Caution: Darvon Subject to Misuse
Propoxyphene, best known as Darvon, is a popular pain-killer, but new evidence has prompted FDA to urge caution on its use.

Keeping Your Pet Healthy
Maintaining the physical condition of a dog or cat requires more than giving it regular meals.

The Saga of T's and Blues
T is for Talwin, blue is for an antihistamine. Together they can give a heroin-like high. So Talwin's use has been restricted.

Matching the Message to the Medicine
What patient package inserts should say and how they should look is discussed by experts.

New Face Lift Not All Smiles
Liquid silicone face lifts are somewhat the rage, but only limited testing of the method has been approved.

Drug Effects Can Go Up in Smoke
Here's another reason to quit the habit: smoking can cut into the efficacy of drugs.

Marihuana: Hints of Medicinal Value
Medical science takes a serious look at the therapeutic potential of marihuana.

Seeking the Safest X-ray Picture
Better films and better equipment are sought to provide quality x-ray pictures with minimal radiation exposure.

Update

News Highlights

Regional Reports

State Actions

Seizures and Postal Service Cases

Notices of Judgment

Inside Front Cover: It's a wise owner that keeps his pet healthy and on its best behavior, even in the presence of a "natural" enemy, as shown in the photo. Just how to do that is discussed in some detail in the article Keeping Your Pet Healthy, beginning on page 6.
Ectopic Pregnancies and IUD’s

What users of intrauterine devices (IUD’s) should watch for was described in an article, IUD’s and Pelvic Infection, in the November 1978 issue of FDA Consumer. Here’s an update.

Recent clinical studies indicate there is a considerably higher incidence of ectopic pregnancy (pregnancy outside the uterus) with the Progestasert medical intrauterine device than with other IUD’s. FDA has alerted physicians and other health professionals through the December 1978-January 1979 issue of the FDA Drug Bulletin to carefully evaluate patients who become pregnant while wearing Progestasert IUD’s to determine whether the pregnancies are ectopic.

The overall incidence of ectopic pregnancy with Progestasert IUD’s appears to be about the same as that for women who do not use contraception and become pregnant. However, the incidence of ectopic pregnancy is lower among women who use unmedicated and copper IUD’s. In a Population Council report of 2,822 accidental pregnancies associated with the use of unmedicated IUD’s 115, or 4.1 percent, were ectopic. Of 1,349 pregnancies reported with copper IUD’s 40, or 3 percent, were ectopic. But of 184, or 16.3 percent of pregnancies associated with the use of Progestasert IUD’s, 30 were outside the uterus.

Warning to Pregnant Mothers

An article, Alcohol and Birth Defects, in the May 1978 FDA Consumer, identified the Fetal Alcohol Syndrome. The article pointed out the dangers of deformities and defects in the babies of women who drink while pregnant. Product warning labels were suggested for alcoholic beverages. The Bureau of Alcohol, Tobacco and Firearms (BATF) in the Treasury Department, which controls alcoholic beverage labeling, asked for comments on the warning label proposal in a Federal Register notice, on January 16, 1978. Here’s an update on BATF’s plan of action after it reviewed comments on the warning label proposal.

The Department decided not to require a warning label on alcoholic beverage containers at the present time. The Department said it wants to avoid unnecessary Government regulation and to give the alcoholic beverage industry opportunity to take appropriate action before imposing regulations.

The Treasury Department is to work with the alcoholic beverage industry, other interested groups, and other Federal agencies, including FDA and the National Institute on Alcohol Abuse and Alcoholism, in developing the public awareness program.

The Department will use polling to measure the success of the educational effort. Polls will be taken at the beginning of the campaign and again in 6 months to a year. If the campaign is not successful, the Department will again consider requiring warning labels.

The educational program is intended to include the distribution of a report about the effects of alcohol on the fetus, distribution of brochures to the public and the medical profession, public service announcements on radio and television, and educational programs in the schools.
Measuring Ultrasound

High-frequency sound waves known as "ultrasound" can be used diagnostically to produce "pictures" of the body much like x rays. They can also—with different equipment—be used to treat muscle and joint pain with deep-heat therapy. These Medical Uses of Sound were discussed in the March 1977 issue of FDA Consumer. Here's an update.

Two physicists in the Bureau of Radiological Health of the Food and Drug Administration have been granted U.S. Patent No. 4,133,212 for a device that measures the output of diagnostic ultrasound equipment used in hospitals and clinics. Bruce A. Herman, staff physicist, and Harold F. Stewart, chief of the Bureau's acoustics branch, received the patent in January and have assigned it, as required of Government employees by law, back to the Federal Government to be administered by the Department of Health, Education, and Welfare for licensing to possible manufacturers.

Diagnostic ultrasound is a high-frequency, inaudible pulsation directed through a hand-held instrument to the patient's body. Scanning the body, the equipment can distinguish—through an echo effect—various soft tissues and organs which it displays on a screen as light and shadow. Ultrasound can, in many instances, supplement or replace x-ray diagnosis because it "sees" soft tissues better.

Diagnostic ultrasound is widely used in hospitals and clinics for examination of pregnant women because it can show development and positioning of the fetus. It is also used for diagnosis of tumors, which show as masses on the screen, and for outlining the liver, kidneys, and other organs, which the physician can study on the screen for abnormal size, shape, or placement.

Operating at much higher power ratings and using completely different equipment, ultrasound produces a deep-heat effect that has long been used to treat joint and muscle conditions such as sprains and bruises.

FDA surveyed such equipment 3 years ago and found that the treatment units tended to lose calibration after they had been in use and could give the patient too large or too small a treatment dose.

To correct this, the Bureau of Radiological Health developed performance standards for ultrasound therapy equipment that became effective—after hearings and public comment—on February 17, 1979. A Bureau electrical engineer, Ronald A. Robinson, also designed a portable radiometer for which he received a patent in 1976 to measure and calibrate the output of this equipment. Having such a measuring device ensures that ultrasound therapy units can be held to the Agency's performance standards.
\textbf{Caution: Darvon Subject To Misuse}

Propoxyphene, known best by the brand name Darvon, is one of the most frequently prescribed painkilling drugs in this country. In light of new concerns about its safety, FDA urges caution in the prescribing and use of this popular pain reliever.

People who use propoxyphene for relief of mild pain should be careful not to take more than the recommended dose or to mix the drug with alcohol or certain other drugs, cautions the Food and Drug Administration.

Disregard of this advice may have fatal consequences.

Most people know propoxyphene by the brand name Darvon or Darvon Compound, although there are other similar products on the market under such names as Progesic, Scip-Dyne, SK-65, and Wygesic. The drug also is prescribed under the generic name of propoxyphene.

Generally considered safe when taken as directed, propoxyphene is one of the most frequently prescribed drugs for relief of mild to moderate pain. In 1978 more than 30 million prescriptions were written for propoxyphene products in this country.

FDA is issuing the warning because of several serious risks associated with the drug.

- An estimated one to two thousand deaths a year are associated with propoxyphene, when taken alone or in conjunction with other drugs. The majority of these deaths appear to be suicides. Propoxyphene ranks second only to the barbiturates as the leading prescription drug associated with drug deaths.

- The possibility of accidental death associated with propoxyphene is of growing concern. Some of these deaths have occurred among drug abusers using propoxyphene in large doses with other drugs or alcohol to get a “high.” Other deaths, however, appear to have occurred among people who are not habitual drug abusers and who apparently took propoxyphene unwittingly in conjunction with tranquilizers, alcohol, or sedatives without understanding the danger.

- There is increasing concern that some of these accidental deaths may have occurred when propoxyphene was taken in doses only slightly higher than the largest recommended dose.

- When taken for an extended period of time propoxyphene produces physical and psychological dependence of the morphine type. Dependence may occur if patients take as few as 8-12 pills a day. Because of this potential for dependence propoxyphene was placed in Schedule IV of the Controlled Substances Act in 1977, which limits prescription refills to 5 every 6 months and requires pharmacists to keep special records, but places no limits on production and allows prescriptions to be filled merely by a telephone call to the pharmacist.

Present public attention about the potential hazards associated with propoxyphene was generated by the Health Research Group (HRG), an organization affiliated with Ralph Nader. The group petitioned HEW Secretary Joseph A. Califano, Jr., on November 21, 1978, to either ban the drug as an “imminent hazard” or to recommend to the Attorney General that it be shifted from Schedule IV of the Controlled Substances Act to the more restrictive Schedule II. This move would place limits on the manufacture of the drug, prohibit dispensing it without a written prescription, and ban refills.

On February 15, HEW Secretary Joseph A. Califano, Jr., denied the HRG petition, saying that there was not sufficient justification at that time to declare propoxyphene an “imminent hazard” and to remove it from the market without a hearing.

At the same time Califano called on FDA to take steps to protect the public from the health risks associated with propoxyphene by calling the serious risks of this drug to the attention of physicians, dentists, pharmacists, and other health professionals and by providing information about the drug to consumers.

Medical and health professionals have been urged to use caution in prescribing and dispensing propoxyphene-containing products and to warn patients about possible risks associated with their use.

The message to consumers is this:

- Take care when using propoxyphene products. Do not take more than the dose recommended by your doctor.

- Do not use alcohol, or other drugs such as tranquilizers or sedatives, when taking propoxyphene.

- Tell your physician about any other drugs you are taking.

FDA is reevaluating all propoxyphene products to determine whether there is a need for additional warnings in the information that is provided to physicians; whether there should be additional controls on the drug under the Controlled Substances Act; or whether the drug should be taken off the market.

The reevaluation will include a study of the effectiveness of propoxyphene. The drug is prescribed most often in combinations which also contain aspirin, phenacetin, or acetaminophen (a nonaspirin painkiller). Several studies suggest that the propoxyphene in such combinations adds little to their overall effectiveness, and that the primary effect comes from the other ingredients. As a single ingredient, the standard dose of propoxyphene is less potent than codeine and is no more effective—and may be less effective—than the usual doses of aspirin or acetaminophen.
Owning a dog or cat and assuming responsibility for the animal’s health and good behavior can be a test of your humaneness and your character. For some people it can mean unlearning previously held beliefs about the pet’s nutrition or other health needs. What you need mostly is common sense and a willingness to work with the veterinarian to keep your pet fit.

by Bill Rados with Catherine W. Carnevale, V.M.D.

By learning a little about your dog or cat—the routine care it needs to stay healthy, what to do if it is sick or injured, and when to seek advice from your veterinarian—you can help assure it a long and vigorous life.

Feeding

Most popular dog and cat foods have been formulated to fulfill all your pet’s nutritional needs, except for water. Pet foods that provide total nutrition often state on the label: “Complete and Balanced” diet, or words to that effect. Manufacturers must back up such claims with evidence that the product meets standards set by the National Research Council of the National Academy of Sciences, or through feeding studies. FDA’s Bureau of Veterinary Medicine works closely with State regulatory officials to assure that pet foods are honestly and informatively labeled.

A label claim for total nutrition may be limited to one stage of the animal’s life. A diet designed for an adult dog may be inadequate for a growing or gestating dog. So it is always a good idea to read the label.

If you feed your pet a “complete and balanced” food, vitamin and mineral supplements generally are not needed. In fact, they may harm your pet by causing an excess or imbalance of vitamins or minerals.
Pet foods can be separated into three general categories based on moisture content—dry, semi-moist, and moist. All three types can provide sound nutrition. Most pets find canned and semi-moist foods tastiest, and some owners think this justifies the generally higher cost. But a dry food can provide just as good nutrition and, if not mixed with water, prevents excessive tartar buildup on the pet's teeth. The economical dry dog foods are the most popular. Canned cat foods are more popular than dry and semi-moist varieties. Some experts believe that a dry food diet may contribute to a common urinary disorder in cats called urolithiasis, although the initiating cause is thought to be a virus. Small mineral stones form in the cat's bladder and drop down into the urethra, where they block the flow of urine. This condition occurs more often in male cats.

If your cat is spending more time in its litter box without passing urine, paying extra attention to cleaning its hindquarters, moaning, or passing drops of bloody urine, you should suspect urolithiasis and contact your veterinarian immediately.

Once you have set a balanced diet for your pet, it is usually unwise to upset the balance by feeding table scraps. Some treats meet the standards for balanced nutrition and can be fed as "rewards" without upsetting your pet's diet. Unlike most of us, dogs and cats rarely get bored eating the same food every day. On the contrary, changes in your pet's teeth. The economical dry dog foods are the most popular.

if you are thinking of having her bred. The doctor will make sure she is in good health and free of parasites before she undergoes the stress of carrying and giving birth to a litter. Your veterinarian also will advise you on her special feeding needs during gestation and bring her vaccinations up to date. This is important since the mother will be giving her antibodies to her nursing young, through the colostrum, the first milk produced after birth. These antibodies help prevent infections in the pups or kittens until they are old enough to receive vaccinations of their own. Remember, the mother will have increased nutritional demands while nursing and may eat three to four times as much as usual.

Ask your veterinarian when he or she wants to see the puppies or kittens after they are born. A series of vaccinations and physical examinations should be given to every pet early in life. After that, pets should have a physical examination when they receive their annual vaccinations. Generally, it is also wise to bring in a stool sample for a parasite check twice a year.

Parasites

Several internal parasites can infect your dog or cat. The most common are roundworms, whipworms, hookworms, and tapeworms, which don't usually cause serious problems. In fact, infected pets may appear absolutely normal. But early detection and proper treatment are essential because these parasites can lower resistance to other diseases and be spread to other pets, or even humans.

It is usually best to leave the diagnosis and treatment for worms to your veterinarian, who can select from a wide variety of products that have been extensively tested for safety and effectiveness. Such testing is required by the Federal Food, Drug, and Cosmetic Act and is reviewed by FDA's Bureau of Veterinary Medicine. Your veterinarian may treat the pet or advise you how to use the medication.

Roundworms are most common in puppies and kittens but adult pets can also be infested. Adult dogs may harbor dormant roundworm infestations that can become active if the animal undergoes stress.

Roundworms feed on the intestinal contents of the pet, robbing it of its food and damaging internal organs as well. In severe cases, the young pet's digestive tract may be so loaded with roundworms that it cannot eat. It may even vomit or defecate quantities of the worms (which look like spaghetti).

Hookworm infections are most serious in young animals. Your pet can become infected either by eating hookworm larvae found in dirt or feces or by the larvae burrowing through its skin. Hookworms attach themselves to the intestinal wall and survive by sucking blood. They can cause severe anemia and even starvation by blocking absorption of nutrients from the intestine. Sometimes you may see blood in the animal's stool, but since hookworms are much smaller than roundworms, they do not block the digestive tract and will not be vomited.

Whipworms can give your dog chronic diarrhea with a foul-smelling mucus stool. Puppies and adults may appear generally "sickly" because they are not eating or not getting the
benefit of their food. Whipworms are more common in adults than in puppies. (Whipworms rarely infect cats.)

Tapeworms come in many varieties and are common in both dogs and cats. They can be difficult to get rid of. These flat, ribbon-like worms, which can grow to several feet in length, are made up of many, many segments. Single segments, each containing hundreds of eggs, break off from the worm and may be found in the stool of an infected pet, around the hair at the base of the tail, or in the pet's bedding. They are white and look like grains of rice. Signs of tapeworm infestation are a good appetite accompanied by a loss of weight.

Heartworms—deadly parasites—are becoming increasingly common in dogs and cats. They are particularly prevalent in coastal and marshy areas where mosquitoes transmit the heartworm larvae. Larvae deposited in the skin migrate to the pet's heart, where they mature and restrict blood flow. Reproduction by the adults releases great numbers of larvae into the blood, where they are picked up by the thirsty mosquito. Signs of heartworm infection include coughing and difficult breathing. The pet may become exhausted after even light exercise. But the animal may show no signs at all if the number of adult worms is small.

Treatment for heartworm is risky, especially if delayed until physical problems are evident. If the worms are killed off too rapidly or if a dog exercises too strenuously while the dead worms are decomposing, they can clog blood vessels in the lungs and cause death. Followup treatment to kill remaining larvae also is necessary. Because of the risk in treatment, prevention of the disease is extremely important. Annual blood examination—preferably in early spring—can detect heartworm larvae. If none are found, you can give preventive medication during the mosquito season.

In most cases, internal parasites can be detected by your veterinarian through routine examination of stool samples. Removal of animal's excrement from exercise areas once a day will lower the risk of re-infection.

External parasites—fleas and ticks are the most common—usually can be prevented, too. But use the many kinds of collars, dips, and sprays available in most pet stores with respect. Never use two pesticide forms on your pet at the same time (for example, a flea collar and flea powder), and always follow the label directions.

