A Hard Look At What We're Eating
Sealing Teeth To Prevent Cavities
A group of experts recently agreed that sealants can be effective in protecting teeth of youngsters, particularly those teeth that are pitted and have fissures.

A Hard Look At What We're Eating
In its ongoing study of American diets, FDA gathers data on several hundred chemicals, including some that pose contamination concerns.

Questions Of Substance(s) Concern Cosmetic Users
Judging from letters to FDA, people worry about the ingredients that go into the various beauty aids. This article provides the answers to some of the more common questions.

Do Yourself A Flavor
With herbs and spices, you can gain a reputation as a gourmet cook. The curator of the U.S. National Arboretum's herb garden offers some tips for using those flavoring agents. They're particularly good for people trying to avoid salt.

Bee Pollen As A Health Food
Promoters claim that bee pollen is a good health food because it's full of nutrients and has therapeutic powers. That may be true—for bees.

Food Preservatives: A Fresh Report
Man's quest for extending the shelf life of foods is never-ending. In its new look at preservatives in long use, FDA hasn't yet passed judgment on the safety of some.

Heat Used To Fight Some Cancers
A recently approved device offers a new way to treat four types of cancer. In a process called hyperthermia, cancer cells are destroyed by microwave-type heat.

When winter raged outdoors, it was into the greenhouse for tender herbs such as these, either to tide them over to spring or to use for cooking. For more about cooking herbs, see Do Yourself A Flavor beginning on page 16.
Cancer Painkiller

A new, higher concentration of Dilaudid, a morphine-type drug, has been approved by FDA to ease the pain experienced by some patients with advanced cancer.

The new dosage form, a 10 milligram-per-cubic-centimeter concentration, will provide pain relief as great as can be attained with any other narcotic, including heroin, and can be delivered in a very small volume.

Previously the drug was available in concentrations of one, two, three and four milligrams per cubic centimeter for intramuscular or intravenous injection. Use of these concentrations required relatively large injections to achieve therapeutic doses in patients who had become tolerant of the drug. This posed a problem for terminally ill patients who often do not have the muscle mass needed to take large injections.

In response to the need in this group of patients for a more concentrated dose of a potent painkiller, FDA worked with Knoll Pharmaceuticals of Whippany, N.J., to develop safety data for the new dosage form, which is called Dilaudid-HP.

117 On Carcinogen List

Twenty-two of the 117 entries in the Third Annual Report on Carcinogens are "known carcinogens." This means that evidence from human studies indicates there is a causal relationship between exposure to the substance (or process) and human cancer.

The 22 entries include substances, groups of substances, and technological processes:

- 4-Aminobiphenyl
- Arsenic and certain arsenic compounds
- Asbestos
- Auramine manufacture
- Benzene
- Benzidine
- N,N-Bis (2-chloroethyl)-2-naphthylamine (Chlornaphazine)*
- Bis (chloromethyl) ether and technical grade chloromethyl methyl ether
- Chlorambucil*
- Chromium and certain chromium compounds
- Coke oven emissions
- Cyclophosphamide*
- Diethylstilbestrol*
- Hematite underground mining
- Isopropyl underground mining
- Melphalan*
- Mustard gas
- 2-Naphthylamine
- Nickel refining
- Soots, tars and mineral oils
- Thorium dioxide
- Vinyl chloride

Those marked with an asterisk are therapeutic substances. The remaining 98 entries in the report are substances "which may reasonably be anticipated to be carcinogens" based on limited evidence of carcinogenicity in humans or sufficient evidence of carcinogenicity in experimental animals.

Of all the entries in the report, two are natural substances not used or produced commercially (afatoxins and cycasin); two are food or cosmetic additives (saccharin and safrole); 12 are pesticides; and 15 are therapeutic substances, including the five on the "known carcinogen" list.

The remaining substances are various industrial chemicals and byproducts.

The Third Annual Report on Carcinogens was prepared by the National Toxicology Program, U.S. Public Health Service, Department of Health and Human Services. It was released in December 1983. Summaries of the report may be obtained at no charge from the Public Information Office, NTP, B2-04, P.O. Box 12233, Research Triangle Park, N.C. 27709. The complete report can be purchased for $32.50 from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161. The order number is PB 83-135855.

Ultrasound Safety Questioned

Ultrasound imaging in pregnancy should be used only when there is an accepted medical reason for it, concluded a panel of experts meeting at the National Institutes of Health in February. The panel said it could not endorse routine ultrasound screening of pregnant women because there is not enough evidence of benefit to either the mother or the fetus.

Ultrasound imaging uses high-frequency sound waves to produce an image of the fetus and its...
surroundings on a screen. Doctors use the procedure for evaluation of fetal growth and activity, for detection of multiple pregnancies and physical abnormalities, for determination of fetal age, and for many other purposes. The use of ultrasound in obstetrics has grown rapidly in the United States. The procedure is now available in nearly all hospitals, and many obstetricians have ultrasound equipment in their offices. (See “The Unknowns Of Ultrasound” in the March 1983 issue of FDA Consumer.)

Concerns about the safety and effectiveness of the procedure prompted FDA and the National Institutes of Health to sponsor a consensus development conference to assess the use of ultrasound during pregnancy. The conference was held Feb. 6 to 8 in Bethesda, Md., after a year’s preparation by the panel.

The panel concluded that ultrasound evaluation can improve the outcome of high-risk or complicated pregnancies, but its effectiveness as a routine screening procedure has not been proved. Use of ultrasound to determine the sex of the fetus or to see or obtain a picture of the fetus should be discouraged, the panel said.

The panel also concluded that there is not enough information to reliably assess the risks of ultrasound. Although it is encouraging that no harmful effects to either mother or fetus have been reported in more than 20 years of use, the panel said, it is nevertheless likely that any ill effects would be subtle and would not be immediately apparent.

Many of the studies on the safety of ultrasound in humans have been “inadequate,” the panel members said. They noted, however, that several have shown there is no association between exposure of fetuses to ultrasound and subsequent low birth weight or hearing loss of the newborns.

Some animal and cell culture studies have suggested that ultrasound exposure can retard fetal growth, impair the immune response, and produce cell damage and chromosomal changes. Most of these studies involved higher levels of ultrasound energy than are used in diagnostic evaluations and some of the findings could not be reproduced by other investigators. Nevertheless, the panel said, the reported effects cannot be ignored.

To help answer questions about the safety of ultrasound in pregnancy, the panel called for animal studies designed to detect the long-term effects of in utero ultrasound exposure.

**Reprints Available**

Reprints are available of “Back Pain: Ubiquitous, Controversial,” an article that appeared in the November 1983 issue of FDA Consumer.

Single copies of reprints can be obtained from the Food and Drug Administration, HFE-88, 5600 Fishers Lane, Rockville, Md. 20857. Multiple copies are available from FDA, HFW-40, at the Rockville address. Copies of reprints are also available from FDA’s consumer affairs officers, who are located in 30 cities around the country.

**Gumming Up The Habit**

Cigarette smokers who are participating in an organized program to kick the habit may get an assist from Nicorette, a new nicotine chewing gum recently approved by FDA as a prescription drug product.

Each buff-colored, flat square of gum contains two milligrams of nicotine identical to that found in tobacco. The color and shape of the new product differentiate it from ordinary gum.

Nicorette does not eliminate the desire for cigarettes but can provide a short-term alternative source of nicotine for dependent persons who abruptly stop smoking during an organized smoking-cessation program. In behavior modification programs, the effectiveness of Nicorette was demonstrated to be significantly greater than plain chewing gum.

According to the labeling approved by FDA, smokers who have a high physical dependence on nicotine are most likely to benefit from use of Nicorette. Such persons typically smoke more than 15 cigarettes a day, prefer brands of cigarettes with more than 0.9 milligrams of nicotine each, inhale, and find the first cigarette in the morning the hardest to give up.

Pregnant women and some heart patients should not use the product, nor should they smoke. The U.S. Public Health Service regards cigarette smoking as “the single most important preventable cause of illness and early death” in the U.S.

Nicorette is a product of Merrell Dow Pharmaceuticals Inc., Cincinnati, Ohio.
Fluorides in drinking water and toothpaste have played a major role in reducing the number of cavities in the teeth of children and young adults in the United States. But the problem of cavities hasn’t been licked. By age 16, American children have an average of nearly 10 decayed or missing (extracted) teeth or filled tooth surfaces.

What’s interesting is that the locations of the cavities have changed. Now they’re occurring mainly on the chewing surfaces of the molars instead of the smooth tooth surfaces, where they predominated before the advent of fluorides. The molars and premolars (the teeth directly in front of the molars) have always been particularly susceptible to decay because their surfaces contain pits and fissures where food and bacteria can be trapped, eventually leading to cavities.

In young people 50 percent of cavities develop in these pits and grooves of the chewing surfaces, which are least benefited by fluorides. (Plaque, not easily cleaned from these surfaces, prevents the fluoride from doing its job.)

Fortunately, such damaging tooth decay can be prevented by sealing the teeth with a plastic resin to protect them from bacteria in the oral environment, according to participants at a recent National Institutes of Health consensus development conference. Unfortunately, dental sealants have been under-used by dentists and overlooked by or unknown to parents, the panel of experts said.

Concern about pit and fissure cavities predates the advent of fluorides. As early as 1923 some dentists advocated recontouring the tooth surface and filling the ground-out fissures with restorative material, techniques that were neither preventive nor widely accepted.

Surface sealing got its start in the mid-1950s when a dental scientist, D. Michael Buonocore, discovered that by etching the tooth surface with a dilute solution of phosphoric acid a durable bond could be established between the tooth and a plastic resin. It was not until 1965, however, that Buonocore and his colleagues reported on clinical trials with the new procedure.

The first sealants were made of cyanoacrylates and polyurethanes, plastics that proved to be difficult to handle, and dental researchers in the late 1960s sought better materials. Today sealants are composed of polymethylmethacrylate resins similar to those used in some other dental procedures, such as repairing broken edges of teeth, attaching orthodontic devices, and splinting loose teeth to firm ones.

Currently there are three classifications of dental sealants, which are designated by the manner in which they are cured (hardened):

- Chemically or self-cured sealants consist of two materials that are mixed together just before applica-
- Ultraviolet-light-cured sealants harden to a glossy finish after being exposed to small amounts of ultraviolet light from a hand-held instrument.
- Visible-light-cured sealants harden when exposed to a high-intensity white light from a hand-held instrument.

FDA regulates both the sealants and the ultraviolet and visible light delivery systems under the authority of the Medical Device Amendments of 1976.

The procedure for applying sealants is relatively simple. First the tooth to be sealed is isolated by a rubber dam or cotton rolls to insure that saliva won’t get on the surface (contamination by saliva is one of the primary causes of sealant failure). After being thoroughly cleaned and dried, the surface is etched by application of a 30 to 50 percent phosphoric acid solution for about one minute. The etching creates a porous surface into which the sealant can penetrate.

When the acid is washed away and the tooth is once again dried, the sealant is placed on the tooth surface. The time needed for the sealant to harden varies, depending on which method is used. Generally it takes about a minute.

Those who can most benefit from this preventive treatment are children
Dental sealants appear as white patches on the chewing surface of the molars to which they have been applied (picture at top left). The effectiveness of the sealants is evident in the photo below (left). The tooth on the left in the picture was treated a year after it appeared in the patient's mouth. Five years later the tooth is still protected, while its untreated neighbor developed a cavity that required filling.

(Photos by Richard J. Simonsen, D.D.S., National Institute of Dental Research, National Institutes of Health.)

Dental sealants are not a substitute for fluorides, the panel stressed. Sealants should be used along with fluorides in their various forms. In the last several years clinical trials on sealants in several countries have resulted in findings that are remarkably consistent and positive. The trials showed that the occurrence of pit and fissure cavities was reduced by approximately 95 percent at the end of one year and at least 50 percent at the end of five years.

