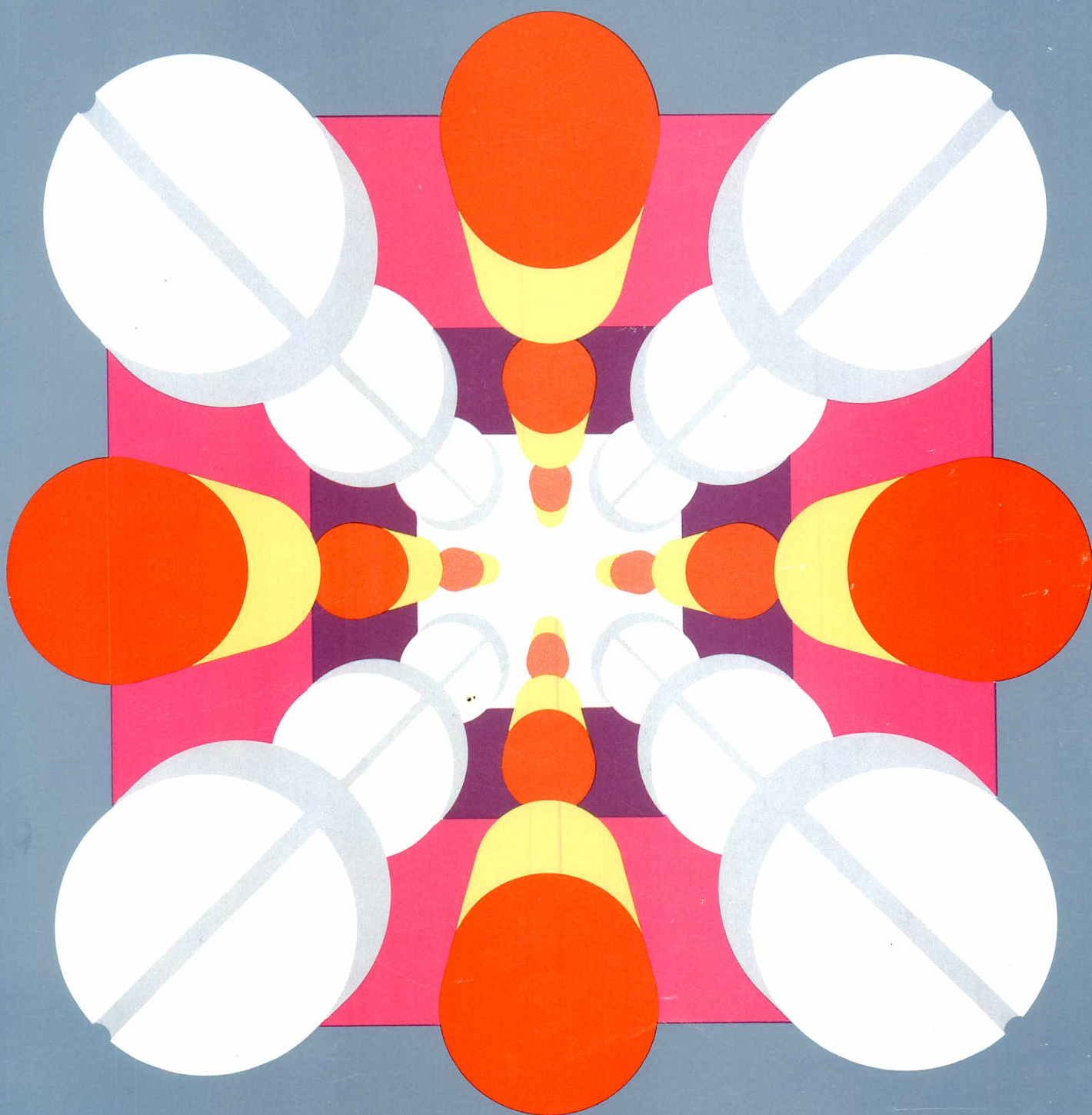


FDA CONSUMER

February 1978

Generic Drugs: How Good Are They?





This Month

A consumer who wants to know the ingredients in a jar of mayonnaise need only look on the label. Right? Well, not necessarily. Mayonnaise and other so-called standardized foods are not required to carry a list of basic ingredients on the label. It's the law. The assumption behind the law is that standardized foods, which must be made according to recipes specified by FDA, are so familiar that consumers know the basic ingredients that go into them. Many consumers and consumer groups find that assumption questionable.

A consumer who is allergic to a particular chemical food coloring agent need only look on the label to find out if it is used in a food product. That's not true either. If artificial colors are used in food that fact must be indicated on the label, but the specific chemical need not be shown. And there is even an exception to that rule. Artificial colors are permitted to be used in dairy products without any indication on the label. It's the law.

The laws and regulations governing the labeling of food and some of the other products FDA regulates can be a matter of confusion and frustration for consumers. How product labels can be improved to help consumers make better informed choices in the marketplace is the subject of an interview this month with Commissioner of Food and Drugs Donald Kennedy.

When consumers do read food labels, more and more of them apparently are looking to see if the product contains nitrates or nitrites. These additives, which are found most often in bacon and other cured meats, are used to help prevent the growth of the bacteria that cause botulism, a very dangerous type of food poisoning. But troubling questions have been raised about the safety of nitrites and nitrates. There's a report on what is being done to resolve these questions beginning on page 8.

The label the consumer sees on a prescription drug often is nothing more than typed instructions giving the name of the medicine and when and how it should be taken. On prescription drug containers the consumer may never see the kind of brand label that appears on most packaged products—that is, a printed label showing the name of the product and the name of the manufacturer or distributor. Brand names, however, play an important role in the prescribing and purchasing of both prescription and over-the-counter drugs. What consumers want to know is whether brand name drugs are safer or more effective than drugs sold under their generic or chemical names. Put another way, it's a question of *Generic Drugs: How Good Are They?*

Also in this issue is an article on intraocular lenses, plastic devices that can be permanently implanted in the human eye to replace the natural lens.

Inside Front Cover Photo: *The use of nitrates and nitrites in cured meats, smoked fish, and certain other foods is getting a close look from the Federal agencies responsible for regulating these additives. The concerns that prompted this scrutiny and what actions are being taken are the subject of Nitrites: Focusing on Safety.*

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

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

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

Cover Design: Zeb Rogerson

Update

Cancer Warning Proposed for Hair Dyes

What FDA can and can't do to regulate the safety and labeling of cosmetics was covered in Cosmetics: The Substances Beneath the Form in the April 1977 FDA CONSUMER. Here's an update.

The Food and Drug Administration has proposed a warning label for many permanent type hair dyes.

The label would say: "Warning—Contains an ingredient that can penetrate your skin and has been determined to cause cancer in laboratory animals."

The Agency further proposed that posters be placed in all beauty salons warning consumers that: "Some hair dyes contain ingredients which may cause cancer. These hair dyes are required to bear a label warning. Ask to see the label of the product intended for your hair."

The posters would have to be supplied to beauty salons by hair dye manufacturers and would have to be at least 11 × 14 inches, with a heading "Hair Dye Notice."

The warning labels would be required on all hair dyes containing 4-methoxy-m-phenylenediamine (4MMPD) and its sulfate (4MMPD sulfate). These chemicals also are known as 2,4 diaminoanisole (2,4 DAA) and 2,4 diaminoanisole sulfate (2,4 DAA sulfate).

These chemicals are used as tinting agents in many and possibly most permanent type hair dyes at concentrations as high as 2 to 4 percent. They are generally found in the so-called "cool" or "drab" colors—shades of black, brown, and ash tone blondes.

Correction

Four lines of type were left out of the article *Reducing X Rays and Health Costs* in the December 1977-January 1978 issue of FDA CONSUMER. The missing type was the second half of the incomplete sentence that appears at the bottom of the second column on page 17. The complete sentence should have read:

According to the National Academy of Sciences/National Research Council (NAS/NRC), reducing the x-ray dose by this much would mean a savings of \$750 million annually in health care costs generated by genetic defects in future generations.

They are less likely to be found in vivid warm shades such as reddish or golden blonde, and are not in temporary or semi-permanent tints or rinses.

The FDA action is based on recent studies conducted by the National Cancer Institute which show that 4MMPD sulfate causes cancerous skin, lymph, and thyroid tumors when fed to laboratory mice and rats. FDA also has evidence that 4MMPD can be absorbed through human skin and enter the bloodstream.

According to industry figures, about two out of every five American women regularly use hair dyes, and about 75 cents out of every dollar spent on hair dyes is for permanent types.

Donald Kennedy, Commissioner of Food and Drugs, said: "The evidence shows that 4MMPD sulfate can cause cancer in test animals and can get into the human bloodstream when used on the scalp.

"The warning label and posters will tell consumers that they take certain risks by using hair dyes with this substance. This is the most we can do under present law."

Under the Food, Drug, and Cosmetic Act a cosmetic is considered adulterated if it contains a harmful substance and FDA can seek to have it removed from the market. However, hair dyes derived from coal tar are specifically exempted from the adulteration provision of the law if they carry a label alerting consumers to the risk of skin irritation. The hair dyes containing 4MMPD and 4MMPD sulfate are coal-tar products. FDA has long urged repeal of the coal-tar hair dye exemption in the Food, Drug, and Cosmetic Act.

FDA advises that consumers who want to identify hair dyes containing 4MMPD or 4MMPD sulfate before the warning label appears should check the ingredient listing. Under an FDA regulation, all cosmetics must now identify ingredients on the labeling.

The Environmental Defense Fund (EDF), a consumer organization, petitioned FDA in October to require warning labels on hair dyes containing 4MMPD and 4MMPD sulfate. Representatives of the hair dye industry opposed the request, questioning the relevance of feeding studies to products used externally.

EDF also supported Congressional repeal of the coal tar exemption in the cosmetic law.

Notice of the proposed warning label and poster appeared in the FEDERAL REGISTER January 6, 1978. FDA allowed 60 days from that date for public



comment. After the comments are evaluated, FDA will issue final regulations, which would take effect 90 days later. Comments on the proposal may be sent to the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20857.

Court Ruling on Laetrile Appealed

The history of the development and promotion of Laetrile and the reasons FDA has not approved it for sale in the United States were covered in Laetrile: The Making of a Myth in the December 1976-January 1977 FDA CONSUMER. Here's an update.

The Federal Government has appealed a decision by a U.S. District Court judge that prohibits the Food and Drug Administration from interfering with the interstate shipment or sale of Laetrile.

Judge Luther Bohanon of the U.S. District Court in Oklahoma City ruled December 5 that Laetrile is exempt from the effectiveness requirement of the 1962 drug law and that FDA may not prohibit its interstate shipment or importation, or interfere with physicians prescribing it.

The Government asked for and was granted an emergency appeal of the Bohanon decision by the U.S. Court of Appeals for the Tenth Circuit. Oral arguments on the appeal were scheduled to be heard on January 26.

Judge Bohanon ruled that his order prohibiting FDA from interfering with the use or sale of Laetrile would not go into effect until FDA's appeal of the decision is decided. This means that pending the outcome of the appeal the importation or interstate shipment of Laetrile continues to be prohibited except for patients who have physicians' affidavits saying they are terminally ill with cancer and who meet other conditions set by Judge Bohanon in an earlier order.

Laetrile is a substance made from the pits of apricots and other fruits. Its advocates claim it is effective in the treatment or prevention of cancer. FDA has held that Laetrile is an illegal drug because it has not been shown to be safe and effective under the requirements of the Food, Drug, and Cosmetic Act.

Judge Bohanon ruled that Laetrile is not subject to FDA regulation because it was in use before 1962, when the Federal drug law was amended to require that new drugs be shown to be effective as well as safe before they could be approved for sale.

Rules Issued on Saccharin Warning Label

Last November Congress enacted a law imposing an 18-month moratorium on any FDA action to ban saccharin but requiring a warning label on food products containing the artificial sweetener. The congressional action was prompted by an FDA proposal to end the use of saccharin as a general purpose food additive. FDA's reasons for seeking to halt the use of saccharin were explained in The Saccharin Ban in the May 1977 FDA CONSUMER. Here's an update.

The Food and Drug Administration has taken two actions to specify how the public is to be warned that the use of saccharin-containing food may be hazardous to health.

The actions provide guidance to manufacturers, labelers, and retail establishments in warning consumers about the artificial sweetener. The actions implement requirements of the Saccharin Study and Labeling Act passed by Congress last November.

Under that law, FDA is prohibited for 18 months from banning saccharin from the food supply. The law requires that during the 18-month moratorium warning labels appear on saccharin-containing food, and posters be placed in retail stores that sell such food.

In the first action, FDA issued final guidelines to assist industry in placing the warning label on food. The labels must appear on all saccharin-containing foods shipped in interstate commerce after February 21, 1978.

Under the guidelines, the warning must appear in a conspicuous place on the label, usually on each principal display panel, in easily readable boldface type, with each letter at least one-sixteenth of an inch high. Generally the warning must appear immediately above or below the product name.

The language of the warning was included in the law passed by Congress. It says: "Use of this product may be hazardous to your health. This product contains saccharin which has been determined to cause cancer in laboratory animals."

In the second action, FDA proposed regulations on how retail stores must warn customers about saccharin-containing foods.

Under the proposed regulation, stores selling such foods must post notices at least 11 by 14 inches. The notices would be posted near the store's entrance, in the aisle where saccharin-containing soft drinks are sold, and where the largest amount of other saccharin-containing food is sold.

FDA is proposing that each manufacturer of



saccharin-containing food supply at least three notices to each retail store where its food is sold so that stores will have a sufficient supply of posters.

Under the proposed regulation, the notice would say: "SACCHARIN NOTICE. This store sells food including diet beverages and dietetic food that contain saccharin. You will find saccharin listed in the ingredient statement on most foods which contain it. All foods which contain saccharin will soon bear the following warning: 'Use of this product may be hazardous to your health. This product contains saccharin which has been determined to cause cancer in laboratory animals.' This store is required by law to display this notice prominently."

FDA held a public hearing January 12 to get comments on the proposed regulation on the retail store notices. Retail stores will have to begin displaying the posters 90 days after the final regulation is published.

Notices of the label guidelines and the proposed warning poster for retail stores appeared in the FEDERAL REGISTER, December 9, 1977.

Letters Warn on Mercury Vapor Lamps

The potential hazards from some lamps that produce ultraviolet radiation as well as visible light were explained in Shedding Some Light on Light in the September 1976 FDA CONSUMER. Here's an update.

The Food and Drug Administration has mailed about 68,000 letters to architects, building managers, school officials, State officials, and others alerting them to the potential hazards of mercury vapor lamps.

Mercury vapor lamps are recognizable because they produce a unique bluish-white light. They are commonly used for street lights and parking areas and for indoor facilities such as gyms, sports arenas, and department stores. They have long life and are economical to operate. More than 25 million mercury vapor lamps are in use in the United States.

The lamps consist of an inner tube and an outer glass globe. If the inner tube continues to operate when the outer glass is broken, punctured or missing, the lamp emits intense ultraviolet radiation. Such radiation has produced severe eye irritation and skin burns. Repeated exposure to ultraviolet radiation has been known to lead to skin cancer.

The letters mailed by FDA explain the hazard and tell people to check the lamps regularly and replace them if necessary. The notice advises that people exposed to ultraviolet light from mercury vapor lamps should see a doctor if symptoms such as skin

burns or eye irritation occur and should report injuries to State health departments or FDA.

About 200 incidents resulting in injuries requiring medical attention have been reported to FDA, although FDA believes many injuries are not reported. People can be injured at distances up to 30 feet or more from the damaged bulb. Injuries have most often occurred where bulbs are installed indoors, such as in school gymnasiums or warehouses.

FDA is developing a mandatory safety performance standard for mercury vapor lamps and similar types of lamps and expects to publish the proposed standard in a few months.

The standard would permit two kinds of lamps: one which goes out automatically when the outer globe is broken, and one which may not self-extinguish but is for use only where human exposure to the lamp is not likely to occur.

The self-extinguishing lamps would have to go off within 15 minutes after the outer globe is broken. Lamps that do not go off will have to be labeled with a warning about possible hazards.

The proposed standard also would require lamp manufacturers to provide adequate labeling and information to users of both types of lamps and require the warning to accompany all descriptive literature and advertisements.

Animal Test Laboratories Surveyed

Evidence of sloppy and in some cases fraudulent conduct of animal studies used to support industry requests for the approval of new drugs and food additives prompted Congress to grant FDA additional funds and personnel to strengthen its monitoring of laboratories that carry out these studies. One action taken by FDA was to issue proposed Good Laboratory Practice Regulations (GLP's) which set standards for every aspect of laboratory studies from building maintenance to recordkeeping. The proposed regulations were explained in an article in the March 1977 FDA CONSUMER entitled New Standards for Test Laboratories. Here's an update.

Laboratories run by firms that sponsor new drugs or food additives have a higher rate of compliance with FDA's proposed Good Laboratory Practice Regulations than commercial or university laboratories that conduct animal studies under contract, according to a pilot compliance survey recently completed by FDA.

Manufacturers seeking FDA approval to market a new drug or food additive must submit evidence



from animal tests to show that the product is safe. The purpose of the proposed Good Laboratory Practice Regulations is to assure that such tests are carried out in accordance with acceptable scientific procedures.

Using a 155-point questionnaire based on the proposed regulations, FDA inspectors collected data from 39 animal test laboratories. Data also were collected from 67 studies conducted by these laboratories. Of the 67 studies, 19 were in progress at the time of the FDA pilot compliance survey and 48 had been completed. Twenty-three of the laboratories were operated by firms that market drugs or food additives (sponsor operated), 11 were operated by commercial contractors, and 5 were run by universities.

About half of the questions related to general laboratory operations, while the remainder pertained to the conduct of a specific study.

Sponsor-operated laboratories gave affirmative answers to 69 percent of the questions on general operations, indicating that they are already following the proposed regulations to a large degree. Commercial contract laboratories gave affirmative answers to

56 percent of the general operations questions, and university laboratories had "yes" answers to 46 percent.

The questions relating to specific studies conducted by the laboratories showed that compliance with the proposed regulations was greater for studies in progress at the time of the FDA review than it was for studies already completed. Overall, the laboratories gave affirmative answers to 73 percent of the compliance questions for studies still in progress compared to 57 percent for completed studies. These findings are not surprising since some laboratories changed their procedures after the proposed regulations were published in November 1976.

Generally, the laboratories reviewed scored lowest in their quality assurance programs. The reason for the poor showing in this area, according to the survey report, is that some laboratories have not set up quality assurance units.

According to FDA, the pilot compliance survey helped the Agency learn about the current state of animal test laboratories and showed that the proposed Good Laboratory Practice Regulations are not unrealistic.

Consumer Forum

Chiropractors: Pro and Con

You will probably get many letters from chiropractors who are angry that criticism of chiropractic was allowed in your publication (*Health Frauds and Quackery*, FDA CONSUMER, November 1977). But Dr. Stephen Barrett is quite correct in suggesting that going to a chiropractor is risky. Chiropractic is based on a false theory that most ailments are the result of spinal problems. Chiropractors are inadequately trained in diagnosis and many of them do not know their limitations. As an independent consultant in malpractice cases, I know of many patients who were harmed because chiropractors examined only their spines and failed to recognize serious medical problems located in other parts of their bodies.

Peter J. Modde
Chiropractic Physician
Renton, Washington

Any member of a non-allopathic healing art is well acquainted with the name Stephen Barrett, M.D., of Allentown, Pa. As a chiropractic physician, I am very much cognizant of his (Barrett's) attitude pertaining to health care, when it does not follow the narrow he has charted as a proper course.

This response is not a total effort to respond to Barrett, since this approach would be essentially fruitless. Any exchange of ideas between intelligent individuals requires a solid foundation and some semblance of understanding between the involved parties.

The real issue and culprit here is the FDA CONSUMER, which is a public information, tax supported vehicle. You have provided a platform for Barrett to make his prejudicial and damaging pitch against an accredited, regulated and licensed profession (chiropractic). Now, this kind of garbage emanates from the FDA CONSUMER about every six to twelve months with negative views and/or innuendoes pertaining to chiropractic, whether it be medicine, training or what!