You should suspect external parasites if you notice your dog or cat scratching itself. Or you can detect them by examining your pet's skin as you brush its fur. Mange mites, however, cannot be seen with the naked eye. In getting rid of fleas or ticks, it's usually necessary to treat not only the dog or cat, but also its living quarters, bedding, and so forth. Followup treatment after a couple of weeks is generally needed to kill any insects that have hatched since the first treatment.

Grooming

Little grooming is ordinarily needed to keep a pet in good health. Short-haired cats normally require no grooming at all, not even baths. Dogs need to be bathed infrequently. When you do bathe your dog, use petroleum jelly in its eyes to avoid irritation from the shampoo.

Some dogs can tolerate hot summer weather much more easily if their hair is clipped short. Long-haired breeds (dogs and cats) must be brushed regularly to avoid matting of their fur. Matted hair can catch urine, causing foul odors and skin burns. Poodles and certain other breeds have hair that will grow down inside the ear canal, increasing the risk of ear infections. These hairs should be trimmed during grooming.

Unless your dog runs on rough ground or concrete, it will need its nails clipped from time to time. If your dog has dewclaws, however, make sure they are clipped routinely so they won't grow into the pad of the animal's paw.

Dogs and cats, like humans, get and lose “baby” teeth. Puppies need something to chew on that is tough, too big to swallow, and can't be torn apart. Oldcr dogs also should have chewing exercise to remove tartar that builds up on the surface of their teeth. A large knucklebone is safe for most dogs, but hard dog biscuits and rawhide bones will also work well. You can also remove tartar by rubbing the teeth with a cloth moistened with peroxide. In extreme cases your veterinary-
ian may have to clean your pet’s teeth under anesthesia. Tartar buildup can lead to infection and loss of teeth.

First Aid

If an accident occurs, knowing what to do, and doing it quickly and calmly, may save your pet’s life.

In a serious injury, such as a car accident, fall, or burn, a dog or cat may go into shock. Get the injured animal to a veterinarian promptly, moving it as little as possible. (It helps to call and let the veterinarian know you’re coming so he or she can make preparations.) Cover the animal with a blanket, if one is handy. For serious bleeding, apply just enough constant pressure directly on the wound to stop the bleeding (with the cleanest cloth available). If a bone is broken, take extra care not to move that part of the pet’s body.

Poisoning: Puppies and kittens may get into any of a great number of dangerous items around the house. Be especially wary of poisonous houseplants (particularly around cats) and household pesticides. If you think your pet has consumed a poisonous substance, take the pet and the poison (in its original container, if you can find it) to your veterinarian at once. If you can’t get to a veterinarian, check the label on the poison container for a recommended antidote or call your Poison Control Center (listed in your phone directory).

Unless the label says not to induce vomiting, give your pet syrup of ipecac or salt water to get him to regurgitate the poison.

Choking: Your pet’s greatest danger of choking is by swallowing splintered bones that can lodge in the throat or tear the esophagus, especially chicken and turkey bones. If your dog or cat starts to choke, check the back of the mouth first to see if the object can be dislodged with your fingers.

Cuts: Minor wounds usually can be treated by trimming the hair from around the wound, flushing the area thoroughly with a 50-50 water and peroxide solution, spraying with an antiseptic, and covering with a sterile gauze and plenty of tape (be careful not to cut off the circulation). After 4 days, remove the bandage to see if the wound is healing without obvious infection. Rebandage and continue to check the wound every 4 days until it’s healed.

If the wound appears too big to heal by itself, take the animal to the veterinarian so it can be sutured. Don’t delay—bacterial infections can set in within hours.

Don’t attempt to treat puncture wounds (from bites or nails, etc.), no matter how minor they appear. Contact your veterinarian.

Diarrhea: If your dog or cat has diarrhea, you can give small (child-size) doses of simple diarrhea products, such as Kapectate, every 2 to 6 hours. If the condition persists, call your veterinarian.

Vomiting: If your dog or cat has persistent vomiting, contact your veterinarian (since any oral medicine you would give would probably be vomited). To prevent vomiting due to motion sickness, you can try withholding food from your pet for 3 or 4 hours before your trip. Preventive medicine can be prescribed.

Responsible Ownership

You have an additional responsibility to assure that your dog or cat does not become a public nuisance. It is not only irresponsible but cruel for pet owners to ignore their duty to control the breeding of their dogs and cats.

Permanent methods of birth control are castration of male dogs and cats and spaying of females; that is, neutering of the pet. Castration before puberty virtually guarantees that undesirable male behavior, such as roaming, fighting, and urine spraying (tomcats) will not occur. Neutering after puberty may not stop all undesirable male behavior, but will accomplish its main purpose: avoiding unwanted puppies and kittens.

Spaying stops the recurrence of heat and its undesirable side effects in females. Spaying is also recommended before puberty because the operation is easier, and will reduce the risk of mammary cancer later in the pet’s life.

Vasectomies in male pets and tubal ligations in females also can be performed, but these procedures do not prevent heat or undesirable sexual behavior. Some veterinarians are starting to use birth control devices to prevent conception. But, more commonly, veterinarians are prescribing drugs that temporarily prevent a female dog from going into heat. These products should be used only as temporary alternatives to spaying, which is permanent.

You also should observe all leash laws. Keep all pet refuse away from public areas, where it can be a health hazard. Pick up and dispose of all waste material. Take special precautions to avoid bite injuries to children and strangers.

Visiting the Vet

Here are a few basic tips to make sure you and your pet get the most out of a visit to the veterinarian.

First, as the Boy Scouts advise, “Be prepared.” Call your veterinarian’s office to make an appointment. It’s common courtesy and will save you time. (Also, the doctor may want you to bring along a stool or urine sample or to prepare the pet in some other way for the visit.) Tell the receptionist exactly what’s wrong so the doctor can schedule enough time for the visit.

Write down a detailed history of your pet’s illness and any questions you want to ask. The more information you can provide, the more easily your veterinarian can diagnose the problem and begin proper treatment.

It’s also a good idea to write down the veterinarian’s instructions for home care. If you don’t think your schedule or situation will permit you to follow the instructions, let the veterinarian know. Another treatment plan can usually be arranged. Above all, ask questions if you don’t understand. Professional advice is worthless if you don’t understand it.

When your pet is being examined, don’t be upset if you can’t be at its side; it will be well treated. There may be times, on the other hand, when the veterinarian will ask you to hold your pet to keep it calm during treatment. If the animal tends to be a biter, snapper, or scratcher, warn the doctor (or the assistant) before he or she finds out the hard way.

With a little preparation and a commonsense attitude during the visit, you and your veterinarian can work together to keep your pet healthy.

Bill Rados is a writer in FDA’s Bureau of Veterinary Medicine and Catherine W. Carnevale is a veterinarian in the Bureau with a background practice in treating small animals.
The Saga Of T's and Blues

Talwin or pentazocine, a prescription painkiller, has been on the market for several years. But recently it was put on Schedule IV of the Controlled Substances Act and now can be refilled only 5 times in 6 months. Why it was put on that limited schedule is a story of “T’s and Blues” and how an ordinary prescription drug becomes a drug of abuse.

by Annabel Hecht

“T’s and Blues.” The phrase may sound like a song title, but it is, in reality, street jargon for a combination of drugs that is being used as a substitute for heroin.

Chicago TV reporter Peter Karl said he first learned of T’s and Blues from a prostitute who was being treated for drug abuse in a local hospital. The end result of this interview, 7 months later, was a TV documentary that “blew the lid” off a newly emerging drug abuse problem that was sweeping Chicago’s south and west sides and spreading into the suburbs. What was perhaps more shocking—the taxpayers were footing some of the bill.

At the same time, FDA and the Drug Enforcement Administration (DEA), whose sources of information were less esoteric than Karl’s, were taking steps to bring under Federal controls the “T” in the combination. T stands for Talwin, a prescription painkiller. Its generic name is pentazocine.

Talwin mixed with an antihistamine, Pyribenzamine, and injected can produce a “rush” or “high” as good or better than heroin. Pyribenzamine is sold as a blue tablet, hence the street name, T’s and Blues. As street supplies of heroin have become scarce, expensive, and of poor quality, addicts have turned to T’s and Blues as a cheap and readily available substitute. Euphoria isn’t all they are getting for their money, however. Overdoses of Talwin can cause psychotic effects and may result in convulsions, coma, and possibly death.

Chicago wasn’t the first area where T’s and Blues were used. In 1977 reports of abuse of the combination turned up in such cities as Syracuse and Cincinnati. Drug wars over street distribution rights led to six deaths in St. Louis. Nothing, however, approached the size of the operation in Chicago.

Peter Karl’s TV cameras filmed “storefront” clinics where “patients” from all over the city, carrying public assistance medical cards, could get a week’s supply of Talwin, Pyribenzamine, Valium, and paraphernalia such as syringes and cotton balls just by walking in.

Copies of checks and Medicaid records obtained from one clinic revealed its owners had received more than half a million dollars in payments between January 1, 1978, and the time the TV program was aired. This clinic, according to the TV account, issued more prescriptions for T’s and Blues than any other in the entire State of Illinois. Dealing in the new drug combination is big business on the street. “T’s and Blues are being passed out on the street like candy,” Peter Karl reported. “Intelligence from narcotics agents say that druggists are main suppliers and wholesale distributors are delivering the pills by the millions... Street gangs known for extortion and gambling are now fighting on the street for control of the T’s and Blues market.”

What made it so easy for the new form of drug abuse to flourish was the fact that both drugs were legal and neither was “controlled.” This means there were no restrictions on the amount that could be prescribed, nor the number of refills that could be dispensed. Records on distribution were not required. Drug abuse authorities were caught off guard when the combination appeared on the streets. No one realized that such a combination had been tried. No research had been done; nothing had been written about it. As a result of this experience FDA has asked the National Institute of Drug Abuse to search for other possible drug
On January 31, 1979, the Drug Enforcement Administration (DEA) issued a final rule putting pentazocine into Schedule IV of the Controlled Substances Act. The rule became effective March 21, 1979. DEA will enforce this rule by following the same procedures for auditing pharmacies and inventory controls and investigating legitimate handlers that it uses for Schedule II and III drugs. The amount of pentazocine available followed the same pattern of initial use in hospitals and nursing homes, followed by illegal diversion and related problems. This led to several cases and reports of abuse involving pentazocine.

Abuse combinations involving Talwin. Taken according to directions, both Talwin and Pyribenzamine are safe and effective. However, Talwin does have a potential for abuse, which has been recognized for many years. It came on the market in 1967 as an injectable analgesic. The tablet form was introduced in 1969. The result of a search for a painkiller lacking the abuse and dependence-producing properties of morphine, Talwin is a mixture of agonist (morphine-like) and antagonist (morphine-blocking) effects. It was believed that this combination of effects would not produce physical dependence and that the drug would not be used as a substitute for morphine or heroin by persons addicted to these drugs.

This belief was shattered early on. Reports of abuse began to turn up in 1968. The following year the manufacturer sent a "Dear Doctor" letter to physicians throughout the United States and Canada indicating that initial hopes for the drug had not been realized. Physician labeling was changed to include a prominent warning calling attention to the drug’s potential for dependence.

Despite these warnings, abuse of Talwin continued. In 1969, 1970, and 1972 DEA’s predecessor, the Bureau of Narcotics and Dangerous Drugs, surveyed State and local agencies dealing with drug abuse problems and in each year learned that Talwin was being found in possession of some persons arrested for drug offenses; that the drug was implicated in thefts from nursing homes, hospitals, and pharmacies; and that it was being obtained on false prescriptions. In many cases the drug had been used initially for legitimate medical reasons.

From these and other sources the Bureau also learned that Talwin is a drug with special appeal to those associated with health care. Case after case was reported involving doctors, nurses, their spouses, and even their children. The fact that the drug was inexpensive, available, and not controlled partially explains why Talwin abuse in the medical professions appears to be disproportionate to that in the general population.

DEA gathered these facts in 1974 and submitted them to FDA with the recommendation that Talwin be controlled. Under the provisions of the Controlled Substances Act, a drug can be put under Federal restrictions only on FDA’s recommendation, based on the Agency’s evaluation of appropriate medical and scientific evidence.

That recommendation must be based on one or more of these findings: that people are taking the drug in amounts sufficient to be a hazard to health or to the safety of others in the community; that it is being diverted from regular drug channels; that people are taking it on their own rather than on the advice of a physician; or that the drug is so like another controlled substance that it is likely to be abused.

Although there were reports of abuse of pentazocine at that time, the abusers appeared to be limited to members of the health professions who had access to the drug and to others who had legitimate prescriptions from physicians. It wasn’t yet a problem on the streets. On the basis of information then available, FDA decided not to recommend control for pentazocine.

In announcing results of the review by the Agency’s Controlled Substances Advisory Committee and its Drug Abuse Staff, HEW Assistant Secretary for Health Charles C. Edwards, M.D., said, “Although reports on abuse and dependency with pentazocine have all been documented, the actual or potential risk to public health associated with such abuse does not at the present time seem to be sufficiently well defined to warrant control.” FDA did ask DEA to continue to monitor trends and abuse of the drug with a promise to reconsider control if new data were found to support it.

Within a few years new information was forthcoming. In December 1977 FDA again presented data to FDA with a recommendation to control pentazocine. Extensive documentation of the drug’s abuse potential came from animal studies, case records, and the medical literature. Reports from the Drug Abuse Warning Network (DAWN) presented a picture of a drug generally obtained by legal prescription and to a large extent associated with suicide attempts. The data also suggested that the drug was obtained often from illegal sources and used for its euphoric effect.

By 1977 12 States already had imposed control over pentazocine and three more were contemplating such action, according to DEA. A year later the number of States controlling the drug reached 16 and an additional three had proposed control. One of the first was South Carolina, where evidence to support control included abuse cases, fraudulent prescriptions, and illegal sales. Among the cases cited was that of the daughter of a physician who stole injectable Talwin from her father. She was caught in the act of injecting the drug into the arm of a neighbor.

Coupled with this evidence was the unfolding story of the abuse of T’s and Blues. A DEA pharmacist, appearing before FDA’s Controlled Substances Advisory Committee in March 1978, reported on a case in Chicago which clearly established pentazocine as a drug of abuse. City investigators audited records of a local wholesaler and found that 18 pentazocine orders were filled for one pharmacy in a 3-month period. A check of the pharmacist’s records found a discrepancy of approximately 1.5 million pentazocine and Pyribenzamine tablets between the amount ordered and the amount used to fill legitimate prescriptions. This represents $5 million at the price addicts were paying on the street. A diversion of this size is possible with uncontrolled drugs, according to DEA, because they are not subject to audits and inventory controls and investigators cannot see sales records except with a court order. Chicago authorities were able to build a case because they suspected a problem existed.

On the basis of this and other evidence including reports of newborn babies addicted to pentazocine as a result of abuse by mothers during pregnancy, FDA recommended that DEA put pentazocine into Schedule IV of the Controlled Substances Act. DEA issued the final order January 10, making the scheduling effective 30 days later, on February 9, 1979.

Under Schedule IV, a prescription can be refilled only 5 times every 6 months. Strict accounting and record-keeping is required of manufacturers, drug wholesalers, pharmacies, and other legitimate handlers. Pharmacies are subject to routine investigations and audits of those records. Federal criminal penalties for the illegal handling of Schedule IV drugs can bring up to 3 years in prison and/or a $10,000 fine for the first offense, and double that for subsequent offenses.

While controlling such drugs as Talwin may not wipe out their abuse overnight, it can help curtail illegal street distribution.

Annabel Hecht is a staff writer with FDA’s Office of Public Affairs.
Four hundred years ago, England's physicians were forbidden to teach their patients about medicines. In a more enlightened 20th century, the patients' "right to know" is an accepted fact. Not so certain is just what information they should get. FDA recently asked the experts for their views on what should go into a patient package insert and what the insert should look like and got some forthright answers.

"Use of the PPI as a communication tool could be the best thing that ever happened to pharmacy for developing the 'family pharmacy' concept of practice."

—Milton Skolaut, Duke University Medical Center

The Food and Drug Administration has a long-term commitment to implement this concept and in the near future will issue guidelines for an overall patient information program that will call for patient package inserts (PPI's) for a number of drugs. A PPI is an easy to read brochure or other type of material for patients tailored for specific prescription drugs. PPI's already are required for a number of products including oral contraceptives and estrogens.

To get the best thinking on what should go into PPI's, FDA held a conference late last year on "Patient Package Inserts: Content and Format." Some 300 participants, representing the drug industry, medicine, pharmacy, law, marketing and advertising, and consumer interest groups attended the 2-day meeting. The purpose was not to argue

the pros and cons of PPI's. "There will be PPI's and they will be legally mandated," Dr. J. Richard Crout, Director of FDA's Bureau of Drugs, told the assemblage in his keynote address. What the Agency wanted of the conferees was their views on how the information in a PPI should be designed to be of the most benefit to the patient.