As far as safety is concerned, the consensus conference panel found no evidence that the sealant materials, the acid used for etching, or the ultraviolet light used to harden dental sealants are harmful to the patient or the dentist. The group warned, however, that looking at the unshielded ultraviolet light reflected from the tooth and surrounding tissues for long periods without ultraviolet-absorbing glasses could have deleterious effects on the eyes of the dental personnel applying sealants. (FDA is also concerned about the possible hazard of exposure to the blue part of the spectrum in the visible-light-cured sealant system.)

Despite a record of effectiveness and safety that spans more than 15 years of clinical study, many dentists in private practice and in public dental health-care programs aren't using dental sealants to prevent cavities. Among the reasons for this under-use, cited by the panel, are unfamiliarity with the technique, early failures of the sealants to stay in place, and difficulties in explaining the procedures to patients and parents.

Dentists have been concerned that cavities might develop underneath the sealant. They don't, according to the consensus panel’s findings. In fact, the process of tooth decay seems to be arrested because the bacteria are sealed off from their nutrient supply. Even when the sealant wears off or comes off, treated teeth are no more susceptible to cavity formation than untreated teeth. According to one report presented to the conference, the sealant penetrates the pores of the enamel and continues to serve as a protectant even though the sealant appears to be lost.

The public has not been well informed about this preventive procedure, added the panel. Cost may also have played a part in parents’ reluctance to accept sealants for their children. The sealing of tooth surfaces is not covered by most insurance plans and other third-party payment agencies, including Medicare.

Gathering more information on the cost effectiveness of using sealants in community dental health programs was one of the recommendations of the consensus panel. The group also urged continuing research to improve sealant technology.


Annabel Hecht is a member of FDA’s publications staff.
A Hard Look At What We’re Eating

What were chemicals once used in electrical transformers and carbonless “carbon paper” doing in the breakfast cereal? Chemists testing the cereal as part of a study of contaminants in the American diet were puzzled. Where had the polychlorinated biphenyls (PCBs) come from?

Further testing showed that the PCBs were migrating into the cereal from the cereal boxes. Although the quantities were minute, it was important to find their source because PCBs can cause liver damage and other toxic symptoms in humans.

Investigation by the Food and Drug Administration revealed that the cereal boxes were produced from recycled paper containing, among other materials, carbonless carbon paper. At one time PCBs were used in making carbonless carbon paper.

The laboratory’s finding ultimately led to the writing of an FDA regulation limiting the amount of PCBs allowed in paper food packaging. Although no longer used in carbonless carbon paper, PCBs still turn up occasionally in recycled paper made from discarded files that include the old-style carbonless carbon paper. The FDA regulation assures that excessive levels of PCBs will not end up in any more cereal boxes—or other paper food packaging.

FDA’s Total Diet Laboratory, meanwhile, continues to check for contaminants in America’s food supply. Located in Kansas City, Mo., it is responsible for the analytical end of the agency’s Total Diet Study. The 20 chemists and technicians assigned to the Total Diet laboratory analyze chocolate milkshakes, quarter-pound hamburgers, beer, bologna, lasagna, frozen pizza, dill pickles, watermelon, chocolate chip cookies, and more than 200 other foods Americans hanker for each year. They are interested in what shouldn’t be in those foods: unsafe amounts of pesticides, industrial chemicals, and toxic elements such as arsenic, lead, cadmium and mercury. On the positive side, they also measure the quantities of several essential
The Total Diet Study begins with the purchase of food in several cities around the country. FDA inspector Michelle Barry loads the first of several carts.

minerals in foods.

Experts at FDA headquarters then interpret the data and compare the residue findings with daily intake levels of contaminants found acceptable by the Food and Agricultural Organization of the United Nations and by the World Health Organization. (An "acceptable" daily intake is one that appears to present no appreciable risk.) Although residues of 70 to 80 pesticides, pesticide metabolites (breakdown products), and industrial chemicals are frequently found, they are always well below FAO/WHO limits.

Only once has a residue reached a level considered of health significance: In 1966 the pesticide dieldrin approached the FAO limit. Since that time, dieldrin has been banned for use on food crops and residue levels have declined steadily.

The Total Diet Study was inaugurated in 1961 to measure levels of various substances in kitchen-prepared foods. It is unlike most other FDA food surveillance programs because it analyzes table-ready foods (as purchased or prepared) rather than raw or unprocessed commodities. Since the amount of chemical residues and minerals in food can be affected by processing, cooking, washing, peeling and other forms of preparation, table-ready foods give a more accurate picture of the actual American diet.

The Total Diet laboratory is specially equipped and staffed to find and measure low levels of several hundred chemicals that might be present in food. Unfamiliar chemicals frequently show up, so a special research team established in 1981, the Total Diet Research Center, assists in identifying unknowns and in developing new and improved analytical methods for the program. Several methods originated in the Total Diet program have been published for use by the scientific community at large.

Once a year, food samples are also sent to FDA's Winchester Engineering and Analytical Center in Massachusetts, where they are analyzed for
A forest of separatory funnels marks a corner of the Total Diet laboratory where technician Kevin Cline prepares extracts from food samples that will be analyzed for chlorophenoxy acid herbicides.

radioactive isotopes.

The Total Diet program supplements FDA’s routine and special food surveillance programs, serving as a backup and occasionally an early warning system for contamination incidents.

In one instance, fish meal intended for use in chicken feed became contaminated in a warehouse where a fire had vaporized PCBs in a large electrical transformer. Chickens that had eaten the feed were later collected for analysis in the Total Diet Study. The laboratory discovered relatively high PCB levels and alerted FDA headquarters. It happened that the contamination had just been discovered in the course of a separate FDA investigation—but it was clear that the warning system was working.

Several years ago residues of PCP (pentachlorophenol) were detected in unflavored gelatin, a product made from collagen derived from animal hides and other tissues. PCP was once used in slaughterhouses as a fungicide to retard spoilage of animal hides awaiting shipment (sometimes to gelatin manufacturers), but this use of PCP had long been stopped in the United States. FDA investigated the gelatin manufacturer and discovered he was producing a mixture of domestic and imported gelatin. The foreign gelatin was found to contain PCP and was diverted from food use.

Over the years the Total Diet Study has tracked residues from several groups of pesticides, including organochlorine or chlorinated pesticides (DDT, dieldrin, heptachlor); organophosphates (parathion, malathion); chlorophenoxy acids (herbicides such as 2,4-D and 2,4,5-T); and carbamates (from an important, relatively new family of pesticides that includes such compounds as carbaryl and carbofuran).

The Total Diet Study has shown a steady decline in the levels of chlorinated pesticide residues over the past decade. DDT, once widely used but now banned, shows up today only at...
very low levels and almost always in products of animal instead of plant origin. However, low levels of DDE, a breakdown product of DDT, are found in about 40 percent of samples currently being analyzed. Since these chemicals can accumulate in the fatty tissues of animals exposed to them, the findings indicate that environmental contamination continues but is declining. Low-level, decreasing dieldrin residues also continue to be found in products of animal origin.

At the same time that levels of chlorinated residues are diminishing, the Total Diet Study is showing an increase in the frequency of low-level residues of organophosphate pesticides. Most common is malathion, today being found in approximately 20 percent of food items analyzed.

About a dozen previously undetected pesticides have been found since the revised Total Diet Study began in 1982 (see accompanying article). More residues have also been detected in potatoes and peanuts as a result of analyzing foods individually instead of in composites, which was done before 1982. These residues are usually metabolite and breakdown products of sprout-suppressant chemicals in potatoes and soil fungicides in peanuts.

Essential minerals evaluated in the Total Diet Study are iron, calcium, phosphorus, copper, manganese, magnesium, potassium, sodium, iodine, selenium and zinc. Two of these, iodine and sodium, seem to be more than plentiful in the U.S. diet. The mid-70s' Total Diet data indicate that intake of iodine is two to five times the U.S. Recommended Daily Allowance (RDA) for all groups, and that dairy and grain and cereal products are proving extremely frequent sources of that mineral. Iodine can get into dairy products via feed supplements, iodized salt blocks, some veterinary medications, and products used to sanitize equipment and housing for animals. Iodine can be added to cereal and grain products via certain dough conditioners, and it turns up in some food colorings and other
additives. There is growing belief that iodine, once deficient in many areas, is now excessive in U.S. diets (see "Iodine: Going From Hypo To Hyper" in the April 1981 FDA Consumer).

Grain and cereal products are the largest sources of sodium among foods studied in the Total Diet Study except for salt added directly by the consumer. Other research has shown that the average American's daily intake of sodium is 4 to 5 grams, considerably higher than the 1.3 to 3.3 grams per day estimated by the National Research Council to be an "adequate and safe intake." Sodium is also added to many foods as salt (sodium chloride) and in other ingredients during processing. The data generated by the Total Diet Study helped support FDA's decision to propose voluntary sodium labeling for foods and to encourage food processors to reduce sodium content in the products they manufacture.

FDA's Total Diet Study continues to be the most comprehensive analysis of the American diet. Total Diet findings are used by the Environmental Protection Agency and other government agencies, nutritionists and other health professionals, industry and consumers in evaluating levels of chemical contaminants and some essential nutrients in the U.S. diet. Other governments have established similar programs to survey their food supply, and FDA has trained a number of foreign chemists in Total Diet analytical procedures.

Louise Fenner is a member of FDA's publications staff.
How Your Diet Is Analyzed

At one time the Total Diet Study evaluated three standard projected diets: those of a typical teen-age boy (considered the family's biggest eater), a 2-year-old toddler, and a 6-month-old infant. (The normal caloric intake of the teen-age boy, 2,800 to 3,000 calories, was raised to almost 4,000 calories as an added safety margin.) The diets were based on the 1965 Household Food Consumption Survey of the U.S. Department of Agriculture. Every year FDA analyzed 30 “market baskets” of food bought in supermarkets. Of these, 20 baskets were geared to the adult (teen) diet and 10 to infants and toddlers. One market basket encompassed a two- to four-week supply of food, depending on the diet being studied.

Each adult market basket contained about 120 items. The food was divided into 12 groups and blended into composites of similar types of items, such as root vegetables, dairy products, or grains and cereals.

In spring 1982 the Total Diet Study was modified to account for changes in American eating habits and to provide more specific information about individual foods. FDA turned to an updated version of the USDA food consumption survey done in 1977-78, and to the Second National Health and Nutrition Examination Survey (HANES) of the National Center for Health Statistics, done in 1976-80. Together these surveys queried some 50,000 people and collected information on 3,700 foods Americans are eating. From these, FDA selected 234 food items for a revised market basket. In addition to staple items, the new market basket includes convenience products such as lasagna and spaghetti with meat sauce, and—for the first time—alcoholic beverages.

The revised Total Diet Study evaluates the diets of eight groups of Americans instead of three. A mathematical model takes into account the amount and types of foods typically eaten by various population groups. Using this model, data from the 234-item market basket can be applied to the diets of infants, toddlers, teen-age females and males (age 14 to 16), adult females and males (25 to 30), and older females and males (60 to 65).

Another important change is the switch to analyzing individual foods instead of composites. Composites presented the problem of dilution—that is, contaminants or minerals were mixed throughout the entire composite and were diluted during analysis.

In the current study, four market baskets are collected and analyzed each year, one each from the eastern, western, central and southern regions of the country. FDA employees visit supermarkets in three cities within the same region, purchase exactly the same 234 items, pack them with dry ice if necessary, and ship them to Kansas City. Each market basket is collected over a four-week period.

