

FDA CONSUMER

April 1983

The Ear Collects Sounds And Other Things.



Form Approved: OMB No. 0910-0046

**DEPARTMENT OF
HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

ENTRY DATA TAKEN FROM

FOOD AND DRUG ADMINISTRATION									
<input type="checkbox"/> ID Advance Notice		Number							
<input type="checkbox"/> Manifest		Date							
<input type="checkbox"/> IT Advance Notice		Commercial invoice attached <input type="checkbox"/>		ENTRY NO. AND DATE					
BILL OF LADING NO.		PORT OF LADING		COUNTRY OR ORIGIN		PORT OF UNLOADING		PORT OF ENTRY	
BROKER'S REF NO.		C.H. BOX NO.		VALUE OF ENTRY IN U.S. \$		CONTAINER NO.		IMPORTING VESSEL	
								ARRIVAL DATE	
FOR THE ACCOUNT OF		(Name & Address)		IMPORTER OF RECORD		(Name & Address)		MANUFACTURER/SHIPPER (Name & Address)	
				BROKER (If not same as above)		LOCATION OF LOT (For FDA examination)		DATE AVAILABLE	
Number of items sampled from this Entry.				Related Sample Numbers		LEAD SAMPLE			
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(FOR BROKER'S USE)

GENERAL DESCRIPTION OF SHIPMENT

GENERAL DESCRIPTION OF SHIPMENT		
QTY.	PACKAGED	ITEMS (Include IND, NDA, FCE, Antibiotic Cert Nos., etc.)

THIS IMPORTATION

MAY PROCEED
Without FDA Examination

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VALID ONLY IF SIGNED

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FDA Representative Date

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1. Earliest date the shipment will be available for sampling.
2. Location in local area of the shipment on that date.
3. Breakdown as shown on the invoice-number and size of units each lot, and \$ value each lot.

FDA CONSUMER

VOL. 17 NO. 3

APRIL 1983

A Future for Orphan Drugs

A new law is designed to speed up the development of orphan drugs. This article takes a hypothetical look at such a drug in the future.

4

The Mystery of Crib Death

Sudden infant death syndrome is the fear of parents everywhere. The cause remains unknown, but sometimes monitoring devices help.

7

The Public Knows and Cares About Sodium

Sodium moderation has become a chief aim of Americans, a fact recognized by food processors in developing product lines.

10

Hair Analysis? May as Well Be Bald

Some claim that they can tell much about a person's nutritional state by analyzing locks of that person's hair. Might just as well analyze the hair from bald heads, the experts say.

16

Sorting Out Imports

Foods that don't come up to U.S. sanitary standards and quack drugs are main concerns of FDA's import inspectors. How these inspectors and the new Brooklyn import district operate is told in this article.

18

How the Body Fights for Its Health

The immune system in the body is clever and complicated. But occasionally it fails, as in the case of the AIDS difficulties.

23

The Ear Collects Sounds and Other Things

The other things aren't just earrings, for the ear picks up some bad stuff from within the body and from the outside.

25

Birds Sing the Blues

Parrots may carry a disease called psittacosis, also known as parrot fever. This lead Investigators' Report item tells of one couple that caught the disease from a pair of fine feathered friends.

29

Updates

2

The Notebook

28

Consumer Forum

3

Investigators' Reports

29

Hundreds of thousands of forms such as the one on the left-hand page are filled out each year as part of FDA's program to assure that products imported into the United States meet requirements of the Food, Drug, and Cosmetic Act. How the import monitoring program works is reported in Sorting Out Imports, beginning on page 18.

Margaret M. Heckler
Secretary, U.S. Department of
Health and Human Services

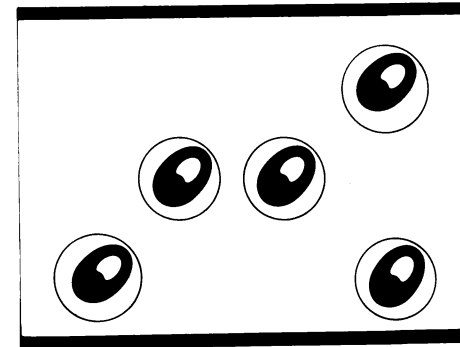
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Valium Still Top Seller

For years Valium has topped the list of the most often prescribed brand-name drugs in the United States, and 1981 was no exception. However, diazepam (the generic name for Valium) wasn't the most often prescribed drug chemical in that year, the most recent year for which figures are available, according to FDA's division of drug experience. That honor goes to hydrochlorothiazide, an ingredient found in many diuretics. Codeine, the many forms of oral contraceptives, erythromycin (an antibiotic) and propranolol (a beta blocker) also outranked diazepam in terms of the drug chemicals consumers are most frequently exposed to.

The agency's conclusions were arrived at by combining all data for single-entity and combination prescription products containing a particular drug chemical. This analysis showed that hydrochlorothiazide was by far the most frequently dispensed drug chemical, with 73.4 million prescriptions. Codeine had 65.4 million; oral contraceptives, 54.4 million; erythromycin, 32.5 million; and propranolol, 30.6 million prescriptions. Almost one out of every 10 prescriptions dispensed from retail pharmacies in 1981 contained either hydrochlorothiazide or codeine, according to FDA.

The data on the top drug chemicals was published in "Drug Utilization in the U.S.—1981," FDA's third annual review of outpatient drug use. The statistics for the report were obtained from several sources, including drug sales auditing services.

Epinephrine Withdrawn

Abbott Laboratories voluntarily withdrew from the market certain lots of its epinephrine product manufactured before July 1982 after two doctors reported in the *American Journal of Medicine* in January 1982 that the product had a high acid content and was more acid than two other brands on the market. Epinephrine is a drug used by doctors for injection into a stopped heart to try to restart it.

The article discussed two cases in which the patient's blood was found abnormally acid after the Abbott product was used. Abbott said the doctors had reported their findings earlier to the company, which then reduced the total acidity of its product to the

level of the competing brands.

On Jan. 14 FDA recommended that the newer formulation or competing brands be used pending a review by the agency. Ten days later the agency and Abbott agreed that a risk could not be defined. However, FDA felt a theoretical possibility existed that the higher acid in the older formula might add to the burden of the heart. Epinephrine must be acidic for stability and, although the older product met the standard for acidity in the *U.S. Pharmacopeia*, the company agreed to a withdrawal.

The epinephrine in question is in 10-milliliter Abboject syringes with intracardiac needles, coded 44-145-DK and lower.

Oraflex Use Restricted

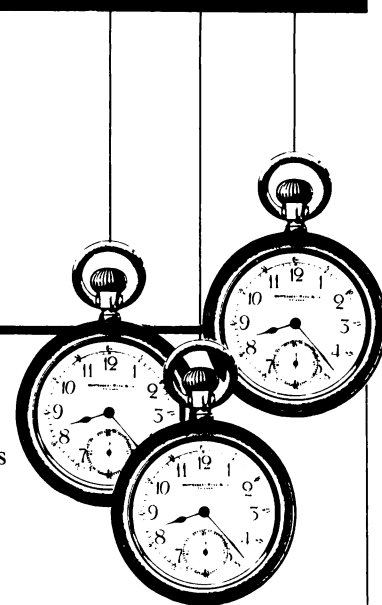
A limited number of arthritis patients may be able to get Oraflex under a restricted treatment program planned by Eli Lilly and Co. The anti-arthritis drug was withdrawn from the market in August 1982 after being linked with deaths in England and the United States.

Lilly has no plans to remarket the drug but will make it available on a very restricted basis for patients who have not tolerated or responded to other treatments. Patients will not be charged for the drug but will be responsible for the costs of regular and continuing tests that may signal adverse effects early. The tests are required; the drug will not be supplied unless they are conducted.

Patients cannot apply to the company for the drug. Only physicians can participate in the program. Initially, the program will be limited to fewer than 100 physicians, all of whom participated in the clinical trials earlier, and to patients who participated in the clinical trials and who are not responding adequately to other treatment. Later, the company may extend availability of the drug.

Advertisement Adjusted

"Never underestimate the power of your competition" might be the slogan of the advertising community's self-regulatory system. In any event, it's a lesson any number of advertisers have learned, including one maker of an over-the-counter diuretic. Thompson Medical Company of New York City



recently revised its advertising for Aqua-Ban to conform to an agreement reached with the National Advertising Division of the Council of Better Business Bureaus Inc., which oversees the self-regulatory system. The system was set up in 1971 to maintain high standards of truth and accuracy in national advertising.

Thompson's magazine advertising for Aqua-Ban had carried this claim: "Clinical tests prove that Aqua-Ban not only reduces water weight-gain, but also helps to relieve the bloating, tenderness, cramps, and swelling that women suffer along with it." The ads went on to say that the product's "maximum strength formula is the strongest diuretic available without a prescription. A U.S. Government Panel of medical experts has approved Aqua-Ban's clinically tested formula as safe and effective."

According to the National Advertising Division, a competitor questioned the claim "strongest diuretic available without a prescription," and the reference to cramps, since an FDA-appointed panel studying OTC oral menstrual products did not include "cramps" among the symptoms that could be effectively treated by diuretics. The competitor also questioned use of the word "depression" in the context of a testimonial to Aqua-Ban's effectiveness.

As a result of this challenge, the advertiser agreed not to use references to cramps and the claim "strongest diuretic available without a prescription" in future advertising. While maintaining that "depression" is a colloquialism to indicate a woman's frustration at the temporary weight gain associated with menstruation, the advertiser did agree to use the term "frustration" instead.



The National Advertising Division agreed that the advertiser's claim "proven, prompt, and safe relief" was supported by the advisory panel's conclusions about the combination of ingredients in Aqua-Ban. However, in the interest of complete accuracy, the advertiser agreed to modify the reference to the panel to state, "An advisory panel appointed by the U.S.

Government has recommended Aqua-Ban's clinically tested formula as safe and effective."

Consumer Forum

All Right, Santa, Sign Up

I had an opportunity to read the story, "All Right, Santa, Where's the Red Dye No. 2?" by E. Pitt Smith in the December/January *FDA Consumer*.

The first thing I did was to check our files to see if Santa Claus was a member of this Association. He is not.

Had Santa been a member of the Association, he would have known a long time ago that Red No. 2 was banned by FDA in 1976.

Had he been a member of this Association, he would also have been aware of the Cacao Products and Confectionery Good Manufacturing Practices which would likely limit the presence of extraneous matter in his factory. Using the GMP's, he would have established Critical Control Points in his operation and thus reduced the probability of contamination.

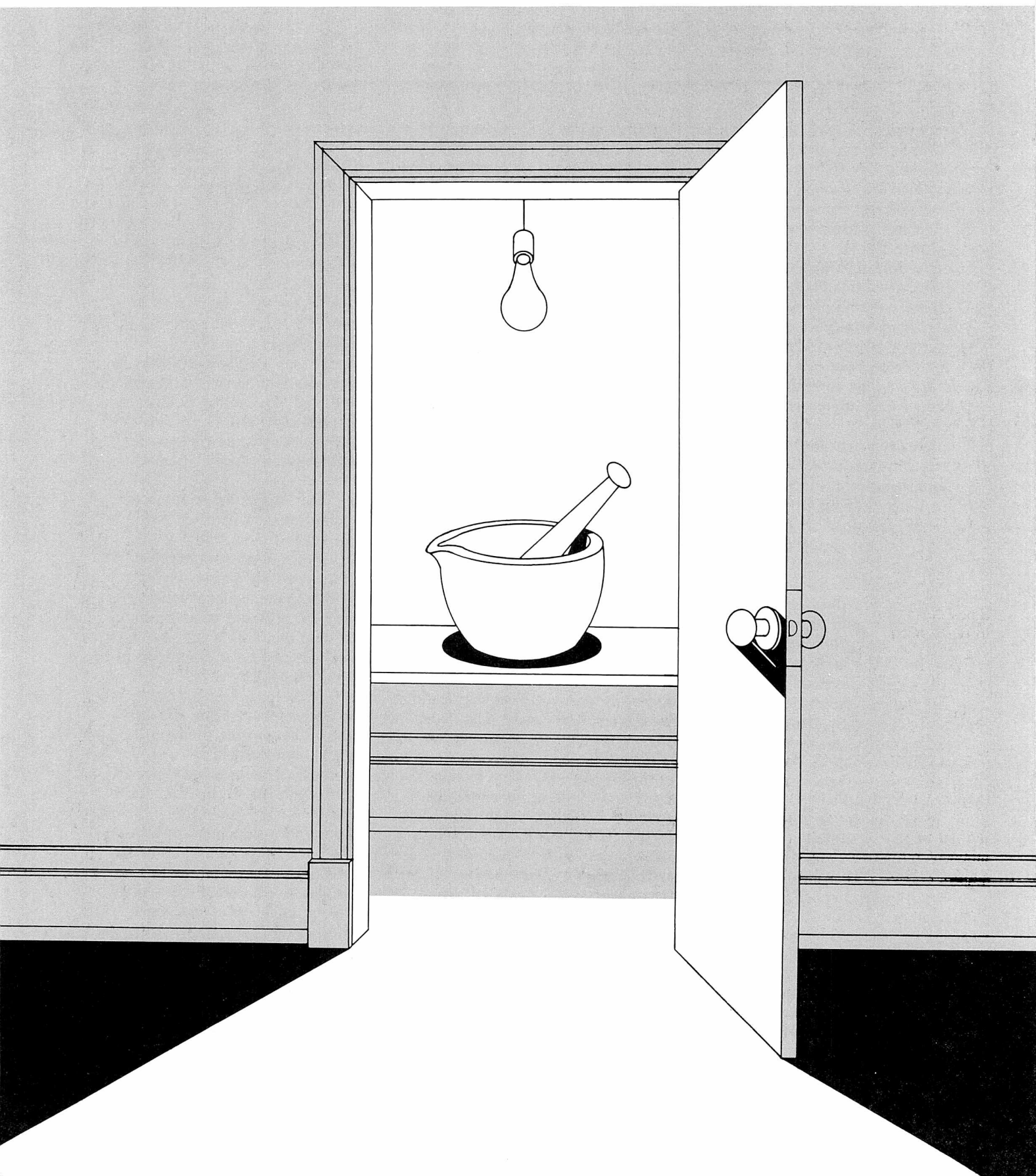
Had Santa Claus been a member of this Association, he would have been aware of the limitations on the presence of alcohol in confections.

However, since Santa Claus represents a figure of charitableness, we will try to exercise the same on the story.

I don't want to initiate a jurisdictional brouhaha within the Food and Drug Administration, but the latest I heard is that the Seattle office is in charge of Alaska, and, I presume, the North Pole. I can visualize Jim Swanson riding out of the west and going stomping in the Buffalo Pitt.

Richard T. O'Connell
Executive Director
National Confectioners Association
Chicago, Ill.

A Future For Orphan Drugs



Editor's Note: The following article might be called medical science fiction. It depicts a situation eight years in the future. It may seem like science fiction, but it could happen.

by Christopher Smith

The date is Dec. 12, 1991. The morning paper announces that sales of the new solar cars are brisk. Cross Country Airlines will soon be introducing a new high-speed jet that can fly from New York to Los Angeles in less than 30 minutes. And in the sports news, fans are wondering who will play in the upcoming Super Bowl XXVI.

All interesting news, but for Susan Byrnes, 30, a headline on page three holds the most interest. It reads: "FDA Approves Drug for Rare Muscular Disease." For Susan, the news marks the end of a success story that began almost nine years earlier, when President Reagan signed into law the Orphan Drug Act of 1983.

The disease struck Susan when she was 16 years old. Night after night, she would awaken with cramps in her legs. After a few months, the cramps grew worse, and soon it took her what seemed like hours just to get out of bed in the morning. The cramps eventually turned into a constant, unabating, almost unbearable pain. Her leg muscles would twitch uncontrollably several times during the day. Her feet swelled to twice normal size. By the time she was 19, Susan's legs could not support her weight at all and she was confined to a wheelchair.

She saw many doctors. Their conclusions were always the same—there was no cure for her disease, only pills to ease the pain and to help her sleep at night. But the hurt Susan remembers the most is not that from the disease, or that which she felt when doctors told her there was no cure. For her, the pain came when she realized that the drug industry wasn't looking for a cure. (See "RX for Orphan Drugs" in the September 1980 *FDA Consumer*.)

Susan suffers from a rare disease. It strikes less than 1,000 persons each year in the United States. It is just one of as many as 2,000 rare diseases that affect patient populations, not of millions—as does heart disease or asthma or the flu—but only hundreds or even fewer persons.

Before the Orphan Drug Act became

law, these rare diseases had not been of enough interest so that treatments could be developed. The cost of bringing a drug to market can reach millions of dollars, and generally a pharmaceutical company could hope to make a profit only on drugs that could help large numbers of people—which means drugs for common diseases. Thus, the term "orphan drug" was given to drugs for which little effort or investment was made in development and improvement because the cost was not expected to be recovered in sales. Most were for rare diseases, like Susan's. Some of the drugs were for more common diseases, but commercial interest was lacking because the drugs could not be patented and thus offered little or no chance for profit.

