

FDA CONSUMER

June 1979

Pregnancy Test Kits:
No Sure Thing
But Sometimes Helpful





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FDA CONSUMER, the official magazine of the Food and Drug Administration, is published monthly, except for combined July-August and December-January issues. Subscriptions may be ordered from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402, at \$12.00 a year (\$15.00 foreign mailing).

Address for editorial matters: **FDA CONSUMER**, HFI-20, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

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

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

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

Application to mail at second-class rates is pending at Rates & Classification Department, U.S. Postal Service, Washington, D.C. 20260.

Cover Photo: Norman E. Watkins, Jr.

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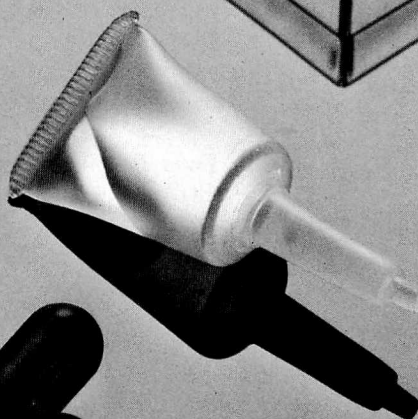
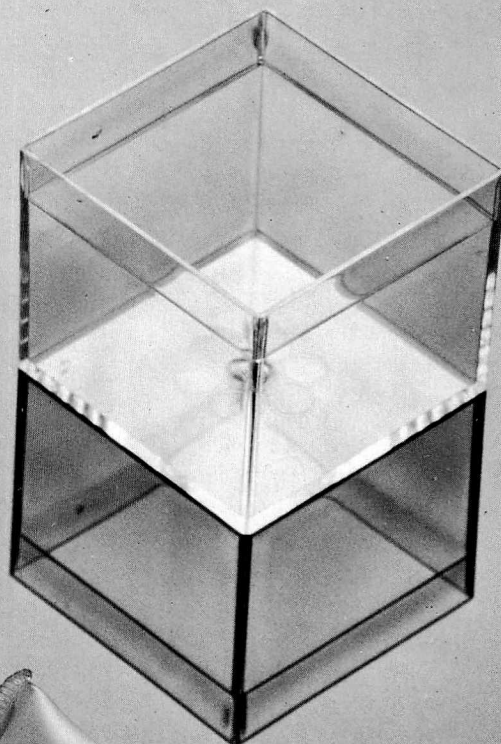
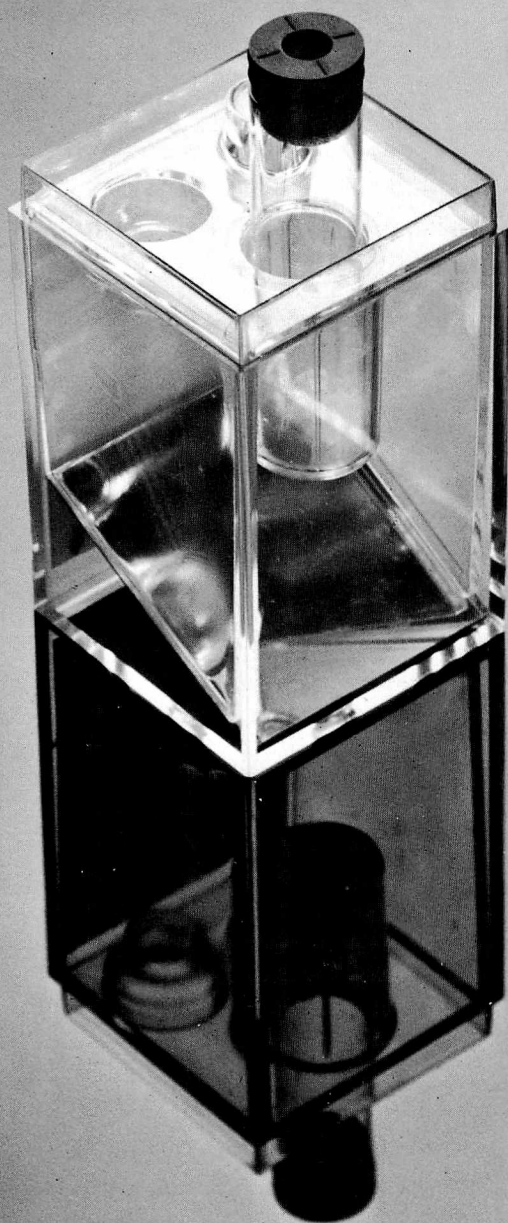
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Inside Front Cover: *Drinking and driving don't mix and neither does drinking and taking medication. Not only can alcohol increase the sedative effects of many drugs, but it can change the way drugs are metabolized by the liver, making them less effective or increasing their potential for toxicity. What happens when you put drink and drugs together is the subject of Liquor May Be Quicker But . . . , beginning on page 8.*



Pregnancy Test Kits: No Sure Thing But Sometimes Helpful

To be or not to be pregnant is the question women through the ages have asked of the mirror, such odd sources as watermelons, and finally science. Now they are offered an over-the-counter, do-it-yourself pregnancy test kit (PTK) for use at home. FDA, after reviewing data from several makers, finds the various PTK brands are reasonably accurate for preliminary personal checkups if special care is used in testing and a number of variables are taken into account.

by Jacqueline Maio

Possibly the first recorded test for pregnancy dates back to 1350 B.C. According to an Egyptian papyrus, "A watermelon pounded is mixed with the milk of a woman who has borne a son, and is given to the patient to drink; if she vomits, she is pregnant."

Hippocrates suggested in 400 B.C. that a woman be given honey and water before she goes to sleep. If her stomach swells during the night, she is pregnant.

By the 13th and 14th centuries physicians believed a woman's urine that "floated milk" or "covered an iron needle with black spots" indicated pregnancy.

It was not until 1926 that the first laboratory test to determine pregnancy was developed. That test was followed in the 1930's and 40's with the use of frogs, rats, and rabbits. The animals were inoculated with urine of the woman undergoing the test. Forty-eight hours later they were killed and their ovaries were examined. An excessive amount of blood in the vessels of the ovaries affirmed a pregnancy.

Because of the high cost of laboratory animals, advancing scientific capabilities, and the desire of physicians and their patients to diagnose pregnancy more quickly, scientists developed a test in the 1960's using animal antiserum and hormones and their interaction with a woman's urine to determine pregnancy. These tests have been relied on by physicians for the past 2 decades.

Then, in 1978, women began reading in their favorite magazines that they could use this same test at home.

Though the first over-the-counter (OTC) pregnancy test kit (PTK) was available in 1976, it was not until early 1978 that extensive promotional campaigns began appealing to women to diagnose themselves "... in the privacy of your own home ... in just a few hours ... without waiting for a doctor's appointment."

The at-home PTK's have generated hundreds of letters and phone calls to FDA. Women want to know if the PTK's are FDA approved, how they work, and if they are reliable and safe.

The OTC PTK's have never been directly approved by FDA. However, they are on the market because they predated the 1976 Medical Device Amendments of the Food, Drug, and Cosmetic Act. A section of that law also allows marketing of new products judged by FDA to be "substantially equivalent" to preamendment products to enter the market. Substantially equivalent, in this particular case, means that similar ingredients and techniques are used in each product to obtain like results.

The first at-home PTK ("E.P.T." manufactured by Warner-Chilcott) was a preamendment product. In 1978 five additional products were introduced, based on substantial equivalence. Each product—"Answer," by Diagnostic Testing; "Pregna-B" and "R-U," by North American Biologicals; "Predic-

tor," by Organon; and "Acu-Test," by J. B. Williams—uses the same procedure as "E.P.T." to diagnose pregnancy.

A pregnant woman's urine contains a special hormone, HCG (human chorionic gonadotropin). When a sample of urine is exposed to rabbit anti-HCG serum, the HCG in the urine will combine with the antiserum and form a bond. Sheep cells coated with HCG (the antigen) are then added to this solution. If the HCG has bonded with the antiserum, the antigen can find no free cells with which to form a bond, so the antigen (sheep red blood cells) settles in the solution and forms a ring on the bottom of the container. This ring indicates a positive test result, or pregnancy.

Conversely, if there is no HCG pres-

ent in the urine, the antiserum will not find HCG with which to bond. When the antigen is added, it will form clumps in the solution creating a smooth, milky fluid with no ring, indicating no pregnancy.

Though FDA did not review safety data prior to the marketing of the OTC PTK's, the Agency has reviewed effectiveness data from all manufacturers. This information was requested as part of the overall effort by FDA to verify the labeling claims of each OTC PTK.

In addition, a panel of non-Government experts has recommended that all PTK's—professional and OTC—be classified as Class II devices which means performance standards (outlining accuracy levels, manufacturing guidelines, patient information, etc.)

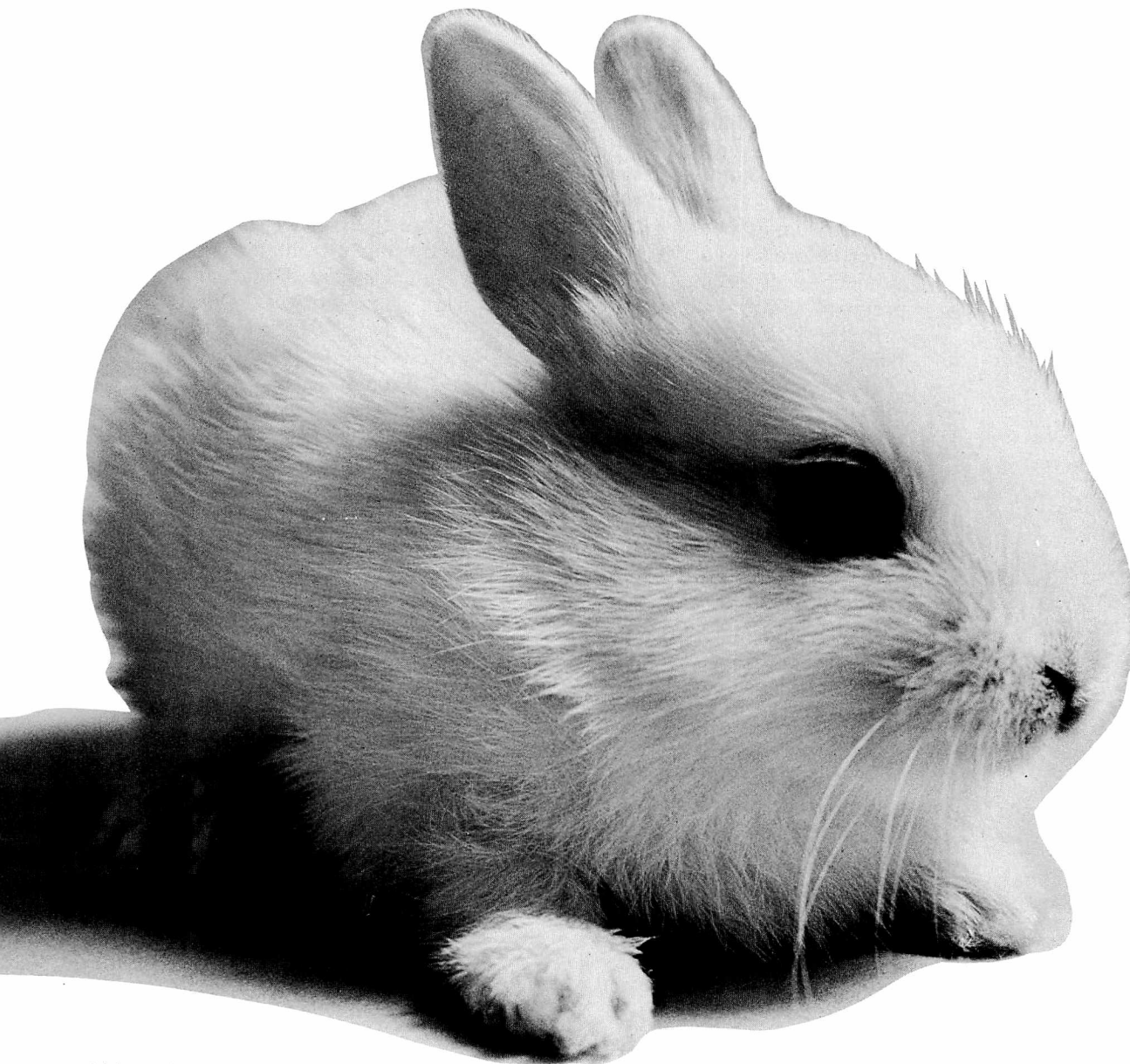
will be required for all PTK products—both pre- and post-amendment.

After reviewing limited clinical data submitted by each firm, FDA has determined that the reliability claims of 95%-98% accuracy made by the manufacturers for the products seem to be valid.

There are several points, however, which users should keep in mind about OTC PTK accuracy.

- Though products stress "early" diagnosis (i.e., 7-9 days after a missed period), product accuracy claims are actually based on tests run 15 or so days after a missed period.

- Results of this type of test can be easily, though inadvertently misinterpreted or botched, even when instructions are quite specific about the materials to be used, room tempera-





ture, and timing of the test. If there is a slight residue of detergent or dirt in the container used to hold the urine, the test may give an inconclusive and possibly faulty reading. The slightest movement (children running through the room, an accidentally jostled or shaken container, vibration from a refrigerator or air conditioning unit) can change a reading. Placing a container in direct sunlight or reading a test too early or too late may also alter results. Women should keep in mind that, when used by professionals, these tests are conducted with sterile utensils in laboratories with controlled equipment and conditions.

- A woman should inspect her urine before beginning the test. Normal urine should be clear, free from particles, and be of a "straw-like" color. If a sample is lumpy, cloudy, or appears to contain blood, test results may be inaccurate. More important, these conditions may indicate other medical problems which require a doctor's attention and may go undiagnosed or untreated.

False positives (incorrectly indicating pregnancy) and false negatives (inaccurately indicating no pregnancy) can present some special medical risks to certain women. For example:

- Women who have had a recent difficult pregnancy may receive a "false positive." This reading may be indic-

ative of something abnormal, but not a pregnancy. The abnormal condition may be the beginning of uterine cancer (a not too uncommon problem in women who have had difficulties with pregnancies). The woman may be elated about the pregnancy and, relying on the results of the test, may wait a month or more before seeing her doctor. During that period of time, the uterine cancer (one of the fastest spreading) may go beyond the early, easily treatable stages.

- Physicians should always be made aware of pregnancy. Women who have received a "false negative" may neglect to mention a possible pregnancy and may receive medical treatment that could endanger the fetus. For example, exposure to radiation from x rays or an inoculation for rubella (measles) or certain drugs may damage a fetus unnecessarily.

- A "false negative" may also result if an ectopic (outside the uterus) pregnancy has developed. The HCG level is generally very low in the early weeks of an ectopic pregnancy and could easily go undetected by a PTK. There is a high risk for any woman with an ectopic pregnancy. Therefore, early diagnosis and close medical supervision is extremely important in all such pregnancies.

While an at-home pregnancy test can give an accurate diagnosis, con-

sultation with a doctor is essential to assure proper medical care. A doctor will order a second, laboratory controlled test. Labs run both a "control" test and a "comparison" test to double check results. Laboratories may routinely run additional tests on the sample to identify other potential problems namely pH, proteins, glucose, ketones, bilirubin, blood, and nitrite contents. Questionable results are always followed by a repeat test.

The PTK was one of the leading "new" products in the OTC drug product line last year, resulting in sales of an estimated \$15 million. As prices for the kits decline and volume of advertising increases, sales will surely climb and other kits are likely to appear on drugstore shelves.

Women choosing to use an OTC PTK should keep in mind that the at-home test is only a method of making a preliminary diagnosis; that instructions must be strictly followed; and that false readings may create or disguise other medical problems.

In all circumstances, a positive reading should be followed by an immediate visit to a doctor. A woman should also consult her physician if symptoms of pregnancy continue after a negative reading.

Jacqueline Maio is a member of FDA's Public Affairs staff.

Rub-A-Dub-Dub,

As far back as 1494, Columbus' physician knew that capsicum, a derivative of red pepper, helped relieve muscle aches and pains when it was rubbed on the skin. Still used in liniments and "rubs," capsicum is one of 32 ingredients considered safe and effective as topical painkillers by a panel of non-Government experts.

“**M**ustard, tabasco pepper, jasmine, peppermint, wintergreen . . .” It could be a gourmet cook’s shopping list, but it isn’t. These ingredients with their widely varying taste sensations are, in fact, the sources of a number of drugs a panel of non-Government experts says can be used safely to relieve minor muscle aches and pains and the pain and itching that comes from minor burns, sunburn, and insect bites.