As you well know, chiropractic is federally ap-



proved for medicare. Chiropractic care is included in all State workmen's compensation acts. Most insurance companies and the public recognize chiropractic as a vital alternative health care necessity to chemical medicine. And certainly I must ask—since the subject of training arises so frequently—when was the last time the FDA (or Barrett) visited a chiropractic college for an inspection of facilities, student-faculty ratio, etc.? You should be aware that all accredited chiropractic colleges require a minimum of six (6) years of education and must be approved by the Council on Chiropractic Education which functions under the cloak and guidance of the U.S. Department of Health, Education, and Welfare.

Certainly, if we want to describe medical abuses in detail and all the quackery which abound in medicine it is easily done. Take the back part of your magazine, put it up front with an index and give each article a by-line. This will undoubtedly infuriate the public and cause a chaotic schizoaffective dilemma for the Allentown crusader.

As an original subscriber to the FDA CONSUMER (FDA PAPERS), I am incensed that public funds are used in such a dictatorial and indiscreet fashion to downgrade an accredited and recognized profession. These same funds paid for my education as a chiropractic physician.

I can only assume that there has been some impropriety in the actions of the FDA CONSUMER by publishing tripe such as espoused by Barrett. I further realize that you are a political entity and possibly politics (and education) might enlighten and teach you to serve with impartiality. With this in mind, I trust that those I copy can help you achieve and realize your public trust.

Paul Vogel
Chiropractic Physician
President, Florida Board of Chiropractic Examiners
Jacksonville, Florida

The question and answer article by Stephen Barrett, M.D., was excellent.

His comments on chiropractic were accurate. Chiropractic is controlled and dominated by cultists and frauds. I have been fighting for years to stop these chiropractic quacks, and have been on radio and television shows in the Miami area attacking my own profession for their excessive claims.

You will probably be attacked by the chiropractic profession, but rest assured that they will furnish plenty of heat, but very little light.

Herbert W. E. Poinsett
Chiropractic Physician
Hollywood, Florida

Quackery and the Media

Dr. Barrett's comments on *Health Frauds and Quackery* in the November 1977 issue of the FDA CONSUMER reveal keen insight into why quackery is burgeoning today. His statement, "the media have become the label," describes how quacks have learned how to make false, unfounded or exaggerated claims for health products and services and get away with it by putting them under the umbrella of freedom of the press. Students in my consumer health classes investigating health foods stores find that the clerks regularly refer to publications as the authoritative sources of information for the usefulness of their products. As Barrett says, if the claims were made on the labels, they would be illegal, but are not when separate.

Another way quackery manipulates the media is by exploiting its affinity for sensationalism. Today it seems that nearly every supermarket checkout counter has several nationally syndicated half-sized newspapers which will promote psychic healers, miracle cures, or fast weight-loss diets. An important part of quackery media strategy involves a constant barrage of accusations designed to undermine the public's trust in orthodoxy. Claims that drugs like Laetrile are suppressed, fluoridation causes cancer, organized medicine is only self serving and the public health leadership is corrupt or misguided, serve to prod the public paranoia.

When the public is convinced it cannot trust conventional health products and services, its alternative is to turn to the substitutes offered by quackery. It is easy to see why the salesmen of unproven health products and services have formed organizations which lobby for "health freedom"—which in reality becomes a hunting license for quackery.

It is time for more of us to realize what is going on in today's consumer health politics. Consumer protection is in its greatest jeopardy since the first Food and Drug Law of 1906 due to distortion of the media by quackery. It is frightening to think of what the health marketplace would look like if products and services need only be judged as to their safety, as is currently being promoted, rather than both safety and effectiveness. What is most incredible is that this is being done under the guise of consumerism.

Thanks for publishing Dr. Barrett's insights on this critical matter.

William T. Jarvis
Consumer Health Specialist
Loma Linda University
Loma Linda, California



Nitrites:

Focusing On Safety

The Food and Drug Administration and the Department of Agriculture have called on food processors who use nitrites and nitrates to prove that these chemicals don't pose a hazard to consumers. If tests don't show these additives are safe, their use will be prohibited. Restrictions on the use of nitrites and nitrates could have a major impact on the marketing of bacon, ham, and other cured meats.

by Harold Hopkins

People are concerned about the safety of certain foods processed with nitrates and nitrites and so is the Federal Government, which is speeding up its plans to do something about it.

FDA consumer affairs officers stationed around the country report rising public concern about the possible cancer-causing consequences from the use of nitrates and nitrites. Nitrates (sodium nitrate and potassium nitrate) and nitrites (sodium nitrite and potassium nitrite) are water soluble inorganic salts. They are used to preserve or cure meats, poultry, and fish, and in some cases to impart or fix colors that will improve the marketing acceptance of these foods.

"People write us about it. They call. They bring up the subject at meetings. Consumers want to know how safe nitrites are and what we're doing about them," one consumer affairs officer said.

One of the actions FDA has taken is to require poultry processors who use nitrates and nitrites to file requests for temporary permission to continue using the chemicals as food additives. Those making requests must agree to run tests with laboratory animals to determine whether the proposed uses will be safe for consumers of the products. They must also satisfy other requirements of the regulations governing the use of food additives. If these requirements are not met, FDA will prohibit the use. If they are met, FDA will continue to permit present uses of nitrates and nitrites in poultry pending completion of the required tests to resolve the safety questions.

Notice of FDA's actions on the use of nitrates and nitrites in poultry was published in the *FEDERAL REGISTER* September 2, 1977. The notice invited comments by all interested persons concerning this use and the safety questions involved.

The spreading concern about nitrates

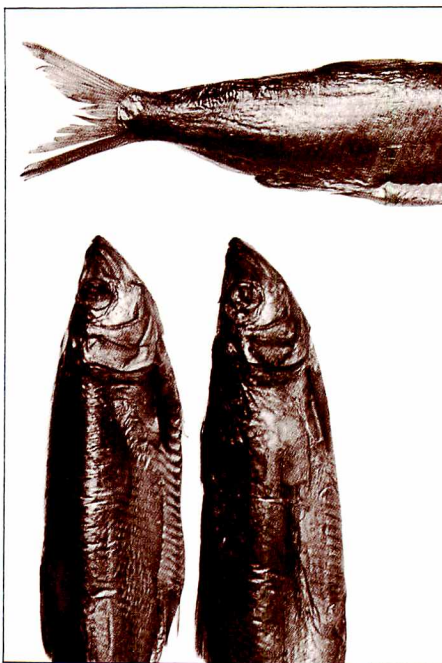
and nitrites in meats, poultry, and fish has led FDA and the U.S. Department of Agriculture (USDA), the Federal agencies responsible for the regulation of these products, to coordinate statements of what they plan to do. Both have announced their intentions to accelerate and intensify efforts to assure that these chemicals are being safely used and to eliminate uses for which this assurance cannot be given. FDA is formulating new regulatory proposals concerning the use of nitrates and nitrites in the processing of smoked fish.

The apprehension about the use of nitrates or nitrites is that they may combine with certain amines present in the meats, fish, and poultry being processed and form substances called nitrosamines, some of which have been shown to cause cancer in laboratory animals. The Government's immediate objective is to eliminate any uses in which nitrosamines may be formed in the processing of a food product or in its preparation (such as cooking) before it is eaten. It hasn't been conclusively established by research so far whether nitrates or nitrites will combine with amines that are present in the human body and form nitrosamines after the

food is eaten. Investigations on this question continue.

There is also concern about possible excessive use of nitrites, which in heavy doses impair the capability of the blood to carry oxygen. Nitrates are far less toxic than nitrites and occur naturally in water and vegetables and other parts of the environment. This being the case, the ingestion by humans of nitrates and to a much lesser extent, nitrites, is not confined to what they consume in cured meats, fish, and poultry. The nitrates used as food additives account for only a fraction of the total nitrates ingested by the average person.

The task of resolving the questions on use of nitrates and nitrites places the Federal Government in a Solomon-like position. Some of these compounds have been used for hundreds of years to preserve or cure and process meat and fish. This use produces known and accepted characteristics of taste and appearance of the product as well as protection against spoilage, so the product can be transported and stored for long periods, all important factors in the economy and in planning for the Nation's continuing food supply. These chemicals not only prevent ordinary spoilage, but also inhibit



growth of *Clostridium botulinum*, the bacterium that produces botulinal toxin, the most dangerous and deadly food poison.

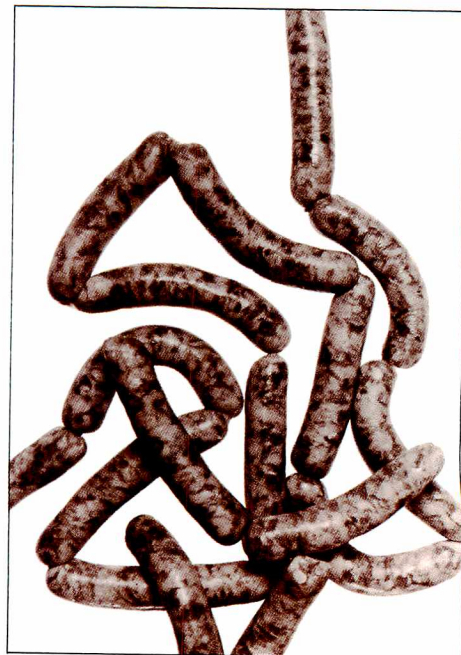
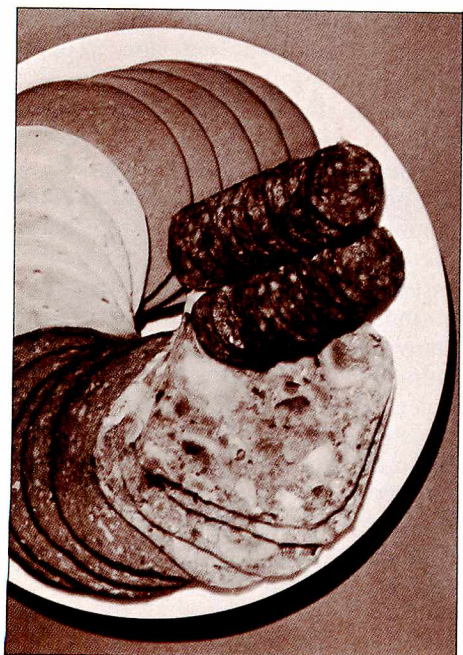
The difficult question is whether certain processed meat, poultry, and fish products could still be made microbiologically safe to eat while retaining the characteristics which give them their identity if the use of nitrates and nitrites in their processing were prohibited. If they cannot be made safe without these chemicals, the alternative would be to prohibit the marketing of cured meat, fish, and poultry as we know them. These products thus would then have to be eaten fresh only or preserved by other methods such as freezing or canning. In short, there would no longer be ham, bacon, cured sausage, salami, bologna, liverwurst, smoked fish, and other cured products of the kind we now take for granted.

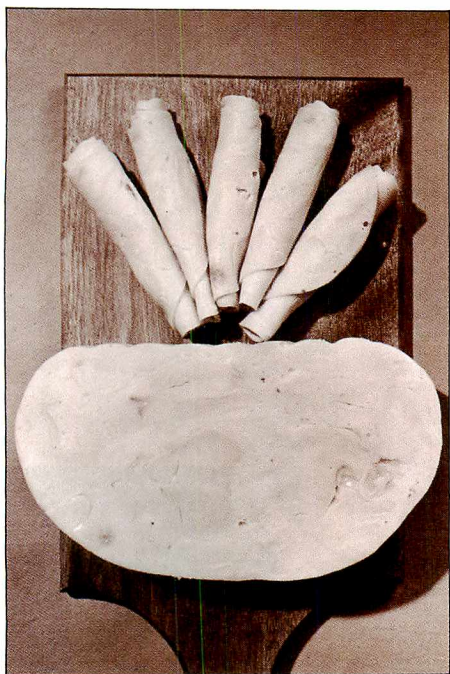
The bacteria that cause botulism grow only in the absence of oxygen and under other ideal growth conditions such as warm temperatures and low acidity. Botulism has been associated mainly with improperly prepared canned foods, but it is possible that the bacteria that cause botulism may thrive in the interior parts of meats and fish where there is little or no oxygen. The

use of nitrates and nitrites in the preserving process inhibits or prevents this growth. Up to now, according to industry claims, there have been no known safe substances as effective as these to protect the products from contamination by botulinal toxin.

Some persons critical of the use of nitrates and nitrites have claimed not only that the industry may be using more of these chemicals than necessary for safety but that some uses may not be needed at all for health protection. These critics claim that the chemicals are used principally to make the product more attractive in appearance and taste.

FDA's action requiring processors to determine if nitrates and nitrites are safe for continued use in poultry was followed six weeks later by a Department of Agriculture announcement giving the meat industry until January 16, 1978, to supply data showing how bacon can be processed with nitrates and nitrites without the formation of cancer-causing nitrosamines during processing or preparation for eating. The industry was given six to 24 months to supply similar information about various other meat products. The risk that nitrosamines will form in the processing or preparation of other





meat products is not as great as for bacon. The Agriculture Department said that after reviewing the industry data it will consider eliminating those uses of nitrates and nitrites in meat that result in the formation of nitrosamines.

Such an action could have a major impact on the processing and availability of ham, bacon, and other cured meats.

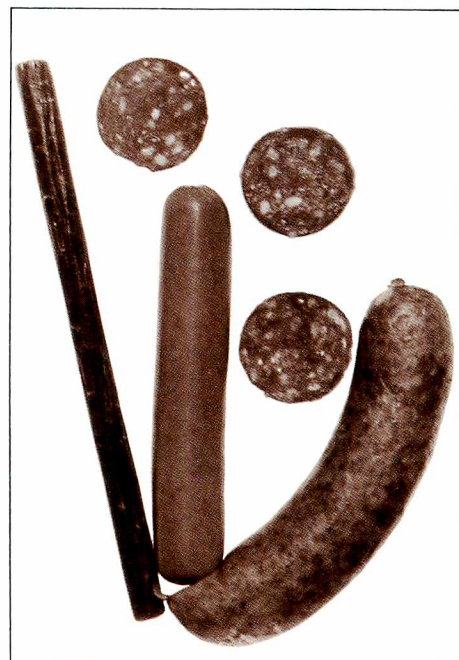
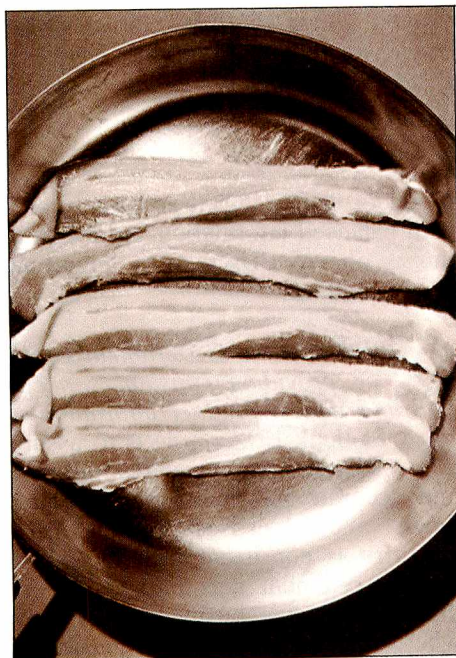
The announcements and other recent actions by FDA and the Agriculture Department concerning nitrates and nitrites followed an investigation by the Assistant Secretary of Agriculture for Consumer Services Carol Tucker Foreman. Her inquiries turned up the information that, although both FDA and USDA had assumed otherwise for two decades, these substances apparently were not approved for use in poultry by USDA under the "prior sanction" provisions of the Food Additives Amendment of 1958.

Prior sanctioned substances are those that had received some type of Federal Government permission for use in food before passage in 1958 of the Food Additives Amendment to the Food, Drug, and Cosmetic Act. Since these substances already had received official approval, they were not subject

to the same requirements for proof of safety as additives coming into use after passage of the amendments. When it was found that USDA had not given prior sanction status to the use of nitrites and nitrates in poultry, FDA held that they now are subject to the requirements of the 1958 amendments and this use must be regulated by FDA even though principal responsibility for all other poultry processing matters rests with USDA.

FDA has sole authority under the Food Additives Amendment of 1958 to approve the use of an additive in food. FDA approval of an additive, however, does not automatically mean that it can be used in the products regulated by the Agriculture Department. The Agriculture Department can prohibit the use of additives in meat and poultry even though such use has been approved by FDA.

FDA, having labored under one mistaken assumption—that USDA had conferred prior sanctioned status to use of nitrates and nitrites in poultry—moved on September 14, 1977, to make sure no similar misassumptions exist concerning use of the substances in red meats. The Agency asked USDA to specify which additives had been granted prior sanction status un-



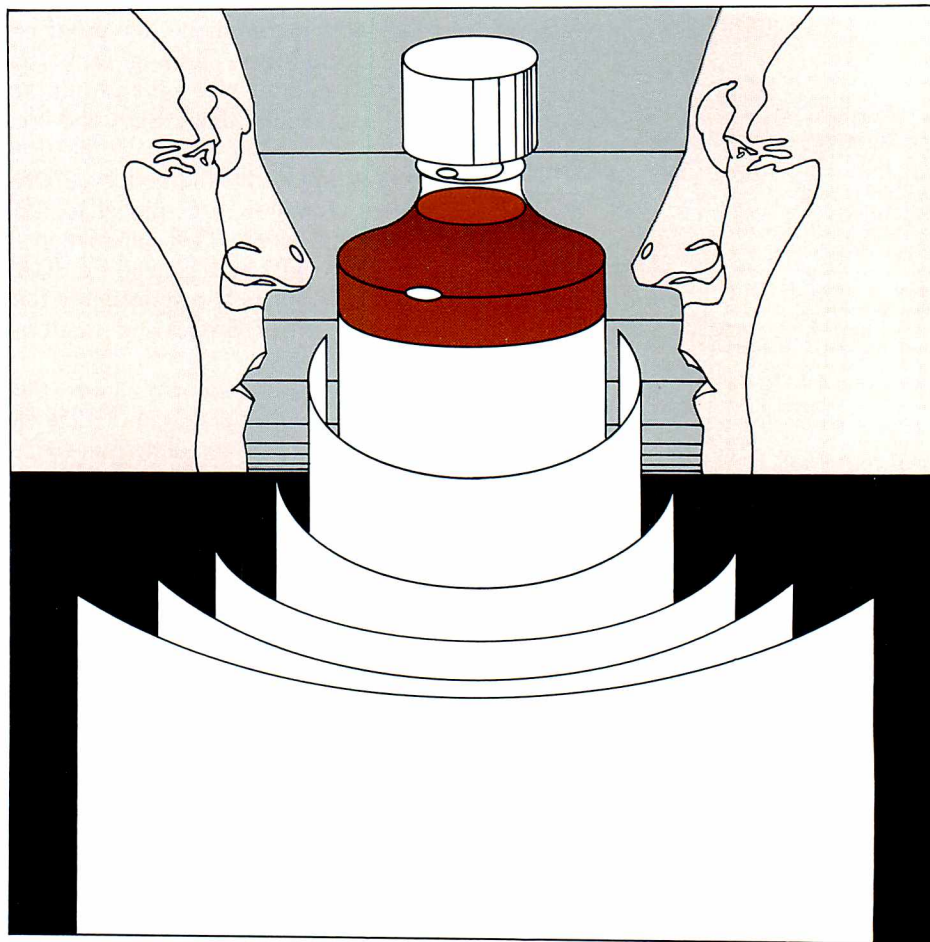
der the Meat Inspection Act of 1907 for use in red meat. FDA also requested information on the levels of the chemicals USDA permits for each use.

In the September 2 FEDERAL REGISTER notice calling for information and comments on the use of nitrates and nitrites in poultry, FDA said that the legal granting of prior sanction status is a weakness in the law that has provided certain ingredients in food with "shelter" from the basic requirements of the Food Additives Amendment of 1958.

Debate over the prior sanctioned status of nitrates and nitrites, the statement said, "has for too long deflected attention from the central issues on the use of these substances." These issues are whether they are useful in reducing the risk of botulism that could result from eating contaminated poultry products, whether they form nitrosamines in poultry products prior to ingestion, and whether nitrates or nitrites are otherwise safe for human consumption. "The time has come to assemble the data required to resolve these questions," the FDA statement said.

Harold Hopkins is editorial director of FDA CONSUMER.

Better Regulation Through Labeling



Since becoming Commissioner of Food and Drugs in April 1977, Dr. Donald Kennedy has emphasized the need for improved product labeling. He expects major FDA initiatives in labeling in the years ahead. In this interview with Wayne L. Pines, deputy assistant commissioner for public affairs, Dr. Kennedy explains why he believes labeling is a key to enlightened regulation, and the plans he has for FDA in this critical area.