It was back in the summer of 1984 that Susan met Dr. Thomas Crissey. Dr. Crissey was to become a physiology teacher at a prominent medical school in the Midwest. But back in 1984 he was a young physician with an enthusiastic interest in research and a fascination for the unusual disease that, without warning, had stricken persons such as Susan Byrnes. In his research into the disease, Dr. Crissey was able to isolate a chemical from the leg muscles of patients who had the disease, a chemical never found in healthy individuals.

Experimenting on animals, he was able to induce the symptoms of the disease by using injections of the isolated chemical. Then, by injecting a second chemical, an extract from a tropical plant, he was successful in reversing the crippling effects.

Dr. Crissey thought that his discovery might be one of the keys to developing a drug for treatment of the disease, and eventually he published his findings in a medical journal. In earlier years the discovery may have gone unnoticed, but in 1983 his article was seen by FDA's new Office of Orphan Products Development.

Established in March 1982, the Office of Orphan Products Development was created for the express purpose of searching out promising new therapies for rare diseases and locating drug firms to sponsor the development and marketing of the treatments that proved effective. In its first year, FDA's new office was successful in linking up drugs with sponsors in 14 cases. This task was eased somewhat because, in many cases, the basic research had al-

ready been done and sponsors were needed only to carry out the final marketing.

In time, new discoveries such as Dr. Crissey's were made, and in each case a sponsor was needed to do more than simply adopt a drug that was already developed. The sponsors were needed to conduct the necessary research on new products.

It was a red-letter day for situations of this kind when, on Jan. 4, 1983, President Reagan signed the Orphan Drug Act into law. An amendment to the Food, Drug, and Cosmetic Act, the new law was designed by Congress to facilitate the development of new drugs for rare diseases. Under the act, drug companies can take tax deductions for about three-quarters of the cost of conducting clinical trials on orphan products.

Aided by the tax benefits allowed in the new Orphan Drug Act, FDA's Office of Orphan Products Development had little trouble finding a drug firm interested in meeting with Dr. Crissey and using the data he had developed in animals to plan and conduct trials in humans for the treatment of the rare muscular disorder. With its larger resources, the drug firm was able to set up facilities for cultivating the tropical plant that supplied the needed counteracting chemical. In addition, the firm's manufacturing experts developed a highly purified form of the new drug that was safer and more effective. Dr. Crissey was able to work closely with specialists in pharmacology, statistics and other areas in designing the necessary protocols to show that his discovery could be useful in humans.

Susan's orphan disease wasn't the only one that got attention back in the 1980s. The Orphan Drug Act also authorized \$4 million in grants and contracts for each of the years 1983 through 1985 to fund research on orphan drugs. During those years, FDA provided funds to physicians, medical schools and private firms, all of which were pursuing promising treatments for orphan diseases.

By 1990, Dr. Crissey's research had proved to be on the right track. Susan and others suffering from the disease had made remarkable improvements because of the experimental chemical. Susan's pains had subsided to occasional cramps, she could sleep again without drugs, and she could even get around without a wheelchair.

Orphan Drugs For Which Sponsors Were Located In 1982

Drug	Sponsor	Use
methacholine chloride	Roche Laboratories, Nutley, N.J.	For use in the diagnosis of occult bronchial asthma
Hematin	Abbott Laboratories, N. Chicago, Ill.	For the treatment of hepatic porphyria
NP-59 (6-beta-19-iodonorcholesterol)	Mallinckrodt Inc., St. Louis, Mo.	For use as an agent in adrenal cortical imaging
L-5 hydroxytryptophan	Bolar Pharmaceuticals Inc., Copiague, N.Y.	For the treatment of postanoxic myoclonus
carnitine	McGaw Laboratories, Santa Ana, Calif.	For the treatment of carnitine deficiencies
hydroxy-ethyl starch	American Critical Care, McGaw Park, Ill.	For use in white blood cell harvesting
Bacitracin	A. L. Laboratories Inc., Englewood Cliffs, N.J.	For the treatment of pseudomembranous enterocolitis
Trien (triethylene tetramine dihydrochloride)	Merck Sharp & Dohme, West Point, Pa.	For the treatment of Wilson's disease
amiodarone	Ives Laboratories Inc., Covina, Calif.	For treatment of cardiac arrhythmias
vitamin E	Roche Laboratories, Nutley, N.J.	For use in the treatment of neuromuscular disorders secondary to cholestatic disease in vitamin E-deficient patients
pentamidine isethionate	Zenith Laboratories Inc., Northvale, N.J.	For the treatment of <i>Pneumocystis carinii</i> pneumonia
Pimozide	McNeil Pharmaceutical, Spring House, Pa.	For the treatment of Tourette's syndrome
indium ¹¹¹ oxine	Medi-Physics Inc., Emeryville, Calif. Amersham Corp., Arlington Heights, Ill.	For use as an agent in platelet imaging
ethanolamine oleate	Disclosure of sponsor not authorized	For the treatment of bleeding esophageal varices

For the drug firm, the provisions of the Orphan Drug Act allowed a return of about 73 cents of every dollar spent in the clinical development of the new drug. In addition, because the drug was a naturally occurring chemical and nonpatentable, FDA was able to grant the firm an exclusive licensing arrangement for a marketing period of seven years. This licensing was another incentive provided in the Orphan Drug

Act to encourage manufacturers to develop nonpatentable products that show promise in the treatment of orphan diseases.

But for Susan, Dec. 12, 1991, was the biggest day of all, and the story contained in the pages of the morning paper heralded more than the approval of a new drug. It was an example of the success that is possible when FDA, the Congress, the pharmaceutical in-

dustry and the research community work together to bring an orphan drug to market. It's the story of a better life for those so unfortunate as to be afflicted with an uncommon disease. For Susan, it's the story of her future.

Christopher Smith is a member of FDA's press staff.

The Mystery Of Crib Death

by Richard C. Thompson

In the United States it's known as "crib death"; in England as "cot death." But both are softened words that cannot hint at the despair they carry. It is almost better to use the harsh, unforgiving language of "sudden infant death" that is found in the medical literature.

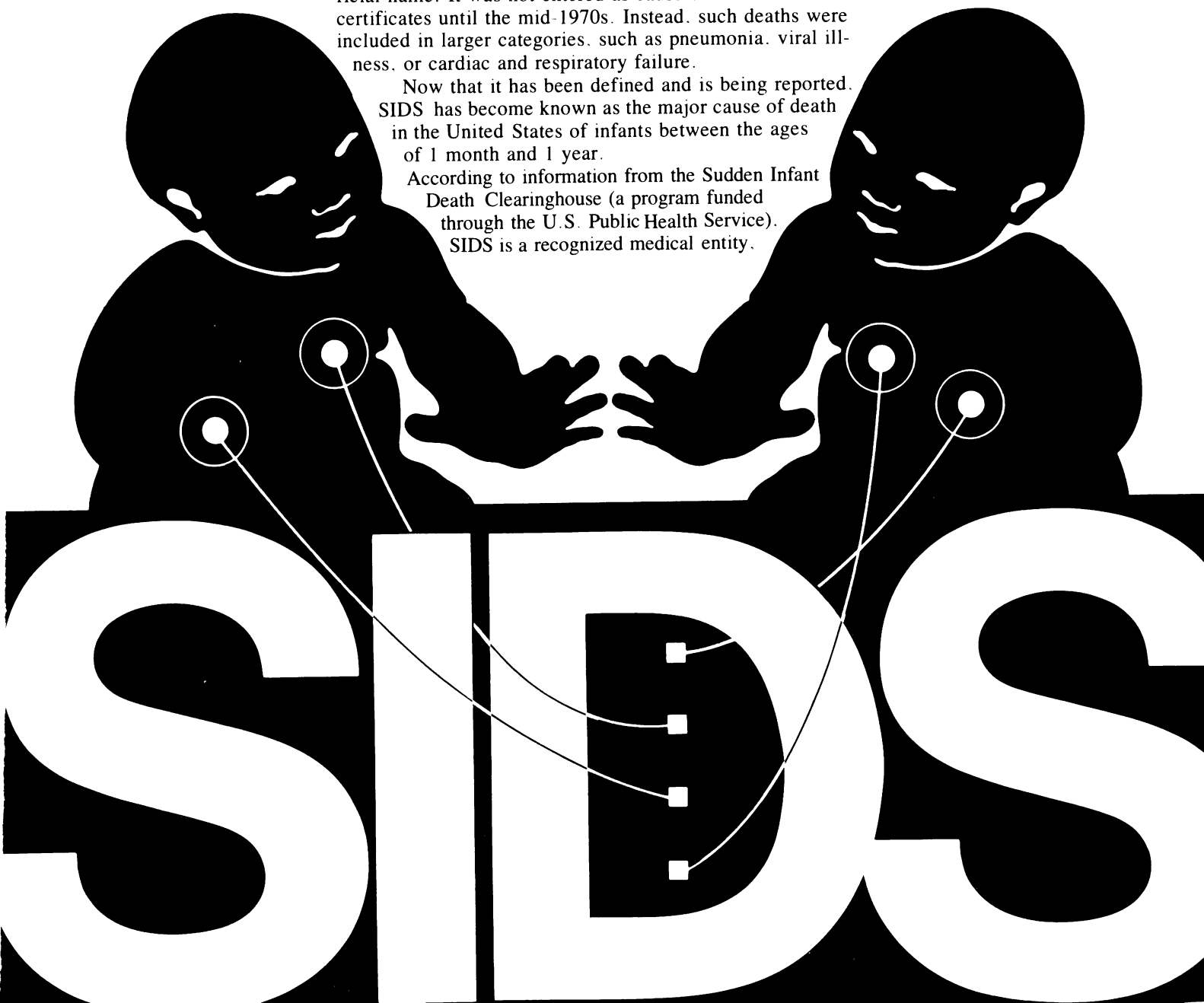
That literature informs us that unexplained infant deaths have occurred since biblical times, and throughout the world for hundreds of years. But it's small comfort to parents who place an apparently healthy baby in its crib and come back in the morning, or even within an hour, to find it dead. The grief—and the blame they may fix upon themselves or each other—can devastate their lives and destroy the family structure.

Sudden infant death syndrome (SIDS) is the sudden, unexpected and unexplained death of an apparently healthy baby. Until the 1960s, this phenomenon did not have an official name. It was not entered as cause of death on death certificates until the mid-1970s. Instead, such deaths were included in larger categories, such as pneumonia, viral illness, or cardiac and respiratory failure.

Now that it has been defined and is being reported, SIDS has become known as the major cause of death in the United States of infants between the ages of 1 month and 1 year.

According to information from the Sudden Infant Death Clearinghouse (a program funded through the U.S. Public Health Service),

SIDS is a recognized medical entity.



meaning that it has a name, a code number, and a place in the medical literature. Still, very little is actually known about it.

From what is known, SIDS is not believed to be hereditary. It is not contagious, although a viral infection may be present. It cannot yet be predicted or prevented, neither by parents nor physicians. The baby may seem healthy and there will be no signs to suggest what is about to happen. And though it is small consolation to the parents, there appears to be no suffering; the baby dies within minutes, usually during sleep.

In a typical case, an apparently healthy baby, usually between the age of 1 and 7 months, is put to bed. There is no indication that anything is wrong. Some time later the baby is found dead. There were no sounds of struggle, no crying out.

The baby may have changed position or moved about, as babies do. Some may be found burrowed down in their blankets, and the speculation may be that they smothered—until the autopsy shows that this is not what happened. Many are completely free of blankets, toys and coverings. Suffocation is not the answer.

The assumption may be that the baby choked on its food, but autopsy findings generally dismiss this. A bit of frothy milk may appear near the baby's mouth, but that's evidence of a reflex action, not a cause of death.

An autopsy may reveal minor inflammation of the upper respiratory tract, but this, too, is incidental and not a cause of death. There is usually no finding of illness in a SIDS baby.

About 10 percent of crib deaths do reveal, at autopsy, a rapidly fatal disease (such as meningitis) or a previously unsuspected abnormality. But this 10 percent does not qualify as SIDS deaths because the cause has been found. A true SIDS baby dies of unknown and unexplained causes. The designation of SIDS is made post-mortem and says, in effect, that we don't know why this baby died.

In 1975 the U.S. Office of Maternal and Child Health awarded grants to 24 communities for SIDS information and parent counseling projects.

The grants encouraged autopsies on infants who died suddenly and unexpectedly, and use of "sudden infant death" on the death certificates, instead of other designations of cause. They also encouraged immediate notification of parents about the autopsy results, and follow-up counseling for the families by knowledgeable health professionals. Since many grants went to communities where autopsies were already being done, the funds have been used primarily for parent counseling and for public information and education.

The 1975 grants represented a concerted effort to guarantee that autopsies would be undertaken and relevant information obtained about cases of sudden infant death, so as to determine what these babies had in common that might have caused their deaths. It also gave SIDS an identity of its own (coded 798.0 in the International Classification of Disease), so that data on SIDS occurrence can be reported and studied to see what the patterns might be. The grant program was preceded by a conference of pathologists familiar with SIDS, who developed the protocols (rules and requirements) for SIDS autopsies.

The original 24 projects have more than doubled, and there are SIDS projects throughout the United States, usually administered through state maternal and child health programs. There are SIDS studies being done in medical centers and hospitals, and many physicians have a research and reporting interest in SIDS.

Most states now have laws requiring autopsies involving sudden, unexplained deaths of infants. These autopsy findings will help researchers determine what may—and may not—be the true nature of SIDS.

In the United States, SIDS is responsible for the deaths of about 7,000 infants a year. This averages almost two deaths per 1,000 live births. SIDS clusters among infants 2 to 4 months of age, and seems to occur most often during the winter months. It is not common (but does occur) beyond 6 months of age. Babies born to very young mothers and in poorer socioeconomic circumstances seem most susceptible. SIDS, as heretofore noted, is the leading cause of death for infants from 1 month to 1 year of age.

The original grant program, now expanded and funded by federal block grants to the states, made parent and family counseling a major goal in SIDS.

This is because the unexplained loss of the baby can have a destructive effect on a family. With nowhere to place the blame, parents may accuse themselves or each other, and perhaps be blamed by other members of the family. What would be a normal period of grief and mourning is prolonged and intensified for SIDS families. The loss of a baby to accident or disease can be understood, but not the loss of the baby to an unknown.

Much of the work of the SIDS Clearinghouse is directed to family counseling referrals and information. There is also the SIDS Foundation and the Council of Guilds for Infant Survival. Together with the clearinghouse, they form a national SIDS network.

Many of the local chapter volunteers are SIDS parents who, having lived it themselves, can help the families through this experience. The strongest single message these counselors carry is that in the mystery that is SIDS, no one is to blame. Not the family, not the physician, nor anyone. This reassurance must be given over and again to parents, and also to children in the family, who will be confused and often fearful.

It is the suddenness—with no warning or time to prepare—and the finality of their baby's death that so devastates a SIDS family. But it can also be the attitude of officials investigating the case, who may know nothing of sudden infant death and will question the parents to determine if there has been child abuse. To have this added to their loss may be more than the parents can bear. Ambulance crews, usually the first to respond to a SIDS death, are instructed to be especially aware of the emotional trauma they may encounter, and to attempt emergency resuscitation of the infant, even when they know it is too late.

The need to establish a possible cause of death and to remove parental uncertainty and guilt is one reason the SIDS or-

Monitoring The Monitors

FDA's Office of Medical Devices receives and investigates reports of problems and failures with apnea monitors, forwarded to the agency by hospitals, physicians, parents and other users. Some of these go back to the 1970s. Following is a sample of more recent reports:

November 1980—Hospital reports Becton Dickinson would not repair two units that malfunctioned because they had been discontinued from the product line. Insurance carriers notified.

June 1981—Apnea monitor failed to trigger alarm and showed respiration long after infant had expired. Manufacturer (Hewlett Packard) found a relay in the circuit had failed, something the firm said seldom happens:

March 1982—Respiratory monitor failed on Healthdyne unit. Parents responded to the unit's cardiac alarm (showing heartbeat had slowed or stopped), but 5-month-old infant had already expired.

March 1982—Switch positioning and design on Parks Electronic unit allowed switch to be set at "battery check" instead of "alarm" location. Several users reported this problem, including parents of an infant who died unnoticed during an apnea episode.

October 1982—Poor shielding on a Healthdyne unit allowed radio transmission signals to interfere with the unit's alarm system.

January 1983—New model Healthdyne unit either fails to sound an alarm on heart and respiration lines or sounds an alarm on all systems when there is no reason.

January 1983—New model Medicom unit failed to respond during apnea episode, and baby died.

ganizations want an immediate autopsy, with results made known to the parents, and to have health professionals brought into the investigations.

A possible relationship between SIDS and sleep apnea—a momentary pause in breathing while asleep—has intrigued medical scientists for many years. Studies have shown that hesitant breathing does occur in infants. It is, within limits, normal in newborns, whose body systems are still making functional adjustments. Their breathing will resume automatically. But some babies have repeated and prolonged episodes throughout their sleep periods. This has been reported by hospital nursery staff, by medical researchers, and by parents observing their babies at home.