The panel was one of 17 appointed by FDA to evaluate the ingredients in the more than 300,000 drug products available to the consuming public without a prescription. This panel’s task was to determine the safety and effectiveness of a class of drugs called topical analgesics—painkillers that are applied directly to the skin. Because of the wide range of products included in this classification the panel divided its review into four major areas: external analgesics, skin protectants, topical otics (ear medicines), and sunscreens. Reports of the panel’s recommendations on protectants, otics, and sunscreens already have been published.

In its fourth and final report, to be published in the *FEDERAL REGISTER*, the panel reviewed 44 ingredients and found 32 safe and effective as painkillers when applied to the skin. Some of these ingredients have been around for centuries. Allyl isothiocyanate, which comes from mustard, was mentioned as a medicant by Theophrastus, the Greek philosopher and botanist. Capsicum, derived from the dried ripe fruit of a variety of pepper plants, was known to the physician who traveled with Columbus on his second voyage in 1494. Some ingredients studied are of more recent lineage.

The panel grouped these ingredients according to whether they depress or stimulate receptors (nerve endings) in the skin that perceive pain, itching, cold, warmth, touch, and pressure. There are three types of drugs that depress pain receptors: (1) topical analgesics—externally applied substances that partially block pain without causing numbness; (2) topical anesthetics—externally applied substances that completely block pain receptions resulting in a sensation of numbness; and (3) topical antipruritics—externally applied substances that relieve itching.

Substances that stimulate pain receptors produce sensations such as burning, warmth, or coolness which distract from deep-seated pain in muscles, joints, and tendons. These substances are called topical counter-irritants.

The panel said the following topical analgesics, anesthetics, and antipruritics are safe and effective:

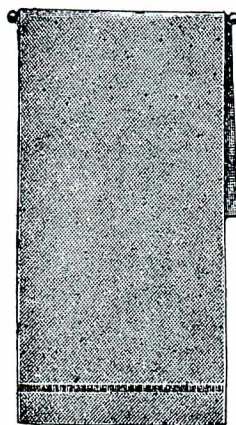
- Benzocaine, dibucaine, dibucaine hydrochloride, dimethisoquin hydrochloride, dyclonine hydrochloride, lidocaine, lidocaine hydrochloride, pramoxine hydrochloride, tetracaine, and tetracaine hydrochloride.

- Benzyl alcohol, butamben picrate, camphor, juniper tar, menthol, phenol, resorcinol, and sodium phenoxide.

- Diphenhydramine hydrochloride, methapyrilene hydrochloride, and tripeleminamine hydrochloride.

In addition, the panel recommended that hydrocortisone preparations, namely hydrocortisone and hydrocortisone acetate, be allowed for over-the-counter use as topical antipruritics only. Hydrocortisone is a naturally occurring hormone produced by the adrenal cortex. Preparations of synthetic hydrocortisone have been marketed as prescription drugs since 1952 to treat skin conditions.

Attempts in 1956 to change hydrocortisone preparations from prescription to over-the-counter status were denied by FDA on the basis that the manufacturer failed to show the drug was safe for self medication and that there was a need for more testing to determine whether the drug was absorbed through the skin.



There Can Be Relief In A Tub(e)

The panel recommended that hydrocortisone preparations for OTC use be marketed as single ingredients in the lowest dosage range. Approved labeling should read: "for temporary relief of minor skin irritations and itching due to eczema; dermatitis, including itchy genital and anal areas; and allergic rashes, such as poison ivy, poison oak, poison sumac, or due to soaps, detergents, cosmetics, and jewelry."

The following counterirritants were declared safe and effective by the panel:

- Allyl isothiocyanate, ammonia water, methyl salicylate, and turpentine oil.
- Histamine dihydrochloride, methyl nicotinate.
- Camphor and menthol.
- Capsaicin, capsicum, and capsi-oleoresin.

Among the counterirritant ingredients methyl salicylate is the most widely used. Not only is it the principal ingredient in a large number of OTC products, but it is the most often used ingredient in "locker room" athletic rubs.

Of the 44 ingredients reviewed one, chloral hydrate, lacked evidence of effectiveness, and therefore should not be marketed as a topical analgesic or counterirritant, according to the panel report. There was insufficient evidence to permit final classification of 11 other ingredients at this time. The panel recommended that manufacturers be given a 2-year pe-

riod in which to conduct further tests of effectiveness, after which the ingredients would be reclassified or taken off the market. Included in this group were aspirin, camphorated metacresol, chlorobutanol, cyclomethycaine sulfate, eugenol, glycol salicylate, hexylresorcinol, salicylamide, thymol, and triethanolamine salicylate marketed as topical analgesics, anesthetics, or antipruritics. Further tests also would be required to establish the effectiveness of eucalyptus oil as a counterirritant.

Labeling for topical analgesic, anesthetic, and antipruritic products, excluding hydrocortisone preparations, should read "for the temporary relief of pain and itching due to minor burns, sunburn, minor cuts, abrasions, insect bites, and minor skin irritations," according to the panel. In addition, there should be warning statements alerting users to the fact that these products are for external use only, that contact with the eyes should be avoided, and that use should be discontinued if the condition being treated gets worse or persists more than 7 days. These products should not be used on children under the age of 2.

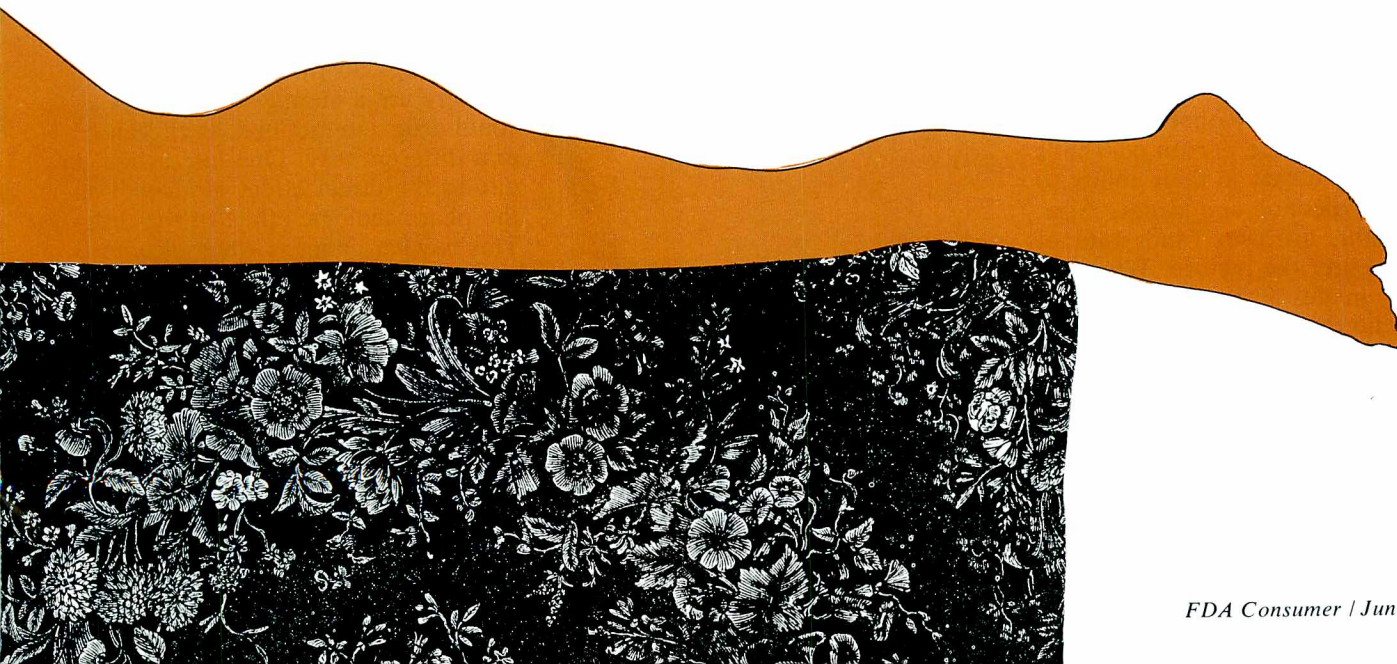
Counterirritant products can claim on the label to be "for temporary relief of minor aches and pains of muscles and joints, such as simple backache, lumbago, arthritis, neuralgia, strains, bruises, and sprains." Warnings called for by the panel include "do not apply to wounds or

damaged skin" and "do not bandage." Counterirritants, with the exception of turpentine oil, are not to be used on children under the age of 12 years.

Everything in the product, including inactive ingredients, should be listed on the label, the panel said. Labels for both types of products would be prohibited from carrying claims relating to product performance, such as "fast cooling pain relief," "rubs out pain fast," or "stops pain," according to the panel. However, product characteristics, such as "soothing or cooling relief," "does not burn," or "penetrating cooling action," are acceptable.

Further research would be required if manufacturers wish to continue to claim that their product "penetrates deep into the skin and relieves pain arising from deep down inside" or provides "penetrating heat relief."

The report of the external analgesics panel is the fourteenth to be issued in FDA's overall review of over-the-counter drugs. The panel's findings are a recommendation and are not binding on FDA, but are published by the Agency so interested persons can comment on them. After all comments have been evaluated a monograph will be published establishing the ingredients and labeling information that will be approved for this class of drug products.



Liquor May Be Quicker But...

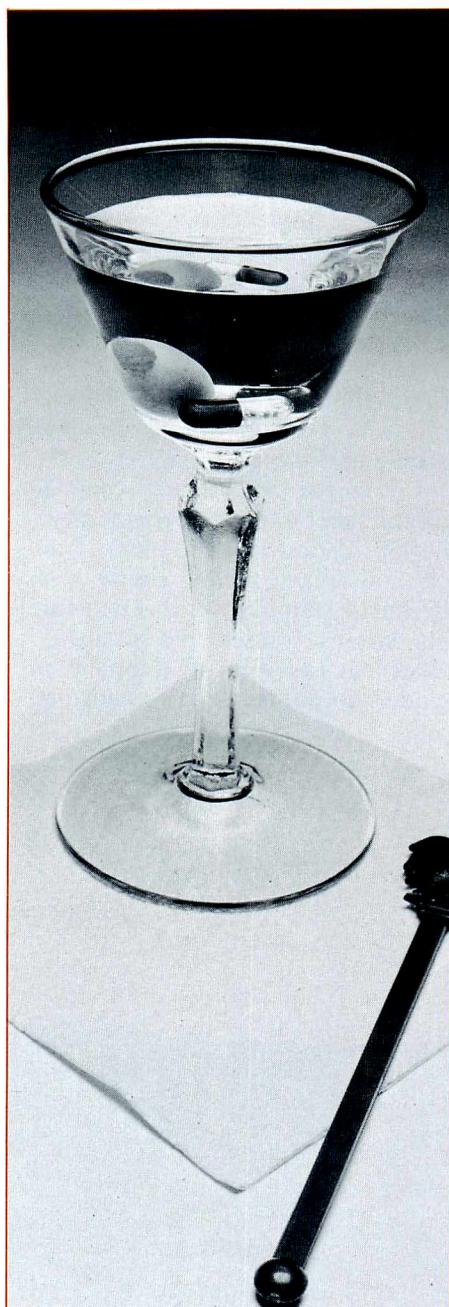
Millions of medicinal drugs and bottles and bottles of alcoholic beverages are consumed annually in the United States. Many people do not realize that some drugs—both prescription and over-the-counter types—can have unpleasant effects when mixed with drink. Alcohol also can interfere with the effectiveness of other drugs. All of which suggests the wisest course is not to drink if you are taking medication.

His wife was a mild diabetic on medication, the man wrote to FDA. One day she had a glass of wine before lunch. "The reaction between alcohol and Orinase was almost immediate," he recounted. "She passed into a condition of shock and almost lost consciousness, becoming violently ill."

This experience was one of many reported in response to FDA's call for comments on the need for patient information. The letters revealed a common complaint: a lot of people don't realize, and apparently aren't told, that some drugs and alcohol just don't mix.

Just how much a person is affected by the mixture of alcohol and drugs depends on who the person is. That's because people vary in their ability to metabolize alcohol and drugs. Size, body weight, age, sex, and state of health all enter the picture. What's in the genes makes a difference as well. People who drink a lot or who take a lot of medicines run a greater risk of encountering alcohol-drug reactions.

Not all drugs have trouble getting along with the contents of that cocktail glass. However, of the 100 most frequently prescribed drug products, over half contain at least one ingredient



known to react adversely with alcohol. Many nonprescription, or over-the-counter, drug products have this same effect.

Alcohol-drug interactions can range from the relatively minor drowsiness that comes with mixing a cocktail with an antihistamine all the way to loss of consciousness and death. Information from the Drug Abuse Warning Network (DAWN) shows that more than 47,000 people who have taken alcohol in combination with other drugs are treated in hospital emergency rooms every year. More than 2,500 deaths annually are attributed to alcohol-drug combinations.

Drink and drugs are at cross purposes primarily because what comes out of the bottle is more than just a little cheer. Alcohol itself is a drug—one of the oldest known to man. Consumed alone, especially in large amounts, it can have a powerful effect on the body. When a person is taking medicinal drugs, even moderate amounts of alcohol can alter the way those drugs do their job.

There are a number of different alcohol-drug interactions, each caused in a different way. One interaction is due to the direct effect of alcohol on the pharmacologic effect of the drug. This is what happens when alcohol is consumed while a person is taking a drug that is a central nervous system (CNS) depressant. Narcotics, barbiturates (Phenobarbital, Luminal), the so-called "minor" tranquilizers (Valium, Librium, Miltown), sedative hypnotics (Doriden, Quaalude, Nembutal), and prescription painkillers (Darvon, Demerol, Talwin) and antihistamines are among the drugs that are CNS de-

“ . . . of the 100 most frequently prescribed drug products, over half contain at least one ingredient known to react adversely with alcohol.”

pressants. They tend to make the user drowsy and to impair the ability to drive and operate machinery.

Alcohol also is a CNS depressant that can cause drowsiness and, depending on the amount imbibed, difficulty in walking, talking, driving, and thinking. Mix alcohol with another CNS-depressant drug and the effect is compounded. Performance skills, judgment, and alertness can be slowed down dangerously. The combined effect of alcohol and overdoses of some CNS depressants—such as barbiturates, Valium, and Darvon—can be fatal. Overdosing may not always be a key factor in such reactions. A report of the National Institute of Alcohol Abuse and Alcoholism cites a study which found that the lethal dose of barbiturates was nearly 50 percent lower when taken with alcohol than when the drug was taken alone.

The “major” tranquilizers, used to treat serious emotional disturbances, may have a CNS-depressant effect. Alcohol in combination with these drugs, which include Thorazine, Mellaril, Prolixin, and Serpasil, can cause additional depression to central nervous system functions which, in turn, can result in severe impairment of voluntary movements, such as walking or using the hands. The combination also can produce severe and possibly fatal depression of the respiratory system. Heavy drinking in combination with the major tranquilizers may increase the potential for liver damage.

Another drug that should not be mixed with alcohol because of the potentiating effect is chloral hydrate (Noctec), a sedating agent. The two together can literally knock a person

out and produce a prolonged sleep (chloral hydrate is the drug used in the legendary “Mickey Finn”). This combination also can cause flushing, rapid heartbeat, and headache, all adverse effects that could be dangerous for a person with cardiovascular disease.

Alcohol does not have to be taken at the same time as a CNS-depressant drug to produce the added depressant effect. According to the National Institute of Alcohol Abuse and Alcoholism, one study has shown that drinking affected people who had taken medium or short acting barbiturates several hours earlier. They tended to fall asleep or have problems with motor skills.

A recent report of the Institute of Medicine of the National Academy of Sciences suggests that metabolites of flurazepam hydrochloride (Dalmane), a sleeping pill, remain in the body for several days. When alcohol is consumed the day after this drug has been taken, driving skills are very much impaired, according to the report.

Although consumers may be wary of drinking when taking a prescription drug, they may not be so cautious when taking milder over-the-counter (OTC) products. Many popular cough and cold remedies contain antihistamines and some also contain alcohol. Antihistamines, which have a tendency to cause drowsiness, also are used to treat allergies and prevent motion sickness. Anyone who plans to treat a cold with a hot toddy and an OTC antihistamine remedy had better head for bed. The two together can increase that drowsiness and make driving or operating machinery difficult, if not hazardous.