Recognizing that writing an effective package insert is not going to be an easy task, the conferees agreed that inserts can't be all things to all people. However, as Dr. Crout pointed out, they should do the most good for the people most likely to read them.

PPI's can fill the communications gap between health professionals and patients, said Barbara Cox of the American Medical Writers Association, who called for patient involvement in PPI development. At the same time other speakers cautioned against letting PPI's take the place of the counsel of physician or pharmacist. The PPI "must first do no harm," noted Dr. H. Winter Griffith of the University of Arizona. It must not decrease confidence in the physician

"PPI's can be a means of improving the quality of health care, but they should not be used to make decisions whether to take medication."

—Ruth Fishback, Boston Beth Israel Hospital
or usurp his “responsibility and privilege” to teach patients about the drugs he prescribes.

The conference participants did not reach complete agreement on the precise purpose of a package insert. Should it be a “right to know” document, a form of “informed consent,” or simply an educational piece to encourage the patient to follow the doctor’s orders? If the PPI is intended to obtain the patient’s “informed consent,” said one speaker, it should not be distributed by the pharmacist, because at that point it is too late.

There was no question on what the conference thought about style. It should be short, concise, easy to read but not too simplistic, nonthreatening, and printed in large type. As Alan Siegel of Siegel and Gale, a consulting firm, reminded the group, “People aren’t conditioned to read labels, instructions, and booklets in a discriminating manner.” The appearance of a PPI should invite the reader to read, but not overwhelm him, and the style should be personal, using words such as “you” instead of “the patient.”

As to what goes into a PPI, Joan Hoover, American Diabetes Association, said the patient wants to know what’s in the drug, what it will do for and to the individual. The conference in general agreed with this view, calling for inclusion of such information as the trade and generic names of the drug, what it is used for, how to store it, and contraindications. The tone should be balanced, emphasizing benefits as well as risks of taking the medication. Dr. Peter Wright, Stanford University Business School professor, called for a “here’s what to do next” method of presenting this information. Thus, if patients are told to keep drugs in a cool, dry place and that place is the refrigerator, the message should say so.

At the same time, Dr. Joseph Danks, Kent State University professor, warned that the patient will be “turned off” if he is given too much detail or is told the same thing too often in different PPI’s.

Unresolved during the 2-day conference was the problem of how to handle adverse reactions. Should all be listed or just those that are most common? Should they be grouped in terms of the more frequent and less severe versus the rare and more serious? Addressing the legal implications of PPI’s, Dr. Harold Hirsch, Howard University Medical School, said that there are pitfalls in giving patients detailed information about possible adverse reactions, but that careful explanation by physicians and pharmacists can ease their fears. Withholding such information would defeat the purpose of the insert, he warned, and could invoke legal sanctions against the physician.

The format of a PPI should be flexible, it was agreed, since not all inserts will convey precisely the same information. One speaker suggested following the format of the physician’s labeling, but with simplified headings. Others disagreed, saying that the patient’s concerns may not follow the same order. In any event, information in PPI’s should be organized in a logical manner, Siegel noted.

Regardless of what the PPI looks like or what kind of information is in it, conference participants generally agreed that the final product should be pre-tested, using real people in real life situations, before being given to patients, and it should be reevaluated after being in common use for awhile.

Who should distribute PPI’s also was a matter of concern for which there were no ready answers. When should this information material be given to the patient in the physician’s office? What should be done when the pharmacy is not involved in the distribution chain? Or, as Marsha Greenberger of the Center for Law and Social Policy, a consumer group, asked: What if there is no medicine bottle? If there is a container, the PPI should be permanently af-fixed to it, Siegel said. Dr. Jerome Ryan of Tulane University suggested putting basic information about how to take and store the medication on the container, in addition to providing detailed information in the PPI.

Although a consensus was not reached on all aspects of developing PPI’s, FDA believes the conference results will enhance the state of the art of providing written communications to the consumer as a method of improving the quality of health care.

**"PPI’s will force the physician into greater dialog with patients regarding prescription drugs."**

—Dr. Jerome Ryan, Tulane University

"If patient package inserts are to become effective teaching aids, physicians, pharmacists, and other health workers must not only be convinced of their usefulness, but also must become enthusiastic endorsers of the concept."

—H. Winter Griffith, University of Arizona
FDA has approved limited testing of liquid silicone by its manufacturer, Dow Corning Corporation, as a medical device for correcting severe facial disfigurement. Up to 300 people may participate in the tests each year and a specially trained group of doctors will carry out the testing.

by Paula Klevan

To Napolean III’s mistress, the Countess of Castiglione, physical beauty mattered above all else. At the age of 39, she shattered every mirror in her Paris apartment, then locked herself inside—vowing never to show her aging face in public again.

Today, a century later, American men and women value youthful good looks just as the Countess did. But instead of hiding, many choose the route of facial cosmetic surgery. It is not only widely available, but is also attaining a new acceptance, even status, in parts of our society—witness the highly publicized operations of former First Lady Betty Ford and comedienne Phyllis Diller. The countless other people who undergo similar surgery have fairly routine variations on face-lifts, ear, eyelid, and nose operations. Results generally range from fair to excellent improvement of facial contours.

A relatively new type of facial surgery is becoming increasingly popular throughout the United States. The procedure is liquid silicone injection. Thousands of people have received injections, hoping to smooth out wrinkles, crow’s-feet, laugh lines, and acne scars. A national magazine reported recently that a prominent fashion designer sees his dermatologist twice weekly for the injections. Similar stories give the treatment an aura of faddish respectability. What the articles rarely tell are the possible consequences of forcing this clear, colorless, odorless substance into human flesh.

These side effects first became evident in the 1960’s, when liquid silicone injections became popular among women who wanted their breasts enlarged. The initial enthusiasm for the operation cooled rapidly as more and more women experienced serious and sometimes fatal complications. These included swelling, discoloration, cyst formation, and migration of silicone particles to the brain, lungs, or heart.

Injection of liquid silicone into facial tissue can result in the formation of cysts, tumors, and granular masses. Even small amounts of the liquid silicone have the potential to clump and travel, blocking circulation, discoloring the skin, and eventually stretching the treated area so that it hangs in grotesque folds. The surgical procedures that are used to remove these complications are neither simple nor foolproof. Cutting occurs perilously near such vital structures as the facial nerve. Why should so dangerous a practice be considered medically sound?

In fact, it is not. Despite its popularity, most liquid silicone surgery practices are condemned both by FDA and the American Medical Association.

While surgery per se is outside FDA’s jurisdiction, the drugs and devices used in such procedures are subject to FDA’s regulatory authority. Sterile injectable liquid silicone is considered a medical device, and is subject to regulation by FDA under the Medical Device Amendments of 1976. This law gave FDA authority to set standards and require premarket clearance for medical devices.

The major manufacturer of liquid silicone, Dow Corning Corporation of Midland, Michigan, has been conducting research during the past decade on the uses of this material for facial cosmetic surgery. In the spring of 1978, FDA approved a Dow Corning test program in which liquid silicone would be administered on a limited, nonprofit basis by a small group of physicians. The study will cover 3 years, followed by a 7-year followup on each patient. Twenty-four doctors have been specifically trained in the administration of liquid silicone and in specialized postoperative care.

Because of the great risk associated with injectable liquid silicone, only the most severe types of facial disfigurement will be considered for treatment under the Dow Corning experiments. These vary from a condition called facial lipodystrophy, in which the fat beneath the facial skin progressively shrinks away, to the branchial arch syndrome, characterized by the retention of gill-like ridges on the neck of the human fetus—a growth which normally disappears before birth. These conditions are rare; they are usually congenital and other methods of treatment are inadequate to correct them.

The study guidelines specifically forbid the use of this device for minor imperfections such as frown lines, acne scarring, and other common facial aberrations. Distribution of liquid silicone beyond the auspices of the testing program across State lines is prohibited by FDA.

Paula Klevan is on FDA’s public affairs’ staff.
Drug Effects Can Go Up In Smoke

The 1979 Surgeon General's Report on smoking revealed that the health consequences of smoking are even more serious than was supposed when the first smoking report was issued in 1964. Among the more recent findings is evidence that smokers who are taking drugs may be puffing away the effectiveness of the drugs. The studies have indicated that smokers may need a greater dose of a drug to get the same effect as nonsmokers and may need it more often.

January 11, 1964, marks the day when the Surgeon General of the Public Health Service released the now famous Smoking and Health Report indicting cigarette smoking as a major health hazard. Subsequent reports, issued almost every year since then, have contributed to a growing body of scientific evidence that links smoking to a variety of disabling and fatal diseases.

The 1979 report, released January 11, is no exception. It reveals that the health consequences of smoking are even more serious than was supposed 15 years before, particularly for women and teenagers. While much of the data in the latest report has a familiar ring there are some things completely new. Almost in the middle of the monumental 1,200-page volume is this startling statement:

"...Smoking of tobacco should be considered as one of the primary sources of drug interactions in man."

The chapter goes on to say that smoking can affect the way drugs behave in the body. For certain drugs, but not for others, smokers may need a larger dose or may have to take the drug more often than nonsmokers. The report also reveals that smoking may result in increased risks with drug use, affect an individual's response to certain common diagnostic tests, and interact with certain food constituents.

Scientists in FDA's various bureaus compiled the information for this chapter of the report. Although most of these facts have long been known in the scientific world, this is the first time they have been brought into focus in a major smoking and health report destined for wide public distribution.

One specific smoking-drug problem, already well publicized, is the increased risk of heart attack, stroke, and other circulatory diseases among those women who smoke and also use oral contraceptives. This risk is higher in women older than 37 and in heavy smokers. As a result of studies completed between 1975 and 1977 FDA has called for changes in the information on oral contraceptives that manufacturers must provide to physicians and users of "The Pill." The warning is clear: "Women who use oral contraceptives should not smoke."

The new smoking and health report also suggests that there is evidence from one study that women aged 39 to 45 may run an increased risk of heart attack if they smoke and use noncontraceptive estrogens.

Other smoking-drug interactions may not be as dramatic as these but they are none the less important. The new report points out that the dominant effect of smoking on drug metabolism comes from the ability of nicotine and other tobacco constituents to speed up the process by which the body uses and eliminates a drug. This means not only that a drug may be less effective, but that the duration of its effect may be shortened. In such a case that drug won't be able to do the job it is supposed to do, and patients and their physicians may be led to conclude that a particular drug is ineffective. Smokers may therefore need different doses or may have to take a drug more frequently than nonsmokers. For this reason it is important for the physician to know about his patient's smoking habits.

Two drugs for which this effect can be critical are theophylline and pentazocine. Theophylline is an important bronchodilator used for treating acute and chronic asthma or bronchitis. Studies have shown that smokers may need one and a half to two times as much of the drug as nonsmokers to get the same relief. Even if a person quits smoking, these effects may linger for as long as 3 months. A further complication is that smokers used to higher doses of theophylline may be in danger of getting too much of the drug if they quit and their dose of the drug is not adjusted by their physician as the effect of smoking wears off.

Pentazocine is a prescription pain-killer sold under the trade name Talwin. Comprehensive in-hospital monitoring by the Boston Collaborative Drug Surveillance Program has shown that smokers need more pentazocine than nonsmokers when the drug is used in combination with nitrous oxide for anesthesia. The findings have been confirmed by other studies which found that smokers metabolize, or burn up, 40 percent more of the painkiller than do nonsmokers. In other words, smokers need more of the drug to reduce pain.

The Boston program also found that propoxyphene (Darvon) is less effective in smokers than in nonsmokers. One possible explanation for this effect is that smokers have a lower threshold for pain.

Smoking also appears to interact with a number of other drugs such as imipramine, an antidepressant; gluthethimide, a sedative; furosemide, a diuretic; and propranolol, a beta blocker.

Further complicating the picture is the fact that smokers tend to consume other drugs and chemicals more frequently than nonsmokers. They take more cough medicine, aspirin-containing drugs, pain medicine, sleeping pills, tranquilizers, diuretics, hormones, iron medicine, amphetamines, antibiotics, stomach medicine, and laxatives than nonsmokers.

Although the drug-smoking relationship has been established for some drugs, the functions of others have been reported by the Boston study to be completely unaffected by the patients' smoking habits. Among them are the minor tranquilizer diazepam.
(trade name Valium); a pain drug, meperidine (trade name Demerol); and a major tranquilizer, chlorpromazine (trade name Thorazine). The therapeutic effectiveness of these drugs may be the same in most people, but side effects are not. Smokers apparently are less drowsy than nonsmokers when taking diazepam or chlorpromazine.

Giving up smoking is good preventive medicine to reduce the risk of developing heart disease or lung cancer. Quitting also may be a factor in another form of disease prevention—vaccination. Vaccines work by stimulating the development of antibodies, the body's natural defense against disease. It has been suggested, on the basis of limited research, that there is a rapid decrease in numbers of antibodies produced by influenza vaccine among smokers as compared to nonsmokers. Further research is needed here, but if this finding is substantiated it would mean that such vaccines would provide less protection against disease for the person who smokes.

Smoking may also affect responses to certain diagnostic tests. Evidence cited in the new Surgeon General's Report indicates clear differences between smokers and nonsmokers in "normal" values in various biochemical and clinical tests done routinely in the clinical laboratory. These differences can be erased when smoking is stopped.

For instance, smokers show higher levels of white blood cells even when they don't have an infection or other illness that would tend to raise the white cell count. These differences hold true for all ages from 15 to 79, both sexes, and the three races studied—yellow, black, and white. The heavier the smoking the higher the count. How much smoke gets into the body also appears to be significant. Smokers who inhale have a greater average number of white cells than those who don't, regardless of the amount smoked.

Smoking can change the red blood cell picture as well. Among other changes, the size of red blood cells increases in smokers. Some researchers believe this occurs because the high levels of carbon monoxide in cigarette smoke reduce the amount of oxygen the blood can carry. Smokers' systems apparently adapt by increasing the red cell's mass.

Smoking also can affect the way the blood behaves in standard tests for clotting time. Researchers have found that whole blood of healthy smokers appears to clot faster than that of nonsmokers. This effect could provide an incentive to quit for smokers who have had clotting problems.

A dramatic example of how smoking can affect lab tests involves a component called carcinoembryonic antigen (CEA), which can be detected in the blood of patients who have cancer of the colon. Sensitive tests have been developed which aid in the diagnosis of this disease by measuring blood levels of CEA. However, studies have shown that CEA levels in smokers often are as high as those observed in patients with proven colon cancer.

FDA was aware of this particular interaction when CEA Antigen Diagnostic Kits were licensed for manufacture in 1972. Information in the labeling for physicians alerts them to the fact that "normal" individuals who smoke can have high blood levels of CEA.

That smokers differ from nonsmokers in the way they respond to some standard laboratory tests doesn't mean that they are ill and don't know it. Nor does it mean that false diagnoses will be made as a result of such tests, although that is a remote possibility. However, if a doctor finds unusual test results that don't seem to match with other aspects of his patient's physical condition he might order additional lab work. This will, of course, add to the patient's bill. To assure correct interpretation of diagnostic tests, the Smoking and Health Report concludes that the smoking status of an individual should be included in reports of clinical tests performed on that individual.

As for the effects on nutrition, the report points out that scientists have known since 1939 that smoking causes changes in blood levels of certain nutrients, which may help explain why this habit is harmful to health. For one thing, investigators have found that smoking alters the way the body handles carbohydrates and proteins. Impairment of protein metabolism reduces the body's efficiency in retaining nitrogen. Some studies have found that smoking increases the amount of cholesterol in the blood, although not all scientists agree with this finding.

In addition, it is possible that smokers may have increased needs for vitamin C, vitamin B12, and vitamin B6. The reason for these changes has not been established. These smoking-nutrition interactions may be a key to the fact that smoking mothers tend to have smaller babies who come into the world with an increased risk of dying early in life.

Vitamin C is essential to certain biochemical functions in the body. Low levels of this vitamin may be responsible for some of the bone mineral loss smokers experience. Two studies cited in the report found significantly more bone mineral loss in smoking, post-menopausal women than in their nonsmoking peers.

Cigarette smoke includes a number of trace metals, including cadmium, lead, arsenic, and selenium, which may accumulate in the body. Radioactive polonium, which is present in the leaves of tobacco, can enter the lungs. One cigarette yields as much polonium as a person would inhale from the atmosphere in 24 hours. However, there is no information that the increased body burden of these toxic elements represents a danger to health. Another component of cigarette smoke is a form of nitrosamine known to produce tumors in the esophagus, pharynx, and nasal cavity in rats. The report suggests the increased incidence of cancer in humans who smoke and chew tobacco may be related to the cancer-causing properties of this nitrosamine.
Marihuana is a plant that can grow nearly anywhere in the world. It has been used by man for thousands of years for a variety of purposes. Yet, only recently has medical science begun a serious investigation into its possible uses to treat disease. If present studies continue to show favorable results, yesterday's symbol of protest may become tomorrow's medical tool.

by James Greene

Marihuana seemed to burst upon the scene in the mid-1960's—its illegality seized upon by many young people as a symbol of their protest against many established values. The outlaw status was disdained by that generation, which viewed marihuana as a simple recreation drug.