Q. Dr. Kennedy, you've stressed the need for products to be adequately labeled. What is your philosophy about labeling?

A. I start from the premise that people are intelligent and rational, and inclined to act in their own best interest when presented with choices. Obviously, information is the key element in deciding among several options. The products regulated by FDA are marketed in such a way that labeling appears to be a uniquely effective means of communicating information to prospective purchasers. So I place strong emphasis on the need for

products to be labeled accurately and with balanced information. In my view this is one of FDA's most important responsibilities.

Q. What is the Government's role in providing consumers accurate and honest product information?

A. I think FDA's role is to assure that industry provides full, fair, and accurate information on product labels, and advertises products in a way that is consistent with the label. The Government gets into the information providing business itself only where it finds serious inadequacies or

systemic defects in the efforts of manufacturers. Otherwise we in Government are regulators of what industry does, or stimulators encouraging industry to do a better job.

Q. FDA's experience with Laetrile and saccharin indicates that many people want the Government to get out of the business of banning products, and merely make sure products are labeled adequately, and let people make up their own minds. How do you feel about this?

A. These controversies certainly have had some effect on my own thinking about labeling and product hazards. But they have not made me withdraw or step back from the need sometimes to regulate the availability of products as well as their labeling. I continue to believe in the basic soundness of the law that prohibits the addition of unsafe additives

to food, because in a complex universe like this you really can't ever hope to supply consumers with enough information about all products to enable them to exercise voluntary choices safely. And I don't believe we should ever permit the sale of unsafe or ineffective drugs merely by labeling them as unsafe or ineffective and letting the consumer decide for himself. The basic concept of our drug approval system is that drugs must be proved safe and effective; in other words, that's the point of departure for the labeling of drugs. But when it's possible to give people enough information about benefits and risks to make their own selections in the marketplace, that is certainly the best step to take.

Q. *Where do you draw the line between a product that is so hazardous that its availability should be restricted, and one that can be adequately labeled?*

A. The line doesn't involve only hazard; the level of hazard is only one of several factors. For example, the complexity of the product is an important consideration. If 10 different food additives are included in a processed food, I wouldn't have great confidence in the willingness of consumers to go down a list that size to see if something hazardous is there. And if there were a separate warning for each additive, that would be ludicrous. Another factor is whether label information can be presented in a way that will be understood and heeded by the public. So hazard is not the only factor; we must balance many different ones. That's what makes my job so interesting.

Q. *Do you see any conflict between FDA's traditional role as a law enforcer or "cop," and its role in requiring labeling information from industry, which is more of an educational function?*

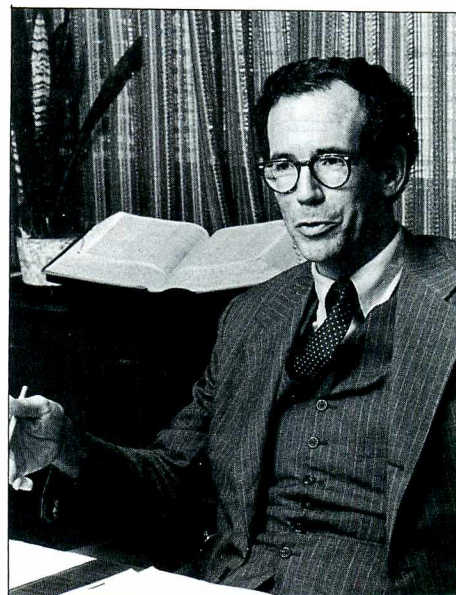
A. Absolutely not. Some problems can be solved by making adequate information available and some can best be dealt with in other ways. There is no way you're going to get a quack product off the market simply

by labeling it. There are products that are intentionally fraudulent and the people who sell them are guilty of deliberately misleading the public. What you need to do in those cases is to get the product off the market and throw the people who are selling it in jail. So we need a strong enforcement posture. But enforcement is not enough, and I am committed to the concept that FDA must play an educational role as well as a "cop" role.

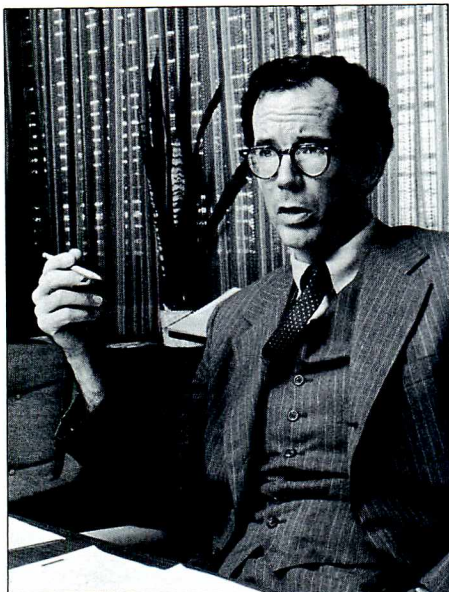
Q. *Dr. Kennedy, we've now had a decade of experience with the cigarette warning label, and cigarette smoking has not diminished. How effective is labeling in affecting consumer behavior?*

A. I'm not sure I accept the assumption implicit in your question, that the cigarette warning has not worked. If you look at selected classes of people in American society—for example, middle and upper income males—you find a dramatic drop in the amount of cigarette usage. Women have increased their smoking to some extent, but that may be because they sense a broader series of choices available to them in all sorts of areas as a result of the women's movement. And women got a false sense of security from the early public health analyses indicating that they were less vulnerable to health problems from cigarette smoking than were men. But I am not prepared to accept the fact that the warning label did not have a powerful impact. We might be in a much worse situation were it not for the warning label and the warning advertising that was done for a period of time. Even more important may be the ban imposed by Congress against television advertising.

Turning to the broader question of whether we know well enough how labels work—this is a difficult question. I've been discussing it, as well as the issue of how you handle warnings in radio and television advertising, with Mike Pertschuk, the chairman of the Federal Trade Commission (FTC). We think a lot more serious social science research needs to be applied to this problem about how labels work. But



"... my common sense tells me that people want to know what they are buying and what risks they may be running, and that this information is most effective and useful when a purchasing decision is being made—that is, on the label of a product."



"... we have nutrition labeling now only for certain foods—those that make a nutritional claim, or to which nutrients are added. We need to have it on all foods."

my common sense tells me that people want to know what they are buying and what risks they may be running, and that this information is most effective and useful when a purchasing decision is being made—that is, on the label of a product. So I'm not going to hold up our labeling initiatives until we study to death the question of labeling; we must move forward, while at the same time looking for better ways.

Q. *What other things are you discussing with the Federal Trade Commission?*

A. I believe that food advertising should be allowed to make no claims that are not permitted on labels, and I've been discussing it with my colleagues at FTC who regulate food advertising. So far I've been quite pleased with the spirit of cooperation I've found at FTC on the subject of food labeling and advertising.

Q. *Specifically, what initiatives need to be taken to improve food labeling?*

A. Let me start by saying that I consider food, and food labeling, to be at least as important to health as drug labeling. Good nutrition can prevent illness, while drugs only can cure or alleviate conditions that have not been prevented. As to specifics, we have nutrition labeling now only for certain foods—those that make a nutritional claim, or to which nutrients are added. We need to have it on all foods. I recognize this may require legislation, but it's terribly important. Another area we're looking at is standardized foods—that is, products that must be made according to a basic recipe written by the FDA. We can't require ingredient labeling on standardized foods, and even though FDA knows what's in the food that doesn't help consumers. For example, a person with allergies can't select from among different versions of a standardized food because there isn't an ingredient label. Again, new legislation may be needed.

Another matter I'm interested in is naming of new foods. There has been some significant confusion on this issue. The question is how you name a new food that is similar to an existing

food. Do we just call it "imitation?" We've been trying to develop a policy that would allow the product to carry an entirely different name, and not be stigmatized with the "imitation" adjective, if the food has the same nutritional quality as the original product. Many consumers have told me that they are not satisfied with this, that it doesn't prevent them from being misled about the nature of the food. Besides, many foods that are labeled "imitation" have been quite successful, so the "imitation" adjective might not be as much of a stigma as we thought—mayonnaise is a good example. We may have to rethink the whole strategy of how we name foods that are similar to existing foods.

I'll be addressing the whole issue of food labeling in hearings this coming spring. We hope to get some information from the public to help us develop a long term Agency strategy in this area.

Q. *What about color additives and labeling?*

A. That's another area that needs more attention. There should be specific identification on food labels of the color additives used. As you know, under present law the label must declare only that a color additive has been added; the color additive does not have to be identified by name. But our knowledge of allergic reactions is increasing, and some people may want to avoid specific color additives, so labels should declare specific colors. And we intend to encourage industry to do so. At present, we are proposing to require that Yellow No. 5 be declared on all food labels by name because we have identified a specific allergic problem with it. About 100,000 people may be allergic to it, and they should be able to avoid it.

Q. *You've also spoken out on the need for new labeling on alcoholic beverages.*

A. That's right. Alcoholic beverage labeling has been deemed by the courts to be within the province of the Bureau of Alcohol, Tobacco and Firearms (BATF) in the Treasury Department, so all we can do is work with them and recommend actions. I

am concerned about two aspects here. First, alcoholic beverages should carry ingredient statements, so consumers will know what they are buying and drinking. Second, and more importantly, I am concerned about the exposure of pregnant women to alcohol and the evidence that excessive drinking can adversely affect offspring. I have asked BATF to look into this. We already have warned doctors about this problem in the FDA DRUG BULLETIN, but I think the warning ought to be right there on the label so women can know of this risk.

Q. *Let's turn to drugs. A lot of people have expressed concern that labels on over-the-counter drugs are inadequate. How is FDA responding to this problem?*

A. Our review of all over-the-counter (OTC) drugs is a major step toward improving the labels of these products, which I agree need improvement. We must make sure that the labels of OTC drugs are limited to claims that can be justified scientifically. Beyond that, I am concerned that OTC drug labels contain adequate warnings and cautions. After all, OTC drugs are by definition those that can be used by the consumer on the basis of label directions, and I'd like to see vast improvements in the way OTC drugs are labeled. Another point is that labels can be useful in changing the public's view of OTC drugs. Many consumers tend to think of OTC drugs casually, and do not accord these products the respect they are due. All drugs should be taken with utmost caution and the label has to convey some sense of that caution.

A larger concern of mine is not OTC drug labels, but advertising. It's no wonder the public doesn't treat OTC drugs with respect when they see the preposterous campaigns waged on behalf of some products. I am thinking specifically of a recent campaign between the aspirin and acetaminophen manufacturers, which really contributed little to better public understanding of these products. I've asked FTC to look into this campaign. I think OTC drug advertising over the years has tended too often to create diseases that don't exist and then offered solu-

tions that ignore the fact that all drugs carry risks. I think these types of ads have been bad for our society.

Q. *Should FDA have authority over OTC drug advertising, as it does over prescription drug advertising?*

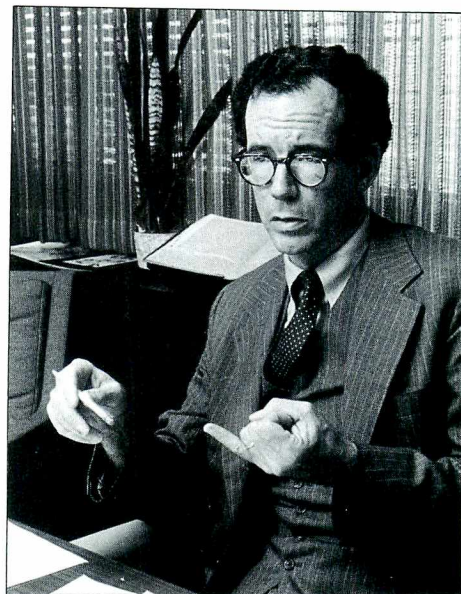
A. Our cooperation with FTC has been good and so I don't see any reason to switch the authority over OTC drug advertising to FDA.

Q. *Probably the most controversial area of labeling involves patient package inserts for prescription drugs. Doctors have expressed fears that these inserts will interfere with their relationships with their patients. What is your view?*

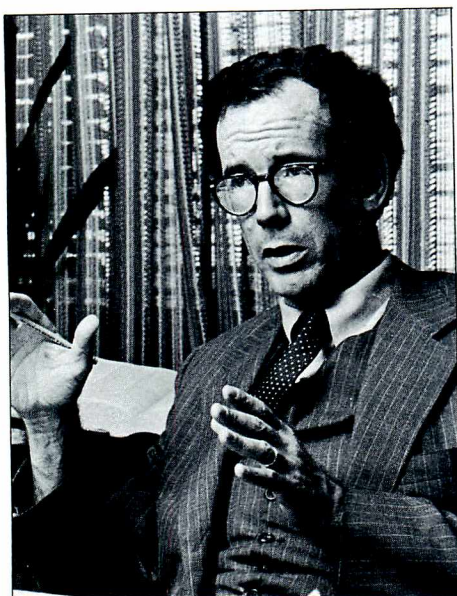
A. I am anxious to see more labeling for patients about prescription drugs. There are several reasons for this. First, an informed patient is apt to be more thoughtful and to follow instructions. There is a serious problem in this country of people not taking prescription medicine when they should, or not being told or not remembering what their doctors said about how often or when to take it. Package inserts for patients will provide that type of information. Second, people should be able to know what drugs they are taking—what benefits they can expect and what risks they run. Going to a doctor does not mean that we give up all responsibility for our own medical care.

My primary concern about patient package inserts is that there may be some tendency on the part of some patients to overreact to a long list of adverse reactions. They may become afraid to do what's best for them because they are frightened by the long list of side effects. We are being careful about that in writing the patient package inserts, and I don't think patients will be frightened—certainly not as frightened as some in the medical profession think they will be.

Patient labels are especially important when there are substantial risks with a drug of which patients have not been made aware. I am thinking in particular about estrogen drugs. These drugs are overused, but women must understand that prolonged use of estro-



"I think OTC drug advertising over the years has tended too often to create diseases that don't exist and then offered solutions that ignore the fact that all drugs carry risks."



"... I view the patient package insert as an important element of health education, as part of a process that makes people much more curious and much more involved in their own health care and thus more likely to do things that will lead to better health."

gen drugs can cause cancer. A large percentage of estrogen prescriptions are for purposes for which the drug has not been shown to be effective, and when we're talking about a risk of cancer, then the patient should be fully cognizant of that risk.

Q. *What about the charge that the inserts will interfere with the doctor-patient relationship?*

A. I'm less concerned about that. Doctors ought to expect to be asked questions and should be willing to answer them. I think the inserts will lead to a better flow of information between doctor and patient.

Q. *What kinds of drugs, in your view, should have patient package inserts?*

A. Several criteria come to mind right away. First, I would say drugs that need relatively detailed patient instructions with them are suitable candidates for patient package inserts; insulin is an example. Another criterion would be whether the drug is elective, as is the case with birth control pills and estrogen, for example. Obviously a person taking an elective drug must participate more fully in deciding whether to take it. Still another criterion is how long the drug is to be taken. A drug taken for long periods likely will pose a greater risk. Also, we would concentrate, at least at first, on drugs that have a significant share of the market.

Q. *If you had to put into a few sentences what you hope to accomplish with patient package inserts for prescription drugs, how would you put it?*

A. The most important goal is to allow more informed decision-making about a particular therapy so a patient can participate with his or her doctor in making a decision. Knowledgeable people are apt to take better care of themselves. So I view the patient package insert as an important element of health education, as part of a process that makes people much more curious and much more involved in their own health care and thus more likely to do things that will lead to better health.

Q. *We've discussed advertising in several contexts. What is your view of advertising?*

A. I begin with the premise that no one has the right to lie about a product, or to mislead people. In a complex world the Government must assure people that advertising is accurate. I think advertising is too little regulated now as it relates to health products. There are some very real questions in my mind as to whether some products should be advertised at all, or whether they should be advertised to certain groups of people, such as children. And often advertising does not provide the type of information needed for people to make informed judgments. That brings us back full cycle, in a sense, to labeling, because labels must provide full, accurate, balanced, objective information so people can decide in a rational way whether to buy a product. Advertising doesn't provide that kind of information.

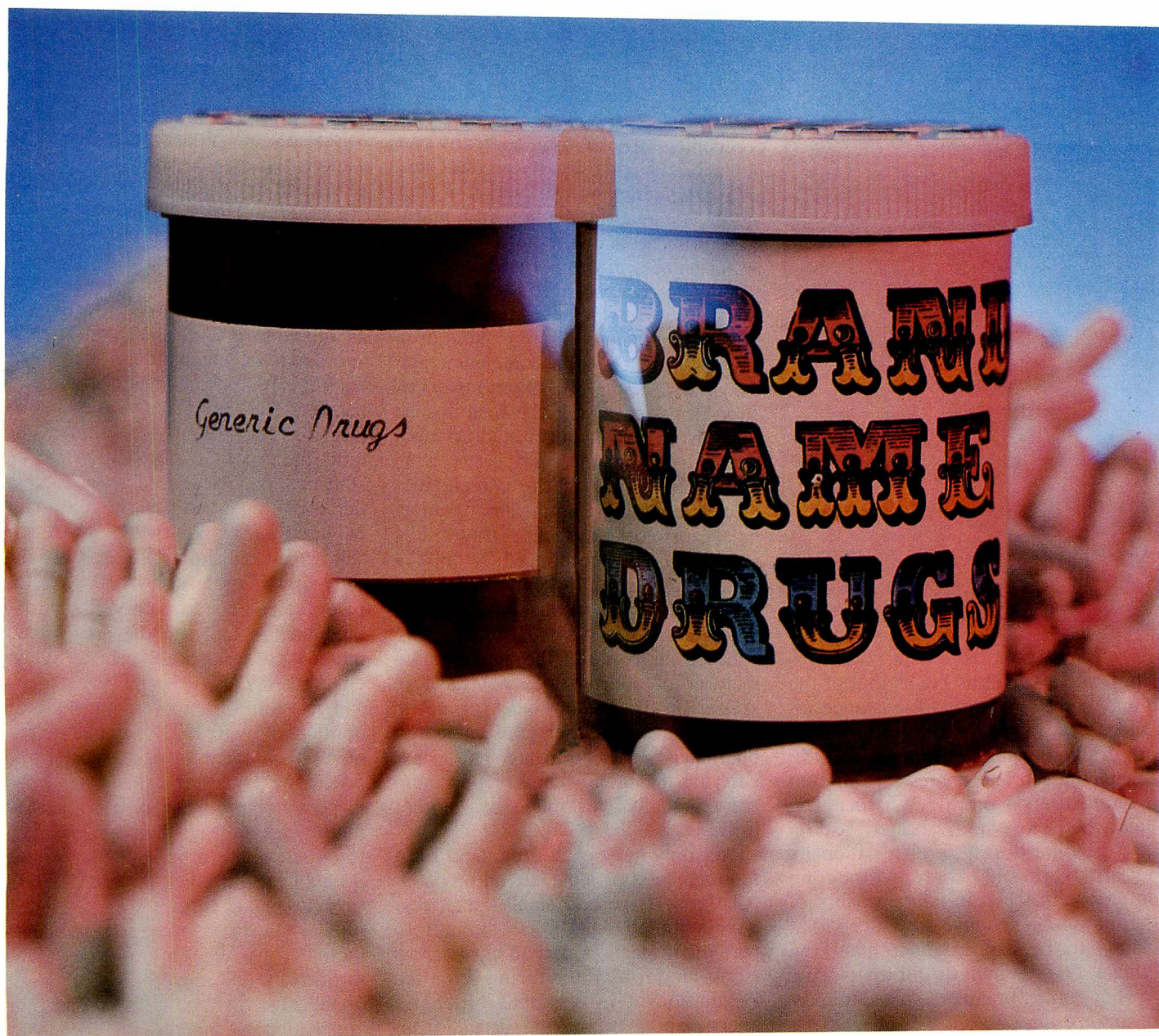
Q. *Do you think there can be too much label information?*

A. Yes, there can. We have to decide what really is important and what isn't, and concentrate on getting important information on product labels. We don't know enough right now about where the saturation point is and how people use information, so as we develop our labeling strategies we are going to have to evaluate each program.