Another mechanism through which

alcohol and drugs interact involves the role of the liver in metabolizing both substances. Metabolism is the chemical process by which all ingested substances ultimately are changed in order to be eliminated from the body. Chronic, and even moderate, use of alcohol can stimulate certain metabolizing enzymes in the liver which speeds up the metabolism of some drugs as well as alcohol. This makes many drugs less effective because they do not stay in the system as long as they should to do their job. In such cases, a person may have to take larger doses of the drug. Among drugs that respond in this way are anticonvulsants such as Dilantin, anticoagulants such as Coumadin, and the antidiabetes drug Orinase.

Prolonged alcohol abuse can produce the opposite effect, damaging the liver so that it is less able to metabolize certain drugs. The drugs remain in the body longer than they should, thus increasing the possibility of serious side effects. This hazard is increased when the drug also has a potential for damaging the liver, as is the case with the major tranquilizers of the phenothiazine class (Tindal, Thorazine, Mellaril).

Chronic consumption of alcohol also may lead to a decreased effectiveness of some drugs due to development of a cross-tolerance. Thus, a person who has developed a tolerance to the sedative effects of alcohol may not get the desired effect from normal doses of drugs, such as sleeping pills and the “minor” tranquilizers, when he is not drinking. More and more of the drug is then needed. Unfortunately, the drug’s ability to produce respiratory depression is not affected and over-

“Although consumers may be wary of drinking when taking a prescription drug, they may not be so cautious when taking milder over-the-counter (OTC) products.”

New HEW Program to Combat Alcoholism

Calling alcoholism not only a treatable but a “beatable” disease, Secretary of Health, Education, and Welfare Joseph A. Califano, Jr., has launched a four-part program to deal with the problems of alcoholism. In a speech delivered May 1 to the National Council on Alcoholism, Secretary Califano outlined the new Government initiative to improve research on alcoholism and treatment of problem drinkers, particularly teenagers and women.

One aspect of the new program concerns the dangers of combining alcohol with certain other drugs, especially sedatives and tranquilizers. “This ‘combination abuse’ can kill—and does kill—thousands of people each year,” Secretary Califano said.

To deal with combination abuse, the Secretary called on the Surgeon General of the Public Health Service to issue a special advisory to all physicians in the Nation warning them of the dangers of combination use of alcohol and certain drugs. Physicians are urged to limit the amount of drugs dispensed with each prescription and to monitor prescriptions to patients who may have alcohol problems. In addition, information on the dangers of combining alcohol with specific drugs will be published in FDA’s DRUG BULLETIN, which is sent to physicians and other health professionals.

FDA also was asked to prepare a list of commonly prescribed drugs that may present health hazards when used with alcohol and for which new label warnings may be needed.

Another area of concern is fetal alcohol syndrome, the third leading cause of birth defects. Last year, one in every 2,000 babies born had a physical or mental impairment caused by a mother’s alcohol intake during pregnancy, Secretary Califano said. To insure that people will know that some medicines contain considerable alcohol, FDA has begun proceedings to determine whether warning labels for pregnant women and others should be required on such drugs.

dosing can occur without the person realizing he is close to the fatal dose.

Just as alcohol interferes with the metabolism of drugs, the metabolism of alcohol in turn, can be altered by drugs. This is what happens when drink is mixed with disulfiram, known by its trade name Antabuse.

Heavy drinkers who want to break the habit sometimes are prescribed Antabuse. The drug is not a cure for alcoholism, but it certainly discourages drinking. When a person takes this drug even a small amount of alcohol will bring on flushing, throbbing in the head and neck, respiratory difficulty, vomiting, sweating, and rapid heart-beat. In severe reactions there may be respiratory depression, congestive heart failure, convulsions, and even death.

Usually this reaction lasts about 30 to 60 minutes, although it can persist for several hours in severe cases. The person fighting the “demon rum” with Antabuse already knows what will happen when he takes a drink. However, Antabuse stays in the system for as long as 14 days and during that time virtually any amount of alcohol consumed can set off a reaction. A person on Antabuse should take care to avoid any other products that contain alcohol, including over-the-counter cough and cold remedies, food such as sauces made with wine, and vinegar.

A number of other drugs can cause minor Antabuse-like reactions when they are taken along with alcohol because of interference with alcohol metabolism. People who drink may experience such reactions with certain antimicrobial drugs i.e., chloramphenicol (Chloromycetin), furazolidone (Furoxone), griseofulvin (Fulvicin),

“Chronic consumption of alcohol also may lead to a decreased effectiveness of some drugs due to development of a cross-tolerance.”

metronidazole (Flagyl), and quina-crine (Antabrine). Antidiabetes drugs also may produce such reactions.

Alcohol and drugs may also interact in a number of other ways that do not involve the central nervous system or liver metabolism. For instance, aspirin can cause bleeding in the stomach and intestines in some people. Alcohol also irritates the stomach and can aggravate this bleeding.

The blood-thinning effects of anti-coagulants (Panwarfin, Dicumarol, Sintrom) may be increased when a person taking these drugs also drinks. It is believed that this effect occurs because alcohol interferes with some of the clotting factors in the blood.

Diabetics who depend on insulin to regulate the body's use of sugar may find that drinking increases the activity of the insulin and thus produces an unexpected lowering of blood sugar. Combining alcohol with diuretics, taken to help rid the body of excess water, may cause a reduction in blood pressure, which may result in dizziness when a person stands up.

A class of drugs called monoamine oxidase inhibitors (such as Eutonyl, Nardil, Parnate), used both as anti-depressants and as antihypertensives, present a unique problem. Patients taking these drugs should be warned against drinking alcoholic beverages such as Chianti wines and beer, not so much because of alcohol interactions, but because they contain a substance called tyramine. Also present in some foods, including aged cheese, chocolate, and pickled herring, tyramine can increase the blood pressure to bring on hypertensive crisis.

Contrary to popular belief, some

stimulant drugs that are supposed to counter the effects of alcohol in reality do no such thing. Caffeine, for instance, is at best only a weak antagonist of alcohol's depressant effects and does not improve driving performance in the intoxicated person. Plying someone in such a state with black coffee won't help his coordination and may, on the contrary, give him a false sense of security when he tries to drive.

Knowing when it is safe to have a drink while on medication presents some problems. In general, the information manufacturers provide physicians about prescription drugs, called physician labeling, advises when patients should avoid alcohol. Whether the patient gets the message depends in large part on the information he gets from the physician and pharmacist.

In the near future such warnings will be included in patient package inserts (PPI's), easy-to-read brochures intended to provide information to patients about some of the prescription drugs they take. FDA, at present, is establishing guidelines for the development of PPI's to accompany certain drugs.

Unfortunately, the labels on over-the-counter drugs don't always include warnings about alcohol-drug interactions. However, labels on products containing antihistamines do alert users to potential side effects, such as drowsiness, and this should be a clue that the drug in question will not mix well with alcohol.

To be on the safe side, here are some things the consumer can do to avoid unpleasant alcohol-drug interactions:

- Be honest with your physician when discussing the amount you drink.

Knowledge of present and past drinking habits is important in determining how much of certain drugs you should take.

- Be sure to report any changes in your drinking habits. Some people who are chronic alcohol users, whose drug dosage has been adjusted to the metabolic state of their liver, could upset the balance by giving up drinking without having their drug dosage adjusted accordingly.

- Ask your physician about possible alcohol interactions with the drugs prescribed for you.

- Check your prescription drug container for any warnings the pharmacist has attached.

- Read the labels on over-the-counter drug products. Know what's in the product and what side effects you might experience.

- If you have any questions about either prescription or over-the-counter drugs, check with your pharmacist.

- When in doubt, don't take a drink while on medication.

It was Ogden Nash who penned those immortal lines entitled "Reflections on Ice-Breaking":

"Candy is dandy,
But liquor is quicker."

With hundreds of millions of drugs taken annually in this country, plus bottles and bottles of alcoholic beverages, those lines might be rephrased to remind the users of both:

"When medicine is right,
your ills will take flight;
But together with liquor,
it may make you sicker."

More Than You Ever Thought You Would Know About Food Additives... Part III

by Phyllis Lehmann



"Not the same thing a bit!" said the Hatter. "Why, you might as well say that 'I see what I eat' is the same as 'I eat what I see'!"

—From ALICE IN WONDERLAND

"In sight, it must be right."

—Advertising slogan of a Midwest-based fast food chain

The Mad Hatter lived more than a hundred years ago in the imagination of Lewis Carroll. Yet his seemingly nonsensical remark about eating what one sees and seeing what one eats makes a lot of sense today. That's because today food additives are used to make foods look, taste, and even feel the way we want them to look, taste, and feel.

Some of the additives are put into foods simply to make them more appealing. Others are there to aid in the processing and preparation of the foods. These additions rouse more than a little suspicion among eaters. That's why the fast food chain uses the slogan about preparing its food

out in the open so everyone can see it.

This article, the third in a series on food additives, will take a look at those two groups of additives: substances used to spark the color or taste of foods, and those that make foods behave the way we expect them to even after they've left the manufacturing plant.

Making Food More Appealing

Four classes of additives are used to heighten the appeal of foods: colors, flavors, flavor enhancers, and sweeteners.

Colors

Coloring agents add controversy along with color. They add controversy because they are used solely to improve appearance. They contribute nothing to nutrition, taste, safety, or ease of processing. And some consumer advocates argue that food is often made to look more appetizing at the risk of increasing health hazards.

Today food colors are used in virtually all processed foods. While their use is not restricted, per se, they cannot be used in unnecessary amounts or to cover up unwholesome

products. Artificial colors must be listed as ingredients in all foods except butter, ice cream, and cheese.

There are 35 colors currently permitted for use in food. Nearly half of them are synthetic colors, which are created in laboratories. The man-made colors find the widest use because they are stronger than natural colors and thus can be used by manufacturers in smaller quantities and at less cost.

The first food colors were generally harmless vegetable dyes. In the 19th century days of the Mad Hatter, toxic mineral pigments, such as lead and copper, were used to change the color of foods.

Testing and certification of food colors were first required in the original Food and Drugs Act of 1906. Today food colors are regulated under 1960 legislation that makes the food industry responsible for proving the safety of the additives.

Synthetic food colorings usually refer to the coal-tar dyes, which are laboratory creations that are chemically different from anything found in nature. (They are now derived from petroleum rather than from coal tar.) For identification, the colors are assigned initials, the shade, and a num-

ber. FD&C Red No. 40, for example, indicates that it is a red coloring used in foods, drugs, and cosmetics.

In the past half dozen years, FDA has prohibited four colors from use in foods. A violet used to stamp meats; Red No. 2, which was suspected as a carcinogen; Red No. 4, used in maraschino cherries and shown to cause bladder lesions and damage to adrenal glands in animals; and Carbon Black, used in candies such as licorice and jelly beans.

FDA also proposed to prohibit Orange B, used in sausage and hotdog casings, because of possible contamination with a carcinogen. The manufacturer voluntarily stopped producing it in 1978.

The two most widely used food colors now are Red No. 40 and Yellow No. 5, and both are under fire because of reports of possible health risks. Red No. 40 is suspected of causing premature malignant lymph tumors when fed in large amounts to mice. In 1977, the Health Research Group petitioned FDA to prohibit its use along with several other colors. FDA denied the petition, but tabled a final decision on Red No. 40 pending a study review.

The problem with Yellow No. 5 is that it causes allergic reactions—mainly rashes and sniffles—in an estimated 50,000 to 90,000 Americans. The reactions are usually minor but in some instances can be life threatening. Because of its relatively narrow effect, FDA has proposed a regulation to require manufacturers to list Yellow No. 5 on the labels of any food products containing it.

Flavors

Some 1,700 natural and synthetic substances are used to flavor foods, making flavors the largest single category of food additives. Most of the flavors are synthetic because they are cheaper than the real McCoy and because there probably would not be enough of the real McCoy—strawberries, for example—to produce all the strawberry flavoring desired by diners. Artificial flavorings are usually not derived from a single chemical but are the result of a complex process that involves analyzing the individual chemicals present in a fla-

vor, reproducing those in a laboratory, and synthesizing them to create a taste approximating the real thing.

Flavors are listed on food labels in general terms, such as “artificial flavor” or “spices.” If a product contains any added flavoring, either natural or synthetic, that fact must be noted on the label. For example, a label that says “strawberry yogurt” means that the product contains all natural strawberry flavor. “Strawberry-flavored yogurt” indicates that it contains natural strawberry flavor plus other natural flavorings. “Artificially flavored strawberry yogurt” means that it contains only artificial flavorings or a combination of artificial and natural flavors.

Flavors have come under less criticism than colors, perhaps because they serve a more direct purpose in foods. Still, some consumer groups question the necessity of using artificial flavors. FDA scientists maintain that anyone sensitive to artificial flavors would be likely to react to natural ones as well because of the chemical similarities.

A few flavorings have been prohibited in the past 10 to 15 years because of health hazards. Probably the best known outcast was safrole, the principal flavoring in sassafras root, once widely used in root beer. FDA banned safrole after tests showed it caused liver cancer in rats. Coumarin, used as an anticoagulant drug, was once present in imitation vanilla extract and other flavorings but was banned for food use because large amounts could cause hemorrhaging.

Flavor Enhancers

These compounds magnify or modify the flavor of foods and yet do not contribute any flavor of their own. Some of them work by temporarily deadening certain nerves—those responsible for perception of bitterness, for example—thereby increasing the perception of other tastes.

The best known flavor enhancer is the amino acid, monosodium glutamate (MSG), widely used in restaurants and in prepared foods. Scientists are not sure exactly how it works, but suspect that it increases the nerve impulses responsible for

perception of flavors. Several years ago, public pressure persuaded manufacturers to stop using MSG in baby foods after studies showed that large amounts had destroyed brain cells in young mice.

MSG also produces the so-called “Chinese restaurant syndrome,” which causes some people to have a burning sensation in the neck and forearms, tightness in the chest, and headache after they consume the relatively large amounts of MSG often used in food served in Chinese-style restaurants.

Sweeteners

Though technically flavors, sweeteners are generally considered a separate category. They are among the most commonly known food additives. Who has not heard of saccharin?

Sweeteners are classified as nutritive and non-nutritive. The nutritive ones, metabolized by the body to produce energy, include the natural sugars such as sucrose (common table sugar), glucose, and fructose, as well as sugar alcohols, such as sorbitol and mannitol. Non-nutritive sweeteners, which are not metabolized and therefore contribute no calories to the diet, include cyclamate, which is currently prohibited from use in food, and saccharin.

Natural sugars are widely used in foods, not just as sweeteners but also to create a heavier mouth feel in soft drinks and as browning agents in baked goods. Some consumer groups oppose adding sugar to food because they say it represents “empty” calories devoid of vitamins, minerals, or protein. They also argue that sugar contributes to tooth decay.

The sugar alcohols, chemical variants of natural sugars, have been around for decades but have been promoted in recent years as “low-cal” alternatives to sugar and as less likely to cause tooth decay. Foods containing these sweeteners, are not truly low-calorie. Nor can they be considered completely “free” foods for diabetics, as they can and do lead to the production of some blood sugar. An FDA regulation scheduled to become effective in 1980 will require manufacturers to state on la-

bels that inclusion of these nonsugar sweeteners does not mean the product is "low-cal" or "reduced calorie."

The most widely used sugar alcohol is sorbitol, put in chewing gum, mints, candies, and dietetic ice cream. Though safe, it does have a laxative effect in large amounts. Mannitol, on the other hand, may cause diarrhea in relatively small amounts because it accumulates water during its extremely slow passage through the intestinal tract. This side effect has caused mannitol's use to be limited to the powdery coatings on some chewing gums.

Xylitol, another sugar alcohol promoted several years ago for sugarless gum and dietetic food, fell from favor following several negative health reports and studies. Some manufacturers have voluntarily stopped using it.

The non-nutritive sweeteners—cyclamate and saccharin—have proved to have a taste for controversy. FDA banned cyclamate in 1969 after studies indicated it caused cancer in animals. The manufacturer has sought reinstatement, citing new studies, but so far it remains off the store shelves.

Saccharin was originally on the GRAS (Generally Recognized As Safe) List but was removed in the early 1970's when evidence of health hazards began to mount. In April 1977, FDA proposed to ban saccharin as an additive in food (it's primarily used in diet sodas) following a Canadian government study that showed it caused bladder tumors in rats. The ban would have allowed the continued use of saccharin as a tabletop sweetener if the industry could prove it was beneficial to diabetics or to people on weight-reduction diets.

