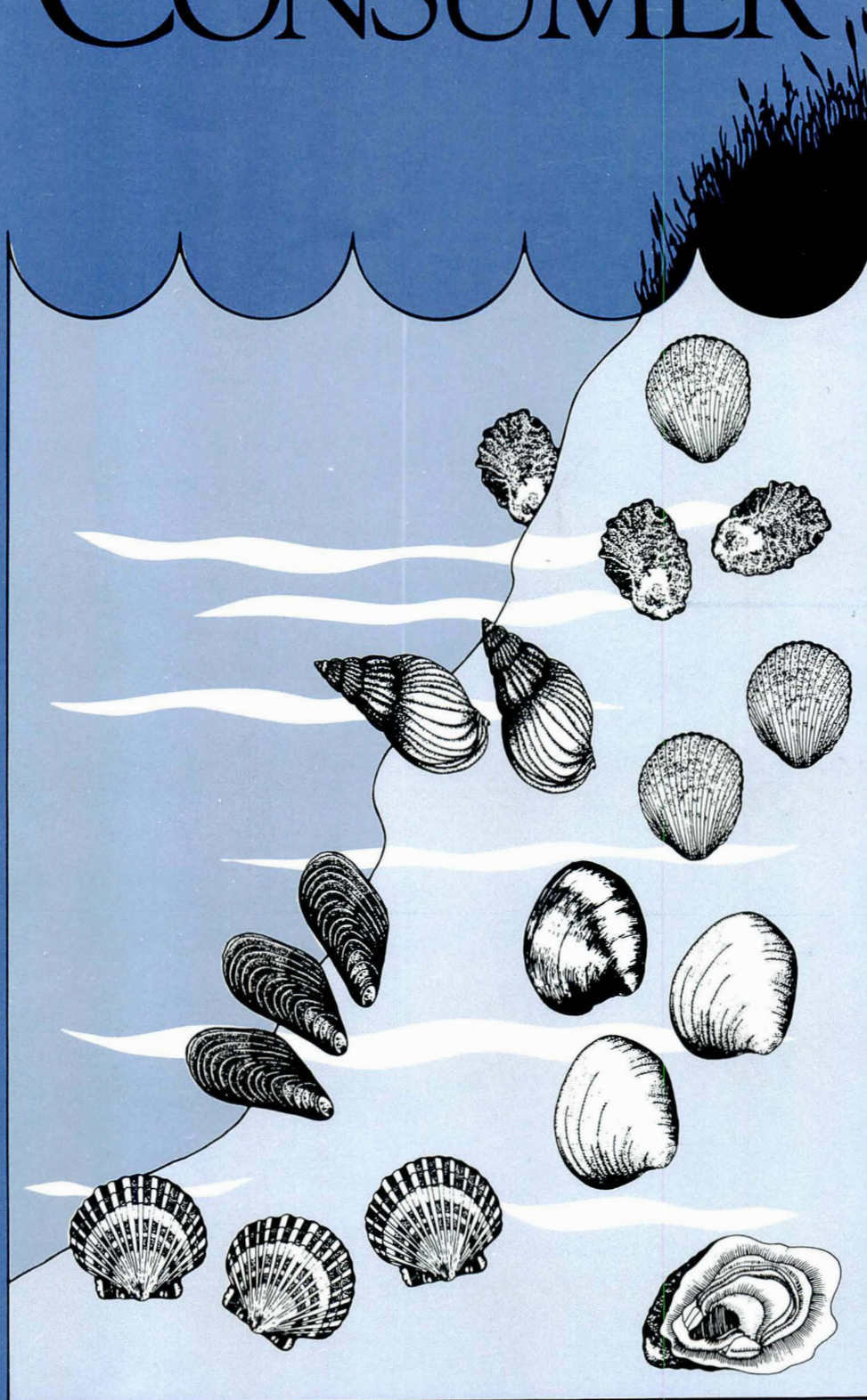


FDA
CONSUMER

October 1984



For Oyster And Clam Lovers,
The Water Must Be Clean



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FDA CONSUMER

VOL. 18 NO. 8

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Sulfa: Yesterday's Hero Is Still Taking Bows 8
Nearly 50 years ago, sulfonamides were hailed as "wonder drugs." They remain the drugs of choice in many situations, and they've led to development of other drugs.

For 100 Years, They've Tested The Testers 12
Little known outside scientific circles, the Association of Official Analytical Chemists—now 100 years old—sets standards that protect consumers.

Soft Contacts Need Some TLC 16
For those who prefer corrective lenses without frames, here's some advice from an optometrist on how to take care of them.

For Oyster And Clam Lovers, The Water Must Be Clean 20
These bivalve mollusks along with mussels have complex filtering systems that can accumulate illness-causing bacteria from polluted waters.

Diet And The Elderly: Research Points To Some Special Needs 26
Research into the diets of the fast-growing population of the elderly has been scant. What is being done shows that this group may have nutrition requirements that differ from other adults for a number of reasons.

How Onions And A Baked Potato Became Sources Of Botulism Poisoning 30
Onions and potatoes are considered unlikely sources for the development of botulinal toxin. The problem was in the preparation of the foods.

The Flaw In Cytotoxic Testing: There's No Proof It Works 34
Promoters, often operating from storefronts, claim they can provide blood testing to determine food allergies that undermine health. But they haven't backed their claims.

Updates	2	Investigators' Reports	38
Consumer Forum	7	Summaries of Court Actions	41
The Notebook	37		

GIs in World War II suffered the same miseries as soldiers in previous wars, but they were at least fortunate enough to have sulfa drugs to help them recover from wounds. These "wonder drugs," which came into use just shortly before the war, not only were given in tablet form but also applied to bandages to help control infections. For more on the history and applications of this still widely used class of drugs, see Sulfa: Yesterday's Hero Is Still Taking Bows, beginning on page 8.

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16



34

FOOD ALLE
e Cytotoxic T

Latin for cell and "Toxic" for p
totoxic Test is a measure of yo
sensitivities to over 400 foods, c
vities responsible for symptoms
bloating after meals, migraine

Funny Honey Dealers Guilty.

Two men who admitted to packing and shipping fake honey and maple syrup to stores across the country have been fined and given probationary sentences by a federal judge in Jackson, Miss.

Oliver Anthony and Dewey Garland Clark were charged with 13 felony counts of violating and conspiring to violate the federal Food, Drug, and Cosmetic Act by placing adulterated and misbranded foods in interstate commerce. (See Investigators' Reports, *FDA Consumer*, May 1983.)

After the conspiracy charges were set aside, Anthony pleaded guilty to six of the remaining charges and Clark to three. Judge Dan M. Russell Jr. placed both men on four years probation and ordered them to report every three months to a probation officer. Anthony was fined \$20,000 and Clark \$10,000, the fines to be paid in stated amounts over two years.

Anthony and Clark were charged with manufacturing, processing, shipping and selling foods labeled as maple syrup, maple table syrup, honey and sorghum syrup that were actually corn and sugar syrups, sometimes blended with the labeled product and sometimes artificially flavored. The charges covered a five-year period.

During those five years, Anthony had purchased over 6 million pounds of corn syrup and 1,600 gallons of artificial maple flavoring from a legitimate Virginia supplier. These cost much less than the maple syrup and honey for which they were offered, and the U.S. attorney who handled the prosecution said he "could not estimate the profits" the two defendants had made.

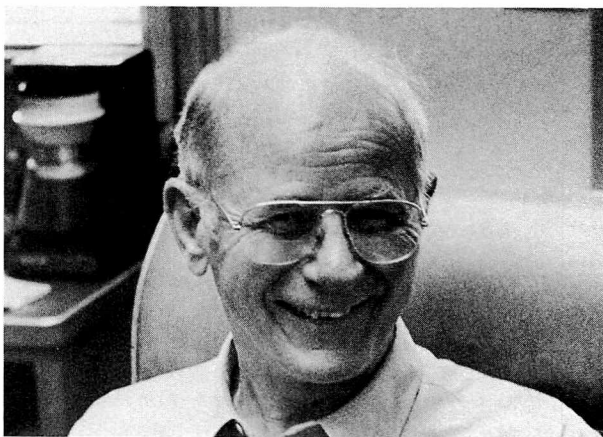
The products were variously labeled Anthone's Pure Sourwood Honey, Anthone's Wild Flower Brand Honey, Anthone's Pure Maple Syrup, Pure Pioneer Maple Syrup, and Clark's Farm Pure Sorghum. Typically they were packed in one-pint canning jars. Seizures were made in Texas, Tennessee, Kentucky, Arizona, Louisiana, Oklahoma, Oregon, Utah and Virginia. After repeated

seizures, several states embargoed the trading of Clark and Anthony products within their borders.

Honey, maple syrup and sorghum all have FDA "standards of identity," as do other foods. Laboratory analysis showed that the seized products were not what the labels claimed but were inferior substitutes. The maple syrup industry of Vermont and the honey industry in a number of states had long been objecting to these fake products being sold to unsuspecting consumers across the country.

Hopkins Retires

Harold Hopkins, No. 2 editor of this magazine and its predecessor, *FDA Papers*, for more than 16 years, has retired. During this time, Hopkins served as both an editor and writer. He was known among staff members for his keen editor's eye. Readers are familiar with his writing. Probably the best-written piece ever to appear in this magazine was his June 1980 article "Blue Language And The Jakewalk Blues." His last article, "The Dental Plaque Battle Is Endless But Worth It," appeared in last month's issue. Anyone who read that article and didn't go out and buy his or her first roll of dental floss had to be reading with closed eyes.



Cordless Phone Warning

Cordless telephones may be the latest thing in conversational convenience, but they also can be hazardous. Complaints of hearing damage in users have been collected by both the Consumer Product Safety Commission and the American Academy of Otolaryngology-Head and Neck Surgery.

The problem occurs because in some cordless phones the bell is in the earpiece. The user must make a conscious effort to switch off the ringing mechanism before using the phone. In addition, some cordless phones have a paging feature that rings or emits a loud signal when a switch on the base unit, which can be some distance away, is activated by someone else. In some phones this can happen even when the phone is in the "conversation" mode.

The paging and ringing signals are relatively loud. Laboratory tests indicate that some signals may exceed thresholds for hearing loss as well as established standards for occupational exposure.

On April 30, the Consumer Product Safety Commission turned responsibility for the cordless phones over to FDA, having determined that FDA has superseding authority.

FDA recommends that purchasers consider only those phone models that do not have the bell in the earpiece and/or provide other protection against potentially hazardous exposure to the ear.

Those who already own cordless phones with the bell in the earpiece should take every precaution to prevent exposure to the ringing signal when the phone is in use, FDA says. They should:

- Keep cordless phones out of the reach of small children.
- Instruct all household members about the importance of turning off the bell before placing the phone to the ear.
- Disconnect the paging feature on any phone that can be activated when the handset is in the "conversation" mode.

After completing an assessment of the health

problems related to cordless phones and of the effectiveness of a 1983 CPSC education campaign, FDA will decide if a further FDA-industry public information campaign is needed. The agency could also mandate corrective action by industry (recall, repair, replace) under the defect provisions of the Radiation Control for Health and Safety Act of 1968.

Herb Pills Pose Danger

"Sup-Herb" herbal pills contain potentially dangerous amounts of prescription drugs and should not be purchased or consumed, FDA has warned. The product has been heavily promoted in Hawaii and distributed in lesser quantities throughout the United States.

The pills are round, black and about a quarter inch in diameter. The labeling for the product lists only herbal contents, but FDA's San Francisco laboratories have found they contain four milligrams of indomethacin, a prescription arthritis drug that can have serious side effects; approximately 2.2 milligrams of hydrochlorothiazide, a powerful diuretic; and traces of diazepam, a tranquilizer.

Although no deaths are known to have been caused by "Sup-Herb," so-called Chinese herbal remedies containing a similar combination of drugs were associated with deaths and hospitalizations in 1974 and 1980. The Chinese herbal remedies were produced in Hong Kong and Taiwan.

People taking prescription medications for arthritis and high blood pressure may be at greater risk from this product because of the possibility of overdose or drug interactions. FDA says people taking the herbal product should stop and, if taking other medication, should check with a physician.

The distributor of "Sup-Herb" in the Honolulu area, Sup-Herb Warehouse of Hawaii, has agreed to recall the product from its 650 accounts in Hawaii. The distributor received the product from

Marketing Three International of Las Vegas, Nev. FDA is negotiating with this firm for total removal of the product from 1,100 distributors nationally. FDA is attempting to locate the product's manufacturer. Marketing Three International purchased the product from an address in Fitch, Texas.

"Sup-Herb" is sold in plastic bags of 120 pills. Accompanying literature recommends it for relief of arthritis and high blood pressure, at a maximum dosage of 12 pills a day. The labeling, however, recommends only four pills a day.

(For more about unapproved arthritis medicines, see "Hocus-Pocus As Applied To Arthritis" in the September 1980 issue of *FDA Consumer*, and "Confucius Say: Chuifong Bad Medicine" in the May 1981 issue.)

Reprints Available

Reprints are available of the following article that appeared in the July-August issue of *FDA Consumer*: "When Digestive Juices Corrode, You've Got An Ulcer." Single copies of this reprint can be obtained from the Food and Drug Administration, HFE-88, 5600 Fishers Lane, Rockville, Md. 20857. Multiple copies are available from FDA, HFW-40, at the Rockville address. Copies of reprints also are available from FDA's consumer affairs officers, who are located in 29 cities around the country.

Vet Drug Used Illegally

Sales of oral chloramphenicol solution, which had been used illegally in food-producing animals, have declined significantly, thanks to an FDA national information program aimed at veterinarians, the animal health-care industry, and the livestock industry.

On March 26, FDA sent a "Dear Doctor" letter to more than 40,000 veterinarians to alert them to the hazards of using chloramphenicol in food-producing animals. The letter was intended to alert

veterinarians to the extreme toxicity of the drug to humans; to solicit the support of the veterinary profession in stopping illegal uses of the drug; and to inform veterinarians and others of the agency's plan to "effectively eliminate usage of chloramphenicol in food animals."

Fatal aplastic anemia has occurred in persons who were exposed to chloramphenicol while administering it to animals. Although FDA is unaware of any reported illnesses from human consumption of animal products, the drug's veterinary label warns against using it to treat animals that produce milk, eggs or meat. This use of the drug could result in harmful residues in meat, egg or milk products from treated animals.

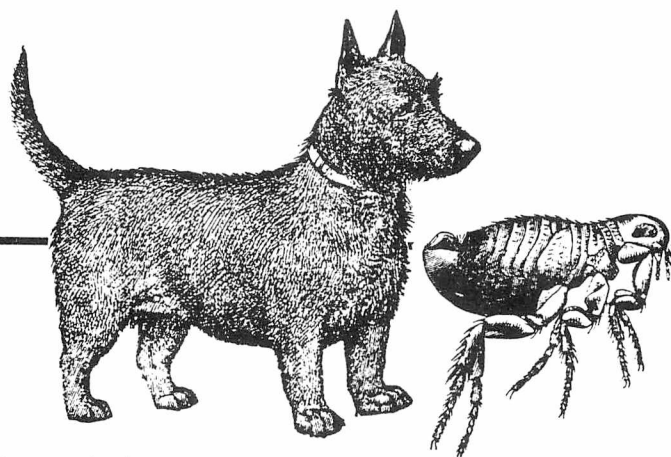
Chloramphenicol is only to be administered or prescribed by a licensed veterinarian for the uses in dogs specified on the approved labeling.

FDA initiated its information program because the unapproved use of chloramphenicol to treat infections and respiratory illnesses in food animals appeared to be widespread. Since then, reports reaching FDA indicate that many veterinarians, feedlot managers and cattlemen have heeded the agency's requests to discontinue these uses of the drug.

FDA has asked manufacturers of oral chloramphenicol solution to voluntarily withdraw the product from the market to prevent further misuse. If manufacturers do not agree, FDA will issue a "Notice of Opportunity for Hearing" or take other action that could lead to removal of the oral solution from the market, leaving tablets, capsules, oral suspension, injectables and topical ointments available for dogs.

Ring Cancer Victims Sought

FDA and the U.S. Centers for Disease Control want to know about any cases of skin cancer or dermatitis of the finger that might be related to wearing a radioactive ring. In a letter in the June issue of the *Journal of the American Academy of*



Dermatology, the agencies asked dermatologists to report such cases to FDA.

The source of radiation in rings was gold originally used to encapsulate radioactive radon gas for cancer treatment. Although the radon gas eventually dissipates, the gold capsule can remain radioactive. It is believed that some of these spent radon capsules, or "seeds," found their way into jewelry manufacturing, where they were melted down to make and resize rings.

In the 1960s, FDA investigated several cases of excessive radiation exposure resulting from wearing rings made of radioactive gold. In 1969 an FDA advisory committee concluded that the radioactive contamination was not a widespread public health hazard.

An article in the January 1981 *Medical World News* prompted renewed public concern, including initiation of programs to check for potentially contaminated gold jewelry. To date, the New York State Department of Health has screened about 160,000 pieces of jewelry for radioactivity, mostly in the western area of the state. About 200 contaminated items have been found. Fourteen cases of cancer of the ring finger have been found among persons identified as wearing contaminated rings.

In a letter to dermatologists, FDA and CDC said the problem may be confined to western New York, but that it could exist in other parts of the country because, at one time or another, 30 to 40 radon-producing facilities may have operated in various cities in the United States.

FDA will arrange to have any suspect jewelry checked for radioactivity, and both agencies will follow up cases of radioactive jewelry to determine exposure history, radiation doses, health effects, ring source, and other pertinent information.

Flea Treatment Limited

FDA has denied the American Cyanamid Co. permission to sell its prescription anti-flea product,

Proban Cythioate Oral Liquid, as a nonprescription product.

The June 20 decision affirms the initial decision by Administrative Law Judge Daniel J. Davidson in June 1981 finding that American Cyanamid had failed to show that Proban would be safe for non-prescription use and that adequate directions could be written for lay use.

In affirming the previous denial to market Proban as a nonprescription product, then Acting Commissioner Mark Novitch found that American Cyanamid did not submit results of testing required by law to demonstrate Proban's safety and effectiveness. This finding raises questions about the strength of the effectiveness data provided for the original approval of the prescription product.

Proban was approved in 1968 as an oral flea formulation for dogs. In 1976 the company requested approval for sale of Proban directly to consumers.

Viruses Linked To AIDS

Two common viruses may play an important role in the manifestation of AIDS (acquired immune deficiency syndrome), FDA scientists have reported.

The two are cytomegalovirus (CMV) and Epstein-Barr virus (EBV). These are in the herpesvirus family, but are not the cause of oral or genital herpes. Gerald V. Quinnan Jr., M.D., of FDA and his colleagues from FDA, the National Institutes of Health and the Mayo Clinic found CMV and EBV in nearly 100 percent of AIDS patients—significantly more often than expected compared to incidence in the general population—and more frequently than other viruses that normally tend to produce serious infection in transplant patients whose immune systems have been suppressed.

