In so ruling, the court rendered an opinion saying:

"The principal contention of the claimant is that the amount allowed to the plaintiff as costs for witness and subsistence fees herein is limited to those respective amounts established by statute, viz., 28 U.S.C. § 1821. The Congress has provided that *** [a] witness shall receive \$20 for each day's attendance and for the time necessarily occupied in going to and returning from the same *** and to an additional allowance of \$16 per day for expenses of subsistence. *** *Idem*.

"Although this Court has discretion in the awarding of taxable costs, it *** cannot grant an amount larger than that allowed by the applicable statute. *** . . . Thus, the plaintiff is entitled to a \$20 per-day witness-attendance fee plus \$16 per-day subsistence allowance for each such witness who is not an employee of the United States.

"As to the plaintiff's attempt to tax as costs against the claimant witness fees, etc. for individuals who were present but did not testify at the trial, it is the general rule that *** no fee may be taxed for someone who comes to the courthouse but does not testify at the trial, the presumption being that he was not a necessary witness. *** . . . Although such presumption may be rebutted . . . the explanations offered by the plaintiff are insufficient for such purposes. Accordingly, such claimed costs are improper.

"Finally, the claimant contends that the mileage fees for witnesses provided for under 28 U.S.C. § 1821 are limited to the mileage incurred within the district and to a radius of 100-miles-travel from the situs of this Court. Although the aforementioned statute provides no such mileage-limitation, it has generally been held *** that a witness [can only] receive the statutory amount for a maximum of 100 miles to and from the place of *** [the] trial. *** 10 Wright & Miller, [Federal Practice and Procedure] at 231, § 2678. Such a rule developed, because *** it was reasonable to conclude that mileage fees under [28 U.S.C.] § 1821 were geared to the effective limits of the subpoena; and hence, where the subpoena was subject to the general territorial limits, mileage allowance taxable as costs was [likewise so] limited. *** 6 Moore's Federal Practice (2d ed.) 1726, ¶ 54.77 [5.-1].

"Thus, *** [m]any decisions of district courts and courts of appeals have held that since witnesses cannot be compelled under [Rule 45(e), Federal Rules of Civil Procedure.] to travel more than 100 miles, a party who persuades them to do so by paying their transportation expenses cannot have those expenses taxed as costs against his adversary. *** *Farmer v. Arabian American Oil Co.* (1964), 379 U.S. 227, 231, 85 S. Ct. 411, 13 L. Ed. (2d) 248, 252 [1]. Under Rule 54(d), *supra*, it is within the discretion of the District Court, however, to determine whether the prevailing party should be allowed the transportation-expenses of its witnesses in excess of the 100-mile limitation. *Ibid.*, 379 U.S. at 232, 13 L. Ed. (2d) at 252-253 [2]. Nevertheless, *** the discretion to allow the costs of bringing witnesses from a point more than 100 miles away from the place of [the trial] and outside the district is not as broad as the



discretion conferred upon district judges in many other areas. *** *Grogan v. United States*, C. A. 6th (1965), 341 F. (2d) 39, 43 [6].

"Applying these criteria, the Court is of the opinion that, in the exercise of its limited discretion, the plaintiff should be permitted to tax herein against the claimant its witnesses' mileage expenses in excess of the 100-mile limitation. The Congress has explicitly provided that, in actions, such as this, brought under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., *** [s]ubpenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district. *** 21 U.S.C. § 337. Thus, the rationale behind any 100-mile limitation does not exist in the present situation.

"In *United States v. Arizona Canning Co.*, C. A. 10th (1954), 212 F. (2d) 532, 534 [3-7], an in-rem action brought under the aforementioned act, it was held that the trial court was empowered to assess costs for the allowance for travel of two of the plaintiff's witnesses in excess of 100 miles as an incident to the issuance of the subpoenas under 21 U.S.C. § 337. To blindly apply the so-called 100-mile rule herein, would require the Court to ignore the reasons and policy underlying its adoption. This the Court declines to do. Accordingly, the plaintiff may recover such actual mileage of its trial witnesses in excess of 100 miles.

"The plaintiff will forthwith submit to the clerk a revised bill of costs in accordance with this opinion." (F.D.C. No. 60122; S. No. 59-214 H; N.J. No. 29)

MEDICAL DEVICES

Comforters, elastic, for knees, hands, elbows, and ankles, Thermolastic, at St. Louis, E. Dist. Mo.