The public outcry was such you would have thought FDA was trying to take real candy from all the Nation's babies. Congress heard the outcry and passed an 18-month moratorium on the FDA ban proposal. The moratorium ended May 23, 1979, and FDA has announced its intention to repropose the ban—a regulation-making process that could take 15 to 18 more months.

Preparing and Processing Foods

The final category of food additives consists of those used in the preparation and processing of foods. These additives are used by manufacturers to get desired effects during processing and beyond. To the consumer, the additives give the food some of the characteristics that are associated with the products.

The functions of these additives are many. Some cause baked goods to rise. Others prevent ice crystals from forming in ice cream and keep peanut butter from separating into oily and dry layers. Because of such additives, shredded coconut stays fresh and moist in the can.

Of the four major categories of food additives, these are the least clouded by controversy. Consumer groups caution about using some specific compounds, but there is nothing like the furor generated by other additives such as saccharin and nitrites.

There are seven major groups of additives that are considered aids in processing or preparation of foods:

Emulsifiers (Mixers)

Some liquids don't mix unless there is an emulsifier around. In salad dressing, for example, oil and vinegar normally separate as soon as mixing stops. When an emulsifier is added, the ingredients stay mixed longer. In pickles, beverages, and candies, emulsifiers help disperse flavors and oils that otherwise would not be soluble in water. Without these compounds, ice cream and other frozen desserts would separate and lose their creamy texture. In baking, emulsifiers improve the volume and uniformity of breads and rolls as well as make batter and dough easier to handle.

Many emulsifiers come from natural sources. Lecithin, naturally present in milk, keeps fat and water together. Egg yolks, which also contain lecithin, improve the texture of ice cream and mayonnaise. The mono- and diglycerides come from vegetables or animal tallow and make bread soft, improve the stability of margarine, and prevent the oil and peanuts in peanut butter from separating.

Several emulsifiers have elicited

concern about health risks. The Center for Science in the Public Interest, in its poster "Chemical Cuisine," advises consumers to avoid brominated vegetable oil (BVO), used to maintain the characteristic cloudy appearance of citrus-flavored drinks by keeping oils in suspension. The Center warns that residues from the additive accumulate in body fat.

Because of this problem, FDA has removed BVO from the GRAS List and set specific levels at which it may be used.

Stabilizers and Thickeners

These compounds "improve" the appearance of food and the way it feels in the mouth by producing a uniform texture. They work by absorbing water. Without stabilizers and thickeners, ice crystals would form in ice cream and other frozen desserts and particles of chocolate would settle out of chocolate milk.

Stabilizers also are used to prevent evaporation and deterioration of the volatile flavor oils used in cakes, puddings, and gelatin mixes.

Most stabilizers and thickeners are natural carbohydrates. Gelatin—made from animal bones, hooves, and other parts—and pectin—from citrus rind—are used in home and commercial food processing. Extra pectin, for example, is added to thicken jams and jellies.

In the past 30 years, vegetable gums—from trees, seaweed, and other plants—have become widely used as thickeners. These are so effective that 0.1 percent can produce the same degree of thickness in water as a high concentration of starch. One problem is that some, such as tragacanth gum and gum arabic, cause allergic reactions in a few susceptible people. The Center for Science in the Public Interest warns consumers especially about tragacanth gum, which it says has caused some severe allergies. FDA does not believe this problem is any more prevalent than allergies from eggs, chocolate, milk, or other natural foods.

pH Control Agents

These affect the texture, taste, and safety of foods by controlling acidity or alkalinity. Acids, for example,

give a tart taste to such foods as soft drinks, sherbets, and cheese spreads. A more important use is to insure the safety of low-acid canned foods, such as beets. Normally, these low-acid foods have to be cooked longer at higher heat than acidic foods to render them sterile because they are more receptive to the bacteria that cause botulism. By adding acids, manufacturers can eliminate the need for extra heat that might detract from the marketable quality of the food. Natural organic acids, such as citric, fumaric, tartaric, and malic acids, are used in canned foods, although mineral acids, such as hydrochloric, are preferred in some cases.

Alkalizers alter the texture and flavor of many foods, including chocolate. After cocoa beans are picked, they are allowed to dry and ferment before they are made into chocolate. During processing, alkalizers are added to neutralize the acids produced during fermentation and to provide a darker, richer color and milder flavor in the finished product.

Leavening Agents

Although air and steam help create a light texture in bread and cake, carbon dioxide is the key to making baked goods rise properly. Without leavening agents that produce or stimulate production of carbon dioxide, we would not have light, soft baked goods.

The earliest leavening agent was yeast, which produces carbon dioxide through fermentation. Today two other leavening agents are found in home kitchens and commercial bakeries. One, baking soda (sodium bicarbonate), releases carbon dioxide when heated. Usually an acid ingredient, such as sour milk, is used along with baking soda to eliminate the soapy-tasting byproduct of this chemical reaction. The second is baking powder, a combination of sodium bicarbonate and acid salts that react in the presence of water to produce carbon dioxide.

Maturing and Bleaching Agents

Maturing and bleaching agents are used primarily to get flour ready for baking because natural pigments give freshly milled flour a yellowish color.



Flour also lacks the qualities necessary to make a stable, elastic dough. When aged for several months, it gradually whitens and matures to become useful for baking.

In the early 1900's scientists discovered they could hasten bleaching and maturing—and eliminate costly storage—by adding certain chemicals. These agents do not remove anything from the flour and leave little residue. They simply change the yellow pigments to white and develop the gluten characteristics necessary for baking.

Bleaching agents, such as benzoyl peroxide, also are used to whiten milk used for certain cheeses known for their whitish curd, such as blue cheese and gorgonzola. Bleaching is considered necessary because the grass that cows eat causes them to yield buff-colored milk.

Anti-caking Agents

Compounds such as calcium silicate, iron ammonium citrate, and silicon dioxide are used to keep table salt, baking powder, confectioner's sugar, and other powdered food ingredients free flowing. By absorbing moisture, these chemicals prevent caking, lumping, and clustering that

would make powdered or crystalline products inconvenient to use.

Humectants

Humectants are substances that retain moisture in shredded coconut, marshmallows, soft candies, and other confections. One of the most common is glycerine. The sweetener sorbitol also is used for this purpose.

Although these are the major additives used in processing and preparation, there are other additives with specialized uses, such as clarifying agents, which remove small mineral particles that cloud such liquids as vinegar; firming agents that help coagulate certain cheeses and improve the texture of pickles, maraschino cherries, canned peas, tomatoes, potatoes, and apples; foam inhibitors that prevent foam formation on pineapple juice or on other foods during washing, cooking, or processing; and sequestrants that chemically "hold" minerals in soft drinks that might otherwise settle out and cloud the beverage.

Phyllis Lehmann is a freelance writer. Charts for these articles were developed by Sandy Barwick, CAO at Grand Rapids.

Benzoyl peroxide
Hydrogen peroxide

Calcium/potassium bromate

Sodium stearyl fumarate

Breads

Yeast-leavened breads, instant potatoes, processed cereals

quantities.

ADDITIVES: What, Where, Why They Are ...

PURPOSE: To Aid in Processing or Preparation

CLASS: Anti-caking Agents

Some Additives	Where You Might Find Them	Their Functions
Calcium silicate	Table salt, baking powder, other powdered foods	Help keep salts and powders free-flowing; prevent caking, lumping, or clustering of a finely powdered or crystalline substance.
Iron ammonium citrate	Salt	
Silicon dioxide	Table salt, baking powder, other powdered foods	
Yellow prussiate of soda	Salt	

PURPOSE: To Affect Appeal Characteristics

CLASS: Flavor Enhancers

Some Additives	Where You Might Find Them	Their Functions
Disodium guanylate	Canned vegetables	Substances which supplement, magnify, or modify the original taste and/or aroma of a food— <i>without</i> imparting a characteristic taste or aroma of its own.
Disodium inosinate	Canned vegetables	
Hydrolyzed vegetable protein	Processed meats, gravy/sauce mixes, fabricated foods	
MSG (monosodium glutamate)	Oriental foods, soups, foods with animal protein	
Yeast-malt sprout extract	Gravies, sauces	

PURPOSE: To Affect Appeal Characteristics

CLASS: Flavors

Some Additives	Where You Might Find Them	Their Functions
Vanilla (natural)	Baked goods	Make foods taste better; improve natural flavor; restore flavors lost in processing.
Vanillin (synthetic)	Baked goods	
Spices and other natural seasonings and flavorings, e.g., clove, cinnamon, ginger, paprika, turmeric, anise, sage, thyme, basil	No restrictions on usage in foods—found in many products	

PURPOSE: To Affect Appeal Characteristics

CLASS: Natural/Synthetic (N/S) Colors

Some Additives	Where You Might Find Them	Their Functions
N Annatto extract (yellow-red)	No restrictions	Increase consumer appeal and product acceptance by giving a desired, appetizing, or characteristic color. Any material which imparts color when added to a food. Generally <i>not</i> restricted to certain foods or food classes. May <i>not</i> be used to cover up an unwholesome food, <i>or</i> used in excessive amounts. <i>Must</i> be used in accordance with FDA Good Manufacturing Practice Regulations.
N Dehydrated beets/beet powder	No restrictions	
S Ultramarine Blue	Animal feed only .5% by wt.	
N/S Canthaxanthin (orange-red)	Limit = 30 mg/lb of food	
N Caramel (brown)	No restrictions	
N/S Beta-apo-8' carotenal (yellow-red)	Limit = 15 mg/lb of food	
N/S Beta carotene (yellow)	No restrictions	

give a tart taste to such foods as soft drinks, sherbets, and cheese spreads. A more important use is to insure the safety of low-acid canned foods, such as beets. Normally, these low-acid foods have to be cooked longer at higher heat than acidic foods to render them sterile because they are more receptive to the bacteria that cause botulism. By adding acids, manufacturers can eliminate the need for extra heat that might detract from the marketable quality of the food. Natural organic acids, such as citric, fumaric, tartaric, and malic acids, are used in canned foods, although mineral acids, such as hydrochloric, are preferred in some cases.

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ADDITIVES: What, Where, Why They Are ...

PURPOSE: To Aid in Processing or Preparation

CLASS: Emulsifiers

Some Additives

Carrageenan

Lecithin

Mono/diglycerides

Polysorbate 60, 65, 80

Sorbitan monostearate

Diocetyl sodium sulfosuccinate

Where You Might Find Them

Chocolate milk, canned milk drinks, whipped toppings

Margarine, dressings, chocolate, frozen desserts, baked goods

Baked goods, peanut butter, cereals

Gelatin/pudding desserts, dressings, baked goods, nondairy creams, ice cream

Cakes, toppings, chocolate

Cocoa

Their Functions

Help to evenly distribute tiny particles of one liquid into another, e.g., oil and water; modify surface tension of liquid to establish a uniform dispersion or emulsion; improve homogeneity, consistency, stability, texture.

PURPOSE: To Aid in Processing or Preparation

CLASS: Stabilizers, Thickeners, Texturizers

Some Additives

Ammonium alginate

Calcium alginate

Potassium alginate

Sodium alginate

Carrageenan

Cellulose derivatives

Flour

Furcelleran

Modified food starch

Pectin

Propylene glycol

Vegetable gums: guar gum, gum arabic, gum ghatti, karaya gum, locust (carob) bean gum, tragacanth gum, larch gum (arabinogalactan)

Where You Might Find Them

Dessert-type dairy products, confections

Frozen desserts, puddings, syrups, jellies

Breads, ice cream, confections, diet foods

Sauces, gravies, canned foods

Frozen desserts, puddings, syrups

Sauces, soups, pie fillings, canned meals, snack foods

Jams/jellies, fruit products, frozen desserts

Baked goods, frozen desserts, dairy spreads

Chewing gum, sauces, desserts, dressings, syrups, beverages, fabricated foods, cheeses, baked goods

Their Functions

Impart body, improve consistency, texture; stabilize emulsions; affect appearance/mouth feel of the food; many are natural carbohydrates which absorb water in the food.

PURPOSE: To Aid in Processing or Preparation**CLASS: Leavening Agents****Some Additives**

Yeast

Baking powder, double-acting (sodium bicarbonate, sodium aluminum sulfate, calcium phosphate)

Baking soda (sodium bicarbonate)

Where You Might Find Them

Breads, baked goods

Quick breads, cake-type baked goods

Quick breads, cake-type baked goods

Their Functions

Affect cooking results; texture and increased volume; also some flavor effects.

PURPOSE: To Aid in Processing or Preparation**CLASS: pH Control Agents****Some Additives**

Acetic acid/sodium acetate

Adipic acid

Citric acid/sodium citrate

Fumaric acid

Lactic acid

Calcium lactate

Phosphoric acid/phosphates

Tartaric acid/tartrates

Where You Might Find Them

Candies, sauces, dressings, relishes

Beverage/gelatin bases, bottled drinks

Fruit products, candies, beverages, frozen desserts

Dry dessert bases, confections, powdered soft drinks

Cheeses, beverages, frozen desserts

Fruits/vegetables, dry/condensed milk

Fruit products, beverages, ices/sher-bets, soft drinks, oils, baked goods

Confections, some dairy desserts, baked goods, beverages

Their Functions

Control (change/maintain) acidity or alkalinity; can affect texture, taste, wholesomeness.

PURPOSE: To Aid in Processing or Preparation**CLASS: Humectants****Some Additives**

Glycerine

Glycerol monostearate

Propylene glycol

Sorbitol

Where You Might Find Them

Flaked coconut

Marshmallow

Confections, pet foods

Soft candies, gum

Their Functions

Retain moisture.

PURPOSE: To Aid in Processing or Preparation**CLASS: Maturing and Bleaching Agents, Dough Conditioners****Some Additives**

Azodicarbonamide

Acetone peroxide
Benzoyl peroxide
Hydrogen peroxide

Calcium/potassium bromate

Sodium stearyl fumarate

Where You Might Find Them

Cereal flour, breads

Flour, breads & rolls

Breads

Yeast-leavened breads, instant potatoes, processed cereals

Their Functions

Accelerate the aging process (oxidation) to develop the gluten characteristics of flour; improve baking qualities.

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Vanillin (synthetic)	Baked goods	
Spices and other natural seasonings and flavorings, e.g., clove, cinnamon, ginger, paprika, turmeric, anise, sage, thyme, basil	No restrictions on usage in foods—found in many products	

PURPOSE: To Affect Appeal Characteristics**CLASS: Natural/Synthetic (N/S) Colors**

Some Additives	Where You Might Find Them	Their Functions
N Annatto extract (yellow-red)	No restrictions	Increase consumer appeal and product acceptance by giving a desired, appetizing, or characteristic color. Any material which imparts color when added to a food. Generally <i>not</i> restricted to certain foods or food classes. May <i>not</i> be used to cover up an unwholesome food, <i>or</i> used in excessive amounts. <i>Must</i> be used in accordance with FDA Good Manufacturing Practice Regulations.
N Dehydrated beets/beet powder	No restrictions	
S Ultramarine Blue	Animal feed only .5% by wt.	
N/S Canthaxanthin (orange-red)	Limit = 30 mg/lb of food	
N Caramel (brown)	No restrictions	
N/S Beta-apo-8' carotenal (yellow-red)	Limit = 15 mg/lb of food	
N/S Beta carotene (yellow)	No restrictions	

N Cochineal extract/carmine (red)	No restrictions	
N Toasted partially defatted cooked cottonseed flour (brown shades)	No restrictions	
S Ferrous gluconate (turns black)	Ripe olives	
N Grape skin extract (purple-red)	Beverages only	
S Iron oxide (red-brown)	Pet foods only .25% or less by wt.	
N Fruit juice/vegetable juice	No restrictions	
N Dried algae meal (yellow)	Chicken feed only	
N Tagetes (Aztec Marigold)	Chicken feed only	
N Carrot oil (orange)	No restrictions	
N Corn endosperm (red-brown)	Chicken feed only	
N Paprika/paprika oleoresin (red-orange)	No restrictions	
N/S Riboflavin (yellow)	No restrictions	
N Saffron (orange)	No restrictions	
S Titanium dioxide (white)	Limit = 1% by wt.	
N Turmeric/Turmeric oleoresins (yellow)	No restrictions	
S FD&C Blue No. 1	No restrictions	Synthetic color additives subject to certification: inspected and tested for impurities.
S Citrus Red No. 2	Orange skins of mature, green, eating-oranges. Limit = 2 ppm.	
S FD&C Red No. 3	No restrictions	
S FD&C Red No. 40	No restrictions	
S FD&C Yellow No. 5	No restrictions	

PURPOSE: To Affect Appeal Characteristics

CLASS: Sweeteners

Some Additives

Nutritive Sweeteners:
Mannitol—sugar alcohol
Sorbitol—sugar alcohol

Where You Might Find Them

Candies, gum, confections, baked goods

Their Functions

Make the aroma or taste of a food more agreeable or pleasurable.