Q. *Looking down the road a bit, when you leave this office, what would you like to have accomplished in the area of labeling?*

A. I would like to have revised our food statute to provide for more complete nutritional and ingredient listing. I would like to provide, either by statute or regulation, for increased information on both OTC and prescription drugs, with the emphasis on prescription drugs, because this is the area in which the most work needs to be done right now. I would also like to advance our knowledge about how people use information and how products should be labeled to allow people maximum capability to make informed choices in the marketplace.

Generic Drugs: How Good Are They?



by Annabel Hecht

All drugs, whether they are sold under their brand names or their generic names, must meet the same FDA standards for safety, strength, purity, and effectiveness. And all drug manufacturers, big or small, are subject to FDA inspection and must follow the Agency's Current Good Manufacturing Practice Regulations. That is why FDA believes there is no significant difference in quality between generic and brand name drugs.

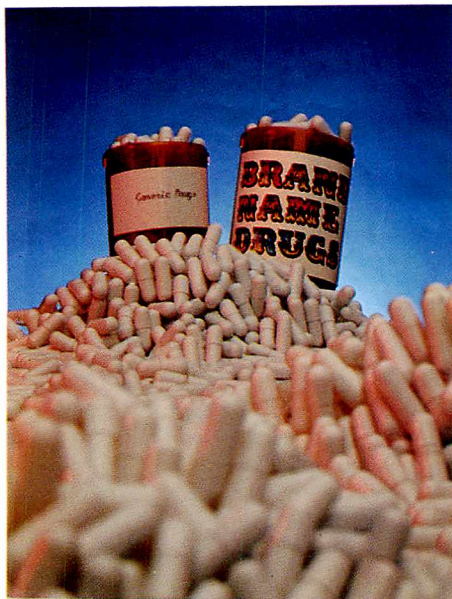
Are generic drugs as good as brand name products?

The answer to that frequently asked question is, for the most part, "yes," according to the Food and Drug Administration. As FDA Commissioner Donald Kennedy has said, "There simply is no evidence to support the notion of serious quality differences between generic and brand name drugs."

The differences are largely semantic. All drugs have a generic name, also called the "official" or "nonpropri-

tary" name. A generic name is assigned to a drug when it appears that it has some therapeutic usefulness. Newly developed drugs also are given brand or trade names. Unlike generic names which usually are contractions of a complex chemical name, brand names generally are short, easy to remember, and often devised to suggest the pharmacological action of the drug.

It is the brand name that is used to advertise a drug to the medical profession, although the generic name must appear in advertising and labeling in



letters at least half as big as that of the brand name. Aspirin, for instance, is the generic name for the leading non-prescription painkiller; Bayer and St. Joseph's are brand names for different manufacturers' aspirin. Whether you buy a bottle of "house brand" aspirin at a discount drugstore or a nationally advertised brand, there will be no difference in the pain-killing quality of the products because any drug that claims to be aspirin must meet the official FDA standards for that drug.

The same principle applies to prescription drugs.

Tetracycline is a widely used prescription antibiotic. A physician may write a prescription for this drug by its generic name, or may prescribe it under the brand names Achromycin, Sumycin, or Tetracyn. No matter what name is used, each drug must meet the same standards for tetracycline. (Antibiotics have an extra measure of assurance because every batch of antibiotics must be tested and certified by FDA before it can be sold.)

It is a popular misconception that brand name drugs are produced only by large, well-known firms, while generics are made by small, unknown

companies. A small drug company can put a brand name on its product just as a large company can market a drug under its generic name. And many large drug firms distribute, under their brand names, products that have been manufactured, packaged, and labeled by firms that make generic drugs. Some manufacturers may make a drug and sell it under both a trade name and its generic name. In other instances large firms may make the final dosage form from drugs purchased in bulk from other companies.

As an example of the complexities of drug marketing, ampicillin, a widely used antibiotic available under 224 product labels, is produced by only 24 formulators, and 219 conjugated estrogen products are produced by 45 manufacturers.

Since the name of the actual manufacturer of a drug does not have to appear on the product label (except in a few States), neither consumers nor pharmacists may be aware that a drug carrying the brand name of one company actually was made by another firm.

Not only must each drug meet FDA requirements, so must each drug plant. All firms—large and small—must register with FDA; all are subject to periodic inspection, and all must follow FDA Good Manufacturing Practice Regulations (GMP's) that touch on every aspect of making drugs, from building maintenance to quality control. These regulations apply to all producers and are intended to assure that all drugs meet the same standards of safety, strength, purity, and effectiveness. These requirements, in fact, were built into the 1962 amendments to the food and drug laws for the very purpose of encouraging physicians to make wider use of generic drugs in order to lower the cost of medical care, according to the co-sponsor of the legislation, the late Senator Estes Kefauver.

Other FDA standards provide further assurance of drug equivalence.

Before a new drug can be put on the market, the manufacturer must submit an application to FDA. It must include the results of tests carried out by the manufacturer in several phases—in the laboratory, in animals, and finally in human volunteers—which demonstrate that the drug is safe and effective for its intended use. If the application is approved the manufacturer may market the drug. If the manufacturer has patented the product, that manufacturer has the sole right to sell the drug until the patent expires. In some instances a patent holder may give other firms the right—usually in return for payment of a royalty—to make and sell a patented drug. Drug patents run 17 years. If there is no patent or the patent has expired, other firms may manufacture and sell the drug, either under its generic name or under different brand names.

These firms, however, must file an application with FDA giving details about their plants and personnel, and how they will make the drug. FDA inspectors visit these plants to determine whether they have the capability to produce the drug. Samples of the product are tested in an FDA laboratory to make certain they meet the official standards. While these manufacturers usually do not have to go through the full range of tests required of the firm that submitted the original application to market the drug, they may be required to carry out some studies to assure FDA that their products will be up to standards established for the drug.

Another assurance of drug quality stems from FDA's monitoring programs. FDA periodically collects samples of all drug products, both generic and brand name, from manufacturers and from the marketplace to test them for purity and strength. FDA has two specially equipped laboratories for this testing. The National Center for Drug Analysis in St. Louis, Missouri, does the bulk of this work, while about 10 percent is carried out by the Winches-

ter Engineering and Analytical Center near Boston. Automated equipment in these labs permits rapid analysis of many drug samples at the same time. When trouble is found or suspected, the drug company is notified immediately. Faulty products are removed from the market.

Batch testing and certification is required by law for insulin and for biological products such as vaccines and serums, as well as for all antibiotics. When FDA discovers particular problems with a drug, as it did for the heart drug digoxin a few years ago, it may require that each batch of that drug be tested before it can be released for sale.

Testifying before a Senate subcommittee, FDA Commissioner Kennedy noted that as far as quality is concerned FDA's analysis of drug samples revealed "no evidence of widespread differences between the products of large and small firms, or between brand name and generic name products." In regard to recalls of defective products, Kennedy said, "We are unable to conclude that there is any clear difference between large and small firms based on the recall record."

As better methods have been developed to determine how fast a drug dissolves, a new dimension has been added to FDA's testing program. Under new FDA regulations, manufacturers seeking Agency approval to market a new drug product or make changes in an existing product must conduct tests in human volunteers to determine how much of the active drug ingredient is absorbed by the body, how fast it is absorbed, and the length of time it circulates in the blood. This becomes the standard for that drug and other manufacturers who want to market the same drug are required to meet the same standard.

Certain drugs have shown inconsistencies in their absorption rate or in how long they remain in the bloodstream. For example, tests may have shown that different batches of the

FDA Endorses New York Equivalent Drug List

The Food and Drug Administration (FDA) has advised New York that the State's newly published drug list is an accurate guide to prescription drugs considered by FDA to be safe, effective, and equivalent in therapeutic performance.

FDA said that the New York drug list may be useful to other States which, like New York, allow pharmacists to substitute less expensive "generic" drugs for equivalent higher priced brand name products.

The New York drug list was prepared and issued as part of a new State program to reduce prescription drug costs without sacrificing quality.

Under the New York law, beginning April 1 physicians may, after notifying the patient, instruct the pharmacist to fill a prescription with a less expensive product provided it is listed in the State's list of drugs.

In explaining the significance of FDA's action, Commissioner of Food and Drugs Donald Kennedy said: "FDA concurrence in the New York list reflects the Agency's view that there is no consistent difference in quality between drug products sold by large and small firms or between drugs sold under a brand name or 'generic' name. We have a single standard for drugs in this country."

The Commissioner continued: "FDA plays no formal role in how prescriptions are written or filled. State laws govern whether pharmacists can use their professional judgment in substituting a less expensive product when a doctor writes a prescription for a more expensive one."

"The list compiled by New York State contains drug products we believe doctors can prescribe and pharmacists can dispense with confidence."

"States that permit substitution and want some assurance of therapeutic equivalence can use this New York State publication with knowledge that FDA has approved all the products on the list and the manufacturers listed have FDA approval to make them."

The New York drug list was compiled with FDA assistance after the State legislature enacted a law that requires all prescription forms used after April 1, 1978, to contain two signature lines for the physician. Beneath one line the words "substitution permissible" are imprinted; beneath the other are the words "dispense as written."

The doctor may sign either line. If the doctor decides that substitution is permitted, the pharmacists must substitute a less expensive product, provided it is on the State list.

As an example of how a drug is listed, tetracycline hydrochloride, a frequently prescribed antibiotic, is listed as being made by 26 manufacturers. Ten of those manufacturers are listed as selling the antibiotic under a brand name such as Achromycin, Panmycin, or Tetracycline, while the remaining 16 sell it under its generic name, tetracycline hydrochloride.

A drug product will remain in the official listing as long as there are no unresolved problems about its equivalence.

Commissioner Kennedy's endorsement of the New York State list was contained in a letter to State Health Commissioner Robert P. Whelan.



same drug made by the same manufacturer have differed in their absorption rate. In other instances, a drug made by one manufacturer may have shown a different absorption rate than the same drug made by another manufacturer. When this occurs, the drug is said to have "bioequivalence" problems, which means that there has been difficulty in assuring that different batches of the drug will always behave in the body in the same way.

The new FDA regulations spell out special procedures for drugs with known or suspected bioequivalence problems. Manufacturers wanting to market such drugs will have to conduct certain additional tests in humans and animals as well as in the laboratory. Batch-by-batch certification by FDA could be a part of the requirement if the Agency considers it necessary. After the requirements have been satisfied, FDA will continue to check on these drugs from time to time to make certain they are up to standard.

While most drugs do not pose "bioequivalence" problems, about 30 have been identified which will require additional tests for bioequivalence.

FDA's program to assure that generic drugs are as good as brand name products should be of more than pass-

ing interest to consumers, for it concerns their wallets as well as their health. Because generics generally are cheaper than their brand name equivalents, economists long have maintained that one way to help hold down the rising cost of medical care is to encourage physicians to prescribe drugs by their generic names, and to encourage pharmacists to fill prescriptions with the lowest-cost version of the prescribed drug.

There has been a growing movement among the States to overturn laws which forbid pharmacists from dispensing any version of a drug product other than that specifically prescribed by the doctor. Under such laws, if a doctor prescribes a certain brand of tetracycline a pharmacist cannot substitute generic tetracycline or even another brand, although they may cost less and are the chemical "twin" of the prescribed brand. Only twenty-one States still have these so-called anti-substitution laws. Some States that have relaxed them now permit the pharmacist to choose a substitute product unless the prescriber forbids it, while other States require a prescription form with two signature lines on which the prescriber must indicate approval or disapproval of substitution.

Even without changes in the law, generic prescribing is on the rise. A national audit of prescriptions filled in retail pharmacies showed that 86.5 million generic prescriptions were filled in 1976, nearly 12 percent of the total new prescriptions for that year. Ten years earlier generic prescriptions accounted for only 6.4 percent of the total. Another survey predicts that by 1985 the number of generic prescriptions will triple as drug patents expire. At present, of the 200 most frequently prescribed drugs, about 60 to 70 are available generically, but of these only 15 are prescribed with any frequency.

Antibiotics top the list of the 20 leading generic drugs. Prescriptions for the six most popular generic antibiotics totaled well over 46 million in 1976, representing 54 percent of all generic prescriptions.

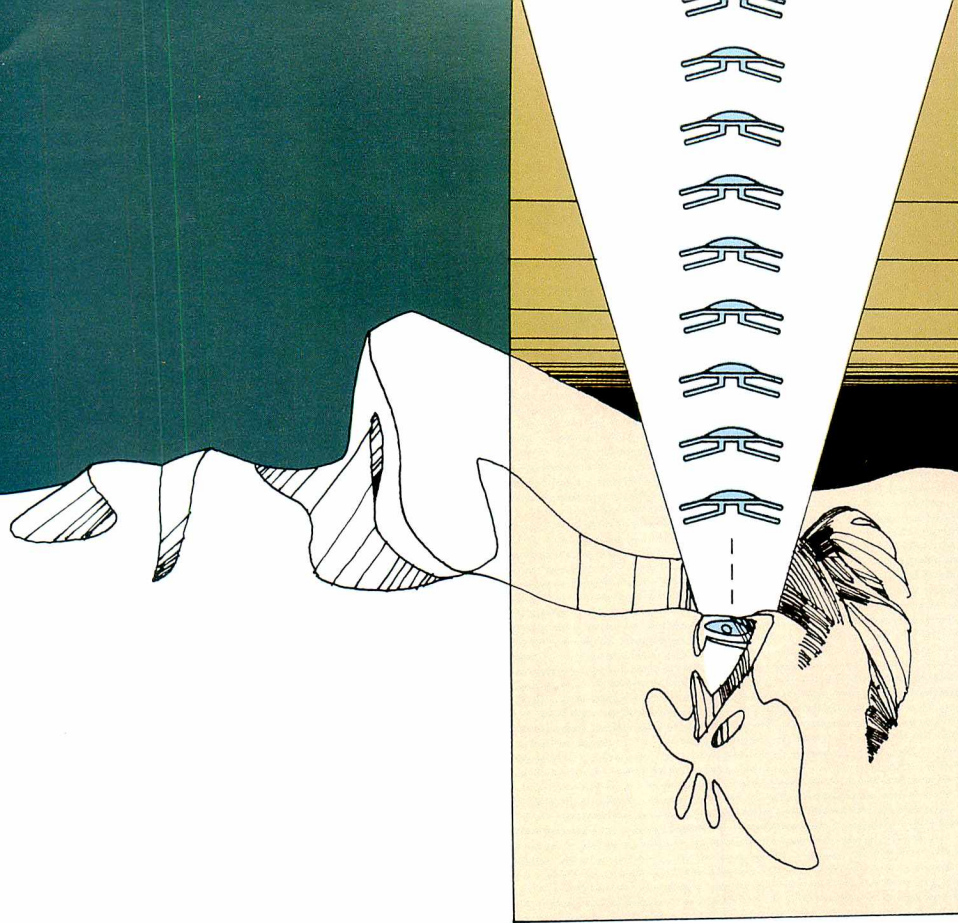
In the face of FDA's assurances that there are no differences between generic and brand name drugs, consumers might ask why physicians don't write more generic prescriptions. There is no single answer to that question. Some physicians may feel more confidence in the products of familiar drug companies. Others may not be aware of the difference in price between a brand name drug and its generic equivalent, or they may not know that a generic version of a particular drug is available. Patients who are concerned about their health care dollars may wish to ask their physicians to prescribe and their pharmacists to dispense generic drugs when they are available.

Another factor that plays an important role in influencing physicians' prescribing practices is the promotional activities of drug manufacturers. One form of this promotion is advertising in medical journals. Another is personal visits from representatives, called "detail men," who talk up their company's products and leave samples and attractive literature with the physicians they call on. A third channel of promotion is the PHYSICIANS' DESK REFERENCE, a publication made available without charge to physicians and pharmacists. Drug companies pay to have essential information about their products included in this valuable reference work. Those that do not pay do not have their products listed.

After years of this kind of promotion, it is little wonder that physicians tend to prescribe a drug by its brand name purely out of habit, even when a generic version is available.

As the public and the medical, pharmacy, and other health professions gain more understanding of the quality assurance programs enforced by FDA, generic prescribing and purchasing is likely to increase. The result should be lower cost, but equal quality health care.

Annabel Hecht is a staff writer with FDA's Office of Public Affairs.



Artificial Lenses For The Eye

Surgeons can replace the natural lens of the eye with a plastic one that restores vision to near normal for some cataract victims. These artificial intraocular lenses have produced good results but because there is no information on their long term safety FDA has issued regulations calling for studies in volunteer patients before the devices can be marketed for general use.

by James F. Greene

From Mary Shelley's tale of Frankenstein to television's saga of the Six Million Dollar Man, fictional scientists have tried to replace damaged body parts by substituting parts of other humans or using artificial replacements. In the real world of medicine such substitutes, whether a transplanted kidney or an artificial leg, are not improvements over the undamaged originals. But they do perform important functions that often allow the recipients to live near normal lives.

Such is the case with approximately 45,000 people in the United States who

last year underwent cataract surgery in which their natural eye lenses were surgically removed and replaced with permanent plastic substitutes called intraocular lenses. When cataracts develop, the natural lens of the eye becomes cloudy due to a chemical change in its molecular structure. Cataracts can be caused by exposure to radiation or certain toxic chemicals but the overwhelming majority occur as a natural part of the aging process.

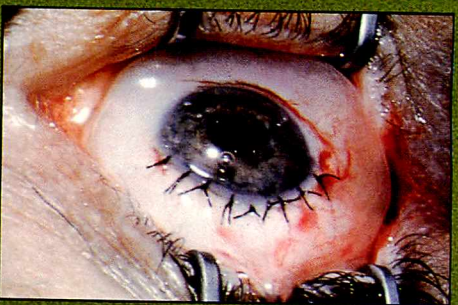
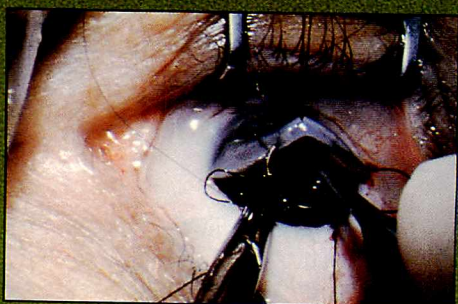
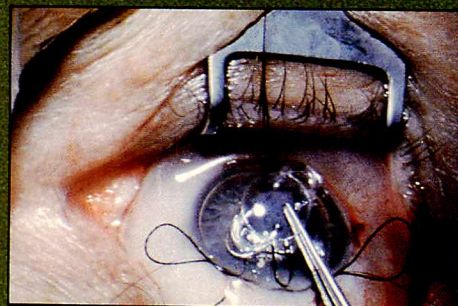
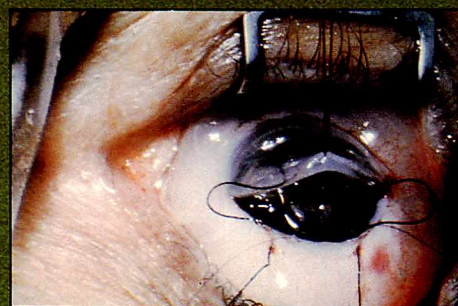
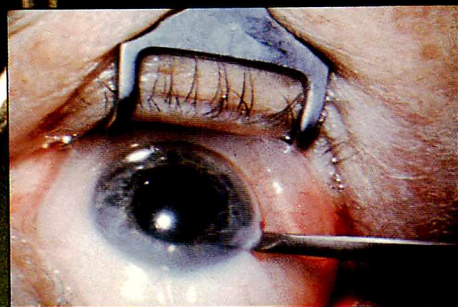
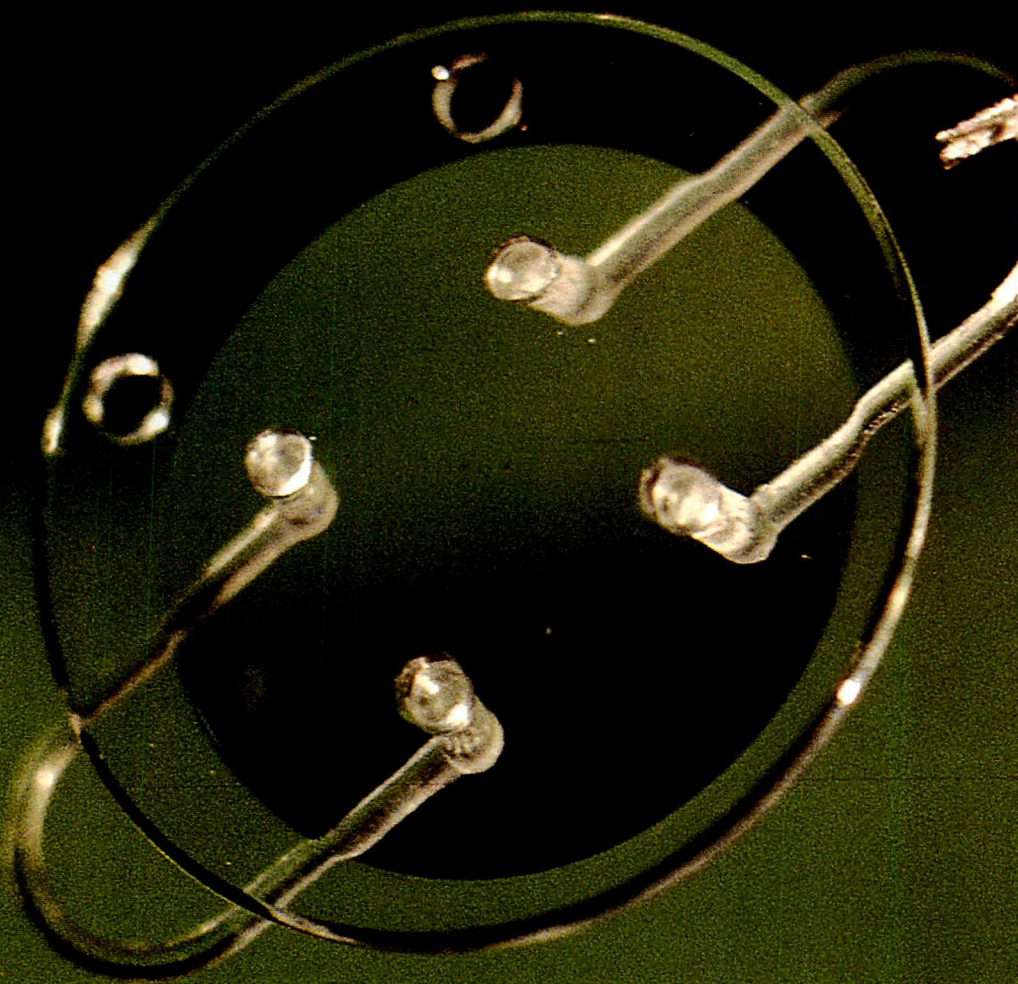
Of the nearly 400,000 people who last year underwent surgery for the removal of cataracts, about ten percent were fitted with intraocular lenses. People who are very nearsighted or have detached retinas, poorly controlled glaucoma or other eye diseases generally are not good candidates to wear the lenses.