Foods ready to eat—such as fresh fruit or quarter-pound hamburgers—are analyzed as is, after suitable laboratory preparation. The rest of the food goes to the home economics department of St. Mary College in nearby Leavenworth, Kan., where, under a contract with FDA, it is prepared as it would normally be eaten. Here cake mixes are turned into cakes, pancake mixes into pancakes, and ingredients from the supermarket into lasagna, homemade pork chow mein, beef stew, and the like. Then back to the FDA laboratory, where identical foods collected in the three cities are combined into a single sample. If unusual findings turn up, analyses are performed on reserve portions of the samples when possible (e.g., nonperishable items).
Questions Of Substance(s) Concern Cosmetic Users

Rousseau once said, "Man can be cured of every folly but vanity." From the amount of money spent on cosmetics these days, it's safe to say that times haven't changed much. Last year more than $10 billion was spent on hair preparations, mouthwash, makeup, shaving cream and perfume. But along with our love for looking pretty is a need to reassure ourselves about the safety of cosmetic products. To help people who are concerned about what's in the cosmetics they use, here are some answers to typical questions received in the mail by the Food and Drug Administration. The answers were prepared by experts in FDA's cosmetics division.

Q. I want to inquire about a substance called BHT found in some soap products. Is it a carcinogen?
A. BHT is used at very low levels as an antioxidant that protects against rancidity or discoloration. We are not aware of any information that indicates BHT may be harmful or cancerous when so used in soap.

Q. Attached to this letter is a label from a bottle of nail polish remover. I call your attention to the contents: acetone, water, other ingredients. What are other ingredients?
A. Cosmetics labeled after April 15, 1977, must declare their ingredients. Ingredients must be listed by uniform names in descending order of predominance. This means the first ingredient shown must be present in the largest amount. Ingredients that constitute less than 1 percent of the product need not be listed in order of predominance, and color ingredients may be listed in any order, regardless of the amount used in the product.

The ingredient list is not required to include the names of specific fragrances or flavors used in a product. These may be listed simply as "fragrance" or "flavor." Some ingredients used in cosmetics are claimed by the manufacturer to be trade secrets. If FDA agrees that a specific ingredient is a trade secret, it need not be carried on the list. Because of this and the complexity of most fragrance formulas, these substances may be listed as "fragrance" on the label.

Thus, the designation "and other ingredients" on the label of this polish remover is an FDA-approved way to describe ingredients that are recognized as trade secrets and which
the manufacturer is not required to reveal.

Q. Does using cosmetics such as eye liner, eye shadow, blush, a foundation, or any other cosmetic for that matter, have any long-term effects?
A. Very little is known about the long-term effects of cosmetics. A long-term effect may be systemic and not just an irritation on the surface of the skin. Many ingredients can penetrate the skin. Skin penetration studies are now under way to determine likely chronic effects of some cosmetic ingredients from long-term use.

Q. A highly advertised body spray product contains the following ingredients: SD alcohol 40B, isobutane, propane, fragrance, propylene glycol. While the advertising of this product entices consumers to buy it because of its seemingly sensuous smell, it contrasts with the warning on the label that states: "Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal." Which of the listed ingredients would cause harmful or fatal consequences if inhaled directly and why would the manufacturer put a dangerous chemical in the product?
A. The problem is not one of toxicity of any particular ingredient under usual use conditions but of misuse causing oxygen deprivation. Such a warning is required for self-pressurized containers in which the agent used to expel the product is partially or wholly a halocarbon or hydrocarbon. Such propellants have been responsible for the deaths of persons, usually juveniles and adolescents, who concentrated the vapors from such products and inhaled them to induce a euphoric effect, or "high."

According to reports of these cases, the sprays have been concentrated in a number of ways, often by spraying the contents of the container into a plastic bag.

The required warning statement is intended to caution against deliberate misuse rather than accidental misuse. FDA does not have any information that injuries or deaths have ever resulted from normal use of the products involved.

Q. Are too many permanent waves bad for the health? Do they have any relationship to cancer?
A. Generally speaking, permanent wave products present no hazard to the consumer when used according to directions on normal healthy hair and scalp, although some consumers may occasionally experience minor itching and scalp reddening or, in some cases, an allergic reaction.

Q. A quick and easy way to determine likely chronic effects of some cosmetic ingredients is by penetration studies. Are such studies now under way?
A. Generally speaking, penetration studies are now under way to determine likely chronic effects of some cosmetic ingredients from long-term use.

Q. An advertisement for a cosmetic cream claims that it "has been FDA-cleared as a multifaceted moisturizing, oxygen-transporting cosmetic preparation." Is this true?
A. The advertisement mentions that this product has been "cleared" by FDA. This statement is untrue. Firms that manufacture cosmetics are neither required to register their company nor to obtain premarket FDA approval for their formulas.

Some statements made for products are in the nature of "puffery" to promote the product. Cosmetic manufacturers often claim their products contain some secret ingredient that is superior to the ingredients used by other brands or some magic formula that will accomplish extraordinary results. But the great majority of cosmetic products in any category—lipstick, face creams, etc.—basically are similar in composition. A popularly priced cream or lotion usually is just as effective in keeping the skin soft as the most expensive face cream. In the expensive cream the buyer may be paying for a pretty jar, an appealing fragrance, or a feeling and aura of exclusivity.

Q. I am interested in obtaining the name of a hair coloring that would be nonallergenic and would not contain any coal-tar hair dye.
A. As a regulatory agency, the Food and Drug Administration is not permitted to recommend brand-name products. Even if permitted, it would be unwise to do so, since any ingredient in any product may cause a reaction in some sensitive person.

Coal-tar hair dyes are exempted from the adulteration and color additive provisions of the Food, Drug, and Cosmetic Act if the labels bear a caution statement alerting consumers to the risk of skin irritation.

The warning label is as follows: "Caution—this product contains certain ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness."

If a label bears this warning statement, the additional measures that FDA can take to protect the public are severely limited unless Congress repeals the exemption for coal-tar products. In the past, many bills have been proposed by Congress, but none has passed.
"Take one bay leaf" is good recipe advice for many soups, stews, casseroles and the like. Here the author, who is curator of the national herb garden, clips a basketful of leaves from the cooking bay, Laurus nobilis, a.k.a. the classic laurel of antiquity. She's just reducing the foliage to keep the plant from outgrowing its greenhouse space.
Herbs can provide creative, tasteful alternatives to salt for flavoring foods. Through the skillful use of herbs and spices, imaginative flavors can be created and simple foods made into gourmet delights.

Herbs and spices differ only in that herbs tend to be plants grown in temperate areas while spices grow in tropical regions. Many people prefer to grow their own herbs to have a fresh supply throughout the growing season, thereby assuring top quality. Professional cooks prefer fresh herbs, if available. But fresh herbs are less concentrated, and two to three times as much should be used if a recipe calls for dried herbs.

If growing herbs for drying, the harvesting should be done in the morning after the dew has evaporated but before the sun is very bright. The essential oils in herbs will evaporate into the atmosphere during the day, so it is important to collect them when flavor is at its peak. Cut only the amount to be used in one day.

The herbs should be dried in bunches or laid on screens in a warm, dark, well-ventilated spot. An attic is ideal although closets or dry basements will suffice. Ideally, the temperature should not be over 90 degrees. If it’s too hot, the herbs will cook. The length of time required for drying will vary according to the thickness of the plant parts. Herbs should be stored away from direct sunlight to prevent bleaching. Be sure they’re well labeled. Most dried herbs will keep for at least one year in glass or plastic containers. But eventually they lose most of their potency and should then be thrown out. Certain herbs, such as chives, parsley, French tarragon, mint, basil, lovage, and sorrel, keep well in the freezer. Put them into individual plastic bags or small plastic jars and freeze them.

There are no strict limits to the use of herbs. A good general rule is not to mix two very strong herbs together, but rather one strong and one or more milder flavors to complement both the stronger herb and the food.

Here are some tips for cooking with herbs and spices:

- In general, the weaker the flavor of the main staple item, the lower the level of added seasoning required to achieve a satisfactory balance of flavor in the end product.
- Dried herbs are stronger than fresh, and powdered herbs are stronger than crumbled. A useful formula is: 1/4 teaspoon powdered herbs = 3/4 to 1 teaspoon crumbled = 2 teaspoons fresh.
- Leaves should be chopped very fine because the more cut surface exposed the more flavor will be absorbed.
- A mortar and pestle can be kept in the kitchen to powder dry herbs when necessary.
- Scissors are often the best utensil for cutting fresh herbs.
- Be conservative in the amount of an herb used until you’re familiar with its strength. The aromatic oils can be strong and objectionable if too much is used.
- The flavoring of herbs is lost by extended cooking. Add herbs to soups or stews about 45 minutes before completing the cooking. But for cold foods such as dips, cheese, vegetables and dressings, herbs should be added several hours or overnight before using.
- For casseroles and hot sauces, add finely chopped fresh or dried herbs directly to the mixture.
- To become familiar with the specific flavor of an herb, try mixing it with butter and/or cream cheese, let it set for at least an hour, and spread on a plain cracker.
- Beware when purchasing herbal salt blends. Many are merely herbs added to salt. Read the ingredients carefully or just blend your own combinations.
- Dried herbs should be stored in plastic bags, boxes or tins rather than cardboard containers. Keep the containers out of the direct sunlight (because that will bleach their color and reduce their strength) and don’t place them too near the stove (to avoid the high humidity).
Strengths of Herbs

**Strong or Dominant Flavors:** These should be used with care since their flavors stand out—approximately one teaspoon for six servings. They include bay, cardamom, curry, ginger, hot peppers, mustard, pepper (black), rosemary, and sage.

**Medium Flavors:** A moderate amount of these is recommended—one to two teaspoons for six servings. They are basil, celery seed and leaves, cumin, dill, fennel, French tarragon, garlic, marjoram, mint, oregano, savory (winter and summer), thyme, and turmeric.

**Delicate Flavors:** These may be used in large quantities and combine well with most other herbs and spices. This group includes burnet, chervil, chives, and parsley.

Herb Blends

Herbs can be combined for specific foods. Having the combinations on hand will speed cooking and enhance one's reputation as a gourmet. They can be added loosely or wrapped in cheesecloth and removed before serving. Following are some suggested herb blends:

| Egg herbs: | basil, dill weed (leaves), garlic, parsley |
| Fish herbs: | basil, bay leaf (crumbled), French tarragon, lemon thyme, parsley (options: fennel, sage, savory) |
| Poultry herbs: | lovage, marjoram (two parts), sage (three parts) |
| Salad herbs: | basil, lovage, parsley, French tarragon |
| Tomato sauce herbs: | basil (two parts), bay leaf, marjoram, oregano, parsley (options: celery leaves, cloves) |
| Vegetable herbs: | basil, parsley, savory |
| Italian blend: | basil, marjoram, oregano, rosemary, sage, savory, thyme |
| Barbecue blend: | cumin, garlic, hot pepper, oregano |

French herbal combinations:

- **Fines herbes:** parsley, chervil, chives, French tarragon (sometimes adding a small amount of basil, fennel, oregano, sage or saffron)
- **Bouquet garni mixtures:** bay, parsley (two parts), thyme. The herbs may be wrapped in cheesecloth or the parsley wrapped around the thyme and bay leaf.

**Basic herb butter:** one stick unsalted butter, one to three tablespoons dried herbs or two to six tablespoons fresh herbs, ½ teaspoon lemon juice, and white pepper. Combine ingredients and mix until fluffy. Pack in covered container and let set at least one hour. Any of the culinary herbs and spices may be used.

**Herb vinegars:** Heat vinegar in an enamel pan and pour it into a vinegar bottle and add one or several culinary herbs (to taste). Do not let the vinegar boil. Let the mixture set for two weeks before using. Any type of vinegar may be used, depending on personal preference.
Herb Blends To Replace Salt

(These can be placed in shakers and used instead of salt.)

**Saltless surprise:**
2 teaspoons garlic powder and 1 teaspoon each of basil, oregano, and powdered lemon rind (or dehydrated lemon juice). Put ingredients into a blender and mix well. Store in glass container, label well, and add rice to prevent caking.

**Pungent salt substitute:**
3 teaspoons basil, 2 teaspoons each of savory (summer savory is best), celery seed, ground cumin seed, sage and marjoram, and 1 teaspoon lemon thyme. Mix well, then powder with a mortar and pestle.