But marihuana is hardly new on the scene—the pages of history are stained with its mind-altering legacies. Simple recreational drug it is not, either. What can be said for sure about marihuana is that it is an uncertain batch of chemical compounds. The overwhelming scientific view, however, is that it is an unsafe batch.

Just how unsafe that concoction of chemicals is awaits determination by medical science, but it has been discovered to have a promising potential for treating some diseases.

That discovery is hardly new, however, as early man also found some medical value—and other uses for the drug. In ancient China, for example, generations used the substance as a folk remedy, a ritual potion, an intoxicating agent, and even a condiment. In 2737 B.C. the Chinese Emperor Shen Nung taught his subjects to employ marihuana as an anesthetic and in medicinal preparations.

Other ancient uses of marihuana, which comes from the leaves and flowers of a variety of hemp plants, varied from culture to culture. In Vietnam, for example, marihuana in a variety of concoctions was used in treatment for
allergies, rheumatism, and tape-worms, and to prevent hair loss. In Cambodia, the plant, known as ganja, was used in hemp preparations to facilitate contractions during difficult childbirths. Hemp preparations, smoked daily, also were supposed to reduce polyps of the nose and relieve asthma. Other cultures used marihuana to treat leprosy, gonorrhea, arsenic poisoning, and the juices of its leaves to treat dandruff, vermin infestations, and other skin conditions.

Most of these uses of marihuana do not hold up under the glare of today's scientific spotlight on its pharmacological activities. However, its use by some societies, past and present, to treat painful menstruation, and tooth-aches and other types of nerve pain, can be partially justified on the basis of the effect marihuana has on the central nervous system. For example, there is some scientific sense in the Ukrainian practice of inhaling hemp vapors to treat toothaches, or marihuana's use in rural India to treat asthma and loss of appetite.

In most societies today, however, people use marihuana in attempts to achieve a state of euphoria. This is true even though growing, selling, and use of the drug, except under tightly controlled scientific studies, is against international law and the laws of nearly every country in the world. In the United States, the drug has been listed in Schedule I of the Federal Controlled Substances Act of 1970, which imposes strict controls on the production, sale, distribution, and use of the drug. Drugs, such as LSD, mescaline, and heroin, that have a high potential for abuse and no accepted safe medical use are also placed in this category. The Drug Enforcement Administration (DEA) and the Food and Drug Administration implement the provisions of this act.

As a psychoactive drug, marihuana usually is smoked in pipes or loosely

THC, the chemical found in marihuana, is responsible for most of the effects while using the drug. However, use of synthetic THC (photo above) enables researchers to conduct better clinical tests because, unlike natural THC, its purity and strength can be controlled. Recent tests have shown that synthetic THC is useful in treating glaucoma by reducing the intraocular eye pressure associated with the disease. Patient is examined by doctor using a device that blows a stream of compressed air at the eye, which flattens the cornea and produces a beam of light that is reflected back into the instrument. The time it takes—measured electronically—to do this determines the fluid pressure within the eye, which is then displayed on a small digital screen on the instrument.
rolled cigarettes called joints, reefers, or rope. Marihuana is also known by a host of other slang expressions including grass, pot, dope, roach, hooch, or Maryjane. Physical changes in the body during smoking may include a temporarily accelerated heartbeat, dilation of the pupils, a rise in blood pressure, and a slight lowering of body temperature. Some smokers may also experience a reddening of the eyes.

Actual physiological effects of the drug depend on the amount smoked and the potency of the marihuana, as well as the psychological attitude of the smoker. In low doses the drug tends to produce an increased sense of well-being and relaxation; an illusory expansion of time and space; a more vivid sense of touch, sight, smell, taste, and sound. It might also increase hunger, especially for sweets.

Moderate doses may result in a state of intoxication that intensifies these reactions. Other moderate dose effects may include rapidly changing emotions, a dulling of attention, and impaired memory. High doses can result in fantasies, hallucinations, aggressive behavior, and loss of personal identity. Marihuana is often used with alcohol and that combination may well be more of a health hazard—particularly when driving.

The Controlled Substances Act of 1970 and FDA’s new drug testing regulations do provide, however, for research and clinical testing of marihuana to determine any valid medical uses for the drug. Over the last 20 years pharmacological studies by the National Institute of Drug Abuse, FDA, other Federal agencies, and private, scientific organizations have confirmed that the most active ingredient in marihuana is the chemical compound delta-9-tetrahydrocannabinol (THC). That compound is found in the gooey, yellow, fragrant resin of the upper leaves and flowers of the plant. As the most active ingredient, THC is, therefore, responsible for most of the physiological and psychological effects experienced in using the drug.

Research scientists at the University of Mississippi use this laboratory (photo, below left) to determine the strength and purity of the THC found in marihuana plants grown on the farm. Other lab work involves assaying confiscated marihuana and hashish to determine their potency as part of a monitoring program conducted by the Drug Enforcement Administration. Samples of hashish, hash oil, and marihuana in glass containers (photo below) await analysis. Researcher Mardi Russell (photo, below corner) weighs one gram of marihuana for analysis.
Over 100 varieties of marihuana from all over the world, including South America, Mexico, Africa, India, and Afghanistan, are grown under Government contract on a 12-acre farm at the University of Mississippi. Marker (photo at right) identifies young marihuana plant grown from seeds collected in 1971. To determine how marihuana affects a person’s ability to drive, studies are being conducted under Government contract at the Southern California Research Institute at Los Angeles. Woman attempts to perform a series of driving maneuvers in a simulator (photo above) after receiving a dose of marihuana. The headgear contains a tiny electrode which, when placed on the eyelid, allows researchers to track eye movements.
During the mid-1960's research scientists were able to reproduce this chemical compound synthetically by mixing and purifying various chemicals. This ersatz product permits clinical testing under conditions in which the purity and strength are controlled. Marihuana plants, on the other hand, vary considerably in strength of THC. In addition, marihuana plants are known to contain another 249 chemical compounds. The mixture makes the extraction of THC time consuming and costly. The synthesis of THC assures medical researchers of sufficient supplies of the pure material for continued research and testing.

About 35 clinical studies currently are being conducted using both synthetic THC in capsules or liquid and marihuana cigarettes, all made under Federal Government contracts. Most medical researchers are associated with universities and private cancer clinics; others are associated with the National Institutes of Health and a few with State health organizations.

Current research and clinical tests point to three major areas where the synthetic THC or cigarettes may prove to be therapeutically beneficial. They are:

- **Glaucoma.** Tests have shown that synthetic THC in capsules reduces elevated (intraocular) eye pressure associated with glaucoma. The synthetic THC is believed to increase the outflow of fluid from the anterior chamber of the eye, thereby relieving some of the pressure.

- **Antinausea agent.** Synthetic THC is showing promising results in relieving nausea, vomiting, and loss of appetite among cancer patients undergoing chemotherapy. Such use would be of great value to cancer patients because present attempts to control these side effects are often unsuccessful.

- **Spasticity.** A preliminary clinical study shows that synthetic THC reduces muscle spasms in people afflicted with multiple sclerosis, cerebral palsy, or who suffer a stroke. The study suggests that THC has a special inhibitory effect on nerve reflexes.

Researchers who want to do studies involving marihuana or its synthetic THC must register with the Drug Enforcement Administration and submit an Investigational New Drug Application (IND) to FDA. If both agencies approve, the researchers must submit an order form to the National Institute on Drug Abuse (NIDA), which will supply the necessary quantity of drug.

Under the Controlled Substances Act, the research and the product are carefully scrutinized. The DEA, for example, checks all researchers for criminal records including drug violations, inspects facilities for security, and requires comprehensive records.

To get approval from FDA, the researchers must—as with all IND’s—provide detailed information on the type and purpose of study to be conducted, number of patients involved, and the amount and dosage form of marihuana to be administered.

One project recently approved by FDA was submitted by the Health and Environment Department of the State of New Mexico. The State will use THC capsules or marihuana cigarettes on selected cancer patients undergoing chemotherapy treatment. New Mexico is the first State to be approved by FDA as a sponsor for a clinical test of THC. The project is being conducted by the University of New Mexico.

THC is manufactured by a private firm in Massachusetts under contract with NIDA. The marihuana used in experiments is grown on a 12-acre farm at the University of Mississippi at Oxford. Research scientists at the University under contract with NIDA manage the day-to-day operation of the farm, which includes planting marihuana seeds; maintaining quality control—primarily the strength and purity of the THC content; harvesting; and crop storage. Marihuana takes about 6 months to grow in the Mississippi climate. The harvest is shipped to a processing plant in North Carolina and made into cigarettes for clinical testing by researchers. Scientists at the University also perform followup analyses of the cigarettes to check the quality of the finished product. They also perform similar assays on confiscated marihuana sent to them by the Drug Enforcement Administration as part of a potency monitoring program. As to potency, marihuana grown at the University usually contains 1 to 25 percent THC.

Many in the scientific community believe that marihuana and another drug that is much abused, heroin, may have considerable potential for therapeutic use. The regulating Government agencies—FDA, and the Drug Enforcement Administration—are working with NIDA to streamline procedures and make it easier for medical researchers to get Schedule I drugs for clinical testing. Along that line, FDA has prepared guidelines on marihuana and THC for researchers to follow in applying for IND’s.

In addition, scientists and physicians from these three agencies and the National Institutes of Health last year set up a Committee on New Therapies for Pain and Discomfort. One of the main objectives of the committee is to develop recommendations to aid in the research of some drugs with potential. Included are the so-called street drugs, marihuana and heroin.

Science may learn that the ancients in their folklore had a certain instinctive wisdom in using marihuana. And eventually the protesters of the 1960’s and 1970’s may come to realize that making political statements with drugs is a curious kind of wisdom.

*James Greene is a staff writer with FDA’s Office of Public Affairs.*
Seeking The Safest X-ray Picture

Reducing the amount of radiation exposure in x-ray picture taking is one of the challenges of the Bureau of Radiological Health. Through scientific analysis, the Bureau is looking for new equipment and techniques that will minimize the amount of radiation passing through individuals in the more than 200 million medical examination pictures taken each year. This article describes the Bureau’s work along those lines.

by Robert T. DeVore

In the first medical applications of x-rays after their discovery by Wilhelm Konrad Roentgen in 1895, film was exposed directly to radiation that had passed through the patient. Exposures were much higher than they are today. In those days, the patient had to be immobilized by sandbags for considerable periods of time while undergoing an x-ray examination.

Now, however, x rays often are converted into light by intensifying screens. Since film is much more sensitive to the light than to x rays, the film exposures may be reduced as much as 5,000 percent.

Today, in fact, the entire x-ray system—from tubes to cassettes that hold films and screens to the development of films themselves—has been so improved that patient exposures now average about two percent of levels that prevailed in Roentgen’s day.

Scientists in the Food and Drug Administration’s Bureau of Radiological Health believe, however, that many exposures are still higher than they need to be. For this reason, they have under way a long-term program of patient x-ray exposure reduction. As a central feature of that program, they are examining the fundamental physics of x-ray picture making to determine the absolute minimum x-ray exposure required to obtain medically needed information.

“Technique charts,” which give guidance on the amount of radiation to use for a certain diagnostic procedure, are developed today from experience and, therefore, reflect the limitations of present equipment. Now the Bureau of Radiological Health is replacing this procedure with scientific analysis. By this means, the weak links—where information is being lost through the inefficiency or poor performance of the system—can be identified and suggestions made for equipment improvements, which will reduce radiation dose requirements.

The program is important for one basic reason: many believe today that no radiation exposure is so low that it cannot induce a health effect. In other words, the most minute exposure may be harmful. The hazards include cancer, genetic effects sometimes reflected in disease or disability in the offspring of exposed persons, and minor damage to other parts of the body.

Bureau scientists researching the physics of x rays often are concerned with films and intensifying screen combinations. However, in all of them a portion of the diagnostic information may be lost. As a result, patients undergoing diagnosis often receive nonproductive radiation.

A substantial amount of nonproductive exposure occurs either because films lack sharpness and speed or because of deficiencies in screens. The problem is to find a balance of films and screens that will produce high-quality x rays. Although researchers realize that the best film-screen combinations may never be found, their
Can you tell the difference?

Skull x-ray images made with older calcium tungstate intensifying screens (top) and new rare earth intensifying screens (bottom) are shown in these x-rays from the Bureau of Radiological Health. Contrast, sharpness, and “noise” are identical for the two images, but the image on the bottom required only 50% of the exposure needed for that on the top.
These x-ray images of the leg are identical except for sharpness, an imaging characteristic measured in Bureau of Radiological Health laboratories. The pictures demonstrate the need for sharpness for diagnosis. The poorer image (left) resulted from using an improperly designed cassette that allowed air to be trapped between the intensifying screens and the film.

The quality of sharpness—the absence of blur in films—is especially important and methods for improving it get a lot of attention from the scientists. Without sharpness, for example, it is unlikely that tiny calcifications, which may signal developing cancer, would be detected in breast x rays, called mammograms. Sharpness also is important—and sometimes is lacking—when physicians are trying to find hairline bone fractures.

Film speed and a quality known as latitude have major roles to play in x-ray examinations in which the physician wants to picture tissue and bone varying in density, as in certain chest x rays. Here, the contrast range is from dense rib bone and solid tissue, such as the heart, to relatively soft between-the-ribs tissue and softer lung tissue. Correct film speed and latitude can help the physician obtain the required contrasts with one exposure.

In most film-screen combinations, two screens are held in a rigid, light-proof container called a cassette. X rays penetrate the walls of the cassette, interact with the screens, and are converted into light. When one x-ray photon strikes the intensifying screen, as many as 1,000 photons of light may be generated.

In exploring ways to improve intensifying screens the scientists recently demonstrated that, for screens using chemical compounds known as "rare earths," diagnostic x-ray exposure could be cut by 50 percent. The rare earth compounds first were used in color television picture tubes. They became available in intensifying screens around
1975. Before that, most intensifying screens were made from calcium tungstate, introduced by Thomas A. Edison not long after Roentgen made his x-ray discovery.

The x-ray-to-light conversion abilities of intensifying screens depend upon how well they stop radiation. For typical diagnostic x-ray beams, calcium tungstate stops 20 to 40 percent of the rays. Some 60 to 80 percent of the radiation, therefore, passes through the entire cassette without contributing to the x-ray picture. Studies made with rare earth screens show that they are up to 2.5 times more efficient than calcium tungstate in stopping x rays.

The energy going into screens is always greater than the energy used. The gap between energy delivered and energy used can be accounted for in a number of ways. Probably the greatest loss is caused by intensifying screens that fail to stop x rays. Rays that pass through the screen, of course, cannot be converted into light.

Because of the potential of rare earth intensifying screens for lowering patient exposure, the Food and Drug Administration has published in the Federal Register a notice of its intention to develop a radiation protection recommendation calling for voluntary use of these screens to the fullest possible extent.

With rare earth screens, the speed at which the picture is taken can be doubled and the duration of exposure halved with no loss of diagnostic information or picture quality. But Bureau scientists believe that x-ray exposure could be reduced 80 to 90 percent in some examinations if physicians would accept x-ray pictures that contain less information than the ones now used, but which still have sufficient information for diagnosis. To make this concept work it is necessary to know how much x-ray exposure is sufficient for various diagnostic procedures.

Basically, what Bureau scientists are doing is defining and writing down, in mathematical form, the relationship between the information in the x-ray image and the radiation dose the patient receives. Much of this research is being conducted in a laboratory considered to be one of the most sophisticated and advanced in the United States for making precise measurements of screen and film response to x-ray exposure.

This fully computerized and automated laboratory has three main components—an x-ray sensitometer, a microdensitometer, and an x-ray spectrometer.

On the sensitometer, x-ray films—alone or in combination with intensifying screens—are exposed to precisely known amounts of radiation. The films are then developed in a carefully controlled chemical process and taken to the microdensitometer, which compares film density—that is, degrees of darkening, in relation to exposure. Twin microscopes—one on each side of the film—measure density variations over a spot of film as tiny as one-thousandth of a millimeter in diameter. The microdensitometer processes as many as 1,000 measurements in a second with measurements per film totaling hundreds of thousands.

These measurements are printed out by computer as dots on paper rising upward in a curve, the film density increasing mathematically in accordance with increases in the amount of x ray to which the film was exposed on the sensitometer. From these curves scientists can determine the film’s contrast and its speed.