Some people who have the artificial lenses implanted encounter various medical problems including adverse changes in the cornea, inflammation of the iris, and increased pressure in the eye which could lead to glaucoma. According to a 1970 study of 600

intraocular lens patients, six percent had to have their lenses removed for various medical reasons.

Nevertheless, for a growing number of patients, primarily the elderly, the lenses offer the best hope for near normal vision. Unlike the extra thick glasses that many cataract victims wear, intraocular lenses do not magnify images or seriously impair peripheral vision. Regular contact lenses produce less distortion than thick glasses and permit adequate peripheral vision, but many patients find them uncomfortable to wear and a nuisance to clean and store, or lack the steadiness of hand to position them in the eye.

Much of the research and development of intraocular lenses was done in the Netherlands, and until recently most lenses were manufactured in Europe. The lenses have been available for about 25 years, but they have been used more extensively in Europe than here. Over 100,000 people in this country now wear intraocular lenses and about 90 percent of them are between the ages of 65 and 85. About 80,000



If there are no complications, an eye surgeon usually can remove a diseased lens and replace it with an artificial implant in less than an hour. To remove the damaged lens and insert the artificial one, the surgeon makes a small incision at the edge of the patient's cornea. After the cataract has been removed, the cornea is held open and the intraocular lens placed in position. The incision in the cornea is then sutured, completing the operation.

had the lenses implanted within the last three years.

Although most intraocular lenses that have been implanted have worked out well, FDA considers them to be investigational devices because not enough scientific evidence has been collected and analyzed on their safety when worn over a long period of time.

FDA's position is backed by most surgeons who implant the lenses. For the most part the lenses are used only in elderly patients and then only in one eye, even if a patient has cataracts in both eyes. If studies of wearers over a period of years reveal no serious adverse effects, then surgeons probably would be much less hesitant about recommending the implants for people of all ages, including infants born with cataracts.

The rapid increase in the use of intraocular lenses in recent years has prompted FDA to issue a separate regulation governing the testing of the devices to assure their safety and effectiveness. Under the medical device law of 1976, intraocular lenses must be approved for safety and effectiveness by FDA before they can be commercially distributed. The premarketing approval process includes a requirement that the lenses be tested in volunteer patients.

Until enactment of the 1976 medical device law FDA did not have authority to require premarketing approval of medical devices. It could take action against medical devices only if they were shown to be ineffective or hazardous after being placed in general use. Intraocular lenses are one of the first medical devices for which FDA has established premarketing approval requirements under the 1976 law.

FDA's intraocular lens regulation, which went into effect in February 1978, sets requirements manufacturers must follow in testing their lenses. The requirements are similar to the procedures drug manufacturers must follow if they want to market a new drug in this country.

In addition to its regulation on testing of the lenses, FDA also has issued manufacturing guidelines to reduce the possibility that defective or bacterially

contaminated lenses will get into consumer channels. Last year a California manufacturer voluntarily recalled 7,500 lenses after FDA learned that at least 400 patients had suffered medical problems from wearing the lenses.

Manufacturers seeking FDA approval to market intraocular lenses must provide a detailed description of their plans to test their lenses in volunteer patients. Patients who consent to be part of the study will be chosen by qualified ophthalmologists who agree to implant the firm's lenses and to work with the manufacturer to perform the necessary followup studies over a period of 18 to 36 months. The followup studies will gather information on each patient's experience with the implanted lens, including any complications. It is largely on the basis of this information that FDA will determine whether a particular manufacturer receives approval for general marketing of its lenses.

Fifteen manufacturers, including three foreign firms, are expected to take part in the testing program, which will involve the implanting of more than 150,000 lenses at 2,500 hospitals across the country. During the testing, research monitors in FDA's Bureau of Medical Devices will routinely check the records of ophthalmologists to see that they match the information given to FDA by the manufacturers.

The American Intraocular Implant Society estimates that about 2,000 ophthalmologists in the United States are trained to implant these lenses. The implant usually is done immediately following removal of the diseased lens. The complete operation generally takes less than an hour and often is performed under a local anesthetic.

The surgeon, looking through a microscope, makes a tiny, curved incision between the cornea and the sclera. The cornea is the clear part of the eye that covers the iris and pupil and admits light to the interior. The sclera is the outer white part of the eye. Through this slit, the surgeon removes the diseased lens and inserts the plastic one, which is a quarter inch or less in diameter. The artificial lens is attached to the iris, a membrane of

muscular fibers in front of the natural lens which enables the pupil to dilate. Most lenses are either sewn onto the iris, or hooked over it with tiny nylon loops which protrude from the lens. A third type fits snugly—without loops or sutures—between the front edge of the sclera and the iris. This is the easiest lens to remove if complications arise. To remove any of the lenses, a surgical procedure similar to the one used to implant the lens is followed.

Intraocular lenses cannot change shape for focusing at different distances, as the normal lens of the eye can, so the artificial lenses are designed for either distant or close-up vision. The patient then wears the appropriate conventional glasses to compensate.

The most common problem with new implants is that they can become dislocated in the eye. This can happen to the clip-on type when the iris becomes too widely dilated, permitting the lens to slip back through the pupil.

A similar problem can be encountered with the lens which is wedged between the sclera and iris. In some cases slippage can cause damage to the eye and on rare occasions, loss of vision. In the majority of cases, however, the lens can be resealed by the ophthalmologist without surgery.

The use of any medical device implanted in the body involves a certain degree of risk. The decision to use an intraocular lens rests, as it should, with the patient and the physician. For elderly patients who decide that the chance for near normal vision for their remaining years outweigh any future risks, the implants are effective substitutes for the natural lenses they replace, and FDA's guidelines will help assure that they have been made in accordance with good manufacturing practices.

For future patients of all ages, the clinical testing and followup studies being carried out under FDA's regulations will help evaluate the risks of wearing the lenses over a long period of time.

James Greene is a staff writer with FDA's Office of Public Affairs.

News Highlights

Warning Label Proposed for Diet Protein

The Food and Drug Administration has proposed to require this warning label for all protein supplements intended for use in weight reduction or maintenance programs:

“WARNING—Very low calorie protein diets may cause serious illness or death. DO NOT USE FOR WEIGHT REDUCTION OR MAINTENANCE WITHOUT MEDICAL SUPERVISION. Do not use for any purpose without medical advice if you are taking medication. Not for use by infants, children, or pregnant or nursing women.”

The proposed regulation was published in the *FEDERAL REGISTER* December 2, 1977, with 30 days from that date allowed for public comment.

If adopted after FDA reviews the comments received, the warning would apply to protein products marketed as “liquid protein” solutions or as powders with instructions for mixing with a liquid. These protein products are commonly used to replace whole meals and some are promoted as the principal or sole source of nourishment.

FDA also proposed this label for all protein supplements not intended for use in weight reduction: **“WARNING—Very low calorie protein diets may cause serious illness or death. DO NOT USE FOR WEIGHT REDUCTION OR MAINTENANCE.”** FDA believes this additional warning is needed because many protein supplements that are not explicitly labeled for use in weight reduction are nonetheless used for this purpose by consumers.

FDA Commissioner Donald Kennedy, said:

“Many people are using low calorie protein diets for weight control without knowing the possible dangers of serious illness or even death. Many of the products used in these types of diets do not bear labeling to warn that they may be dangerous and that strict medical supervision is required. Neither does their promotion reflect the serious risks associated with indiscriminate use. Uniform, mandatory labeling is necessary to tell consumers of both the potential hazards and the need for physician care when using the products.

“If we determine that the risk to consumers cannot be controlled by labeling, then FDA will act to remove the products from the market.”

In addition to proposing the mandatory label, FDA asked for public and legal comment on the possible need for a banning action and the most appropriate statutory basis for such action if required.

The Agency further asked the medical community to supply all information available on adverse reactions.

FDA's actions on the protein diets are based on growing evidence of serious medical problems, including death, associated with their use. FDA has received information on

31 deaths with possible association to protein products. Of this number, 10 deaths have been categorized by the Center for Disease Control (CDC) as having a possible association with the use of the liquid protein products. Five among the 31 have been disqualified by CDC because they involved individuals with underlying medical conditions that cannot be separated from the protein diets as a possible explanation for death. The remaining 16 of the 31 cases are still being investigated.

FDA has also received 133 complaints of illness (including the 31 deaths) associated with use of special diet protein products. Side effects described in the accounts of illness include nausea, vomiting, diarrhea (particularly with liquid protein products), constipation (particularly with powder protein), cold intolerance, fatigue, irritability, euphoria, faintness, muscle weakness, potassium deficiency, and dehydration.

Immediately following a November 9 press conference alerting the public to the possible health hazards associated with the protein diets, FDA sent letters to manufacturers, repackers, and distributors of liquid protein products asking that they begin immediately to use a suggested label statement voluntarily. Only 13 of 97 firms contacted have acted to comply.

FDA, meanwhile, continues a major investigation of the protein diet industry and is inspecting manufacturing plants, testing products for content and quality, checking label claims for accuracy, and acting to inform health professionals of the facts as they become available.

‘Action Level’ Set on Aflatoxin in Milk

The Food and Drug Administration has established an “action level” for aflatoxin in whole milk, skim milk, and low-fat milk.

The action level is 0.5 part per billion (ppb). This means that FDA will prohibit the shipment in interstate commerce of milk that contains more than half a part of aflatoxin per billion parts of milk.

FDA established the action level because it appears that aflatoxin-contaminated corn is being fed to some dairy animals in the Southeastern United States. Adverse weather conditions and insect damage probably caused the 1977 corn crop in the Southeast to be significantly affected by aflatoxin.

Aflatoxin can get into milk if dairy animals consume feed contaminated with it. An FDA survey taken in Alabama, Georgia, and North and South Carolina indicated that of 302 milk samples collected, 19 or 6 percent had aflatoxin of 0.5 ppb or above.

Aflatoxin is a naturally-occurring carcinogen (cancer-causing agent) produced as a by-product of the growth of

certain molds. When dampness and other environmental conditions favor the growth of these molds, aflatoxin can contaminate corn, wheat, peanuts, cottonseed, rice, soybeans, and other foods. Aflatoxin has been shown to cause cancer and liver damage in test animals.

Aflatoxin is regulated as an unavoidable contaminant. The Food, Drug, and Cosmetic Act provides that FDA can set legal limits for food contaminants that cannot be avoided.

Donald Kennedy, Commissioner of Food and Drugs, said: "FDA will take necessary action against the shipment in interstate commerce of milk that violates this action level, and we are encouraging State governments to take similar action against milk in intrastate commerce that exceeds our action level.

"FDA already acts against the shipment in interstate commerce of food with more than 20 ppb of aflatoxin. The lower level for milk is being imposed because milk containing high levels of aflatoxin poses a special risk to infants and young children who may consume large quantities."

The action level for aflatoxin in milk was announced in a notice published in the *FEDERAL REGISTER*, December 6.

Sale of Poisoned Feed Brings Jail Terms

Punishment has been dealt out to two criminal offenders and potentially serious health and economic threats averted as a result of action by FDA and State agencies in breaking up a conspiracy to sell poisoned animal feed.

The case resulted in the conviction of Billy D. Hicks of McGehee, Arkansas, and Jesse P. Barnett, Jr., of Opelousas, Louisiana, for criminally conspiring to introduce poisoned cottonseed products into commerce for use in animal feeds. Judge William C. Keady of the U.S. District Court at Oxford, Mississippi, sentenced Hicks to three years and Barnett to six months imprisonment and each was fined \$5,000 plus about \$2,700 court costs. Judge Keady also fined Barnett & Sons Salvage Ltd., Opelousas, \$1,500 for shipping adulterated food and for misbranding, that is, concealing the true nature of the poisoned cottonseed.

The cottonseed had been treated with pesticides and originally was intended for planting. It is illegal for pesticide-treated seed to be diverted into animal (or human) food supplies. FDA requires that such treated seeds (mainly grains, legumes, oilseeds) be dyed a distinctive color such as red or blue to prevent accidental diversion into the food supply and that they carry labels specifying that they are for non-food use only.

In 1975 Hicks and Barnett agreed to pay Richard D. Flowers, president of Planter's Oil Mill, Tunica, Mississippi, for meal, hulls, and oil processed from poisoned cottonseed by the mill. Flowers bought the treated cottonseed from various sources.

Hicks and Barnett then contracted to sell 1,000 tons of cottonseed meal to Southern Feed Ingredients Co., Memphis, but did not tell the company that the meal was contaminated and in one instance assured the company it wasn't. The Memphis company then made agreements to sell meal to feed mills in Louisiana, Mississippi, Alabama, and Florida.

Invoices from Planter's Oil Mill and some bills of lading specified that the meal was not to be used for feeds or food, but this information apparently was not passed on by Hicks

and Barnett to the Memphis company nor later to the feed mills. A total of 12 carloads containing 850 tons of contaminated meal were shipped from Planter's Oil Mill to the feed mills.

The manager of one of these feed mills noticed that the meal had an unusual reddish color and sent a sample to the Mississippi Department of Agriculture whose labs found that it contained Disyston, an insecticide. State officials promptly notified FDA's Nashville District, which confirmed the contamination after obtaining samples of the meal from Planter's Oil Mill where it had been processed.

FDA then began a series of actions to remove the contaminated products from food supply channels.

Of the 850 tons of cottonseed meal sent to feed mills, seven carloads or about 600 tons were recalled intact and another 50 tons were recovered before being mixed into feeds. About 200 tons were processed into feed and of this amount about half was included in finished feeds withdrawn from food use. About 100 tons thus ended up in feed and was never recovered.

FDA believes its action in removing most of the contaminated cottonseed products from the market averted what could have been an "economic disaster" because of the poisoned products' potential to kill or injure dairy and beef cattle.

In addition to the conviction of Hicks and Barnett, the case also resulted in the issuance of FDA administrative letters to Southern Feed Ingredients Co. and MFC Services, two of the firms that agreed to buy the contaminated feed, pointing out that they were less than vigorous in assuring themselves and their customers that the meal was safe for feed use.

FDA also noted that Planter's Oil Mill, the facility where the poisoned cottonseed was processed, is now contaminated and should not be used to process seed for feed. Richard Flowers, president of Planter's, has not resumed processing at the mill since September 19 when the mill was visited by FDA investigators. The recalled products were returned to Flowers and subsequently seized by the Government; Flowers has entered into a consent decree agreeing to convert the products to fertilizer and other non-food uses.

Use of Six Colors in Drugs, Cosmetics Ended

The Food and Drug Administration has terminated, effective December 12, 1977, the provisional approval for six colors used in drugs and cosmetics. This means that the colors no longer are permitted to be used in drugs or cosmetics. The colors were not approved for use in food.

This action is another step in FDA's program to settle the status of all colors on the "provisional list" established by the 1960 Color Additive Amendments to the Food, Drug, and Cosmetic Act. These amendments require that colors for use in foods, drugs, or cosmetics be shown to be safe for their intended uses. Colors in use when the amendments were passed were permitted to continue to be used on a provisional basis pending additional safety testing. FDA approval of a provisional color for regular use means the Agency has been satisfied as to the color's safety. Removal from the provisional list without further approval means the safety of the color has not been established.

The colors terminated are External D&C Yellow No. 1;

D&C Blue No. 6 (except for one limited use); and D&C Red Nos. 10, 11, 12, and 13.

Yellow No. 1 and Blue No. 6 were used in drugs and cosmetics. (Blue No. 6 will continue to be permitted to be used as a color for surgical sutures.) The red colors had been used in a wide variety of cosmetics, including some that may be subject to ingestion, such as lipstick. They were also used in drugs.

The four red colors and Yellow No. 1 were terminated because they contain or are suspected of containing potentially cancer-causing substances. "Provisional" listing of D&C Blue No. 6 for drugs and cosmetics was terminated because manufacturers failed to submit required data by the dates set by FDA.

Notices of the termination of the six colors were published in the *FEDERAL REGISTER* on December 13, 1977.

In recent months FDA has terminated the provisional listing for three other colors used in drugs and cosmetics. These colors are bismuth citrate, External D&C Green No. 1, and graphite.

Since September 23, 1976, when FDA announced a schedule for resolving the status of 84 colors still on the "provisional list," 19 colors have been terminated, and 37 added to the "permanent" list. Twenty-eight colors remain on the "provisional list." Each of the 28 is to be dealt with according to an announced FDA schedule.

Cigarette Regulation Petition Denied

FDA has denied a petition, submitted by Action on Smoking and Health (ASH), asking the Agency to regulate cigarettes as a drug and to permit them to be sold only by pharmacies. ASH petitioned FDA on May 26, 1977, and submitted supplemental information November 15.

FDA denied the petition because ASH could not show that FDA has jurisdiction over cigarettes as a drug. FDA's position is that the Agency can regulate cigarettes as a drug only when health claims are made. While some courts have held that cigarettes are covered under the definition of a "drug" when the advertising suggests that they are effective in preventing diseases or makes other health claims (such as weight reduction), no court has held that cigarettes are a drug under the Food, Drug, and Cosmetic Act when no health claims are made.

ASH has informed FDA that it plans to submit another petition on the question of whether cigarettes or cigarette filters are medical devices. FDA will respond to it within 180 days after receiving it.

Study Data Awaited on Xylitol

FDA will decide whether any regulatory action is warranted on xylitol after the Agency receives final data from a safety study being conducted on the sweetener by a British laboratory.

Xylitol, a nonsucrose sugar, is used in this country only in "sugar-free" chewing gum. The gum contains only very small quantities of xylitol and FDA believes that any potential health threat from the sweetener is small.

Huntingdon Research Center of Great Britain is carrying out mouse and rat studies on xylitol for Hoffmann-La Roche, a firm that distributes the sweetener in the United States. Preliminary results from the mouse study showed a

substantial number of mice fed high doses of xylitol developed bladder stones late in their lives, and some mice with the stones developed bladder tumors. In the rat study, no bladder stones or tumors were found, but some rats had changes in their adrenal glands and in a few instances adrenal tumors. However, similar changes were found in rats fed another compound for comparison, suggesting that such changes may not be unique to xylitol.