If these episodes are recurrent, if the babies become cyanotic with a bluish tinge to lips and mouth, if the heart rate slows to less than 60 beats a minute, the babies need immediate medical attention. Parents have reported finding their babies not breathing, limp and pale or bluish when they had thought they were simply asleep. Sometimes shaking and resuscitation is needed to get them breathing again.

The term "near-miss SIDS" has been applied to these babies, for the reason that they may have come close to death. But some researchers do not accept this designation, because the SIDS puzzle is too large and complex for such an easy answer. They point out that incidents of "near-miss SIDS" account for very few of the cases of sudden infant death. They believe that sleep apnea babies have a physiological problem, a "respiratory dysfunction" unrelated to SIDS. It is misleading, they say, to identify sleep apnea too closely with SIDS, and can divert interest from finding the true cause of SIDS.

One result of the sleep apnea problem has been the appearance of devices that monitor the infant and sound an alarm if breathing stops. These are often soft foam belts that encircle

the infant's chest and signal through an electronic contact when the chest is not moving and breathing has supposedly stopped. Crib pads with sensors also are available and do much the same thing. Some monitors include a sensor that reacts if the heartbeat slows or stops, which can happen in severe cases of apnea.

They are widely used in hospital nurseries, especially in the newborn intensive care units, where trained staff watch the babies closely. In such a locale—and used on infants that are at risk—they can be very effective.

They are also being used in the home, where parents may have been told by their physician that their baby needs this kind of monitoring. If the baby had a monitor in the hospital nursery, this device may be taken home by the parents to use.

There can be problems with these monitors. Having the unit in the baby's room creates an added feeling of tension among members of the household, as though they were waiting for something to happen. The settings must be precise or the unit will sound too often, or not sound when it should. If it sounds too often, some parents may disregard it or even disconnect it.

The Food and Drug Administration regulates the manufacture and marketing of apnea monitors as medical devices. FDA requires that they be labeled for restricted (prescription) use only, but not all states enforce this.

Some dealers advertise and attempt to sell the devices directly to parents (often door-to-door and by mail) by following birth announcements in the newspapers. These dealers may use alarmist advertising and news stories about the dangers of sudden infant death, and claim that their product will prevent it. FDA has taken action against dealers who make such exaggerated claims.

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

The Public Knows And Cares About Sodium

by Roger W. Miller

For the person looking to cut down on salt, everything from soup to nuts is available today.

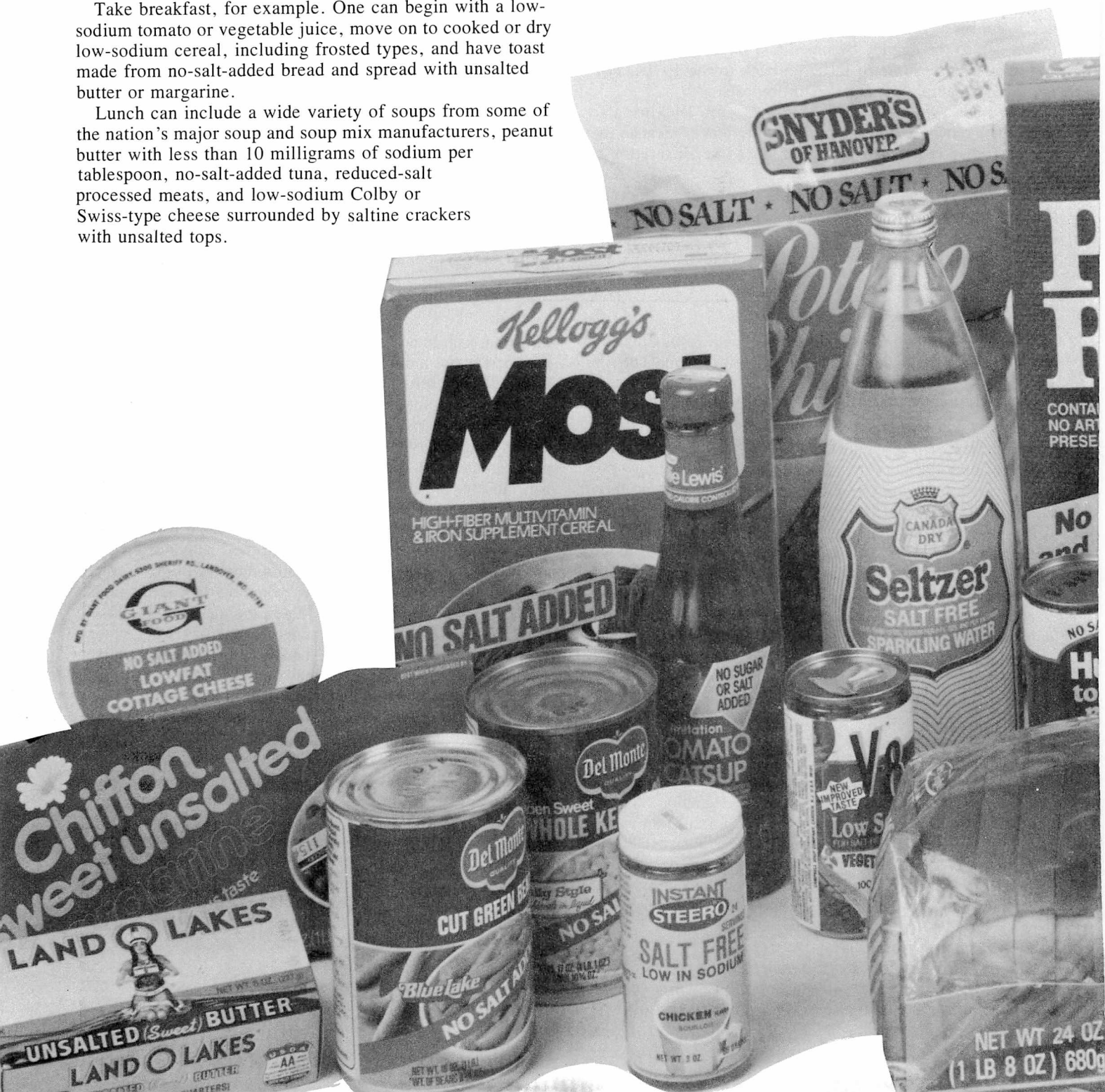
Indeed, the salt-conscious person (and there now are many of them) can dine for days on processed foods with a minimum of repetition as well as very little sodium.

Take breakfast, for example. One can begin with a low-sodium tomato or vegetable juice, move on to cooked or dry low-sodium cereal, including frosted types, and have toast made from no-salt-added bread and spread with unsalted butter or margarine.

Lunch can include a wide variety of soups from some of the nation's major soup and soup mix manufacturers, peanut butter with less than 10 milligrams of sodium per tablespoon, no-salt-added tuna, reduced-salt processed meats, and low-sodium Colby or Swiss-type cheese surrounded by saline crackers with unsalted tops.

For dinner, there's tomato paste, spaghetti sauce, pasta, a long list of no-salt-added canned vegetables, cottage cheese, turkey breast, bread sticks, condiments such as ketchup and salad dressings, cookies, candies and frozen desserts.

In between these meals, there's snacking available on unsalted peanuts, pretzels or potato chips. Soda water and bottled water with low-sodium content are available for those who like it plain or with a little spirit in their snacks. Melba toast, pastries, rice cakes and tea crackers are among the other items available for the snacker who wishes to slight sodium.



Ah, but the list is not ended. Should the diner overindulge in this low-sodium orgy, there are antacid and antifatulent medicines available in low-sodium versions.

The situation was not always such. Two years ago most of the items listed above were not available or even on the food processor's drawing board. What has happened since then is that the public became aware of some possible health consequences of consuming too much sodium. The public's consciousness got nudged when FDA and other government agencies focused on the connection between high blood pressure and sodium and other dietary components. The food processing industry and others then followed suit. The result was that the public got what it wanted.

It was two years ago this month that FDA laid out its sodium program. Included were certain food labeling requirements, a public education program, and an effort to get food processors to voluntarily label their products as to sodium content.

The success of the program can be judged in part by a trip to the grocery. Three members of FDA's publications staff made such trips recently and came up with the items listed above. The rest of the story is probably best told in these figures:

- Nearly three out of four adults have read or heard about health problems related to sodium or salt.
- Slightly better than half of the adult population connects



high blood pressure with salt consumption.

- Four out of ten adults are trying to avoid or cut down on salt or sodium.
- By mid-1982, consumers had a 50 percent better chance of finding salt content on food labels than they did two years earlier.

The high public awareness of sodium and its link to hypertension was found in a nationwide survey conducted by telephone in October and November 1982. The survey was sponsored by FDA's Division of Consumer Studies and the High Blood Pressure Education Program of the National Heart, Lung and Blood Institute. The interviewing was done by Market Facts Inc. of Chicago.

In all, 4,000 people were interviewed in groups of 1,000. Asked about awareness of sodium and health problems, 73 percent in one group said they had read or heard of such problems. In another group, 81 percent said they had read or heard that high blood pressure was related to what people ate or drank. Just over half of that group named salt (or sodium) as the food item linked with hypertension.

A question about foods people were trying to avoid probably gave the best indication of the change in the public's awareness of sodium and hypertension over the past few years. In 1978, the three items that people were trying to avoid the most were:

- Sugar—27 percent trying to avoid
- Salt/sodium—14 percent
- Preservatives—10 percent

The same question was asked in 1982, and the order and figures changed as follows:

- Salt/sodium—40 percent trying to avoid
- Sugar—30 percent
- Preservatives—10 percent

The researchers pointed out that the salt avoidance jump occurred even though percentages for all other items remained relatively the same. Other items mentioned included artificial food colors and dyes, additives, oils, fats, saccharin and caffeine.

The fact that salt had been No. 2 on the public's avoidance list indicates that FDA had a lot to build on when it began its public education program in 1981. The Heart, Lung and Blood Institute had been including the sodium theme in its long-term education program, but a threefold jump in four years was termed remarkable by the researchers.

The U.S. Department of Agriculture has joined FDA and the National Institutes of Health in the public education program. That program has included radio and TV public service announcements featuring such personalities as singers Billy Eckstine and Charlie Pride; special brochures and reprints; countless news stories generated in part by mailings to science and medical writers around the country; bus and subway cards; and a scripted TV program for use by local stations and cable networks.

Also included was a letter from FDA Commissioner Arthur Hull Hayes Jr. to the nation's 440,000 physicians and 50,000 medical students.

Singled out for special attention were two groups that are highly susceptible to hypertension—blacks and the elderly. The American Association of Retired Persons has been working with FDA on a separate education program for its 12 million members.

The education program has not been exclusively a government affair. A number of food processors and industry groups as well as consumer organizations have pitched in to

deliver the sodium message. Separate brochures have been printed by the Salt Institute, the National Soft Drink Association, the Food Marketing Institute, General Mills, the American Spice Trade Association, Sunkist, and Lea & Perrins Inc., makers of Worcestershire sauce. Literature is also provided by a number of grocery chains, including Alpha Beta, Finast, First National Stores, Giant, Purity Supreme, ShopRite, Vons Grocery and Wegmans.

Materials, including a 30-second public service TV announcement, have been made available in Spanish, and the Iowa Commission for the Blind has taped the Salt Institute's brochure "Straight Talk About Salt."

More salt information is getting on food labels. FDA surveyed labels in 1982 and found that 19 percent carried information on sodium content (i.e., how much sodium is in the food). That represented nearly a 50 percent increase from the 13.4 percent found in 1979 on the dollar volume of packaged processed foods.

Last year's surveying was done between March and June and did not reflect the labels on the 1982 "pack" (food from the 1982 harvest). More surveying is being done this year.

Much of the sodium labeling information is going on nutrition labels, which are required to carry information on specific nutrients in food. Nutrition labeling becomes mandatory when a nutrient is added or a nutritional claim is made, such as "low in calories" or "high in vitamin C." However, food processors—acknowledging a health-conscious public—have been using the nutrition label on many products that make no such claims, so that today more than 40 percent of processed food labels carry nutrition information.

Sodium is not one of the items that must be listed on a nutrition label. However, regulations proposed in 1982 would require sodium listings. FDA has received some 2,700 comments on those regulations, which are still under review.

As might be expected, the sodium program has not been without controversy. Some question whether the message should be aimed at all people. Part of the problem has been that the scientific basis is not absolutely definitive. Experts can't state flatly that excessive sodium consumption *causes* hypertension. Rather, the predominant medical/scientific view is that there is an association or link between sodium consumption and high blood pressure, particularly for salt-sensitive persons.

And who is a salt-sensitive person? As Dr. Alan Forbes of FDA pointed out in an interview in the October 1981 *FDA Consumer* ("The Case for Moderating Salt/Sodium Consumption"): "It is very difficult . . . to determine in advance who is and who isn't [salt sensitive]."

Dr. Forbes also noted in that article that the cause of hypertension is multifactorial. That is, there are believed to be a number of causes or contributing factors. These include smoking, stress, heredity, obesity and possibly other dietary components—but not necessarily in that order.

The controversy was summed up quite well recently in *ACSH News & Views*, a publication of the American Council on Science and Health. Said writer Harry Schwartz in that publication: "In summary, many medical experts and policy makers have expressed the view that sodium reduction for everyone can't hurt and might help prevent hypertension in some people."

Roger W. Miller is editor of FDA Consumer.

What They're Doing About Sodium

These are examples of efforts by various food processors and organizations to reduce the sodium content of the food supply. The list reflects FDA's information on lowered-sodium products at approximately the end of 1982. Additional sodium-modified products may be currently marketed.

Adams Foods, Tacoma, Wash.—no-salt-added peanut butter

Adolph's Ltd., N. Hollywood, Calif.—unsalted, natural tenderizer

American Meat Institute, Washington, D.C.—initiated studies in university laboratories on the reduction of sodium in processed meats

American Frozen Food Institute, McLean, Va.—40 percent of member firms plan to review cooking instructions that call for salt, and 32 percent plan sodium reductions in products

Anderson Pretzel, Lancaster, Pa.—unsalted snacks

Association for Dressings and Sauces, Atlanta, Ga.—a significant percentage of member firms are considering sodium reduction in some or all products

The Bachman Co., Reading, Pa.—unsalted snacks

Baltimore Spice Co., Garrison, Md.—low-sodium formulated spice mixtures for food processing

Banquet Foods Corp., St. Louis, Mo.—formed task force to study lower-sodium products

Beatrice Foods Co., Chicago, Ill.—low-sodium hydrolyzed vegetable protein for use as an ingredient in processed foods. Beatrice Foods' Fisher Nut Co. has introduced reduced-sodium nut snacks

Big Bear Stores Co., Columbus, Ohio—introduced private-label line of three no-salt-added canned vegetables

Biscuit and Cracker Manufacturers' Association, Washington, D.C.—passed resolution encouraging members to reduce the sodium content of products

Blackstone Potato Chip Co., Woonsocket, R.I.—unsalted snacks

Bon Ton Foods Inc., York, Pa.—unsalted snacks

Borden Inc., New York, N.Y.—introducing low-sodium bouillons (Wyler) and no-salt-added potato chips (Wise)

John Boyd Co., Lynn, Mass.—unsalted snacks

Buffalo Chips Potato Chips, Rancho Cordova, Calif.—potato chips, unsalted snacks

Cadbury Schweppes, Stamford, Conn.—producing "no-sodium-added" soda water

California Almond Growers Exchange, Sacramento, Calif.—roasted, unsalted almonds (Blue Diamond)

Campbell Soup Co., Camden, N.J.—introduced new line of low-sodium soups, active research program to reduce salt content of all products

Canada Dry Corp., New York, N.Y.—"salt-free" seltzer water

Cantisano Foods—a no-salt-added version of spaghetti sauce

Carnation Co., Los Angeles, Calif.—no-salt-added tomato paste (Contadina)

Charolette Charles Inc.—low-sodium salad dressings and condiments

Chicago Dietetic Supply Inc., La Grange, Ill.—provides about 100 low-sodium or no-sodium food products under the Featherweight label

Crane Potato Chip Co., Decatur, Ill.—unsalted snacks

Cross & Peters Co., Detroit, Mich.—unsalted snacks

Culbro Corp., New York, N.Y.—unsalted snacks

Custom Food Products Inc., Chicago, Ill.—offers a line of low-sodium soup, gravy and sauce bases for food processors

Tommy Dale Potato Chips Inc., Reading, Pa.—unsalted snacks

Del Monte Corp., San Francisco, Calif.—introduced a major line of canned vegetables prepared without salt (14 items)

(Continued)