Blood studies in 34 AIDS patients revealed that all had CMV, 33 had EBV, eight had herpes simplex virus, and four had varicella zoster (chicken pox virus). Eight of nine chronic lymph-
(Continued on next page)

adenopathy patients had CMV, while all had EBV. Five of 13 healthy homosexuals had CMV and seven of another group of eight healthy individuals had EBV.

The authors of the study, published in the July 6 *Journal of the American Medical Association*, concluded that "the potential importance of herpesviruses (CMV and EBV) in AIDS is twofold They are leading causes of disease and death . . . and it is possible that infections with CMV and/or EBV are associated with exposure to or are specifically reactivated by the cause of the syndrome."

It is also possible, said Quinnan, that infection with these viruses could influence the severity of infections with HTLV-3 (recently identified as the cause of AIDS) or possibly even influence whether or not AIDS occurs after exposure to HTLV-3. "The clinical significance of herpesvirus diseases in AIDS is clear," the authors continued, "but clarification of their relationship to the etiology of AIDS must await results of subsequent studies."

It is possible, the authors think, that homosexuals with many partners infect each other over and over with the two herpesviruses, and that these may contribute to the susceptibility to AIDS.

Co-authoring the paper from FDA were Drs. Alain Rook, Winston Frederick, Jay Epstein and Charles Mitchell, along with Gary Armstrong, Jody Manischewitz and Lozannie Jackson. Co-authors from NIH were Drs. Henry Masur, Abe Macher, Margaret Parker, Joseph Parrillo and Stephen Straus, as well as John Ames and Holly Smith. Dr. Gary Pearson was the co-author from the Mayo Clinic.

Background information on AIDS can be found in "What The Experts Know About AIDS" in the September 1983 issue of *FDA Consumer*.

Rx Contents To Be Told

Member companies of the Pharmaceutical Manufacturers Association will voluntarily list the

inactive ingredients of prescription drugs in the official labeling, the board of directors has announced.

The board said the action is intended to provide added safety for persons sensitive to inactive ingredients, such as flavors, binders, colors and preservatives. A listing of such ingredients in the official labeling can enable physicians to identify products containing substances that may cause allergic reactions. Currently companies provide this information to physicians on request. Listing of active ingredients, but not inactive ingredients, is required by U.S. drug laws and regulations.

The Proprietary Association, trade association for nonprescription drug manufacturers, announced in May that its members had agreed to list on the package the inactive ingredients of products they make.

Unapproved Drugs Probed

Full-page newspaper ads that have been promoting unapproved drugs have drawn the investigative interest of three federal agencies to activities of the Robertson-Taylor Co. of Fort Lauderdale, Fla.

The promotion of these products has included false and misleading claims. Investigating the firm are the U.S. Postal Service, the Federal Trade Commission and FDA.

According to the U.S. Council of Better Business Bureaus, Robertson-Taylor Co. was incorporated in Florida on July 28, 1982. The company is a division of Intra-Medic Formulations Inc., located at the same Fort Lauderdale address.

It has been reported that Robertson-Taylor operated mail drops under the name W. G. Charles Co., Chicago, Ill., and J. F. Pharmaceuticals, Westport, Conn.

The Robertson-Taylor firm has been selling a variety of mail-order products. According to information from consumers and the firm's advertisements, these products include: Actavin-917 (for

mental alertness), Cellulase-EFX (cellulite dissolver), Tranquinol (nerve relaxer), Derma-Tec 90 (wrinkle remover), Medi-Tec 90 (for baldness), Testorex-35 (for sexual dysfunction or impotence), Mamralin-BX (breast augmentation cream), Arthrex (for arthritis), Revitalin SL 90 (multivitamin), Veritin 516 (sexual product), Libutol-1500 (sexual stimulant), Lipogene GHX (diet aid), Synertrim No. 9 (spot reducer), L-2000 (aphrodisiac), Metabolite 2050 (diet aid), and Calor-Bloc 30 (starch blocker).

Calor-Bloc was seized in November 1982, and the product was destroyed.

After complaints by the U.S. Postal Service that Robertson-Taylor Co. had violated postal statutes in seeking money through the mails by false representations, an administrative law judge recommended that stop orders be issued directing postmasters to return to the sender all orders for Calor-Bloc 30, Derma-Tec 90, Mamralin-BX, Synertrim No. 9, Medi-Tec 90, Libutol 1500 and Testorex-35.

Consumer Forum

Praise From Canada

The July-August, 1984 issue of your magazine just arrived, and as usual, it is outstanding. The time has come for me to compliment you on this excellent publication and to thank you and the FDA for your efforts.

As Public Health Nutritionist, my job is to provide reliable nutrition information to just under half a million people. The *FDA Consumer* has helped me immeasurably to do this task. I copy almost every article in every issue. These are used as background reference for materials I prepare, to educate other Health Department staff, or to recopy directly for clients. Your articles are extremely well-written, relevant to current issues, ac-

curate, and informative. Best of all, they are more "punchy" and outspoken than is usual for government publications!

U.S. consumers are lucky to have access to this information. While I realize your primary target is the U.S. audience, consumers in Scarborough have also profited by your achievements. Congratulations to you and your staff for a job well done and to the FDA for funding the publication.

Beverly Musten, M. Sc.
Public Health Nutritionist
City of Scarborough
Scarborough, Ontario

Pesticide Ban Limited

I certainly enjoyed reading "The Search For Pesticide Residues" which appeared in the July-August 1984 issue of *FDA Consumer*. However, I did find one significant flaw which could cause some anxiety for certain pesticide users. I refer to your statement that chlorothalonil (a fungicide sold in the U.S. under such brand names as *Bravo* and *Daconil 2787*) has been banned in the U.S. It is true that chlorothalonil is not registered for use on peas in the U.S., but the chemical is certainly not banned in this country. It is in fact used extensively to control a variety of fungus diseases on a wide range of vegetables, fruits, and ornamentals.

I might add that I enjoy reading *FDA Consumer* Keep up the good work and interesting articles.

Winand K. Hock
Extension Pesticides Specialist
Pennsylvania State University
University Park, Pa.

Mr. Hock is correct. The pesticide has many uses. The ban referred to chlorothalonil found on Mexican peas and FDA's closing the border to that product until the problem was resolved.

Sulfa

Yesterday's Hero Is Still Taking Bows

by Annabel Hecht



What really put the sulfas in the headlines in 1936 was the dramatic cure of Franklin Roosevelt Jr., who was suffering from a severe streptococcal infection.

Before penicillin, there were the sulfa drugs. The sulfonamides, as they are more correctly called, were the first effective chemotherapeutic agents for the prevention and treatment of bacterial infections in humans. Their introduction into the world of medicine in 1935 opened up the "golden age of drugs."

Initially the sulfonamides were greeted with enthusiasm as "wonder drugs." Their popularity, however, has diminished over the years. The introduction of more effective and less toxic antibiotics and the development of bacterial resistance to sulfonamides have limited their usefulness; yet sulfonamides continue to have an important place in medicine and are, in fact, the drugs of choice against certain infections. Further, they have led to the discovery of treatments for a variety of other diseases, including high blood pressure and glaucoma.

The story of the sulfonamides began in Vienna near the turn of the century. Medicine was not what chemistry student Paul Gelmo had in mind when he synthesized para-aminobenzenesulfonamide from coal tar in 1906. His interest was in dyes. Gelmo published a paper on his work in a German chemical journal in 1908 and offered it as a thesis in his candidacy for a doctoral degree.

The following year, scientists at I.G. Farbenindustrie, the German chemical giant, experimented with sulfonamides as dyes for textiles. While some studies of the medical uses of these dyes were made in the following years, intensive investigations in this area probably did not begin until sometime in 1930.

On Dec. 25, 1932, the German Patent Office issued to Drs. Fritz Mietzsch and Joseph Klarer of I.G. Farbenindustrie a patent covering a sulfonamide-containing dye called Prontosil. In the same year Gerhard Domagk, a research director of the same company, observed that mice with streptococcal and other infections could be protected by Prontosil. Domagk is also said to have given the new compound to his own daughter after she pricked her finger and developed blood poisoning.

In May 1933 the first clinical report about Prontosil was made in Dusseldorf, Germany, by a Dr. Foester who described the dramatic cure of a 10-month-old child suffering from staphylococcal septicemia.

Domagk did not publish his findings until 1935. Three other clinical reports on Prontosil appeared in the same German medical journal, indicating that other German

scientists were studying the new drug in the early 1930s. Domagk was awarded the Nobel Prize in 1938, although the Nazi regime prevented him from accepting it and actually imprisoned him. In 1947 the scientist did go to Sweden to deliver the Nobel lecture and received the gold medal and diploma.

Chemistry student Gelmo was never heard of again.

Once the news was out, the rest of the world took notice. In 1935 scientists at France's Pasteur Institute reported that para-aminobenzenesulfonamide was the active part of the molecule. In England, other investigators reported favorable clinical results with Prontosil and sulfanilamide in puerperal sepsis (blood poisoning following childbirth) and meningococcal infections.

Although the first reference to the new chemotherapy in the *Journal of the American Medical Association* was an abstract from a French journal and did not appear until June 1936, there was no lack of interest in the new drug in the United States. Scientific investigations began in earnest in a number of institutions, including the National Institutes of Health and Johns Hopkins University. Scientists at Johns Hopkins proved that sulfonamides are bacteriostatic and not bacteriocidal—that is, they slow down, rather than kill, bacteria.

What really put the sulfas in the headlines in 1936 was the dramatic cure of Franklin Roosevelt Jr., who was suffering from a severe streptococcal infection. The new drug had been flown to Boston after an appeal from the president's wife. Another name associated with the early sulfonamides is that of Winston Churchill, who is reported to have been cured twice of pneumonia with sulfapyridine, a compound synthesized in 1937.

American pharmaceutical companies were quick to see the potential of the new compound. In April 1937, at the request of a number of manufacturers, the American Medical Association's Council on Pharmacy and Chemistry adopted "sulfanilamide" as the nonproprietary (non-trade) name for the new drugs. The next month the council accepted for inclusion in its list of "New and Nonofficial Remedies" various brands of sulfanilamide manufactured by the Calco Chemical Co. Inc.; Lederle Laboratories Inc.; Eli Lilly & Co.; Merck & Co.; Parke, Davis & Co.; E.R. Squibb & Sons; and Winthrop Chemical Co. Inc.

It was only a few months later that the AMA began

Servicemen were issued sulfanilamide tablets (later, pouches with sulfa in powder form) to be used in the event of injury.

receiving reports of deaths attributed to “Elixir Sulfanilamide,” a liquid version that had been made with diethylene glycol, a deadly poison. More than 100 people, including many children, died after taking this preparation, described in an *AMA Journal* editorial as “apparently hastily rushed into the market to meet an overenthusiastic reception of a new remedy.”

The tragedy hastened the enactment in 1938 of the federal Food, Drug, and Cosmetic Act (see “Taste Of Raspberries, Taste Of Death” in the June 1981 *FDA Consumer*), but it did not slow down the search for new and more effective sulfonamides. Thousands of derivatives of the compound were tested for antibacterial activity both here and abroad, though only a few made the grade. Sulfapyridine, the first sulfa compound successful in combating pneumonia, was synthesized in England in 1937. Sulfathiazole, sulfadiazine and a host of others followed.

At the same time, clinical use boomed. In 1941, an estimated 3,450,000 pounds of several sulfonamides were produced and 10 to 15 million people were treated with sulfa drugs.

From the very beginning of World War II, starting with those wounded at Pearl Harbor, sulfonamides got high marks for controlling infection in battle casualties. Servicemen were issued sulfanilamide tablets (later, pouches with sulfa in powder form) to be used in the event of injury.

The postwar years marked the beginning of a new “golden age” of microbe-fighting therapy. Penicillin, until war’s end produced almost exclusively for the military, became available for civilian use. The sulfonamides began to take second place to the new and more effective antibiotics. Their usefulness was also diminished by a phenomenon known as “bacterial resistance.”

Bacterial resistance, known to bacteriologists even before the advent of the sulfa drugs, develops because the drug does not kill invading organisms but merely stops their growth, thus allowing the body’s defenses to take over. A few of the stronger organisms continue to reproduce and eventually a new strain of resistant organisms emerges.

Because of this drug resistance, sulfonamides are no longer effective in treating gonorrhea or meningococcal meningitis. They are still among the drugs of choice for acute, uncomplicated urinary tract infections; for nocardiosis, a rare fungal infection; and for chancroid, a

venereal infection. They also may be used to treat a variety of other infectious diseases and conditions.

Sulfonamides are generally classed according to the length of time they stay in the body.

The **short-acting sulfonamides** are rapidly absorbed and excreted and are usually preferred for the treatment of urinary tract infections caused by susceptible strains of bacteria. Sulfacytine, sulfisoxazole and sulfamethizole belong to this class of sulfonamide.

Sulfisoxazole also may be prescribed for certain types of meningitis and otitis media, an infection of the middle ear. Two eye infections, trachoma and a form of conjunctivitis, may be treated with this drug. Nocardiosis, chancroid, toxoplasmosis (a disease caused by a parasite) and one type of malaria also are susceptible to sulfisoxazole.

A fourth short-acting sulfonamide, sulfadiazine, is sometimes used to treat nocardiosis and as preventive therapy in rheumatic fever patients who are allergic to penicillin.

Intermediate-acting sulfonamides are excreted more slowly so they need to be given only once or twice a day. At this time there is only one such drug on the market—sulfamethoxazole—and it is used for the same indications as sulfisoxazole.

Once there were **long-acting sulfonamides**, but these are no longer marketed because they caused Stevens-Johnson syndrome, a severe skin infection characterized by blisters in the mouth, pharynx, eyes and elsewhere in the body. Nearly 20 years ago FDA ordered one manufacturer to withdraw its long-acting sulfonamide from the market and two others to revise the labeling on their products because of this serious side effect.

Sulfonamide products not included in the above classes include sulfacetamide sodium, used in ophthalmic solutions; and sulfasalazine, indicated for treatment of mild to moderate ulcerative colitis. Silver sulfadiazine and mafenide acetate are topical sulfonamide preparations used as auxiliary treatment of second- and third-degree burns.

Combinations of two or three short-acting sulfonamides came on the market early in the game when it was discovered that such combinations reduced the risk of crystalluria (formation of crystals in the kidney). One mixture consisted of equal parts of sulfadiazine, sulfamerazine and sulfamethazine. Called trisulfapyrimidines, they are rarely used today. Another triple combina-

The introduction of more effective and less toxic antibiotics and the development of bacterial resistance to sulfonamides have limited their usefulness; yet sulfonamides continue to have an important place in medicine . . .

tion—unequal parts of sulfathiazole, sulfacetamide and sulfabenzamide—is marketed for the treatment of vaginal infections.

Sulfonamides have been combined with other non-sulfa drugs to produce such mixtures as sulfisoxazole, aminacrine hydrochloride and allantoin, used to treat vaginitis; sulfamethizole, phenazopyridine plus a tetracycline for cystitis and urethritis; or sulfisoxazole and erythromycin for otitis media.

The combination trimethoprim and sulfamethoxazole is considered an important advance among antimicrobial agents. It was widely used in Europe for about five years before its introduction into the United States in 1973. When tested in the laboratory, the two drugs together are 20 to 100 times more active than the sulfonamide alone because each blocks the growth of susceptible bacteria at a different step. The combination is indicated for the treatment of urinary tract infections, acute otitis media in children, acute exacerbations of chronic bronchitis in adults, intestinal inflammation and *Pneumocystis carinii* pneumonitis.

Unfortunately, the combination can cause Stevens-Johnson syndrome.

FDA has been disturbed by reports of fatalities in otherwise healthy children who died after developing Stevens-Johnson syndrome while being treated with trimethoprim/sulfamethoxazole for urinary tract infection, septic arthritis of the knee, and otitis media. There also have been deaths due to aplastic anemia in children taking an erythromycin/sulfisoxazole combination.

Because these drugs are so widely used for common infections, the agency has changed the drug's labeling (material prepared for physicians and pharmacists) by expanding the adverse reactions section and highlighting these problems in the warning section. Physicians were alerted to the potential severity of these reactions in the April 1984 issue of FDA's *Drug Bulletin*.

While severe reactions such as Stevens-Johnson syndrome are probably rare, there are other side effects associated with the sulfonamides. These include increased sensitivity to sunlight, itching or rash, diarrhea, dizziness, headache, loss of appetite, nausea and vomiting. Occasionally the patient taking a sulfonamide may experience blood in the urine, lower back pain, pain or burning on urination, or swelling of the front part of the neck.

The sulfonamides cross the placenta and are excreted in

breast milk. Therefore, they should not be prescribed for pregnant women near term or for those who are nursing their babies.

The legacy of the sulfonamides is not limited to the handful of drugs described above. In the 1940s scientists discovered that sulfanilamide blocked the activity of an enzyme called carbonic anhydrase that plays a role in the exchange of sodium and hydrogen ions in the kidneys and other organs. When the number of hydrogen ions is reduced, more sodium is excreted and the output of urine is increased. From this knowledge came acetazolamide, a drug used to reduce the intraocular pressure in glaucoma, to treat epilepsy and to reduce edema (swelling) due to congestive heart failure.

Later it was learned that, by modifying acetazolamide slightly, new compounds could be made that not only increased urinary output but also caused increased excretion of chloride. Thus was born a new class of drugs called benzothiadiazides. More commonly called thiazide diuretics, these drugs are the mainstay of the treatment of high blood pressure.

Yet another group of drugs that evolved from the sulfonamides are diabetes drugs called sulfonylureas. Their history began in 1942 when French scientists studying typhoid fever discovered rather unexpectedly that sulfonamide lowered blood sugar. Later it was learned that the compound works by stimulating the pancreatic islet cells to secrete insulin.

In 1955 German researchers testing the sulfonamide derivative carbutamide again discovered that it lowered blood sugar. Carbutamide was widely used in Europe to treat diabetes, but because of its toxicity it was never used to any extent in this country. A less toxic form of the drug, tolbutamide, was introduced in 1957 and is currently used to treat patients with adult-onset diabetes who have not responded to treatment through dietary management and who cannot take insulin.

Drugs to treat infections, diabetes, glaucoma, epilepsy, heart failure and high blood pressure—who would have thought all this would come from an obscure chemistry student's search for a textile dye? ■

Annabel Hecht is a member of FDA's publications staff.



For 100 Years, They've Tested The Testers

by Wallace F. Janssen

Americans eat food, use medicines, and apply cosmetics with a great deal of confidence in the safety of the products. Consumers know that industry and government have standards that protect them.

In part, the standards are set by the marketplace—good products generally sell better than bad products. But that doesn't keep drug or pesticide residues out of foods, for the marketplace and our laws favor technology that increases production, provided there are no bad consequences for consumers.

Take milk, for example. Cows are subject to a disease of the udder known as mastitis. It is a common disease that can be readily treated with penicillin. The marketplace would dictate that penicillin be used for such treatment. But any traces of penicillin in milk of recently treated cows can adversely affect those people who are sensitive to this antibiotic.

So, milk has to be tested for penicillin, and that which contains penicillin has to be rejected for marketing. Every day thousands of dairies across the country use the penicillin screening test prescribed by the Association of Official Analytical Chemists (AOAC). It's just one of the practical uses of AOAC methods that protect consumers 24 hours a day. In the case of milk, incidentally,

the farmer gets paid for his milk according to results of other AOAC methods that measure fat, protein and total solids.