**Spicy saltless seasoning:**
1 teaspoon each of cloves, pepper, and coriander seed (crushed), 2 teaspoons paprika, and 1 tablespoon rosemary. Mix ingredients in a blender. Store in airtight container.

**What Goes With What**

**Soups:**
- bay, chervil, French tarragon, marjoram, parsley, savory, rosemary

**Poultry:**
- garlic, oregano, rosemary, savory, sage

**Beef:**
- bay, chives, cloves, cumin, garlic, hot pepper, marjoram, rosemary, savory

**Lamb:**
- garlic, marjoram, oregano, rosemary, thyme (make little slits in lamb to be roasted and insert herbs)

**Pork:**
- coriander, cumin, garlic, ginger, hot pepper, pepper sage, savory, thyme

**Cheese:**
- basil, chervil, chives, curry, dill, fennel, garlic chives, marjoram, oregano, sage, thyme

**Fish:**
- chervil, dill, fennel, French tarragon, garlic, parsley, thyme

**Fruit:**
- anise, cinnamon, coriander, cloves, ginger, lemon verbena, mint, rose geranium, sweet cicely

**Bread:**
- caraway, marjoram, oregano, poppy seed, rosemary, thyme

**Vegetables:**
- basil, burnet, chervil, chives, dill, French tarragon, marjoram, mint, parsley, pepper, thyme

**Salads:**
- basil, borage, burnet, chives, French tarragon, garlic chives, parsley, rocket-salad, sorrel (these are best used fresh or added to salad dressing. Otherwise, use herb vinegars for extra flavor).

Holly H. Shimizu is curator of the herb garden at the U.S. National Arboretum in Washington, D.C.
Bee Pollen
As A
Health Food

by Tim Larkin

It seems there's always someone willing to consider unlikely substances as capable of curing an illness or promoting better health. In the case of bee pollen, the philosophy seems to be that what's good for bees will be better for humans.

Bee pollen is flower pollen gathered by the common honeybee and carried to the hive on the bee's legs as tiny pods formed by mixing the pollen with nectar. The pollen is used as food by the bees. But some bees don't get their food because humans have intervened to claim the supply for themselves. Humans get into the act by placing devices in the hive that strip the bee of her pollen before she can deliver the purloined pollen is collected in trays, processed into several forms, and marketed as an extraordinarily nutritious food, often accompanied by claims of therapeutic qualities.

The idea of what's good for the bees is good for the beekeeper needs examination. Following are some of the principal claims made for bee pollen, along with scientific evidence and other facts associated with those claims.

Claim: Pollen is a "giant germ killer in which bacteria cannot exist."

The most authoritative scientific study of the biology, biochemistry, and management of pollen (Pollen, by R.G. Stanley and H.F. Linskens) shows that pollen, when exposed to air, is rapidly attacked by bacteria, yeast and other fungi. Therefore, consumers should use the same precautions when storing pollen as with any other perishable food product.

Claim: Pollen is nature's most perfect food.

There is no one perfect food, only those that are better for various forms of life. The perfect food for the sea cucumber is organic debris sucked up from the ooze at the ocean's bottom. To larva of the silphid beetle, decaying meat is a perfect food. For the hookworm, there's nothing better than blood. According to studies by the National Academy of Sciences, the best dog food differs from the best cat food which differs from the best guinea pig food, and all of them differ from the ideal human diet. Thus, because pollen may be the best food for bees (or at least the best they can lay their hind legs on), there is no basis for a conclusion that it is the best, or anywhere near the best, food for human beings.

Claim: Pollen retards aging, as witness the longevity of natives of the mountains of Russia who owe it all to their pollen-rich diet.

According to a study of the eating habits of elderly persons in the Caucasus region of Soviet Georgia, "Sixty percent ate a mixed diet of milk, vegetables, meats, and fruits. Seventy percent of the calories were of vegetable origin and the remainder from meat and dairy products. Seventy to 90 grams of protein were included in the diets. Milk was a main source of protein." Although honey (which contains some pollen) was sometimes included in the breakfast menu, along with cheese, bread and tea, the scientists conducting the study made no mention whatever of bee pollen, even though they were looking for some dietary clue that might explain why these people live so long. One centenarian's recipe might be less than attractive to those men who believe bee pollen wards off old age. Gabriel Chapnian, estimated to be 117, gave his prescription for longevity as: "Active physical work, and a moderate interest in alcohol and the ladies."

Claim: Pollen is the richest source of protein known to science.

The major constituent of pollen is carbohydrate, not protein. And the protein quality of pollen varies, depending on the plant from which it comes. As pointed out by Dr. Hachi-
scientists believe that bee pollen is especially hazardous for persons with allergies, asthma or hay fever. Dr. M. D. Levin, director of the Carl Hayden Bee Research Center in Tucson, Ariz., warns pollen users "...to be aware of its potential to trigger an allergic reaction."

This view is supported by cases in scientific studies. In one instance, 15 minutes after a 46-year-old man with a history of seasonal allergy took bee pollen he developed anaphylactic shock and required emergency treatment.

Dr. Steven Cohen, an allergy specialist conducting research on stinging insects and bee pollen at the Milwaukee County Medical Complex, tested two women who experienced acute allergic reactions after eating small quantities of bee pollen. He stated that bee pollen can be deadly to persons with allergies. "Some people are sensitive enough that oral exposure to it will cause a significant reaction," he said. An entomologist with the Mississippi Cooperative Extension Service, Dr. James Jarratt, also pointed out that, "If you were not aware of a specific allergy, one that you didn't notice due to the low levels of the allergen you encounter in day-to-day behavior, you might ingest a pretty good-sized slug of it in bee pollen and have an allergic reaction." This is fair warning for the 10 to 20 percent of the U.S. population that suffers from some form of allergy.

Claim: Various athletes state that bee pollen has improved their performance.

Assuming the person making such a statement is not doing it for a fee, such claims, called testimonials, are based on personal belief, not evidence of effectiveness. Medical history (as well as the history of food fads) is crammed with instances of people claiming various types of benefit from useless, and sometimes even harmful, substances, primarily from the plant world.

During a high point of the quack patent medicines era, just before the 1906 Food and Drugs Act, magazines and newspapers were full of testimonials about the curative powers of "medicines" that were little more than alcohol and colored water. Such ads, then and now, capitalize on an oddity of human nature: People are often (temporarily) helped, not by the food or drug being touted, but by a profound belief it will help. The renowned physician Sir William Osler had this in mind when he advised physicians "...to treat as many patients as possible with a new drug while it still has the power to heal."

Some testimonials are sincere expressions of erroneous belief, and the still mysterious translation of hope magnified by belief into benefit, but others are fraudulent. And some are purchased. Noting how people lend their names to preposterous claims, one cynical newspaper editor said, "If your brains won't get you into the papers, sign a 'patent medicine' testimonial. Maybe your kidneys will."

Claim: Scientific tests prove that bee pollen enhances athletic performance.

In a 1975 test sponsored by the National Association of Athletic Trainers, the Louisiana State University swimming team participated in a six-month experiment in which half the team took 10 pollen tablets a day, one-quarter received 10 placebo tablets (externally identical to the pollen tablets but devoid of pollen), and the other quarter received five pollen and five placebo tablets. There was no measurable difference in performance among the three groups.

The test later was repeated with 30 swimmers and 30 high school cross-country runners. As one of the researchers, Dr. John Wells of LSU, said, the bee pollen was "absolutely not a significant aid in metabolism, workout training or performance."

Claim: Bee pollen can alleviate a virtual encyclopedia of ailments, including sexual malfunction and tendencies toward suicide. (One promotional pamphlet listed 80 separate afflictions, from "growing pains" to cancer, which it claimed bee pollen had treated successfully.)

There is no valid scientific evidence for any therapeutic benefit from bee pollen. In view of what's known about bee pollen, compared with what's claimed, the conclusion of the authoritative Stanley-Linskens study is worth repeating. "While pollen, or its equivalent, may be irreplaceable in the bee diet," the study said, "we fail to see a correlation with suggested benefits to man...."

What is the position of the Food and Drug Administration regarding bee pollen? Under the law, since the pollen has not been shown to be harmful other than to those suffering from an allergy, bee pollen may be marketed as a food, provided no nutrition or therapeutic claims are made or implied regarding it.

Thus, if the labeling (including pamphlets or advertising associated directly with the product) does not suggest that it is intended for use other than as food, bee pollen marketed as a food need meet only the same general labeling requirements as other foods, and be prepared, packed and held in a sanitary manner.

Although FDA has legal authority to require that new food additives pass certain tests before being allowed on the market, it cannot demand the same proof of foodstuffs, such as bee pollen. This is not the case with drugs.

If those selling bee pollen, or anything else, claim it can cure or alleviate any illness or produce some therapeutic benefit, the law says the product is a drug and must meet rigid scientific requirements for both safety and effectiveness. The exact language of the law is strict and precise. To gain approval as a new drug, a product must support its claims by "adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could be fairly and responsibly concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the labeling or proposed labeling."

Obviously, some bee pollen distributors have been making drug claims. In a recent instance, FDA asked that all shipments of a particular product and its promotional literature be immediately recalled by the manufacturer. The firm responsible swiftly complied, possibly aware that FDA can take other steps. These include seizure, injunction, and criminal prosecution where the law is violated regarding sale of an unapproved drug or a product classified as a drug due to therapeutic claims made for it.

Tim Larkin is a freelance writer.
Food Preservatives: A Fresh Report

by Chris Lecos

The 20th century has seen vast changes in agricultural technology and food production and enormous demands upon the food industry. Food today is produced in massive quantities and transported not only coast-to-coast but to all parts of the world. It would be impossible for many foods to be processed, packed, shipped, stored and stacked on supermarket shelves safely for long periods without chemical preservatives.

Wide use of chemical additives in foods is of concern to many people, however, and it is the task of regulatory agencies such as the Food and Drug Administration to protect public health through enforcement of the nation's food safety laws.

Of the array of chemicals used in foods, some are added to improve nutritional content; some to give color; some to impart or enhance flavor; and others to extend the food's shelf life and stability. Some are added to keep food from spoiling or from becoming rancid and poor tasting. It is this last group—the preservatives—with which we are here concerned.

Humans have always sought ways to make food last longer and still be edible. Salt, sugar, acids, and smoke (for meat and fish) have been employed in the past to preserve food, in treatments usually done on the farm or in the home kitchen.

Preservatives used by the modern food industry perform either or both of two major functions: As antimicrobial agents, they keep food from spoiling; and as antioxidants, they keep foods from becoming rancid or developing off-colors and flavors.

Antimicrobial agents are added to food formulations to inhibit or prevent the growth of molds, yeasts and bacteria that spoil foods. Antioxidants are used in a wide variety of food products—particularly the large number that contain fats and oils—to prevent rancidity.

Antimicrobial agents are added to food formulations to inhibit or prevent the growth of molds, yeasts and bacteria that spoil foods. Antioxidants are used in a wide variety of food products—particularly the large number that contain fats and oils—to prevent rancidity.

Antioxidants slow the development of off-flavors and odors and color changes, caused by chemical reactions that take place when foods are exposed to oxygen, moisture, heat, or certain enzymes present in many natural fats. The time it takes for fats and oils to become rancid varies with the particular fat and storage conditions. Unsaturated fats have less resistance than saturated fats to rancidity. Vegetable oils contain more unsaturated fats, but also small amounts of naturally occurring antioxidants such as tocopherols. Although animal fats are more saturated, they have fewer naturally occurring antioxidant substances. Therefore, animal fats generally require added or higher levels of antioxidants than do vegetable oils.

The chemical reaction that occurs when a food be-comes rancid is either oxidative or hydrolytic. In a hydrolytic reaction, enzymes speed the reactions of the fat with other chemical elements of a food to produce foul-smelling fatty acids. An oxidative reaction results when foods are exposed to oxygen.

Foods high in carbohydrates and protein also are subject to microbial deterioration that can affect flavor. Those with large amounts of carbohydrates also may undergo changes in color instead of developing off-odors and off-tastes. This change in color is sometimes referred to as the "browning effect." Consumers are used to seeing this cosmetic defect in some fresh fruits and produce, after they are cut.