- N. Dorman Cheese Co., Syosset, N.Y.—introduced four no-salt cheeses
- East Smithfield Farms, East Smithfield, Pa.—announced a reduced-salt cream cheese
- Estee Corp., Parsippany, N.J.—low-sodium instant soup mixes, salt-free alternative seasonings, and low-sodium pretzels
- First World Cheese—reduced-salt cheeses
- Flaherty Potato Chip Co., Akron, Ohio—unsalted snacks
- Foremost-McKesson Inc., San Francisco, Calif.—producing controlled-sodium whey products for use in reduced-sodium food processing
- Francesco Rinaldi—a no-salt-added version of spaghetti sauce
- Friday Canning Corp., New Richmond, Wis.—achieved a 25 percent reduction in added salt in canned products. Producing no-salt-added packs for customers
- Friendship Food Products Inc.—low-sodium cheese
- Frito-Lay Inc., Dallas, Texas—unsalted snacks
- Giant Food Inc., Washington, D.C.—introduced line of no-salt-added vegetables and no-salt bread
- Golden Flake Snacks Foods Inc., Birmingham, Ala.—unsalted snacks
- Granite State Potato Chip Co., Salem, N.H.—unsalted snacks
- Granny Goose Foods Inc., Oakland, Calif.—unsalted snacks
- Griffith Laboratories Inc., Alsip, Ill.—producing low-sodium beef flavors for food processing
- Health Valley Natural Foods—no-salt-added condensed soups
- Hercules Inc., Wilmington, Del.—produces low-sodium hydrolyzed vegetable protein for producers of lower-sodium foods
- Herr's Potato Chips Inc., Nottingham, Pa.—unsalted snacks
- Heying Products Inc.—producing a sodium-reduced scrambled egg product
- Homestead Provision Co.—producing 13 varieties of reduced-salt luncheon meats
- Hunt-Wesson Foods Inc., Fullerton, Calif.—announced a no-salt-added tomato products line
- Jays Foods Inc., Chicago, Ill.—unsalted snacks
- Jewel Companies Inc., Chicago, Ill.—marketing a line of no-salt-added and low-salt products
- Jones Potato Chip Co., Mansfield, Ohio—unsalted snacks
- Keebler Co., Elmhurst, Ill.—will examine ways to reduce sodium in existing products, and will attempt to market and develop additional low-sodium products
- Kellogg Co., Battle Creek, Mich.—test-marketing low-sodium cornflakes and Rice Krispies; committed to lower the sodium level in cereal line to lowest extent possible
- Kelly Food Products Inc., Decatur, Ill.—unsalted snacks
- Kikkoman International Inc., San Francisco, Calif.—introducing reduced-sodium soy sauce
- Made Rite Potato Chip Co., Bay City, Mich.—unsalted snacks
- McDonald's Corp., Oak Brook, Ill.—working with suppliers to obtain lower sodium levels in all products
- Milk Industry Foundation—urging members to reduce discretionary sodium levels
- Mister Bee Potato Chip Co., Parkersburg, W.Va.—unsalted snacks
- L. J. Minor Corp., Cleveland, Ohio—producing low-sodium meat, seafood and poultry flavor bases for food processors
- Morton Salt Division, Chicago, Ill.—researching information on use of sodium chloride and potassium chloride mixtures in food formulations
- Mother Earth Enterprises Inc.—unsalted snacks
- Mrs. Howe's Food Products Inc., Milwaukee, Wis.—unsalted snacks
- Munch King Inc., Forest Park, Ga.—unsalted snacks
- Nabisco Brands Inc., New York, N.Y.—unsalted margarines
- National Pasta Association, Palatine, Ill.—recommended that members indicate in the cooking instructions on their product labels that the addition of salt to cooking water is optional
- National Pretzel Bakers Institute, New York, N.Y.—most members make products that have no added salt
- New England Organic Co.—low-sodium relishes
- Nibble with Gobble's Inc., Chambersburg, Pa.—unsalted snacks
- Old World Creamery—low-sodium cheese line

Orbit Finer Foods Inc., Choctaw, Okla.—unsalted snacks	Snyder's of Hanover, Hanover, Pa.—unsalted snacks
Panipulus Co., Kansas City, Mo.—developed salt-free yeast foods, providing a means for reducing the sodium content of baked goods	S.S. Pierce Co. Inc., Dundee, N.Y.—converted line of Libby's canned vegetables to no-salt-added products
Paramount Potato Chip Co., Flint, Mich.—unsalted snacks	Star-Kist Foods Inc., Terminal Island, Calif.—introduced a 60-percent-less-salt tuna
Peerless Potato Chips Inc., Gary, Ind.—unsalted snacks	State Line Snacks Corp., Wilbraham, Mass.—unsalted snacks
Pickle Packers International Inc., St. Charles, Ill.—developing technology for eliminating some sodium from pickled vegetables	Stella D'Oro Biscuit Co. Inc., Bronx, N.Y.—produces specialty no-salt-added baked goods
Pillsbury Co., Minneapolis, Minn.—Green Giant division preparing a line of low-salt vegetables	Stop & Shop Companies Inc., Boston, Mass.—introduced a no-salt-added line of canned vegetables and a line of no-salt-added breads
Planters Peanuts, Suffolk, Va.—unsalted peanuts	The Stouffer Corp., Solon, Ohio—formed task force to study lower-salt products
Potato Chip/Snack Food Association, Arlington, Va.—over 40 member firms now produce no-salt-added snacks	Tom Sturgis Pretzels Inc., Shillington, Pa.—unsalted snacks
Presco Food Products Inc.—developed a line of low-sodium seasoning blends and flavorings for food processors of low-sodium products	Sun Valley Mineral Water—low-sodium mineral water
The Prince Co. Inc., Lowell, Mass.—no-salt-added pasta products	Super Valu Stores Inc., Eden Prairie, Minn.—no-salt-added canned vegetables
Pure Culture Products Inc.—produces low-sodium autolyzed yeast products for flavoring salt-free foods	Swift & Co., Chicago, Ill.—low-sodium peanut butter (Peter Pan) and low-sodium cheeses (Pauly)
Quaker Oats Co., Chicago, Ill.—low-sodium cereals; conducting a major research program to reduce sodium content of products	Terrell's Potato Chip Co. Inc., Syracuse, N.Y.—unsalted snacks
Ralston Purina Co., St. Louis, Mo.—producing a 50-percent-less-salt tuna (Chicken-of-the-Sea); exploring the possibilities of using salt substitutes in many products	Terry's Inc., Bristol, Va.—unsalted snacks
Reisman Pretzel Co., Pennsauken, N.J.—unsalted snacks	Thomasson's Potato Chip Co., Elyria, Ohio—unsalted snacks
Rhineland Foods Inc., Rhineland, Wis.—unsalted snacks	Tri-Sum Potato Chip Co. Inc., Leominster, Mass.—unsalted snacks
Safeway Stores Inc., Oakland, Calif.—introduced a line of unsalted bread products	Utz Quality Foods Inc., Hanover, Pa.—unsalted snacks
Salem Potato Chip Co.—unsalted snacks	Venus Wheat Wafers Inc., Boston, Mass.—salt-free crackers
Sargento Cheese Co. Inc., Plymouth, Wis.—lowered-salt cheeses	Vincent's Potato Chips Inc., Salem, Mass.—unsalted snacks
Laura Scudder's, Anaheim, Calif.—unsalted snacks	Vlasic Foods Inc., West Bloomfield, Mich.—testing a line of salt-reduced pickles
Seyfert's Inc.—unsalted snacks	Wachusett Potato Chip Co., Fitchburg, Mass.—unsalted snacks
Smithfield Foods Inc., Gwaltney Division, Smithfield, Va.—will market processed meat products with 25 to 40 percent less salt than traditional formulations	Weetabix Company—establishing a five-item line of low-sodium cereals

Hair Analysis? May As Well Be Bald

by Louise Fenner

Can a lock of hair tell all? Is there a laboratory test for tresses that will reveal nutritional deficiencies and excesses in your diet and diagnose a number of diseases as well?

The people who want you to send them \$35 or \$40 for a hair analysis say yes. But many scientists, physicians and nutritionists say it's just another way to make some people richer and you poorer.

Hair analysis is performed by commercial laboratories that promote their

and will be advised to take a number of supplements—which the same firm offers for sale in many cases. Vitamins may be recommended even though it is impossible for hair analysis to provide any vitamin information since there are no vitamins in hair trimmings.

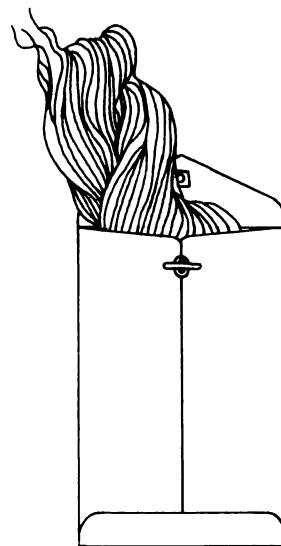
One firm told a woman who was in good health that her hair analysis revealed a deficiency of phosphorus, manganese, iron and zinc, and that she had “toxic levels” of selenium, aluminum and nickel. The firm advised her to start a daily regimen that included 28 doses of 15 different products, including vitamins, minerals and other food supplements. Although the company implied that its advice was based on the customer's hair analysis (even suggesting a second analysis in four months to “update the program”), it recommended virtually the same supplements to other customers. Recommendations for nearly a dozen “nutrition health tests”—most scientifically useless—also appeared on the printout for each customer.

Some hair analysis laboratories come close to diagnosing medical problems and prescribing therapies for them. Advertisements for hair analysis often imply that chronic health problems such as fatigue, depression or headaches may be alleviated by achieving proper mineral balances, although there is no scientific evidence to support this. In the case of the woman mentioned above, the firm stated that her mineral “ratios” were out of kilter and that numerous diseases are often associated with mineral imbalances, including arthritis, diabetes, mental disorders and arteriosclerosis.

In addition, the firm recommended chelation therapy for the woman's alleged “aluminum toxicity.” Currently, there is no chelating agent approved by FDA for removing aluminum from the body. Chelating agents are used to treat metal poisonings because they bind to metal ions to speed their elimination from the body. They must be administered under the guidance of a physician and are generally recommended only when the metal toxicity is a severe threat to the patient's health.

mail-order services through health food stores, health magazines and books. The customer is asked to cut approximately two tablespoons of hair from the scalp and send it to the laboratory. The firm sends back a computerized listing of the minerals found in the customer's hair and may interpret them in terms of the body's nutritional status. Hair analysis is also used by some chiropractors, nutrition “consultants,” dentists and practitioners of holistic medicine as a diagnostic aid.

One purpose of hair analysis appears to be to promote the sale of vitamin and mineral supplements. More often than not the customer will be told he or she has deficiencies of several minerals



Chelating agents themselves can be toxic; some can cause kidney injury and, in large doses, even death.

At least one criminal court case has ensued from hair analysis, according to *Vitamins and 'Health' Foods: The Great American Hustle* by Dr. Victor Herbert, J.D., and Dr. Stephen Barrett (George F. Stickley Co., 1981). The Los Angeles City Attorney's Office initiated prosecution in 1980 after a woman complained that the owners of a health food store said that her hair analysis indicated she had a bad heart valve, abscesses of the pancreas, arsenic in her system and benign growths of the liver, intestine and stomach. Two “herbal” substances were prescribed. The store owners later told the woman her earlier conditions were gone, but that she now had lead in her stomach. After pleading “no contest” to one count of practicing medicine without a license, the owners were fined \$2,000, given a 60-day suspended jail sentence and placed on probation for two years.

The popularity of commercial hair analysis has grown in the past 10 years, partly because of the development of new analytical techniques. In

the past a separate analysis was done for each mineral, and thus considerable amounts of hair could be involved if numerous analyses were required. Now a multitude of minerals can be accurately measured using a small amount of hair.

When performed by a qualified scientist, hair analysis can be of limited use in the detection of toxic levels of a few minerals, including lead, arsenic, cadmium and methyl mercury. For example, hair analysis may be helpful in diagnosing a suspected poisoning by arsenic, but confirmation must be made by other tests. Hair analysis is useful in the study of population groups when enough samples can be taken to produce statistically significant results. But its use is still "extremely limited" for study of individuals, according to Dr. K. Michael Hambidge, writing in a recent article in *The American Journal of Clinical Nutrition*.

One problem is that factors such as the color of hair, the part of the body it came from, the season of the year, and the individual's age, sex and race can have a bearing on the mineral content of hair. In addition, elements can be added to or removed from hair by contact with water, environmental pollutants, shampoos (some dandruff shampoos contain zinc or selenium), hair sprays, hair dyes, color "restorers" containing lead, hair dressings and other products, and treatments for bleaching, straightening and permanent waving.

Furthermore, the results of hair analysis can be affected by the portion of hair analyzed (near the scalp or farther along the shaft), washing and preparation by the laboratory, and the kind of analytical methods used. Specialized procedures are required for analysis of some elements. Researchers have tried to develop suitable standardized procedures for hair preparation and analysis, but they don't exist yet.

Commercial hair analysis laboratories claim that they compare the mineral content of customers' hair with a "normal" range, but there is no clear definition of normal concentrations with any physiological or health-related significance, according to Dr. Hambidge.

Another problem: limited information about correlations between mineral content of hair and the body's tissues and organs. It's known that the concentration of some minerals in the hair does *not* correlate with nutritional sta-

tus. "There are no data to indicate that low concentrations of an element in the hair indicate low tissue levels, or that high concentrations reflect high tissue stores," says the American Medical Association's Committee on Cutaneous Health and Cosmetics. "The state of health of the body may be entirely unrelated to the physical and chemical condition of the hair."

In light of all these drawbacks, does a consumer who sends a hair sample to a commercial laboratory have much chance of getting an accurate assessment of his or her nutritional status—or even of getting accurate analytical results? The answer isn't very reassuring. The Herbert-Barrett book describes an investigation in which samples of hair from three healthy men were sent to three commercial labora-



tories for analysis. Included were duplicate samples from each person. The reported results varied not only from one laboratory to another, but also from sample to sample of the same individual.

Because of abuses such as the one that prompted the Los Angeles legal action, several state and federal agencies are raising questions about commercial hair analysis—for example, whether some firms are practicing medicine without a license, violating licensure requirements for laboratories engaged in interstate commerce, making false or misleading claims for hair analysis, or otherwise acting outside the law. FDA regulates the marketing

of diagnostic testing products similar to those used in hair analysis and is currently evaluating the role it should take.

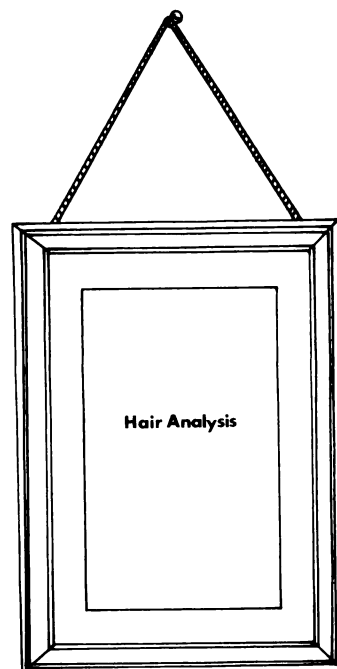
"You can't take someone's hair sent to you in a bag and tell them what their nutritional status is—that's foolishness," says Richard M. Jacobs, Ph.D., chief of FDA's nutrient toxicity section and consultant in a number of investigations of hair analysis laboratories.

"We have no basis with which to apply hair mineral composition to nutrition status, and in fact we have compelling reasons *not* to, at least on an individual basis.

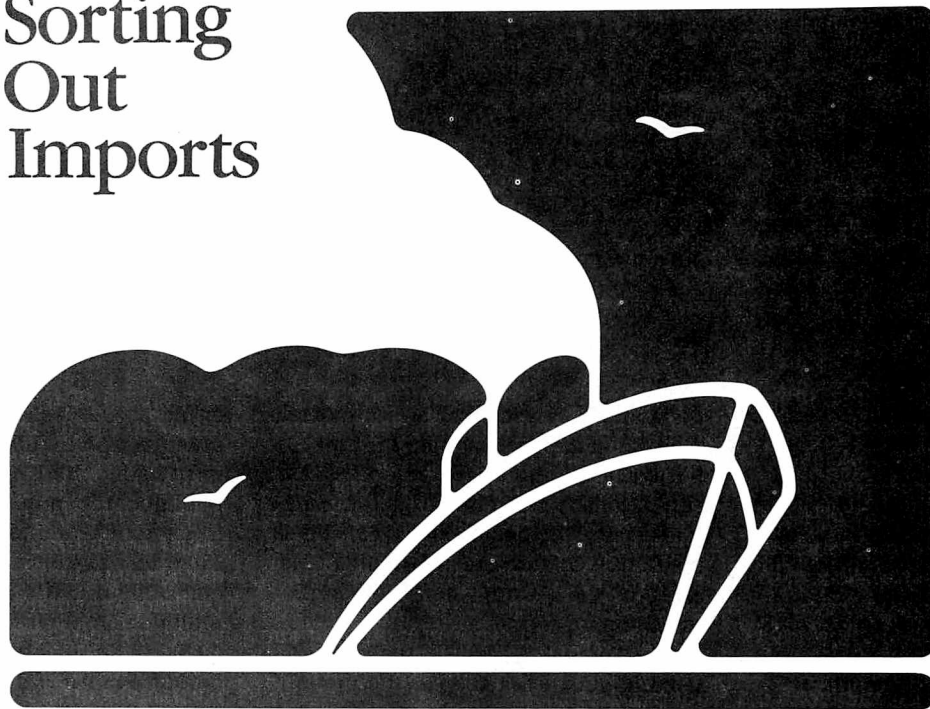
"These people are usually selling something in addition to the hair analysis. They tell their customers they are deficient in something and try to sell them supplements and additional tests. Or worse, they make hazardous recommendations such as chelation therapy. Then it's not a benign activity. It's extremely dangerous."