AOAC is a scientific institution that makes possible the effective application of the laws, regulations and standards that insure safety and fair dealing in foods, drugs, cosmetics and a lot of other products. It does this by testing, validating and approving methods of analysis developed by its members and used in laboratories throughout the United States and the world.

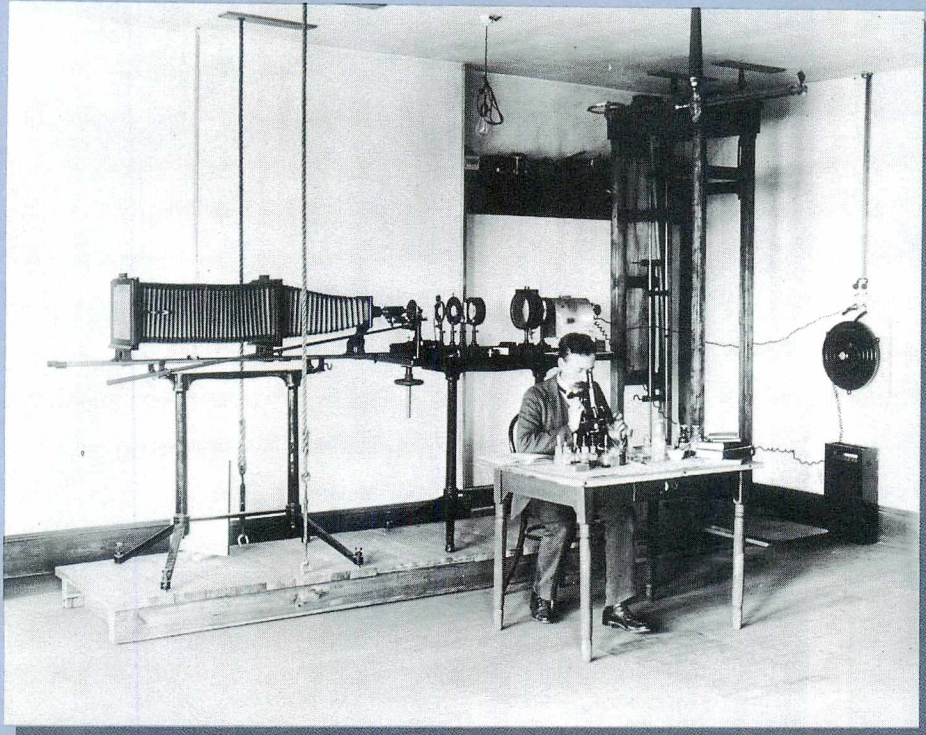
The AOAC itself has no laboratories, conducts no research, performs no tests. The actual work of devising, improving and testing methods is done in the laboratories of AOAC members, who include staff scientists of federal, state and municipal regulatory agencies, experiment stations, colleges and universities, commercial firms, consulting laboratories, and the like. AOAC serves as the center for receiving and evaluating the results of scientific studies, giving official sanction to the acceptable methods, and publishing and disseminating them.

In brief, the system works like this: The AOAC recognizes the need for a method of analysis and appoints an associate referee to work under a general referee, who is an expert in the same or an allied field. The

associate referee may devise an original method or adapt a known method for the particular need. After he has done enough experimental work in his own laboratory to satisfy himself that the method is suitable, he writes directions for carrying out the method in such a form that they can be followed with success by any competent and experienced analyst. He then sends the instructions and whatever else is needed to analysts, called collaborators, in other laboratories who are willing to cooperate in an objective test.

Each collaborator works independently to analyze the sample, whose composition is not revealed, following the method in every detail. The associate referee coordinates all results and any further work needed and makes recommendations to the general referee.

The general referee evaluates the associate referee's report and in turn makes a recommendation to the appropriate committee of the AOAC Official Methods Board. The committee passes upon the recommendations of the general referee and makes final recommendations to the association. If the association then votes approval at its annual meeting, the method is adopted as official. Every five years the new and reviewed methods are compiled, added to those of previous
(Continued on page 15)



A test that has stood the test of time is the Howard Mold Count, used to determine whether decomposed ingredients have been used in food products. Below, the test is performed by its developer, Dr. B. J. Howard, in 1939. The Howard Mold Count remains one of the official analytical methods of the Association of Official Analytical Chemists. At left, a younger but no less diligent Dr. Howard is at work in the Bureau of Chemistry (the forerunner of the Food and Drug Administration) at the turn of the century. Behind him is a microphotography apparatus he developed to identify such then-common frauds as ground charcoal in pepper and starch in cocoa.



OFFICIAL
METHODS OF ANALYSIS
OF THE
ASSOCIATION OF OFFICIAL
ANALYTICAL CHEMISTS

Regarded as the "bible" in laboratories testing food, agricultural and other products is the how-to manual Official Methods of Analysis of the Association of Official Analytical Chemists (left). Below, the manual provides step-by-step instructions for insuring that canned fish (in this case, salmon) are correctly identified on the label. The scales serve as the fish's tell-tale "fingerprints."

302

18. Fish and Other Marine Products

AOAC Methods (1980)

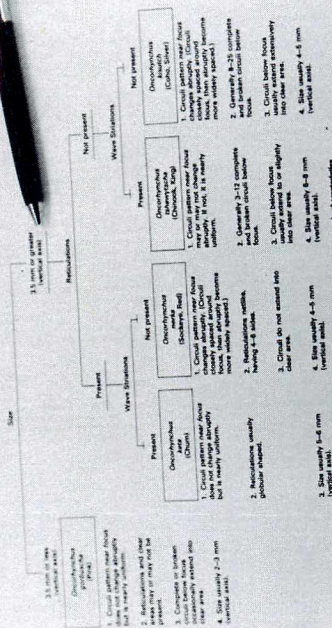


FIG. 18-10—Key to identification of canned salmon species by scale characteristics.

AOAC Methods (1980)

Fish Species

303

(a) Breasted raw sticks and portions—Remove breeding by soaking for few sec. in H₂O and scraping off breeding with spatula. Treat in same manner as in (b) or (c).
(b) Precooked sticks and portions—Trim breeding and all surface meat until internal center section remains. Treat as in (a).

Determination

Soak cellulose polyacetate strips 30 min in buffer (soaking is required to bring strips back to original gel structure). Use new buffer supply each time. Since 6 strips can be run simultaneously, each with different sample, identify each strip with pencil notation before soaking.
Add chilled (1°C, 34°F) buffer to each chamber of cabinet and level to point slightly below compartment dividers. Remove 1 strip from buffer and gently blot between sheets of filter paper to remove excess buffer.

Take up sample of tissue fluid into capillary tube and transfer to applicator. Draw capillary tube along applicator to within 6 mm of both ends. Then press applicator firmly against strip about 5 cm from one end. Place strip containing sample across cabinet dividers so that sample is on cathode side and both ends are immersed in buffer in the 2 outer chambers. Secure cabinet dividers so that sample is on cathode side and both ends are immersed in buffer in the 2 outer chambers. Secure cabinet dividers so that sample is on cathode side and both ends are immersed in buffer in the 2 outer chambers. Secure cabinet dividers so that sample is on cathode side and both ends are immersed in buffer in the 2 outer chambers.

Identification of Canned Pacific Salmon (1980)—Official First Action

Appearance and Reagent

18.097

(a) Microscopes.—(1) Wide-field; and (2) compd, with variable iris diaphragm.
(b) Glycerol jelly.—To 60 mL H₂O add 5 g gelatin and heat gently until completely dissolved. Add 40 mL glycerol and 0.5 g phenol, and mix. Cool and store in closed container at room temp.

Method

18.098

Empty entire contents of can into pan. Remove as much skin as possible from meat with aid of spatula and place skin in petri dish. Keep skin surface moist with H₂O at all times. If skin is allowed to dry, scales will curl, become brittle, and be unsuitable for mounting. Examine skin under wide-field microscope, using ca 10 \times magnification. Scales generally will be inside folds of skin (scale pockets) with portion of one end of scale protruding from pocket. Scan entire surface of skin, and select largest and most nearly intact scales available. This is very important; if size difference is seen on same piece of skin, larger scales will have the most intact clear areas, and also internal scale pattern will be more complete.
Gently insert thin-tipped spatula well underneath whole scale between bottom side of exposed portion of scale and skin.

Completely fluid back this entire portion to make whole scale visible. Again, gently insert spatula between scale and skin and remove scale with back-and-forth motion. While keeping scale moist with H₂O, rub very gently with small tool, such as artist's brush, to remove any adhering skin or foreign material. Place small amt glycerol jelly on microscope slide and melt by placing slide on heat source. Pick up scale with spatula and remove any excess H₂O by touching gently to towel. Place scale on jelly and cover with cover glass. If scale curls during mounting, invert, uncure, and cover quickly. Examine under compd microscope at 25–50 \times , using transmitted light. Adjust light intensity for optimum contrast of scale patterns.

Examine whole scales, with intact clear areas, avoiding undamaged, distorted, or damaged scales. Intact clear area must be present for accurate identification (except pink salmon). Do scales in Figs. 18-07–11 with pertinent features noted. Examine sufficient no. of scales to ensure pink identification.

Precautions.—Use only scales that contain distinct wave striations and reticulations for comparison with key and photographs. Scale patterns of coho and chinook species are somewhat similar. Circuli extending into clear area (coho), and wave striations in clear area (chinook) can be mistaken for each other.

Note differences in Fig. 18-08 carefully. Coho and chinook scales have only few striations. Coho and chinook scales are both reticulated, but sizes and shapes of this feature differ. Under low (30 \times) power, coho reticulations appear globular, or like small round air bubbles; in sockeye they are netlike, 4–6 sided, and larger.

When pink salmon scales occur with reticulations and intact clear area, they may be differentiated from sockeye by their length. Vertical axis of pink is >3.5 mm; of sockeye <3.5 mm. Relative size of scales (set length of vertical axis) is important in identification of all 5 species; chinook and coho have largest scales (7 and 6 mm, resp.), coho and sockeye scales are 4–5 mm, and pink salmon scales (leastly recognized) by their small size are <3.5 mm.

Distorted scales which are damaged, have hard rib-like structure, or are distorted (all circles surrounding focus are completely missing with the void extending about half way to scale edge)



FIG. 18-07—Sockeye (red) salmon scale (Osteichthys markii). 10 \times . Reticulations. Not like dimensions at junction of circuli and clear area. B. Clear area.



The [AOAC] manual, a bible for industry and regulators, runs more than 1,000 pages, about 75 percent relating to foods and agricultural products such as fertilizers and pesticides.

years, and published in book form as the Official Methods of Analysis of the Association of Official Analytical Chemists. The manual, a bible for industry and regulators, runs more than 1,000 pages, about 75 percent relating to foods and agricultural products such as fertilizers and pesticides.

To be worthy of adoption by the AOAC, a method must meet these criteria:

- It must be reliable—that is, give accurate, precise, and reproducible results when used by any qualified analyst.
- It must be practical—that is, must be as simple and as rapid as possible. Yet it must meet the test of reliability.
- It must be available to all analysts. A method involving a “trade secret” or that is part of a confidential document thus cannot be considered for adoption.

AOAC methods are subject to such careful scrutiny because, among other things, they have to be able to stand up in court. Thus far, they have stood up very well. Not once in thousands of cases has an AOAC method been invalidated. What usually happens is that the attorneys limit their questions to whether the method was followed exactly.

AOAC began 100 years ago as an

association of state and federal chemists who wanted to ensure that farmers were getting their money's worth of nitrogen, phosphorus and potash when buying fertilizer. Indeed, the original constitution of the AOAC stated that its purpose was to “secure, as far as possible, uniformity in legislation with regard to regulations on the sale of fertilizers in the different states and uniformity and accuracy in the methods of fertilizer analyses.” One of the founding fathers was Dr. Harvey W. Wiley, who was also the founding father of FDA.

Notwithstanding the word “chemists” in its name, the AOAC is involved in much more than chemistry. Of special importance are AOAC's microbiological methods for identifying such bacteria as *Clostridium botulinum*, which produces the deadly botulinus toxin, and less deadly bacteria such as *Clostridium perfringens*, salmonella, staphylococcus, and the vibrios and coliforms. Knowing which bug caused an illness is the objective of the AOAC methods, and is vital in both treatment and preventive action.

Another area of intensive AOAC study has produced reliable analytical methods for aflatoxins and other mycotoxins—toxins produced by

molds that naturally infest growing or stored crops. Seafood toxins, such as ciguatoxin, saxitoxin and tetrodotoxin (puffer fish poison), are another active field of AOAC methods development.

But all the time, as some AOAC members confront exotic new problems, others find themselves working on problems that seem to need solving not once but several times. Years ago, the adulteration of pure fresh orange juice with water and sugar was countered with analytical methods to expose the deception. But apparently the rewards are too great for the defrauders to be deterred permanently, and they have devised more sophisticated means of adulteration. Now AOAC members are again working with advanced methodology to find new ways to identify and head off those practices.

It is commonly said that government, or the law, protects the consumer. Actually, the consumer is protected because a great many people in the different industries do what is required to put out safe, clean and dependable products. For a century the AOAC and its methods have been playing a major part in this. ■

Wallace F. Janssen is FDA's historian.

Soft Contacts Need Some TLC

by Kenneth A. Bortnick



People who use soft contact lenses will find wearing them is easier and more rewarding, and that they can avoid or minimize many problems, if they know something about proper handling, inserting and removing, and caring for these relatively new types of visual aids.

Wearers need to have some knowledge about two important parts of the eye—the tear film and the cornea.

The tear film has three layers, composed of a mixture of secretions from various glands of the eye and surrounding area. Each layer has its own function. The tear film keeps the cornea wet, inhibits growth of microorganisms and creates a smooth optical surface. Each time a person blinks, new tears rewet the eye. Inadequate blinking or a deficient tear film can lead to contact lens troubles.

The cornea is the eye's front surface, upon which the contact lens rests. It's transparent and has to stay that way for good vision. The cornea does a good job when there is a normal tear film, when there is no mechanical irritation caused by dirt or the lens rubbing the eye, when there is no irritation from noxious vapors or the chemicals in eyedrops or contact lens solutions, and when sufficient oxygen is reaching the eye.

Since soft contact lenses are made of plastics that can retain water like a sponge, it's imperative to store and rinse them only in approved lens solutions. Distilled water is not sterile; and tap, spring and mineral water not only lack sterility but also contain minerals and other contaminants that build up on the lens, discolor it, and make it unwearable. Therefore, only disinfected or preserved saline solutions should be used.

Lenses generally are more comfortable in a humid environment. Dry heat and air conditioning dehumidify the air and can cause problems. Medications such as cold pills and diuretics decrease the tear film. If the eye is too dry, lenses may burn, sting or make vision fuzzy. A slowed rate of blinking will dry out the eyes. Blinking rate decreases when reading, watching TV, doing close work, and staring in general.

Deposits of various eye secretions and contaminants accumulate faster on the contact lens when it is on a dry eye, since the tear film debris is

not flushed off effectively during blinking. Coated lenses can lead to lots of problems, so adequate blinking and an adequate tear film are musts.

Wearing contact lenses of any kind reduces the amount of oxygen that can reach the cornea. Lacking oxygen, the cornea can swell with fluids, and the lenses may not fit as well, reducing the quality of vision. Vision can become hazy or steamy after a number of hours of lens wear. Leaving lenses off an hour or so permits the extra fluid in the cornea to dissipate. Therefore, the lenses should be removed at least an hour before going to bed. The cornea also swells a little during sleep, so it's good to wait an hour or so after arising, until the corneal swelling goes down, before putting the lenses on.

Soft contact lenses when in use must be disinfected every day to prevent contamination and eye infection. Each of the two ways of disinfection, cold and heat, has advantages and disadvantages.

Cold, or chemical disinfection, is the simpler system and in general allows the lenses to last longer. Upon removal from the eye, the lenses are cleaned and rinsed with special solutions and then stored in a disinfecting solution at least four hours. Putting dirty lenses in the disinfecting solution reduces its effectiveness. The solution must be changed daily since it weakens over time.

Wearer reaction to the preservatives chlorhexidine and thimerosal in some chemical disinfection solutions causes the biggest problem. These chemicals are effective, but as many as a third of all users may experience allergic type reactions. Mild reactions include dryness, itching, stinging, increased light sensitivity, nasal stuffiness, tearing, tired eyes or a gritty sensation. More severe reactions may include red swollen lids, red eyes, burning or severe discomfort. Reactions can be immediate or occur months later. Over time lenses become coated with deposits that in turn hold onto more of the preservatives. This buildup causes the delayed sensitivity reactions.

Some people may react to chemicals more at certain locations or at certain times of year. For example, a mild spring allergy might cause increased sensitivity. When a reaction

occurs, the chemical disinfecting regimen must be changed, usually to heat disinfection or to solutions without the offending preservatives.

Heat disinfection is quick and effective, and is the method of choice for sensitive eyes. Essentially, the lenses are removed, cleaned, rinsed again with special solutions, and put into their case with preserved or non-preserved saline. The lens case is then put into the electric heating unit, which completes its cycle and cuts off in 30 to 45 minutes. Usually the lenses are left in the unit at bedtime and are ready for use next morning. The unit's functioning should be checked periodically. In emergencies lenses can be disinfected by putting the case in boiling water for 15 minutes.

Heat, besides its effectiveness and speed, has another advantage. It permits use of a saline solution (one without thimerosal) for sensitive eyes or a non-preserved saline. A solution change should be made only after consulting an eye-care practitioner.

The big disadvantage of heat disinfection is that the coatings build up on lenses quicker. That's because any dirt left on the lens will be cooked onto it. Proper cleaning dramatically reduces this problem.

Non-preserved saline is available in sterile unit-dose containers or large containers, or can be made at home with special salt tablets and distilled water.

In the salt tablet and distilled water system, neither the salt tablets nor the distilled water is sterile, so it's imperative to follow the proper procedures. A fresh solution must be made daily. Once a week the plastic bottle used for mixing the solution should be boiled in water 15 minutes to kill any contaminants that might be growing in the bottle. The bottle should be rinsed daily after each use and allowed to air-dry. Distilled water should be stored in the refrigerator to minimize risk. Never apply the solution in the bottle directly to the eyes nor rinse the lens with it before insertion.