The microdensitometer also is used to analyze film for sharpness. For this test, a cassette containing unexposed film and two intensifying screens is entirely blanked out except for a slit about three-quarters of an inch long and ten microns (ten-millionths of a meter) wide. The screens and films are exposed to x rays through the slit and the resulting image is examined in the microdensitometer. Invariably, the light generated through the conversion of x rays striking the intensifying screens is diffused. This often substantially blurs image sharpness. In fact, images produced on the film commonly have been found to be about one hundred times wider than the slit. Nevertheless, a slit image a little narrower—around 500 microns—indicates a film that can give fair to excellent sharpness.

Finally, films are analyzed in the microdensitometer for what is called “noise.” This is unwanted variation in film density due partially to random x-ray absorption in the intensifying screens. Clarity of image obviously requires a minimum of noise.

The spectrometer measures the energy that strikes the intensifying screens and the energy actually used in making x-ray pictures. The device, specifically, helps measure screen speed.

Through technical publications, professional contacts, and conferences, Bureau scientists are spreading the word that reduced consumer x-ray exposure and maximum picture quality are objectives that may be linked to studies of nonproductive x rays, and to film sharpness, speed, contrast, and noise.

Film and intensifying screen manufacturers and people who use x rays—physicians, technologists, and medical physicists—are beginning to pay attention. Especially encouraging to Bureau scientists has been the progress recently made in getting many x-ray users to employ rare earth instead of calcium tungstate screens.

Bureau scientists estimate that their work eventually could significantly lower exposure to the total radiation dose now received yearly by the American people from diagnostic x rays. Put another way, hazards could have been dramatically reduced in the vast majority of the more than 240 million x-ray exposure procedures performed during 1978.

Robert T. DeVore is a freelance writer and a former employee of the Bureau of Radiological Health.
No Ascorbic Acid Hazard Seen

In a tentative evaluation of the health aspects of using ascorbic acid (vitamin C) and erythorbic acid (iso-ascorbic acid) as food ingredients, a committee of the Federation of American Societies for Experimental Biology (FASEB) said it found no evidence that ascorbic acid poses a hazard to the public health when used at current levels or at levels that might reasonably be expected in the future.

Although there is no evidence that erythorbic acid and its salts present a health hazard at the levels of today, additional data are needed to determine whether a significant increase in consumption would constitute a dietary hazard, the committee said. Ascorbic acid and erythorbic acid are widely used in food and beverages as preservatives and antioxidants and are on a list of food ingredients generally recognized as safe (GRAS).

The tentative evaluation of the two ingredients was made by the Select Committee on GRAS Substances of FASEB, a non-Government organization evaluating 356 GRAS substances for safety under an FDA contract. To date, FASEB has completed evaluations of about 300 GRAS substances.

Responding to Consumers

A report recently released by the White House gives FDA high marks among Federal agencies for its handling of consumer complaints. The report documents the results of a study commissioned by the Office of Consumer Affairs of the complaint-handling mechanisms of 22 Government agencies, of which 15 are regulatory and 7 providers of benefits and services.

Included were the Federal Trade Commission, the Department of Labor, the Department of Agriculture, the Civil Aeronautics Board, the Department of Energy, and five agencies of the Department of Health, Education, and Welfare. The study found that—compared to a similar study done in 1975—most agencies were doing an “adequate” job of handling consumer complaints. A few were faulted for not yet having the most basic structure for dealing with individual complaints, and a few others—among them FDA—were praised for their “dramatic improvements” in the past 3 years.

In its analysis, the study rated FDA excellent for its logging of mail and telephone complaints by consumer name and address, date received, type of complaint, and disposition. It cited “very efficient” a system for receiving and responding to consumer complaints about foods, drugs, and other products that the Agency regulates, and the way field and headquarters staff handle threats to public health and safety, mobilizing whatever forces are necessary to identify and remove dangerous products.

The study drew particular attention to a “Consumer Memo”—an FDA public information sheet available at all FDA offices—that tells how to make a product complaint to the Agency. It also suggests that a consumer education program describing FDA’s regulatory role might be useful, since other agencies often get product complaints that should be directed to FDA.

Industry Alerted to Contamination Problem

FDA has sent letters to industry officials alerting them to a potentially widespread contamination problem resulting from the use of micronized (pulverized) materials in foods, drugs, and cosmetics.

The problem: with micronized materials came to light during regular FDA inspections of regulated industries. Micronizing is a process by which dry materials are pulverized into fine particles, some of micron size. Manufacturers of foods, drugs, and cosmetics sometimes contract out micronizing to custom pulverizers. Blending of different micronized materials also may be done at these facilities.

FDA inspections revealed instances where the micronizing equipment was improperly or inadequately cleaned following processing of industrial chemicals and pesticides or where processors failed to control the minute dust created during the micronizing process. If the same equipment or plant later is used to micronize materials for foods, drugs, or cosmetics these materials can become contaminated by residues of the industrial chemicals previously processed. Such contamination can bring regulatory action, FDA warned in its letter to industry officials.

Firms which use materials micronized by contract processors were advised to review all phases of their operation to assure compliance with Federal food, drug, and cosmetic laws and regulations. They also were asked to assure that contract processors use good manufacturing practices and register with FDA.

Veterinary Hotline

The FDA Bureau of Veterinary Medicine’s “adverse reaction hotline” has proved a quick, convenient way for veterinarians to report problems they have encountered in using drugs in livestock, poultry, or pets. The hotline (301) 443-1209 was installed last year. It is an extension of the Bureau’s Adverse Reaction Reporting Program intended to detect patterns of unexpected side effects or
lack of effectiveness of veterinary products under actual use conditions.

The Bureau evaluates all new animal drugs for safety and efficacy before they can be legally marketed. But not all problems can be foreseen before the product is put to the greater test of day-in, day-out use. That’s where the adverse reaction reporting program, when used by veterinarians, can reveal undetected problems.

If a number of veterinarians consistently report the same kinds of problems with a drug and they cannot be resolved, the drug may be removed from the market. But usually the manufacturer, after being notified by FDA, changes the labeling to alert vets to the potential problem so they can avoid any risky situations. In other cases, sufficient study of reports may reveal that a product formulation needs to be changed or new directions written for its use.

The Bureau receives several hundred written adverse reaction reports yearly, many volunteered by veterinarians, but most coming from drug firms obliged by law to report any such problems of which they are aware. The hotline is intended to supplement, rather than replace, these written reports. The Bureau began receiving calls last April, after letters announcing the trial project were sent to some 3,000 veterinarians in five Eastern States and the District of Columbia. But soon calls began coming in from as far away as North Dakota and California because of notices about the hotline in several veterinary journals and through word-of-mouth “advertising” among veterinarians.

The Bureau urges veterinarians to report all suspect adverse reactions, either in writing to BVM, (HFV-210), 5600 Fishers Lane, Rockville, Maryland 20857 (special reporting postcards are available on request) or through the hotline.

Glassware Leaching Standard Set

Three Government agencies have established a voluntary standard to control toxic lead and cadmium metals leaching from the lip and rim of decorated drinking glasses.

The standard was set by the Food and Drug Administration, Environmental Protection Agency, and Consumer Product Safety Commission. The three agencies have been studying the problem since July 1977, when questions first were raised about the safety of decorations applied to the outside surface of these glasses.

The standard says that lead leached from cartoons, drawings, or other decorations on the lip and rim of the glasses cannot exceed 50 parts per million (ppm) and that cadmium leached from these decorations cannot exceed 3.5 ppm.

The three agencies set a voluntary, rather than a mandatory, standard since there is no evidence at present that a mandatory standard is needed. If the industry does not comply with the new standard on a voluntary basis, the agencies will consider the need for further action.

The voluntary standard results from a report on the safety of decorated glassware issued by a special task force from the three agencies. The task force was formed in July 1977, after the Massachusetts Department of Health raised the possibility of lead leaching from promotional glasses distributed by fast-food chains.

The effects of lead ingested by people can range from impairment of the nervous system to brain damage. Cadmium in people’s bodies may cause kidney damage and emphysema and is a suspected cause of cancer.

Laboratory tests conducted by the three agencies on nine types of decorated glasses found that certain glasses released unacceptably high levels of lead or cadmium.

But the task force also determined that the health risk from these glasses is minimal and is limited to children under 6 years old and certain handicapped persons. Individuals in these groups may do an unusual amount of chewing or licking of glasses.

The agencies concluded that a standard was necessary only for the lip and rim area of decorated glasses (the top 20 millimeters) because people at risk contact this part most frequently. Good quality control procedures during glass decoration will also reduce the risk of leaching from all parts of the glasses.

Decorated glassware falls under the jurisdiction of FDA, CPSC, and EPA because of the different laws under which the agencies regulate potential hazards. FDA regulates glasses because they are food containers; CPSC regulates hazards involved with consumer products; and EPA has authority over toxic environmental contaminants, such as lead and cadmium.

Notice of the new standard was published in the Federal Register, December 15, 1978. It will take effect in March.
"Regional Reports" consists of important information on inspections, product seizures, court proceedings, and other regulatory and administrative actions initiated by FDA’s regional and district field offices across the country to provide protection to consumers under Federal laws. “State Actions,” the section immediately following “Regional Reports,” consists of similar information about the consumer protection activities of State and local governments.

REGION I

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

More than $75,000 worth of products were detained by FDA’s Boston District after routine import inspections at the Port of Boston revealed that the products were in violation of FDA regulations. Some major detentions: frozen shrimp from India for Salmonella contamination, canned crabmeat from Taiwan for decomposition, frozen lobster tails from Japan for Salmonella contamination and labeling violations, and frozen swordfish fillets from Japan for high mercury levels.

A U.S. marshal seized $3,000 worth of whole wheat flour at the Boston and Maine Rail Terminal, Salem, Massachusetts, because it was contaminated by rodents. The seizure occurred after the Boston District inspected a Massachusetts bakery suppliers’ distributor and was told that the firm had just rejected a railcar of flour, which was still on the siding adjacent to the firm’s premises. FDA inspectors took samples of the flour and enlisted the aid of State officials to embargo the goods pending confirmation of contamination.

REGION II

New Jersey, New York, Puerto Rico, Virgin Islands

West Side Cold Storage Co., Inc., New York City, and the firm’s president, Irving J. Zimbaum, pleaded guilty in the U.S. District Court for the Southern District of New York to charges of operating a public warehouse under insanitary conditions. The company was fined $5,000, and Zimbaum received a $1,000 fine and a 1-year suspended prison sentence. The court action followed a series of inspections by FDA’s New York District which extended over a 2-year period. The inspections, which revealed that foods stored in the warehouse were rodent contaminated, resulted in several seizures by U.S. marshals and the destruction of various lots of food, including spices, cheeses, and dried eels. When the firm failed to correct the conditions over a prolonged period, FDA initiated criminal court proceedings.

Service Corp., Jersey City, New Jersey, destroyed $300 worth of wheat bran and wheat bran powder after investigators from FDA’s Newark District inspected the firm and found live insects in bags of bran. Laboratory analysis confirmed that both the bran and bran powder were contaminated. Following the seizure, the products were destroyed under supervision of District officials.

Organon, Inc., West Orange, New Jersey, notified the Newark District that it had recalled approximately 1,000 pregnancy test kits because each kit contained 50 or 100 “Pregnosticon Slide Tests” that may have become defective. The recall occurred after testing by the firm revealed that the human chorionic gonadotropin (HCG) antiserum used in the slide tests had deteriorated prematurely and might falsely indicate pregnancy. HCG antiserum, which normally causes agglutination (thickening) of urine specimens, is neutralized by a hormone found in the urine of pregnant women. Pregnancy is indicated, therefore, when the antiserum does not cause agglutination of a urine specimen. The antiserum in the slide tests, which had a 12-month expiration date, had deteriorated in only 2 months and was not causing agglutination in any urine samples, thus indicating pregnancy in all tests. The firm contacted all its customers, including doctors, nurses, and health clinics across the country, and instructed them to return the test kits for examination. The kits were valued at approximately $34,000.

REGION III

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

FDA’s Philadelphia District began legal action against American Consumer, Inc., Philadelphia, after receiving numerous consumer complaints that the firm, a catalog mail-order distributor, was making false and misleading claims for products. District inspectors found evidence at the firm’s headquarters regarding several products, including “Slimcycle” (an exercise device), “Calmeze” tablets (a product said to be a nutritional aid for relaxing), a device for use by diabetics to measure the specific gravity and sugar content of urine, and “Infra-lux Painkiller” (a heat lamp said to relieve pain). The inspections led to seizure of $670,000 worth of medical devices and food supplements by a U.S. marshal and initiation of injunction proceedings in the U.S. District Court for the Eastern District of Pennsylvania. Under the terms of the proposed injunction, the firm was instructed to notify buyers that the gravity measuring device designed for diabetics could prove harmful when used as directed. In addition, the court
ordered the firm to submit labeling and descriptions of all its foods, devices, and cosmetic products to FDA for review within 60 days.

A U.S. marshal seized 5 kilograms of amygdalin imported by W. Leo Tew, president of Metabolic Products, Inc., Wilmington, Delaware. Amygdalin is a chemical substance found in apricot pits and other fruit kernels and is used to make Laetrile, an unapproved drug claimed to be effective to treat cancer. U.S. Customs officials in Wilmington held the product in custody when Tew attempted to bring it into the country, and notified the Philadelphia District, which initiated seizure action. Previously, the District had initiated legal action against Metabolic Products because the firm was illegally distributing amygdalin. The District investigated after learning from a radio advertisement that the company was promoting noninjectable amygdalin. The U.S. District Court for the District of Delaware in a preliminary injunction ordered the firm to stop distributing or advertising the product unless it was approved by FDA. The company also was instructed to deliver any of the chemical in its possession to the U.S. marshal.

The Federal Government seized 22 cases of “Old Fashioned Mustard Pickle” relish, valued at approximately $125, at William Kleinberger & Sons, a pickle manufacturer in Scranton, Pennsylvania. The seizure resulted from a routine inspection by FDA's Philadelphia District that revealed the product was short in volume.

A U.S. marshal seized $90,000 worth of various foods in soft containers, including flour, sugar, and rice, at L. M. Sandler & Sons, a wholesale food warehouse in Norfolk, Virginia. The seizure resulted from a routine inspection by FDA's Baltimore District that revealed the presence of live rodents, insects, and food contaminated by rodent excreta in the warehouse.

REGION IV

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

Marriott In-Flight Kitchens, East Point, Georgia, was allowed to continue operations on a provisional status after closing down for 24 hours to correct insanitary conditions. The firm, which supplies approximately 2,000 meals a day to Eastern Airlines at Atlanta Hartsfield Airport, was classified “not approved” after inspections by FDA's Atlanta District and FDA Regional Milk and Food Specialists revealed widespread insanitary conditions, such as improper food storage, insects in the kitchen and food production areas, dirty equipment, and inadequate employee sanitation procedures. The facility was closed and the management enlisted corporate sanitarians from Miami and Washington to correct the conditions. When reinspection 2 days later showed improvements in sanitary conditions, the District reclassified the facility as “provisional.” Under provisional status the facility may resume operations provided it corrects remaining deficiencies and passes reinspection in 30 days.

Poss' Famous Foods, Inc., a food distributor in Athens, Georgia, recalled seven lots of Poss' Hot Dog Chili Sauce, after inspectors from the Atlanta District found good manufacturing practices almost nonexistent at the product's manufacturer, Mask and Gay Food Products, Inc., Brooks, Georgia. The inspection revealed numerous violations of Good Manufacturing Practice Regulations (GMP's) for low-acid thermal processing, including failure of the firm to register with FDA, to submit a description of its manufacturing process, and to keep adequate records. Low-acid GMP Regulations were developed and adopted by FDA in an effort to protect consumers from botulism, a deadly foodborne disease caused by the microorganism Clostridium botulinum, which can contaminate low-acid foods that are improperly processed.

Latin Trade Corp., an importer in Miami, destroyed over 30,000 pounds of unfrozen grouper and cod fillets, valued at $46,000, because of decomposition. The destruction occurred after a consumer safety inspector from FDA's Orlando District made a routine sample collection at a Miami cold storage warehouse and noticed a truck on the firm's premises that contained apparently decomposed fish. The inspector checked the firm's records and identified the owner as Latin Trade Corp. Further investigation revealed that some of the firm's products stored in the warehouse appeared to be decomposed. When laboratory analysis confirmed the decomposition, FDA notified the owner company, which agreed to destroy the contaminated products.

REGION V

Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin

A U.S. marshal seized approximately $150,000 worth of rodent-contaminated food products at Springfield Baker's Supply Co., a warehouse in Springfield, Illinois. The seizure followed a routine inspection by FDA's Chicago District that revealed the warehouse was infested with and the products gnawed by rodents. The District initiated seizure action against all products stored in the warehouse, including beans, icing mix, popcorn,
flour, and desiccated coconut.