The best advice may come from Dr. Jeffrey Lieblich, a Chicago-area endocrinologist who was asked by a television reporter what he would tell his patients about hair analysis: "It's a worthless piece of information. I'd tell a patient of mine to frame it, because about all it's worth is to hang it on the wall as a piece of art."

Louise Fenner is a member of FDA's publications staff.



Sorting Out Imports



An enterprising Mexican exporter decided that the way to get his illegal product into the United States was through Taiwan. So round about it went.

The product—spirulina—entered the United States and was made into tablets. But the tablets didn't stay on the market long because the filth that caused the product to be illegal for importation was still in the manufactured tablets.

The incident illustrates extremes to which some foreign exporters will go to get their goods past U.S. import officials. It also illustrates the fact that if an illegal item gets through one law enforcement net, it may well get tangled up in another.

Spirulina is typical in another way: It is a simple alga plant that has been promoted as beneficial to health. In other words, it's peddled as a quack item. The health claims have never been proved (or disproved) but that hasn't been the reason for the Mexican product being kept out of the United States. The reason for that is too many insect parts and other pieces of filth.

Quack items are always high on the list of items turned back (detained) by FDA import inspectors. In the 1982 fiscal year (ending Sept. 30), an estimated 1,854 quack drug items were detained at the nation's 302 points of entry. They included a wide variety of items, ranging from Chinese herbal medicines to Gerovital (KH₃, GH₃, et

al.). (See "Time Marches On Despite Gerovital" in the March 1980 *FDA Consumer*.)

But phony cures aren't the only concern of FDA's import specialists. Unclean and poorly processed foods, dangerous medical devices, illegal cosmetics and untested veterinary drugs are also sought out. In the 1982 fiscal year, a total of 10,868 items were detained, led by 4,604 food products that had sanitation problems. (See listing accompanying this article.)

The import business has been booming. A dozen years ago an estimated 500,000 "entries" were logged in a year's time (an entry is each line on an importation listing that is worth \$250 or more). Now the volume is estimated at 750,000 entries a year that are subject to FDA coverage. The agency inspects about 125,000 of these entries, or approximately one out of six. The uninspected ones are mainly those that are known quantities from known shippers. To do this work, the agency devoted 174.8 person-years in 1982, or about 12.6 percent of its investigatory efforts. (About that same percentage of the consumer dollar goes for imported products regulated by FDA.)

While quack items and produce with illegal or overdoses of pesticides are recurring problems, "international crises" crop up often. A recent one involved shrimp from the Far East. There were more than 1,500 detentions in 1982 of shrimp from India, Hong



Investigator Vince Taormina of FDA's New York Import District handles a case of green peppers from Israel at the Port of Newark. FDA makes about 125,000 import inspections such as this one each year.



Kong, Thailand, Bangladesh, Taiwan and Indonesia. The problem goes back three years now and has involved filth, decomposition and *Salmonella*.

Then there's the sesame seed situation. Sesame seeds from Guatemala have been found violative, as the import people say, because of insect filth. The problem was so extensive that all sesame seeds from that country are to be denied access to the United States. Specifically, 10 of 22 shipments of the seeds from Guatemala were found to contain bug parts in excess of FDA's defect action levels. That's a 45 percent violation rate. Under the law, products can be automatically detained when they have a "past violative history." FDA's criteria for automatic detention is that at least 25 percent of the shipments are in violation and 10 or more detentions have been made within the last six-month period. This criteria establishes the product's post-violative history.

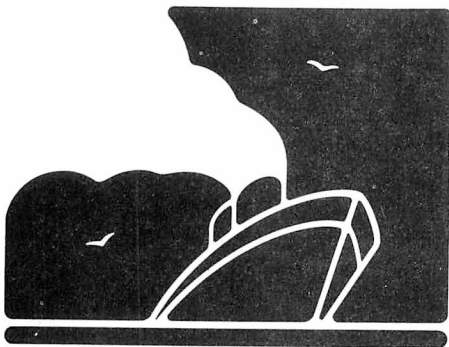
Automatic detention means that entries of the involved product are detained without samples first being tested in an FDA laboratory. Automatic detention may be applied to the products of a single importer, to all entries of a particular product from a particular country, or to all entries of a product itself. Products that are detained may be destroyed, returned to the country of origin or some other acceptable foreign country, or reconditioned to bring them into compliance with U.S. standards.

Crude papain is an example of a product that is automatically detained no matter from what country it originates. Refined papain is used in meat tenderizers. The problem is insects. Papain comes from a tree sap that attracts insects as it is being collected. Crude papain has been on automatic detention status since 1975.

When hazardous or highly violative products are found, import alert bulletins are issued to all FDA import inspectors. A total of 19 new import alerts were issued in 1982.



Tom Mascari, an investigator at New Orleans, checks bananas. In addition to seeing that food items meet U.S. standards, FDA investigators have to watch for a variety of other products that may be illegally shipped to this country, including quack drugs and medical devices.



Low-acid and acidified canned foods, such as peppers, green beans, ripe olives and asparagus, are among the products that have the potential for becoming hazardous. If not processed properly, such foods can cause food poisoning. To market those products in the United States, foreign manufacturers must file their manufacturing processes with FDA. The processes are verified by technologists in FDA's Bureau of Foods, who edit the filed forms for accuracy and completeness of data.

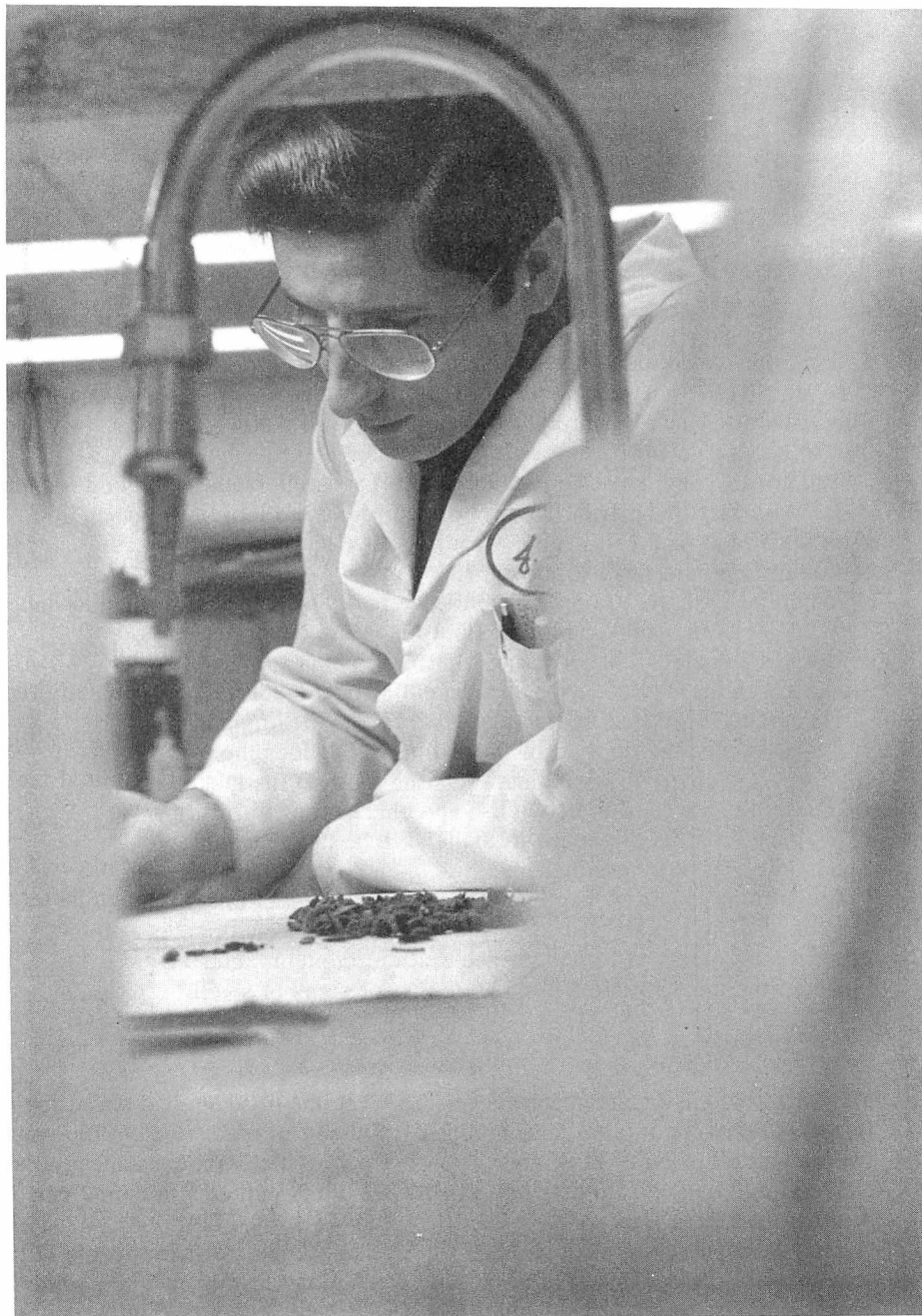
FDA may send inspectors to do a full inspection of a foreign food or drug plant at the invitation of the host country. (See "Japan Diary: Bullet Trains Between Drug Plants" in the July/August 1980 *FDA Consumer*.) The invitations may come if a manufacturer wishes to sell his product in the United States. In other cases, the invitation may result after products have been detained and the manufacturer wants advice on how to produce goods that meet FDA standards.

Just recently the agency sent out an import alert covering dozens of firms in countries all over the globe after the companies failed to respond to letters requesting that their processes be verified.

FDA and U.S. Customs Service employees keep each other informed on what products importers may be trying to slip through. Sometimes it's a matter of a customs official noting that a particular container looks suspiciously like one that FDA has just detained from that shipper. And that may be just the case: A shipper may try to re-enter an illegal product in the same container but "false-invoiced" under a different name.

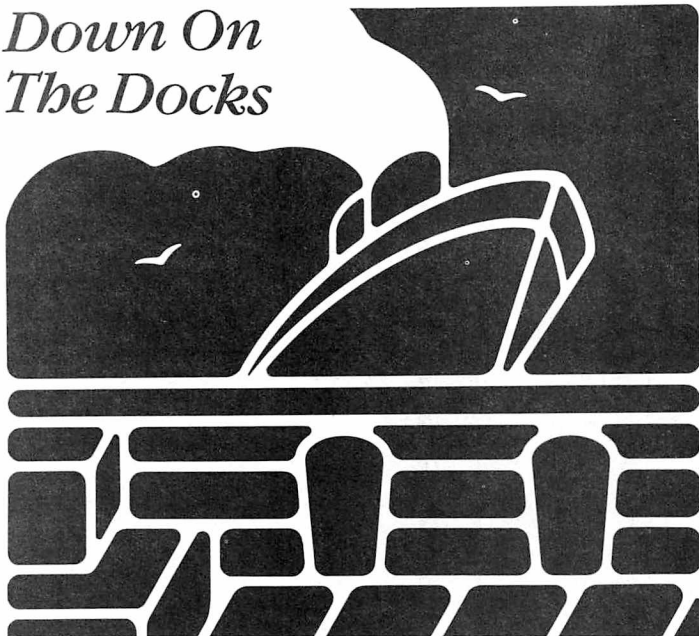
A separate import district was formed last year by FDA in Brooklyn. The district is authorized a staff of 74, including 30 lab specialists (chemists, technicians and microbiologists). The personnel were taken from FDA's regular Brooklyn District, which now handles all other FDA matters in the area.

The import unit was established to



Framed by a water pipe and spout, Joe Simeti checks anise from Singapore for signs of insect filth. Simeti is a physical science technician at the New York Import District's laboratory.

Down On The Docks



The rows of containers seem endless at the Port of Newark. To the amateur's eye, they're also indistinguishable—each is simply a trailer looking for a truck cab to drive it away.

But before they leave, Inspector Vince Taormina of the New York Import District has his work to do. He's looking first for a load of green peppers from Israel. He knows where to look and what to look for.

When he finds the trailer he wants, he parks his car next to it, unlocks the trunk, and hauls out his white coveralls with the FDA sleeve patch, a hard hat, a clipboard, a package-sealing device, wire cutters and a short ladder.

He cuts the wire sealing the door, loosens its locking handle, and swings the door open. Spreading the ladder, he climbs it and enters the container. First he looks at the label on one of the boxes of merchandise and checks it against the entry papers on his clipboard to make sure he has the right commodity. That ascertained, he slits open a carton and pulls out a large can of peppers. He checks this label to see first of all if it's in English, and then if it conforms with other requirements as to weight declaration, contents, etc.

When the label satisfies him, he looks for signs of swell-

ing and other indications of the food inside gone bad. His checks are sporadic among the merchandise because he knows that the firm's manufacturing process has been registered with FDA. Had it not been on the list of approved processes, he would have had to check with headquarters to see if the firm was a late registrant. If that brought a blank, he would have checked about one can out of 10 for swelling or other defects and would have taken cans back to the district laboratory for examination.

Finding no unusual problems, he returns the cans he has looked at to the carton and reseals the container. He climbs back down the ladder, closes the door, and secures it with an FDA seal.

In addition to such individual inspections and general wharf examinations, Taormina also does the usual tasks of an import inspector of overseeing reconditioning of products. As an inspector with the New York Import District, he also performs warehouse inspections and special investigations and monitors recalls.

Import Detentions — Oct. 1, 1981, to Sept. 30, 1982

Description	Detentions
Food—sanitation	4,604
Food—chemical contamination and pesticides	807
Food—additives	239
Food—labeling and economics	769
Cosmetics	71
Human drugs (including biologics)	2,389
Animal drugs and devices	105
Animal feed	1
Medical devices	912
Medical X-rays and household appliances, such as televisions, that emit radiation*	971
Total	10,868

* Mainly microwave ovens not properly certified as meeting U.S. standards.

allow its personnel to concentrate on imports. It covers an area that includes the busy ports of New York and Newark, and handles almost one-fourth of all the nation's imports.

The 19 inspectors are trained not only to work the docks and airports but also the import warehouses. Thus, they can go into the warehouse and follow up on items previously scrutinized, as well as catch occasional violative products that slipped through. Some 250 such inspections will be done in a year.

Import district officials have also been training customs personnel in the nuances of the business from the food, drug and medical device perspective.

Customs officials had asked for the training in order to stem the smuggling trade, which is a constant problem. Customs will also do some perfunctory lab work for FDA.

The import district people will also be able to follow up when bonds are violated by shippers. Today, many shippers are willing to pay the bond penalty, in the expectation that they will more than recoup the money in profits from their illegal items. However, inspectors now return to the shipper to ascertain that the product is not sent into the marketplace. If the importer or shipper doesn't send it back overseas, a court order will be obtained to seize

the shipment if necessary.