Lens deposits are a major problem with soft contact lenses. These deposits consist of tear film components, hair spray, fumes, or oil from the fingertips. Deposits can

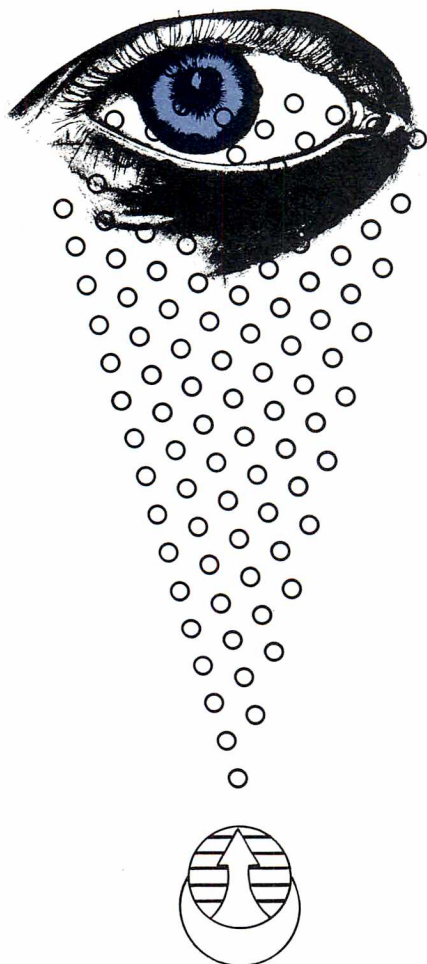
Leaving lenses off an hour or so permits the extra fluid in the cornea to dissipate. Therefore, the lenses should be removed at least an hour before going to bed.

(Continued on page 19)

Tips On Cleaning, Caring

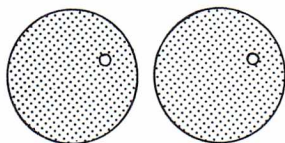
Following are some tips on keeping lenses clean:

- Never use anything that leaves a residual film on your hands before handling your lenses.
- Clean your hands well with a good "pure" soap and rinse well before handling your lenses.
- Close your eyes when using spray deodorants, insect spray, etc.
- When possible, use brands of makeup made for contact lens wearers.



wearers. Insert lenses first, then carefully apply makeup.

- Use water-based makeup and good quality mascara.
- Use distilled water marked USP (U.S. Pharmacopeia) on the label as it is the most bacteria-free.
- When available, use a generic saline solution as it is usually less expensive.
- If you don't wear your lenses for a while, clean and disinfect before wearing them again.



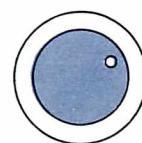
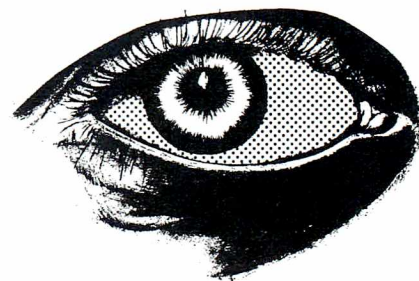
Here are some handling tips:

- Make sure the drain is closed if you handle a lens over the sink.
- Keep the nails short on the fingers that handle lenses.
- If you drop a lens, check the area below you first, as well as your clothes. A wet lens will stick to anything.
- To facilitate lens removal, put a drop of saline solution in each eye, and wait 30 seconds before removing.
- Be careful not to close the lid of the case on your contacts.
- If you're not sure the lens is on the eye, talk to your doctor. Sometimes a lens gets "lost" under the upper lid.

Here are some wearing and comfort tips:

- Make sure both lenses are in by alternately covering each eye and checking vision.
- If a lens dries out, soak it in a saline solution at least an hour and disinfect before wearing.
- A lens that has been turned inside out usually will feel less comfortable and will sit a little higher on the eye.
- If you have blurred vision in one or both eyes after insertion, you may have switched lenses by mistake. Try switching.
- Remove daily wear lenses before sleeping or naps, before swimming, or when working near fumes.
- If lenses stick to the eyes, **Never Try To Forcibly Remove Them.** If they don't loosen after about 15 minutes, try continuous flushing with a saline solution. If this doesn't work, call your doctor.

- An uncomfortable lens may be torn, coated, scratched, have a piece of dirt in it, or have rough edges.
- Blurred vision could mean a coated lens, poor position, or the need for a new prescription.
- If your eyes are irritated, don't wear your lenses. If you have a cold, don't wear them, particularly if you are taking cold medications.
- If a lens stings, burns, or the eye turns red after insertion, remove the lens, clean it, rinse well and reinsert. If it still irritates, remove it and call your doctor.
- Always have an updated pair of prescription glasses you can wear when you can't wear your contact lenses.



(Continued from page 17)

change the shape of the lens, and this may result in too much pressure on the little blood vessels surrounding the cornea, making the eyes appear bloodshot. A dirty lens may ride higher on the eye, being pulled up by the upper lid, and possibly altering vision. Constant rubbing by dirty lenses can be irritating and produce more mucus. Eventually the lenses may become too uncomfortable to wear or the buildup may cause an allergic reaction.

Surfactant and enzyme cleaners, used together, do a good job of preventing the buildup of surface deposits. Surfactants work like hand soap or detergents, removing dirt from the lenses so it can be rinsed away. Each side of the lens should be rubbed gently between a finger and the palm of the other hand for about 15 seconds, working from the center of the lens outward.

Surfactant cleaners remove surface deposits—proteins, fats, oils, protein-bound preservatives, mucus, creams and other contaminants—but they won't clean heavily coated lenses nor a denatured protein coating bound to the lens. Lenses should be cleaned with a surfactant upon removal from the eyes before disinfecting.

Most enzyme cleaners are tablets that contain the enzyme papain. This enzyme can break down protein on the surface of the lens as well as some denatured protein bound within the lens matrix itself. Some other bound tear components are removed along with the protein coating.

The enzyme breaks down a large protein unit into smaller ones but does not remove these smaller units from the lens. Therefore, after a soak in a solution of the enzyme and distilled water solution, the lens must be thoroughly cleaned with a surfactant cleaner and rinsed well. Disinfecting follows.

Enzyme cleaning should be done on heat-disinfected lenses, every one to three weeks, or for chemically disinfected lenses, every two to four weeks. When using chemical disinfection and when the lens material has a water content greater than 45 to 55 percent, it's advisable to soak the lenses in distilled water for 15 minutes both before and after use of

the enzyme solution. This helps remove residual chemicals in the lenses.

One enzyme product breaks down fats as well as proteins. Its active ingredient is the enzyme pancreatin. This tablet is mixed with a saline solution, not distilled water. Another product breaks down oils and fats as well as protein. An eye-care practitioner can advise which system to use.

Lenses dry out faster than normal on windy days, in a low humidity environment, or with dry heat in the home or car. Soft contact lens lubricants are sold to help rewet the eyes and increase lens comfort during these times. These help some people some of the time. Most brands contain thimerosal. To avoid possible contamination of the bottle, the applicator tip should never touch the eyes or lids (this applies to all contact lens bottles). Other eyedrops sold over the counter should not be used while wearing lenses. They contain chemicals that might damage your lenses.

A number of medications can affect the wearer of contact lenses. Antihistamines and diuretics can decrease tear film, as can some ulcer medicines. Birth control pills and tobacco smoke can affect comfort. Heart medications may increase sensitivity to light and glare. Patients should always inform their eye doctors about the medications they are taking.

Cosmetics cause many soft contact lens problems. If the cosmetics get under the eyelids, the eyes may itch, burn or turn red. If makeup blocks some glands on the eyelid margin, an inadequate tear film may result. Cosmetics can get onto the lenses from fingertips, from vapor in the air, or from the eyelid margins.

The average life of a soft contact lens is two years, give or take six months, depending on the disinfection system used and the care given to the lenses. Good cleaning habits will extend lens life.

Any problem not resolved upon removal of contact lenses may indicate a more serious situation and a doctor should be consulted. This would include a painful red eye, pain with excessive tearing, poor vision, and increased light sensitivity with glasses on. ■

Since soft contact lenses are made of plastics that can retain water like a sponge, it's imperative to store and rinse them only in approved lens solutions.

Kenneth A. Bortnick practices optometry in Salisbury, Md.

For Oyster And Clam Lovers, The Water Must Be Clean

by Carol Ballentine

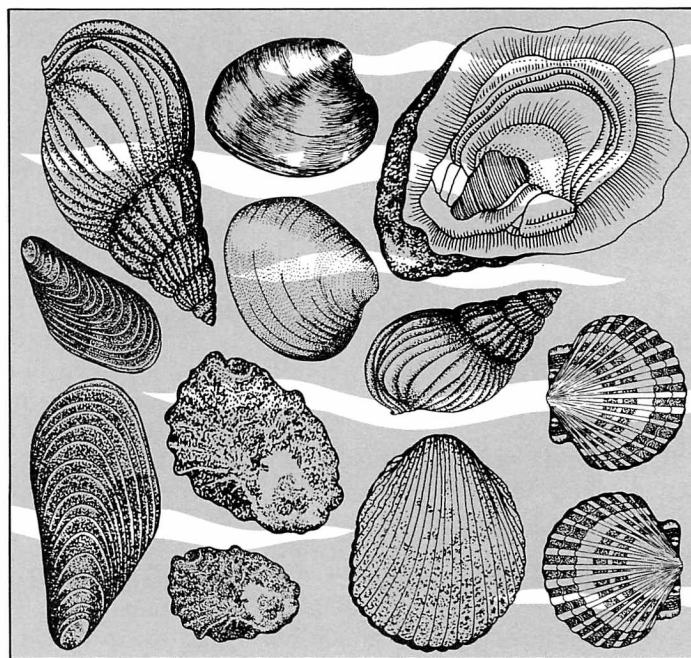
Oysters Rockefeller, clams casino, moules (mussels) marinières. These are mollusks with all the trimmings: laid on a bed of spinach, topped with bread crumbs and bacon, or mixed with white wine and parsley.

Most molluscan shellfish commonly eaten in the United States are bivalves—that is, they have two valves, or shells, hinged together. Single-shelled mollusks, or univalves, such as snails and whelks, are found more often on European menus. Bivalve mollusks include oysters, clams, mussels, scallops and cockles.

Although some clams live in fresh water and some deep in the ocean, most mussels, clams and oysters thrive in estuaries that contain mixtures of seawater and fresh water from rivers. These mollusks get food and oxygen from their surroundings by pumping large quantities of water across their complex gill systems (see diagram). Oysters can process about four quarts an hour, clams about three quarts.

They also take in whatever bacteria, viruses, chemical contaminants and other impurities are in the water. Perhaps it is a peculiar form of revenge on their human predators, but mollusks are quite happy and healthy with a gutful of organisms that are toxic, and sometimes deadly, to *Homo sapiens*. The bacteria that cause cholera and gastroenteritis, the virus that causes hepatitis A, the toxin responsible for paralytic shellfish poisoning—these are all baneful to humans but don't even give a mollusk heartburn.

What's worse for humans, mollusks have an extremely efficient method of filtration and will concentrate microorganisms at much higher levels in their guts than are found in their habitat. The level of harmful bacteria in a mollusk can be from three to twenty times that found in the water from which it was taken.



The job of ensuring that shellfish are harvested from clean waters falls to the states. Under the terms of the National Shellfish Sanitation Program (an organization comprising the Food and Drug Administration, state regulatory agencies, and the shellfish industry) state agencies prohibit shellfish harvesting in areas that are contaminated by sewage or industrial wastes or that have a high level of the organisms that cause paralytic shellfish poisoning. These areas are patrolled by state officials. (An article on shellfish sanitation and regulation will appear in an upcoming issue of *FDA Consumer*.)

Monitoring these growing areas has been effective. Typhoid fever, once the disease most commonly caused by mollusk consumption, is rarely transmitted by shellfish today. Similarly, few cases of cholera are transmitted by mollusks because only shellfish harvested from sewage-contaminated beds become carriers.

However, once mollusks enter commerce, the consumer can take some protective measures. To guard against eating mollusks that contain harmful organisms, consumers can take these precautions:

- **Obtain shellfish only from approved sources.** Shellfish shippers that meet federal standards are certified by state shellfish control authorities, and a list of such shippers is published each month by FDA. One way to help ensure that shellfish come from a certified shipper is to buy them from a name grocery store. Roadside hucksters with "bargain" prices are chancey.

Shellfish that have been illegally harvested from polluted waters are the most frequent cause of shellfish-related illness; outbreaks of hepatitis A caused by shellfish consumption, in particular, almost always are traced to illegally harvested products. The mollusks become carriers of this virus when their beds are contaminated by un-

treated sewage containing the virus, which is quite likely to cause illness since it is not always killed by cooking and never by freezing.

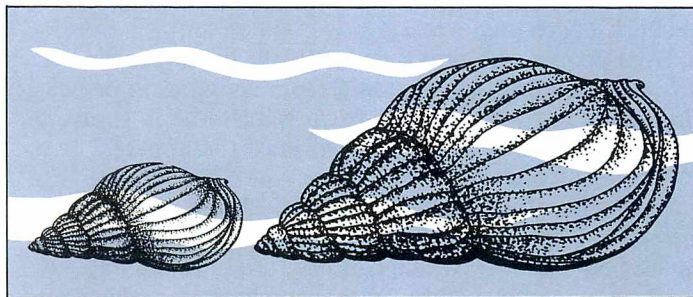
• **Obey posted warnings when harvesting shellfish.** This is particularly important when the warnings are about paralytic shellfish poisoning (PSP), frequently referred to as a "Red Tide." The neurotoxin that causes PSP blocks nerve impulses, causing paralysis of the respiratory muscles and extremities. It is so poisonous that consumption of even one contaminated mussel could be fatal.

Cleaning will not neutralize PSP toxin, nor will cooking or freezing. The best thing to do with mollusks that have been exposed to this toxin is to throw them away. There is no antidote for the toxin, and a person believed to have consumed toxic shellfish should go immediately to the hospital.

The toxin that causes PSP is produced by microscopic organisms called dinoflagellates, sometimes called plankton (see accompanying article), that belong to the

(Continued on next page)

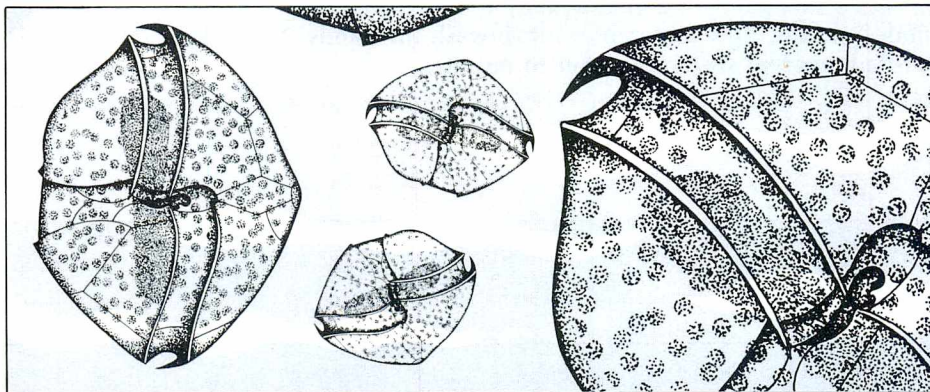
Mollusks are quite happy and healthy with a gutful of organisms that are toxic, and sometimes deadly, to Homo sapiens.



Dino Flagellates Who?

Dinoflagellates are organisms that "bloom" to create "Red Tides." They are some of the tinier denizens of the deep. If the creatures could read scientific journals, they would have a massive identity crisis because zoologists claim them as animals and botanists call them plants. They are frequently identified as a type of plankton. The confusion arises because the microscopic dinoflagellates propel themselves through the water with two whiplike appendages (flagella) and ingest solid food (animal attributes), but they're also capable of photosynthesis, using light to manufacture food (a property of plants).

Dinoflagellates are so tiny they cannot be seen unless they "bloom" in such large numbers they color the water. Much of the phosphorescence of the sea results from coloration by these plant-animals, which can be green, yellow, brown or red. The bloom ensues from a combination of factors, including a rise in water temperature, increased freshwater runoff, upwelling of nutrients, and heavy rainfall along coastal regions.



The species of dinoflagellate called *Gonyaulax* is responsible for most paralytic shellfish poisoning incidents in the United States.

Legend is that in the days before the arrival of Europeans in the Americas, the Mendocino Indians of California set one of their number to watch the color of the ocean, knowing that when it turned red the clams and mussels were not safe to eat. This may have been the best technique at the time, but it is not considered so good today.

For one thing, not all Red Tides are produced by toxic dinoflagellates.

And when the Red Tide is produced by the dangerous *Gonyaulax* species, the shellfish can be toxic for several days before the color is visible. This is especially true of mussels, which seem to be the most efficient at storing the toxin and are the most common cause of paralytic shellfish poisoning. Luckily, scientific equipment now can detect low levels of these microscopic toxin-producers, so regulatory agencies monitoring chronically affected areas can determine when shellfish are toxic without depending on the visual evidence of a Red Tide. ■

(Continued from page 21)

species *Gonyaulax*. The West Coast and New England states facing on the Atlantic Ocean monitor shellfish for these toxic dinoflagellates and post warnings when concentrations in the shellfish make them dangerous to eat.

Another neurotoxin that can cause mollusks to be an unhealthy dish is that produced by a species of dinoflagellate called *Ptychodiscus brevis*, which inhabits the Gulf of Mexico. Perennially affected areas off Florida are monitored by that state's Department of Natural Resources; consumers who want to go oystering on their own should contact this department and ask about safe shellfish harvesting areas.

Even people who don't eat shellfish, however, can get an unhealthy dose of this toxin from activities in or near the water. In rough surf the toxin is airborne in spray; when inhaled, it can cause irritation of the upper respiratory tract.

- **Keep all seafood chilled**—between 32 and 40 degrees Fahrenheit (0 to 5 degrees Celsius). All raw seafood contains some bacteria, which can proliferate rapidly at temperatures above 40 F. *Salmonella* bacteria, which can get into mollusk beds from sewage, are not killed by cold temperatures, but the cold will prevent the bacteria from proliferating.

- **Do not store seafood for prolonged periods.** Even under ideal storage conditions, fish and shellfish will deteriorate, permitting harmful bacteria to multiply.