REGION VI
Arkansas, Louisiana, New Mexico, Oklahoma, Texas
A wholesale warehouse in Baton Rouge, Louisiana, destroyed over 12,000 pounds of flour, valued at about $1,800, because it was contaminated by rodents. The U.S. Department of Agriculture reported to FDA’s New Orleans District that nine lots of flour, stored in bags at the warehouse, were defiled. During the subsequent inspection, District investigators observed rodent excreta on bags of flour and bags gnawed by rodents. However, the District found no other evidence of insanitary conditions at the warehouse and concluded that the flour was probably defiled while being transported by railcar from the manufacturer to the warehouse. The flour was taken to the city dump and buried.

REGION VII
Iowa, Kansas, Missouri, Nebraska
Investigators from FDA’s Kansas City District witnessed the destruction of approximately $4,000 worth of various bagged nuts by United Fruit and Produce Co., a wholesale distributor of fruit, produce, and nut products in St. Louis. The destruction followed an inspection by the District that revealed extensive rodent infestation of the firm’s warehouse. At FDA’s request, the nuts were embargoed by the Missouri Health Department, pending laboratory analysis of samples collected during the inspection. When analysis disclosed the bags contained rodent excreta and had been gnawed by rodents, the firm had the goods destroyed at the St. Louis city incinerator.

The Kansas City District supervised the destruction of about 20,000 pounds of contaminated flour and rice by Sciales Grocery Co., a wholesale food warehouse in St. Louis. The destruction followed a routine inspection by the District that revealed the products, stored in the warehouse, were contaminated by insects. The contaminated goods were transported to a local landfill and buried by bulldozers.

REGION VIII
Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming
State agriculture and health officials in Colorado and Utah directed dairy farmers in both States to stop feeding cottonseed meal or feed to their dairy cattle until it has been analyzed for aflatoxin content because of the probability the cottonseed contains dangerous levels of aflatoxin. Both States have facilities for such tests. Aflatoxin is a naturally occurring cancer-causing contaminant produced by mold that, under certain conditions, grows on products such as cottonseed, peanuts, corn, wheat, rice, and tree nuts. Under Federal regulations, these products may contain no more than 20 parts per billion (ppb) aflatoxin, and milk may contain no more than 0.5 ppb aflatoxin. State and Federal officials began investigating interstate cottonseed shipments after FDA’s Denver District and Salt Lake City Resident Inspection Post learned from the Los Angeles and Dallas Districts that possibly contaminated cottonseed had been shipped into Utah and Colorado from Arizona. State and Federal investigators joined to test suspect cottonseed and milk in both States. When laboratory testing revealed unacceptable levels of aflatoxin, State officials in both States issued the directive to dairy farmers and embargoed approximately 3,000 tons of cottonseed meal and feed at over 150 farms and feed mills. Additional seizures of contaminated products were made by the Denver District. The bulk of the embargoed and seized products were destroyed, but some may be used for composting mushroom rooms provided the mushrooms are then tested for aflatoxin. Colorado State authorities also supervised the destruction of about 150,000 pounds of milk at three dairies.

A U.S. marshal seized approximately 10,500 pounds of assorted dried beans, valued at about $2,500, at D & D Bean Co., Greeley, Colorado, because of rodent contamination. The seizure occurred after a routine inspection by the Denver District revealed that the beans, as well as about 2,250 pounds of white field corn, were contaminated. The company buried the corn in a local landfill and intends to bring the beans into compliance by cleaning and re-bagging and converting the rest to animal feed.

REGION IX
Arizona, California, Guam, Hawaii, Nevada
The Purdue Frederick Co., Norwalk, Connecticut, recalled over 80,000 units of Betadine Aerosol Spray, a topical antiseptic, which had become adulterated. A pharmacist from Anaheim Memorial Hospital, Anaheim, California, brought the problem to the attention of the U.S. Pharmacopeia (USP) in Washington after he noticed that the product contained dark particles and had turned an unusual color. The USP notified both FDA’s Bureau of Drugs in Washington and Purdue Frederick Co. At the request of the Bureau of Drugs, FDA’s Orange County Resident Post obtained a sample of the product from the pharmacist. FDA analysis revealed that a recently introduced valve assembly in the spray container was reacting with the iodine in the product, causing reduced potency of the product. After recalling the defective products, the firm corrected the design for future products.
State Actions

Chemical Spilled in River

Investigators from the Arkansas Game and Fish Commission worked to stop the spread of the toxic chemical crotonaldehyde after a tank car carrying the chemical was derailed into the Saline River near Benton, Arkansas. The tank car burned, but an undetermined amount of crotonaldehyde, a flammable liquid used in chemical warfare, escaped into the river. Since the river is not used for commercial fishing or municipal water supplies there was no imminent hazard to public health, but the spilled chemical killed fish downstream for approximately 55 miles.

State health officials requested analytical methodology from FDA's New Orleans District and then worked with representatives of the owner company, Eastman Chemical Co., Kingsport, Tennessee, to accelerate dispersion of the chemical. On the seventh day after the accident, samples of river water showed chemical concentrations of less than one part per million. The New Orleans District then assigned the Little Rock Resident Post to monitor cleanup operations.

Restaurant Fined

ARAR Restaurant Corp., doing business as the Steak Pub, Monticello, New York, was fined $14,000 by the New York State Department of Health for violating State health regulations. A series of State inspections at the Steak Pub revealed continued violations, such as insanitary kitchen conditions, dirty utensils and dishwashing equipment, improper food storage, and inadequate plumbing facilities. When the restaurant failed to correct the conditions, despite repeated warnings from State inspectors, the fine was imposed.

Food Destroyed

Food products valued at $15,000, including crackers, cornstarch, spaghetti, and beans, were buried in a local landfill after a joint inspection, conducted by Oklahoma City/County Health officials and investigators from FDA's Oklahoma City Resident Post, revealed that the food was contaminated by insects and rodents. Investigators learned during the inspection at an Oklahoma City warehouse that the previous owner of the goods had gone out of business and the food had been sold to P & B Sales, Inc., Oklahoma City. The Health Department ordered the destruction of all the stored foods, which the new owners had been planning to sell to area nursing homes.

Spinach Embargoed

The California Department of Agriculture supervised the destruction of 21,000 pounds of pesticide-contaminated spinach, imported from Mexico by Sun World Marketing, Coachella, California. The department routinely examines samples of imported vegetables for unapproved pesticides and for approved pesticides that exceed accepted tolerance levels. When laboratory analysis revealed residues of Monitor—an illegal pesticide—on the spinach, the State embargoed all of the product at the importer. In addition, the importer sent letters to customers nationwide requesting return of all previously distributed spinach so that it could be destroyed.

‘Imitation Hamburger’ Exposed

Fitzi’s, Inc., doing business in San Diego as Fitzi’s Grub ‘N Suds, agreed in a civil suit brought by the San Diego Consumer Protection Unit to stop false advertising practices.

The California Department of Health had inspected the restaurant after learning from the San Diego County Sealer, Weights and Measures Department, that the restaurant had purchased a quantity of hamburger meat containing soy flour. California law defines hamburger as chopped fresh or frozen beef which contains less than 21 percent fat and no added water, binders, or extenders. If any amount of binder or extender is added to the beef, it must be classified as “imitation hamburger.”

State inspectors found the restaurant’s hamburger was 5 to 7 percent textured soy flour, which was not indicated in the restaurant’s advertising or on its menus. The State reported the violation to the San Diego Consumer Protection Unit, which filed suit against the firm. The firm agreed in an out-of-court settlement to stop its false advertising practices and to pay $500 in investigative costs to the Department of Health and $1,500 to the city of San Diego.
Seizures and Postal Service Cases

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

A total of 25 actions to remove from the consumer market products charged to be violative was reported in January. These actions included 15 of foods: 5 involved charges concerning poisonous and deleterious substances, 9 involved charges concerning contamination, and 1 involved charges concerning economic and labeling violations. Others included 2 of food additives, 6 of drugs (including 3 of veterinary), and 2 of medical devices.

<table>
<thead>
<tr>
<th>PRODUCT, DISTRICT &amp; DATE Filed</th>
<th>FIRM &amp; PLACE OF BUSINESS</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cottonseed, bulk/U.S. District Court for the Western District of Texas 10/24/78</td>
<td>Monty Corbin/Gila Bend (Theba), Ariz.</td>
<td>&quot;</td>
</tr>
<tr>
<td>Cottonseed, bulk/U.S. District Court for the Western District of Texas 10/24/78</td>
<td>Commingled shipments from Ariz. and elsewhere.</td>
<td>&quot;</td>
</tr>
<tr>
<td>Beans, blackeye/U.S. District Court for the Eastern District of California 10/18/78</td>
<td>Tarke Warehouse, Inc./Meridian, Calif.</td>
<td>Held under insanitary conditions; contains insects.</td>
</tr>
<tr>
<td>Cocoa/U.S. District Court for the Eastern District of Missouri 10/31/78</td>
<td>Chapman Ice Cream Co./St. Louis, Mo.</td>
<td>Held under insanitary conditions.</td>
</tr>
<tr>
<td>Flour/U.S. District Court for the Virgin Islands 11/15/78</td>
<td>Scotty's Bakery/St. Croix, V.I.</td>
<td>Held under insanitary conditions; insect contaminated.</td>
</tr>
<tr>
<td>Lima beans, dried, large/U.S. District Court for the Northern District of Texas 11/8/78</td>
<td>Shipped from Oxnard, Calif.</td>
<td>Insect contaminated.</td>
</tr>
<tr>
<td>Mustard bran/U.S. District Court for the Middle District of Alabama 11/6/78</td>
<td>Piknik Products Co./Montgomery, Ala.</td>
<td>Contains insects and was held in insect-infested bags.</td>
</tr>
<tr>
<td>Popcorn, unpopped/U.S. District Court for the District of Massachusetts 10/30/78</td>
<td>Shipped from Bremen, Ind.</td>
<td>Held under insanitary conditions; contains insect filth.</td>
</tr>
<tr>
<td>Scallops, frozen/U.S. District Court for the District of Massachusetts 11/2/78</td>
<td>Shipped from Cranston, R.I.</td>
<td>Contains decomposed scallops.</td>
</tr>
<tr>
<td>Sugar, and wholesale foodstocks/U.S. District Court for the Eastern District of Virginia 10/26/78</td>
<td>L. M. Sandler &amp; Sons, Inc./Virginia Beach, Va.</td>
<td>Held under insanitary conditions; one lot of sugar was rodent gnawed.</td>
</tr>
<tr>
<td>&quot;Sole&quot; fillets/U.S. District Court for the Eastern District of Missouri 10/31/78</td>
<td>New York Seafood Exchange/New York, N.Y.</td>
<td>Greenland turbot was offered for sale under the name &quot;sole&quot;; Greenland turbot was substituted for the &quot;sole&quot;; and labeling is false and misleading in representing that the only fish in the article was sole.</td>
</tr>
<tr>
<td>Calcium pangamate tablets/U.S. District Court for the Middle District of Florida 8/28/78</td>
<td>B. T. Products/Tampa, Fla.</td>
<td>Contains the nonconforming food additive calcium pangamate.</td>
</tr>
<tr>
<td>Calcium pangamate tablets/U.S. District Court for the Middle District of Florida 9/7/78</td>
<td>General Nutrition Center Corp./Pittsburgh, Pa.</td>
<td>&quot;</td>
</tr>
<tr>
<td>PRODUCT, DISTRICT &amp; DATE FILED</td>
<td>FIRM &amp; PLACE OF BUSINESS</td>
<td>CHARGES</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-------------------------</td>
<td>---------</td>
</tr>
<tr>
<td><strong>DRUGS/Human Use</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amygdalin (Laetrile) powder/U.S.</td>
<td>Darpin Co./Taipei, China</td>
<td>New drug without an effective approved New Drug Application; the label fails to bear an accurate quantity of contents statement, and the established name of the drug; and the labeling lacks adequate directions for use.</td>
</tr>
<tr>
<td>District Court for the Southern</td>
<td></td>
<td></td>
</tr>
<tr>
<td>of Florida 8/31/78</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caffeine capsules, caffeine</td>
<td>B. T. Pharmaceutical, Inc./Tampa, Fla.</td>
<td>Phenylpropanolamine HCl (PPA) had been substituted for pseudoephedrine HCl in some tablets; all the articles were subpotent as to one or more active ingredients; and the labels of the article were false and misleading as to the ingredient amounts; circumstances used for the manufacture, processing, packing, and holding of the product do not conform with current good manufacturing practice.</td>
</tr>
<tr>
<td>combination tablets, and similar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>drugs/U.S. District Court for</td>
<td></td>
<td></td>
</tr>
<tr>
<td>the Middle District of Florida</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/26/78</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dipyridamole tablets, other</td>
<td>Medi-Save Pharmacies, Inc./Baton Rouge, La.</td>
<td>Circumstances used for the packing and holding of drugs not in conformity with current good manufacturing practice.</td>
</tr>
<tr>
<td>repacked drug tablets and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>capsules, and drugs being</td>
<td></td>
<td></td>
</tr>
<tr>
<td>repacked/U.S. District Court for</td>
<td></td>
<td></td>
</tr>
<tr>
<td>the Middle District of Louisiana</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11/9/78</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DRUGS/Veterinary</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ideal Calf Booster No. S,</td>
<td>Ideal Laboratory (subsidiary of Western Feed Supplements)/Modesto, Calif.</td>
<td>New animal drug and no New Animal Drug Application is in effect with respect to its use and intended use; circumstances used in the manufacture and processing of the drug not in conformity with current good manufacturing practice.</td>
</tr>
<tr>
<td>medicated/U.S. District Court</td>
<td></td>
<td></td>
</tr>
<tr>
<td>for the Eastern District of</td>
<td></td>
<td></td>
</tr>
<tr>
<td>California 10/31/78</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sulfaguanidine boluses/U.S.</td>
<td>Quality Plus Products Co., Inc./Fort Dodge, Iowa</td>
<td>New animal drug and no approved New Animal Drug Application is in effect with respect to its use or intended use; label lacks the name and place of business of the manufacturer, packer, or distributor; lacks an accurate statement of quantity of contents; lacks the established name of the drug; and lacks the established name and quantity of each active ingredient; the labeling lacks adequate directions for use; and the drug was also manufactured, prepared, and processed in an unregistered establishment.</td>
</tr>
<tr>
<td>District Court for the District</td>
<td></td>
<td></td>
</tr>
<tr>
<td>of Colorado 10/19/78</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccine for sheep/U.S. District</td>
<td>Willamette Animal Medical Laboratory, Inc./Portland, Oreg.</td>
<td></td>
</tr>
<tr>
<td>Court for the District of Oregon</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11/1/78</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MEDICAL DEVICES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diapulse device/U.S. District</td>
<td>Diapulse Corp. of America/New Hyde Park, N.Y.</td>
<td>Labeling fails to bear adequate directions for use for its intended purposes, and neither adequate directions for lay use nor adequate information for use by licensed practitioners could be supplied.</td>
</tr>
<tr>
<td>Court for the Northern District</td>
<td></td>
<td></td>
</tr>
<tr>
<td>of Florida 10/12/78</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P/EmF device/U.S. District Court</td>
<td>DCA Leasing Corp./New Hyde Park, N.Y.</td>
<td></td>
</tr>
<tr>
<td>for the Northern District of</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Florida 10/12/78</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**U.S. POSTAL SERVICE** actions taken in medical cases as authorized in the Mail Fraud Statute (18 U.S.C. 1341) and/or the False Representation Statute (39 U.S.C. 3005) as reported by the Chief Postal Inspector.

Complaints Filed by Law Department Under 39 U.S.C. 3005 (False Representation)

November 22, 1978: Penn-Bio Pharmaceuticals, Caroline Road, Philadelphia, Pennsylvania. Advertising and sale through the mail of the product “Health Watcher Nutrient Tablets,” representing the ability to cause weight loss.

November 22, 1978: Startime Industries, Box 702, Cooper Station, New York, New York. Advertising and sale through the mail of the product “Super Pump-It Hyperemiator,” representing the ability to increase the size of the penis.

November 30, 1978: Nurse Ann, P.O. Box 365, Wayne, Pennsylvania. Advertising and sale through the mail of the product “Arthritis Miracle,” representing the ability to cure arthritis.

December 11, 1978: Terminal Cancer Treatment, Box 270, RD 2, Coopersburg, Pennsylvania. Advertising and sale through the mail of the product “Terminal Cancer Treatment,” representing the ability to cure cancer.

December 12, 1978: Self-Method, P.O. Box 1501, Pompano Beach, Florida. Advertising and sale through the mail of the product “Hair Growth Method,” representing the ability to promote hair growth.

False Representation Orders Issued by Judicial Officer Under 39 U.S.C. 3005

December 4, 1978: Against Mar-Dee Corporation, 4015 S.W. 1st Street, Plantation, Florida. Advertising and sale through the mail of the product “Liquid Reducing,” representing the ability to cause weight loss.