Dextrose
Fructose
Glucose
Sucrose (table sugar)

Cereals, baked goods, candies, processed foods, processed meats

Corn syrup/corn syrup solids
Invert sugar

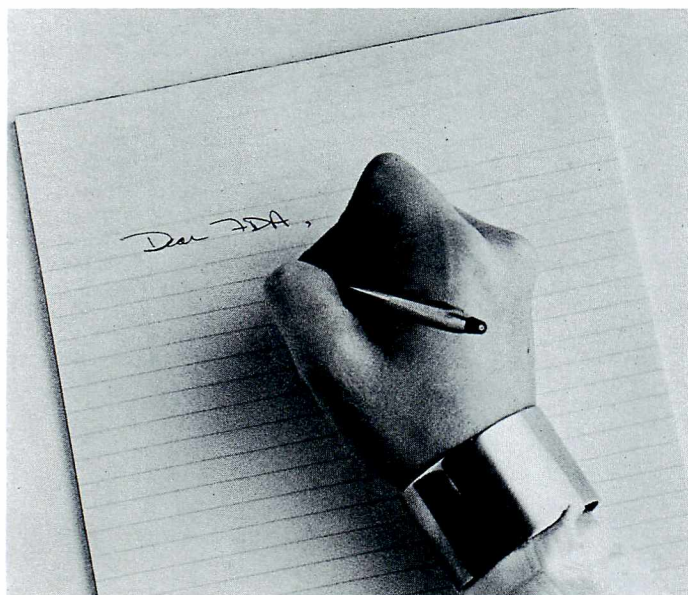
Cereals, baked goods, candies, processed foods, processed meats.

Non-nutritive sweeteners:
Saccharin

Special dietary foods, beverages

Dear FDA: I Want To Know About...

One way of finding out what's on the public's mind is to take a look at what the public gets off its mind by writing letters. FDA gets some 50,000 letters a year from consumers. The following article takes a look at those letters and what they tell about public concerns over foods, drugs, cosmetics, and medical devices.



The handwriting is neat. The letter is direct, not unintelligent. The letter writer is apparently a homemaker and obviously concerned. But let her tell the story:

Food and Drug Administration
Director:

I have become concerned about the ingredients in hot dogs since the program "60 Minutes" stated that they contained earthworms. I feel there must be some truth in that statement since it appeared on such a prestigious program as "60 Minutes." I had previously heard that such things as pig snouts were permitted to be used. Two preservatives or ingredients that I see on the labels are sodium earthobate and sodium ascorbate.

Could you please tell me if earthworms really are permitted in hot dogs, and what are the best brands if indeed there are any? Also could you please send me a listing of ingredients used, and the preservatives and an explanation as to what each particular preservative is supposed to do?

My family and I always enjoyed hot dogs in the past, but we haven't touched one in months.

I would sincerely appreciate any information you could send me concerning this matter.

Yours truly,

(Name Withheld)

For the Food and Drug Administration it was a typical letter.* So typical, in fact, that it was answered with a standard reply that began like this:

Dear Mrs. _____:

This is in reply to your letter concerning sodium erythorbate and earthworms.

The additive sodium erythorbate is not another name for earthworms. This additive is a relative to vitamin C. Sodium erythorbate is synthesized in various ways.

It has been used to provide color in meat products.

Worms are not permitted for use in food sold in interstate commerce. Before worms or products derived from them could be marketed . . .

Earthworms are just one of the many subjects confronted by the people who answer citizens' mail in the Food and Drug Administration. The letters come in at the rate of 50,000 a year and probably show—as well as any yardstick—what is on the minds of the public when it comes to food, drugs, cosmetics, and medical devices.

The woman who wrote about earthworms had a genuine concern. Mistaken as it was, it had preyed on her mind enough to cause her and her family to quit eating frankfurters and to cause her finally to sit down and write a letter to FDA. Writing letters usually tops many people's list of items-that-can-be-put-off-until-tomorrow-or-some-other-day. And yet more than 50,000 people manage to put off something else so they can write that letter today to find out what's in their food, what to expect from drugs, the how of medical devices, who put the earthworms in my hot dogs, and so forth.

The 50,000 letters sent are in a typical year. Just one well publicized event—such as the controversial proposal to ban saccharin—can bring in that many letters in a matter of weeks.

But aside from the major subjects, such as saccharin, what does cause Mr. and Mrs. America to take pen in hand and write to the bureaucracy? Generally leading the list of subjects are nutrition and vitamins. Health in general, food additives, and food labeling and standards are always high on the list. Concern about drugs usually comes in about fifth. Farther down the line but still in the top dozen are cosmetics, radiological health, quackery, and medical devices.

Of course, much of the mail is from students, ranging from third graders to those writing college papers. In the 9 school months, their letters may account for 40 percent of the mail referred to FDA's Consumer Communications Management Section, which handles a majority of the Agency's consumer mail. But even the student vote is in-

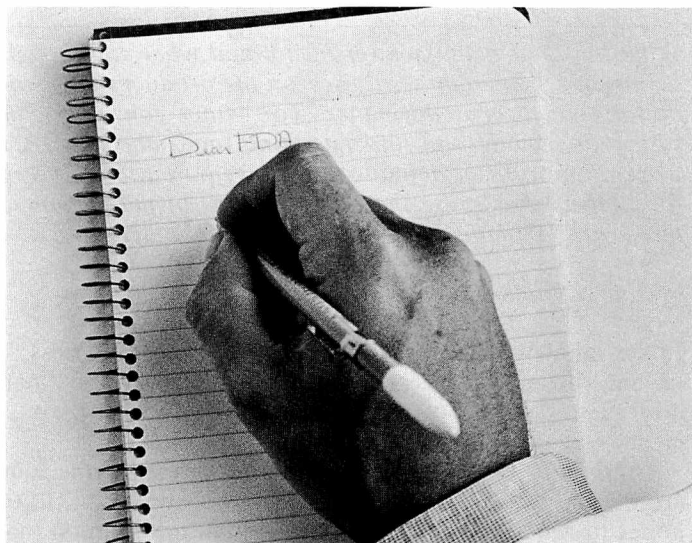
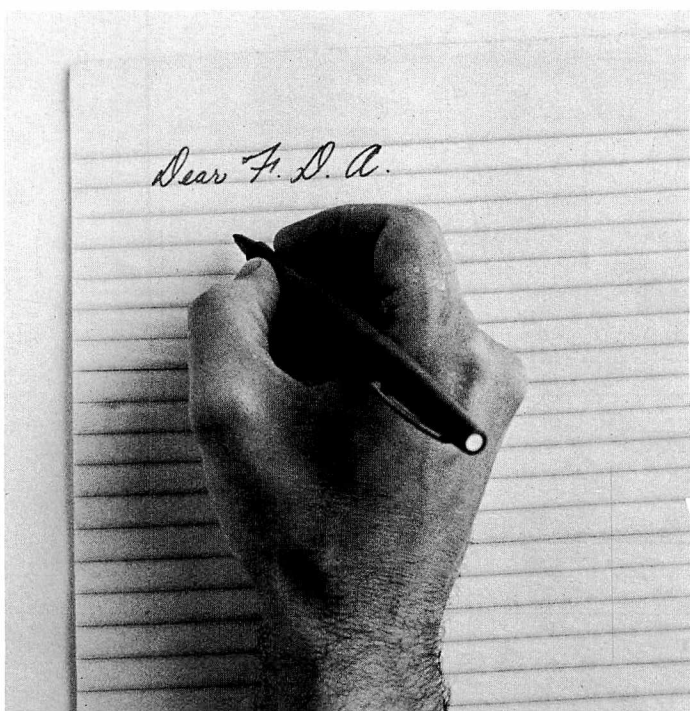
*CBS News told FDA CONSUMER that the letter writer was misinformed. No item was carried on "60 Minutes" concerning earthworms in food.

dicative of public concern, for it often reflects what teachers believe that their charges should learn about.

Most of the food letters to FDA are handled by the Consumer Communications Management Section. The section answers a total of about 40,000 letters a year and another 5,000 queries over the telephone. Letters on the subject of drugs, radiological health, biologics, and medical devices are forwarded to the respective bureaus for answering, unless satisfactory answers are contained in brochures, pamphlets, or reprints of FDA CONSUMER articles—and about half of the mail is handled in that fashion. The bureaus get about half of their mail from consumers and the other half from industry and special interest groups. Another group with mail answering responsibility is the Office of Legislative Affairs, which takes care of all congressional, White House, and Health, Education, and Welfare inquiries.

Aside from answering letters by the use of available publications on the subject, standard replies also fill the bill for a big hunk of the citizen mail. But it's not that the stock reply letter is a "thank you for your opinion" type. Some of the preprepared replies run into several pages, with great detail about the subject in question. Or a publication may provide further information to an explanatory stock letter.

A look at the standard reply letters gives some idea of what's on the consumer's mind. In the area of foods, the list runs all the way from apricot kernels to xylitol, a sugar substitute. Other subjects include: BHA and BHT, animal testing in research, caffeine, food dating, herbs, ice cream, MSG, nitrates and nitrites, "Pop Rocks" and "Space Dust" candy, weight control, plastic containers, red dye No. 40, saccharin, soup, sugar (in three variations), worms, vitamins, and world hunger.



Drug subjects that generate enough mail to require a pre thought-out reply by the Bureau of Drugs letterwriting experts include: Laetrile, Darvon, DMSO, drug prices, patient package inserts, the drug Gerovital, marijuana as a medicine, and pangamic acid.

In radiological health, there is a continuing stream of letters asking about the safety of color television sets, a subject now years old. The TV radiation scare has also found new life with questions coming in about the safety of television games that are played on the sets. Concerns over microwave ovens are widespread enough for more than a dozen different replies to be waiting on hand to inform the consumer.

Of course, thousands of letters require individual responses, and many take hours to research and write.

Response times can vary from a few hours to a few weeks, depending on the priority. The Office of Legislative Affairs tries to turn around congressional mail in 5 days and White House mail in no less than 10.

Internal and outside audits are conducted to see that FDA's responses are prompt, courteous, and accurate. The White House and HEW will even follow up with spot checks of recipients, calling them by telephone to see if they were satisfied with their responses.

The variety of the consumer letters range from thoughtful to poignant, from intelligent to absurd, and from curious to quarrelsome. A letter writer's questions may be pointed or pointless. It makes no difference. The citizen deserves an answer and gets one. Although sometimes framing the answer may not be all that easy. Like the woman who wrote in to complain about food additives. "They cause untold harm and misery," she wrote. "Yet you allow this." The woman cited chemicals used in animal feeds as a particularly bad example of additives. She knew, she said, because: "When I eat beef my neck and shoulders hurt. When I eat chicken I fight with my husband. When I eat eggs that came from chickens that have been fed with chemicals, I feel like ending it all!"

Food Terminology: What It Says Is Not Always What It Is

What the food manufacturer meant and what you thought he meant by a certain term used on the product's label can be far enough apart to matter. To remove consumer confusion in reading and understanding food labels, FDA is working on official definitions to be required for terms on food labels that cause the most trouble. In the meantime, this article explains some currently popular terms.

by Nancy Glick

The labels of chewing gum say that it is “sugarless,” and those on the cereal that it’s made from only “natural” ingredients. You may think you know what these mean. But do you really?

There is no doubt that the terms used to describe food are often confusing. To help reduce this confusion, FDA hopes to require that food labels contain information that consumers want and that they state the facts in a way consumers can understand. Already FDA has issued new regulations with definitions for certain food terms. The regulation stating how vegetable oil and flour must be labeled went into effect July 3, 1978. Regulations govern-

ing the terms "saturated" and "hydrogenated" become effective this July and rules defining "low calorie" and "reduced calorie" foods take effect in 1980.

FDA also is planning more comprehensive action. Together with the Federal Trade Commission and the U.S. Department of Agriculture, the Agency is developing an overall policy for improving food labeling. Following a series of nationwide public hearings in 1978 and a major campaign to obtain consumer opinions on labeling issues, the agencies are now evaluating the more than 9,500 written comments and testimony received. Once the comments are evaluated, the agencies will announce a plan, probably by summer, and propose new regulations and other actions to improve food labels. Consumers and industry will be urged to comment.

All of this is good news for the future. But what about now? Is there any way to make better sense of the food terms used today so that you can feel more confident about what you are buying?

To help you, FDA CONSUMER provides this glossary of most commonly used food terms and their meanings, whether required by regulation or not.



Sugarless/Sugar free: The word sugar by FDA standards is synonymous with sucrose, common table sugar. However, there are other "sugars" such as glucose and fructose. In addition, there are related natural sweeteners called "sugar alcohols"—xylitol, sorbitol, and mannitol—that contain as many calories as sugar and break down in the body in a similar way. Therefore, a food can be labeled sugar free and still be high in sugar-contributed calories. Only if the food is sweetened with an artificial ingredient (the only artificial sweetener currently approved for use is saccharin) will it be lower in calories normally contributed by sugar. Sugar alcohols do not contribute to the development of cavities in the teeth and, therefore, often are used in chewing gum and candy.

No Added Salt/Low Sodium: At present, there are no regulations that define this term. Most commonly, the term implies that no salt—sodium chloride—has been added to the food. It does not mean, however, that other substances that contain sodium are absent. FDA plans to issue regulations as part of its food labeling plan to define this term.

Dietetic: There is no regulation that gives a definition for "dietetic" and FDA discourages the use of this term because of its similarity to the word "diabetic." In fact, there is no consistent meaning for "dietetic" although most people presume it to mean lower in calories. Before buying a food that claims to be "dietetic," read the label to find out to what the term is referring.

Natural: The FTC staff has recommended that final rules be issued governing how manufacturers use the terms "natural," "organic," and "health." It recommends that advertisers be prohibited from using the term "natural" if the food or any of its ingredients has been more than minimally processed (processing involves cutting, grinding, or other procedures which change the form of the food) to make it safe, edible, or to preserve it. A food claimed to be "natural" would also have to be free of any artificial ingredients such as artificial flavorings, color additives, and chemical preservatives.

Organic: The FTC staff has recommended that the term "organic" apply only to those food products grown with organic fertilizers and minerals and without direct application of synthetic fertilizers.

Health Food: The FTC staff has recommended that use of this term be prohibited because it cannot be defined or qualified in any meaningful way.

Food Energy: Under the FTC staff proposals, any advertising containing "food energy" claims would have to define "food energy" as meaning merely that the food provides calories. The FTC staff recommends that advertisements be required to disclose the number of calories in stated servings of the foods. The proposal would prohibit claims about the value of

foods and nutrients alone as sources of energy. (The only way the body gets energy from food is by burning calories.)

Polyunsaturated: This term has proved misleading to consumers concerned about the association between fats and oils and cholesterol. The term refers to a characteristic of fat which many believe is related to the amount of serum cholesterol levels in the blood—large amounts contributing to onset of certain heart diseases. All fats are to some degree both saturated and unsaturated. Many people feel that the more saturated the fat, the more it contributes to cholesterol levels in the blood. For general purposes, vegetable fat is more unsaturated and animal fat is more saturated.

Hydrogenated: Starting this July, manufacturers will be required to use this term, instead of saturated, in labeling fats and oils. "Hydrogenated" and "partially hydrogenated" describe the chemical process of adding hydrogen to an unsaturated fat or oil to make it more solid (for example, to turn an oil into shortening). The more hydrogenated an oil, the less polyunsaturated it is.

Fats and Oils: Since July 3, 1978, this term has had to be accompanied on the label by identification of the specific fats or oils used—for example, "cottonseed oil," "corn oil," "soybean oil," or "beef fat." The manufacturer is permitted to carry a list of fats or oils on the label, any of which may be used in the product.

Flour: The regulation governing ingredient source labeling also applies to flour products, such as crackers and bread. Under the new rule, manufacturers can explain what ingredients are in the flour in one of two ways. First, they can list the term "flour" followed by a statement of its component ingredients in parentheses—for example, "enriched wheat flour (flour, niacin, ferrous sulfate, thiamine hydrochloride, riboflavin, and barley malt)." Labels can also list the flour components as if they were all added separately to the finished food product, such as bread, without listing "enriched wheat flour" in the ingredient statement.