FDA was unable to reach any conclusions on the basis of this preliminary data and is awaiting a final report from Huntingdon, which expects to complete its study early this year.

Xylitol was developed many years ago in Finland out of birch chips and berries. It has as many calories as ordinary sugar and the same sweetening power.

There are theories that xylitol may protect teeth from decay and for this reason it has been promoted for use in chewing gum.

In 1963, FDA issued a regulation giving limited clearance to xylitol for use in special dietary foods. In 1971, FDA proposed to revoke this clearance after learning of reports of adverse effects when xylitol was used as an intravenous solution. In its 1971 proposal FDA also reported that xylitol was not being used in special dietary foods.

In response to the FDA proposal, Hoffmann-La Roche asked that continued use of xylitol be permitted and began conducting studies to support its use in foods.

No final action was taken on FDA's proposal to revoke approval for xylitol's use in special dietary foods because the Agency needed more information about the sweetener's possible benefit in preventing tooth decay and its effect on diabetics. A study funded by the National Institute of Dental Health was designed to provide information in the first area. The Federation of American Societies for Experimental Biology (FASEB) is currently studying the effect of xylitol on diabetics.

Based on the British information, the National Institute of Dental Health suspended its study, in which xylitol gum was being given to about 1,000 children to determine the effect of the substance on the incidence of dental caries.

Nitrosamine Skin Penetration Under Study

FDA is giving high priority to a study designed to determine if nitrosamines in cosmetics can penetrate the skin and to the development of a method to measure nitrosamines in finished cosmetic products, particularly creams and lotions.

A study made by the Thermo Electron Research Center of Waltham, Massachusetts, and reported in March 1977 said that certain cosmetic products contained detectable amounts of nitrosamines, chemicals that cause cancer in animals when ingested. The chemical is not used as an ingredient in any cosmetic product but is believed to be formed in some products by the interaction of two or more ingredients.

Little is now known about the ability of nitrosamines to be absorbed into the body through the skin.

Lack of Gerovital Effectiveness Data Cited

There is no evidence at present that a drug known as Gerovital H3, which is promoted as being effective in

rejuvenating elderly people, is useful for that purpose, FDA has advised consumers.

FDA said it is concerned about the promotion and use of Gerovital for treating mental depression or manifestations of aging because it has not been adequately tested for these purposes.

Gerovital H3 is procaine hydrochloride, a drug that has been marketed as an injectable local anesthetic by many firms for many years in the United States. Procaine hydrochloride is sold under the brand name of Novocaine as well as other names.

Gerovital H3 is the trade name for a product promoted for many years by Dr. Ana Aslan of Rumania as being effective in treatment of various manifestations of the aging process. Patients come from all over the world to treatment centers in Rumania that specialize in the use of Gerovital H3. Many articles have appeared in the U.S. press on the use and effectiveness of Gerovital H3 as a rejuvenant in the elderly.

Dr. Aslan claims that Gerovital H3 is not ordinary procaine hydrochloride but that it has special qualities by virtue of its compounding. As far as FDA can determine, the drug is identical to procaine hydrochloride as used in the United States.

Several years ago, Rom-Amer submitted an Investigational New Drug Application (IND) to FDA seeking permission to study Gerovital H3 in depression in elderly patients. FDA was interested in ascertaining whether the drug is effective in the treatment of mental depression not only in the elderly but in other patients as well. FDA's Division of Neuropharmacological Drug Products spent considerable time advising the sponsor on appropriate study designs.

Rom-Amer sponsored several controlled double-blind studies but to date no acceptable studies have clearly demonstrated effectiveness. On December 30, 1976, the management of Rom-Amer sold the majority of its stock to Marvin Kratter, a real estate developer based in Nevada.

Last year, the Nevada State legislature enacted a law to legalize Gerovital H3 within the State (it was part of a Laetrile legalization law). In May 1977, after the law passed, Kratter notified FDA that Rom-Amer was discontinuing its clinical research program and withdrawing its IND. In a public statement Kratter had indicated his intention to market Gerovital H3 in Nevada.

FDA is closely monitoring Rom-Amer's operations within the State of Nevada to assure that the Federal drug law is not violated.

Effects of Therapeutic Iodine-131 Studied

FDA has awarded a contract to the Mayo Clinic, Rochester, Minnesota, to conduct a followup study of 3,100 women treated for thyrotoxicosis (hyperthyroidism) with radioactive iodine-131 or surgery.

Purpose of the study is to find out whether exposure to the radioactive material is related to an increased risk of death or sickness, particularly that due to cancer. This will be done by comparing the post-treatment medical history of patients treated with iodine-131 to that of patients treated by surgery.

Iodine-131 has been used as a treatment for hyperthyroidism since the late 1940's and is now considered the treatment of choice in most U.S. hospitals. In the late

1960's FDA sponsored the Cooperative Thyrotoxicosis Therapy Followup Study at 26 clinical centers, including the Mayo Clinic. That study provided medical data on some 36,000 persons treated for hyperthyroidism between 1946 and 1964, 19,000 of whom were treated with iodine-131. However, the followup period of 7 years was considered too short to adequately document the possible adverse effects of iodine-131 on health.

The present study will follow for an additional 8 years 1,000 of the women treated with iodine-131 and 2,100 treated surgically for hyperthyroidism at the Mayo Clinic. Medical charts of those still alive at the end of the first study in 1968 will be examined for medical and demographic information. Survivors will be located and sent a questionnaire, while information on those who have died will be obtained from death certificates and autopsy reports, if available.

Additional Data Sought on Epilepsy Drug

FDA has sent a letter to Abbott Laboratories identifying the additional information required by law that FDA needs to approve the drug sodium valproate for marketing.

Sodium valproate is an epilepsy drug for which Abbott has submitted a New Drug Application (NDA).

In the letter to Abbott, FDA said that:

- Valproic acid shows drug activity in patients with epilepsy.

- Abbott still needs to provide a second well-controlled study of the drug. At least two studies are required by FDA to approve a drug for general marketing.

- FDA is asking Abbott to submit the additional data as soon as it can be obtained.

- To shorten the overall review time, Abbott and FDA will begin work immediately on basic labeling for sodium valproate.

The additional data requested by FDA is expected to be available early in 1978, according to Abbott.

An FDA advisory committee has recommended that FDA approve sodium valproate. The committee, however, did not identify two studies demonstrating safety and efficacy. The committee apparently based its recommendation on its own expertise and on available data. FDA must meet minimum criteria set forth in the law and in FDA's own regulations concerning the need for two studies.

FDA's conclusion that two adequate studies do not exist is consistent with Abbott's own previous evaluation. In July 1977, Abbott advised FDA that it did not feel there were adequate studies to submit an NDA, and that it would not have sufficient data until mid-1978 or later. Abbott submitted the NDA after FDA asked to review available data. FDA has made no commitments to approve sodium valproate by any particular date.

Abbott, meanwhile, has been supplying sodium valproate with FDA approval as an investigational drug to physicians treating about 400 patients.

Abbott said it would expedite the submission of its data and that it would continue to make the drug available for investigational use.

Although sodium valproate has been available overseas since the late 1960's, no company in the United States showed any interest in marketing it until Abbott started research in 1975.

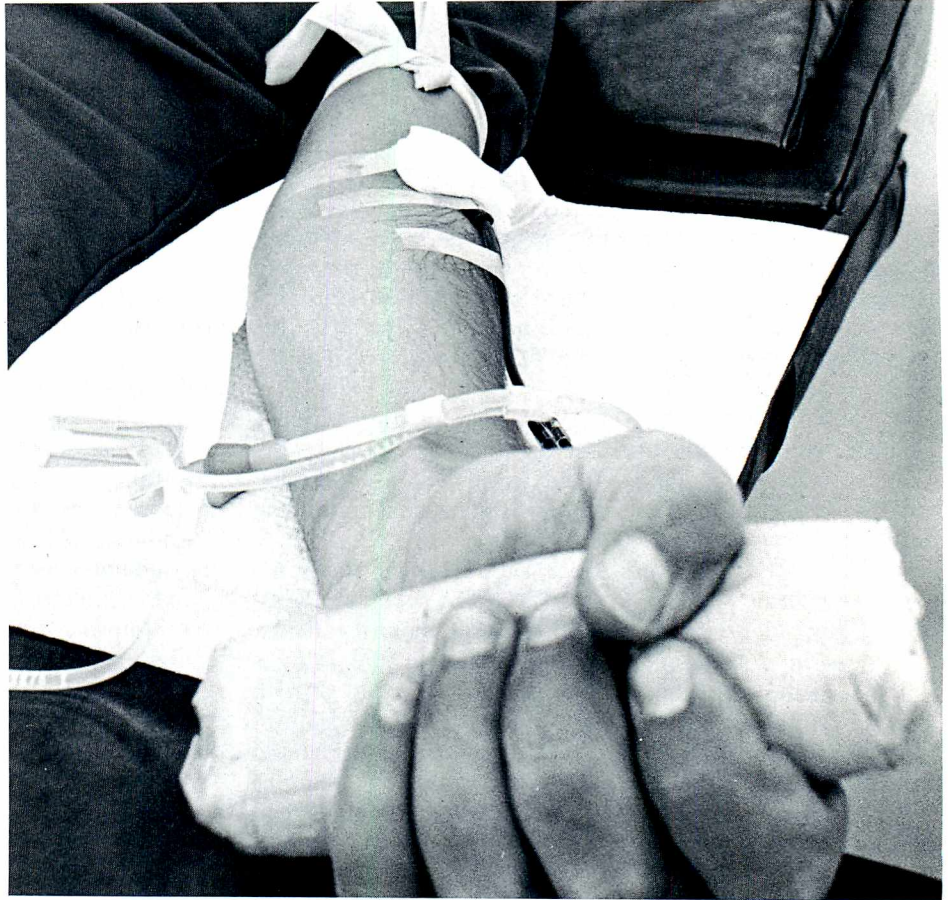
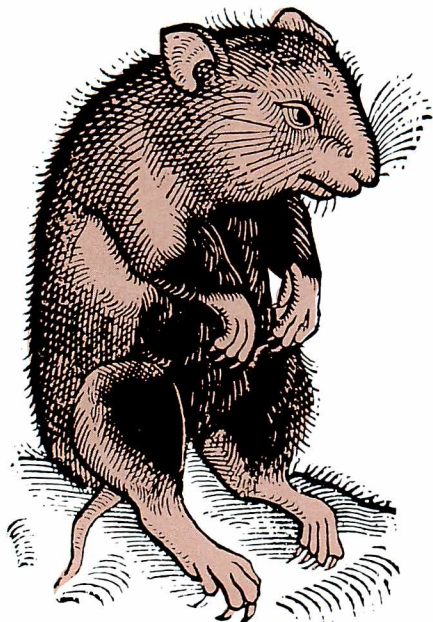
Regional Reports

"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

The Leavitt Corp., Everett, Massachusetts, and its president James Hintlian, were fined \$5,000 by Judge W. Arthur Garrity of the U.S. District Court of Massachusetts for allowing the firm's peanut butter processing equipment to become contaminated with insect filth. The court action resulted from inspections at the firm by FDA's **Boston District** based on a consumer's complaint that she found dead white worms in peanut butter processed by the firm. Subsequent analysis of samples of the product collected by the Boston District confirmed insect and rodent filth.



Hyman and Howard Rothstein, president and treasurer respectively of B. Rothstein and Company, Inc., Dorchester, Massachusetts, were each fined \$1,500 in the U.S. District Court of Massachusetts for allowing a shipment of flour in their warehouse to become contaminated with rodent and bird filth. In addition, the corporation was fined \$1,200. The contaminated flour was discovered by the Boston District during a routine inspection and led to a mass seizure of all foodstuffs at the warehouse. Both officials had pleaded guilty to the charge.

The Boston District detained nine mail shipments of a drug called Wobenzym at Boston's main post office because the drug has not been approved by FDA. The drug, offered for import from Germany, contained amygdalin, a substance often promoted as a cancer cure. The product was in tablet form and contained an insert saying it was useful in treating gout and the common cold.

REGION II

New Jersey, New York, Puerto Rico, Virgin Islands

A seizure of about 78,000 tablets was made by the Federal Government at Edom Laboratories, Deer Park, New York, after an investigation by FDA's **New York District** revealed they contained selenium, an unsafe food additive. The tablets, packed in bottles of 100, 250, or 500, were labeled as a dietary supplement. Even though FDA lists selenium as essential or probably essential in human nutrition, no U.S. Recommended Daily Allowance (RDA) has been established for it. The use of selenium as a dietary supplement is not generally recognized as safe because it has certain toxic potential. The investigation resulted from a consumer inquiry to the New York District about the legal status of the tablets.

Pioneer Blood Service, Inc., New York, has agreed to revise the labeling

it uses on units of recovered blood plasma to conform to FDA's Current Good Manufacturing Practice Regulations. Pioneer's labeling was deficient because not all units distributed by the firm included a date of collection; a list of the amount and kind of anticoagulant used in the plasma; the name and address of the manufacturer, packer, or distributor; and a statement of content by volume. In addition, the labeling failed to state that the plasma was intended for manufacturing use and did not bear a hepatitis warning statement. Recovered plasma is obtained from units of blood that are too old to be used for transfusions. The recovered plasma can be pooled and used in the manufacture of various therapeutic and diagnostic products if it meets certain FDA quality standards. The labeling violations were discovered by inspectors from FDA's Orlando District during a routine inspection of a blood storage facility in Orlando. They, in turn, notified the New York District where inspectors traced the plasma to the New York based firm.

FDA's Newark and New York Districts monitored the recall of all outstanding stocks of phenformin, a drug widely used in the treatment of diabetes. The recall stemmed from a decision by Joseph Califano, Jr., Secretary of Health, Education, and Welfare, to end marketing of the drug as an imminent hazard to public health. Phenformin has been associated with an unacceptably high risk of lactic acidosis, a metabolic disorder that is often fatal. Under the Secretary's order, doctors were given 90 days to arrange an orderly transition of their diabetes patients to insulin and other treatments. The recall in the **Newark District** involved Ciba-Geigy Corp., Summit, New Jersey, which sold the drug under the trade names of DBI and DBI-TD. The firm estimated there were about 11 million units in wholesale and retail channels. The New York District was responsible for monitoring the recall by the other manufacturer, USV Pharmaceutical Corp., Tuckahoe, New York, which sold phenformin under the name Meltrol. USV estimated that about 2.5

million dosage units remained on the market. Both firms agreed to contact by letter or personal visits all hospitals, pharmacies, and wholesalers in the United States, as well as doctors who purchased the drug, to direct them to return the product to the manufacturer.

Joint action by the United States Department of Agriculture (USDA) and FDA's **Buffalo District** resulted in the voluntary recall by Independent Buyers Association, Millbury, Massachusetts, of all stocks of IBA brand Neo-Tet tablets because of mislabeling violations. IBA is a private label drug distributor with independent franchises nationwide. The tablets contained the antibiotic tetracycline and are used to treat diarrhea in calves. The problem came to light after USDA inspectors during routine surveillance of a slaughterhouse in Marcy, New York, found traces of the antibiotic in the meat tissues from a calf. They notified FDA's resident post in Albany which traced the antibiotic to a farm in Millerton, New York, where the calf was raised. The investigation revealed the tablets used at the farm failed to include a label statement indicating that they should be withheld from animals thirty days prior to slaughter. After learning of the improper labeling, IBA's facility in Millerton notified its main office in Massachusetts. The firm then issued the recall of all stock which had been distributed in eleven States including New York, Massachusetts, Vermont, and Wisconsin.

Buffalo Labs, Inc., Paterson, N.J., voluntarily recalled and destroyed about 25,000 gallons of liquid predigested protein valued at about \$600,000 because of bacterial contamination. FDA became aware of the problem as the result of a consumer complaint to its Newark District about a swollen bottle of the liquid, which is used as an oral dietary food supplement. Samples of the product were collected by investigators from the Newark District, and laboratory analysis revealed bacteriological contamination, abnormalities in the plastic bottles, and wide variations in the acid level of the

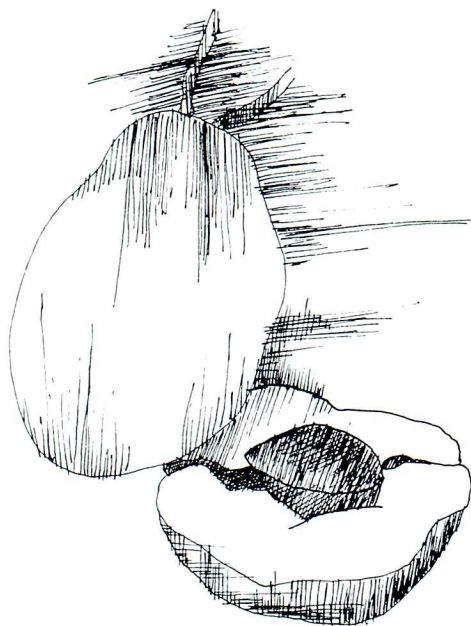
product, a condition not permitted in low-acid foods. The liquid protein had been manufactured by Peer Park Corporation in Hackensack, N.J., and was being repacked in plastic pint and quart bottles under Buffalo Labs' "Gro-Lean" liquid protein label and at least seven private labels.

Krall Manufacturing Inc., Brewster, New York, has complied with a preliminary injunction issued by the U.S. Court for the Southern District of New York requiring the company to discontinue the manufacture and distribution of products until the firm can comply with FDA's Good Manufacturing Practice Regulations (GMP's). Krall produces an annual volume of about \$750,000 in over-the-counter analgesics and other drugs, vitamins and dietary supplements in bulk form, and other food and drug specialties for private label customers. The injunction resulted from routine inspections conducted by FDA's Buffalo District that showed the firm was operating in serious violation of current GMP's for drugs. Among other violations, FDA found that one active ingredient was more than ten times too potent. FDA investigators also observed unclean equipment being used. The firm is attempting to salvage some of the raw materials and products under FDA supervision.

Tablicaps, Inc., Franklinville, New Jersey, voluntarily recalled about 500,000 tablets of ergotamine tartrate and caffeine, a prescription drug used for migraine headaches. The Newark District learned of the problem while following up a consumer complaint that the product was ineffective. Subsequent laboratory analysis showed the drug to be subpotent in ergotamine. The tablets, packaged in three sizes—100, 500, and 1,000 to a container—were sold under the manufacturer's label and six other labels, and bear the lot numbers 32106 and 31947.

REGION IV

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



South Carolina, Tennessee

A shipment of over 22,000 pounds of frozen fruit products, offered for import from the Dominican Republic, was detained at the Port of Miami by FDA's **Orlando District** because of decomposition. The shipment had been delayed at Port Everglades, Florida, because of a dock strike and the ship's refrigeration unit malfunctioned, causing the products, which included coconuts, mangoes, papaya, white malanga, and yams to thaw and decompose. A Miami-based food broker, who was to receive the products, notified FDA's Orlando District of the problem which then led to the FDA detention.

The Federal Government seized over 10,000 pounds of frozen breaded shrimp at a warehouse in Omaha, Nebraska, because of overbreeding. The shrimp, valued at nearly \$6,000, was packed by Deal's Seafood Co., Miami, Florida. FDA's Orlando District inspected the firm after receiving a trade complaint that the shrimp, which had been shipped to Omaha, was overbred. Laboratory analysis of other samples collected at the Miami firm revealed the product contained less than 42 percent shrimp. FDA requires that frozen breaded shrimp contain at least 50 percent shrimp. The seized shrimp was donated to Mount Michael Abbey and School, Elkhorn, Nebraska.

REGION VI

Arkansas, Louisiana, New Mexico, Oklahoma, Texas

A lot of nearly 280,000 bags of rice at the Port of Lake Charles, Louisiana, was fumigated by its owners, Cook Industries in Memphis, after inspectors of the Grain Inspection Division of the United States Department of Agriculture observed live insects on the outer bags. The Agriculture Department notified FDA's **Houston Section**, which confirmed the insect activity, but no actual infestation in the rice. The Agriculture Department monitored the reconditioning of the rice before allowing it to be exported.