Charged 12-14-76: the labeling of the articles (which were distributed by Futuro Division of Jung Products, Inc., Cincinnati, Ohio) contained false and misleading claims for reducing edema often associated with arthritis, for reducing swelling, to soothe and relieve stiff and aching joints, and (hand comforter only) for providing an assist to the return flow of blood from the hand and fingers, reducing fluid and swelling in the fingers and hand, and reducing the edema that occurs during sleep; and the labeling of the articles lacked adequate directions for use for the articles' intended purposes since adequate directions for use could not be written and the articles were not exempted therefrom as prescription devices; 502(a), 502(f)(1). Default decree ordered constructive destruction by the delivery to FDA for training purposes. (F.D.C. No. 61026; S. Nos. 77-24-173/7; N.J. No. 30)

NOTICES OF JUDGMENT on Criminal Actions

FOOD

Beattyville Wholesale Grocery Inc., and James M. Baker, president, and **Ralph Roberts**, vice president, Beattyville, E. Dist. Ky.

Charged 9-22-76: self-rising all purpose flour, self-rising cornmeal mix, plain cornmeal, popcorn, and self-rising flour (count 5) were held under insanitary conditions in a building accessible to rodents and all of the articles except the self-rising flour (count 5) were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Guilty pleas by individuals; fines, and probations. (F.D.C. No. 60667; S. No. 60-160 H et al.; N.J. No. 31)

Bennett Distributing Co., and **Albert W. Bennett**, president, Denver, Dist. Colo.

Charged 10-7-75: salted soybean halves (count 1) and soybeans (count 2), were held under insanitary conditions and exposed to rodent contamination. Guilty pleas; fines. (F.D.C. No. 60262; S. No. 80-787 H et al.; N.J. No. 32)

Ramar International Corp. t/a Orientex, San Francisco, N. Dist. Calif.

Charged 9-24-76: Chinese-style noodles were held under insanitary conditions in a building accessible to insects and rodents, were exposed to contamination by insects and rodents, and one of three lots contained insects; 402(a)(3), 402(a)(4). Guilty plea; fine. (F.D.C. No. 60775; S. No. 76-49-186 et al.; N.J. No. 33)

NOTICE OF JUDGMENT on Injunction Action

Strege & Rousar Fish Co., and **Gerald E. Rousar**, partner, and **Henry E. Strege**, partner, Racine, E. Dist. Wis. (Civil Action No. 71-C-160); **Raymond S. Strege, t/a Ray's Fish Co.**, Racine, E. Dist. Wis. (Civil Action No. 71-C-229); **Robert E. Strege, t/a Robert Strege Co.**, Racine, E. Dist. Wis. (Civil Action No. 71-C-230);

Harold A. Goodman, Sr., t/a Goodman Fish Co., Kenosha, E. Dist. Wis. (Civil Action No. 71-C-157); and **G&M Fisheries, and Lorman Greenfeldt**, partner, and **Charles McDowell**, partner, Racine, E. Dist. Wis. (Civil Action No. 71-C-231).

Charged 4-16-71, 5-18-71, 5-18-71, 4-15-71, and 5-18-71 in complaints for injunction; that the defendants in the five actions were engaged in distributing in interstate commerce raw chubs containing DDT and derivatives of DDT; that such raw chubs were nonconforming raw agricultural commodities, since no tolerance or exemption for such pesticide chemicals in fish had been prescribed by regulations and since the total amount of DDT and its derivatives present in the raw chubs was in excess of the 5 parts per million interim limit, established by FDA, for all fish; and that defendants were well aware that their activities were in violation of the law; 402(a)(2)(B).

The defendants denied the charge. The defendants alleged that FDA's interim limit was not a "tolerance" as required by law; that, if DDT was found to be a poisonous or deleterious pesticide chemical or a pesticide chemical not generally recognized by qualified experts as safe for use, the HEW Secretary had in effect established a zero tolerance for DDT in fish; that a zero tolerance was permissible only if the scientific data did not justify a greater tolerance; that the scientific data justified a greater tolerance than zero; that the HEW Secretary's failure to promulgate a regulation establishing a tolerance for DDT in fish was contrary to law, was an arbitrary, unreasonable, and discriminatory abuse of administrative authority and was a deprivation of property without due process of law; that all foods contain some levels of DDT and, therefore, the absolute prohibition of all fish containing any DDT while permitting the interstate shipment of other foods containing DDT under promulgated tolerances, was a denial of due process; and, if FDA's interim limit of 5 parts per million of DDT was found to be a "tolerance," such limit was arbitrary, unreasonable, discriminatory, and a deprivation of property without due process. The opposing parties served written interrogatories on each other. The defendants filed requests for admissions about all foods containing some levels of DDT and about fish being the only food for which interim enforcement guidelines having been established. These five actions against distributors of raw chubs, together with an action against a distributor of smoked chubs (*U.S.A. v. Ewig Bros. Co., Inc., and Eugene W. Ewig*) were consolidated for trial.