Since so many foods contain fats and oils, which are susceptible to oxidative and other reactions that cause rancidity and off-odors, the food industry considers it important to inhibit these reactions so as to extend the shelf life of the food products.

The 1938 Food, Drug, and Cosmetic Act gave FDA broad authority to move against any chemicals in food that are unsafe for human consumption. This power was strengthened 20 years later with the passage of the Food Additives Amendment, which required those in the food industry desiring to add a substance to food to first demonstrate its safety. The 1958 amendment, however, applied only to new additives. Hundreds of substances had been in common use by the food industry at the time. Many of those had a long history of use and were considered safe. They were placed on what is known as FDA's GRAS (generally recognized as safe) list.

Starting in the early 1970s, FDA contracted with the Federation of American Societies for Experimental Biology (FASEB) to review the scientific literature to determine which additives on the GRAS list could retain their status as GRAS substances. There are more than two dozen antimicrobials and antioxidants on FDA's GRAS list. There also are many other additives—including antimicrobial and antioxidant agents—that have come into use since 1958 and are regulated by FDA.

Of the more than two dozen GRAS antimicrobials and antioxidants, FDA has reaffirmed that six may continue to be safely used. These are benzoic acid, methylparaben, propyl gallate, propylparaben, sodium benzoate, and stannous chloride. Of the remainder, FDA has either not finally acted on its published proposals to reaffirm their safety or is still evaluating data before taking final action. The two most widely used antioxidants still being reviewed by the agency are butylated hydroxyanisole (BHA) and its related compound, butylated hydroxytoluene (BHT).

BHA and BHT are used in a large number of products that contain fat and oil. Other substances often used in combination with BHA and BHT include propyl gallate and sometimes citric acid, phosphoric acid and ascorbic acid. These substances help enhance the effectiveness of BHA and BHT.

A brief summary of these GRAS substances, their food uses, and their status in FDA's continuing evaluations follows:

Ascorbates and erythorbates (ascorbic acid, ascorbyl palmitate, calcium ascorbate, erythorobic acid, sodium ascorbate, sodium erythorbate)—FDA has proposed that all of
these antioxidants except calcium ascorbate be reaffirmed as GRAS substances. FASEB concluded in 1979 that using these substances in food presents no health hazard. In general, they are used in small concentrations to inhibit enzymatic browning and/or as preservatives in many foods and beverages, including concentrated milk products, some meat products, pickling brine for pork and beef cuts, baked goods, soft and hard candies, fats and oils, gravies, breakfast cereals, and processed fruits and vegetables.

Ascorbic acid (vitamin C), a natural constituent in many products and an essential nutrient, has many food uses. It is used mostly as an antioxidant but is an antimicrobial in some foods. It is often used with other major antioxidants—BHA, BHT and propyl gallate—to make them more effective.

Ascorbyl palmitate is a fat-soluble antioxidant made by combining ascorbic acid with palmitic acid. Calcium ascorbate and ascorbyl palmitate are derivatives of ascorbic acid but have more limited uses in foods. Erythorbic acid and its sodium salt are effective antioxidants but contribute little vitamin C to food.

Benzoic acid and sodium benzoate—Benzoic acid and its sodium salt, sodium benzoate, have been used as antimicrobial preservatives most of this century, particularly in highly acidic foods. They are especially effective against yeasts and bacteria, less so against molds. The GRAS status of benzoic acid and sodium benzoate was affirmed by FDA after FASEB reported there was no evidence of a hazard to public health at the levels used by industry in foods.

Benzoic acid occurs naturally in some foods, including raspberries, cranberries and other berries, prunes, cinnamon, cloves, tea, and anise. It is used mainly in condiments and relishes, sugar substitutes, imitation dairy products, nonalcoholic beverages, soft candy, chewing gum, baked goods, alcoholic beverages, frozen dairy products, fats and oils, gelatins and puddings, and cheese. Sodium benzoate, sometimes identified as benzoate of soda, is also used as an antimicrobial agent in sweet sauces, baked goods, condiments and relishes, processed vegetables, salted margarine, seasonings and flavors, jams and jellies, fats and oils, gelatins and puddings, frosting, processed fruit, imitation dairy products, gravies, alcoholic and nonalcoholic beverages, fruit ices, milk products, soft candy, frozen dairy products, instant coffee and tea, meat products, breakfast cereals, hard candy, and cheese. By FDA regulation, the maximum level permitted in food for both ingredients is 0.1 percent.

BHA (butylated hydroxyanisole and BHT (butylated hydroxytoluene)—BHA and a chemically similar compound, BHT, are antioxidants used for more than 40 years to retard rancidity in a wide array of food products containing fats and oils as well as in certain processed meat products. They are both direct additives and indirect additives put into defoaming agents, food packaging materials, adhesives, and lubricants that come into contact with food.

The most common antioxidant formulations combine BHA, BHT and/or propyl gallate with citric acid, according to the second edition of the Handbook of Food Additives (published by CRC Press, a division of the Chemical Rubber Co.). These additives are considered more effective than other antioxidants to prevent rancidity in fats and oils. Potency, ability to prevent off-flavors and odors, and low cost are among the factors that make an antioxidant attractive or unattractive to industry for use in food.

BHA and BHT generally are used in breakfast cereals, chewing gum, convenience foods, vegetable oils, shortening, potato flakes, enriched rice, potato chips, and candy—to name some. Their ability to intercept oxygen before it gets to fat molecules is what makes them effective in keeping food from becoming rancid. FDA limits their use in food—alone or in combination with other antioxidants—to no more than 0.02 percent of the total fat and oil content. BHT is used less than BHA because the former is less stable at high temperatures.

Parabens (methyl paraben and propyl paraben)—Used in many foods for more than 50 years, these two antimicrobial agents were affirmed as GRAS by FDA. Closely related to benzoic acid—which is more effective in acidic foods—methyl and propyl paraben are used to inhibit molds and yeast in various foods but are not as effective against bacterial spoilage. Yeasts and molds are more of a spoilage problem in foods high in acid and can be controlled better with the less costly sodium benzoate. The two parabens are sometimes used to extend the effectiveness of benzoic acid.

Both are listed as GRAS for addition directly to food, and they are permitted as indirect food additives in food packaging materials when used in adhesives for packaging, transport, or holding of food. Generally, these additives are used in such products as processed vegetables, baked goods, fats and oils, seasonings, sugar substitutes, frozen dairy products, processed fruit, jams, jellies, preserves, olives, pickles, syrups, soft candy, gelatins and puddings, grain products, alcoholic and nonalcoholic beverages, cheese, and sweet sauces.

Propionic acid and its salts (calcium propionate, sodium propionate, dilauryl thiodipropionate, thiodipropionic acid)—Propionic acid and its salts, calcium propionate and sodium propionate, generally described as propionates, have been used extensively for many years in baked goods and in processed and blended cheese products. The propionates blend well with emulsifying agents used in cheese and dough products and are effective against fungi, but not against yeasts, and against organisms that cause "rope" in doughs. Characterized by gelatinous threads in the center of a loaf of bread, rope is caused by a bacterium that contaminates dough and survives baking. The bacteria multiply and digest the bread, causing off-flavors, discoloration and softening. Baking destroys most molds but contamination can occur in the humid environment within the bread wrapper if the additives are not used.

Calcium propionate is commonly used in bread products. Sodium propionate is often used with pies and cakes. Many dairy products contain propionic acid as a
naturally occurring ingredient. It is partly responsible for the aroma of butter and cheese, especially Swiss cheese. FDA regulations also permit propionic acid as an optional ingredient in artificially sweetened jams, jellies and preserves.

Dilauryl thiophosphinate and thiophosphoric acid were approved as GRAS substances for use in products with edible fat, but they are not considered as effective as BHA, BHT and other antioxidants. These two sulfur-containing compounds tend to cause odor and flavor problems. FASEB’s 1979 report revealed no use of these substances in foods and said they were of “limited value.” However, FASEB said they may serve a more important role in food-packaging film. FDA is considering whether to affirm their GRAS status. FDA at present limits their use, along with any other antioxidants, to a total of 0.02 percent of the fat and oil content of food and to 0.0005 percent in food when they migrate to it from the food package.

Propyl gallate—This widely used antioxidant was affirmed as a GRAS substance after FASEB concluded in 1973 that present levels of commercial use posed no health hazard. Used in foods since 1948, propyl gallate often is combined with BHA and/or BHT and even other additives and put into fats, oils and fat-containing foods susceptible to rapid rancidity and other oxidative reactions that could affect taste and color. Besides fats and oils, it is added to meat products, snack foods, baked goods, nuts, grain products, frostings, chewing gum, soft candy, frozen dairy products, gelatins and puddings, and alcoholic and nonalcoholic beverages.

Sorbic acid and its salts (calcium, potassium and sodium sorbate)—Used in foods for more than 30 years, sorbic acid and its salts—often called sorbates—are used as antimicrobial preservatives and as sprays, dips or coatings on wrapping materials. A 1975 FASEB report found no evidence of potential harm to public health when sorbic acid and its salts are used at present or anticipated levels. FDA has proposed that they be affirmed as GRAS substances. FDA food standards, however, limit the amounts of sorbates added to various foods.

Sorbic acid and potassium sorbate are the only sorbates used as preservatives. They may be found in baked goods, fats and oils, milk products, cheese, frozen dairy products, processed vegetables and juices, condiments, soft candy and other confections, jams and jellies, sweet sauces, nonalcoholic beverages, and gravies. Potassium sorbate also is used with processed fruits, juices and drinks, fruit ices, meat and fish products, snack foods, alcoholic beverages, and seasonings and flavors.

Sorbic acid, a potent inhibitor of molds and fungi, generally is more effective over a wide range of acid levels in foods and thus has broader uses than sodium benzoate.

Sodium sorbate is considered too unstable for use as a food preservative, but it and potassium sorbate are listed as GRAS for paper and paperback food-packaging materials. Calcium sorbate is employed mainly in margarine.

Stannous chloride (tin chloride)—Described as a chloride salt of metallic tin, stannous chloride prevents oxygen from combining with chemicals in foods and causing color changes and offensive odors. It was affirmed as a GRAS substance by FDA after FASEB reported in 1974 that it posed no health hazard. Its use in food cannot exceed 0.0015 percent, calculated as tin, under FDA regulations. Its main food uses are in processed vegetables, processed fruits, and nonalcoholic beverages.

Sulfiting agents (potassium bisulfite, potassium metabisulfite, sodium bisulfite, sodium metabisulfite, sodium sulfite, sulfur dioxide)—Sulfiting agents such as sodium bisulfite and sodium metabisulfite, marketed as “vegetable fresheners” or “potato whitening” agents, are used by the food service industry—restaurant salad bars are a major example—to keep lettuce and other vegetables fresh and crisp and to prevent discoloration of fruits and other produce when cut or peeled.

In March 1983, after receiving reports of adverse reactions to sulfites among certain segments of the population, particularly asthmatics, FDA advised the state agencies responsible for overseeing the food service industry that consumers should be informed when sulfiting agents are used through display of “conspicuous and easily readable labels, signs, placards, menu statements” or by other means. FDA added that foods treated with sulfiting agents would not be considered safe unless consumers were properly informed of their use. The National Restaurant Association has since reported that many of its members have stopped using sulfiting agents.

Sulfur dioxide is a colorless gas that has been used for many years to sanitize food containers and fermentation equipment, to inhibit microbial spoilage, and as an antioxidant. Sulfur dioxide is not to be used in meats or other foods that are substantial sources of thiamine (vitamin B.) because of its adverse effects on this vitamin.

In 1982, FDA proposed to affirm the GRAS status of sulfur dioxide, sodium bisulfite, and sodium and potassium metabisulfite, with limitations on their use, but not sodium sulfite and potassium bisulfite because of a lack of information about their current food uses. When FDA became aware of the more recent data on adverse reactions to sulfites in some people, the agency undertook further review and is reevaluating its earlier proposal.