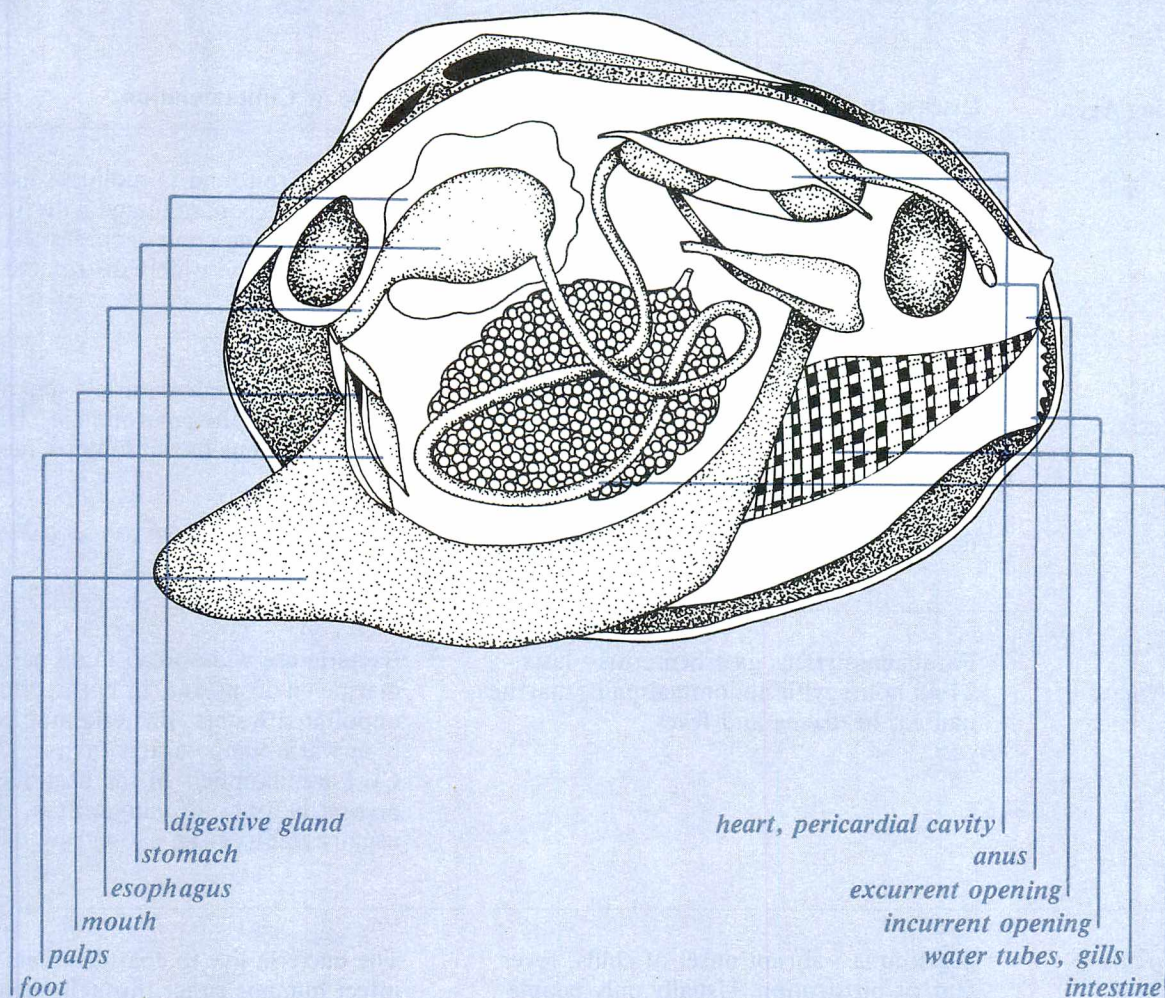
- **Observe proper sanitation when preparing seafood.** Human skin is covered with bacteria, such as *Staphylococcus*, that can contaminate many foods, including mollusks. It is especially important to wash the hands before preparing seafoods meant to be eaten raw.

Shellfish that have been illegally harvested from polluted waters are the most frequent cause of shellfish-related illness.

- **Cook shellfish thoroughly** if it comes from a questionable source. Most illness associated with shellfish is caused by eating the food raw. A typical example is the illness caused by *Vibrio parahaemolyticus*, a bacterium that occurs widely in the marine environment, including water and sediment and in both finfish and shellfish. Outbreaks of illness caused by this species occur rarely in the United States; in Japan, however, it is the most common

(Continued on page 25)





Anatomy Of A Clam

This clam can process about three quarts of water in an hour. It pulls the water into its body cavity through the **incurrent opening**, and the water flows up the **water tubes** in the **gills** (the gills actually extend to the mouth but have been cut away in the illustration to show the other body parts). Particulate matter (such as plankton) left on the surface of the gills is sorted, mostly by size and weight, and silt and other undesirable materials are rejected. Lighter particles are transported from the gills to the **palps**, a pair of folds on each side

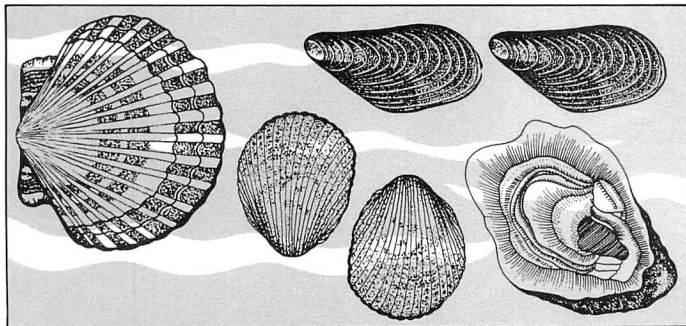
of the **mouth**, where further sorting occurs. Material acceptable to the clam's system as food goes into the mouth, and travels down the **esophagus** to the **stomach** and **digestive gland**. It winds through the **intestine**, which makes several coils through part of the **foot** and passes through the **pericardial cavity** that surrounds the **heart**, appearing to pass through the heart itself (in fact, the heart is wrapped around the intestine). The **anus** opens near the **excurrent opening**, from which the feces are carried away by the outgoing current.

Major Disease-Causing Organisms Transmitted By Shellfish

Disease-causing Agent	Disease In Humans	Mode of Contamination
<i>Vibrio cholerae</i> -01 bacteria	Cholera—ranges from subclinical (a mild uncomplicated bout with diarrhea) to fatal (intense diarrhea with dehydration). Severe cases require hospitalization.	Bacteria are found in mollusks harvested from waters contaminated with human sewage. During cholera epidemics, the bacteria may be widely distributed.
<i>Vibrio cholerae</i> non-01 bacteria	Gastroenteritis—diarrhea (mild to severe), vomiting, fever, abdominal cramps. Lasts 1-2 days. The bacteria can cause septicemia (chills, fever, prostration) in people with liver disease.	The bacteria occur naturally and are widely distributed in the environment. They are more numerous in the summer months.
<i>Vibrio parahaemolyticus</i> bacteria	Parahaemolyticus gastroenteritis—lasts 24-48 hours with abdominal pain, diarrhea, nausea, headache and fever.	Bacteria are widespread in all parts of the marine environment, in both polluted and unpolluted waters. Bacteria multiply rapidly in warm temperatures (above 37 degrees C). Large numbers of the bacteria must be present before poisoning occurs. Illness usually results from eating raw shellfish.
<i>Vibrio vulnificus</i> bacteria	Septicemia—abrupt onset of chills, fever and/or prostration. Usually only people with liver disease are at risk.	The bacteria live in coastal waters and can infect humans either through open wounds or via the gastrointestinal tract (through consumption of contaminated seafood). The bacteria are more numerous in warm weather.
<i>Salmonella</i> bacteria (more than 1,700 kinds)	Salmonellosis—nausea, fever, headache, abdominal cramps, diarrhea and sometimes vomiting. Can be fatal in infants, the elderly, and the infirm.	Mollusks usually acquire only small numbers of <i>Salmonella</i> bacteria in the water. Unsanitary handling can allow the bacteria to multiply to the point that food poisoning occurs.
Hepatitis A virus	Hepatitis—begins with malaise, appetite loss, nausea, vomiting and fever. After 3 to 10 days the patient develops jaundice with darkened urine. Mild cases often are mistaken for flu; severe cases can cause liver damage and death.	Mollusks become carriers when their beds are polluted by untreated sewage. Raw shellfish are especially potent carriers, although cooking does not always kill the virus.
Norwalk virus	Gastroenteritis—causes transient flu-like symptoms, including nausea, vomiting, diarrhea and abdominal pain.	The virus enters the mollusks' environment in untreated sewage. Raw shellfish are especially potent carriers.

Major Disease-Causing Organisms Transmitted By Shellfish (Continued)

Disease-causing Agent	Disease In Humans	Mode of Contamination
<p><i>Gonyaulax</i>, a genus of dinoflagellate ("plankton"). Major species causing PSP in the U.S. are: <i>G. tamarensis</i> (East Coast) <i>G. catenella</i> (West Coast)</p>	<p>Paralytic shellfish poisoning—Symptoms occur within 30 minutes of ingestion and include tingling, numbness or burning sensation in the lips, gums, tongue and face. This progresses to muscular weakness, respiratory paralysis, and gradual paralysis of the extremities. PSP CAN BE FATAL. Medical help should be obtained immediately.</p>	<p>Mollusks become poisonous after eating one of several species of dinoflagellates. The dinoflagellates produce neurotoxins that may not affect the mollusks but are deadly to humans. The organisms are especially prolific during warm weather. In great numbers they can cause the ocean to turn color in the phenomenon known as "Red Tide."</p>
<p><i>Ptychodiscus brevis</i> (formerly <i>Gymnodinium breve</i>), a dinoflagellate found in the Gulf of Mexico that causes Florida's Red Tides.</p>	<p>Neurotoxic shellfish poisoning—similar to but milder than PSP. Symptoms include tingling of the extremities, reversal of hot and cold sensation, vomiting and diarrhea.</p>	<p>Contamination occurs as with paralytic shellfish poisoning. In addition, the toxins produced by the dinoflagellates can be airborne in rough surf, and when inhaled can cause respiratory irritation, including runny nose and nonproductive cough.</p>



(Continued from page 22)

cause of summertime food illness because in that country it is customary to eat fish products raw.

Worm-borne infections that result from mollusk consumption are found primarily in the Pacific and Far West, where fish are commonly eaten raw. Cooking kills these parasites. Transmission of parasitic diseases by shellfish is not a problem in North America or Europe.

Cooking will kill bacteria, such as *Salmonella* and members of the *Vibrio* species. However, as noted, only very high heat will destroy hepatitis A virus, and no amount of cooking will completely deactivate the toxins that cause paralytic shellfish poisoning.

• **Do not eat raw seafood if you have liver disease.** A person whose liver is weakened by disease is particularly susceptible to a newly identified species of bacteria, *Vibrio vulnificus*, described as the *Vibrio* species most likely to kill. The bacteria can enter the body through an open wound (such as a cut from a mollusk shell) or by ingestion and usually causes mild infection; however, the infection can lead to septicemia (fever, chills and prostration)

in people with liver disease. Illness caused by *V. vulnificus* is associated with a 40 percent mortality rate, according to an article in the *Journal of the American Medical Association* (January 1984). Infections tend to occur in men over 40, particularly shellfish shuckers; wounds are the usual source of transmission, but consumption of raw oysters has been linked to the infection.

Another recently identified species of bacteria particularly hazardous to those with liver disease is *Vibrio cholerae* non-01. This is a relative of the bacterium that causes the disease cholera (called *Vibrio cholerae*-01). The non-01 form, unlike its classic relative, is a normal part of marine flora and is widely distributed in brackish surface waters, particularly during the summer months. It can cause a variety of gastrointestinal diseases similar to cholera, but milder, in anyone exposed to it. It can also cause septicemia in those with liver disease.

• **Eat mollusks when the weather is cold.** There may have been some wisdom in the old saying about eating clams and oysters in months with an "R" in them, which means the chillier months. Levels of bacteria and the dinoflagellates that cause PSP tend to decrease when the water gets colder. Cold water also puts a damper on the appetites of many mollusks, and thus they do not accumulate harmful organisms. ■

Carol Ballentine is a member of FDA's publications staff.



Diet and the Elderly

Research Points To Some Special Needs

This is the second in a series on dietary needs of the elderly.

by Chris W. Lecos

A growing amount of research into the way elderly men and women eat and live is expected to produce new recommendations on the specific nutrient needs of this rapidly growing segment of the American population. Some studies now under way suggest that the elderly have special dietary requirements and that some of them may need more of certain nutrients than they did when younger.

The data are indicating that many elderly Americans, especially women, don't get enough calcium and that some older citizens may have other deficiencies in their day-to-day diets.

In one study conducted under a grant from the National Institute on Aging, separate panels of scientists analyzed the information available for six essential nutrients—calcium, vitamin D, iron, folate, thiamine and zinc. The panelists looked at the consumption of the nutrients by the elderly, the dietary requirements of the elderly (as far as they are known), and any known association of inadequate intake with specific diseases. In reporting their findings, however, the panelists stressed that it was difficult to evaluate the nutritional status of elderly people because information about specific needs was lacking.

"Few studies of nutrient requirements have been done on the very old," they reported. "There also is a great need for more effective techniques to detect deficiencies in the elderly."

The panels—whose findings were published in a November 1982 supplement issue of *The American Journal of Clinical Nutrition*—concluded that calcium deficiencies are prevalent among many older Americans but that consumption of four other nutrients—folate, thiamine, vitamin D and iron—appeared to be generally adequate. The panelists also said that consumption of zinc may be less than desirable but that data supporting such as "impression" is too limited to permit a firmer conclusion.

Many researchers believe that a deficiency of dietary calcium is a factor in osteoporosis, a disease that leaves the bones brittle and the individual prone to fractures, a common injury among the elderly. (See "Please Pass That Woman Some More Calcium And Iron" in the September 1984 *FDA Consumer*.) Of primary concern are women, whose calcium intake is usually less than that of men. Far more elderly women than men suffer from osteoporosis.

Generally, bone strength increases until about the age of 30 to 35. Thereafter, it begins to decline until menopause. Then, following menopause, the amount of bone loss in women tends to accelerate during the next three to seven years, possibly as a result of decreased estrogen levels associated with post-menopause. The panel further noted that as people get older—especially women—they tend to consume fewer calcium-rich foods,

Many researchers believe that a deficiency of dietary calcium is a factor in osteoporosis, a disease that leaves the bones brittle and the individual prone to fractures, a common injury among the elderly.

such as milk, cheese and other dairy products. The situation is further aggravated, the panelists noted, by reduced physical activity as a person ages. Bone renewal is aided by exercise. Women may face a greater risk from osteoporosis in later life because their bone mass is generally less than that of men to begin with.

The panel concluded that women of all ages need to consume more calcium, and they stressed that it is important for women to develop the habit of eating plenty of calcium-rich foods when young and to continue doing so throughout life.

Vitamin D is needed along with calcium to maintain healthy bones. It can be obtained by exposure to sunlight and by consuming foods fortified with vitamin D, by eating foods in which vitamin D is naturally present (liver, eggs and saltwater fish), and by taking dietary supplements. Absorption of vitamin D declines with age and many older people are less exposed to the sun, the report noted. However, the panel of scientists investigating this nutrient reported that most elderly people in the United States have adequate vitamin D levels, which is related to many foods being fortified with the nutrient as well as to the use of vitamin supplements in this country. Deficiencies, however, may occur among those who are ill, those confined to institutions, those who are heavy alcohol and drug users, and those whose food budgets are limited by small incomes (factors that could lead to deficiencies of other nutrients as well).

Iron, which plays a vital role in transporting oxygen to body cells and in the cells' utilization of oxygen, is generally adequate in the diets of most elderly people, another panel concluded. Inadequate dietary iron can lead to iron deficiency anemia. The body's need for iron is not believed to be any greater in the elderly than in younger adult males, and lower than those for children and menstruating women. The Food and Nutrition Board of the National Academy of Sciences noted in its 1980 report that of all the trace minerals, deficiency of dietary iron probably is the one that poses the greatest nutritional concern, particularly for infants and children, pregnant women and women of child-bearing age, and older people with low food intakes.

Folate deficiencies also can lead to anemia, but the scientists said they could find no evidence that such deficiencies are a main factor in anemia problems of the elderly. The principal exceptions, they said, are hospital patients, people on medicines, and alcoholics. The panel's

view was that folate intake among the elderly is "probably adequate."

Thiamine (vitamin B₁), which is necessary for the healthy functioning of the nervous system, also was considered adequate by the panelists, although they indicated that alcoholism can interfere with absorption of the vitamin. Severe disease and poverty, of course, can affect dietary intake of thiamine and other nutrients as well. Severe deficiencies of thiamine have been associated with neurological disorders and heart disease, but such deficiencies are seldom seen in this country.

Acknowledging the lack of data, another panel tentatively concluded that zinc intake may be inadequate in some elderly people. Meats, seafoods and eggs are especially good food sources of zinc. A mineral, zinc is essential for various metabolic processes such as the functioning of enzymes. The healing of wounds and the body's immune response—that is, its ability to resist disease and infection—can be affected if zinc is consumed in inadequate amounts. Nutrition authorities generally agree, however, that severe zinc deficiency is rare in this country.

Two other nutritional surveys now under way also are expected to shed more light on the special nutritional needs of the elderly. One, a five-year project scheduled for completion by the end of 1984, involves 270 healthy men and women aged 60 and over. It is being conducted by Dr. James S. Goodwin, chief of gerontology at the University of New Mexico's department of medicine. The other is a nutritional survey of 1,000 men and women between 60 and 102 in the Boston area. It is being conducted by the U.S. Department of Agriculture's Human Nutrition Research Center on Aging at Tufts University in Boston.

Goodwin's project, supported by the National Institute on Aging, is designed to determine the consequences of subclinical malnutrition—deficiencies that do not cause obvious symptoms—in healthy people, and whether there is any correlation between nutritional deficiencies and the decreasing ability to resist disease as people age. The Tufts project, now in its second year, is attempting to examine the relationship between diet and aging and to establish recommended dietary allowances for older people. The Tufts data is being analyzed, with final results expected to be issued in late 1985.

The 270 volunteers participating in the Goodwin study are free of major illnesses and take no prescription drugs.

Low consumption of dairy products and insufficient exposure to sunlight may be principal reasons for [vitamin D] deficiencies.

They live independently in the community, can afford to buy a variety of foods, and are considered generally knowledgeable about nutrition. Sixty percent of them regularly take one or more vitamin and mineral supplements. Their food intake also is part of the study.

Goodwin's preliminary findings indicate that the diets of the 270 men and women are generally adequate except for the intake of calcium and vitamin D among the women. Goodwin's dietary intake data suggest that more than two-thirds of the women consume less than the recommended dietary allowance (RDA) for calcium, and slightly more than half take in less than the RDA for vitamin D. (To make his comparisons, Goodwin is using the recommended dietary allowance levels set by the Food and Nutrition Board of the National Academy of Sciences.)

Goodwin also has found that blood levels of vitamin D in some of the volunteers appear to be "very low." Scientists are using laboratory measurements of blood plasma levels rather than measuring dietary intake to get more accurate data on the subjects' nutritional status.

Low consumption of dairy products and insufficient exposure to sunlight may be principal reasons for the deficiencies, according to Goodwin. That's a surprising finding considering that the volunteers live in a relatively warm, sunny climate. Goodwin believes that many elderly people avoid the sun to minimize the risk of skin cancer and that participants are not consuming many dairy products in order to lower their fat and cholesterol intakes. Another possibility, Goodwin speculates, is that some of the participants may have a decreased ability to absorb vitamin D, as absorption of the vitamin declines with age.

Generally, Goodwin's preliminary findings indicate that most of the participants are consuming more vitamin C than they need—about 2.4 times the RDA. More than half the volunteers are taking vitamin C supplements. Excess vitamin C is not stored by the body but is excreted in the urine.

Goodwin's preliminary data thus far indicate that riboflavin (vitamin B₂) intake appears to be generally adequate for both sexes, although women consume smaller amounts than men. Young adults generally are at greater risk of riboflavin deficiency than other people.

Many of the volunteers are taking "megadose supplements" of vitamins and minerals, defined as at least five times the RDA, and Goodwin has reported that the most popular supplements are vitamins C and E. Good-

win is attempting to assess the effect of such large supplement use on the immune system—which affects the body's ability to resist disease and infections—by making comparisons between those taking large amounts and those taking no supplements. So far, he has found that taking large doses of supplements has "very little effect."