Fortified/enriched/added: These terms refer to the addition of nutrients to foods. They do not mean that all vitamins and minerals are added. The added nutrients must be listed on the label.

Recommended Daily Allowance (RDA): Established by FDA, the U.S. RDA lists nutrients (and the daily amounts of them) which research has shown to be needed for good health. Nutrition labels list the U.S. RDA by percentage. The percentages of each essential nutrient from various foods eaten should add up to about 100 percent each day for each person.

Nancy Glick is a member of FDA's Public Affairs staff.

Most Popular Generic Drugs Listed



The list of generic drugs that can be substituted for the usually more expensive brand name products is long. And not always can a generic substitution be made. As a guide to consumers, the following article tells about the 14 most popular drugs that are usually prescribed generically. Some of their brand name counterparts are also listed.

Physicians write more than six out of seven prescriptions by brand name. In less than one out of seven cases are prescriptions written generically, permitting the pharmacist to dispense a cheaper but therapeutically equivalent product.

FDA believes that the prescribing of generic drugs can offer consumers an opportunity to cut the costs of their health care while assuring that the products they use meet the same FDA standards as brand name drugs for safety, strength, purity, and effectiveness.

Generic drug products are those sold under their established chemical names. Tetracycline, for example, is the generic name for a leading antibiotic. Achromycin and Sumycin are brand names for different manufacturers' tetracycline. Whether you use the generic or the brand name, the quality is the same. But the generic brand may well be cheaper.

To encourage increased prescribing of generics, FDA has published an Approved Drug Products List with more than 2,400 therapeutically equivalent prescription drugs that are sold by more than one manufacturer.

Even though the prescribing of generic drugs has been increasing over recent years, some physicians are reluctant to write prescriptions for anything but brand names. Some may feel more confidence in the products of familiar drug companies. Others may not be aware of the difference in price between a brand name drug and its generic equivalent, or they may not know that a generic version is available.

The following table lists the 14 most often prescribed drugs that are available generically. If you are taking one of these drugs under a brand name, it may save you money to ask your physician to write a generic prescription instead. There may be a sound medical reason that your doctor prefers a brand name. But if not, you should have the opportunity to save on the cost of your prescription while still getting essentially the same product. Remember, this list is of only the most frequently prescribed drugs. Many others also have generic equivalents. So whenever your doctor writes a prescription, ask if the drug is available generically.

Generic Name	Commonly Prescribed Brand Names	Purpose of Drug
Ampicillin	Amcill Omnipen Polycillin Principen	To fight infection (antibiotic)
Tetracycline	Achromycin V Panmycin Sumycin Tetracyn	To fight infection (antibiotic)
Acetaminophen/codeine	Tylenol with Codeine	To relieve pain, fever, and cough
Hydrochlorothiazide	Esidrix HydroDIURIL Oretic	For hypertension and edema (diuretic)
Penicillin V-K	Pen-Vee K V-Cillin K Veetids	To fight infection (antibiotic)
Chlordiazepoxide hydrochloride	Librium	To relieve anxiety and tension
Propoxyphene hydrochloride, aspirin, phenacetin, and caffeine	Darvon Compound-65	To relieve pain (analgesic)
Erythromycin stearate	Erythrocin Stearate	To fight infection (antibiotic)
Amitriptyline hydrochloride	Elavil Endep	To relieve symptoms of depression
Diphenhydramine hydrochloride	Benadryl	Antihistamine (also for motion sickness and parkinsonism)
Diphenoxylate hydrochloride with atropine sulfate	Lomotil	To help control diarrhea
Meclizine hydrochloride	Antivert	To control nausea and vomiting, and dizziness from motion sickness
Chlorothiazide	Diuril	For hypertension and edema (diuretic)
Erythromycin ethyl succinate	E.E.S.	To fight infection (antibiotic)

Regional Reports

Dates And The Guessing Game

No one has figured out exactly what trick of nature brought on a problem with the overseas date crop in fiscal 1977. The complete explanation may never turn up.

But the fact remains that 60 percent of all processing dates offered for import in U.S. ports were rejected that year, considerably higher than the 7.1 percent rejection rate of the previous year. Most rejections were made for insect infestation. The mystery is why the insects were so much busier that year than previous years.

FDA is responsible for examining imported dates intended for use in manufacturing, and the U.S. Department of Agriculture for all domestic dates and those imported dates for sale directly to consumers. From September to early February, the official date season, shipments of dates arrive by ship at several ports, most entering at Los Angeles, New York, and Savannah, Georgia. Samples are collected by FDA inspectors for analysis at District laboratories. The fruits are examined for insect infestation, mold, decomposition, and—if labeled as pitted dates—for pits that shouldn't be present.

The primary foreign supplier of dates is Iran, although many shipments come from Iraq. In fiscal 1977 over 4.5 million pounds of dates were offered from Iran, and about 3 million pounds of these were rejected (almost three-quarters). A little over 200,000 pounds of the 1 million pounds of dates offered for import from Iraq were rejected.

What happened that year with all the companies, such as bakery suppliers, that were relying on Iranian dates for date bread, Christmas pudding, and filled pastry? According to Tom Schwarz, program analyst and



entomologist with FDA's Bureau of Foods, they did several things. They turned to domestic date producers in California. They used eating dates in place of processing dates. And they hiked up prices. Christmas pudding was an expensive item that year.

In the opinion of Lloyd Lehrer, compliance officer in the Los Angeles District, the Iranians simply found a better market. Lehrer said that an Iranian-based inspection service segregates the good from the inferior dates. Prior to fiscal 1977 the Iranian companies that ship to a major importer in Los Angeles had been sending top quality dates. Apparently in 1977 the companies made a better deal with another foreign buyer, sent that buyer

the good dates, and tried to import the remainder to Los Angeles.

FDA headquarters offered several hypotheses for the abnormally high rejection rate. Officials theorized the insect population could have increased because of errors in normal fumigation practices, because of transportation delays leading to extended storage of the products, or because of such adverse environmental conditions as untimely rains.

Program Analyst Schwarz feels it was just a fluke year. Although the figures for fiscal 1978 aren't all in, Schwarz said, it's evident already that the past year's high rejection rate hasn't carried over into 1978, and good dates are again plentiful.

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

REGION I

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

A U.S. marshal seized 9,800 pounds of food at National Warehouse, New Bedford, Massachusetts, after an inspection by FDA's **Boston District** revealed rodent infestation and structural defects in the warehouse. The District made the inspection after finding two lots of rodent-contaminated flour at a food processing company in Boston. The processor had purchased the flour from the warehouse. Over \$1,200 worth of cornmeal, sweet bread mix, flour, and popcorn was seized.

Over \$60,000 worth of contaminated food was seized by a U.S. marshal at Mayco Packaging and Storage Co., Boston, as a result of an inspection by the Boston District. District investigators noticed rodent infestation at the warehouse while collecting samples. A large number of foods stored in soft containers, such as rice, spices, and wheat, were exposed to contamination. The District filed for a mass seizure after investigators returned for a second look and found rodent excreta, urine stains, and hair in and on food containers; live mice and rats among the products; and pigeons perched on bags of food pecking at the contents. Investigators also reported structural defects, such as holes in the walls and broken windows, and poor housekeeping practices.

REGION II

New Jersey, New York, Puerto Rico, Virgin Islands

Cooperation between FDA officials and merchants in New York City's Chinese community resulted in the destruction of large quantities of

medicines containing methyl salicylate. The medicines, imported from China and claimed as being able to cure virtually any ailment, were considered hazardous because the labels directed users to take the products internally. While external use of products containing small concentrations of methyl salicylate is harmless, even one or two teaspoons of the substance can cause death when swallowed. Symptoms of poisoning include vomiting, headache, restlessness, and rapid breathing. In response to an alert from FDA headquarters, the **New York District** sent investigators, including those competent in the Chinese language, to survey the Chinese community. The investigators found stocks of the drugs at 25 retail stores and advised the merchants that the drugs were misbranded and hazardous. The drugs, embargoed by the New York State Board of Pharmacy at the District's request, were destroyed by the merchants, making Federal seizure unnecessary.

Fisher Scientific Co., Orangeburg, New York, recalled over 9,000 disease test kits, which are used in hospitals and medical laboratories to detect systemic lupus erythematosus, a degenerative disease of the connective tissue (such as skin and muscle tissue). The District, which inspected the firm after receiving complaints from hospital personnel that the kit was defective, found that the reagent in some of the kits had become inactivated due to bacterial contamination and was giving false negative readings.

Investigators from FDA's **Newark District** witnessed the destruction of approximately 9,100 pounds of contaminated spices, including paprika and New Mexico cracked chilies. Griffith Laboratories, Inc., Union, New Jersey, destroyed the products, valued at over \$5,000, after a District investigator reported that the spices were contaminated by mold.

Over 33,000 50-milliliter bottles of two types of multivitamin products were recalled and destroyed by G & W Laboratories, Inc., South Plain-

field, New Jersey, because the vitamin C in the products was subpotent. The deficiency was discovered by Newark District investigators during a routine inspection of the firm's laboratory records. The products, "Polyvitamin with Fluoride Drops" and "Triple Vitamin with Fluoride Drops," are sold as a preventive for dental cavities and as a vitamin supplement for infants and children. The products were valued at over \$35,000.

A U.S. marshal seized over 1,000 cases of "Sangria Senorial," a carbonated beverage manufactured by Enlatadora Del Patio, Carolina, Puerto Rico, because the product contained External D&C Red No. 10, an unapproved color additive. Investigators from FDA's **San Juan District** sampled the product at the firm based on District findings that a shipment of the concentrate used in the beverage had been detained at the Port of San Juan because it contained the illegal additive. Although the products at the firm had been manufactured using a previous shipment of the concentrate, analysis of samples of the beverage itself revealed traces of the additive. The seized product was valued at over \$5,000.

REGION III

Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia

The Marriott In-Flite Kitchen at Dulles International Airport, Virginia, near Washington, was classified "approved" by FDA's **Baltimore District** after the company corrected insanitary conditions. The firm, which caters to many major airlines, was placed on a 30-day provisional status after District inspectors found evidence of cockroaches in the scullery and food stored at incorrect temperatures that could permit spoilage. Under provisional status, a caterer may continue operations but must pass reinspection in 30 days or be closed down.

K & P Enterprises, Inc., a railroad and airline caterer in Fairmont

Heights, Maryland, has been prohibited from selling food to interstate carriers because of repeated violations of FDA regulations. The Baltimore District put the firm on "use not approved" status after investigators found rodent excreta in the storage area and food stored at incorrect temperatures that could result in foodborne poisoning. The firm cannot resume service to interstate carriers unless it passes reinspection by FDA; however, such an inspection can be requested only by one of the firm's customers.

REGION IV

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

Carrington Foods, Inc., Mobile, Alabama, destroyed approximately 10,000 pounds of seafood breading and batter mix after investigators from FDA's **Atlanta District** discovered the ingredients were contaminated by insects. The inspection at



the firm, a manufacturer of breaded seafood products, revealed widespread insect infestation of the firm's raw material storage area. The District also initiated seizure of about \$34,000 worth of possibly contaminated raw materials and finished products, including 543 cases of Miss Sally's Brand Stuffed Crab with Fish, 123 cases of Miss Sally's Brand Stuffed Crabs, and 345 bags of breadcrumbs.



REGION V

Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin

Picker Corporation, Cleveland, sent recall letters advising customers to discontinue use of three models of mobile x-ray units that were defective and hazardous. FDA's **Cincinnati District** requested the recall action after a routine inspection of the firm's records revealed eight incidents in which one part of the x-ray unit had either fractured or rolled off its hub and, in several cases, had injured either the patient or operator. The recall letter directed that use of the units be discontinued until safety brackets could be installed on the devices by the firm's technicians. Over 2,000 units, manufactured over a 16-year period, were involved.

REGION VII

Iowa, Kansas, Missouri, Nebraska

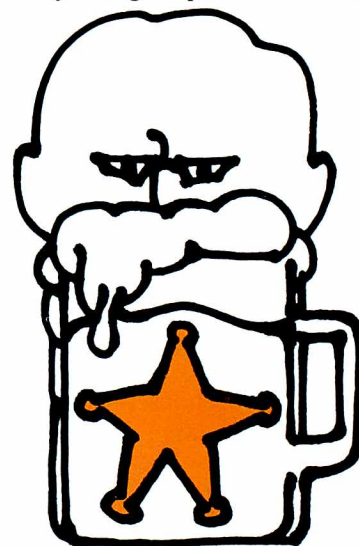
FDA's **Kansas City District** supervised the reconditioning of twenty 50-pound bags of rodent-contaminated cocoa powder by Food Crisis Network, a St. Louis community organization consisting of several dozen area charities. The organization, which maintains a facility equipped to store, freeze, and distribute food donations to its member groups, also possesses the facilities and expertise required for food reconditioning. The cocoa powder, valued at over \$2,500, was seized at Chapman Ice Cream Co., St. Louis, by a U.S. marshal after a District inspection revealed rodent excreta and urine stains on bags of cocoa powder, peanuts, and Fudgsicle mix. The firm destroyed the peanuts and Fudgsicle mix when advised of the contamination by the investigator but failed to take appropriate action with the cocoa, which was eventually seized. When the firm failed to claim the product, the cocoa

became the property of the U.S. District Court for the Eastern District of Missouri and was subsequently donated to Food Crisis Network for reconditioning and distribution to its member charities.

REGION VIII

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

A U.S. marshal seized approximately \$50,000 worth of beer, soft drinks, and water softener salts that were damaged during a fire at Western Wyoming Beverage, Inc., a food storage warehouse in Rock Springs, Wyoming. During the fire, products were exposed to heat up to 1,500 degrees Fahrenheit and toxic fumes from burning insulation materials. Investigators from FDA's **Denver District** inspected the firm at the request of the Wyoming Department of Agri-



culture and found products burned and covered with black, sooty, oily residues. The District initiated the seizure of 10,500 cases of beer, 2,000 cases of soft drinks, and seventy-six 80-pound bags of the water softening material. In addition, Department of Agriculture officials supervised the destruction of approximately 8,000 cases of soft drinks, valued at about \$24,000.

REGION IX

Arizona, California, Guam, Hawaii, Nevada

Under a directive issued by FDA's **Los Angeles District**, three Mexican shippers have been prohibited from

bringing peas into the United States unless certified as free of the pesticide Daconil. Daconil is not registered with the Environmental Protection Agency (EPA) for use on peas. Inspectors from the California Department of Agriculture found residues of the pesticide on samples of peas collected at the wholesale marketplace in Los Angeles. In addition, District inspectors found the pesticide on samples of peas collected during import inspections at Nogales, Arizona, on the Mexican border. After several attempts were made to import peas containing residues of Daconil, the District implemented a "border closing" against these shippers, all from the state of Sinaloa—Benjamin Bustamante of Banoa, Alma de Jesus Robinson Bours of Guasave, and Manuel Rue-las Vazquez of Los Mochis. Under terms of the closing all peas from these shippers must be analyzed and certified by a Mexican government laboratory or a laboratory recognized by FDA. If FDA analysis then confirms that the peas are free of Daconil—as well as from other contaminants—the products will be

released for distribution in the United States.

REGION X

Alaska, Idaho, Oregon, Washington
Société Candy Co., Inc., Bellevue, Washington, destroyed over \$6,000 worth of chocolate peanut clusters because the product had been manufactured under insanitary conditions. An investigator from FDA's **Seattle District** reported seeing live insects in and around the chocolate coating machines. When subsequent laboratory analysis confirmed that samples taken during the inspection contained insects, the firm agreed to destroy approximately 3,000 pounds of the finished product and all chocolate that had been in the machines.

New England Fish Co., Seattle, instituted a program to correct and prevent the recurrence of insanitary conditions after a Seattle District investigator found insects and rodent excreta in the loft area where materials used in the firm's breeding operations were stored. The firm destroyed 11,000 pounds of dried in-

gredients (including tempura batter mix, seafood batter mix, spices, and salt) which may have become contaminated. The firm told FDA officials it would henceforth order materials in smaller and more easily managed quantities, rotate stock more carefully, vacuum the loft area, and correct structural defects that permitted rodents to enter the storage area.

Over \$200,000 worth of seafood was detained by the Seattle District at the Ports of Seattle, Tacoma, and Portland after examination revealed the products were in violation of FDA regulations. Major detentions made because of decomposition included \$75,900 worth of canned shrimp from Thailand, over \$7,000 worth of canned tuna from the Philippines, and over \$30,000 worth of frozen scallops from Hong Kong. Over \$22,000 worth of frozen lobster from Malaysia was held because of *Salmonella* contamination, and officials detained \$21,000 worth of Taiwan canned crabmeat because of a resin-like odor that made the product unfit for human consumption.