Tocopherols—The tocopherols are a group of chemically related substances that, depending on the form of toco- pherol, contribute varying amounts of vitamin E to the diet. There are eight known forms that occur naturally in animal tissues and in vegetable oils, cereals, nuts, and leafy vegetables. Six other tocopherol derivatives are prepared commercially for use as antioxidants in foods, mainly to prevent fats and oils from becoming rancid. Alpha tocopherol is the most potent vitamin E compound. Mixed tocopherol concentrates have been used as antioxidants in food since 1949. These include baked goods and mixes, breakfast cereals, milk products, poultry products, gelatins, puddings, fillings, soups, soup mixes, snack foods, nonalcoholic beverages, seasonings, flavorings, and infant formulas.

Chris Lecos is a member of FDA’s publications staff.
Heat Used To Fight Some Cancers

by Richard C. Thompson

A medical device that uses controlled microwave energy to treat certain kinds of cancer has been approved by the Food and Drug Administration for marketing by the manufacturer.

With this approval, a technique known as hyperthermia (hyper = excessive; thermia = heat) has moved from the experimental closer to the clinical, and prospects for management of four particular cancers is improving.

The approved device and procedure are for treatment of these malignant tumors: melanoma, a rare but very malignant and likely fatal skin cancer; squamous (basal cell) carcinoma, a less threatening but still dangerous and fairly common skin cancer that can spread into and beneath the skin; adenocarcinoma, a soft-tissue cancer that can grow and spread rapidly, with often fatal results; and sarcoma, a bone and organ cancer that also grows and spreads with fatal results. Hyperthermia treatment is limited to patients who have recurrent or regressive cancers of those types despite conventional therapy.

Hyperthermia is a palliative treatment, meaning that it suppresses and perhaps halts the growth of the cancer, but it is not a cure. It will be used to treat cancer sites following radiation, but it is not a cure. It will be used to treat cancer sites following chemotherapy and surgery.

FDA's approval was for a machine produced by BSD Medical Corp. of Salt Lake City.

Clinical studies sponsored by the firm began in 1981 and involved 10 institutions, including the University of Utah, Loma Linda University in California, Presbyterian Medical Center in Denver, Swedish Tumor Institute in Seattle, and the University of Wisconsin.

In the course of the two-year study, researchers treated 179 patients who had late-stage tumors, using hyperthermia combined with radiation. Some additional patients were treated with hyperthermia only, some with hyperthermia and other therapies.

After 1,640 hyperthermia treatments on these patients, researchers evaluated 218 tumor sites and found that 81 tumors showed full regression, another 60 showed at least 50 percent regression, and another 40 showed partial regression. The net result was full to partial regression of 83 percent of the tumors.

Hyperthermia devices radiate energy, much like that of a microwave oven. This energy enters body tissue and silently bombards the cell molecules, causing the tissue to heat up. In living tissue, heat is carried away by the blood that flows through (perfuses) the tissue. Solid malignant tumors have a much smaller blood supply than that of normal tissue and therefore less ability to have heat carried away.

When hyperthermia is applied, tumors will reach a relatively higher temperature than surrounding normal tissue and that destroys the tumor cells.

To administer hyperthermia, the patient is positioned beside the machine, and the physician directs a beam of microwave energy from a small, horn-like applicator to the tumor. The beam heats the cancer cells to 108 to 113 degrees Fahrenheit (42 to 45 degrees Celsius), in effect "cooking" the malignant tumor and causing cells to die. Repeatedly heating such tumors for up to an hour can cause the tumor to shrink, or regress.

During treatment the machine continually monitors the temperature of the tumor and the surrounding tissue through needle-like probes inserted into the body. It automatically adjusts power to maintain the temperature set by the operator. This ensures that the tumor is receiving the intended dose of thermal energy and that surrounding healthy tissue is not overheated.

The possibility of using heat to suppress the growth of cancer cells in the body has long intrigued medical researchers. There are numerous anecdotes in medical literature—many of them confirmed—of a tumor mysteriously disappearing after the patient had a high fever. Applied hyperthermia had to wait, however, until the technology was more fully developed and its medical uses better understood.

Hyperthermia will be used chiefly by oncologists—physicians who specialize in cancer—and by certain radiologists and others who have similar specialization. It is not an office procedure but will be offered in those medical centers throughout the country where such specialists are located and where the equipment is installed.

FDA's National Center for Devices and Radiological Health, which is responsible for the approval of the hyperthermia machine, will continue monitoring the performance of this new technology. The center's staff is providing technical support to the National Cancer Institute for evaluation of equipment for hyperthermia treatment of cancer and is assisting in the selection and analysis of thermometry (measuring) equipment needed with hyperthermia. The center has designed a calibration system for the thermometer probes used in hyperthermia and also has developed materials known as "phantoms," which are foam and plastic shapes that have the same density as human tissue. This allows manufacturers to test their machines without using human subjects.

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

- The week beginning April 23 has been designated National Consumers Week with the theme “Consumers Mean Business” (FR Jan. 6).

- Consumers in the District of Columbia will have better protection during 1984, thanks to an agreement between the district’s Department of Consumer and Regulatory Affairs and FDA’s Baltimore district office. The agreement provides for a cooperative response to public health emergencies, coordination of consumer complaint investigations, joint training efforts, analytical assistance, and mutual exchange of inspection information (FR Jan. 16).

- An index to the compilation of FDA Annual Reports, 1950-1974, is available for $4.00 postpaid from the American Institute of the History of Pharmacy, Pharmacy Building, University of Wisconsin, Madison, Wis. 53706.

- The Department of Defense is proposing to allow coverage of trans-telephonic monitoring of pacemakers under the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) (FR Jan. 18).

- The Nuclear Regulatory Commission proposes to require that licensees use the services of personnel dosimeter processors accredited by the National Voluntary Laboratory Accreditation Program of the National Bureau of Standards. The proposal stems from concern that personnel dosimeters, devices worn by workers to measure radiation exposure, are not being processed accurately (FR Jan. 10).

- Paragon Optical Inc. wants the color additive regulations amended to allow use of D&C Red No. 17 and D&C Yellow No. 10 to color contact lenses. ...The closing date for the provisional listing of D&C Yellow No. 10 was postponed from Nov. 1, 1983, to March 5, 1984, to give FDA time to evaluate objections to permanently listing the color additive (FR Jan. 6, Jan. 3).

- Market-testing of grated cheese containing powdered cellulose as an anti-caking agent is due to begin this month under temporary permits issued by FDA to Pace Dairy Foods, Rochester, Minn.; California Cheese Co., San Jose, Calif.; and Schreiber Foods Inc., Green Bay, Wis. Cheese made by Pace Dairy Foods and Schreiber Foods will be distributed nationwide, while the California Cheese Co. product will be tested in 13 western states (FR Jan. 26).

- About 10 to 20 grants, ranging from $20,000 to $70,000, will be made by FDA this year to support clinical trials of the safety and effectiveness of orphan drug products. Grants of over $70,000 will be considered by the agency if the trial extends over a two- to three-year period (FR Jan. 30).

- FDA has stayed the final decision on ingredients in egg bread and has granted petitions for reconsideration of these amendments to the standard of identity for bakery products (FR Jan. 17).

- Rules governing the export of investigational new drugs and biological products not covered by an investigational new drug application (IND) have changed. Export will be allowed if a written request from the exporting firm satisfies FDA that the product is appropriate for investigational use, would be used for such purposes only, and could be legally used in the importing country. Exports will also be authorized if the requests come from an authorized official of the importing country and adequate information about the product’s use is provided. Previously, requests were processed through the State Department (FR Jan. 18).

- The United States voted to schedule pentazocine under Schedule III and 18 benzodiazepines under Schedule IV of the Convention on Psychotropic Substances at a February meeting of the United Nations Commission on Narcotic Drugs. The convention was established in 1971 to control “mind-altering” drugs according to their actual or potential level of abuse. Control requirements involve licensing of manufacturers, record keeping, security measures, warning labels, and export and import authorization. Adoption of international scheduling does not require rescheduling of drugs marketed in the United States.
On Cabbages And Cancer

"Cabbage, Brussels Sprouts, Carrots, Cauliflower, Spinach and Broccoli vs. Cancer."

That was the banner display line on a magazine ad that appeared last spring for Daily Greens, green oval pills sold by PharmTech Research, San Francisco. According to the ad, Daily Greens "are concentrated servings of cruciferous and carotene-rich vegetables... shaped into tablets and given a protective vegetable coating."

Why all the fuss about vegetables reduced to pill form? Well, said the ad, the National Academy of Sciences reports that a regular diet of cruciferous and carotene-rich vegetables is associated with a reduction in the incidence of certain cancers. Therefore, the ad continued, "Daily Greens allow you to eat cruciferous vegetables regularly, with the convenience of a food supplement." The ad closed with the exhortation: "Help your body defend itself."

These claims for the product raised eyebrows at two government agencies: the Federal Trade Commission and the Food and Drug Administration. The former began investigating the Daily Greens promotion media campaign in magazine, newspaper and television ads. FDA's San Francisco district sent an investigator to inspect the corporate headquarters of PharmTech Research on Montgomery Street.

The investigator interviewed the company president and collected samples of the product, its labeling, and promotional literature. She was denied access to the shipping records.

The labeling collected by the investigator included the statement, "You can take steps to reduce the risk of cancer.... Eat more fruits, whole grains, and vegetables, particularly those contained in Daily Greens. Daily Greens, taken once a day, is designed to deliver the cruciferous vegetables that have been found to be protective."

The investigator informed the president that making unsubstantiated medical claims for a food product such as Daily Greens was a violation of the Food, Drug, and Cosmetic Act. The president denied that the labeling included medical claims. He said that the information on the labeling and promotional literature was taken from a National Academy of Sciences report titled "Diet, Nutrition, and Cancer." He gave the investigator three copies of the report.

Next the investigator paid a visit to Pacific Coast Service Co., the public storage warehouse in South San
Ohio Blood Plasma Inc. of Cincinnati is back in business after its license was suspended and it recalled some products because of faulty record keeping and other violations of plasmapheresis operation regulations.

An investigation by FDA’s Cincinnati district office revealed that the firm’s employees failed to obtain the required medical histories from plasma donors; to properly identify and label donor red cells; to correctly perform saline infusions; and to correctly measure the physical properties of donor plasma. The firm falsified records to conceal these mistakes.

In an attempt to correct inadequacies of its record keeping system, the plasma center employees relabeled plasma in such a way that a mixup could occur between hepatitis negative plasma and hepatitis positive plasma. On one occasion, a donor was mistakenly infused with another donor’s red blood cells.

After the FDA investigation revealed the deficiencies, Ohio Blood Plasma Inc. shut down and retrained some employees. However, the firm’s employees still failed to correct the problems, and the FDA obtained a consent decree permanent barring PharmTech from misrepresenting scientific tests or articles and from making health claims without “reliable and competent scientific evidence.” Both of FDA’s seizure requests were approved and filed with the appropriate district attorneys. PharmTech Research has filed for bankruptcy.

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all employees. It was then allowed to reopen on a limited basis and accept donors, but no shipments of blood products were permitted until FDA had reinspected the operation and lifted the suspension. This was done, and the firm is now in compliance with Good Manufacturing Practices for such centers.

Plasmapheresis is a process by which blood is taken from donors and the plasma (liquid portion) removed. The red cells are returned to the donor unharmed in an injected saline solution. The plasma is used in medical research and drug manufacture and to treat patients with various illnesses. Proper operation of plasmapheresis centers is essential to both donors and patients, and labels and records are an important part of that operation.

**Persuaded**

Farmers' Supply Co. of Bunker Hill, Ill., apparently had problems keeping its pesticide chemicals separated from its feed products. Even after three inspections by FDA's Chicago district, the firm continued to store and mix pesticides in the same work area where it stored and mixed animal feed. As the inspectors pointed out, this could easily lead to contamination of the feed.