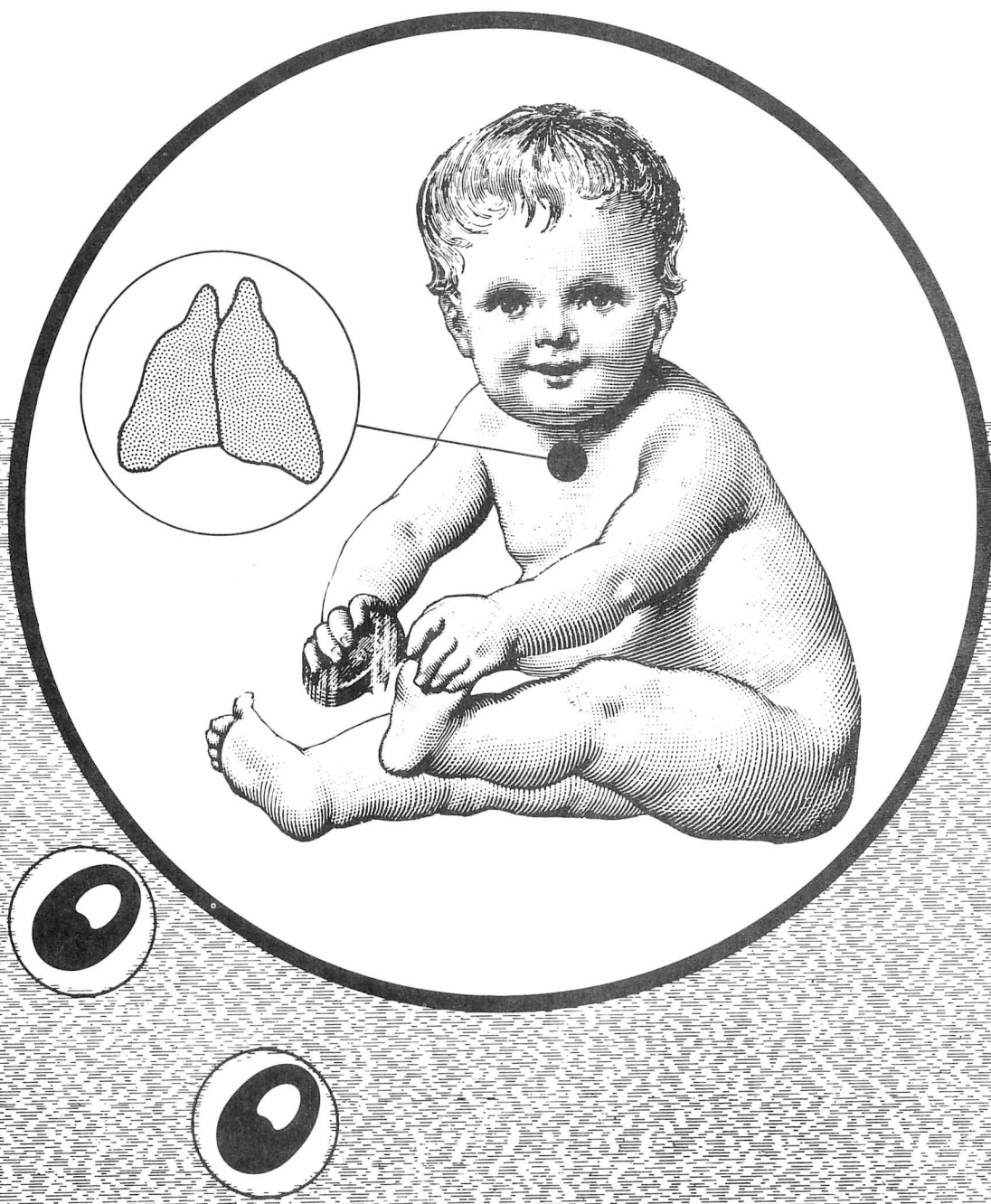
There are many tricks of the trade that import inspectors have to learn and New York, with its wide diversity of ethnic groups, offers a good place to learn them. For example, most people don't know what ackee is. But at the New York Import District they not only know that ackee is a fruit from Jamaica but also that at certain times of the year it is toxic. Its toxicity depends on the stage of maturity.

Such knowledge gets the job done and keeps international commerce flowing—both ways.

—Roger W. Miller

How The Body Fights For Its Health

by Annabel Hecht



A mysterious disease with an unlikely name, AIDS, is making headlines in the United States. The letters stand for "Acquired Immune Deficiency Syndrome." Its victims are said to be "immunosuppressed" or "immunocompromised." What this means to a victim is that the body's immune system—its defense against invading germs—has gotten out of kilter, leaving the person vulnerable to a rare type of cancer or a variety of infections just waiting for an opportunity to invade.

What causes AIDS is not yet known, but it's clear that the syndrome involves the patient's "T cells"—pivotal factors in the body's highly complex

internal immune system.

The human immune system is not contained in a single organ but is dispersed throughout most of the tissues of the body. The basic elements in the system, reduced to the simplest terms, include:

- Lymphocytes—small white blood cells normally present in the blood and in lymphoid tissue
- Antibodies—molecules created by the action of some of the lymphocytes
- A variety of phagocytic (scavenger) cells fixed within the tissues or transported in the blood

Foreign substances that get into the body, such as bacteria, viruses, or tis-

sue from another person (such as an organ transplant), are called antigens. Each lymphocyte is programmed by nature to recognize only one such antigen. Initially, only a small number of lymphocytes capable of responding to a particular antigen circulate in the blood, but when a lymphocyte cell meets an antigen it recognizes, the lymphocyte enlarges, divides and produces many more cells that have the same recognition ability.

There are two major categories of lymphocytes, both of which originate in the bone marrow. One type first migrates to the thymus, a ductless gland at the base of the neck. Here the cells

mature and gain the ability to carry out their assigned functions. They then leave the gland and circulate. Such cells are called T lymphocytes. The lymphocytes in the second category are called B cells.

The T cells are the predominant group, making up about 70 percent of the lymphocytes. T cells have a variety of functions. Some help the B cells in producing antibodies for destruction of invading organisms; others are suppressors, impeding or preventing the work of the B group. Some T lymphocytes also are capable of destroying invading organisms directly. After the T cell interacts with its specific antigen, it secretes factors called lymphokines which activate scavenger cells which, in turn, engulf and destroy the invader.

This process is called "cell-mediated immunity," and it is of major importance in the body's resistance to infection by intracellular organisms, such as those that cause tuberculosis, leprosy, brucellosis (undulant fever) and possibly even in resistance to cancer. Cell-mediated immunity also is a factor in the body's rejection of organ transplants.

The B cells, representing about 25 percent of the lymphocytes, play a major role in the creation of antibodies. When a B lymphocyte meets up with an antigen that it recognizes, it produces large numbers of plasma cells, which secrete the corresponding antigen recognition proteins known as antibodies. Antibodies don't destroy the antigen themselves, but, with the help of another series of blood proteins called "complement," they initiate the process which is carried out by scavenger cells.

Some antigens are able to trigger the B cells' production of plasma cells. In most cases, however, B cells need the cooperation of the helper T cells to start the antibody-making process.

Once they have been formed, the antibodies, which recognize specific antigens, remain in the bloodstream, and the person in whose body all this has taken place is said to be immune to those specific agents. In other words, the next time he or she is exposed to those particular antigens, the antibod-

ies will be ready to start the destruction process. This response is called "humoral immunity." Immunity develops in response to vaccines made from inactivated germs as well as in response to exposure to the real thing.

Antibodies are also known as immunoglobulins. There are five major classes of immunoglobulins, all slightly different in structure. Four of these classes have known biological functions.

For instance, immunoglobulin G (designated IgG) promotes the more efficient uptake, removal and destruction of invading microorganisms by the scavenger cells. IgG is the only immunoglobulin that can pass through the placenta. It is from this source that the newborn infant is given antibody protection that lasts for its first months of life.

Immunoglobulin M (IgM), formed early in response to antigens, is larger than the others and tends to remain in the bloodstream. The A immunoglobulin (IgA) is concentrated in the fluids of the respiratory and gastrointestinal system, while IgE attaches itself to the surface of cells known as basophils or mast cells. When IgE encounters its appropriate antigen, the result is the release of histamine, which, in turn, produces the symptoms of allergies. The fifth class of immunoglobulin, IgD, is secreted in very small amounts and up to now is not known to have a special function.

Normally the immune system behaves in a very efficient manner, but it is not infallible and can break down. Primary deficiency of the immune system may involve failure of both the T and B cell components to mature during fetal development. Without treatment, children born with this defect invariably die of infection before the age of 2. Recent developments in cell transplantation techniques have made it possible to save some of these children through transplantation of bone marrow from a normal person, usually a close relative. An isolated deficiency of the T system that results from the absence or poor development of the thymus is being treated successfully, in some cases, with a thymus or fetal liver transplant.

T and B cell function also can be impaired by diseases such as leukemia, multiple myeloma and certain skin tumors, as well as by viral diseases, such as measles. Defects of the immune system can be "side effects" of treatment with various drugs. Cortisone and drugs used in cancer treatment and radiation all can play hob with the immune system.

In the case of AIDS, the ratio of helper T cells to suppressor T cells is reversed. In the normal person, helper cells outnumber suppressors about two to one. In AIDS victims, the suppressors predominate over helpers, thus upsetting the normal production of antibodies. Recent studies of AIDS victims have shown that helper T cells are not only in short supply, but are also functionally impaired. Although there appears to be an increase in B cells, these do not function normally either. Without this vital protection, the victim is open to "opportunistic" infections—illnesses that usually strike only when the body's defenses are down.

The immune system is usually thought of as a protector, but under some conditions antibodies or immune lymphocytes or both may react with and damage normal body tissues. This process is known as autoimmunity. Autoimmunity is believed to be the major cause of a number of serious diseases such as Hashimoto's thyroiditis (hypothyroidism), lupus erythematosus, myasthenia gravis and rheumatoid arthritis.

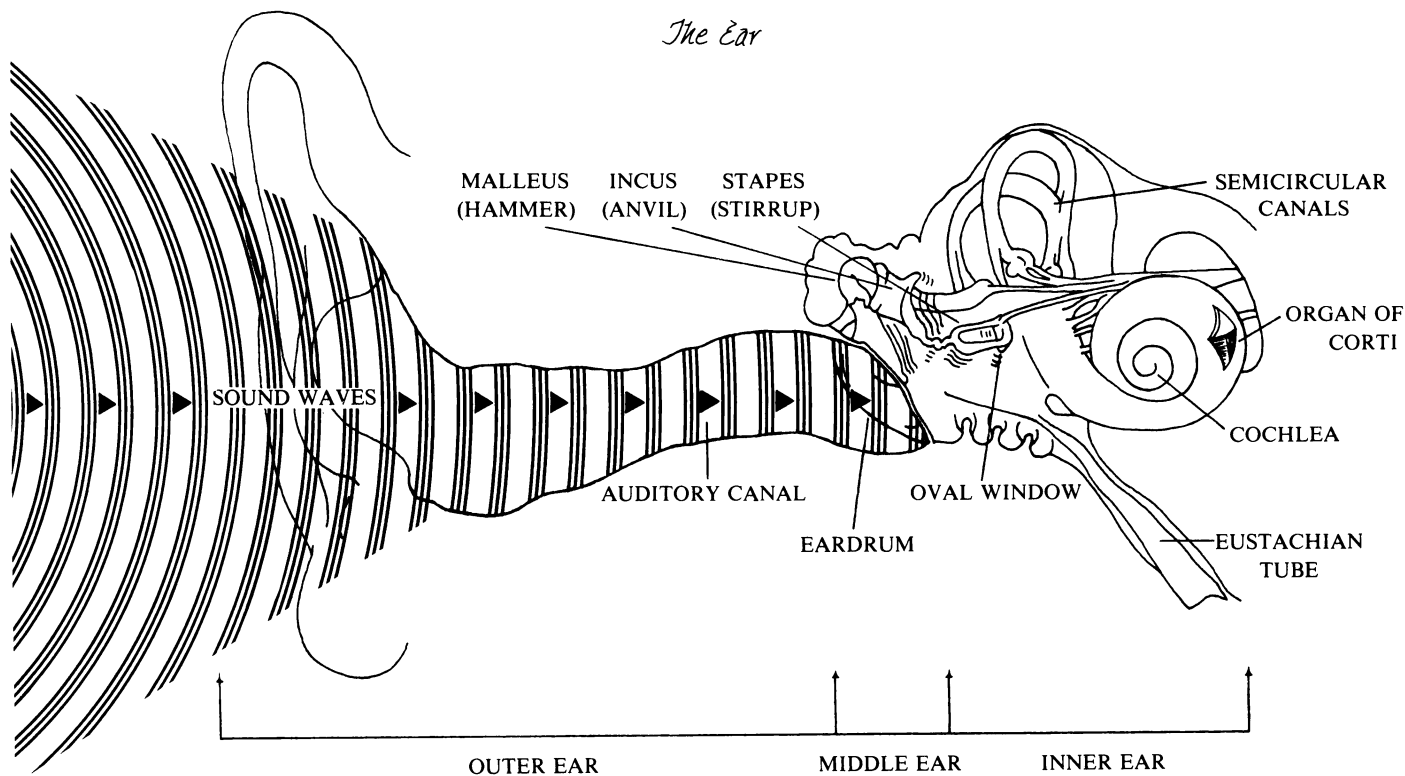
Sometimes it is important to lower the body's defense system—e.g., to prevent the rejection of a tissue transplant. New immunosuppressing drugs are proving successful in extending the life of transplant patients. Such patients, however, are left open to secondary infections.

During the past two decades medical science has made great strides in understanding how the body's immune system works. Yet there still is much to be learned about this vital protective system and about the various environmental influences that may upset its delicate balance.

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

The Ear Collects Sounds And Other Things

by Donald C. McLearn



Aside from being hard to wash for everyone but mothers, the human ear is a marvelous device. When it's working right, the ear can hear sounds from all directions and, at the same time, maintain the body's equilibrium.

When it's not working right, however, the consequences can be deafness, lack of balance, or both.

The ear is actually made of three parts. The outer ear (the flap part that schoolmasters grab) captures and channels sound waves through the auditory canal to a tightly stretched membrane known as the eardrum.

Beyond the eardrum, in the middle ear, are three tiny, linked bones called the malleus (hammer), incus (anvil) and stapes (stirrup). Sound waves on the eardrum cause these bones to vibrate, and the vibration causes the footplate of the stapes to move in and out of a delicate membrane called the oval window, which conveys the sound message to the inner ear.

The Eustachian tube, which forms a tunnel between the middle ear and the back of the nasal cavity, helps drain the middle ear and also permits pressure to equalize on both sides of the eardrum. The Eustachian tube, unfortunately, can also carry infectious bacteria from the upper throat and tonsils to the ear.

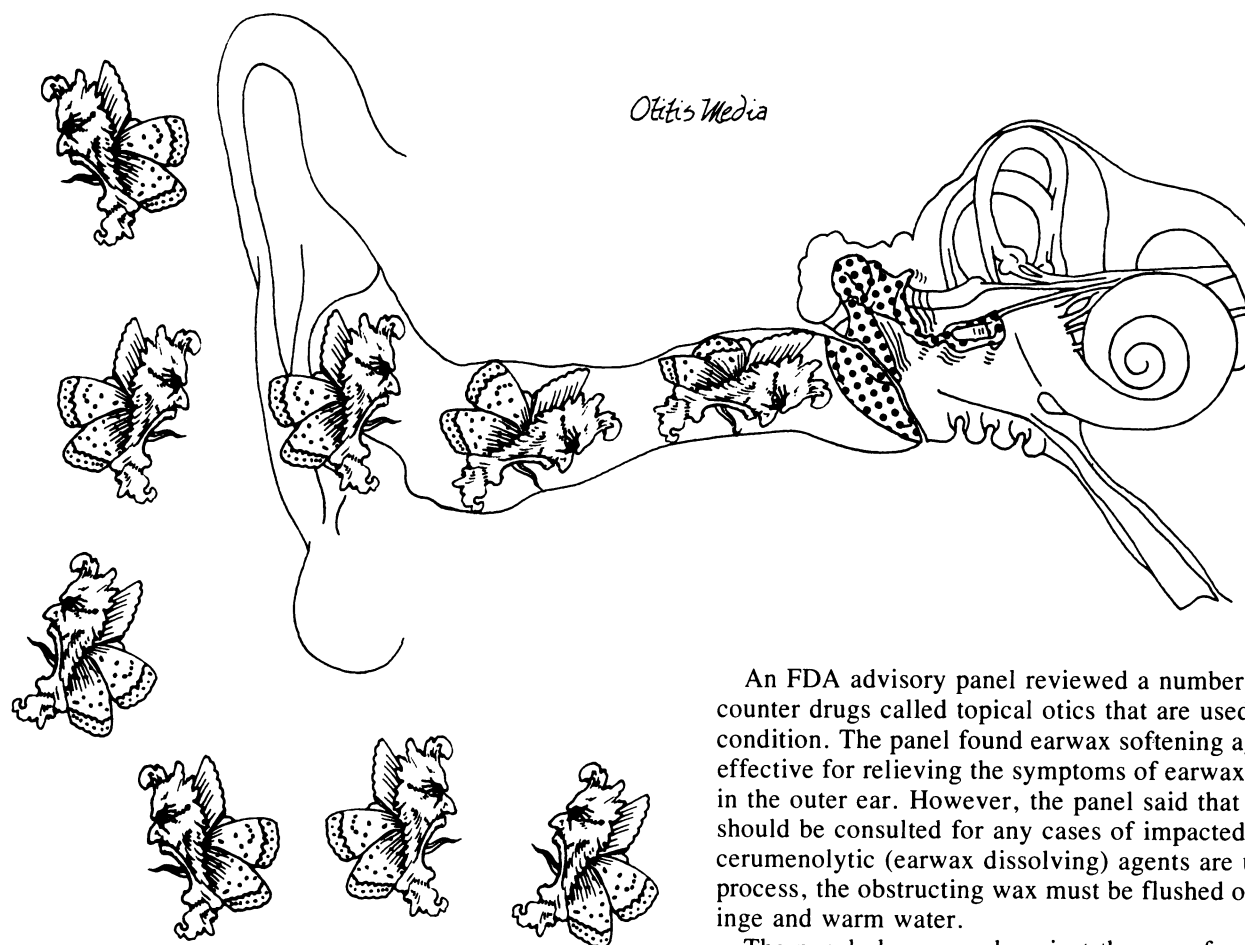
The inner ear, which begins at the oval window, is composed of a number of fluid-filled chambers. Its lower portion ends in a delicate spiral structure shaped something

like a snail. It's called the cochlea.