December 4, 1978: Against Ken-Dee Corporation, 7301 N. University Drive, Suite 202, Tamarac, Florida. Advertising and sale through the mail of the product “Weight Reducer,” representing the ability to cause weight loss.
NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Corn, shelled, at Knoxville, E. Dist. Tenn.
Charged 6-28-78; when shipped by Central Soya Co., Cincinnati, Ohio, in a railcar which some time previously had transported cryofoil (sodium aluminum fluoride), the article contained the added poisonous and deleterious substance sodium aluminum fluoride; and the article was otherwise injurious to health: 402(a)(1), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 61795; S. Nos. 78-130-500; N.J. No. 2)

Fishmeal, at Port Arthur, E. Dist. Tex.
Charged 6-5-78: after being imported from Panama and Peru and subsequently commingled, the article contained a nonconforming pesticide chemical (i.e., a mercurial compound), and no tolerance or exemption for such pesticide chemical on wheat had been prescribed; 402(a)(2)(B). The article was claimed by Roberts Elevator, Inc., Iona, Idaho, who denied the charge and asserted that the FDA tests and samples were inaccurate and not representative of the 208,160 pounds of bulk wheat. The claimant moved for a postseizure sample of the wheat. The claimant served written interrogatories on the Government, and the Government moved for a postseizure sample of the wheat. The claimant served written interrogatories on the Government, and the Government moved for summary judgment. George Noroian moved for the appointment of a master to collect additional samples of the wheat. The court granted an extension of time to answer or to appear. Ultimately, however, a default decree ordered destruction. (F.D.C. No. 61767; S. Nos. 78-115-189; N.J. No. 3)

Wheat, at Ammon, Dist. Idaho.
Charged 10-24-75 and amended 10-28-75 and 12-9-75: when returned from Ogden and Salt Lake City, Utah, to Ammon, Idaho, after shipment by J. M. J. Elevator Co., Iona, Idaho, the article contained a nonconforming pesticide chemical (i.e., a mercurial compound), and no tolerance or exemption for such pesticide chemical on wheat had been prescribed; 402(a)(2)(B). The article was claimed by Roberts Elevator, Inc., Iona, Idaho, who denied the charge and asserted that the FDA tests and samples were inaccurate and not representative of the 208,160 pounds of bulk wheat. The claimant moved for a postseizure sample of the wheat. The claimant served written interrogatories on the Government, and the Government moved for a postseizure sample of the wheat. The claimant served written interrogatories on the Government, and the Government moved for summary judgment. George Noroian moved for the appointment of a master to collect additional samples of the wheat. The court granted an extension of time to answer or to appear. Ultimately, however, a default decree ordered destruction. (F.D.C. No. 61767; S. Nos. 78-115-189; N.J. No. 3)

PESTICIDE CHEMICALS

Caramel candy, at San Diego, S. Dist. Calif.
Charged 3-2-78; when shipped by Dae-Julie, Inc., Chicago, Ill., the article, labeled in part “Carousel’s North Shore Caramels Nougats . . . Division of S. L. C. Enterprises Inc. Cicero, Ill.,” contained rodent filth and had been prepared and held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61570; S. Nos. 78-126-7612; N.J. No. 7)

Chamomile, fine-cut for tea, at Boulder, Colo.
Charged 8-23-77; while held for sale, the article had been held under insanitary conditions, and one lot of the article contained insect filth; 402(a)(3), 402(a)(4). Celestial Seasonings, Inc., Boulder, Colo., claimed the article, intervened in the action, and applied for partial release of the article with the insect filth; 402(a)(3), 402(a)(4). The court authorized the release of the article from the plant and in the storeroom but reserved further proceedings. The Government applied for a reconditioning proposal. The court authorized the release of more than 500 pounds for testing. After testing, the claimant entered into a consent decree of condemnation that authorized export to the original foreign supplier. (F.D.C. No. 61397; S. Nos. 77-79-5545; N.J. No. 8)

Cheese, Sardo, at Brooklyn, E. Dist. N.Y.
Charged 1-27-78; when held by 4 C Foods Corp., Brooklyn, N.Y., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61568; S. Nos. 78-140-218; N.J. No. 9)

Chocolate candy bars, chocolate chip morsels, and other foodstuffs, at Seattle, W. Dist. Wash.
Charged 1-23-78; while held by Reliable Transfer & Storage Co., Inc., Seattle, Wash., some of the articles contained rodent filth, and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61578; S. Nos. 78-152-10027; N.J. No. 10)

Coffee beans, banana flakes, and turmeric fingers, at Brooklyn, E. Dist. N.Y.
Charged 1-5-76; while held by Van Brunt Stores, Inc., Brooklyn, N.Y., the turmeric contained rodent filth, and both articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Pursuant to stipulation, Manufacturers Hanover Trust Co., New York, N.Y., was granted an extension of time to answer or to appear. Ultimately, however, a default decree ordered destruction. (F.D.C. No. 60614; S. Nos. 76-40-8689; N.J. No. 11)

Coffee beans, banana flakes, and flour, at New Orleans, E. Dist. La.
Charged 5-10-78; while held at Thalia Street Wharf, New Orleans, La., some lots of the articles contained rodent filth, and the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). The various owners of the articles claimed the articles and entered into consent decrees of condemnation that authorized release of the articles for salvaging. (F.D.C. No. 61762; S. Nos. 78-136-926; N.J. No. 12)

Peach halves, white freestone, at Sharon, W. Dist. Calif.
Charged 6-4-76; when shipped by Tri Valley Growers, Modesto, Calif., the article, labeled in part “Fruitful Valley Brand Fancy White Freestone Halves Nectar Pecans In Extra Heavy Syrup . . . Packed By Fruitful Valley Sun Dinuba, Calif.,” contained insect-infested peach halves and was held under insanitary conditions; 402(a)(3). George Noroian claimed the article, as owner, and denied the charges. Fruitful Valley Sun (through its president, Miss Archie Noroian) claimed the article, as packer and guarantor of the peaches, and denied the charges. The Government served written interrogatories on the claimant. Thereafter, the Government moved for summary judgment. George Noroian moved for the appointment of a master to collect additional samples of peaches. After considering such motions, the court denied both motions, saying:

“...This action was initiated by a complaint for forfeiture. Specifically, the United States seeks to condemn and destroy a quantity of canned peaches pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 et seq. The case is presently before the Court on plaintiff’s Motion for Summary Judgment and claimant’s Motion to Appoint [a] Master to Collect Samples of Subject Peaches. “A review of the Act indicates that the United States may, properly, condemn any article of food that is ‘held for sale’ and shipped in interstate commerce. 21 U.S.C. § 334. The parties do not dispute that the subject peaches constitute an article of food and have moved in interstate commerce. The issues, as raised by claimant in his defense and motion, deal primarily with the propriety of the government’s...
sampling procedures and the extent to which the peaches are adulterated.

"On the basis of the record, the Court is unable to conclude that the sampling procedures utilized herein were improper. Moreover, we find that the United States furnished claimant with a portion of the official sample and, thereby, complied with the requisites of the Act. 21 U.S.C. § 372. In our opinion, further sampling is not mandated.

"The extent of adulteration required for condemnation is of crucial concern. Although the Act empowers the government to exclude from commerce articles of food containing any degree of filth, certain tolerance levels have been recognized and prosecution for minor violations is discretionary. 21 U.S.C. § § 346, 336. See United States v. 900 Cases, Peaches, 390 F. Supp. 1006 (E.D. N.Y. 1975). Thus, the issue may be characterized as whether the subject peaches contain more than a de minimis amount of filth. Apparently, there is substantial dispute on this point.

"The United States has come forward, by affidavit and deposition, with persuasive evidence that the peaches are adulterated. Claimant has offered declarations and deposition testimony to the contrary. The Court will not comment on the weight of the evidence. On motions for summary judgment, such supporting documents may be utilized only to determine the existence of issues of fact; not to decide them. United States v. Rundle, 453 F. 2d 147 (3d Cir. 1971). In our judgment, the interests of the parties would be better served by a more complete development of the facts."

Shortly prior to trial, George Noroian advised the Government that the dealer (who had had custody of the article) had destroyed the article. FDA investigation showed that the article had been removed from the dealer's warehouse and buried in a dump in the mistaken belief that the action had been terminated. Upon confirmation that the article had been destroyed, the Government moved that the action be dismissed, since, as a result of the destruction of the res, the court had no jurisdiction. (F.D.C. No. 60745; S. Nos. 76-45-163; N.J. No. 13)

Rice and flour, at Salt Lake City, Dist. Utah.
Charged 11-16-77; while held by Nicholas & Co., Inc., Salt Lake City, Utah, the articles had been held under insanitary conditions; 402(a)(4). The articles were claimed by the dealer. The Government served written interrogatories on the claimant. Subsequently, pursuant to stipulation, a consent decree was filed ordering the articles destroyed. (F.D.C. No. 61426; S. Nos. 77-116-842/3; N.J. No. 14)

Sugar, pastry flour, raisins, sweet dough mix, donut mix, and other foodstocks, at Perth Amboy, Dist. N.J.
Charged 11-28-77; while held by Metzendorf Bros., Inc., Perth Amboy, N.J., the above named articles contained rodent filth; and those articles and the other foodstocks had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61584; S. Nos. 78-135-861 et al.; N.J. No. 15)

FOOD ADDITIVES

Calcium pangamate tablets, at Tampa, M. Dist. Fla.
Charged 8-28-78: while held for sale, the article contained the non-conforming food additive calcium pangamate; 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 61871; S. No. 76-41-431; N.J. No. 16)

Calcium pangamate tablets, NATO, at Orlando, M. Dist. Fla.
Charged 9-7-78: when shipped by General Nutrition Center Corp., Pittsburgh, Pa., the article, labeled in part "NATO Calcium Panga- mate, N.J. Tablets/Disodium ATMP Products Carnegie, Pa." contained the nonconforming food additive calcium pangamate; 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 61878; S. Nos. 78-166-022; N.J. No. 17)

Lemon flavoring with eggwhite, Cramores Sweet Sour, at Carteret, S. Dist. N.J.
Charged 6-14-77; when shipped by Cramore Products, Inc. (A-W Brands, Inc.), Carteret, N.J., the article contained the food additive saccharin, which was nonconforming, since the article was not for a valid special dietary use, and its use and its intended use (as a mix for alcoholic beverages) were not in conformity with a regulation or exemption; 402(a)(2)(C). Consent decree authorized release to the shipper for salvaging or destruction. Subsequently, pursuant to stipulation by the parties, the Government destroyed the article. (F.D.C. No. 61257; S. Nos. 77-82-429; N.J. No. 18)

DRUGS/Human Use

Aromatic ammonia inhalant solution ampules, at St. Louis, E. Dist. Mo.
Charged 5-21-77; while held by Marion Health & Safety, Inc., Rockford, Ill., who filled into ampules the bulk inhalant solutions which had been manufactured by American Drug Industries, Chicago, Ill., the article had been prepared, packed, and held under insanitary conditions—501(a)(2)(A); and the circumstances used for the article's manufacture, processing, packing, and holding failed to conform with current good manufacturing practice—501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 61393; S. Nos. 77-16-2078; N.J. No. 19)

Aromatic ammonia inhalant solution ampules, at St. Louis, E. Dist. Mo.
Charged 10-21-77; when shipped by James Alexander Corp., Hackettstown, N.J., who had filled into ampules the bulk inhalant solutions which had been manufactured by Jersey Analytical Services, Inc., Andover, N.J., the circumstances used for the article's manufacture, processing, packing, and holding failed to conform with current good manufacturing practice—501(a)(2)(B); the strength of one lot (lot 1131) of the article differed from its represented strength since it contained less than its represented 35 percent ethyl alcohol, and the quality of another lot (lot 1133) of the article fell below its purported quality, since it lacked lavender oil, lemon oil, and nutmeg—501(c). Default decree ordered destruction. (F.D.C. No. 61430; S. Nos. 77-16-165 et al.; N.J. No. 20)

Caffeine capsules, and caffeine tablets, at Sacramento, E. Dist. Calif.
Charged 5-31-78; while held by Randel S. Crittendon, Sacramento, Calif. (who had repackaged caffeine drugs that resembled controlled drugs into unlabeled bottles), the repackaged articles lacked the name and place of business of the manufacturer, packer, or distributor, and lacked an ingredient statement—502(b)(1), 502(e)(1); and the re-packed and bulk drugs lacked adequate directions for use for their intended purposes; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 61778; S. Nos. 78-138-731/9; N.J. No. 21)

Clozapine tablets, at New York, S. Dist. N.Y.
Charged 6-22-78; while held for sale, the article was a new drug without an effective approved New Drug Application, and the investigator's Notice of Claimed Investigational Exemption had been terminated and was no longer on file—505(a); the article lacked adequate directions for use and was not exempted since the exemption had been terminated and there was no longer on file—502(f)(1). Default decree ordered destruction. (F.D.C. No. 61799; S. Nos. 78-140-623/5; N.J. No. 22)

Cyanocobalamin injection, estradiol valerate injection, promethazine hydrochloride injection, and other injectables, in-process injectables, and drug components, at Rockville, Dist. Md.
Charged 4-14-77; while held by D-M Pharmaceuticals, Inc., Rockville, Md., the articles, labeled in part "Diphenhydramine HCl Injection U. S. P. . . . Manufactured for Veratex Corporation, Detroit, Mich. , . . . Manufactured by D-M Pharmaceuticals, Inc., Rockville, Md." or similarly labeled, had been manufactured, processed, packed, and held under insanitary conditions not in conformity with current good manufacturing practice—501(a)(2)(B); and a number of specified drugs failed to bear adequate directions for use and were not exempted since they were new drugs without effective approved New Drug Applications—502(f)(1). Consent decree authorized release to the processor of the articles. (F.D.C. No. 61144; S. Nos. 77-03-626; N.J. No. 23)


Charged 7-28-77; when shipped by D-M Pharmaceuticals, Inc., Rockville, Md., the circumstances used for the article's manufacture, processing, packing, and holding failed to conform with current good
manufacturing practice; 501(a)(2)(B). The article was claimed by the shipper who denied the charge. Consent decree authorized release to the shipper for bringing into compliance. (F.D.C. No. 61307; S. No. 77–63–809; N.J. No. 25)

Potassium chloride tablets, and other repacked drugs, at Dewey, N. Dist. Okla.
Charged 3–16–77: while held by Medical Products Systems, Inc., Dewey, Okla., who was repacking interstate bulk tablets and capsules into unit-dose packets, the labels of some of the articles lacked the name and place of business of the manufacturer, packer, or distributor; the labels of some lacked adequate directions for use and were not legible; held that the articles lacked the established names of the drugs, lacked the established names of each active ingredient, and lacked the prescription legend; and all of the articles had been repacked in an unregistered establishment and had not been listed pursuant to section 502(b)(1), 502(b)(2), 502(c)(1)(A)(i) & (ii), 502(o), 503(b)(4).