After trial by the court, the court found for the Government, enjoined the distributors of raw chubs from shipping in interstate commerce raw chubs or other raw fish which contained DDT (including derivatives) in excess of 5 parts per million, and similarly enjoined the smoked chubs distributor from the interstate shipment of smoked fish containing more than 5 parts per million DDT. In deciding the actions, the court said:

"At the conclusion of the trial, I indicated that I was satisfied of the plaintiff's entitlement to judgment with but one reservation: I wanted to consider further the defendants' contention that 21 U.S.C. 346a(b) made it mandatory for the administrator to promulgate the regulations establishing tolerances. I have now concluded that the defendants' interpretation is incorrect.

"Under 21 U.S.C. 346a, a 'poisonous or deleterious pesticide chemical, or any pesticide chemical which is not generally recognized . . . as safe . . . shall be deemed unsafe . . . unless a tolerance has been prescribed by the administrator.

"Although the provisions of subsection (b) would seem, facially, to suggest a duty to promulgate regulations that contain tolerances, I am persuaded that the total statutory scheme contemplates a judicial obligation to enjoin the distribution of unsafe foods even in the absence of a formally promulgated regulation.

"The record demonstrates that the foodstuffs in question must be regarded as adulterated because they contain a pesticide chemical which is 'unsafe' within the meaning of 21 U.S.C. 346a(a). The testimony at the trial persuades me that DDT in fish designed for human consumption in an amount in excess of five parts per million does not qualify within the provisions of 346a(a) as 'generally recognized, among experts . . . as safe.'

"In view of the foregoing, I have signed the two sets of findings of fact and conclusions of law and also the orders for permanent injunction which were submitted by the plaintiff in these six cases."

All the raw chub distributors appealed, as did the smoked chub distributor; and the injunctions were suspended pending the outcome of the appeal. While on appeal, another distributor of smoked



chubs (Vita Food Products of Illinois, Inc.) moved that the oral argument in the six actions be deferred to a time when its case had been briefed and was ready to be argued. The court denied such motion; however (after affirming the district court injunctions against the raw chub distributors), the court of appeals found that the case of *Ewig Bros. Co., Inc.*, presented different issues. The court held such firm's appeal for further oral argument, and disposition with the appeal involving the smoked chub distributor Vita Food Products of Illinois, Inc.

In affirming the injunctions against the raw chub distributors, the court of appeals said:

"This appeal presents the problem of whether the Administrator of the Environmental Protection Agency (EPA) must establish by regulation permissible tolerances of DDT and its derivatives in fish before injunctive relief may be granted or whether instead the Secretary of the Department of Health, Education and Welfare (HEW) may enforce an interim enforcement guideline issued by the Food and Drug Administration (FDA) establishing a maximum amount of 5 parts per million of DDT residue in fish shipped in interstate commerce. ***

"Upon the complaints of the United States, the district court in this case, at the conclusion of a trial without a jury, entered findings and conclusions and permanently enjoined five distributors of fish known as raw chubs from distributing in interstate commerce such fish in which the total amount of DDT and its derivatives exceeds the interim limit of 5 parts per million. This limit was established by the FDA for all fish pursuant to an announcement to the public on April 22, 1969. *United States v. Goodman*, 358 F. Supp. 250 (E.D. Wis. 1972). ***

"The pesticide DDT is a chloride naphthalene compound discovered in the late nineteenth century and first introduced in the United States about 1942 as the result of the seizure during World War II of some powder that was being used by the German army in North Africa as lice powder.