Samples of the seized products were sent to the district laboratory, where analysis showed the feed contained the toxic herbicide trifluralin.

Finally, with Farmers' Supply not convinced that its feed handling was faulty, FDA obtained a court order instituting seizure of the firm's entire stock of minerals, concentrates, and feed blocks. This amounted to 14 tons (62 lots) of bagged and uncovered feed products valued at $4,000. Those lots that were contaminated were destroyed under a consent decree.

**When Barges Bump**

It was like something out of a Laurel and Hardy comedy, where one disaster inevitably leads to another. As reconstructed—because it was a dark night and no one witnessed the entire chain of events—the tugboat _City of Greenville_ was pushing a string of barges down the Mississippi River when one of the barges struck an abutment of the Poplar Street Bridge at St. Louis.

The impact broke several barges loose from the string and they floated free down the river. Some of the runaways crashed into a fleet of barges moored on the Illinois side of the river. These were loaded with crude oil and grains, and some caught fire. This collision set more barges free, and soon a flotilla of barges was drifting down the river.

Downstream from St. Louis, at Sauget, Ill., is a 300-foot-long pipeline structure suspended over the surface of the water and terminating in a floating loading dock. The pipeline is used to transport chemicals between barges on the river and a chemical plant nearby.

Three of the barges from the upstream collisions plowed into the pipeline bridge, part of which collapsed on one of the errant barges. This barge contained 45,000 bushels of soybeans, worth $300,000. The pipeline broke through the fiberglass hatch cover protecting the cargo, and leaked some of its contents into the hold where the soybeans were stored (the entire pipeline structure fell a few days later).

The barge with the tainted soybeans was moved to the Missouri side of the river, where investigators from FDA's St. Louis station surveyed the condition of the soybeans and collected some samples to be analyzed by the agency's Kansas City district laboratory. Bad news. The soybeans were contaminated with benzene and toluene.

Because of the accident, the consignee of the soybeans refused to accept the shipment. The damaged cargo now became the responsibility of the barge line transporting the soybeans.

Knowing that the contaminated soybeans were subject to seizure by FDA, the barge line proposed reconditioning, and presented several possible methods to the St. Louis station for consideration.

The first method—a ventilation and aeration process—proved unsatisfactory. After some discussion, the barge line proposed roasting the beans in the hope that heat would volatilize and remove the contaminants. With FDA's approval, a pilot
batch was roasted and tested. The batch tested negative, so the entire 45,000 bushels were roasted. Samples were examined and no unsafe contaminants were found. The cost of reconditioning was some $90,000.

Moral of the story: Be extra careful pushing barges under the Poplar Street Bridge on dark nights when soybean-loaded barges are nearby and a chemical pipeline bridge is just downstream.

Airport 1983

For want of some valves the water supply at Volpe International Terminal in Boston was out—at least temporarily. Airlines using that terminal were being serviced by general aviation companies, who were providing potable water by truck.

Volpe International Terminal is one of five terminals at Boston’s Logan Airport. Like all facilities serving international carriers—buses, trains, airplanes—the terminal’s food and water supplies are routinely inspected by FDA under the International Travel Sanitation Program.

During an inspection in September 1983, an investigator from FDA’s Boston district found problems with the terminal’s “back-flow prevention devices” in the water system. Water normally flows from a point of high pressure to low pressure. A drop in pressure at the point where the hoses connect to the potable water lockers can cause the water to reverse direction and can draw contaminants such as chemicals or waste materials into the clean water source. This is called “back-flow.”

To prevent back-flow, the connecting hoses are equipped with valves that close to prevent the water from reversing direction should the pressure drop. It was these valves that were missing at Volpe International Terminal. The investigator thus assigned the facility a “provisional” rating. This meant the facility should immediately correct the problem and would be reinspected in 30 days.

Unfortunately, the airline companies and Massport Authority (which runs the airport) could not agree on who was responsible for correcting the problem. When the investigator revisited the site in October, the valves were still missing. He therefore classified the facility as “not approved.”

Massport Authority locked the potable water lockers at the terminal and shut off the water supply. When the back-flow valves are replaced, the water supply can be reopened.

Cleanliness Reports Ordered

For some people, writing reports is a terrible chore. For one baker it’s a task that can’t be avoided. Under a consent decree of permanent injunction, the owner of a bakery in Springfield, Mo., has to report to FDA’s Kansas City district office every other month to certify that his plant is free from any insect or rodent activity.

This unusual court-ordered requirement was imposed because of the continuing failure of Roy-El Way Products Inc. to keep the bakery and an adjacent warehouse clean.

Roy-El Way Products Inc., which does business under the name “Bread for Life,” manufactures natural bread products and peanut butter and distributes a line of granola products that are sold in nine states.

In January 1983 investigators from FDA and the Springfield Health Department inspected Roy-El Way Products and found rodent and insect infestations. The January visit was a follow-up to an earlier inspection that had resulted in a written warning to the firm to clean up the facilities.

After the January inspection the firm destroyed approximately 3,500 pounds of whole grain under the supervision of the Springfield Health Department.

In subsequent visits, the FDA investigators found more evidence of sanitation problems at Roy-El Way Products. They photographed rats in broad daylight eating grain from the outside storage area. This is unusual since rats usually feed at night. A drainage ditch next to the building was overgrown with weeds and bushes, providing an ideal home for rodents. Mice were seen inside the bakery. One family of mice was nesting in the insulating material around a hot water heater.

FDA sent several letters outlining what should be done to improve sanitary conditions in and around the bakery. Although the owner did make some improvements, his sanitation problems persisted and FDA had to go to court.

In April 1983, in the U.S. District Court for the Western District of Missouri, Springfield Division, the owner of Roy-El Way Products signed the consent decree. The decree prohibits the firm from manufacturing bakery products that are not in compliance with the sanitation requirements of the Food, Drug, and Cosmetic Act; it also requires the firm to certify, in writing to FDA on a bimonthly basis, that its self-inspection program is maintaining operations free from any insect or rodent activity.

After the consent decree was signed, the firm closed down for several days while corrections were made. It destroyed 2,700 pounds of baked bread, rice, cornmeal, and repacked food.

—This small sample of reports from the field was compiled and edited by Annabel Hecht, Carol Ballentine, Richard Thompson and Evelyn Zamula.
Summaries of Court Actions are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act. Summaries of Court Actions report cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizure proceedings are civil actions taken against goods alleged to be in violation, and criminal and injunction proceedings are against firms or individuals charged to be responsible for violations. The cases generally involve foods, drugs, devices, or cosmetics which were alleged to be adulterated or misbranded or otherwise violative of the law when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. Full court opinions for these cases are published by either the West Publishing Company or the Commerce Clearing House Inc. Texts can be obtained from Commerce Clearing House at 1301 Pennsylvania Ave., N.W., Washington, D.C. 20004.

Summaries of Court Actions are prepared by the Food and Drug Division, Office of the General Counsel, HHS. Published by direction of the Secretary of Health and Human Services.

**SEIZURE ACTIONS**

**Foods/Poisonous and Deleterious Substances**


CHARGED 12-15-82: When shipped by Fisher Ranch Corp., Blythe, Calif., the article bore and contained the pesticide chemical chlorpyrifos, and no tolerance or exemption from a tolerance had been granted for such pesticide chemical in or on lettuce—402(a)(2)(B).

DISPOSITION: Default—ordered destruction. (F.D.C. No. 63935; S. No. 83-347-158; S.J. No. 1)

**Foods/Contamination, Spoilage, Insanitary Handling**


CHARGED 8-13-82: When imported from Mexico, the articles, labeled in part “Mole En Pasta San Luis...Made in Mexico...Productos Dona Lupe, S.A. S.L.P.,” and “Bufalo...Mexican Hot Sauce...Empacadora Bufalo, S.A. Mexico 19, D.F.,” contained insect filth—402(a)(3).

DISPOSITION: Consent—authorized release to Victor Padilla, McAllen, Texas, for export to original foreign supplier. (F.D.C. No. 63762; S. Nos. 82-122-556/7; S.J. No. 2)

PRODUCT: *Swiss cheese blocks*, at Monticello, W. Dist. Wis.; Civil No. 82-C1048-S.

CHARGED: 12-10-82: When shipped by Pleasant Valley Cheese Cooperative, Winslow, Ill., the article had been prepared, packed and held under insanitary conditions—402(a)(4).

DISPOSITION: Default—ordered destruction. (F.D.C. No. 63909; S. No. 83-298-749 et al.; S.J. No. 3)

**Foods/Economic and Labeling Violations**

PRODUCT: “*Apple concentrates,*” five lots, at Skokie, N. Dist. Ill.; Civil No. 82C-7206.

CHARGED 11-23-82: When shipped by Food Complex, Inc., Woodside, N.Y., the valuable constituent, apple juice, had been in part omitted from the articles (analyses showed little or no chlorogenic acid, which is a natural constituent of apple juice); and the articles’ name, “apple concentrate,” was false and misleading as to the articles’ content (analyses showed that the sugar ratios [fructose to glucose ratios] were not characteristic of apple juice concentrates, and demonstrated the presence of added sugar instead)—402(b)(1), 403(a)(1).

DISPOSITION: Default—ordered destruction. (F.D.C. No. 63901; S. No. 82-249-808 et al.; S.J. No. 4)

PRODUCT: *Pepper, black, ground*, at New Orleans, E. Dist. La.; Civil No. 82-5969.

CHARGED 12-29-82: While held by Foltz Coffee, Tea & Spice Co., New Orleans, La., who ground the article and packed the article in tins labeled “Yogi Brand...Ground Black Pepper NET WEIGHT 4 OUNCES. Arnaud Coffee Corporation, New Orleans, La.,” the article was short weight—403(e)(2).

DISPOSITION: Consent—dealer authorized to recondition. (F.D.C. No. 63924; S. Nos. 83-383-7/8; S.J. No. 5)

PRODUCT: “*Sesame oil,*” at Honolulu, Dist. Hawaii; Civil No. 81-0262.

CHARGED 7-28-81: While held for sale, a valuable constituent, sesame oil, had been in part omitted or abstracted—402(b)(1); soybean oil had been substituted for sesame oil—402(b); the article’s labels, which read “Mum’s Sesame Oil...contains a high volume of vitamin E...Packed for Taisei Trading Co., Ltd., Kobe, Japan,” contained false and misleading claims as to consisting wholly of sesame oil—403(a)(1); and the labeling of a number of lots of the product misleadingly failed to reveal certain facts material in light of the “high volume of vitamin E” statement (i.e., all nutrient quantities in relation to the average or usual serving or portion)—403(a)(1).

DISPOSITION: Consent—authorized release to Mum’s Taisei of Hawaii, Inc., Honolulu, Hawaii, for relabeling. (F.D.C.
Drugs/Human Use

CHARGED 10-29-82: When shipped by B.T. Products, St. Petersburg, Fla., the articles were new drugs without effective approved New Drug Applications, and the articles' labeling lacked adequate directions for use—505(a), 502(f)(1).
DISPOSITION: Default—ordered destruction. (F.D.C. No. 63868; S. No. 82-309-437; S.J. No. 7)

PRODUCT: Cough syrups, and cough syrup concentrate, at Linden, Dist. N.J.; Civil No. 82-2242.
CHARGED 7-13-82: When shipped by Anything and Everything, Brooklyn, N.Y., those articles which were labeled in part “Piso’s For Coughs...Active Ingredients: Chloroform...Pinex Company, Inc., New York, N.Y....5 [or ‘3’] Oz.” and “Regular Pinex Cough Syrup For Coughs Active Ingredients...Chloroform...8 Fl. Oz....Pinex Company, New York, N.Y.” were new drugs without effective approved New Drug Applications—505(a); and, while held for sale, those articles labeled in part “Wild Cherry Pinex Cough Syrup [or ‘Super Pinex Cough Syrup,’ ‘Pinex Concentrate,’ or ‘Regular Pinex Cough Syrup’] chloroform...3 Fl. Oz...Pinex Co., New York, N.Y.” had false and misleading labeling because their labels represented that the drugs contained specific amounts of chloroform when chloroform was not present in the labeled amount—502(a).
DISPOSITION: Default—ordered destruction. (F.D.C. No. 63733; S. No. 82-287-133; S.J. No. 8)

CHARGED 1-24-79 and amended 1-31-79: While held by Zenith Laboratories, Inc., Linden, Dist. N.J.; Civil No. 82-119.