State Actions

State Actions reports on important regulatory and administrative actions conducted by State and local government agencies to provide health and economic protection to consumers of foods, drugs, cosmetics, and medical devices.

Dirty Premises Brings Penalty

Master System Bakery, Petersburg, Virginia, was found guilty of allowing food products to be stored under insanitary conditions and was fined \$100 (\$85 suspended for 2 years) by Judge James F. D'Alton, Jr., of the Petersburg General District Court. The Virginia Department of Agriculture and Consumer Services filed four criminal charges against the firm

after inspectors found insects in the building, equipment, and in raw ingredients, including chocolate and sugar. Judge D'Alton found the firm guilty on one charge and suspended the three remaining charges for 1 year. The firm will face additional penalties if it fails to maintain the proper sanitary conditions during this period.

Firm Ordered Closed

Magic Mommy Ltd., a bakery operation in Kingston, New York, was ordered closed by the New York Supreme Court after an inspection by the New York Department of Agriculture and Markets revealed continued insanitary conditions. The firm

has a long history of operating under insanitary conditions, producing adulterated products, and on several occasions preventing State investigators from inspecting the premises.

Bakery Fined for Insects

The Virginia Department of Agriculture and Consumer Services filed criminal charges against Village Foods, Inc., a wholesale bakery in Norfolk, after State inspectors reported finding live and dead cockroaches on the firm's premises, flour beetles in the equipment, and utensils improperly sanitized. The firm pleaded guilty to the charges and was fined \$150 plus court costs in the Norfolk General District Court.

News Highlights

Safeguards for Test Children

Providing safeguards for children who are the subjects of research activities involving drugs, vaccines, medical devices, and other products regulated by FDA is the subject of a regulation proposed by the Agency. The proposal follows recommendations of the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research.

The proposed regulation, which was printed in the *FEDERAL REGISTER* on April 24, requires that all clinical investigations involving children must be approved by Institutional Review Boards, which consists of scientists, lawyers, members of the clergy, laypeople, and others from the geographical area where the research is to be conducted. The boards would review all medical procedures and consider ethical and social implications of the research programs.

Public comments were sought on the proposal through June 22. Of particular concern was the matter of setting the age at which a child is capable of assenting to specific medical research. Suggested options were: setting the age at 12 or 7 or allowing the review board to set the age.

FDA Ready To Act on Reserpine

FDA will give priority attention to a Federal Government study indicating that reserpine, a prescription drug widely used to treat high blood pressure, induces cancer in laboratory test animals.

The Cardio-Renal Drug Advisory Committee of experts will meet on June 21-22 at the Agency's request to discuss this study and other available information on the subject and the Agency has asked these experts to make recommendations for possible regulatory action.

The issue concerns a bioassay conducted by the National Cancer Institute (NCI) Clearinghouse on Environmental Carcinogens. The bioassay found that reserpine induces cancer of the adrenal glands in male rats, of the mammary glands in female mice, and of the seminal vesicles in male mice.

In revealing its plan of action FDA said that because of reserpine's extensive use, the Agency will make a public announcement of whatever decision it makes for regulatory action, if any, and will inform physicians and other health professionals through FDA's *DRUG BULLETIN*. Meanwhile, FDA said it agrees with NCI and the National Heart, Lung, and Blood Institute that patients taking reserpine should not discontinue its use abruptly, but should get in touch with their doctors. Alternative drugs

are available to treat high blood pressure, the Agency said.

FDA will ask the expert advisers, at their June meeting, to consider the results of NCI's bioassay as well as other information about reserpine, including epidemiological studies suggesting a possible increase in breast cancer in women using the drug.

The Agency has been following the NCI bioassay closely and, in anticipation of the study's completion, scheduled the June meeting by the advisory group. Reserpine was approved by FDA in 1954. It is used primarily to treat mild high blood pressure.

Drug Reporting System Changes

FDA is planning to change its adverse drug experience reporting system with a view toward making it more responsive to the Agency's needs and to minimize the reporting burden on the drug industry. The proposed revisions of the reporting requirements, published in the *FEDERAL REGISTER*, would centralize receipt of reports in one office within FDA, extend the reporting period, and limit the types of drug experiences to be reported.

Reports of adverse reactions involving new drugs and antibiotics are required from drug manufacturers and may be submitted voluntarily by physicians, other health professionals, and hospitals. Under the present system, reports are received in various FDA offices which refer them to the Division of Drug Experience for review and evaluation. The proposed revision would require this information to be sent directly to the Division, thus eliminating delays and providing a more efficient method of handling adverse reaction reports.

Existing regulations require that information concerning any "unexpected" side effect, injury, toxicity, or sensitivity reaction be reported to FDA as soon as possible and in any event within 15 working days after a drug company is notified of the event. Reports submitted under this 15-day time requirement are often incomplete and therefore followup reports are required. FDA proposes to extend the deadline to 30 days so that applicants will have time to submit complete information initially. The reports will be fewer as well as more complete. This is expected to improve the overall effectiveness of the reporting system and reduce the number of documents that drug firms must submit and FDA must review.

To eliminate repetitious reports of routine and minor adverse drug experiences already included in the labeling, the proposed revisions would limit the kinds of reactions to be reported to adverse drug experiences. The



reaction reports would be limited to those: (1) not previously recognized as possibly associated with a drug; (2) only recently recognized as possibly associated and not yet determined to be definitely associated with a drug; (3) known to be associated with a drug, but differing in nature, severity, or degree of incidence; and (4) known to be associated with a drug but only if the experience is fatal, life threatening, seriously disabling or debilitating, carcinogenic, teratogenic, or mutagenic.

The proposed revisions in the reporting system are part of an overall plan to reform FDA's adverse drug experience reporting system by centralizing the data collection and dissemination of information within the Agency, improving the effectiveness of the Agency's postmarketing surveillance program, and maintaining a current computer file of significant adverse drug experiences for assessing the risks of a drug throughout its life.

Study Finds No Microwave Harm

No adverse effects from microwave radiation were indicated in a study of 40,000 Navy enlisted men who worked with radar and were exposed to this radiation during their time in the service.

The study, done under a contract let by FDA's Bureau of Radiological Health, covered 20,000 electronic equipment repair personnel for whom potential for exposure was at maximum and 20,000 equipment operators whose potential for exposure was minimal. The men served in the Korean War between 1950 and 1954.

The study showed no unusual patterns of hospitalization for illness during the time of exposure, nor were any effects on long-term mortality rates evidenced.

Exposures were assessed on the basis of occupational duties, length of time on the job, and the power of equipment at the time of exposure. The study looked at later causes of death, hospitalization while in the Navy, later hospitalization in Veterans' Administration facilities, and disability compensation.

The Bureau noted, however, that the study was limited, since the extent of hospitalization outside Government facilities could not be determined. The study also did not cover reproductive performance of the 40,000, the health of their children, or the individuals' employment histories after they left the service.

FDA Helps AMTRAK Upgrading Program

FDA has begun monitoring a new program by AMTRAK—the national rail passenger network—for upgrad-

ing and maintaining good sanitary practices at its food commissaries and watering points and in its dining cars and snack/club cars.

AMTRAK has long had problems meeting FDA standards for interstate travel sanitation in its commissary (food supply) and food service operations, and its dining cars have more than once failed FDA inspections and been returned to the rail yard for cleaning and maintenance.

The new AMTRAK program was developed with FDA assistance and includes the following:

- Upgrading of commissary facilities and equipment (plumbing, ventilation, refrigeration, lighting) in New York City, Oakland, Los Angeles, and Seattle, and construction of new commissaries at AMTRAK locations in Chicago, St. Louis, and New Orleans.

- Improvement of AMTRAK watering point facilities—where the trains take on drinking and other passenger-use water—in New York City, Boston, Albany, Syracuse, and Chicago.

- One day's training for AMTRAK on-board train supervisors in food sanitation and handling and in food equipment use and maintenance, and 2 to 6 days training for cooks, waiters, coach attendants, and commissary workers.

- More frequent and more thorough inspections by AMTRAK sanitation personnel, with assistance from FDA, of commissary operations and on-board (dining car) operations, using a maintenance program for dining cars that will take each car out of service for 2 days each month.

AMTRAK notes that it is acquiring new lounge and dining cars—it has about 116 of the latter—and re-equipping some of its existing cars, which should cut down on problems related to out-of-date equipment. It is also acquiring several new locomotives which will supply head-end electric power throughout the train and eliminate problems related to power failures and fluctuations in on-board equipment such as food refrigerators.

AMTRAK's improvement program for food sanitation began late last year and should be largely completed in 1979. Eighteen FDA district offices throughout the country will conduct audits and inspections of AMTRAK operations in their respective areas, FDA's Baltimore District is acting as coordinator, since AMTRAK's Washington headquarters is in that District's jurisdiction.

The Bureau of Foods' Interstate Travel Sanitation Branch and Compliance Programs Branch have primary responsibility for FDA's AMTRAK operation, and the Office of Regulatory Affairs is responsible for dealing with AMTRAK's senior management.

Seizures

FILED SEIZURE ACTIONS

charge violations of the Federal Food, Drug, and Cosmetic Act and are initiated based upon FDA recommendations. A seizure action is commenced by the filing of a complaint in the U.S. district court where the goods are located. A U.S. marshal is then directed by the court to take possession of the goods, removing the product from commerce, until the matter is resolved.

A total of 24 actions to remove from the consumer market products charged to be violative was reported in April. These actions included 15 of foods: 13 involved charges concerning contamination, and 2 involved charges concerning economic and labeling violations. Others included 7 of drugs (including 1 of veterinary).

PRODUCT, DISTRICT & DATE FILED	FIRM & PLACE OF BUSINESS	CHARGES
FOOD/Contamination, Spoilage, Insanitary Handling		
Breadcrumbs, and frozen stuffed crabs/ U.S. District Court for the Southern District of Alabama 2/16/79	Carrington Foods, Inc./Mobile, Ala.	Stuffed crabs had been prepared under insanitary conditions; breadcrumbs are insect contaminated.
Cocoa beans/U.S. District Court for the Eastern District of Pennsylvania 12/14/ 78	Independent Pier Co./Philadelphia, Pa.	Held under insanitary conditions; bird contaminated.
Cornmeal, and dried peas and beans/U.S. District Court for the District of Puerto Rico 2/9/79	Monllor & Boscio Sucrs., Inc./Ponce, P.R.	Held under insanitary conditions; insect and/or rodent contaminated.
Cornstarch, corn muffin mix, and pop- pyseeds/U.S. District Court for the Northern District of New York 3/1/79	Saratoga Flour & Bakers Supply Co., Inc./Saratoga Springs, N.Y.	Held under insanitary conditions.
Flour, sugar, rice, and other stored foods/ U.S. District Court for the Northern District of Indiana 3/1/79	Quality Foods, Inc./Fort Wayne, Ind.	Held under insanitary conditions; rodent contaminated.
Nonfat dry milk/U.S. District Court for the Middle District of Florida 3/19/79	Jefferies Foods Co., Inc./Jacksonville, Fla.	Held under insanitary conditions.
Pears, canned/U.S. District Court for the District of Delaware 3/8/79	Shipped from Jersey City, N.J.	Contained in abnormal cans (leaking, swollen, dented, and rusty) and most cans are unlabeled (i.e., the labels lack the name and place of business of man- ufacturer, packer, or distributor; lack an accurate quantity of contents statement; and lack prescribed name of food and common names of any optional ingredients).
Rice/U.S. District Court for the District of Puerto Rico 3/16/79	Frigorifico y Almacen Del Turabo, Inc./ Caguas, P.R.	Held under insanitary conditions; rodent contaminated.
Rice, and other stored foods/U.S. District Court for the Northern District of Georgia 2/5/79	Asian Trading Co. Ltd./Atlanta, Ga.	Held under insanitary conditions; some products are rodent contaminated.
Rice, and puffed wheat cereal/U.S. Dis- trict Court for the Western District of Tennessee 1/18/79	Chattanooga Warehouse & Cold Storage Co./Chattanooga, Tenn.	Held under insanitary conditions; rodent gnawed.
Salmon, headed & gutted, frozen/U.S. District Court for the District of Min- nesota 2/2/79	Shipped from Redmond, Wash.	Contains decomposed fish.
Soybeans, sunflower seeds, nuts, and other stored foods/U.S. District Court for the District of Colorado 1/12/79	Colorado Sutler Co./Berthoud, Colo.	Held under insanitary conditions; some articles are ro- dent contaminated.

PRODUCT, DISTRICT & DATE FILED	FIRM & PLACE OF BUSINESS	CHARGES
Sirup, "maple"/U.S. District Court for the District of Utah 1/15/79	Dewey Clark/Philadelphia, Miss.	Another sirup was substituted for maple sirup; article fails the standard of identity for maple sirup.
Sirup, "maple"/U.S. District Court for the Eastern District of Michigan 2/28/79	Nathan Pilgrim/DeKalb, Miss.	"
Walnut pieces, and guar gum/U.S. District Court for the Eastern District of Wisconsin 2/27/79	Taylor Cheese of Wisconsin, Inc./Weyauwega, Wis.	Held under insanitary conditions; walnut pieces are rodent gnawed.
FOOD/Economic and Labeling Violations		
"Honey"/U.S. District Court for the Western District of Kentucky 1/30/79	Anthony's Syrup Co./Philadelphia, Miss.	Sirup substituted for honey; false and misleading claim that article is honey.
"Juices," Juicy Juice Golden 100%/U.S. District Court for the Northern District of New York 3/21/79	Fruitcrest Corp./Garden City Park, N.Y.	False and misleading claim that product is composed of 100% juices. Water and a sweetener substituted for the fruit juice; label lacks common or usual name of ingredients; required information not prominently placed as required; label lacks common or usual name of food, since "Juicy Juice 100% Juices" is not such a name for a blend of sweetened juices from concentrate diluted with water.
DRUGS/Human Use		
Amitriptyline and perphenazine hydrochloride tablets/U.S. District Court for the Western District of Tennessee 3/1/79	M D Pharmaceutical, Inc./Santa Ana, Calif.	New drugs without effective approved New Drug Applications.
Diethylpropion hydrochloride T.D. tablets/U.S. District Court for the Eastern District of New York 12/12/78	Pharmadyne Laboratories, Inc./Hackensack, N.J.	New drug without an effective approved New Drug Application. Labeling is false and misleading.
Diethylpropion hydrochloride tablets and furosemide tablets/U.S. District Court for the Southern District of Florida 12/13/78	"	Circumstances used for products' manufacturing, processing, and packing not in conformity with current good manufacturing practice. Labeling fails to bear an expiration date. New drugs without effective approved New Drug Applications.
Tincture of iodine, spirit of camphor, ipecac syrup, and other drugs and drug components/U.S. District Court for the District of Minnesota 2/20/79	Bennett Pharmaceuticals, Inc./Minneapolis, Minn.	Circumstances used for the products' manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; some U.S.P. & N.F. drugs are not labeled as required by such compendia, since their labels lack expiration dates; the tincture of iodine fails to meet U.S. Pharmacopeia requirements.
Spirolactone with hydrochlorothiazide tablets/U.S. District Court for the Northern District of Illinois 2/22/79	Premo Pharmaceutical Laboratories, Inc./South Hackensack, N.J.	New drug without an effective approved New Drug Application.
Spirolactone with hydrochlorothiazide tablets/U.S. District Court for the Eastern District of Michigan 2/28/79	"	"
DRUGS/Veterinary		
Udder ointment; nitrofurazone powder, solution, & boluses; Gwilate expectorant for large animals & poultry; scour suspension; triple sulfa solution; Uterine boluses with Acriflavine; and vitamin B ₁₂ injection.	Chemvet Laboratories, Inc./Kansas City, Mo.	Vitamin B ₁₂ injection lacked the veterinary prescription legend; some products are new animal drugs and no New Animal Drug Applications are in effect with respect to their uses or intended uses; circumstances used in the production of the Uterine boluses failed to conform with current good manufacturing practice.

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Cottonseed, at Lafayette, Dist. Colo.

Charged 11-8-78: when shipped by Claude Barry & Co., El Paso, Tex., the article contained the added poisonous and deleterious substance aflatoxin; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 61955; S. No. 78-118-564; N.J. No. 1)

Cottonseedmeal, at Longmont, Dist. Colo.