Inside the cochlea is the single most important structure to the hearing process: the Organ of Corti. It is composed of thousands of specialized cells, each equipped with tiny hairlike nerve endings that project from the lining of the cochlea and move in response to the movement of the fluid in the cells. The nature of the movement is set up by the chain reaction of forces from sound waves, to the bones of hearing, to the oval window, to the cochlea. (See diagram.)

Just above the cochlea are three semicircular canals at right angles to one another. Think of them as three pieces of elbow macaroni with the hollow centers being canals filled with a fluid called endolymph. These canals enable us to keep our balance when we sit, stand, walk, run or ride a bicycle. They also enable us to recognize the direction our bodies are moving—forward or backward, up or down, or sideways—even when our eyes are closed. The fluid in the canals and hairlike nerve cells at the end of each U-shaped tube work something like a gyroscope, collecting information so the brain can tell the muscles what to do to maintain body balance.

Diseases or problems of the ear affect all parts of that organ—from outside to in. The main symptoms are earache, loss of hearing, discharge, vertigo (loss of balance) and tinnitus (ringing of the ears). Some of the most prevalent troubles start in the ear canal.



One of the most common problems in the ear canal is itching. And one of the most human responses to itching is scratching. Pens, pencils, paper clips and any number of objects have been used as devices to relieve itchy ears. But doctors will tell you that the only safe thing to put into your ear is your elbow.

Itching may be the result of an allergy, or it may be a symptom of otomycosis, the technical term for a fungal infection of the ear. Neurodermatitis, a disease that produces thickened patches of leather-like skin in the ear canal, is also a source of itching.

Still another itching source is "swimmer's ear," a fungal infection commonly associated with swimming in polluted water. Microscopic fungal organisms, often found in water, multiply rapidly in the dark and damp section of the outer ear, and they cause the skin to be swollen and inflamed. Besides itching, the affected area is usually covered with a flaky crust and exudes a clear fluid.

In textbooks, this condition is known as otitis externa (oto = ear, itis = inflammation, externa = outer). It should be brought to the attention of a physician so that the cause can be determined and the proper eardrops or ointment prescribed. These medications are likely to contain antibiotics and corticosteroids and should be used exactly as directed.

Another troublesome condition of the outer ear is caused by buildup of earwax. The earwax, called cerumen, can build up too much and itch. Or it can accumulate and harden to the point where it will actually block sound waves from passing through the ear canal.

An FDA advisory panel reviewed a number of over-the-counter drugs called topical otics that are used to treat this condition. The panel found earwax softening agents safe and effective for relieving the symptoms of earwax accumulation in the outer ear. However, the panel said that a physician should be consulted for any cases of impacted earwax when cerumenolytic (earwax dissolving) agents are used. In this process, the obstructing wax must be flushed out with a syringe and warm water.

The panel also warned against the use of cotton-tipped sticks. Routine cleaning of the ear with swabs may seem hygienic, but the panel pointed out that the swabs may also damage the ear's natural protective skin barrier, and such devices have also been known to push the wax deeper into the ear canal where it can become impacted.

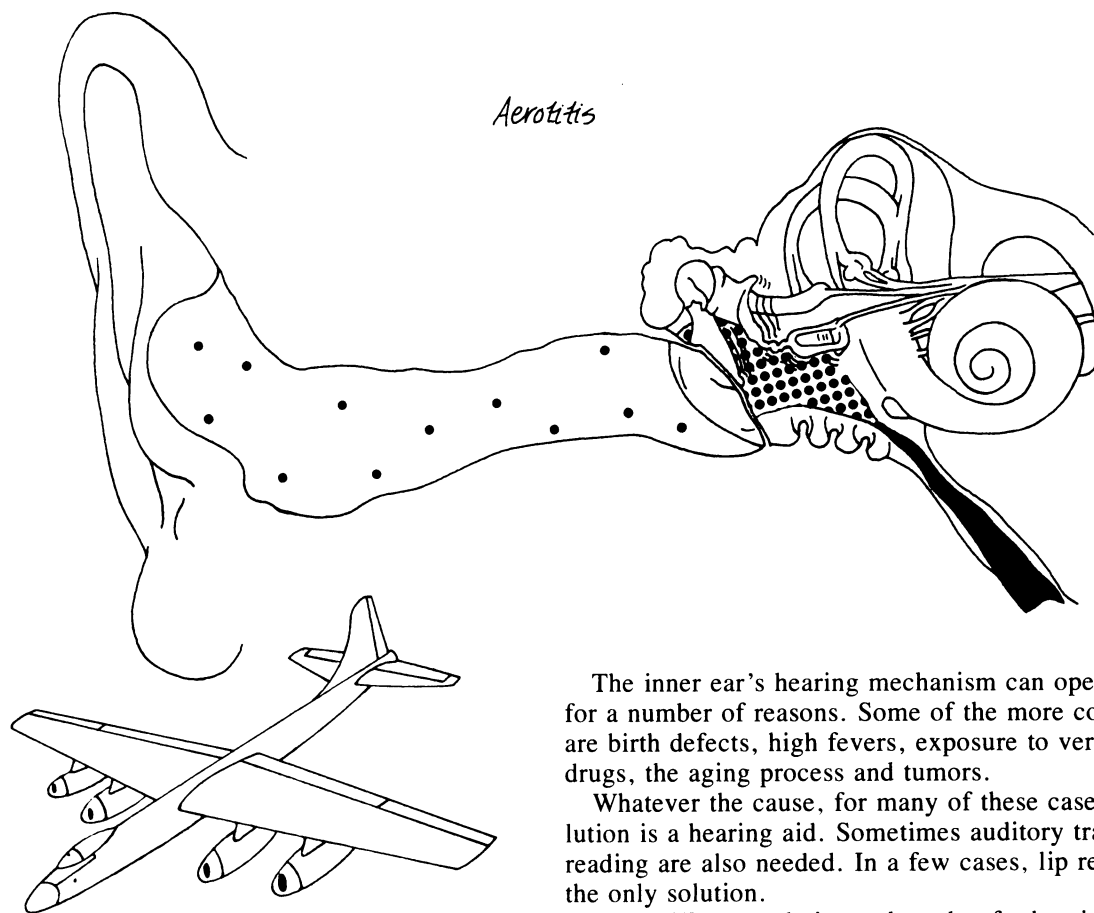
Going one step further, if sharp pointed objects are stuck into the ear, they may even puncture the eardrum. A rupture or perforation of the eardrum can cause hearing impairment and may even damage the tiny middle ear bones. Sometimes a torn eardrum can heal naturally but a substantial rupture may require surgery. After surgery, hearing is improved in many cases.

Infections of the middle ear, otitis media, are very common—especially among children. Half of all children will have an episode by age 1, and nearly 90 percent by age 6.

Middle ear infections, like colds, are more common during winter and early spring. In cold weather, an individual's resistance to middle ear infections seems to be lower. Also, the combination of closed quarters and forced-air heating, which blows bacteria around, makes an almost ideal setting for breeding infections.

Severe cases of otitis media are sometimes accompanied by ringing in the affected ear, hearing loss and fever. Prompt treatment with antibiotics is mandatory. In addition, aspirin or acetaminophen may be taken to ease the earache.

If properly treated, the effects of middle ear infections are generally temporary. However, if treatment is neglected or delayed, the consequence may be loss of hearing. In addition, an untreated middle ear infection may lead to inflammation of the mastoid bone—a condition called mastoiditis.



Significant impairment of hearing also may result from a condition called otosclerosis. In otosclerosis, deposits form between the stapes bone (the stirrup) and the oval window, restricting this apparatus's levering action. Surgery is helpful in many otosclerosis cases.

Another problem of the ear might be called the "jet set" disease. Aerotitis, the doctor's name for it, is caused by a rapid change in barometric pressure—generally that which occurs during an airplane landing—resulting in symptoms of deafness and even severe pain. The Eustachian tubes become blocked and the pressure on the eardrum cannot equalize. When people who have a history of blocked Eustachian tubes must fly, and this includes a lot of children, the tubes must be kept open with decongestants in nose-drop form taken two hours before the plane is due to land.

Travelers in normal health can help minimize discomfort by yawning, chewing gum or swallowing. Alcohol intensifies the problem, so some people are well advised to turn down booze offered by the cabin attendant.

Disorders of the inner ear can affect both hearing and balance. Motion sickness, which includes seasickness, airsickness or carsickness, is a disturbance of the three semicircular canals in the inner ear that control equilibrium. Symptoms go from mild queasiness to acute nausea and vomiting. Other signs, such as a cold sweat, dull headache and dizziness, are often involved. Drugs may help those who chronically suffer from motion sickness. These include anti-nauseants such as Dramamine or, in some instances, a tranquilizer.

The inner ear's hearing mechanism can operate faultily for a number of reasons. Some of the more common causes are birth defects, high fevers, exposure to very loud noises, drugs, the aging process and tumors.

Whatever the cause, for many of these cases the only solution is a hearing aid. Sometimes auditory training and lip reading are also needed. In a few cases, lip reading may be the only solution.

Under FDA regulations, the sale of a hearing aid is prohibited unless the individual has been medically evaluated by a physician and has been found to be an appropriate candidate for the device.

Another problem of the inner ear is tinnitus, a condition marked by a ringing or buzzing sound in the ears. This disorder can often be traced to damage to the hairlike nerve cells in the cochlea resulting from long-term exposure to loud noises, cardiovascular disease affecting the blood vessels of the inner ear, and otosclerosis.

Ménière's syndrome, which affects the organ of balance in the inner ear, is mainly confined to middle-aged people. Although the cause of this disease is unknown, it is believed that excessive fluid and salt intake, overwork and emotional upsets contribute to it.

Ménière's syndrome usually affects one ear, although in about 20 percent of all cases, both ears are eventually involved. In this disease, the endolymph canals of the inner ear become distended with fluid, causing destruction of the hairlike nerve cells.

The symptoms of Ménière's syndrome are a sudden onset of severe vertigo, accompanied by nausea and vomiting. The attack lasts several hours during which the patient is troubled with loss of hearing and with ringing in the ears. Most patients experience alternating remission and intensification of symptoms, with the symptom-free periods lasting up to several months—even years—before flare-ups return.

Therapy includes restriction of salt intake and prescription of diuretics, anti-vertigo drugs, Dramamine and sedatives.

Donald C. McLearn 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.

■ FDA's food additive regulations were amended as of Jan. 14 to codify prior sanctions for the use of **nitrates and nitrites** in cured meat and poultry products. The U.S. Department of Agriculture concluded that such use was sanctioned and approved under the Federal Meat Inspection Act and the Poultry Products Inspection Act prior to Sept. 6, 1958. This means that uses of nitrates and nitrites in red meat and poultry products don't need approval under the food additive provisions of the FDC Act (FR Jan. 14).

■ The FDA standards for **tomato concentrates**, catsup and tomato juice have been amended to, among other things: establish separate standards for tomato concentrates to include tomato puree, tomato paste and concentrated tomato juice; provide for safe and suitable nutritive carbohydrate sweetening ingredients in catsup; and provide for the use of concentrated tomato juice to prepare "tomato juice from concentrate." The new standards become effective July 1, 1985 (FR Jan. 28).

■ **Patient Medication Instructions**, information leaflets for distribution by participating physicians, were introduced March 1 for a second group of 20 prescription drugs by the American Medical Association. The drugs include allopurinol, nifedipine, verapamil, lithium, valproic acid, thyroid replacements and iron supplements, and were selected on the basis of contraindications and precautions about which patients should be notified.

■ FDA has decided not to propose recommendations for the development of voluntary quality assurance programs in **nuclear medicine**, saying the necessary information can be disseminated to the public via technical reports, scientific papers, demonstration projects and cooperative actions with professional organizations (FR Jan. 14).

■ Because many consumers find **child-resistant packaging** too difficult or too inconvenient to use, the Consumer Product Safety Commission is exploring whether special packaging requirements should be amended. Public comments are being sought on suggested changes in testing requirements (FR Jan. 19).

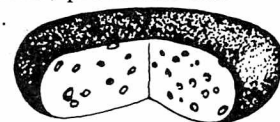
■ The Pet Food Institute has asked FDA to change labeling **requirements for pet foods** to expand the use of class names from 10 to 33 and permit the use of collective names ("processed protein products" or "cereal

grains") for identification of ingredients instead of listing each ingredient by its common or usual name. Such changes would reduce or stabilize the cost of the food, the institute claims (FR Jan. 18).

■ The **OTC external medication** market in Europe is booming, according to Frost and Sullivan Inc. In an international business research report issued recently by the New York City firm, sales were forecast to increase from \$2.96 billion in 1980 to \$3.99 billion in 1986. Growth of annual per capita consumption was projected to \$15.60 from \$11.70 in that time. Highest-volume product categories are predicted to be sanitary protection, external deodorants and antiperspirants, and oral hygiene.

■ Recently published rules regarding **abbreviated new drug applications** (ANDAs) specify that an ANDA is acceptable for products "identical" to products reviewed under FDA's Drug Efficacy Study Implementation (DESI) program. The new rules also establish a procedure drug sponsors can use to find out whether a "related" drug product qualifies. The DESI program was set up to evaluate the effectiveness of pre-1962 drug products. Once effectiveness is established, subsequent manufacturers can submit an ANDA for approval to produce generic versions of those products. An abbreviated application runs 500 to 1,000 pages (compared to 100,000 pages for a full new drug application) and requires only that the manufacturer show it can make the product using adequate quality controls and that it will label it correctly (FR Jan. 21).

■ **CHEESE**: Standards for **nine cheeses** have been amended to require full ingredient declaration on the label, to permit the use of safe and suitable ingredients that don't change the basic identity of the food, and to make their composition consistent with international standards. The amendments, effective July 1, 1985, cover blue, Cheddar, Edam, Gouda, Gruyère, Limburger, provolone, Samsøe, and Swiss and Emmentaler cheeses (FR Jan. 21). . . . **AND MORE CHEESE**: Makers of **mozzarella cheese** and low-moisture mozzarella now can add safe and suitable artificial coloring during the manufacturing process to whiten the cheese (FR Jan. 25). . . . **STILL MORE CHEESE**: FDA is proposing to amend the standards of several cheeses to allow use of **antimycotics** on the surface of the bulk form of these cheeses while being held for curing and storage. Antimycotics, which prevent the growth of mold, are currently permitted for use on the surface of cuts and slices in consumer-sized packages. Cheeses covered by the proposal include Asiago, Caciocavallo Siciliano, mozzarella, provolone and Romano cheeses (FR Jan. 21).





by Carolyn L. Hommel

Birds Sing The Blues

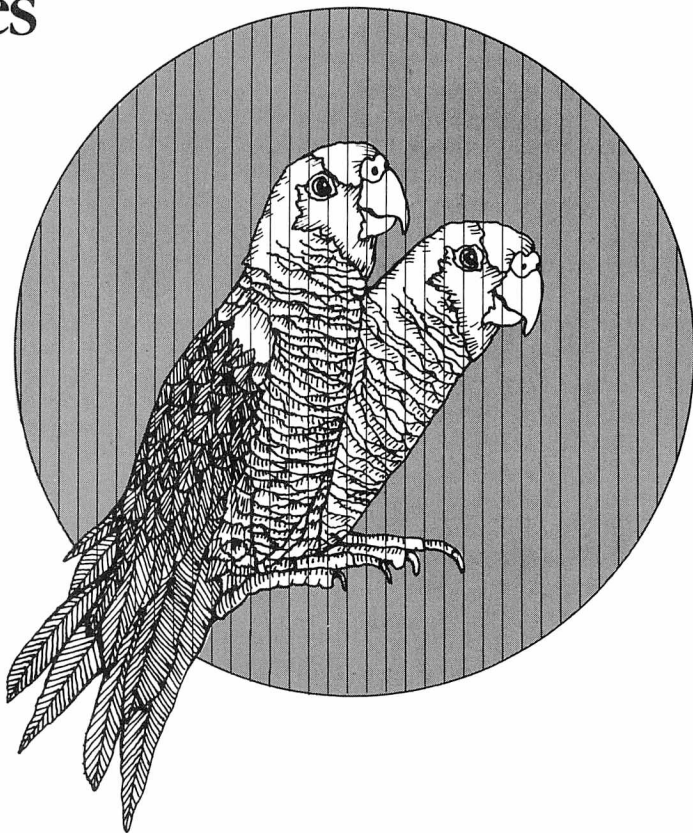
What do parrots have in common with shellfish, turtles, lather brushes, garbage and people? Surprisingly enough, the movement of all of them in interstate commerce can be restricted by the Food and Drug Administration.