PRODUCT: Hydralazine HCl, hydrochlorothiazide & reserpine tablets, U.S.P., Zenith, two lots, at Northvale, Dist. N.J.; Civil No. 82-119.
CHARGED 1-14-82: While held by Zenith Laboratories, Inc., Northvale, N.J., who had manufactured both lots of the article using imported reserpine, the strength and quality of both lots of the article fell below the standard for content uniformity of the U.S.P. (analysis of 30 tablets showed a range of approximately 60 to 125 percent of the declared amount of reserpine, and 12 tablets were outside the U.S.P. limits for content uniformity)—501(b).
DISPOSITION: Default—ordered destruction. (F.D.C. No. 63598; S. No. 81-273-643 et al.; S.J. No. 10)

Medical Devices

CHARGED 3-4-81: The accompanying labeling of the articles, specifically the operator’s manual titled “P-8 Portable Professional Muscle Exerciser...Rev. 3 Dated 7/25/80,” contained false and misleading claims for trimming the waist and for use for adipose tissue deposits—502(a); and the articles’ labeling lacked adequate directions for use, since neither adequate directions for lay use nor adequate information for use by licensed practitioners could be provided for the intended purposes of the devices—502(f)(1).
DISPOSITION: The articles were claimed by Total Approach, Inc., Orange, Conn. The claimant moved for return of the seized articles and for dismissal of the complaint. Ultimately, a consent decree of condemnation ordered delivery of the devices to FDA for evaluation and other disposition and ordered destruction of the accompanying labeling. (F.D.C. No. 63268; S. No. 80-190-868 et al.; S.J. No. 11)

CHARGED 12-28-82: The articles, which were being manufactured by Respirizer Co. (Div. of Campillary Systems, Inc.), Gettysburg, Pa., were accompanied by a brochure titled “Advanced Technology In Respiratory Therapy,” which contained the following false and misleading claims: (1) that the devices were adequate and effective for emphysema, asthma, allergies, sinusitis and sinusitis headaches, bronchitis, colds, flu, migraine headaches, respiratory and sinus illnesses, hay fever, and tensions caused by stress; (2) that the vapor generated by the Respirizer was more effective than the vapor from complicated and expensive hospital equipment; that the Respirizer vapor penetrated areas in the sinus and respiratory tract not reached by the vapor from hospital treatment; that use of the Respirizer was the only known method of natural-
ly treating sinuses and lungs; that moisture was restored to dry tissues; (3) that Respirizer therapy was the safest and most effective single means of treating practically all respiratory ailments without adverse effects; and (4) that the therapeutic value of moisture in a warm gaseous state had been demonstrated by a recent clinical evaluation of the Respirizer at a U.S. government medical center—502(a); and the articles’ labeling lacked adequate directions for lay use for the articles’ intended purposes; and such directions could not be written and the articles were not exempt from such directions because the articles lacked the prescription legend—502(f)(1).

DISPOSITION: The manufacturer claimed the articles. A partial consent decree of condemnation authorized release of the in-process components for bringing them into compliance. After successful reconditioning of the in-process components, another partial consent decree of condemnation authorized release of the finished devices for bringing into compliance. (F.D.C. No. 63780; S. No. 82-226-939; S.J. No. 12)

CIVIL CONTEMPT ACTIONS

DEFENDANTS: Becton, Dickinson & Co. (Bard-Parker Division), and Kenneth J. Summa, plant manager, Hancock, N. Dist. N.Y.; Misc. No. 112.

CHARGED on or about 9-2-77 in a complaint for injunction: That the defendants, with knowledge of the court’s Warrant for Inspection, disobeyed and violated the warrant by refusing to permit inspection of all records, files and papers respecting restricted devices and bearing on violation of the Federal Food, Drug, and Cosmetic Act; and that, by reason of such refusal, the defendants were in civil contempt of the warrant for inspection.

DISPOSITION: The court issued an order to show cause. Meanwhile, the government also filed an injunction action. The defendants countered by filing a declaratory judgment action petitioning the court to declare that FDA lacked authority to inspect, and to forbid such inspection. They also moved for dismissal of the government’s petition and for summary judgment in favor of Becton, Dickinson & Co. and the other defendant. (See S.J. Nos. 15 and 16 of this issue.) The three actions were consolidated for trial. The court ruled against the government, with respect to the civil contempt, because the warrant in question had been vacated and the matter became moot. Accordingly, the petition was denied. (Inj. No. 791; S.J. No. 13)

INJUNCTION ACTIONS


CHARGED 10-22-80 in a complaint for injunction: That the defendants manufactured and sold various hair products, including Hair Medicine Grow Aid, Hair Medicine Grow Aid Shampoo, Roots Protein Hair & Scalp Food, Sulfur X, Tar Grow Aid Conditioner, and Old Fashioned Tar Conditioner Shampoo; that such hair products were drugs because their labeling represented them for the cure, mitigation, treatment and prevention of disease, and for affecting the structure and function of the body of man; that such hair products had been manufactured, processed, packed and held under circumstances that failed to conform with current good manufacturing practice—501(a)(2)(B); that FDA inspections disclosed a number of specified deviations from current good manufacturing practice—501(a)(2)(B); and that the defendants were well aware that their activities were in violation of the law.

DISPOSITION: The defendants had initially been claimants in a seizure action (q.v. S.J. No. 9). That action was concluded with the filing of the complaint for injunction and a consent decree of permanent injunction. The defendants were enjoined from the complained of violations and were enjoined from specified operations involving any drug labeled for or intended for hair or scalp use whose labeling or promotional material made any therapeutic claims unless and until prescribed conditions of current good manufacturing practice were established, a qualified expert certified compliance, and all drugs on hand were destroyed or otherwise brought into compliance. (F.D.C. No. 62083; S. No. 79-143-283 et al.; S.J. No. 14)

DEFENDANTS: Becton, Dickinson & Co. (t/a Bard-Parker Division), and Wesley J. Howe, president, William L. Clark, division vice president and general manager, James A. Levy, vice president for manufacturing, and Kenneth J. Summa, plant manager, Hancock, N. Dist. N.Y.; Civil Nos. 77 CV-337 and (on appeal) 78-6137.

CHARGED 9-2-77 in a complaint for injunction: That the defendants, at the Hancock, N.Y., plant, manufactured, processed, packed, held and distributed in interstate commerce various devices; that a number of such devices were restricted devices because of their potentiality for harmful effect, the method of their use, and/or the collateral measures necessary for their use (i.e., devices restricted to sale, distribution and/or use only upon the written or oral authorization of a practitioner licensed by law to administer or use such devices or measures necessary for their use); that, during a plant inspection, permission to inspect a number of production and control records had been denied; that the defendants’ refusal to permit inspection of records, files and papers bearing on whether restricted devices were in violation was also a violation of the law; that, subsequently, the court had issued a warrant for inspection that authorized inspection and copying of all records bearing on whether restricted devices manufactured, processed, packed, transported or held by the
defendants were in violation of the law; that, after service of the warrant for inspection, FDA investigators were denied access to some records and were refused permission to copy records and to take photographs; and that the defendants were aware that their activities were in violation of the law—301(f).

In addition to the above injunction action, the government initiated a civil contempt action for the continued refusal to inspect, and the defendant corporation brought a declaratory judgment action against the government (see S.J. Nos. 13 and 16 of this issue of FDA Consumer. DISPOSITION: The court dismissed the government's complaint and granted summary judgment to the corporation and its co-parties. In the court's opinion of April 11, 1978, the court described the three companion cases as having arisen from the following simple undisputed circumstances: a routine FDA inspection of the defendants' plant; FDA's request for the production of records under section 704(a), upon FDA's assertion that the plant manufactured restricted medical devices; the denial of FDA's request; the subsequent issuance of an inspection warrant; and the ultimate refusal of access to Bard-Parker records and files.

In the 1976 Medical Device Amendments, Congress had given FDA expanded inspectional authority over records regarding restricted medical devices, and had required FDA to promulgate regulations to classify appropriate medical devices as "restricted" devices. FDA asserted that its existing regulation which defined prescription devices met the requirements of the new law concerning restricted devices. Although the court could not condone the action of the defendants in refusing to abide by a lawfully issued warrant (the warrant's ultimate invalidity being no defense), and although the resistance to the warrant could have subjected the defendants to criminal contempt, the civil contempt was mooted; the warrant was vacated; and the government's complaint for injunction was dismissed—because Congress intended FDA to promulgate new regulations for restricted devices.

The government appealed the decision of the district court as to the injunction action. Upon appeal, the government argued that FDA had published a Federal Register notice one week after the Medical Device Amendments became law, which notice informed the industry that "restricted devices include all prescription devices."

However, on Dec. 27, 1978, the court of appeals found that such notice was not adequate for two reasons: 1) Congress had provided for a rulemaking procedure in which all participants were to have a full opportunity to present their views and analyses of data; and 2) Congress had intended that FDA determine that the particular restrictions on sale, distribution or use were justified by the risks presented by the device. Although broad, categorized regulations could be developed for restricted devices, the rulemaking proceedings leading to the earlier prescription device regulation addressed different circumstances; and a new regulation was required. The opinion of the district court was accordingly affirmed. (Inj. No. 791; Misc. No. 435; S.J. No. 15)

**MISCELLANEOUS ACTIONS**

SUBJECT: Establishment inspection authority of FDA concerning "restricted devices," and the designation of restricted devices, N. Dist. N.Y.; Civil Nos. 77 CV-181 and (on appeal) 78-6109.

CHARGED 5-17-77 by Becton, Dickinson & Co., Hancock, N.Y., against the Food and Drug Administration, FDA Commissioner Donald Kennedy, and FDA investigators William C. Lubas and Richard N. James, in a suit for declaratory judgment, injunction and vacation of an inspection warrant: That the Bard-Parker division of Becton, Dickinson & Co., Hancock, N.Y., manufactured medical devices such as surgical blades, scalpels, suction products and tubing; that, although FDA had not promulgated final regulations implementing medical device establishment registration, the corporation completed and filed a medical device establishment inspection form; that Section 520(e) of the Medical Device Amendments required that the conditions affecting the sale, distribution or use of "restricted devices" be prescribed by administrative regulation; that a June 4, 1976, FDA notice restated certain statutory duties (stated to be imposed directly by the Medical Device Amendments and to be not dependent on the issuance of regulations) including a notice defining restricted devices as defined in 21 C.F.R. 801.109 (i.e., prescription devices); that, because FDA had failed to comply with Section 520(d) of the Food, Drug, and Cosmetic Act and with Section 4 of the Administrative Procedures Act, FDA had failed to adopt a valid and lawful regulation restricting the sale, distribution or use of any device—its notice of June 1976 notwithstanding; that plaintiff demanded judgment determining medical device establishment registration, the corporation completed and filed a medical device establishment inspection form; that Section 520(e) of the FDC Act and Section 4 of the APA; that FDA be enjoined from such inspection until such regulation had been promulgated; and that the Warrant for Inspection, which had been issued by the court, be vacated.

DISPOSITION: The government moved to dismiss the plaintiff's complaint. Subsequently, the government moved for an injunction against the corporation and for civil contempt (see S.J. Nos. 13 and 15 of this issue of FDA Consumer). This action (together with the companion cases arising out of a central set of facts) was heard by the court, which decided for the plaintiff; and that decision was sustained by the court of appeals. (Misc. No. 435; S.J. No. 16)
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