Charged 11-8-76: when shipped by Casa Grande Oil Mill, Casa Grande, Ariz., the article contained the added poisonous and deleterious substance aflatoxin; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 61961; S. No. 78-118-667; N.J. No. 2)

FOOD/Contamination, Spoilage, Insanitary Handling

Barley, at Omaha, Dist. Nebr.

Charged 9-29-78: while held for sale, the article contained insect filth; 402(a)(3). Consent decree authorized release to Scoular-Welsh Grain Co., Omaha, Nebr., for conversion into animal feed. (F.D.C. No. 61900; S. No. 78-149-711; N.J. No. 3)

Beans, dried, various crackers, and melba toast, at Miami, S. Dist. Fla.

Charged 8-1-78: while held by Florida Grocery Co., Inc., Miami, Fla., the articles were held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61775; S. No. 78-141-090 et al.; N.J. No. 4)

Candy drops, fruit bars, snack foods, and other foodstocks, at Virginia Beach, E. Dist. Va.

Charged 12-1-78: while held by Coffee Systems, Inc. (ARA Services), Virginia Beach, Va., the articles had been held under insanitary conditions; 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61969; S. No. 79-103-362 et al.; N.J. No. 5)

Ice cream mix, and nonfat dry milk, at Indianapolis, S. Dist. Ind.

Charged 1-22-79: while held by Maplehurst Dairy, Inc., Indianapolis, Ind., the articles had been held under insanitary conditions and contained rodent filth; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 62111; S. No. 79-119-768 et al.; N.J. No. 6)

Mung beans, at Hialeah, S. Dist. Fla.

Charged 6-29-78: while held by Fashion Imports, Inc., Hialeah, Fla., the article was held under insanitary conditions, and one lot of the article contained rodent and insect filth; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61804; S. No. 78-177-484; N.J. No. 7)

Noodles, and tapioca flour, at Los Angeles, C. Dist. Calif.

Charged 7-27-78: while held for sale, the articles contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61845; S. Nos. 78-153-924 & 78-153-927; N.J. No. 8)

Pimiento, cassia, basil, ginger, and other foodstocks, at Brooklyn, E. Dist. N.Y.

Charged 6-9-78: while held by Pittston Warehouse Corp., Brooklyn, N.Y., some of the articles contained rodent filth, and all of the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decrees entered into by approximately 20 claimants authorized release of specified articles for salvaging. (F.D.C. No. 61806; S. No. 78-147-011; N.J. No. 9)

Rice, at Ogden, Dist. Utah.

Charged 1-30-78: while held by Gateway Distributing Co., Ogden, Utah, the article was held under insanitary conditions and contained insect filth; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61576; S. No. 78-119-045; N.J. No. 10)

Rice, at Tampa, M. Dist. Fla.

Charged 5-17-78: while held by Trans-Florida Warehouse Corp., Tampa, Fla., the article had been held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61761; S. No. 78-141-419; N.J. No. 11)

Rice, nonfat dry milk, desiccated coconut, and other foodstocks, at Hato Rey, Dist. P.R.

Charged 4-26-78: while held by Caceres-Johnson Corp., Hato Rey, P.R., some of the articles contained rodent and/or insect filth and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61748; S. No. 78-147-566 et al.; N.J. No. 12)

Sugar, at Rio Piedras, Dist. P.R.

Charged 10-5-78: while held for sale, the article was unfit for food due to being damaged in a fire which resulted in burned sugar and the melting and burning of plastic bagging in which the sugar was packed; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61902; S. No. 78-147-419; N.J. No. 13)

Sugar, nonfat dry milk, muffin mix, and sesame bread wafers, at Flowood, S. Dist. Miss.

Charged 3-17-78: while held by Bills Institutional Commissary, Inc., Flowood, Miss., the articles contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61653; S. No. 78-130-861 et al.; N.J. No. 14)

Walnuts, cake mixes, and other bakery and pastry stocks, at Detroit, E. Dist. Mich.

Charged 8-21-78: while held by American Bakery & Pastry, Inc., Detroit, Mich., some articles contained insect filth, and all of the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61852; S. Nos. 78-182-070/9; N.J. No. 15)

Wheat germ, and winter wheat, at Bel Air, Dist. Md.

Charged 3-21-78: while held by Laurelbrook Foods, Inc., Bel Air, Md., the wheat germ contained insects, and both articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). The article was claimed by the dealer, who denied the charges. Subsequently, upon motion of the claimant, the claim and answer were withdrawn, and a decree of condemnation was entered that ordered the articles destroyed. (F.D.C. No. 61657; S. Nos. 78-102-850 & 78-102-854; N.J. No. 16)

DRUGS/Human Use

Amygdalin injectable, at Minneapolis, Dist. Minn.

Charged 9-19-78: when shipped by "E. Finley," Palo Alto, Calif., the article was a new drug without an effective approved New Drug Application and was not exempted therefrom—505(a); the accompanying air-freight bill was false and misleading in identifying the article as "office equipment"—502(a); the article's labeling lacked adequate directions for use and was not exempted—502(f)(1); and the article's label lacked the prescription legend—503(b)(4). Default decree ordered destruction. (F.D.C. No. 61894; S. No. 78-187-628; N.J. No. 17)



Aspercreme rub, at Totowa, Dist. N.J.

Charged 4-6-78: while held by Contract Packaging Corp., Totowa, N.J., who manufactured the article using interstate salicylic acid, the article, labeled in part: "External arthritis pain medication Aspercreme Creme Rub . . . Thompson Medical Co., Inc.—Distr.—New York, N.Y.," had been manufactured, processed, packed, and held under circumstances that failed to conform with current good manufacturing practice; 501(a)(2)(B). Consent decree authorized release to the manufacturer for bringing into compliance. (F.D.C. No. 61550; S. No. 77-39-186; N.J. No. 18)

Dexamethasone acetate suspension, at Pasadena, C. Dist. Calif.

Charged 7-27-78: when shipped by Carter-Glogau Laboratories, Inc. (Division of Chromalloy Pharmaceuticals, Inc.), Glendale, Ariz., the article, labeled in part "Dexamethasone Acetate L.A. . . . Manufactured for Pasadena Research Laboratories, Inc., Pasadena, Ca." was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 61835; S. No. 78-153-801; N.J. No. 19)

Mercuric oxide, berberine neutral sulfate, methyl parasept, and propyl parasept, at Bristol, W. Dist. Va.

Charged 12-6-76: while held by Dickey Drug Co., Bristol, Va., who was using interstate components to manufacture eye salve and eye wash, the circumstances used for the manufacture, processing, packing, and holding of the article failed to conform with current good manufacturing practice; 501(a)(2)(B). The manufacturer claimed the articles and denied the charge. The manufacturer moved to dismiss the action because he claimed that the components were not drugs. The Government successfully opposed the motion to dismiss. Thereafter, a consent decree of condemnation authorized release of the articles to the manufacturer for bringing into compliance. (F.D.C. No. 60998; S. No. 77-02-966 et al.; N.J. No. 20)

Penicillin & dihydrostreptomycin injectable suspension, and procaine penicillin G injectable suspension, at Comanche, N. Dist. Tex.

Charged 6-30-77: while held by Gore Bros., Agri Service Center, Comanche, Tex., the circumstances used for the holding of the articles failed to conform with current good manufacturing practice since the articles were being stored without refrigeration; 501(a)(2)(B). The article was claimed by the dealer who denied the charge. Thereafter, a consent decree authorized destruction. (F.D.C. No. 61289; S. Nos. 77-22-108/14; N.J. No. 21)

DRUGS/Veterinary

Calf boluses, at Broomfield, Dist. Colo.

Charged 4-6-78: when shipped by Performance Products, Inc., St. Louis, Mo., the article, labeled in part "Manufactured for Veterinary Division Tutag Pharmaceuticals, Broomfield, Colorado . . . Scour Stop 96 Calf Boluses," was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to its use and intended use; and the circumstances used for the article's manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; 501(a)(5), 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 61661; S. No. 78-123-984; N.J. No. 22)

Master-sul triple sulfa solution for large animals and poultry, at Omaha, Dist. Nebr.

Charged 7-6-78: when returned to Ag American Inc., Omaha, Nebr., by Central Soya, Gibson City, Ill., the article, labeled in part "Master Mix . . . Master-sul A triple sulfa solution with Electrolytes . . . Manufactured For Central Soya Feed Division, Fort Wayne, Indiana,"

was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to its use or intended use; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 61810; S. No. 78-124-106; N.J. No. 23)

Neo-Oxybiotic scour boluses for foals, at Omaha, Dist. Nebr.

Charged 5-11-78: when shipped by Performance Products, Inc., St. Louis, Mo., the article was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to its use and intended use; and the circumstances used for its manufacturing, processing, packing, and holding failed to conform with current good manufacturing practice; 501(a)(5), 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 61764; S. No. 78-124-103; N.J. No. 24)

MEDICAL DEVICES

Diapulse electromagnetic energy generator, at Staten Island, E. Dist. N.Y.

Charged 12-27-77: the article, which had been shipped by Diapulse Corp. of America, New Hyde Park, N.Y., lacked adequate directions for use for its intended purposes and was not exempt, since adequate directions for use could not be written and since adequate information for use by licensed practitioners could not be furnished; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 61536; S. No. 77-90-023; N.J. No. 25)

P/EmF electromagnetic wave generator, at Bronx, E. Dist. N.Y.

Charged 11-22-77: the labeling of the article, which had been manufactured by DCA Leasing Corp., New Hyde Park, N.Y., lacked adequate directions for its intended use, and was not exempted, since neither adequate directions for such purposes by laymen, nor adequate information for use by licensed practitioners, could be provided; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 61464; S. No. 77-90-026; N.J. No. 26)

P/EmF, and Diapulse electronic wave generators, at Bronx, S. Dist. N.Y.

Charged 4-11-78: the articles, which had been shipped by Diapulse Corp. of America, New Hyde Park, N.Y., lacked adequate directions for use for their intended purposes and were not exempted since adequate information for use could not be furnished; and the accompanying literature contained false and misleading claims for sinusitis, exacerbations, lymphadenosis, inflammatory disease, sino-bronchitis, and calcified bursitis; 502(f)(1), 502(a). Default decree ordered destruction. (F.D.C. No. 61651; S. No. 78-140-145; N.J. No. 27)

Thermoslim electric heating pad module, Dermaphoresis electric massage module, and Vibroelectronic muscle stimulator module, at New York, S. Dist. N.Y.

Charged 3-17-77: the articles, which had been imported from Bologna, Italy, by P-Ryton Corp., Long Island City, N.Y., lacked adequate directions for their intended uses and were not exempt—502(f)(1); the labeling of the Thermoslim module and the Vibroelectronic module contained false and misleading claims, respectively, for: (a) reducing the body (due to identifying term "Thermoslim,") and (b) reportioning the body, as a reducing massage, and as a corrective gym massage—502(a); and the labeling of the Vibroelectronic module lacked adequate warnings against unsafe uses—502(f)(2). Default decree ordered destruction. (F.D.C. No. 62067; S. No. 76-41-190; N.J. No. 28)

Urinometer diagnostic sugar tester, at Atlantic City and Pleasantville, Dist. N.J.

Charged 11-27-78: the article (which was promoted to diabetic patients by Brothers Scientific Products, Inc., Chicago, Ill., as a test for



high or low sugar in the urine) was dangerous to health when used as directed—502(j); the article's insert label and catalogue contained false and misleading claims for testing sugar levels in the urine of diabetics—502(a); the article's label lacked the name and place of business of the manufacturer, packer, and distributor and lacked an accurate statement of the content in numerical count—502(b)(1 & 2); and the article's labeling lacked adequate directions for the article's intended use, and such directions could not be written—502(f)(1). Default decree ordered destruction. (F.D.C. No. 61973; S. No. 79-188-563; N.J. No. 29)

COSMETICS/BEAUTY PRODUCTS

Phosphorescent cosmetic dough, at Tempe, Dist. Ariz.

Charged 7-20-77: when shipped by Hannan Products, Corp., Corona, Calif., who packaged the article, which was labeled in part "Imagineering, Inc., Phoenix, Az. . . . GLOW GOOP Put a little on Your Skin and You'll Glow in the Dark," the article contained the nonconforming color additive zinc sulfide; 601(e).

The article was claimed by Imagineering, Inc., Tempe, Ariz., who denied the charge and specifically denied that the article contained a color additive. The Government served written interrogatories on the claimant. After the claimant responded to the interrogatories, the Government moved for summary judgment. Subsequently, pursuant to stipulation by the parties, the claimant was considered to have made no appearance and to have litigated no issue. The claimant agreed not to market or sell Glow Goop as an article of cosmetic; and, accordingly, a default decree was entered ordering the article destroyed. (F.D.C. No. 61310; S. No. 77-10-206; N.J. No. 30)

NOTICE OF JUDGMENT on Criminal Action

FOOD

West Side Cold Storage Co., Inc., and Howard J. Zimbaum, president, New York, S. Dist. N.Y.

Charged 6-7-78: paprika (count 1), blue cheese (count 2), Romano cheese (count 3), dried eel (count 4), and Sardo cheese (count 5) were held under insanitary conditions in a building accessible to rodents and were contaminated by rodent filth; 402(a)(3), 402(a)(4). Guilty plea by individual to count 1; fine and suspended sentence. Guilty plea by corporation to all counts; fine. (F.D.C. No. 61167; S. No. 77-42-683 et al.; N.J. No. 31)

NOTICE OF JUDGMENT on Injunction Action

John Korabik, Gaston Parker, Roland C. Misar, and Joseph Lotilo, individuals t/a Hallmark Laboratories, Inc., & Nacrisan Vial Corp., Chicago, N. Dist. Ill.

Charged 2-14-77 in complaint for injunction: that the individuals were allegedly the president, secretary, vice president, and treasurer, respectively, of Hallmark Laboratories, Inc., a/k/a Nacrisan Vial Corp.; that the defendants were engaged at their plant in manufacturing, processing, packing, labeling, holding, and distributing various sterile injectable drugs (one or more of whose components had been shipped in interstate commerce); that such drugs had been manufactured, processed, packed, and held under circumstances that failed to conform with current good manufacturing practice—501(a)(2)(B); that in addition, the strength of diphenhydramine hydrochloride injection differed from the U.S.P. requirements, and the labeling was false and misleading as to strength since the article was more than 110 percent superpotent—501(b), 502(a); that the cyanocobalamin injection failed

to be packed in light-resistant containers, as prescribed by the U.S.P.—502(g); and that a number of drugs, including a sterile estrone suspension, a lidocaine hydrochloride injection, and estradiol valerate injection, a sterile testosterone suspension, and diphenhydramine hydrochloride injection were new drugs without effective approved New Drug Applications—502(a); that FDA inspections disclosed a number of specified deviations from current good manufacturing practice; and that the defendants were well aware that their activities were in violation of the law.

The court issued a temporary restraining order, temporarily enjoining the defendants from continued operation and interstate shipping unless and until a number of specified circumstances were found to have been effected in accordance with current good manufacturing practice and all the defendants' drugs on hand were appropriately examined. The defendants filed their answer to the complaint denying the charges. The defendants opposed the Government's motion for a preliminary injunction and argued that the court was without authority to order a recall.

The Government served written interrogatories against the defendants. The defendants voluntarily initiated a recall from Hallmark customers of all drugs manufactured by Hallmark and sold after December 5, 1975. Upon motion of the Government, the court ordered a defendant to not destroy the drugs on hand and to deliver them to FDA. A consent decree of permanent injunction was filed. The consent decree permanently enjoined the defendants from the complained of violations, enjoined the defendants' manufacturing and shipping operations with respect to interstate drugs processed at the plant unless and until specified conditions were met, but did not preclude the defendants from functioning as a distributor of finished, labeled, and approved drugs received from other firms and did not preclude the defendants being employees of other pharmaceutical firms. FDA was also authorized to monitor the defendants' recall operations. Ultimately, the Government moved for an order permitting FDA to dispose of the drugs delivered to it and advised the court, as grounds for such action, that the injunction litigation had been resolved by a consent decree; that FDA's Chicago District Office had examined and continued to examine all drugs delivered by the defendants, and that the defendants said they had no further need or use of the drugs and did not oppose the ultimate disposition of the drugs by FDA. Accordingly, the court authorized and directed FDA to dispose of all such drugs and all such drugs which in the future were delivered. (Inj. No. 772; S. No. 76-10-851 et al.; N.J. No. 32)

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

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

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

Donald Kennedy, *Commissioner of Food and Drugs*
Washington, D.C., June 1, 1979

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