"It thereafter became 'one of the most widely used chemicals to control various insect populations and to protect agricultural crops from destruction by insects' but '[r]ecent scientific studies have . . . raised serious questions about the effect on the environment and on human health of the continued use of DDT.' *Environmental Defense Fund, Inc. v. United States Department of HEW*, 428 F.2d 1083, 1085 (D.C. Cir. 1970).

"On April 22, 1969, the FDA issued in the form of a public press release a 'guideline' establishing 5 parts per million as the maximum amount of DDT permissible in fish shipped in interstate commerce. In part the release stated:

'The interim limit has been established primarily because of high residues of DDT and its derivatives found in coho salmon from Lake Michigan.

'This guideline intended to protect the public from excessive levels of DDT in fish while a full scientific review is completed, Food and Drug Commissioner Herbert L. Ley, Jr., M.D. explained. It also gives the fishing industry a specific standard. Fish carrying residues higher than 5 ppm will be subject to seizure.

'The F.D.A. has asked the National Academy of Sciences—National Research Council to nominate a panel of experts to carry out the review of DDT residues in fish. The 5 ppm interim limit may be changed as the result of that study, Dr. Ley said.' ***

"The [district] court concluded that raw chubs containing DDT in excess of 5 parts per million are an adulterated food under 21 U.S.C. § 342(a)(2)(B), that the introduction or delivery for introduction into interstate commerce of such chubs is in violation of § 331(a), and such introduction or delivery is subject to restraint pursuant to § 332(a). ***

"The only issue upon appeal is whether Section 346a of FDCA [Federal Food, Drug, and Cosmetic Act] makes it mandatory for EPA to promulgate regulations establishing tolerances.

"Both the government and the defendants relied upon the language of Section 346a which provides in part that the 'Administrator shall promulgate regulations establishing tolerances with respect to the use . . . of . . . pesticide chemicals which are not generally recognized among experts . . . as safe for use . . . to the extent necessary to protect the public health.' 21 U.S.C. § 346a(b). Section 346a(c) provides in part that the 'Administrator shall promulgate regulations exempting any pesticide chemical from the necessity of a tolerance . . . when such a tolerance is not necessary to protect the public health.'

"The defendants contended that the use of the word 'shall' establishes the mandatory requirement of regulations either (1) to set a tolerance at some level, (2) to exempt a particular pesticide from the necessity of any tolerance, or (3) as further provided in Section 346a(b) to 'establish the tolerance . . . at zero level if the scientific data before the Administrator does not justify the establishment of a greater tolerance.' They argued that a permanent injunction issued pursuant to standards promulgated by an 'interim guideline' denied them the review procedures of 21 U.S.C. § 346a(d)(5) and § 346a(e).

"The government on the other hand contended that the Administrator is to promulgate regulations 'to the extent necessary to protect the public health' and that in the present situation that necessity has not occurred. The government further contended that the EPA Administrator 'may' issue regulations and that the defendants, who argued that they were entitled to the protection of the procedural requirements preceding the promulgation of a regulation, could 'trigger' those requirements by requesting that the Administrator act, which they failed to do.

"Before evaluating the respective arguments regarding the interpretation of FDCA, it is pertinent to note the reasons why EPA, the expert agency regarding pesticides, has not up to this time promulgated any regulations establishing tolerances or exemptions for DDT.

"EPA has recently banned almost all agricultural uses of DDT, effective December 31, 1972. 37 Fed. Reg. 13369 (July 7, 1972). This decision represented the culmination of almost three years of intensive administrative inquiry which resulted in the conclusion that the long-range risk of DDT at the present total volume of use is unacceptable and that DDT presents a carcinogenic risk. 37 Fed. Reg. at 13375. Among the factors which the Administrator is required to consider when he does set a tolerance is 'the other ways in which the consumer may be affected by the same pesticide chemical.' 21 U.S.C. § 346a(b)(2). Because the degree of human exposure to DDT from sources other than fish will undoubtedly soon change, an in-depth consideration of DDT tolerances during this period of fluctuation would be virtually meaningless.

"Also there was evidence presented at the trial that there are several significant studies currently being conducted by the World Health Organization of the United Nations to determine the probable cancer-causing effects of DDT. It is prudent to wait for at least some of these studies before setting definitive tolerances for DDT in raw foods.