REGION VII

Iowa, Kansas, Missouri, Nebraska

A lot of skin cream, valued at \$30,000, was seized by the Federal Government at Lander Co., Inc., St. Louis, following a series of inspections by FDA's **Kansas City District** which revealed the firm was manufacturing drug products without conforming to FDA's Good Manufacturing Practice Regulations. Investigators found that the conditions under which the drugs were manufactured were such that their identity, strength, quality, and purity could not be assured. The manufacturer was unable to propose a reconditioning plan acceptable to FDA to assure the quality and purity of the products. As a result the firm entered into a consent decree of condemnation in the U.S. District Court for Eastern Missouri and the cream was destroyed.

REGION VIII

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

A U.S. marshal seized a lot of approximately 4,200 pounds of colby cheese, valued at about \$5,600, at a warehouse in Spokane, Washington, after a series of inspections by FDA's **Denver District** revealed the cheese was prepared and packed under insanitary conditions at Dimock Dairy Products Co., Dimock, South Dakota. The cheese was produced during a period when the plant was infested with flies.

REGION IX

Arizona, California, Guam, Hawaii, Nevada

A lot of 152 bales of corn husks at Don Juan Foods, a packer and distributor of Mexican foods in Modesto, California, was seized by the Federal Government because of mold and insect contamination. The seizure resulted from an investigation of a consumer complaint by FDA's **San Francisco District**, which traced the contaminated corn husks to the Modesto firm. A followup seizure was made at the Casa Grande Tortilla factory in Sacramento where U.S. marshals seized the remaining 24 bales, which also were contaminated with mold and insects.

REGION X

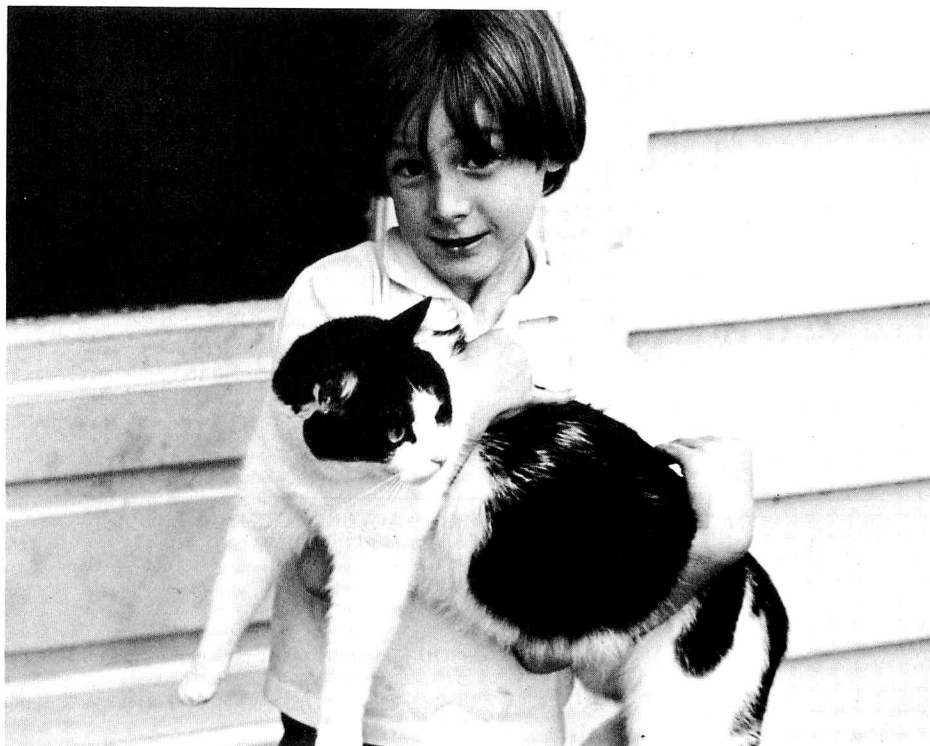
Alaska, Idaho, Oregon, Washington

A U.S. marshal in Seattle seized nearly 2,000 pounds of shelled Spanish peanuts in the possession of C. C. Grains, Seattle, because of rodent contamination. The seizure resulted from an inspection of the dealer by FDA's **Seattle District** which revealed rodent excreta on the peanut bags and rodent, bird, and insect activity in the storage area.

Clancy J. Meyer, owner of the New Health Food Store, Bellingham, Washington, has agreed in court to stop distribution of promotional literature which claimed that glandular concentrates sold by his firm could cure, treat, or prevent a wide variety of serious diseases including anemia, ulcers, cystic fibrosis, and colitis. In entering into a preliminary consent decree of injunction in the U.S. District Court for the Western District of Washington, Meyer agreed to cease distribution of the literature until the firm and the Government can resolve the dispute and enter into a consent decree of permanent injunction or the issue is settled by the court. The legal action resulted from inspections at the firm by the Seattle District which was based on a misbranding complaint by a local county health official. Investigators found that the claims were false.

and misleading in that they were not supported by sound scientific evidence that the tablets were safe and effective for their intended use. In addition, the investigators found that the labeling of the tablets failed to provide adequate directions for use to achieve the desired results.

A U.S. marshal in Boise, Idaho, seized a quantity of veterinary drugs including 45 one-gallon containers of Nitrosol and Bucoderm Suspension at Burns Veterinary Supply in Boise because the drugs have not been approved by FDA. The drugs had been shipped by Burns Biotec, Oakland, California, after the firm was advised by FDA's San Francisco District and Bureau of Drugs that the drugs were in violation of the Federal Food, Drug, and Cosmetic Act. The drugs were topical products intended for use by veterinarians in the treatment of small animals and horses.



State Actions

Corn Products Recalled

Midstate Mills, Inc., Newton, North Carolina, voluntarily instructed its 34 wholesalers to return all lots of Thrifty Maid, Tendabake, and Redimix brand products because of the possibility they were made with aflatoxin-contaminated cornmeal. Aflatoxin is a naturally occurring cancer-causing agent produced by molds which under certain conditions grow on corn, wheat, peanuts, rice, cottonseed, and other foods. Laboratory analysis of samples collected by the North Carolina Department of Agriculture at the firm revealed levels of aflatoxin in cornmeal and cornbread products in excess of the amount permitted by FDA regulations. In addition, the State embargoed 43,000 pounds of cornmeal and over 20,000 bushels of corn at Midstate Mills. FDA's Atlanta District is assisting the State by contacting firms in South Carolina and Georgia which may have received aflatoxin-contaminated lots from the Newton firm.

The X-way Milling Co., Laurinburg,

North Carolina, also agreed to recall products made from corn which may be contaminated after similar laboratory analysis by the State revealed excessive levels of aflatoxin in its products. The State also embargoed over 2,300 pounds of yellow cornmeal and nearly 260 bushels of corn at X-way Milling.

Adverse weather conditions and insect damage to the 1977 corn crop in the Southeastern United States has contributed to an unusually large amount of aflatoxin-contaminated corn. As a result, four of the biggest milling companies in North Carolina are requiring that all lots of corn they receive from suppliers be accompanied with certificates of aflatoxin analysis which show they are free of excess aflatoxin. FDA's Atlanta District is continuing to monitor removal from the market of all corn and corn products which contain excessive aflatoxin levels as well as milk products, which can become contaminated when cows eat animal feed containing unacceptable levels of aflatoxin.

Health Foods Misbranded

Emanuel H. Bronner pleaded no contest in the San Diego County Municipal Court to selling numerous adulterated and misbranded health foods and over-the-counter drugs and was fined \$1,000 and placed on three years probation. Most of the claims for the products were for treatment of mineral and vitamin deficiencies in the human body. Most of the products were subpotent in strength and the name and quantity of active ingredients were not disclosed on the labels. In addition, Bronner agreed to stop the marketing of over 20 of these products until their labeling could be brought into compliance with the California Health and Safety Code. The action resulted from a consumer complaint to the Food and Drug Section of the California Health Department about one of Bronner's health foods. Subsequent analysis of samples collected at Bronner's firm showed the products were in violation of the California Health and Safety Code.

Seizures and Postal Service Cases

SEIZURE ACTIONS charging violation of the Federal Food, Drug, and Cosmetic Act are published when they are reported by the FDA District Office.

A total of 31 actions to remove from the consumer market products charged to be violative was reported in November. These included 11 seizures of foods; 10 involved charges concerning contamination and 1 involved a charge concerning economic and labeling violations. Other seizures included 6 of food additives, 1 of animal feed, 7 of drugs (including 5 of veterinary), 4 of medical devices, 1 of prophylactics, and 1 of cosmetic.

| PRODUCT, PLACE & DATE SEIZED | MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D) | CHARGES |
|--|--|---|
| FOOD/Contamination, Spoilage, Insanitary Handling | | |
| Chilies, whole, dried/Brooklyn, N.Y. 9/12/77 | Gel Spice Co., Inc./Brooklyn, N.Y. (D) | Held under insanitary conditions. |
| Chocolate-flavored powder/Guaynabo, P.R. 8/26/77 | Caparra Milk Products, Inc./Guaynabo, P.R. (D) | Contains insect filth. |
| Coffee beans/New Orleans, La. 9/19/77 | Uiterwyk Corp./New Orleans, La. (D) | Held under insanitary conditions; some beans contained bird filth. |
| New Orleans, La. 9/19/77 | Imported from El Salvador. | Held under insanitary conditions. |
| Cookies, assorted/Puerto Nuevo, P.R. 8/8/77 | Freiria & Co., Inc./Puerto Nuevo, P.R. (D) | Held under insanitary conditions; contains insects. |
| Cornmeal, rice, flour, oat cereals, and other food stocks/Springfield, Ill. 8/9/77 | Springfield Produce, Inc./Springfield, Ill. (D) | Held under insanitary conditions; some foods are rodent gnawed. |
| Milk powder and chocolate-flavored powder/San Juan, P.R. 8/27/77 | Industria Lechera de Puerto Rico, Inc./San Juan, P.R. (D) | Held under insanitary conditions; contain insect filth. |
| Mung beans, dried/Commerce City, Colo. 9/7/77 | Shipped from Drummond, Okla. | Held under insanitary conditions; contains insects. |
| Potato flakes/Rupert, Idaho 9/6/77 | Magic Valley Foods, Inc./Rupert, Idaho (M,S) | Prepared and packed under insanitary conditions; contains <i>E. coli</i> and bacterial filth. |
| Salmon, dressed, frozen/Seattle, Wash. 8/3/77 | Shipped from Anchorage, Alaska. | Contains decomposed salmon. |
| Economic and Labeling Violation | | |
| Shrimp, raw, breaded, frozen/Tampa, Fla. 9/7/77 | Variety Frozen Foods, Inc./Tampa, Fla. (M,S) | Article fails definition and standard of identity for frozen raw breaded shrimp, since article tests less than 50% of shrimp material; label fails to bear name of food, frozen raw breaded shrimp; quantity of contents statement not within bottom 30% of principal display panel area, and is in too small type. |
| FOOD ADDITIVES | | |
| Ginseng capsules, Korean/Denver, Colo. 8/4/77 | Encapsulations, Inc./Newark, N.J. (M,S) | Contains the nonconforming food additive ginseng. |
| Ginseng powder in oil capsules/Greenville, S.C. 8/1/77 | Pharmacaps Inc./Elizabeth, N.J. (M,S) | " |
| Ginseng tablets/Madison Heights, Mich. 8/16/77 | Chase Chemical Co./Newark, N.J. (M,S) | " |
| Lemon flavor mix, Cramores Crystals/Everett, Mass. 7/6/77 | A-W Brands, Inc. (Cramore Products, Inc.)/Carteret, N.J. (M,S) | Contains the nonconforming food additive saccharin and the saccharin is not for a valid special dietary purpose. |

| PRODUCT, PLACE & DATE SEIZED | MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D) | CHARGES |
|--|--|--|
| Selenium tablets, ginseng tablets, RNA tablets, Arthril vitamins, and Head Start tablets/Atlanta, Ga. 9/19/77 Selenium, chromium, yeast & vitamin combination tablets/San Juan Capistrano, Calif. 7/14/77 | Braswell, Inc. t/a Cosvetic Labs, Inc.; Earthquest, Ltd.; and Quest Research, Inc./Atlanta, Ga. (D) Rajar Enterprises, Inc./San Juan Capistrano, Calif. (D,M) | Contain the nonconforming food additives ginseng, selenium, RNA, copper proteinate, dried yucca plant, and chelated trivalent chromium proteinate. Contains the nonconforming food additives selenium, dl-methionine, and aspartic acid. |
| ANIMAL FEED | | |
| Schalick medicated veal formula/Elmer, N.J. 10/21/77 | Schalick Mills/Elmer, N.J. (D); Milk Specialties Co./Dundee, Ill. (M,S) | The article contains a new animal drug and no New Animal Drug Application is in effect with respect to its use and intended use; and it was held under insanitary conditions and contains rodent and insect filth. |
| DRUGS/Human Use | | |
| Amygdalin tablets and ampoules/Baltimore, Md. 8/5/77 | Cyto Pharma De Mexico, S.A./Tijuana, Mexico (M) | The strength of some of the tablets differs from that which it purports and is represented to possess; the circumstances of the articles' manufacture, processing, packing, and holding were not in conformity with current good manufacturing practice; tablets are dangerous to health when used in the manner and with the frequency and duration prescribed, recommended, and suggested in the labeling; articles are new drugs without effective Approved New Drug Applications, and were intended for distribution to persons other than those for whose benefit the articles were imported. |
| Aromatic ammonia ampoules/New York, N.Y. 9/14/77 | Jersey Analytical Services /Andover, N.J. (M); James Alexander Corp./Hackensack, N.J. (P,S) | Circumstances of article's manufacture, processing, packing, and holding not in conformity with current good manufacturing practice; quality falls below its purported quality, since it fails to contain lavender oil, lemon oil, and nutmeg. |
| DRUGS/Veterinary | | |
| Dexamethasone sodium phosphate injection/Strongsville, Ohio 9/14/77 | Lypho-Med, Inc./Chicago, Ill. (M,S) | New animal drug and no New Animal Drug Application is in effect with respect to its use or intended use. |
| Mange preparations (Para-Mite, Otocide, Demolene), electrolyte solutions (Bal-Con, Polylites), vitamin injections (vitamin B ₁₂ , Hydro C), Fer-Co caco-iron & copper injectable, Para dust for ticks, fleas, & lice, and Syn-Aspra-Ject sodium thiosalicylate injection/Baton Rouge, La. 9/27/77 | Hart-Delta, Inc./Baton Rouge, La. (M,D) | New animal drugs and no New Animal Drug Applications are on file with respect to their use or intended use; circumstances of manufacture, processing, packing, and holding of one lot of vitamin B ₁₂ injection failed to conform with current good manufacturing practice. |
| NF-180 concentrated premix/Russellville, Ark. 7/18/77 | Rhodia, Inc., Hess & Clark Div./Ashland, Ohio (M,S) | New animal drug and no New Animal Drug Application is in effect with respect to its use or intended use. |
| Nitrofurazone, N.F./Modesto, Calif. 9/14/77 | H. Reisman Corp./Orange, N.J. (S); Aceto Chemical Co., Inc./Flushing, N.Y. (S); Helm Chicago Chemical Corp./Chicago, Ill. (S) | " |
| Nitrofurazone soluble dressing/Strongsville, Ohio 9/14/77 | Performance Products, Inc./St. Louis, Mo. (M,S) | " |

| PRODUCT, PLACE & DATE SEIZED | MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D) | CHARGES |
|---|--|--|
| MEDICAL DEVICES | | |
| Diapulse devices/Balch Springs, Tex. 7/7/77 | Diapulse Corp. of America/New Hyde Park, N.J. (M) | Labeling fails to bear adequate directions for use. |
| Norfolk, Va. 8/17/77 | " | " |
| Brooklyn, N.Y. 8/5/77 | " | " |
| Kernersville, N.C. 9/15/77 | " | " |
| Prophylactics | | |
| Prophylactics, rubber, Korona & Tops/ Kansas City, Mo. 9/14/77 | M & M Rubber Co./Kansas City, Mo. (D) | Quality falls below purported quality, since an excessive number of units are defective. |
| COSMETIC | | |
| Eye-Lift eye makeup remover/Los Angeles, Calif. 7/14/77 | Beauty Aids, Inc./Los Angeles, Calif. (D,M) | Cosmetic which is not a hair dye, bears and contains the nonconforming color additive FD&C Yellow No. 5, in that its use and intended use is in the area of the eye. Labeling is false and misleading in that the label statement "non-allergenic" represents and suggests that the article may be used by any individual at any time without potential for allergic reaction. The label also lacks a quantity of contents statement, and lacks the identity of the article (i.e., eye makeup remover) on the principal display panel. |

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)

- October 20, 1977: **Meade-Wilson Pharmacal**, Caroline Road, Philadelphia, Pennsylvania. Advertising and sale through the mail of the product "TCP Pills and Weight Loss Program" representing the ability to cause weight loss.
- October 20, 1977: **Permanent Reducing Plan**, Caroline Road, Philadelphia, Pennsylvania. Advertising and sale through the mail of the product "Permanent Reducing Pill Dietary Aid and Weight Loss Program," representing the ability to cause weight loss.
- October 21, 1977: **American Image Industries, Inc.**, 276 Park Avenue South, New York, New York. Advertising and sale through the mail of the products "Sauna Arm Belt" and "Sauna Trim Belt," representing the ability to cause weight loss.
- October 25, 1977: **The Amphenol Co.**, P.O. Box 40-2038, Miami Beach, Florida. Advertising and sale through the mail of the product "Amphenol Diet Pill," representing the ability to cause weight loss.
- October 26, 1977: **All Products Unlimited, Inc.**, P.O. Box 370-162, Miami, Florida. Advertising and sale through the mail of a "Magnetic Bracelet" product, representing the ability to cause the relief of arthritis and bursitis.
- November 9, 1977: **Dr. Knoll Products**, P.O. Box 116, Canfield, Ohio. Advertising and sale through the mail of the products "Ginroy," "Royal Jelly," and "Pollen Tablets," representing the ability to aid in the vitality, rejuvenation, and overall health of the body.
- November 10, 1977: **Wilmont Products**, 8831 Sunset Blvd., Suite 300, Los Angeles, California. Advertising and sale through the mail of the product "Stud" capsules, representing the ability to increase male sex drives, and cause greater, stronger erections in men.
- November 10, 1977: **Meade-Wilson Pharmacals**, Caroline Road, Philadelphia, Pennsylvania. Advertising and sale through the mail of a product consisting of a pamphlet and capsules; representing the ability to cause the user to stop smoking permanently.

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

- November 7, 1977: Against **P&D Distributors**, P.O. Box 35930, Los Angeles, California. Advertising and sale through the mail of the product "Penis-Stretch," representing the ability to increase the length of the penis.

Notices of Judgment

NOTICES OF JUDGMENT ON Seizure Actions FOOD/Poisonous and Deleterious Substances

Beer, Rainier Mountain, at Portland, Dist. Oreg.

Charged 4-15-77: when shipped by Rainier Brewing Co., Seattle, Wash., the article contained an added deleterious substance, glass fragments, which might render it injurious to health, and the article was unfit for food due to the glass fragments; 402(a)(1), 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 61176; S. No. 77-07-182; N.J. No. 1)

Mung beans, at Sacramento, E. Dist. Calif.

Charged 3-23-77: when shipped by Buakao Co., Ltd., Bangkok, Thailand, the article, labeled in part "Lotus of Thailand . . . Packed For Consolidated Import Products of Thailand," bore or contained the pesticide chemical endrin, and there was no tolerance or exemption therefrom for such pesticide chemical in or on mung beans; 402(a)(2)(B). Consent decree authorized release to Wonda Pakt Foods, Sacramento, Calif., for salvaging. (F.D.C. No. 61123; S. No. 77-50-356; N.J. No. 2)

FOOD/Contamination, Spoilage, Insanitary Handling

Almonds, shelled, at Minneapolis, Dist. Minn.

Charged 3-21-77: while held by National Warehouse, Inc., Minneapolis, Minn., the article was held under insanitary conditions; 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 61128; S. No. 77-98-377; N.J. No. 3)

Barley, malted, at West Bend, E. Dist. Wis.