The National Institute on Aging's "Special Report on Aging 1983" noted that this finding suggests that "although other scientists may have noted a temporary rise in immune response following short-term trials of megavitamins, this effect is not a lasting one."

The Tufts project is indicating that older people have different nutritional requirements for some nutrients than do their younger adult counterparts. It also is indicating that some nutritional problems of the elderly arise from the way some live. Less interest in food by those living alone, more emphasis on snacking than eating regular meals, and the effect of medications on nutrient intake are some of the factors cited.

The study has provided evidence of how absorption of some nutrients, such as folic acid, is adversely affected by changes in the intestinal system of older persons. Folic acid is needed for the formation of hemoglobin in red blood cells.

The project also has indicated that many of the elderly participants are consuming less calcium, thiamine, riboflavin and vitamin K than younger adults. Vitamin K is needed for clotting of blood.

The Tufts researchers tentatively concluded that elderly people may need not only certain specific nutrients but more than they did when they were younger, according to Dr. Jeffrey Blumberg, assistant director of the Tufts research center.

"We're questioning the basic assumption that old people require smaller amounts of nutrients because their bodies are slowing down and because they're less active," he said. "While their calorie requirements may be diminished because they're less active, their nutrient requirements are the same or may be even greater than they were. Perhaps if elderly people get more of certain nutrients, the aging process may slow down." ■

Chris Lecos is a member of FDA's publications staff.

NEXT: Do the elderly need more vitamin and mineral supplements?

BOTULISM TRACKING



How Onions And A Baked Potato Became Sources Of Botulism Poisoning

by Roger W. Miller

Botulism is a food poisoning illness of superlatives: extremely dangerous but very rare. It can be treated with an antitoxin that has severe side effects, but the treatment must be fast. If the poison isn't checked, it can be deadly or bring on an illness that requires long hospitalization.

Considering all the food prepared daily in this country, it is surprising that botulism doesn't occur more often. But the conditions to create it must be ideal. First, *Clostridium botulinum*, the bacterium that produces the poison, must be present. These bacteria are widespread in the environment and are considered by some to be ubiquitous. Second, the bacterium that produces the deadly toxin must be treated to an atmosphere that's free of oxygen and to temperatures that are just warm enough but not too warm. Those conditions have to be held long enough for the toxin to develop. In addition, acid will prevent the growth of the organism and the production of toxin. Therefore, high-acid foods such as tomatoes are almost never a problem. And after all that, the toxin itself can be destroyed by high temperatures, as used in cooking foods.

A majority of the cases of botulism reported in this country involve home-canned, low-acid vegetables such as green beans, corn, beets and peppers. But two of the more recent cases were unusual in that the sources were restaurants and the products were onions and potatoes, which had not been canned. One of the cases

ended up being the nation's third worst outbreak of botulism since 1899. The events leading up to the poisonings were in both cases innocent, such as might be repeated in other restaurants or in people's homes.

The severe outbreak occurred in October 1983 in Peoria, Ill., where 28 people who had eaten in a shopping center restaurant were hospitalized. One later died; several others were hospitalized or virtually incapacitated for months.

The 28 victims were among an estimated 1,863 persons who had eaten at the restaurant over a three-day period. And 24 of the 28 had eaten a "patty melt" sandwich with sautéed onions, a statistic that implicated the sandwich as the source of the poisoning. But which item in the sandwich? The toasted rye bread, the hamburger patty, the American cheese, the onions sautéed in margarine, the pickle served with it? And how many of those who became ill actually ate the tomato, french fries, baked potato or garnish of lettuce offered with the patty? Finally, there was the question of the four victims who hadn't ordered patty melt sandwiches.

Investigators who checked a control group consisting of other people who had eaten at the restaurant during the period but didn't become ill were able to implicate the onions. For example, 17 of the controls had eaten the patty melt and had not become ill, but only 10 of the 17 had eaten the onions, while all 24 of those who became victims had eaten the onions with their

The events leading up to the poisonings were in both cases innocent, such as might be repeated in other restaurants or in people's homes.

patty melt sandwiches.

That was enough circumstantial evidence right there to implicate the onions. But there was more. The onions were grown in a three-state western area known to have *C. botulinum* spores in the soil. Testing of the wrapper from a patty melt sandwich taken home from the restaurant showed the presence of botulinal toxin.

No onions or garbage remained by the time the investigation was under way. But onions in the restaurant's supply bin were tested, and botulinum organisms were found on the skins of five of 75 whole onions.

But if the onions were the source, how come four people who didn't eat the sautéed onions got poisoned? Simple enough: Utensils were used interchangeably on foods in the cooking area of the restaurant, a not uncommon practice in many restaurants and households.

So the onions were indicted.

But an indictment isn't a conviction. Yet to be explained was how the conditions—proper incubation temperatures, lack of oxygen, etc.—were created to activate the spores into vegetative bacteria that would produce the deadly toxin. To find out, the investigators had the restaurant's chef cook up a batch of sautéed onions in the usual manner. His method was to slice up six or seven large onions, place them in a pan with two 1-pound blocks of margarine, and sprinkle them with paprika, garlic salt and chicken base powder. Boiled for 10 to 15 minutes,

the onions were transferred to an 11-quart steam table tray and then placed on the corner of a warm stove where they remained for the day.

The investigators re-created the chef's method in the laboratory. After 48 hours, the deadly toxin was present. They had found that although the onions were at 192 degrees Fahrenheit immediately after cooking, they were down to 120 degrees in two hours, and stabilized at 106 degrees. The last temperature is not only well within the range for incubating the bacteria that cause botulism but also very close to the optimum incubation temperature of about 90 degrees. Spores can be killed by heat, but only at high temperatures produced by pressure cookers or commercial steamers.

As to what created the anaerobic (oxygen-free) environment, the answer was the margarine, which sealed the onions off from outside air.

The only difference between the laboratory method and that of the restaurant was that the restaurant people said a new batch of onions was cooked daily, while the lab experts required 48 hours to re-create the problem.

The investigators in the case included Donald A. Kautter, of the Division of Microbiology in FDA's Center for Food Safety and Applied Nutrition, plus representatives of the Illinois Department of Health, the Peoria City/County Health Department, and the U.S. Centers for Disease Control.

The other botulism case involving an unlikely suspect, the potato, occurred in Baton Rouge, La., in May of this year. A 37-year-old woman was hospitalized with slurred speech, blurred vision and respiratory problems—all signs of botulism. The woman had eaten lunch with a friend at a local restaurant. The friend had not become ill, although the two had exchanged food. What they had not exchanged was the baked potato which, the victim had remarked, was "screwed up."

But the potato was suspect before that remark was learned of. The owner of the restaurant, when contacted by health authorities, explained that he had prepared the potato differently on that day. It seems the two women had come into the restaurant before opening time. They were served nevertheless. The baked potato selected was one that had been left over from the day before. As it had previously been baked in a foil wrapper, the owner merely reheated it before serving. It had remained at room temperature overnight.

Those circumstances seemed right for activation of the botulinum spores. And sure enough, a foil-wrapped baked potato was recovered from the restaurant's garbage and sent to FDA's Dallas district laboratory, where an analysis was positive for type A botulinal toxin, the same type recovered from the victim. ■

Roger W. Miller is editor of FDA Consumer.

The Way Of Botulism

Botulism, unlike most food poisoning, does not do its dirty work in the gastrointestinal tract. Botulinal toxin, once absorbed into the tissues, blocks neural function at the nerve endings and produces paralysis. This affects the breathing apparatus, and death usually comes from inability to breathe or other respiratory complications. There are no mental disturbances until shortly before death. There is no fever and the pulse remains normal to slow. Blood, urine and spinal fluid are usually normal.

In foodborne botulism (as distinct from wound botulism and infant botulism) the onset of symptoms is abrupt, usually beginning 18 to 36 hours after ingesting the toxin, although cases have varied from four hours to eight days. Paralysis begins with the nerves on the head and progresses downward, from the eyes and face to the throat, chest, and arms and legs. When the diaphragm and chest muscles become fully paralyzed, breathing becomes impossible and death results.

Common early signs are weakness or lassitude, dry mouth, double vision or other visual malfunctions, and increasing difficulty in speaking and breathing. Vomiting, nausea, abdominal cramps and diarrhea may occur before neurologic symptoms do. Pneumonia may develop as a complication.

It's possible to diagnose botulism entirely from clinical symptoms, but differentiation from some other diseases is difficult. Some diseases with which it may be confused: Guillain-Barré syndrome, poliomyelitis, stroke, myasthenia gravis, tick

paralysis, and curare or belladonna poisoning. Conclusive evidence is furnished by isolation of the organism from the feces and (so as to trace the source) from the contaminated food, if available.

Human poisoning is usually caused by *C. botulinum* toxin types A, B, E or F. Antitoxins are available from the U.S. Centers for Disease Control, Atlanta. Antitoxin should be given as soon after diagnosis as possible, after weighing the risks against the possible benefits. It may be helpful if given as long as 30 days after the toxin has been ingested. Antitoxin will not reverse binding of toxin already bound to the tissues, nor will it reverse nerve damage already done, but it may slow or halt the disease's progress. With antitoxin use there is a risk of an allergic reaction to the horse serum in the antitoxin, or of serum sickness, a kind of drug hypersensitivity.

Botulinal toxin can enter the body through ingestion, inhalation, or absorption through the eye or a break in the skin and special precaution is needed in handling contaminated materials, which should be done by persons who have been immunized by toxoids. Pets may develop botulism from eating the same contaminated food.

For more information about food poisoning, see "Who, Why, When And Where Of Food Poisons" in the July-August 1982 issue of *FDA Consumer*. ■

—Harold Hopkins

The Flaw In Cytotoxic Testing:

There's No Proof It Works

by Richard C. Thompson

Cytotoxic testing is touted as a way of tracking down and curing ills by on-the-spot testing of blood for food allergies. While the idea may sound plausible, there is no proof it works.

Yet such testing has been highly promoted. The promotions began in 1983 with newspaper ads that invited investors to get into the "profitable field" of allergy testing.

For an investment of about \$30,000 the promoters supply test kits and training and show the investor how to operate an allergy clinic. The investor purchases the kits, chooses the location, and provides clinic staff.

Ads were run in national newspapers, among them *The Wall Street Journal*. The ads said investors could get rich using "a scientific breakthrough that charts 245 food allergies simply and efficiently."

Within weeks, storefront clinics began appearing around the country and FDA began receiving inquiries from

the news media, consumers and health professionals.

But these ads to investors—and later ads by the operators themselves—misrepresent the nature of cytotoxic testing. It is not an accepted clinical procedure, and the significance of the test results, if any, has not been established.

The promoters also claim that only a business permit is required to operate a clinic and that cytotoxic testing is "nutritional analysis" and not subject to federal or state regulation. But they are mistaken. The food extracts used are biologics licensed by FDA; thus they are prescription drugs that can be ordered only by a physician. Using them in a blood test gives FDA added jurisdiction under medical device laws. And the clinics themselves may require licensing by state or local health authorities.

In cytotoxic testing, about 10 cubic centimeters (one test tube) of blood are taken from the patient. The white

CYTOTOXIC FOOD TESTS A NEW HEALTH APPROACH

Do you occasionally suffer from headaches, stomachaches, sinus problems, skin problems and rashes, overweight difficulties (even that last 10 lbs that won't come off), stress, fatigue, water retention or any combination of the above? Doctors and nutritionists say food may be the cause.

A new revolutionary nutritional blood test called CYTOTOXIC shows how an individual's system may react poorly to certain foods.

The CYTOTOXIC test is a detailed examination of food and chemical sensitivities. Results are determined by measuring the destruction of your white blood cells caused by exposure to these specific foods and chemicals. CYTOTOXIC means cell poisoning.

"I was feeling sluggish & awful until I applied the CYTOTOXIC test. Then within three days I felt an incredible increase in my energy level and mental attitude," one woman says. "I no longer get tired or moody and I'm back to a normal life."

The examples are numerous: Ed was 60 lbs overweight and had high blood pressure. Caroline was 20 lbs overweight & had continual sinus problems, headaches & swelling. Mike took aspirin daily for 18 years due to

chronic headaches. Ellen went through fits of depression, crying, and withdrawals without warning. All of these problems were eliminated after taking and applying the CYTOTOXIC Test.

The principle behind this exciting discovery is simple. Your blood is tested for its reaction to nearly 200 commonly eaten foods and additives. During this sophisticated test the behavior of your white blood cells with each individual food is observed under a microscope. When a food is compatible with your body, the blood cells stay active, healthy and alive when exposed to that food. If however, a food is causing inconsistencies, your white blood cells begin to wrinkle, crack, burst open and die.

If your white blood cells crack, burst open and die, your immune system is caused impairment and your white blood cells release a powerful & destructive enzyme. In short, the door is thereby opened to poor nutrition and a possible multitude of unpleasant ailments and symptoms.

Once the offending food substances are removed from your meals, healthy white blood cell activity resumes. The body is no longer expending its precious energies fighting substances it identifies as toxic, and begins to function more smoothly and harmoniously than before.

The Bio-Health CYTOTOXIC testing program is directed by a licensed physician and if you currently suffer from any health difficulties, this test is worth taking and may or may not be covered by your medical insurance. It is important to ask Bio-Health Centers for special assistance in this area.

Bio Health Centers of California conducts this specialized test all over the country and is sending a special nutritional team to the Seattle area on Wednesday evening, August 15, 1984 to conduct the CYTOTOXIC test for those who desire testing.

They are limited as to how many persons they can help, and reservations are mandatory. You may not be able to eat for 6 to 12 hours prior to the test so calling for instructions is advised. For more information, call Bio Health Centers CYTOTOXIC Department TOLL FREE at 1-800-821-6605 or at 1-714-898-0808.

This test is not currently approved by the FDA, or recognized by the American Academy of Allergists.

Ad at right is directed to investors and appeared in The Wall Street Journal; items on the facing page, below and on the following page were placed by the clinic operators and are directed to potential customers. The ad on the facing page is from the Aug. 8, 1984, Seattle Post-Intelligencer and includes an insertion by the newspaper that cytotoxic testing is not an approved or recognized procedure. Below is part of a full-page ad that appeared in the July 14, 1984, New York Times. Ad on following page is from the March 18, 1984, Los Angeles Times.

GET RICH!

BE FIRST in your area to open a very lucrative allergy testing center—an **ALL-CASH-UP-FRONT** money-maker which uses a scientific breakthrough—a blood test that charts 245 food allergies simply and efficiently. Not a franchise, but we train, support and assist you. \$30,000 capital outlay.* **ABSOLUTE PROOF** of marvelous earnings by visiting our successful operation at our corporate headquarters. Write or telephone:

NATIONAL ALLERGY CLINICS
405 N. BEDFORD DRIVE - SUITE 301
BEVERLY HILLS, CA 90210
TELEPHONE: (213) 859-0617
MR. BAILEY

*Plus some additional start-up costs.

If you suffer from any of these symptoms, you may be sensitive to the foods you eat.

- | | | |
|---------------------------------------|---|--|
| <input type="checkbox"/> STRESS | <input type="checkbox"/> SINUS PROBLEMS | <input type="checkbox"/> SNEEZING |
| <input type="checkbox"/> HEADACHES | <input type="checkbox"/> CHRONIC COUGH | <input type="checkbox"/> ITCHING |
| <input type="checkbox"/> NAUSEA | <input type="checkbox"/> BACKACHE | <input type="checkbox"/> CONSTIPATION |
| <input type="checkbox"/> RASHES | <input type="checkbox"/> HYPERACTIVITY | <input type="checkbox"/> DIARRHEA |
| <input type="checkbox"/> CANKER SORES | <input type="checkbox"/> HEART PALPITATIONS | <input type="checkbox"/> SYMPTOMS OF COLITIS |
| <input type="checkbox"/> INSOMNIA | <input type="checkbox"/> DEPRESSION | <input type="checkbox"/> CRYING JAGS |
| <input type="checkbox"/> ARTHRITIS | <input type="checkbox"/> WEIGHT GAIN | <input type="checkbox"/> IRRITABILITY |
| <input type="checkbox"/> FATIGUE | <input type="checkbox"/> HOARSENESS | <input type="checkbox"/> CONFUSION |
| <input type="checkbox"/> ASTHMA | <input type="checkbox"/> SORE THROAT | <input type="checkbox"/> MUSCLE ACHES |

Even good foods could be bad for you.

The trouble is that you probably don't even know which foods you're allergic to. So you make your allergies worse by "feeding" them. In fact, the foods that can be toxic to your system are the same foods that you were taught were "good for you."

You're probably allergic to at least 3 foods on this list.

- | | | |
|----------------------------------|------------------------------------|-------------------------------------|
| <input type="checkbox"/> MEAT | <input type="checkbox"/> WINE | <input type="checkbox"/> EGGS |
| <input type="checkbox"/> FISH | <input type="checkbox"/> LIQUOR | <input type="checkbox"/> FRUIT |
| <input type="checkbox"/> CHICKEN | <input type="checkbox"/> CHOCOLATE | <input type="checkbox"/> VEGETABLES |
| <input type="checkbox"/> WHEAT | <input type="checkbox"/> SUGAR | <input type="checkbox"/> COFFEE |
| <input type="checkbox"/> BREAD | <input type="checkbox"/> MILK | <input type="checkbox"/> TEA |
| <input type="checkbox"/> BEER | <input type="checkbox"/> CHEESE | <input type="checkbox"/> SODA |

seminars held by a culinary expert, where you'll learn to prepare delectable and satisfying meals especially designed to aid you in your program.

Lose Weight Easily.

Even if you've tried to lose weight before and couldn't, you'll find it easier after our diagnosis. At The New York Metabolic Group we found that food allergies can cause swelling and water retention, making it impossible for some people to lose weight. So whether you have to lose a little or a lot, The New York Metabolic Group can help.

Enjoy the benefits of a personalized vitamin program.

You will be seen by a physician and a staff member trained in nutrition who will devise a vitamin and mineral regime that will properly supplement and fortify the diet that is developed based on your food intolerances.

Noticeable results within weeks.

When you go on your personalized program you'll feel better within weeks. Some people tell us they feel the difference within days. You will experience more restful sleep, increased energy, easier digestion, less irritability and an overall heightened sense of well being.

So call The New York Metabolic Group today for your appointment or a free brochure.

And find out if the foods you love, love you.

The New York Metabolic Group

Specialists in modern food allergy testing & treatment. (212) 486-1590

cells (leukocytes) are mixed with plasma and sterile water and placed on microscope slides, after each slide has been coated with the dried extract of a particular food. There are generally 200 slides representing 200 different foods. The reaction of the cells to the extracts is examined under a microscope. If the cells collapse, disintegrate or change shape (or the person examining them says they do), the patient is supposedly allergic to that particular food.

This evidence of food allergy is then used to explain a variety of symptoms patients may have or think they have. To correct this condition the clinic typically offers a "personalized diet program," devised by the clinic operator, that includes vitamins and minerals the clinic has for sale. Investors are told they should make even more money on these products than they do for the testing itself.

The claims made by operators of the clinics are not modest.