FDA has had this little-known regulatory authority under the Interstate Travel Sanitation Program since 1969. The purpose of the program is to prevent the spread of communicable diseases, such as anthrax, cholera, leprosy, plague, psittacosis and typhoid, to name a few. Some of these diseases are carried by humans, some by the products they use (for example, anthrax can be spread by shaving brushes made from animal hair), and one—psittacosis—is transmitted by birds.

Psittacosis—or parrot fever—is a disease in man that is acquired from contact with infected birds, both the common barnyard variety (pigeons, ducks, turkeys) and psittacine birds (parrots, Amazons, cockatoos, lovebirds, macaws and parakeets). Although the disease is rarely fatal, it can range in severity from a mild respiratory infection to a protracted illness.

Symptoms of psittacosis include fever, chills, malaise, prostration, dry cough, nosebleed, and enlargement of the spleen. In severe cases delirium, constipation and abdominal distress may occur, followed by difficult breathing and cyanosis, a bluish-purple discoloration of the skin and mucous membranes. Psittacosis is treated with antibiotics, such as tetracycline.

FDA regulations prohibit the transport of psittacine birds in interstate commerce unless the birds are accompanied by a permit from the state health department of the state of destination where such a permit is required. Birds imported into the United States are quarantined for 30 days by the U.S. Department of Agriculture. If the birds show signs of illness or if several in a shipment die, USDA extends the quarantine.



Despite these precautions, infected birds occasionally still find their way into consumers' homes, which is exactly what happened last year. And, although the story begins in Boston, it was FDA's Brooklyn District office that did the bird watching.

Late in March 1982, a young man in Boston purchased a pair of blue-fronted Amazons from a New York City pet shop. Unfortunately, he had little time to enjoy his newly acquired feathered friends because the birds died. An autopsy performed by the Angell Memorial Animal Hospital revealed that the parrots had psittacosis.

To add insult to injury, both the man and his girlfriend subsequently came down with the disease.

FDA's Boston District learned of these events from the U.S. Public Health Service quarantine officer at Boston's Logan Airport. The officer had heard of the case from a local TV consumer reporter. Apparently the Boston bird lover had enlisted the help

of the station in obtaining reimbursement for his loss.

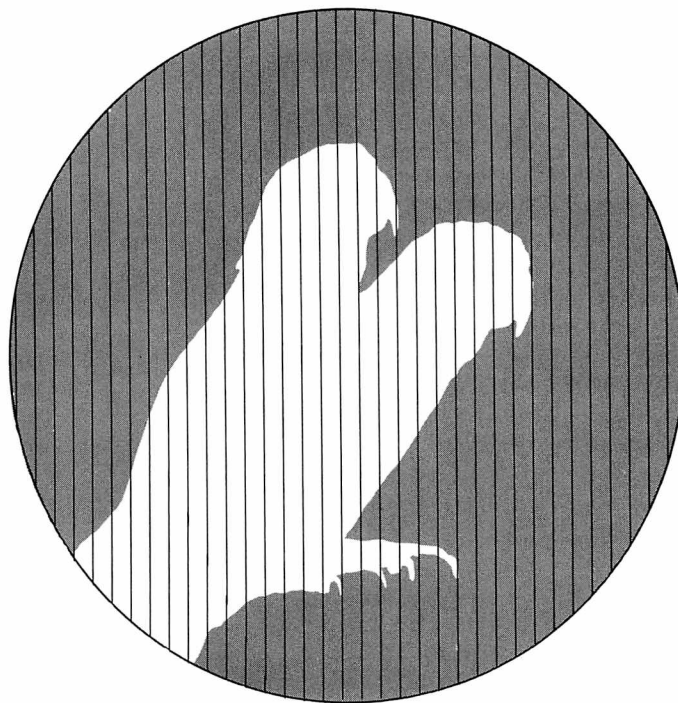
Alerted by the Boston District, an investigator from FDA's Brooklyn District office contacted the pet shop and learned that three other birds had died. All the birds had been purchased from the Tropical Bird Imports Co., Long Island City, N.Y., which was operating as a quarantine center under the supervision of USDA.

A visit to Tropical Bird Imports revealed that the parrots, valued at \$200 each, had been part of a larger shipment of approximately 270 birds imported from Argentina by Supreme Exotics of Mount Vernon, N.Y. About 40 percent of the birds had died during the quarantine period from causes other than parrot fever, including intestinal problems and *Salmonella* infections. The remaining birds had been released in March 1982, following physical examination by a USDA veterinarian.

The Brooklyn District reported the outbreak of psittacosis to the chief epi-

demologists for New York, both state and city, as well as to the U.S. Centers for Disease Control in Atlanta. In addition, the investigator obtained the distribution list for the entire shipment of parrots so that the six other states to which the parrots had been shipped could be notified about the problem.

Carolyn L. Hommel is a consumer affairs officer in FDA's Brooklyn District office.



Unhealthy Oven

A U.S. Postal Service employee in Huntington, N.Y., was right when he suspected that the office microwave oven leaked radiation. Ironically, he became suspicious for the wrong reason.

The employee noted that the oven, leased to Postal Service employees by Mallen Industries Inc., Farmingdale, N.Y., to heat food the company sold to employees, had only a metal screen in the door. Concerned that the oven might be leaking radiation because it lacked glass in the door, he contacted FDA's **Hicksville (N.Y.) Resident Post.**

A **Brooklyn District** investigator tested the oven and discovered that it was leaking—55 milliwatts of radiation per square centimeter. Although the agency established a safety standard in 1971 permitting a maximum emission of 5 milliwatts of radiation per square centimeter at any point 2 inches or more from the oven, the oven was considered "grandfathered" since it had been manufactured prior to the year the standard went into effect.

The investigator noticed black spots around the door which he determined were evidence of electrical sparks. He also determined that the leakage was

not due to the lack of glass in the door but to a combination of factors, including age, excess wear and tear, and improper maintenance of the oven. (Microwaves will pass through glass, so newer microwave ovens are equipped with metal screens also.)

As a result of the investigator's findings, the oven was found to be a "Class A noncompliance" violation, meaning its use posed an imminent, serious health hazard. The dealer was informed of the problem and the appliance was removed from the post office.

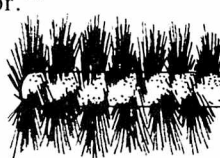
Green on Green

The Countess Maritza Cosmetics Co. of Secaucus, N.J., proved a bit "green" about prohibited color additives.

While conducting a routine inspection of the cosmetics firm, FDA's **Newark District** investigators noticed that the master formula for the firm's Allura brand green eye mascara described the color used in the product as "green color."

FDA regulations stipulate, however, that the official name of a color additive must consist of the official name of the primary color, including a number and letters. Some additives have the letters "F," "D" and "C" to designate that color's approved use in foods, drugs or cosmetics. Other additives have the letters "D" and "C" to denote their uses in drugs and cosmetics only. And some are designated "external" to indicate their uses in drugs and cosmetics that are applied to the external parts of the body only.

A sample of the product as packaged by the supplier was collected, and an analysis by an FDA laboratory showed that it contained the prohibited color additive External D&C Green No. 1. Although the proper description of a color additive is the responsibility of the supplier of the additive, the district issued the manufacturer a Notice of Adverse Findings because the adulterated product was the responsibility of the firm.



Subsequently, the manufacturer destroyed 1,475 tubes of Allura brand green eye mascara.

Overloaded Spuds

A farmer from Chateaugay, N.Y., found himself in a stew after selling potatoes that contained too much pesticide.

The incident began in early October 1982 when an investigator from FDA's **Buffalo District** collected samples from a lot of 50-pound bags of potatoes being sold by the farmer at a roadside stand in Champlain, N.Y. Analysis of the samples by the district laboratory showed they contained residues of the pesticide aldicarb at a level of 1.47 parts per million, well above the established tolerance of 1 part per million for that pesticide on potatoes.

On Nov. 1, another district investigator, accompanied by an inspector from the **New York State Department of Agriculture and Markets**, visited the farmer's Chateaugay farm to determine the cause and scope of the problem. The farmer explained that he had used aldicarb on his crop according to the product's label directions, and he attributed the high concentration of pesticide to drought conditions at the time of use.

During the inspection, all potatoes on hand were sampled, and FDA analyses of the samples showed they contained aldicarb residue levels averaging 1.7 parts per million. Based on these findings, the state inspector placed some 5,000 pounds of potatoes under embargo.

In addition, samples of potatoes were collected from the farmer's customers in Vermont, and a limited survey of potatoes grown within 20 miles of Chateaugay was initiated by the district. However, aldicarb residues in these samples did not exceed the tolerance levels.

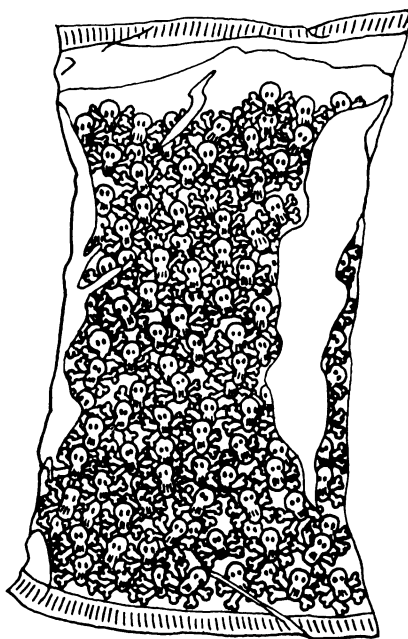
The farmer informed the state inspector that the embargoed potatoes would not be used for food but for planting in the spring, and the state plans to remove its embargo just prior to the planting season.

Unsettled Dust

When Husman Snack Foods, Cincinnati, tried to improve working conditions, it inadvertently contaminated close to \$10,000 worth of food.

Workers in the company's Dayton, Ohio, warehouse had complained about irritating levels of dust in areas of heavy traffic, so the company had the wood floors treated with a sealant containing xylene. That settled the dust, but not the company's problems.

About a week later, the company received a complaint from a consumer who said some Husman potato chips tasted like paint thinner. Husman guessed that fumes from the xylene had permeated the products stored in the warehouse at the time the sealant was applied and set out to correct the problem.



Representatives from the firm visited all retail outlets in the warehouse distribution area in Dayton and pulled all recently received, possibly exposed Husman products from the shelves. The firm informed FDA's **Cincinnati District** that it was recalling approximately 7,500 packages of snack foods, including potato chips, popcorn,

cheese curls, caramel corn and potato skins. The products were destroyed.

Montgomery County (Ohio) health officials inspected the warehouse and ordered the firm to discontinue use of the facilities until the building was once again suitable for food storage. Husman therefore had the residual sealant scraped off the floors and the building ventilated. This got rid of the objectionable fumes.

When Chemicals Burn

It was quite a mess. Smoke and toxic fumes spewed from a burning warehouse as huge quantities of paraquat (a herbicide) and sodium hydrogen sulfide (a chemical used in the manufacture of dyes and other products) were swallowed up in flames. Some 1,500 people were forced to evacuate a five-square-mile area surrounding the warehouse for two days. A stream was contaminated with paraquat from runoff water, and a nearby animal feed mill suffered smoke and water damage.

In the aftermath of the fire at the Baxter-Harris chemical warehouse in Charlotte, N.C., various federal, state and county agencies combined forces to handle the cleanup operations. FDA's **Charlotte Resident Post** office provided information and guidance to local health officials on monitoring the cleanup and collecting animal feed and human food samples to test for residues. (Unless a state requests federal assistance in the form of manpower, equipment or services, FDA routinely assumes an advisory role in local disasters such as fires, floods, etc.)

The **North Carolina Department of Agriculture** inspected the feed mill and supervised destruction of animal feeds that showed any signs of water damage. In addition, the department tested samples of feed and milk and bread from nearby retail stores. No toxic chemical residues were found.

The Environmental Protection Agency, along with Mecklenburg County health officials, took air samples and swabs of surface areas on equipment and in buildings near the warehouse. The results were negative. However, a

stream in the area was discovered to be contaminated with paraquat from runoff water. The county constructed dams to contain the contaminated water until it could be treated.

Who Put Orange in the O.J.?

At some point during its production or processing, someone had attempted to improve on nature by adding a bit of color to imported orange juice intended for the American market. As a result, more than a million pounds of the frozen concentrate shipped into Florida was placed on hold in warehouses while FDA worked on this problem of adulteration.

The concentrate, valued at \$1.5 million, had been produced in Mexico, then reprocessed and shipped in bulk to two Florida firms by the Texas Citrus Exchange. FDA laboratory tests disclosed that some lots of juice in the shipments contained turmeric and annatto, color additives intended to make the juice more appealing. Such adulteration is not permitted if the product is labeled frozen concentrated orange juice. Some of the juice had been diluted or had sweeteners or flavorings added, again not permitted if the label says the product is orange juice concentrate.

Both Florida firms—Golden Gem Growers of Umatilla, and Ben Hill Griffin of Frostproof—had received the shipments as wholesalers. They

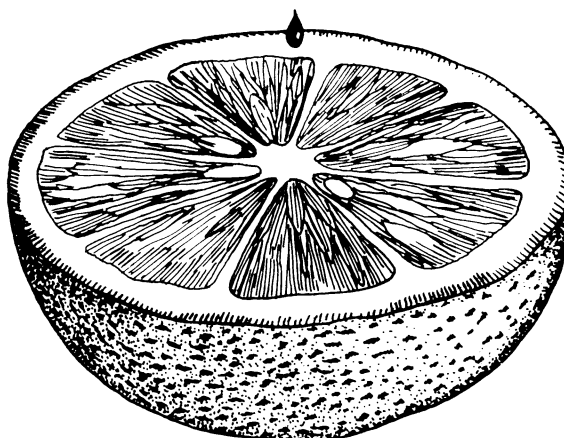
agreed to hold the stocks until the labeling problem could be resolved by FDA and the Texas Citrus Exchange.

After a series of meetings with FDA and federal and state officials, Citrus Exchange officials proposed that they, as the supplier, arrange to analyze the concentrate, then relabel it in one of three ways:

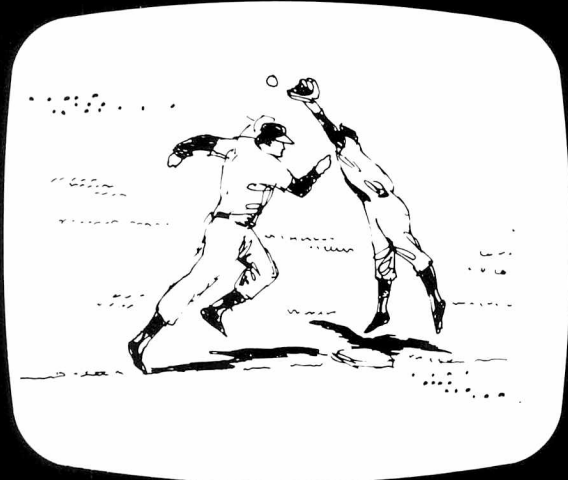
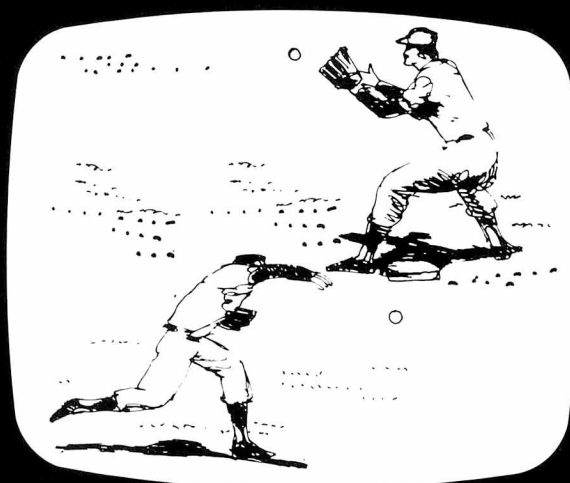
- The product that consisted of 100 percent orange juice be labeled "Frozen Concentrated Orange Juice"
- The product that consisted of 100 percent orange juice plus turmeric and/or annatto declare the artificial color on its label
- The product that consisted of less than 100 percent orange juice show the percentage of juice, then the other ingredients, and be labeled as "concentrate for orange juice beverage"

FDA accepted the proposal as a voluntary correction that would allow legal marketing and labeling of the orange juice. The laboratory and labeling procedures were monitored by FDA, the U.S. Department of Agriculture, and the Florida Department of Citrus. The relabeled juice was then released for sale.

—This small sample of reports from the field was compiled and edited by Annabel Hecht, Carol Ballentine, Louise Fenner, Michael Herndon and Richard Thompson.



Never take baseball with a grain of salt



Baseball is a game of precision; it is decided in split seconds and fractions of inches.

Your body works by precision, too. It needs salt, for example, but not too much.

Most Americans eat too much salt, which is linked to high blood pressure. That can cause heart attack, stroke and other diseases.

So, to keep your body working like a double play combination, use less salt on your food and check food labels for salt content.

The above message was excerpted from a television public service announcement narrated by baseball announcer Don Drysdale and distributed recently by the Food and Drug Administration.