Shortly after the articles were seized, Medical Products Systems, Inc., Dewey, Okla., intervened, filed an answer and counterclaim, and objected to the entry of consent decree authorized release to the shipper for specified testing purposes prior to destruction. The Government moved for an order permitting discovery, in the event that claims were filed, before the hearing on the condemnation of the articles; the Government's grounds were that, if the condemnation proceedings were contested, the Government would need discovery relating to the interests of claimants; that a fully contested hearing would require the Government to present expert witnesses; and that, in the absence of present claims, the Government could not justify the payment of expert witness fees in the absence of formal notice of claims. However, no one filed any claim to the articles, and a default decree of condemnation ordered the articles destroyed. (F.D.C. No. 61611; S. Nos. 77–54–224/31 et al.; N.J. No. 28)

Charged 5–2–78: when shipped by Zenith Laboratories, Inc., Northvale, N.J., the article, labeled in part "Promoxyphene Compound 65/30 (Capsules Manufactured For Cooper Drug Company Division of Chromalloy Pharmaceutical, Inc. Madison Heights, Michigan . . . Final dosage form Manufactured by Zenith Laboratories, Inc., Northvale, New Jersey," was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 61747; S. Nos. 78–120–970; N.J. No. 29)

Serum, human, at Houston, S. Dist. Tex.
Charged 12–20–78: when shipped by Southwestern Plasma Center, Inc., Lakeland, Fla., the circumstances used for the article's manufacture, processing, packing, and holding failed to conform with current good manufacturing practice—501(a)(2)(B); the quality and purity of two lots of the article fell below their represented purity and quality because those lots were reactive for hepatitis B surface antigen; 501(e); the accompanying invoices for two lots of the article contained the false and misleading statements "All tested and found Negative for HAA," "All tested and found to be HAA negative," and/or "All material tested and found nonreactive for HAA"—502(a); all lots of the article lacked the name and place of business of the manufacturer, packer, or distributor; lacked a quantity of contents statement; lacked the established name of the drug; and lacked adequate directions for use—502(b)(1), 502(b)(2), 502(c)(1)(A)(i), 502(o)(1). Default decree ordered destruction. (F.D.C. No. 61004; S. No. 88–285 H et al.; N.J. No. 30)

DRUGS/Veterinary

Dexamethasone sodium phosphate injection, at Strongsville, N. Dist. Ohio.
Charged 9–12–77: when shipped by Lypho-Med, Inc., Chicago, Ill., the article, labeled in part "Dexone–4 Dexamethasone Sodium Phosphate Injection USP Intramuscular-Intravenous . . . use by or on the order of a licensed veterinarian . . . Manufactured for Sterivet Laboratories, Inc., Strongsville, Ohio . . ." was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to its use and intended use: 501(a)(5). Consent decree authorized release to the shipper for specified testing purposes prior to destruction. (F.D.C. No. 61407; S. Nos. 77–81–447; N.J. No. 31)

Neo-Oxybiotic scour boluses with vitamins A, D, E, & electrolytes, at St. Louis, E. Dist. Mo.
Charged 4–4–78: while held by Performance Products, Inc., St. Louis, Mo., who manufactured the article using interstate oxytetracycline hydrochloride, the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to its use and intended use; and the circumstances used for the article's manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; 501(a)(5), 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 61638; S. Nos. 78–123–985; N.J. No. 32)
Prednisone suspension, and adrenal cortex injection, at Fort Collins, Dist. Colo.
Charged 8–16–77: when shipped by Chromalloy Pharmaceuticals (Carter-Glougau Laboratories Div.), Glendale, Ariz., the articles, labeled in part "Sterile Prednisone Suspension [or "Adrenal Cortex Injection"] Manufactured For Triple Crown Pharmaceutical Inc., Fort Collins, CO. 80623," were new animal drugs, and no approval of New Animal Drug Applications were in effect with respect to their uses and intended uses; 501(a)(5). Consent decree ordered destruction. (F.D.C. No. 61379; S. Nos. 77–79–552/3; N.J. No. 33)

Pyrilamine maleate & ephedrine hydrochloride antihistamine tablets, oxycodone injection, glyceryl guaiacolate & ammonium chloride combination cough syrup, and other veterinary drugs, at Lenexa, Dist. Kans.
Charged 6–5–78: while held by Veterinary Labs., Inc., Lenexa, Kans., who was distributing the articles (some of which the firm manufactured using interstate components, some of which it repackaged, and most of which it distributed under private labels), the articles were new animal drugs, and no approval of New Animal Drug Applications were in effect with respect to their uses or intended uses; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 61729; S. No. 78–125–461; N.J. No. 34)

MEDICAL DEVICES

Charged 3–7–78: the quality of the article, which had been shipped by Circle Rubber Corp., Newark, N.J., fell below its purported quality, and the article's label statement "for the prevention of disease" was false and misleading, since the articles contained holes (two defective units out of 275 tested units); 501(c), 502(a). Default decree ordered destruction. (F.D.C. No. 61631; S. No. 78–144–029; N.J. No. 35)

Voltage generator for muscle stimulation, Electro-Galvanic Stimulator, at Houston, S. Dist. Tex.
Charged 7–28–75: when shipped by Electro-Med Health Industries, Inc., Miami, Fla., the article's accompanying labeling contained false and misleading claims for stimulating tissue regeneration, increasing blood circulation, draining fluid that might build up around the knee, ankle injuries, muscle strains, hydrogalvanic therapy, acute inflammatory traumatic conditions, increasing mobility of joints affected by acute or chronic conditions such as rheumatism or arthritis, and preventing sore knees, and that the device was inherently of low energy to provide absolute safety—502(a); the article's labeling lacked adequate directions for use for the article's intended purposes and was not excepted, since neither adequate directions for lay use nor adequate information for use by licensed practitioners could be furnished—502(f)(1); and the article's labeling lacked adequate warnings against unsafe use—502(f)(2). Consent decree authorized release to the shipper for relabeling. (F.D.C. No. 60418; S. No. 88–293 H; N.J. No. 36)

NOTICES OF JUDGMENT on Criminal Actions

FOOD

Charged 12–28–77: flour was held under insanitary conditions in a building and in flour-conveying equipment which were accessible to insects, and some of the flour was contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Guilty pleas by individuals; fines and probations. (F.D.C. No. 61168; S. No. 77–80–628 et al.; N.J. No. 37)

Charged 4–20–78: a rack containing a vegetable oil byproduct was caused to be shipped from Kankakee, Ill., to Jackson, Miss., for use as a component of animal feed, and (count 1) the defendants' invoice falsely and misleadingly failed to reveal the material fact that the vegetable oil byproduct was not safe or suitable for use as or in food for man or animals, and (count 2) the vegetable oil byproduct contained the nonconforming food additive dieldrin—402(a)(2)(C), 402(a)(4), while a rack of vegetable oil byproduct from Kankakee, Ill., labeled in part (invoice & bill of lading) "This Matl May Cont Toxic Compd Not To Be Used For Food or Animal Consumption," was held for sale at Brandon, Miss., the defendants unlawfully caused the transfer of the possession and control of the vegetable oil byproduct to a Jackson, Miss., firm for use as a component in animal feed with different labeling (i.e., an invoice that failed to reveal that the vegetable oil byproduct contained the pesticide dieldrin and was not safe or suitable for use as or in food for man or animals) since (count 7) the new invoice was false and misleading because it failed to reveal the material fact that the vegetable oil byproduct contained the pesticide dieldrin and was not safe or suitable for use as or in food for man or animals, and since (count 8) the vegetable oil byproduct contained the nonconforming food additive dieldrin—402(a)(2)(C), 402(a)(4); and (count 9) the vegetable oil byproduct contained the nonconforming food additive dieldrin—402(a)(2)(C). Nolo contendere plea by individual to counts 1, 7, & 10; imprisonment suspended, and probation. (F.D.C. No. 60771; S. No. 56–565 H et al.; N.J. No. 38)

Southwestern Grocery, Inc., and Belmonte D'Antonio, president, Tucson, Ariz.
Charged 6–6–74: cracker meal, egg noodles, wheat cereal, ground oregano, and whole fennel were held under insanitary conditions in a building accessible to insects and rodents, the whole fennel was contaminated with rodent filth, and the egg noodles and ground oregano were contaminated with insect filth; 402(a)(3), 402(a)(4). The defendants pleaded not guilty and moved to dismiss upon the grounds that the information violated the defendants' right to a speedy and public trial, and upon the grounds that the defendants' rights to due process and against self-incrimination were violated. The court denied the defendants' motion to dismiss. The defendants moved to suppress FDA's inspectional evidence. However, the evidence was not suppressed, and the case came on for trial before a U.S. magistrate. The magistrate found both defendants guilty and fined them. (F.D.C. No. 59–486; S. No. 47–021 F et al.; N.J. No. 39)

NOTICES OF JUDGMENT on Injunction Actions

Charged 7–7–77 in complaint for injunction: that at the defendants' Buhl, Idaho, warehouse, the defendants prepared, packed, held, and distributed in interstate commerce various foods such as dried beans, wheat, and animal feeds; that such foods were prepared, packed, and/or held under insanitary conditions; that FDA inspections disclosed a number of specified insanitary conditions; and that the defendants were well aware that their activities concerning the preparation, packing, and holding of foods were in violation of the law; 402(a)(4). A consent decree of permanent injunction perpetually enjoined the defendants from the complained of violations and enjoined the interstate shipment of any warehouse food and the preparing, packing, or holding in the warehouse of any food consisting of an interstate component, unless and until a number of specified circumstances were effected to assure that food was not contaminated, and unless and until all the food on hand at the warehouse was examined for filth until all the food on hand at the warehouse was examined for filth and against self-incrimination were violated. The court denied the defendants' motion to dismiss. The defendants moved to suppress FDA's inspectional evidence. However, the evidence was not suppressed, and the case came on for trial before a U.S. magistrate. The magistrate found both defendants guilty and fined them. (F.D.C. No. 60125; S. No. 77–71–457; N.J. No. 40)

Campanella Bakeries, Inc., and Joseph J. Campanella, president, Samuel Griglio, vice president, and Joseph R. Griglio, secretary, Jersey City, Dist. N.J.
Charged on or about 11–3–75 in complaint for injunction: that the defendants held interstate flour for use and sale in bakery products and manufactured, packed, and held for sale various bakery products (including bread and rolls); that the flour and bakery products were prepared, packed, and held under insanitary conditions at the defendants' bakery, and a number of the foods contained insects; that FDA inspections disclosed a number of specified insanitary conditions; and that the defendants were well aware that their activities concerning the preparation, packing, and holding of foods were in violation of the law; 402(a)(4). A consent decree of permanent injunction perpetually enjoined the defendants from the complained of violations and enjoined the interstate shipment of any warehouse food and the preparing, packing, or holding in the warehouse of any food consisting of an interstate component, unless and until a number of specified circumstances were effected to assure that food was not contaminated, and unless and until all the food on hand at the warehouse was examined for filth and against self-incrimination were violated. The court denied the defendants' motion to dismiss. The defendants moved to suppress FDA's inspectional evidence. However, the evidence was not suppressed, and the case came on for trial before a U.S. magistrate. The magistrate found both defendants guilty and fined them. (F.D.C. No. 60125; S. No. 77–71–457; N.J. No. 40)
No. 712; S. No. 76-34-771 et al.; N.J. No. 41

Dell Laboratories, Inc., and Jack R. Lyons, president, and Gerald Nacht, chief chemist, Teaneck, Dist. N.J.
Charged 5-9-77 in complaint for injunction: that the defendants manufactured, processed, packed, labeled, held, and distributed in interstate commerce various injectable drugs; that the circumstances used for the manufacture, processing, packing, and holding of such drugs failed to conform with current good manufacturing practice; that FDA inspections disclosed a number of specified deviations from current good manufacturing practice; and that the defendants had been warned of their nonconformance with current good manufacturing practice; 501(a)(2)(B).

A consent decree of permanent injunction enjoined the complained of violations, enjoined the interstate shipment of any drug from the plant, and enjoined the manufacturing, processing, packaging, and holding of any drug containing an interstate component unless and until a number of specified conditions concerning the manufacture, processing, packaging, labeling, and holding of drugs in conformity with current good manufacturing practice were effectuated; and unless and until all drugs and bacterial cultures were made, and all recalled or adulterated drugs were destroyed or otherwise brought into compliance with the law. (Inj. No. 786; S. No. 77-88-556 et al.; N.J. No. 42)

Charged 10-27-76 in a complaint for injunction: that, at the defendants' Philadelphia, Pa., plant, sauerkraut was manufactured, processed, packed, labeled, held, and distributed in interstate commerce; that such sauerkraut contained insects and insect filth and had been prepared, packed, and held under insanitary conditions; that FDA inspections had disclosed a number of specified insanitary conditions in the plant; and that the defendants had been warned of the insanitary conditions; 402(a)(3); 402(a)(4).

A consent decree of permanent injunction perpetually enjoined the complained of violations and enjoined the defendants from shipping any food from the defendants' plant and from preparing, packing, holding, or distributing any food which had been shipped in interstate commerce, unless and until a number of specified conditions to preclude food contamination were met, and unless and until the food on hand had been examined for filth and all such food found to be contaminated was destroyed or otherwise brought into compliance with the law. An amended consent decree permitted the defendants to post a bond and to ship such sauerkraut as to which there was controversy about the possibility of reconditioning to a cold storage facility, pending agreement between the parties as to a salvaging method. (Inj. No. 745; S. No. 77-47-822 et al.; N.J. No. 43)

NOTICES OF JUDGMENT on Miscellaneous Actions

Color additive petitions concerning FD&C Blue No. 1, Green No. 3, & Red No. 4, and suit to compel FDA actions, Sixth Circuit Court of Appeals, Cincinnati, Ohio.
Petitioned 7-14-76 by Glenn M. W. Scott, a Louisville, Ky., consumer, against FDA Commissioner Alexander M. Schmidt and HEW Secretary F. David Mathews, in a suit for mandamus: that the court order the defendants to publish a notice of the plaintiff's petition to repeal the listing of FD&C Blue No. 1, and to refer the plaintiff and industry petitions to list FD&C Green No. 3 and FD&C Red No. 4 (along with all the evidence the plaintiff had sent the Commissioner) to advisory committees for reports and recommendations on the induction of cancer by such color additives.

In response, the Government argued that the notice of the plaintiff's petition to repeal the listing of those color additives had been published and that such issue was accordingly moot; that the remaining issue (release to advisory committees) was not ripe for judicial review and was discretionary with the Commissioner; and that, accordingly, the writ of mandamus was not appropriate. Subsequently, upon consideration of the matter, the court of appeals ordered that the petition be denied for lack of jurisdiction. (Misc. No. 343; N.J. No. 44)

Regulations classifying certain kinds of substances as generally recognized as safe (GRAS) for use in foods, and the validity of such regulations, Washington, Dist. Columbia.
Charged 4-21-76 by Glenn M. W. Scott, a consumer of food, Lexington, Ky., against F.D.A. Commissioner F. David Mathews, and FDA Commissioner Alexander M. Schmidt, in suit for judicial review of the GRAS regulations: that FDA published statements purporting to adopt nine regulations on the subject of GRAS substances, on March 28, 1959; Nov. 20, 1959; Jan. 19, 1960; Jan. 31, 1961; Feb. 18, 1961; May 9, 1961; June 10, 1961; June 10, 1961; and June 17, 1961, which were codified respectively as: 21 C.F.R. §§ 121.1-121.9 & 121.51-121.75; 121.101(a,b,c,d); 121.101(e); amended 121.101(d); 121.101(f); 121.101(g); amended 121.101(e); 121.101(i); and 121.101(h); that FDA failed to incorporate, in such purported regulations, a concise general statement of their basis and purpose, and FDA thereby failed to observe the procedure required by law; that such purported regulations were, in whole or in part, arbitrary, capricious, and an abuse of discretion, and, in particular, the sentence in 21 C.F.R. 121.101(a) [subsequently redesignated 21 C.F.R. 182.1(a)] "It is impracticable to list all substances that are generally recognized as safe for their intended use" was also arbitrary, capricious, and an abuse of discretion.

The plaintiff moved for partial summary judgment in favor of the plaintiff as follows: (1) on the question of whether the challenged regulations were published without issuance of the necessary statements of basis and purpose; (2) that the defendants be ordered to provide an adequate statement of basis and purpose for such regulations; and (3) that the court order the defendants to base such statement on an adequate record made by following the Administrative Procedure Act's notice and comment procedure. The Government moved to dismiss the action on the ground that the court lacked jurisdiction over the subject matter because the action was moot and because the plaintiff had failed to exhaust his administrative remedies.

The court denied the plaintiff's motion, saying:

"Upon consideration of plaintiff's motion for partial summary judgment, defendants' opposition thereto, the memoranda in support thereof and in opposition thereto, and the entire record herein, it appears to the Court that principles of statutory interpretation relating to 5 U.S.C. § 553(c) set forth in Automotive Parts & Accessories Association v. Boyd, 407 F.2d 387 (D.C. Cir. 1968), WAIT Radio v. Federal Communications Commission, 418 F.2d 1153 (D.C. Cir. 1969), Amoco Oil Co v. Environmental Protection Agency, 501 F.2d 722 (D.C. Cir. 1974), and decisions of similar effect, should not be retroactively applied to the regulations at issue in the present case essentially because of the purpose of the new rule [which required a concise general statement of basis and purpose], the extent of administrative reliance upon the former interpretation of Section 553(c), and in the absence of an indication by Congress that it intended to apply such a statement on an adequate record made by following the Administrative Procedure Act's notice and comment procedure. The Government's motion to dismiss was denied])(1968), and the Government's motion to dismiss was denied.

"It is, accordingly, by the Court this 4th day of April, 1977, ordered that plaintiff's motion for partial summary judgment shall be, and the same hereby is, denied.

Subsequently, upon stipulation of the parties, the issues concerning FDA's failure to incorporate a concise general statement of the regulations' basis and purpose was dismissed with prejudice, and the remaining issues were dismissed without prejudice. (Misc. No. 337; N.J. No. 45)

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

Notices of Judgment are prepared by Food and Drug Division, Office of the General Counsel, HEW.
Published by direction of the Secretary of Health, Education, and Welfare.

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

40 / March 1979 / FDA Consumer
PREGNANT...  
Or think you might be?  
Tell your doctor before getting an x ray or prescription.
U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration
5600 Fishers Lane
Rockville, Md. 20857

HEW Publication No. (FDA) 79-1001