"Under the defendants' interpretation of FDCA, the EPA is not given any flexibility with regard to the timing of establishing tolerances or exemptions. The EPA must proceed according to the requirements of 21 U.S.C. § 346a(b)-(c) before HEW is able to exercise any control over the introduction into interstate commerce of commodities containing unsafe pesticide chemicals. This interpretation renders 21 U.S.C. § 342a(a) meaningless. This section clearly provides that a pesticide chemical which is not generally recognized as safe for use, added to a raw agricultural commodity, shall be deemed unsafe *unless* EPA has established a tolerance or provided for exemption. Only in the absence of such action by the EPA is this section activated.

"The defendants contend that this construction denies them the review of procedures of Section 346a(d), but (d) applies only to persons who have registered an economic poison under FIFRA. The defendants, who could hardly have been unaware of the growing national concern over DDT content in fish, could have triggered the rulemaking procedure under 21 U.S.C. § 346a(e) if they had but requested it.

"The language of Section 346a(b) provides for promulgation of regulations establishing tolerances 'to the extent necessary to protect the public health.' EPA has determined that a regulation for DDT in raw fish is not necessary at this time. In fact, they have refrained from promulgating such a regulation because DDT levels in the environment are in a state of flux, a state partially induced by their other control activities concerning DDT.

"In the absence of a tolerance or exemption, the Secretary of HEW is charged with the enforcement of the ban of interstate shipment of adulterated agricultural commodities. 21 U.S.C. § 331(a). Although the cancer aspects of DDT are frightening, the obvious solution to that problem, that is, a total ban on foods containing DDT, is not available. Virtually, every food contains some DDT. The Administrator is required by Section 346a(b)(1) to consider 'the necessity for the production of an adequate, wholesome and economical food supply . . . in setting tolerances. DDT has presented, and apparently will continue to present, a massive



dilemma both for EPA and for society. Since there is no tolerance or exemption for DDT in fish, any amount of this poisonous pesticide chemical must be deemed unsafe and result in an adulterated product under a literal interpretation of the statute. Yet is obvious that at the present time all fish can not be banned inasmuch as it would seriously affect the total food supply. ***

"The defendants now contend that although the Commissioner of Food and Drugs has the undoubted authority to prohibit the distribution of all fish with any DDT residue, they are harmed because he has given them the opportunity to continue to operate if they can distribute fish with 5 or less parts per million of DDT residue. This action is consistent with specific statutory authority in the Act empowering him to refrain from prosecuting minor violations. 21 U.S.C. § 336....

"We conclude that the Commissioner of Food and Drugs, as the delegate of the Secretary of HEW, had the authority under FDCA to abide by the interim guidelines, that in so doing his acts were not arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law or without observance of procedure required by law, and that the district court's findings are not clearly erroneous." (Inj. Nos. 593, 595/8; S. Nos. 116-477 C et al.; 177-354 C et al.; 116-478 C et al.; 177-357 C et al.; 23-271 D et al.; N.J. No. 34)

NOTICE OF JUDGMENT on Miscellaneous Action

Vitamins A & D for oral use, FDA regulations limiting amounts supplied in vitamin supplements, and suit for declaratory judgment and injunctive relief against such regulations, Chicago, N. Dist. Ill.

Charged 8-27-73 by The National Health Federation, Monrovia, Calif., and Gustave E. Heideman, member of such federation and president of its West Suburban Chapter, Addison, Ill., against HEW Secretary Caspar W. Weinberger, and FDA Commissioner Alexander M. Schmidt; that the Federation and its members had the right to choose their diets, including "foods for special dietary use" which consist of various nutritional elements and factors found in various common foods, which are available in pills, tablets, capsules, liquids, and other forms, and which are comprised of vitamins, minerals, proteins, and the like, including vitamins A & D; that such nontoxic and wholly safe foods had been distributed and sold on a nationwide basis to plaintiff's members, who consumed them upon the recommendation (and without prescription) of various nutritionists or licensed members of the healing art, including allopaths, osteopaths, chiropractors, naturopaths, and the like; that the Federation and its membership believes in "freedom of choice" as to diet, and is opposed to "diet dictation" of any type; that the vitamin A & D regulations purport to "interpret" existing law and designate policy that preparations containing vitamin A in excess of 10,000 I.U. and vitamin D in excess of 400 I.U., per unit consumed, were "drugs," and were limited to sale by medical prescription only; that the FDA Commissioner had asserted that the toxicity of vitamins A & D at unstated "high levels" required such limitations; that the regulations' level of vitamin A was less than 1/2 the amount in 1/2 cup of cooked spinach, and the regulations' level of vitamin D had previously been the minimum of the so-called "minimum daily requirement"; that the regulations were arbitrary, capricious, and an abuse of regulatory power; that the promulgation of such regulations was substantive and that facts were decided unilaterally and arbitrarily by the Commissioner without the required public hearings; that the plaintiffs' needs, demands, requirements, and desires would be unnecessarily and unlawfully restricted and the costs involved needlessly escalated; and that plaintiffs prayed for a declaratory judgment declaring such regulations null and void and for a permanent injunction against enforcement of such regulations.