Cytotoxic testing will, says one, deliver you from asthma and arthritis; from canker sores, chronic cough and confusion; from diarrhea and depression; from heart palpitations and headaches; in fact, from 27 flaws in the human condition.

It can, says another, protect you against "the disasters linked to the food you eat"

A third claim is simplicity itself: "Feeling bad? Try cytotoxic testing."

The list of conditions that promoters claim are related to food allergy also includes anxiety and acne; baldness, back pain and bedwetting; constipation, crying and conjunctivitis; eczema and fatigue; hearing loss; insomnia; learning disorders; obesity; rashes; and stomachache, stress and water retention.

Don't believe it. FDA, the National Institutes of Health, and the American Academy of Allergy and Immunology say there's no evidence it works.

The procedure is also known as Bryan's test, leukocyte antigen testing, and food sensitivity testing. But, by whatever name it is called, there's no evidence as yet that it tests for food allergies. There have been no controlled experiments showing that white cells shrink, shrivel and die when exposed to food substances to which a person is allergic. Until there are, the academy and the National Institute of Allergy and Infectious Diseases say cytotoxic testing "must be considered an experimental procedure" with no clinical uses.

The usual patient-doctor relationship doesn't exist in cytotoxic testing. Patients apparently are not seen or examined by a physician, yet use of allergenic extracts can be legally ordered only by a medical doctor.

There is also the question of whether clinic personnel are qualified to assess symptoms, read the microscope slides, and offer nutritional guidance. A technician takes blood from the patient, and lab personnel apply it to the slides. The results may be interpreted by a "nutritional counselor" working on commission who will then note the vitamins and minerals—available right there or next door—that the patient will need to correct this "allergic condition."

Cytotoxic testing is expensive, costing from \$200 to \$400 for the usual series, plus additional charges for the vitamins. Although ads imply this is covered by health insurance, the clinics require that the patients pay and then be reimbursed. Medical insurers are questioning the procedure, and the Health Care Financing Administration that funds Medicare intends to exclude cytotoxic testing from its coverage. HCFA says such testing "lacks evidence of clinical effectiveness and has no scientific rationale."

There are some 1,200 extracts of various substances prepared by licensed suppliers and approved by FDA for allergy skin tests. About one-fourth are food extracts, labeled and intended for certain uses. Cytotoxic testing is not one of those uses, and no manufacturer of these extracts has requested FDA approval to market for such use. Some clinics may be preparing their own food extracts or obtaining them from sources within the state where they are used, which makes them less readily subject to FDA regulation.

FDA is investigating cytotoxic clinics and promotions, which seem designed to operate outside the traditional practice of medicine. Meanwhile, the agency advises persons who believe they may have a food allergy to see a properly trained physician for a complete medical history, physical examination, and thorough diagnosis and proven treatment. ■

DISCOVER YOUR FOOD ALLERGIES

The Cytotoxic Test \$195

"Cyto" Latin for cell and "Toxic" for poisoning, the Cytotoxic Test is a measure of your body's allergic sensitivities to over 400 foods, chemicals and additives. Sensitivities responsible for symptoms such as: difficulty losing weight, bloating after meals, migraine headaches and eczema to name but a few. At the Beverly Hills Health Center your cytotoxic test results are organized into a unique easy to follow computerized program. A blood chemistry panel will also reveal such factors as hypoglycemia, cardio-vascular risk, cholesterol and triglyceride levels, underactive thyroid, liver function and many more. This specialized program is also designed to detect any Vitamin Deficiencies you may have. The doctor will then interpret all your results and make nutritional recommendations as part of your cytotoxic program.

For Further Information Call: 659-5787
THE BEVERLY HILLS HEALTH CENTER
121 N. SAN VICENTE BLVD., BEVERLY HILLS

— SPECIAL OFFER —

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

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

■ Sales of prescription **herpes treatment products** will reach \$225 million in 1988, up from 1983's \$45 million, according to Frost and Sullivan. The New York-based market research firm predicts an increase in the number of genital herpes cases. Also forecast is an increase in the number of generic drugs.

■ The Federation of American Societies for Experimental Biology (FASEB) Life Sciences Research Office has begun a study of all relevant scientific data on the effects of **sulfiting agents** on human health. A tentative report became available Sept. 21 (FR July 9, Aug. 17).

■ FDA has approved the use of **D&C Blue No. 6** for coloring polydioxanone synthetic absorbable sutures (FR July 25).

■ For the next six years FDA will provide **quality assurance** support to the U.S. Army Medical Research and Development Command's program of research, development, testing and evaluation of medical material for military use. The agreement establishing the support program became effective May 11.

■ Public comments have been sought on recently drafted "U.S. Government Principles for the Utilization and Care of Vertebrate **Animals Used in Testing, Research, and Training.**" FDA is represented on the Interagency Research Animal Committee, which prepared the draft at the request of the Office of Science and Technology Policy (FR July 19).

■ FDA's Orphan Products Development Office is seeking a sponsor to submit an investigational new drug application for the use of **guinacrine hydrochloride** powder to prevent recurrence of pneumothorax (accumulation of air or gas in the pleural cavity surrounding the lungs) in patients with cystic fibrosis (FR July 11).

■ FDA hopes to have about \$1,200,000 in fiscal year 1985 to study the **effects of marketed drugs**. Two or three awards averaging \$200,000 to \$500,000 may be made to study adverse drug reactions in general, and several smaller awards of \$20,000 to \$50,000 may be made for studies in specialized population or patient groups. The awards, which are

contingent on the availability of appropriated funds, may be for up to three years (FR July 3).

■ The Drug Enforcement Administration has proposed putting the substance 3,4-methylenedioxymethamphetamine in Schedule I, the strictest schedule of the Controlled Substances Act. The substance, sold on the street as **MDMA or ecstasy**, has a high potential for abuse and no legitimate medical use (FR July 27).

■ After Oct. 29, 1984, FDA will take enforcement action against all **OTC drug products** labeled for any purpose and containing combinations of caffeine and phenylpropanolamine as their sole active ingredients. Such combinations were exempt from enforcement action under a November 1983 advisory decision if labeled as appetite suppressants, diet aids or diet aids/stimulants and in the manufacturing pipeline before that date. Based on its monitoring of the market, FDA decided it is in the public interest to prohibit sale of these products (FR June 29).

MARKET BASKET: In response to a petition filed by Halssen & Lyon, a Swiss firm, FDA has approved the use of **ethyl acetate** as a solvent in the decaffeination of tea (FR July 13).



July 1, 1985, is the effective date for compliance with recent amendments to FDA's standards of identity for **tomato concentrates, ketchup and tomato juice** (FR July 12).

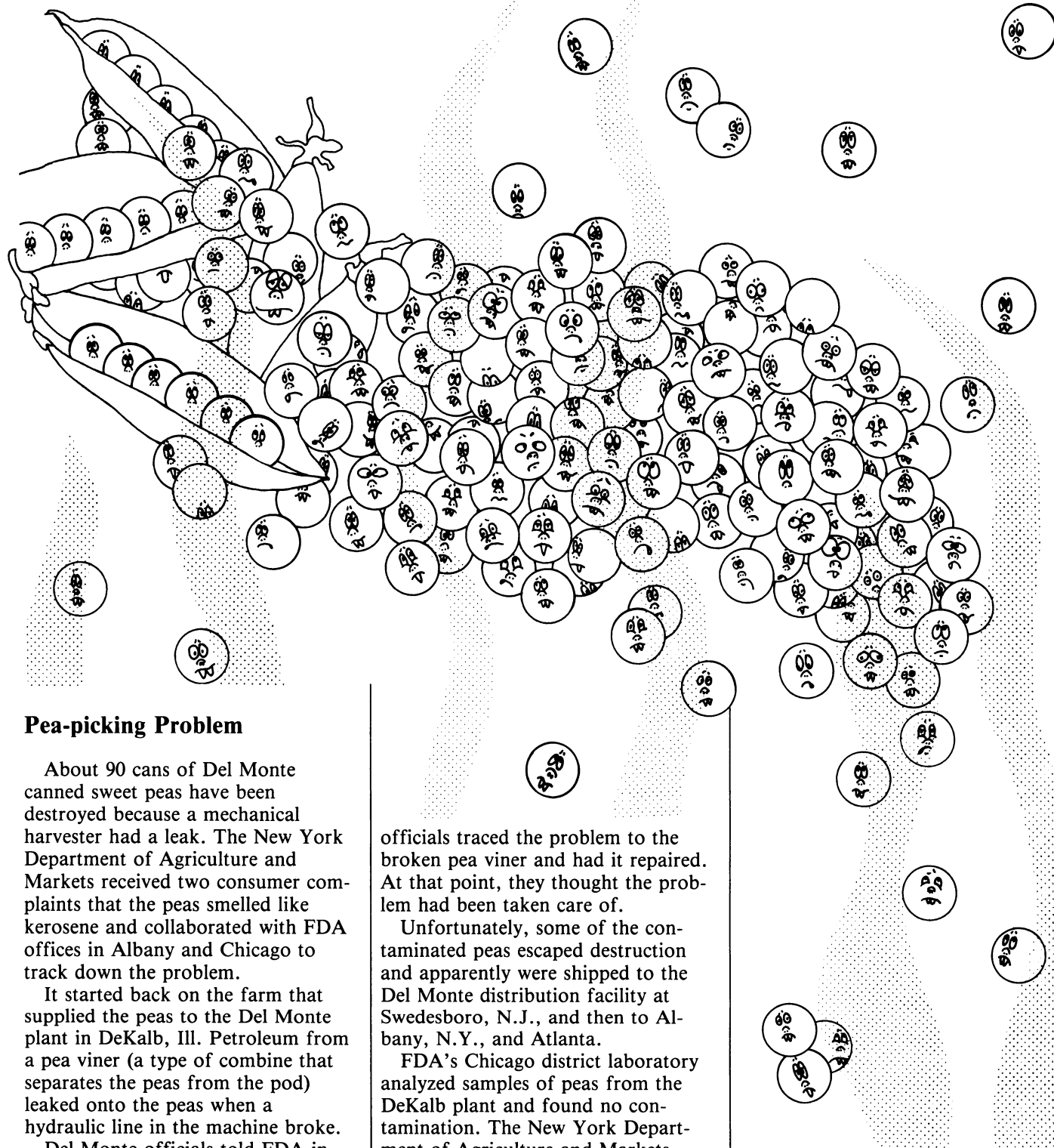
Radiation Technology Inc. has petitioned FDA to allow a cobalt 60 or cesium 137 source of **gamma radiation** to control trichinae and other helminths in pork (FR July 23).

Ralston Purina is market-testing **canned tuna** in vegetable oil and canned tuna in water, each containing a blend of sodium tripolyphosphate and sodium hexametaphosphate to reduce loss of natural fluids and protein during cooking (FR July 16).

Calcium hydroxide and calcium oxide have been affirmed GRAS (generally recognized as safe) as direct human food ingredients (FR June 29).



Investigators' Reports



Pea-picking Problem

About 90 cans of Del Monte canned sweet peas have been destroyed because a mechanical harvester had a leak. The New York Department of Agriculture and Markets received two consumer complaints that the peas smelled like kerosene and collaborated with FDA offices in Albany and Chicago to track down the problem.

It started back on the farm that supplied the peas to the Del Monte plant in DeKalb, Ill. Petroleum from a pea viner (a type of combine that separates the peas from the pod) leaked onto the peas when a hydraulic line in the machine broke.

Del Monte officials told FDA investigators that workers at the plant noticed the smell and production was stopped immediately. The entire plant was cleaned, and all peas processed that day were destroyed. Del Monte

officials traced the problem to the broken pea viner and had it repaired. At that point, they thought the problem had been taken care of.

Unfortunately, some of the contaminated peas escaped destruction and apparently were shipped to the Del Monte distribution facility at Swedesboro, N.J., and then to Albany, N.Y., and Atlanta.

FDA's Chicago district laboratory analyzed samples of peas from the DeKalb plant and found no contamination. The New York Department of Agriculture and Markets found petroleum distillate in the samples that had spawned the complaints and seized the remaining cans at a retail store. The agency contacted the distributor of the product, BI-LO

Wholesalers, Albany, N.Y., which agreed to recall all peas that might be contaminated.

The peas were destroyed under supervision by state officials.

Unsightly Label Mix-up

A 3 percent difference on a label may not seem like much. But for a drug used to treat glaucoma, the difference is 300 percent.

FDA's Newark district recently monitored a recall of pilocarpine hydrochloride ophthalmic solution, USP, manufactured by Optopics Laboratories Corp., Fairton, N.J. The half-ounce bottles labeled as 4 percent pilocarpine actually contained only 1 percent solutions.

Pilocarpine is used to treat glaucoma, an eye disease characterized by intraocular pressure. This can cause impaired vision, ranging from slight loss to total blindness. Pilocarpine, when applied to the eye, stimulates the parasympathetic nervous system to reduce intraocular pressure. (See "Keeping An Eye On Glaucoma" in the June 1980 *FDA Consumer*.)

The drug comes in several strengths, typically ranging from 1 percent to 8 percent. It is important that the strength be adequate to maintain ocular pressure at a level that prevents further damage to the optic disk. Otherwise the patient could suffer loss of vision, and possibly blindness.

The label mix-up was discovered by the manufacturer, which notified FDA. The agency designated the recall as Class I, meaning the product presented an imminent and irreversible hazard to health. Almost 1,500 half-ounce bottles, valued at about \$2,500, were recalled. They were trucked to a local landfill and crushed and buried, under supervision by an investigator from FDA's Newark district.

The Boughs Broke

In the old favorite nursery song, "Rock-a-bye Baby," the bough breaks and both cradle and baby fall to the ground.

A somewhat similar scene—without the tree top—was enacted in real life recently in a Kansas City, Mo.,



hospital when the side rails of several pediatric cribs dropped, sending already ill children tumbling out onto the floor. Although injuries were slight, the hospital notified FDA's Kansas City district office of the problem.

The side rails of the cribs, manufactured by Colson Equipment Co., Caruthersville, Mo., are kept up by two sets of locking mechanisms on each side of the rail. If the mech-

anisms fail, as they did in this case, the sides of the crib drop, and the small occupants may fall out.

An investigation of the manufacturer's facility by FDA's St. Louis office revealed that improperly drilled holes and burrs on the latching mechanism made the malfunction possible. Some deficiencies in good manufacturing practices also were observed.

In the meantime, investigators from FDA's Nashville office inspected a number of cribs that had been shipped to a local hospital by the Colson company but not yet put into service. Seven defective latch mechanisms were found on four of the eight cribs examined.

Following a meeting with FDA, management of the company initiated a nationwide recall of all pediatric hospital cribs that may exhibit the latch mechanism defect.

Starch Blocker?

People who grew up before glue came in convenient plastic bottles know that mixing starch and water produces paste. The Circle Rubber Corp. learned this simple truth after a frozen pipe burst in its Newark, N.J., building and caused extensive flooding.

Upon visiting the firm, officials from the New Jersey State Department of Health discovered that a large supply of latex condoms had been contaminated with dirt and debris from the flooding. State officials embargoed the products to prevent any attempt to salvage and possibly market the contraceptives and alerted FDA's Newark district office.

Any chance the contraceptives could be reconditioned ended when an FDA investigator arrived at the firm to take samples, because he noticed something else.

Most of the damaged condoms were those to which starch had been added. Starch is normally used in the

(Continued on next page)

drying stage of the condom's production. But the flood water had made the starch sticky and the condoms were difficult to open, and thus were unfit for use.

Based on this finding, Circle Rubber Corp. destroyed over 16 million latex condoms, valued at about \$120,000.

No Clowning With Cosmetics

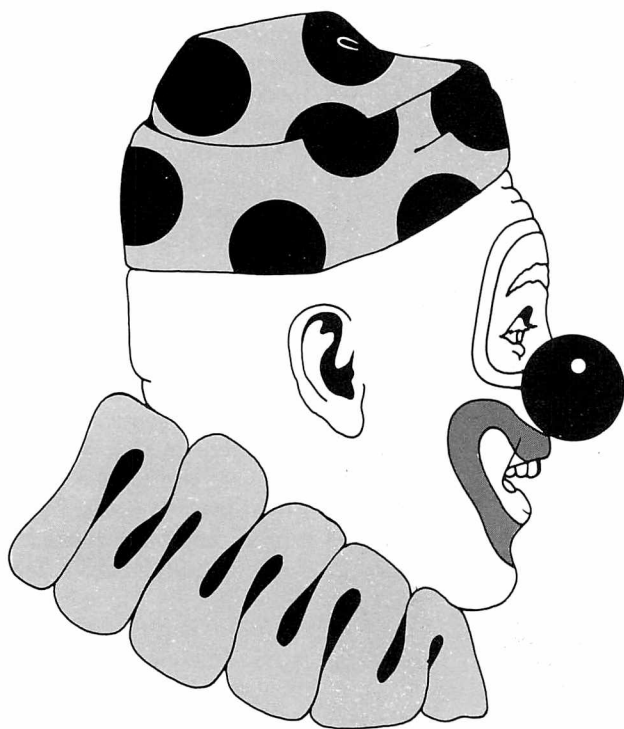
FDA doesn't clown around in assuring the safety of greasepaints.

When Zauder Brothers Inc., Freeport, N.Y., failed to bring its red

Yellow No. 5, D&C Red No. 7, and D&C Red No. 9, which are not permitted for use in the area of the eyes. The investigator also noticed the product label didn't warn against using near the eyes.

After FDA laboratory analysis of a sample collected by the investigator confirmed the presence of the non-permitted color additives, the district sent a letter to the firm pointing out the violations. Meanwhile, an FDA investigator reinspected the firm. This inspection showed no changes had been made.

The owner responded that the



greasepaint product into compliance with cosmetics regulations, FDA's Brooklyn district had the product seized.

Zauder Brothers makes various greasepaint colors and also carnival makeup sets. These products are used by clowns and actors and by individuals preparing for Halloween and other festivities.

During a routine inspection of the Zauder firm, an FDA investigator noticed that the label on the red greasepaint said the product contained the color additives FD&C

product was not eye makeup and therefore was not intended for use around the eyes. The firm also was unwilling to place a warning on the label. Subsequently, over 160 boxes of red greasepaint were seized at the firm by a U.S. marshal.

Now You See Them . . .

Food additives should not perform disappearing acts—in any case not on labels. Recently FDA's Atlanta and Nashville districts encountered such a situation in the labeling of an orange

drink product.

While inspecting a dairy in Columbus, Miss., an investigator from FDA's Memphis office noticed that the orange juice concentrate used to prepare "Dairy Fresh Orange Drink," bore a label showing that it contained FD&C Yellow No. 5, FD&C Yellow No. 6, potassium sorbate and sodium benzoate. The label on the finished orange drink, however, failed to declare these ingredients.

Federal regulations require that FD&C Yellow No. 5 be specifically listed on the labels of any foods containing it because the color is known to cause sensitivity reactions in some individuals. Complete listing of all ingredients is required for foods lacking "standards of identity." (A standard of identity defines what a food should contain—that is, what the consumer is entitled to receive when purchasing the food by its common or usual name.) There is no standard of identity for orange drink, and the labels must name all ingredients. Since the labels for the orange drink did not bear a complete list of ingredients, the product was misbranded.