On the grounds that this action was "identical" to an action pending in the Southern District of New York, the Government moved that the action be transferred to the Southern District of New York, or in the alternative, be postponed until that pending action was decided. The Government also moved that the action be dismissed. The court dismissed the action saying:

"The Court herewith enters this Order granting that alternative motion that this action be dismissed. A review of the complaint discloses that it requests a declaratory judgment and residual injunctive relief. It is well established that declaratory judgment is a remedy committed to judicial discretion. *A. L. Mechling Barge Lines, Inc. v. United States*, 368 U.S. 324, 331 (1961). Courts have a broad measure of discretion to decline declaratory judgments as they also have in requests for injunctive relief. *Abbott Laboratories v. Gardner*, 387 U.S. 136 at 148 (1967).

"It is clear to this Court from the motion and memorandum of the defendants, and exhibits attached thereto, that this is an action identical, except for the named plaintiffs, to an action pending in the Southern District of New York, presently on preliminary appeal to the Circuit Court for the Second Judicial Circuit. The parties plaintiff stand in their respective capacities, in the case here, equivalent to the parties plaintiff in the case in the Southern District of New York. The issues are the same and the defendants are the same. That case entitled *National Nutritional Foods, et al. v. Weinberger, et al.*, numbered in that Court 73 CIV 3448, is on appeal before the Second Circuit on preliminary matters after which it will be returned to the District Court for the Southern District of New York for trial, if trial is indicated. The nature of the two causes of action is such that determination in the New York case will give relief to all parties of interest who might be named plaintiffs throughout the United States. Plaintiffs here could have brought the New York action themselves, or have there joined with the plaintiffs.

"There is no sound reason why the regulations of the Commissioner of Food and Drugs of the United States should be subjected to repeated *de novo* review in successive District Courts. What would result would be the possibility of conflicting decisions, confusion, and staggered appeals. It quite simply makes no sense to have plaintiffs who are free to proceed *de novo* in the Southern District of New York ask individually here in the identical matter the same declaratory judgment and injunctive relief sought by others from the Southern District of New York.

"In light of all of the above and the authority vested in this Court to exercise its discretion in entertaining this type of action, this Court respectfully declines to entertain the same, and, herewith enters its Order dismissing the case."

The order of dismissal was subsequently vacated upon motion of the plaintiffs, who asserted that the critical issue in this case (whether or not the vitamin A and D regulations were wrongfully enacted in the absence of a public hearing) had not been adjudicated or ruled upon in the New York case. After a hearing, the court again ruled for the Government saying:

"This case is before me today for ruling on defendant's alternative motions to transfer or to postpone or to dismiss plaintiffs' claim for declaratory judgment and injunctive relief. I shall first address myself to the defendant's motion to dismiss.

"That motion directs itself to the sole question of whether the Commissioner of the Food & Drug Administration was required to grant an opportunity for a formal evidentiary hearing when he promulgated Regulations 21 CFR 3.94 and -3.95 which required that oral preparations containing Vitamins A and D in excess of 10,000 international units per dosage unit and 400 international units per dosage unit respectively shall be sold by prescription of a medical doctor and then only when the prescription is properly labelled in accordance with the regulations.

"Plaintiffs maintain that when the Commissioner promulgated these questioned regulations without a public hearing he arbitrarily designated Vitamin A products containing more than 10,000 units and Vitamin D products in excess of 400 units as 'prescription drugs.'

"This promulgation, they urged, was in derogation of a long-standing practice followed in both the industry and by the rules and regulations of the Food & Drug Administration, therefore, the questioned regulations properly should be construed as rulemaking pursuant to the special dietary food provisions found in 21 USC 343(j) for which 21 USC 371(e) specifically provides that a public hearing should be granted.

"The defendants maintain that the regulations which interpret and enforce the prescription drug provisions found in 21 USC 353(b)(1) properly are promulgated under 21 USC 371(a), which does not require a formal evidentiary hearing.

"The parties by their motion call upon the Court to decide the issue of whether the Commissioner justifiably could consider his action in promulgating 21 CFR 3.94 and -3.95 as an interpretation of 21 USC, section 353(b)(1) so that he was not acting under 21 USC 371(a), which does not require a public hearing and not—rather, so that he was acting under 21 USC 371(a), which does not require a public hearing, and not under 21 USC 371(e) which does require such a hearing.

"In the recent case of *National Nutritional Foods Association v. Weinberger*, 366 F. Supp. 1341, Southern District of New York, 1973, the plaintiffs there sought to enjoin the enforcement of the same regulations which are questioned in this case and Judge



Frankel in a well-reasoned opinion held, and I quote from his decision:

'The Commissioner's judgments about safety levels in the admittedly uncertain and debated state of knowledge and consumer habits are solidly grounded. It is enough to say his determinations are reasonable and rational.'

"That is to be found at page 1347 of that citation. The plaintiffs in the case before me have in substance urged that the Commissioner's promulgation was arbitrary and unreasonable because he regulates the distribution of vitamins as though they are 'prescription drugs.'

"Considering the circumstances and facts pertinent here, I find it not unreasonable for the Commissioner to have determined that the subject substances fall within the category of substances regulated pursuant to 21 USC 371(i). I find no inconsistency between 21 USC 321(g)(1) which defines the term 'drugs' and 21 USC 353(b) as applied to high dosage preparations of Vitamins A and D which can adversely affect the structure or functioning of the human body, nor do I find unreasonable the Commissioner's judgment as to what quantity of these vitamins may be potentially dangerous to human health.

"The government's duty to safeguard its citizens' health has been historically one of its most fundamental responsibilities. Its power to regulate in the area of health and safety is indeed broad. See *National Nutritional Foods Association v. Weinberger*, cited above at 1345, and the cases that are cited in that decision.

"The Commissioner promulgated the questioned regulations on safety levels at a time when there is much controversy regarding the safe level of vitamin preparations. He has judged that toxicity exists at a certain level and that there may be harmful affects if these vitamins are consumed at that level. That judgment is well within the broad powers delegated to the Commissioner by the Federal Food, Drug and Cosmetic Act, Title 21 of the United States Code, and the Administrative Procedure Act, Title 5, United States Code, nor is it his interpretation that his action falls within 21 USC 371(a), which does not require a public hearing—nor is his interpretation that his action falls within that section, which, incidentally, does not require a public hearing, arbitrary or unreasonable. I cite here *Citizens for Truth in Nutrition v. Food and Drug Administration*, No. 73-2826 and 73-2834, Second Circuit, March 4th, 1974.

"I, therefore, finding it unnecessary to look into the other motions or the other alternative motions, grant the defendant's motion to dismiss the complaint and enter the order of the Court in accordance therewith."

The plaintiffs appealed. The court of appeals affirmed the lower court's dismissal of the action, saying:

"Seeking declaratory and injunctive relief, plaintiffs The National Health Federation (NHF) and Gustave E. Heidemann filed a complaint on September 27, 1973 challenging the validity of two regulations of the United States Food and Drug Administration: 21 C.F.R. §§ 3.94 & 3.95. Those regulations provide respectively that oral preparations of Vitamin A in excess of 10,000 IU (international units) per dosage unit and oral preparations of Vitamin D in excess of 400 IU per dosage unit are drugs and are restricted to sale by prescription. The plaintiffs contend that the regulations are invalid because they were promulgated without a public hearing, and because the classification of these higher dosage forms of Vitamins A & D as drugs by the regulations is arbitrary and capricious.