The investigator collected samples and sent them to FDA's Atlanta laboratory, where analysis confirmed the presence of the two color additives, in addition to sodium benzoate and potassium sorbate.

After a discussion with FDA investigators, the parent company, Dairy Fresh Corp., Greensboro, Ala., decided to recall all lots of the product remaining on the market and to cease production of the orange drink until new, accurate labels were obtained.

The drink was manufactured by three plants in Alabama and Mississippi and was packaged in gallon, half gallon, quart, pint and half pint sizes.

Atlanta district monitored the recall, which was completed June 7. More than 6,000 gallons of orange drink was destroyed.

—This small sample of reports from the field was compiled and edited by Annabel Hecht, Carol Ballentine, Michael Herndon and Carolyn Hommel.

Summaries of Court Actions



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

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

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

SEIZURE ACTIONS

Foods/Poisonous and Deleterious Substances

PRODUCT: **Fish oil**, at Weehawken, Dist. N.J.; Civil No. 80-1968.

CHARGED 6-27-80: While held for sale, the article contained the added poisonous or deleterious substance polychlorinated biphenyls, since the quantity of the substance exceeded the 2 parts per million tolerance—402(a)(2)(A).

DISPOSITION: Consent—authorized release to Scandinavian Oil Co., New York, N.Y., for bringing into compliance or disposal for non-food purposes. (F.D.C. No. 63102; S. No. 80-208-719 et al.; S.J. No. 1)

Foods/Contamination, Spoilage, Insanitary Handling

PRODUCT: **Beans, green, cut, canned**, E. Dist. Okla.; Civil No. 83-295-C.

CHARGED 6-17-83: When shipped by Big Stone, Inc., Bloomer, Wis., the article (labeled "Blue Lake! Fine Fare Cut Blue Lake Green Beans . . . Distributed by Federated Foods, Inc. Park Ridge, Ill.") was unfit for food due to swollen and leaking containers—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64010; S. Nos. 83-320-950/1; S.J. No. 2)

PRODUCT: **Cheese, Cheddar**, at Los Angeles, C. Dist. Calif.; Civil No. 80-02496 MRP (KX).

CHARGED 6-11-80: When shipped by Timber Lake Cheese Co., Timber Lake, S.D., the article (labeled "Cheddar Cheese . . . Dist. by N.C.D. Corporation . . . Los Angeles, Calif. . . . Rindless Longhorns Timber Lake Cheese Co.") had been prepared and packed under insanitary conditions—402(a)(4).

DISPOSITION: Consent decree authorized release for salvaging. (F.D.C. No. 63085; S. No. 80-215-416 et al.; S.J. No. 3)

PRODUCT: **Cheese, Cheshire**, at Gloucester City, Dist. N.J.; Civil No. 83-0795.

CHARGED 3-7-83: While held for sale, the article contained decomposed cheese (there had been a refrigerator system failure previously)—402(a)(3).

DISPOSITION: Since no claim to the article had been filed in the required time, a default decree was entered. Subsequently, Holt Cargo Systems, Inc., Gloucester City, N.J., claimed the article and moved to stay and vacate the execution of the default decree; and Holt also filed a claim and answer. In response to the claimant's motion, the government advised the court that Holt's failure to file a timely claim for the article appeared to be the result of inadvertence. The government requested that the court grant the relief sought by Holt and that the court also accept a proposed consent decree of condemnation which had been signed by the parties. The court accepted a consent decree of condemnation that authorized release of the article to the claimant for salvaging. (F.D.C. No. 63988; S. No. 83-311-938; S.J. No. 4)

PRODUCT: **Fish portions, frozen, and other frozen food stocks**, at Waycross, S. Dist. Ga.; Civil No. 583-38.

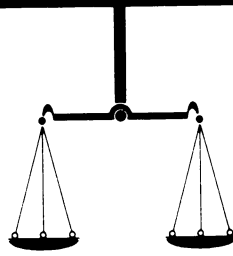
CHARGED 5-12-83: While held by Flanders Provision Co., Inc., Waycross, Ga., the articles were unfit for food, since they contained styrene (a chemical contaminant which apparently came from the resurfacing of part of a freezer floor with a highly modified polyester resin)—402(a)(3).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 64025; S. No. 83-899-777 et al.; S.J. No. 5)

PRODUCT: **Fish-batter mix, and cake-donut mix**, at Sioux City, N. Dist. Iowa; Civil No. C83-4029.

CHARGED 3-11-83: While held for sale, the articles had been held under insanitary conditions—402(a)(4).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63983; S. Nos. 83-262-375/6; S.J. No. 6)



PRODUCT: **Flour**, at Ponce, Dist. Puerto Rico; Civil No. 83-0640 (TR).

CHARGED 4-4-83: While held by Panaderia y Reposteria Victoria (Jorge Martinez), Ponce, Puerto Rico, the article contained rodent filth and had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 63994; S. No. 83-347-509; S.J. No. 7)

PRODUCT: **Macaroni products, and other food stocks**, at New Orleans, E. Dist. La.; Civil No. 83-1499.

CHARGED 3-29-83: While held by Korea House (Won Don Cho), New Orleans, La., some of the articles contained rodent filth, and all of the articles had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 63996; S. No. 83-383-360; S. J. No. 8)

PRODUCT: **Pecan halves and pecan pieces**, at San Antonio, W. Dist. Texas; Civil No. SA-83-CA-517.

CHARGED 3-31-83: While held by Azar & Solomon, Inc., San Antonio, Texas, who had shelled and packed the interstate pecans, the article had been prepared, packed and held under insanitary conditions—402(a)(4).

DISPOSITION: The article was claimed by the dealer. Subsequently, the dealer withdrew his claim to the article, and a default decree ordered the article released for the purpose of destroying it. (F.D.C. No. 63985; S. Nos. 83-260-115/6; S.J. No. 9)

PRODUCT: **Shrimp, frozen**, at Doraville, N. Dist. Ga.; Civil No. C83-893A.

CHARGED 5-5-83: When shipped by Santoni's Markets, Baltimore, Md., the article (labeled "Apex Brand . . . Shrimp . . . Packed by Apex Food Ltd. . . . Chittagong, Bangladesh") contained rodent, insect and other filth—402(a)(3).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 64014; S. No. 83-386-956; S.J. No. 10)

PRODUCT: **Sugar, and rice**, at Milwaukee, E. Dist. Wis.; Civil No. 83-C-0479.

CHARGED 4-4-83: While held by Black Gem Brands, Inc., Milwaukee, Wis., the articles contained rodent filth and had been held under insanitary conditions—402(a)(3), 402(a)(4). **DISPOSITION:** Consent—ordered destroyed. (F.D.C. No. 63999; S. Nos. 83-298-812/4; S.J. No. 11)

PRODUCT: **Tomatoes, canned**, at Baltimore, Dist. Md.; Civil No. M-83-1725.

CHARGED 5-23-83: While held for sale, the article was

contained in swollen, rusty, dented and/or leaking cans—402(a)(3).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 64028; S. No. 83-373-188; S.J. No. 12)

Foods/Economic and Labeling Violations

PRODUCT: **Tomatoes, canned, Lord Chesterfield**, at Ashland, E. Dist. Va.; Civil No. 82-0453-R.

CHARGED 7-6-82: When shipped by McCall Farms, Effingham, S.C., the article failed to conform to the standard of quality for canned tomatoes, since the article contained tomato peel in excess of 1.06 square inches per pound—403(h)(1).

DISPOSITION: Default—authorized donation to a non-profit, charitable organization. (F.D.C. No. 63738; S. No. 82-339-403; S.J. No. 13)

Vitamins/Special Dietary Foods

PRODUCT: **Vitamin C (ascorbic acid) capsules**, at Hollywood, S. Dist. Fla.; Civil No. 83-6544-CIV-EBD.

CHARGED 7-19-83: When shipped by Private Formulations, Inc., Edison, N.J., the articles (labeled in part "Goldline Vitamin C . . . (ascorbic acid) . . . time released . . . capsules . . . another Goldline vitamin distributed by Generix Drug Corp. Hollywood, Fla.") were unfit for food because they contained phenylpropanolamine HCl (a bronchodilator and nasal decongestant)—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64052; S. No. 83-271-205 et al.; S.J. No. 14)

Food Additives

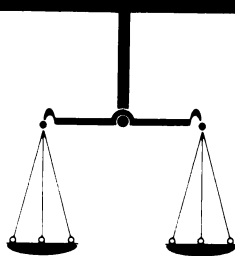
PRODUCT: **Aloe vera juice blends**, at Chattanooga, E. Dist. Tenn.; Civil No. 1-83-492.

CHARGED 9-20-83: When shipped by Rozar Laboratories, Garland, Texas, the articles (labeled "Gigi Aloe 'n Fruit Aloe Vera Juice Blends 90% Aloe Vera Juice 10% Fresh Orange Concentrate [or '10% Fresh Cranberry Concentrate'] . . . Manufactured for Gigi Aloe Vera Products, Chattanooga, TN") contained the nonconforming food additive Germall II (diazolidinyl urea—a preservative for cosmetics intended for external application), and there was no regulation in effect or exemption for such additive and such use in foods—402(a)(2)(C).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64087; S. No. 83-375-444 et al.; S.J. No. 15)

PRODUCT: **Amino acid chelated chromium tablets, ribonucleic acid & DNA combination tablets, amino acid chelate copper tablets, and selenium with chromium tablets**, at Lynbrook, E. Dist. N.Y.; Civil No. 77C-941.

CHARGED 5-5-77 and amended 6-29-78: While held by



Solgar Co., Inc., Lynbrook, N.Y., the articles contained nonconforming food additives (*i.e.*, the chromium tablets and copper tablets contained an unidentified amino acid; the selenium tablets contained selenium; and the ribonucleic acid combination tablets contained ribonucleic acid and deoxyribonucleic acid)—402(a)(2)(C); and mandatory label information (*i.e.*, the common or usual names of each ingredient and the name and place of business of the manufacturer, packer or distributor) were not placed conspicuously—403(e)(1).

DISPOSITION: The articles were claimed by the dealer, who denied the charges. The parties served written interrogatories on each other. Pursuant to stipulation, only the chromium tablets were charged with containing a nonconforming food additive (chromium); and the RNA/DNA combination tablets were released to the claimant. Ultimately, a consent decree authorized release of the remaining articles for salvaging. (F.D.C. No. 61206; S. No. 77-42-981; S.J. No. 16)

Drugs/Human Use

PRODUCT: **Aristolochia acid tablets**, at Livonia, E. Dist. Mich.; Civil No. 83-CV-2684-DT.

CHARGED 7-7-83: When shipped by Metabolic Products, Inc., Albuquerque, N.M., the article (which was labeled "Aristolochia Acid 70 Enteric Coated Tablets (Dragees) . . . Biopharm . . . Norderstedt, West Germany," and which was labeled for use for acne vulgaris, furunculosis, abscesses, cellulitis, osteomyelitis, bronchitis, sinusitis, and other ailments, although no known scientific studies supported such uses) was a new drug without an effective approved New Drug Application—505(a).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64044; S. No. 83-309-705; S.J. No. 17)

PRODUCT: **Carbo-Lite protein concentrate (starch blocker) tablets**, at Memphis, W. Dist. Tenn.; Civil No. 82-2825-W.

CHARGED 10-29-82: When shipped by Bio-Tech Laboratories, Inc., Batesville, Ark., the article was a new drug without an effective approved New Drug Application—505(a).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63822; S. No. 82-276-768; S.J. No. 18)

PRODUCT: **Carbo-Lite protein concentrate (starch blocker) tablets**, and **Calorex protein concentrate (starch blocker) tablets**, at Memphis, W. Dist. Tenn.; Civil No. 82-2822-W.

CHARGED 10-29-82: When shipped by Bio-Tech Laboratories, Inc., and Vita-Lite Laboratories, Inc., Batesville, Ark., the articles were new drugs without effective approved

New Drug Applications—505(a).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63819; S. No. 82-275-513 et al.; S.J. No. 19)

PRODUCT: **Edetate disodium Injection, U.S.P.**, at Miami, S. Dist. Fla.; Civil No. 82-0731.

CHARGED 4-8-82: When shipped by Lemmon Co. (t/a D-M Pharmaceutical Co., Inc.), Rockville, Md., and while held by Ontor Beauty Products, Inc., Miami, Fla., the article's exemption from adequate directions for use labeling expired at the time of shipment to the consignee, Ontor Beauty Products, Inc., since the consignee was not regularly and lawfully engaged in handling prescription drugs and since the article was intended for use in the treatment of generalized arteriosclerosis associated with advancing age, in that James R. Critchlow had continued to distribute the article for this purpose—502(f)(1).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63702; S. No. 82-338-857; S.J. No. 20)

PRODUCT: **Epinephrine solutions of various compositions**, at Mukilteo, W. Dist. Wash.; Civil No. C-83-559V.

CHARGED 4-22-83: While held by V.K. Bhat, Mukilteo, Wash., who manufactured and packaged the articles for Nephron Corp., Tacoma, Wash., the circumstances used for the manufacture, processing, packing, and holding of the articles failed to conform with current good manufacturing practice since, among other things, the manufacturer did not have a written stability testing program for epinephrine solutions (although three of the solutions had 3-year expiration dates); and since, for the fourth solution (called *Adreno Mist*), there was no expiration date and data was lacking to show stability for at least three years—501(a)(2)(B).

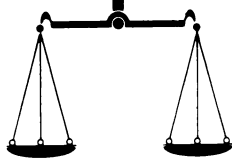
DISPOSITION: Consent—claimed by the manufacturer and authorized release for reconditioning. (F.D.C. No. 63942; S. No. 83-346-804; S.J. No. 21)

PRODUCT: **Heparin sodium injection, U.S.P.**, at Pasadena, C. Dist. Calif.; Civil No. 83-1738-AWT (MCx)

CHARGED on or about 3-22-83: While held for sale, the circumstances used for the packing and holding of the article failed to conform with current good manufacturing practice, since FDA examination revealed that four of 30 glass vials of the article contained cracks near the vial base and two other vials were flawed—501(a)(2)(B).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63989; S. No. 83-396-466; S.J. No. 22)

PRODUCT: **Stimulant tablets, tablets containing caffeine, phenylpropanolamine and/or ephedrine sulfate, and similar drugs**, at Daytona Beach, M. Dist. Fla.; Civil No. 83-434-ORL-CIV-11.



CHARGED 6-9-83: When shipped from outside the state of Florida, most of the articles were new drugs without effective approved New Drug Applications, and they were also articles whose labeling lacked adequate directions for use and were not exempted due to their new drug status—505(a), 502(f)(1); one lot of green and clear capsules was a counterfeit drug since, without authorization, the article bore the identifying mark, imprint and likeness of another drug of another manufacturer, processor, packer or distributor—201(g)(2); a quantity of promotional cards were used and designed for use in making the green and clear capsules a counterfeit drug by emphasizing the physical appearance and similarity of the drug to the like-appearing controlled substance drug, phentermine—201(m); one lot of capsules in unlabeled blister packs lacked the name and address of the manufacturer, packer or distributor, lacked a quantity of contents statement, lacked the required ingredient statement, and lacked adequate directions for use—502(b)(1), 502(b)(2), 502(e)(1), 502(f)(1); and the labels of one lot of 1,000-capsule bottles was false and misleading because the labels represented the article as containing only caffeine and ephedrine sulfate, when the article also contained phenylpropanolamine HCl—502(a).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 60436; S. No. 83-271-952; S.J. No. 23)

MISCELLANEOUS ACTIONS

PRODUCT: Chocolate products with liquid filling containing alcoholic flavoring extracts, Brooklyn, E. Dist. N.Y.; Civil No. CV-82-3659.

CHARGED 11-22-82 by Morris Import U.S.A., Inc., Brooklyn, N.Y., against the United States of America, the HHS Secretary, the FDA Commissioner, the Food and Drug Administration, the Director of FDA Regulatory Guidance Division of the Bureau of Foods, and the Director of the FDA import district office, in a complaint for injunction: That the plaintiff, a wholesale distributor of candy products, purchased chocolate confectionery products (“bottles” and “barrels” of chocolate containing various flavors of liquid fillings) manufactured in France for sale in the United States during the Christmas season of 1982; that the plaintiff became interested in such candy products after a trade show and a review of an FDA letter about liqueurs and flavoring extracts in a “final product”; that plaintiff had been led to conclude that the measurement (for confectionery to be adulterated) of one-half of 1 percent by volume made reference to the volume of the article of chocolate confectionery in its final product; that a shipment of chocolate products costing \$46,000 had been received at the Port of New York, released from the formalities of U.S. Customs, and delivered to the plaintiff’s warehouse in Brooklyn, N.Y.; that an FDA representative determined that it would

be necessary to sample such chocolates; that the government knew that the alcohol in the chocolates was derived solely from flavoring extracts and bore approximately .48 percent alcohol by volume; that the FDA representative reported that the chocolates contained alcohol at 1.5 percent to 2.1 percent by volume of the *liquid filling* of the chocolates, measured center to center of the pieces of chocolate confectionery product tested; that upon oral advice, the chocolates were detained and a list of intended customers for distribution was requested; that the plaintiff was informed that the use of the words “final product” in connection with such “barrels” and “bottles” was not intended to mean the final product into which the liquid was added; that an FDA bureau director of Nov. 18, 1982, concluded that volume as used in the statute meant the liquid only; that the action of the defendants in seeking to detain the plaintiff’s chocolate confectionery products was neither an instance where judicial review was precluded nor an instance of agency action committed to FDA discretion; that the plaintiff was suffering irreparable harm and damage which would render plaintiff insolvent and bankrupt; that the court should enjoin the government action as being arbitrary, capricious, an abuse of discretion, not in accordance with law, without observance of law and unwarranted, should interpret the law to permit the volume of the finished or final product to be measured as the basis of the calculation of alcohol content; should hold that the likelihood of harm to the public by plaintiff’s interpretation of the law was minuscule when compared to the hardship imposed upon the plaintiff.

The plaintiff also asserted that the plaintiff’s conclusion that alcohol in the flavoring extract could not exceed one-half of 1 percent by volume of the finished piece of chocolate was a reasonable conclusion under all the facts and circumstances, and that the quantity of alcohol in the confection was already so small that a further reduction would be *de minimis*; and the plaintiff further asserted that the defendants had an obligation to exercise due care and caution in issuing comment upon statutory interpretation and to refrain from using the words “final product” unless they indeed referred to the final product into which alcohol was incorporated.

DISPOSITION: A consent decree was entered before the taking of any testimony and without trial or adjudication of any of the issues. The plaintiff was permanently restrained and enjoined from importing, producing, distributing or promoting any confectionery bearing or containing alcohol except in accordance with FDA’s current interpretation of 21 U.S.C. §342(d)(2) or any future amended interpretation; but the plaintiff was, however, permitted to distribute and sell two specified lots of imported chocolate confectionery products. The consent decree also dismissed the plaintiff’s complaint with prejudice and without costs and disbursements to any party. (Misc. No. 696; S.J. No. 24)

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