"Prior to the institution of the present suit, different plaintiffs filed a complaint in the United States District Court for the Southern District of New York attacking these same regulations and seeking, in addition to a preliminary injunction, identical relief. *The National Nutritional Foods Association v. Weinberger*, No. 73 Civ. 3448 (S.D.N.Y., filed Aug. 6, 1973). In light of the pending New York litigation, the trial court, in the exercise of its discretion, dismissed the present complaint on December 27, 1973. That order of dismissal was vacated, but subsequently, on March 22, 1974, the present complaint was again dismissed, the court this time reaching the merits. The plaintiffs appeal, and we affirm the dismissal, although for different reasons, believing that the district court should not have entertained the present action. * * *

"Comparison of the complaint here with the one filed in New York makes it clear that the issues raised in both complaints are identical, and a review of the litigation that has occurred so far in New York reinforces that conclusion. Further, a resolution of the

validity of the regulations here would require an inquiry into the entire administrative record made before the Commissioner of Food and Drugs, and counsel for the Government informs us without dispute that the record is voluminous and contains complex scientific data. Consequently, the fact that a full airing of the issues is occurring in the New York litigation, plus a concern for judicial economy of time and a disinclination toward duplication of effort are factors which point to dismissal as the appropriate disposition. Additionally, the desire to avoid piecemeal litigation also counsels for dismissal. . . .

"We recognize that the plaintiffs here are different plaintiffs from those involved in the New York litigation, and that dismissal of the equitable relief sought here has generally occurred where the parties in the other pending action were the same as the parties in the dismissed action. . . . Thus, although there would be dismissal, the parties would still have their day in court. Here, although dismissal would leave the plaintiffs on the sidelines, there is no bar to reinstitution of their complaint, since this discretionary dismissal would operate without prejudice. . . . Consequently, the factors which point to dismissal as appropriate are not diminished by any problem of denying these plaintiffs a judicial forum.

"Another factor convinces us that discretionary dismissal is equitable. Plaintiff National Health Federation is a California corporation with no particular ties to the Northern District of Illinois, and although plaintiff Heidemann, a member of the Federation and President of its West Suburban Chapter, resides within the district, it is undisputed that the Federation maintains a chapter within the confines of the Southern District of New York. Thus, by joining a member of its Bronx chapter, the record shows that the NHF and that member petitioned for direct review in the Second Circuit of other vitamin regulations issued by the FDA, and they appeared as petitioners in the case deciding the validity of those regulations. . . . Further, it is not contested that counsel for plaintiffs, prior to filing the suit here, were aware of the suit filed in the Southern District challenging the validity of the Vitamin A & D regulations. In fact, the NHF, by same counsel as are present here, appeared as *amicus curiae* on the appellate level in conjunction with an appeal to the Second Circuit from an adverse ruling on that complaint. . . .

"In view of these circumstances, it seems to us that this suit could have been as easily brought in the Southern District of New York, and the filing of the complaint here smacks of gamesmanship. Clearly, it has not been burdensome for the NHF to litigate in the Southern District, and there has been no showing that plaintiff Heidemann's interest could not have been equally well advanced by a member of the Federation's Bronx chapter. No reason is given for not filing in that district which might then have led to a consolidation of the suits. We do not think that the plaintiffs should be allowed to so easily avoid real involvement in litigation in one forum, and then impose on a second federal forum the burden of considering anew the same issues. . . . Accordingly, for the reasons discussed above, the judgment of dismissal is AFFIRMED." (Misc. No. 256; N.J. No. 35)

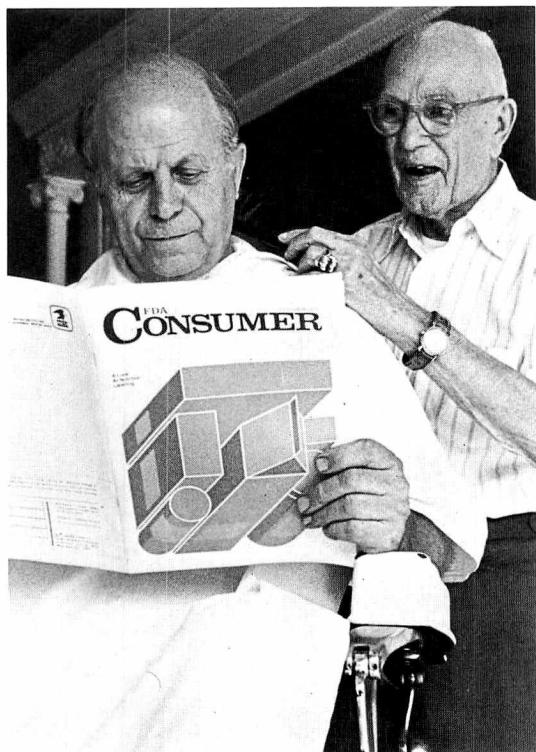
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Donald Kennedy, Commissioner of Food and Drugs
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