Charged 9-24-76 and 11-4-76: while held by West Bend Malt & Grain Co., Inc., West Bend, Wis., some lots of the article contained insect and rodent filth, and all lots of the article had been prepared and held under insanitary conditions; 402(a)(3), 402(a)(4). Industrial By-Products Inc., Kalamazoo, Mich., claimed the article and admitted to the charges. Subsequently, Michigan Agricultural Commodities, Inc., Lansing, Mich., was substituted for Industrial By-Products, Inc. The substituted claimant claimed the article as owner by assignment, adopted as its own the answers of the original claimant, and entered into a consent decree of condemnation. Such consent decree authorized release of the article to the substitute claimant for denaturing, heat treating, and conversion to animal feed. (F.D.C. No. 60929; S. No. 77-30-615; N.J. No. 4)

Cinnamon quills, at Houston, S. Dist. Tex.

Charged on or about 1-20-77: while held by Strachan Shipping Co., Houston, Tex., the article contained bird filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 61057; S. No. 77-23-143; N.J. No. 5)

Cookies, and tamale pie dinner mix, at Puerto Nuevo, Dist. P.R.

Charged 6-17-77: while held by Freiria & Co., Inc., Puerto Nuevo, P.R., the articles contained insects, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61268; S. Nos. 77-83-458/9; N.J. No. 6)

Figs, dried, at Eugene, Dist. Oreg.

Charged 2-16-77: when shipped by Simone Fruit Co., Inc., Fresno, Calif., the article, labeled in part, "Mr. Fig Organic Farmer . . . Organically Grown Dried Fruit Packed By Simone Fruit Co., Inc., Fresno, Calif.," contained decomposed and moldy figs; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 62050; S. No. 77-53-367; N.J. No. 7)

Flour, 2 lots, at Sikeston, E. Dist. Mo.

Charged 7-21-77: while held for sale in two railcars, the article contained insects, and one lot of flour contained flakes of foreign material (which bluish material had flaked off from the bluish coating of the interior surface of the railcar); and both lots of the article were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree authorized release to U.S. Marshal for sale for purposes other than human consumption. (F.D.C. No. 61339; S. No. 77-16-135; N.J. No. 8)

Oat cereal, and white popcorn, at Centralia, E. Dist. Ill.

Charged 1-18-77: while held by Kohl & Meyer Co., Centralia, Ill., the articles contained insect filth, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree authorized donation

to a Government agency for wild animal feed. (F.D.C. No. 61067; S. Nos. 77-10-634/5; N.J. No. 9)

Peanuts, at Suffolk, E. Dist. Va.

Charged 4-14-77: when shipped from, or while in transit from, Cordele, Ga., the article had been held under insanitary conditions; 402(a)(4). Consent decree authorized release to Williams Peanut Co., Inc., Cordele, Ga., for reconditioning. (F.D.C. No. 61142; S. No. 77-60-606 et al.; N.J. No. 10)

Peppers, jalapeno, pickled, at San Antonio, W. Dist. Tex.

Charged 6-6-77: while held for sale, the article contained decomposed jalapeno peppers, and the article was unfit for food due to being held in swollen and detinning cans; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61224; S. No. 77-26-861; N.J. No. 11)

Popcorn, at St. Louis, E. Dist. Mo.

Charged 6-3-77: while held by United Fruit & Produce Co., St. Louis, Mo., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree authorized delivery to a Government agency for feeding to animals or fowl not held for human consumption. (F.D.C. No. 61241; S. Nos. 77-85-127/8; N.J. No. 12)

Popcorn, white, and yellow popcorn, at Winona, Dist. Minn.

Charged 7-27-76: when shipped by Quinn Popcorn Co., Inc., Lakeview, Iowa, the articles contained insects; 402(a)(3). Consent decree authorized release to Watkins Products, Inc., Winona, Minn., for reconditioning. The reconditioning being unsuccessful, the articles were destroyed. (F.D.C. No. 60821; S. Nos. 76-31-062/3; N.J. No. 13)

Sesame seeds, at Cambridge, Dist. Mass.

Charged on or about 11-19-75: while held for sale, the article had been held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60528; S. No. 76-05-375; N.J. No. 14)

Thyme, cinnamon quills, cumin powder, yarrow, peppermint, annatto seeds, curry powder, and other spice and natural food stocks, at San Francisco, N. Dist. Calif.

Charged 1-27-77: while held by San Francisco Herb & Natural Food Co., San Francisco, Calif., some of the articles contained rodent and/or insect filth, and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 62011; S. No. 77-50-108 et al.; N.J. No. 15)

FOOD/Economic and Labeling Violations

Mixed nuts, Thrifty, at Kentwood, W. Dist. Mich.

Charged 5-19-77: while held by Thrift Products Co., Kentwood (Grand Rapids), Mich., who packed the article using peanuts which had been shipped in interstate commerce, the article failed to conform to the definition and standard of identity for mixed nuts, since it contained less than 2% by weight of the nut ingredients almonds and filberts, and since it and its label lacked a statement such as "contains up to 70% peanuts" required for such mixed nuts exceeding 60% total peanut content by weight; 403(g)(1), 403(g)(2). Consent decree authorized release to packer for bringing into compliance. (F.D.C. No. 61213; S. No. 77-68-402; N.J. No. 16)

Pepperoncini, pickled, Gloria, at Boston, Dist. Mass.

Charged 5-9-77: while held by Gloria Packing Corp., Boston, Mass., who had packaged the article, the article was short in volume; 403(e)(2). Consent decree authorized release to the packager for reconditioning. (F.D.C. No. 61225; S. No. 77-91-942; N.J. No. 17)

Pepperoncini, pickled, 2 lots, at Wilmington, Dist. Mass.

Charged 10-12-76: while held by Triangle Import Corp., who had repacked both lots of the article, the article (which was labeled in part "Trico Imported Pepperoncini . . . Packed by Triangle Import Corp., Wilmington, Ma.," or "Oxford Pepperoncini . . . Distributed by Oxford Pickle Co., Inc., Ayer, Mass.") was short in volume—403(e)(2); and both lots of the article were also in violation of the Fair Packaging and Labeling Act, since the labels used the term "Net Wt" with respect to the declaration of net quantity of



contents in terms of fluid ounces, and since the quantity of contents statement, appearing on the principal display panel area not more than 25 inches square was in a type size less than 1/8 inch high—15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Consent decree authorized release to the packer for bringing into compliance with the law. (F.D.C. No. 60947; S. Nos. 77-80-624/5; N.J. No. 18)

Syrup, at Chattanooga, E. Dist. Tenn.

Charged 5-26-77: when shipped by Racoon Mountain Sorghum Syrup Co., Pisgah, Ala., the article, labeled in part "Racoon Mountain Sorghum Syrup . . . Kenneth Farmer Pisgah, Al . . . Ings. 100% Pure Corn Sweetener and Pure Sorghum Molasses," was represented as sorghum syrup, but failed to conform to the definition and standard of identity for sorghum syrup because it contained corn syrup; 403(g)(1). Default decree authorized donation to charitable institution for consumption only. (F.D.C. No. 61232; S. No. 77-32-196; N.J. No. 19)

Syrup and honey mixture, at Princeton, S. Dist. Fla.

Charged 2-7-77: when shipped by Pakhoed Rotterdam, Rotterdam, Holland, the article, labeled in part "Pure Honey Nett Weight 650 Lbs. R dam," had had syrup substituted in part for honey; 402(b)(2). Default decree ordered destruction. (F.D.C. No. 60984; S. No. 77-43-445; N.J. No. 20)

ANIMAL FEED

Skim milk, tallow & lecithin mix, at Minneapolis, Dist. Minn.

Charged 3-29-77: when shipped by Morelli's Overseas Export, Kenosha, Wis., the article contained rodent filth, and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Berns & Kopstein, Div. Imperial Commodities Corp., New York, N.Y., for salvaging. (F.D.C. No. 61135; S. No. 77-98-379; N.J. No. 21)

FOOD/COLOR ADDITIVES

Calcium orotate for manufacturing, at St. Louis, E. Dist. Mo.

Charged 4-26-77: while held by Heun/Norwood, Div. Mogul Corp., St. Louis, Mo., for manufacture into tablets for use as a dietary supplement, the article was the nonconforming food additive calcium orotate; 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 61111; S. No. 77-84-808; N.J. No. 22)

Jam, strawberry, at Lindenhurst, E. Dist. N.Y.

Charged 10-26-76: when returned to Unit Portions, Inc., Lindenhurst, N.Y., from Williamsburg, Va., the article, labeled in part "Unit portions W. Hempstead, N.Y. . . . Strawberry Jam Net Wt. 1/2 Oz.," contained the nonconforming color additive FD&C Red No. 2 (which had been delisted); and the article failed to conform to the definition and standard of identity for strawberry jam, since it contained color additives (FD&C Red No. 2 and FD&C Yellow No. 5) which were not authorized by the definition and standard; 402(c), 403(g)(1). Default decree ordered destruction. (F.D.C. No. 60964; S. No. 77-41-798; N.J. No. 23)

DRUGS/Human Use

Chlorothiazide tablets, 250-mg and 500-mg, at Miami, S. Dist. Fla.

Charged 7-21-76: when shipped by Bolar Pharmaceutical Co., Inc., Copiague, N.Y., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Consent decree ordered destruction of the 500-mg tablets and authorized release of the 250-mg tablets to the claimant following demonstration of compliance with specifications in an approved abbreviated New Drug Application filed after the drugs had been seized. (F.D.C. No. 60810; S. Nos. 76-44-729/31; N.J. No. 24)

Hydrogenated ergot alkaloids sublingual tablets, at San Diego, S. Dist. Calif.

Charged 8-2-76: when shipped by Pharnecon, Inc., Farmington, Mich., the article, labeled in part "Hydrogenated Ergot Alkaloids 0.5 mg Sublingual Tablet Proemmel Pharmaceuticals Riker Laboratories, Inc., Northridge, Calif.," was a new drug without an effective approved New Drug Application; 505(a). Default decree condemned the article and ordered delivery to FDA. (F.D.C. No. 68020; S. No. 76-28-111; N.J. No. 25)

Phenylephrine hydrochloride chewable tablets, at Fenton, E. Dist. Mo.

Charged 4-19-77: while held for sale, after manufacture by Alpha Pharmacal Co., St. Louis, Mo., using interstate phenylephrine HCl, the circumstances used for the manufacture and processing of the article failed to conform with current good manufacturing

practice; 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 61153; S. No. 77-84-829; N.J. No. 26)

Platelet concentrate, source plasma, and other blood components, at Miami, S. Dist. Fla.

Charged 10-22-76: when shipped by Pioneer Blood Service, Inc., New York, N.Y., in an unrefrigerated truck, during such shipment, and while held for the consignee Morris Randolph, North Miami, Fla., in an unrefrigerated condition for more than three weeks at Argo Co., Miami, Fla., the circumstances used for the manufacture, processing, packing, and holding of the articles failed to conform with current good manufacturing practice—501(a)(2)(B); the labeling of the articles designated as "Single Donor Plasma (Human)," "Single Donor Platelets," and "Source Plasma (Human)" was false and misleading in representing and suggesting that those articles had not been stored or held unrefrigerated for extended periods of time—502(a); the labeling of the Platelet Concentrate (Human) failed to bear adequate directions for use, since the article was a salvage product and its label failed to bear the directions "Caution: For Manufacturing Use Only" and "Not for use in products subject to license under section 351 of the Public Health Service Act"—502(f)(1); and the labels of all of the articles [except the Platelet Concentrate (Human), Single Donor Plasma (Human), Single Donor Platelets, and Source Plasma (Human)] lacked the name and place of business of the manufacturer, packer, or distributor, lacked an accurate quantity of contents statement, lacked the established name of the drug, and lacked the name and quantity of each active ingredient; and required information (i.e., the donor or lot number, the test method and result of hepatitis B surface antigen test) was not prominently placed on such articles' labeling, since it was not present—502(b)(1), 502(b)(2), 502(c), 502(e)(1)(A)(i), and 502(e)(1)(A)(ii). Default decree ordered destruction. (F.D.C. No. 60925; S. No. 77-64-439; N.J. No. 27)

Podiatry Pre Tape formula, Trainer's Pre Tape dressing, Mint Glo preparation, Adhesive Balm Pink cream, and active ingredient components such as ethyl alcohol, methyl salicylate, trichloroethane, and menthol, at Erie, W. Dist. Pa.

Charged 3-24-77: while held by Larson Laboratories, Inc., Erie, Pa., the circumstances used for the manufacture, processing, and packing of the articles failed to conform with current good manufacturing practice; 501(a)(2)(B).

The manufacturer moved that the articles be released because the drugs were not alleged to be adulterated as either raw materials or finished products, nor to be dangerous to the health, safety, and welfare of the consumer due to any product defect, dangerous or unfinished ingredient, dilatory conduct by manufacturer, or any reason other than the alleged improper manufacturing procedure; and because the seizure of the products had caused serious injury and would continue to do serious injury so long as such goods were detained preventing the manufacturer from specifically performing upon its existing contracts of manufacturing and delivery. The manufacturer also sought the issuance of an order that the Government show cause why a temporary restraining order should not be granted. The court issued the order to show cause. The Government opposed the manufacturer's motions. The manufacturer also moved for the release of the trichloroethane and filed an answer to the complaint denying the charges. After a hearing, the court denied the manufacturer's application for a temporary restraining order, saying in part:

"The government claims that the articles are adulterated within the meaning of the act and the manufacturing process does not conform to the requirements specifying current good manufacturing practice.

"The court at first was of the opinion that the government's action was very high handed in this case in putting this company out of business and its employees out of work without notice. The action was taken by the government, however, pursuant to the federal Food Drug and Cosmetic Act, 28 USC 301, et seq particularly in exercise of its powers to proceed by libel or information against adulterated products under 28 USC 334. The court has also considered 28 USC 321, 331 and 351 in connection with this case.

"It further appears that there had been correspondence between Larson Laboratories and the government with respect to its manufacturing processes in November and December 1976 and subsequent inspections revealed that the matters objected to had not been corrected. Mr. Berenstein, president of the defendant,



however, had stated that he would proceed to correct the matters by spring 1977. It appeared that by March 1977 nothing more had been done than to obtain literature relative to a machine which was required.

"The court agrees with the government that this type of seizure has been approved by the U.S. Supreme Court in *Ewing v. Mytinger and Casselberry Inc.* 339 US 594; and *Abbott Laboratories v. Gardner*, 387 US 136. See also *Natick Paperboard Corp. v. Weinberger*, 498 F 2d 125 (1st cir 1974).

"This court is bound by the decisions of the Supreme Court of the United States. To grant a temporary restraining order in this case returning the goods to the Larson Laboratories would amount finally to return of the goods which would be the ultimate order in this case if it later found that the seizure was not justified.

"This case is assigned to the Honorable Joseph P. Willson who at the time was sitting in the Middle District of Florida. The undersigned who was at Erie undertook to handle this request for a temporary restraining order in Judge Willson's absence after first communicating by telephone with Judge Willson. The ultimate decision however as to whether a preliminary injunction should be issued or whether the government prayer in the complaint for forfeiture should be granted or whether the government's motion to dismiss the motion for return of the goods should be granted are matters for Judge Willson to determine after he has had time to review the matter. For the present we will merely deny the motion for a temporary restraining order and refer the other matters to Judge Willson."

Ultimately, a consent decree authorized release of the articles to the manufacturer for bringing into compliance with the law. (F.D.C. No. 61136; S. No. 77-45-254 et al.; N.J. No. 28)

DRUGS/Veterinary

Coli-Trol 80, Mycotrol P, Entrol S, Entrol P methylrosaniline chloride (gentian violet) medicated premixes, F4C-60 chelated irons, copper & cobalt feed supplement, and Myconox-LF methylrosaniline chloride litter & feed conditioner, at Gainesville, N. Dist. Ga.

Charged 9-27-71: when shipped by Naremc, Inc., Springfield, Mo., Myconox LF litter & feed conditioner was a nonconforming food additive—402(a)(2)(C); all the articles except the Myconox LF litter & feed conditioner were new animal drugs and no approval of a New Animal Drug Application was in effect with respect to each such drug—501(a)(5); the labeling of all of the articles except the Myconox LF litter & feed conditioner contained false and misleading claims as follows: Coli-Trol 80—for reducing bacterial enteritis and diarrhea caused by *E. coli* in the intestines of chickens, turkeys, swine, and cattle; F4C-60 feed grade for chronic and acute iron deficiency and for preceding periods of stress; Entrol-S Medicated—for reducing the growth of *Candida albicans*, streptococci, and staphylococci in the digestive tract of swine; Entrol-P Medicated—for reducing the growth of *Candida albicans*, streptococci, and staphylococci in the digestive tract of chickens and turkeys; and Mycotrol-P Medicated—for the control and treatment of mycotic diarrhea (*Candida albicans*) in turkeys and chickens; 502(a). The articles were claimed by the shipper who denied the charges. The Government served written interrogatories on the claimant. The Government moved for summary judgment, as did the claimant. The motions were denied and the case came on for trial before the court. At trial, the claimant waived its claim to Coli-Trol 80 medicated premix.

After trial by the court, the remaining articles were found to be violative as charged, except as to misleading labeling for Mycotrol P, Entrol S, and Entrol P. In condemning the articles and ordering them destroyed, the court said:

"Thus at issue were the adulteration, or 'new animal drug' questions plus the misbranding questions as to the four drugs [Mycotrol P, Entrol S, Entrol P, & F4C-60]; and the adulteration or 'food additive' question as to the article of food [Myconox-LF]. Stated differently, and giving due consideration to the burden of proof placed on the government throughout the trial the questions for determination are:

1. Are the drugs not 'generally recognized—as safe and effective'?
2. Are the drug labels misleading?
3. Is the article of food not 'generally recognized—as safe'?

Findings of Fact

"This is another in a continuing series of contests between the Food and Drug Administration and Naremc over the suitability of the latter's divers veterinary products for public sale and consump-

tion. The particular products, with the exception of F4C-60, all contain a composition of small quantities of 'gentian violet' (Methylrosaniline chloride) together with sodium propionate, vitamins and minerals. F4C-60 contains a composition of chelated irons, copper, and cobalt. All contain inert fillers. Generally, it is contended that the gentian violet-based products are effective in the control of the organisms of *Candida albicans*, streptococci, and staphylococci as a cause of difficulties in the digestive tracts of poultry and swine. F4C-60 is represented as effective in the control of iron deficiency anemia in both poultry and livestock.

"Virtually all of the ingredients, save gentian violet, are approved for unrestricted use or are within tolerances set for use by the Food and Drug Administration. 21 CFR 121.101. The contest here revolves primarily around gentian violet. It has been used for decades as a fungicide and bactericide by man, and in the lay sense is recognized as safe and effective for human oral and vaginal consumption, as well as for topical application. A number of patent medicines containing gentian violet are available over-the-counter as old-fashioned remedies for sores, pinworms, thrush and various fungi-aided parasites. The basis of acceptance of gentian violet for human use is that experience shows it 'just works.' There is no study or scientific data on which to base its safety or effectiveness for humans. Claimant's theory is that the passage of gentian violet to the digestive tract of swine and poultry inhibits the growth of harmful organisms as a form of topical application. It is not shown, however, that it can be absorbed by animals out of the mucous-membranes of the digestive tract and into the bloodstream. Myconox as a feed mixture seeks to control the growth of fungi which promotes growth of the organisms in question prior to consumption.

"There is no evidence that gentian violet is not safe for animal consumption. There is no evidence that gentian violet in combination with the other ingredients in the four products is not safe for consumption. Accordingly, the court finds as a matter of fact that all five articles in dispute are safe.

"As to effectiveness, it appears that the gentian violet based products do, in fact, inhibit the growth of the offending organisms *in vitro*, and there is no evidence they do not do so *in vivo*. The problem lies in the need to do so. Increased use of antibiotics sometimes increases the growth in animals, of the organisms which are present in all, but normally controlled by nature's balance, through flora. The incidence of the likelihood of any problem therefrom is minuscule. However, there is no evidence that they are not effective if there were such a problem. As in humans, the evidence preponderates to a finding that the drugs 'just work.' In the case of F4C-60, the problem is even more difficult to isolate. Iron deficiency is simply not an animal problem to any measureable degree. The chelated minerals are more readily absorbed, however; and if there exists a problem of iron deficiency it seems obvious that the addition of iron in any quantity would be effective in reducing the deficiency. Accordingly, the court finds that all of the articles are, in fact, effective.

"To this extent, there is likewise no misbranding. However F4C-60 is also represented to be effective against 'stress' in a flock or herd. As the court understands, stress in the veterinary concept means nervousness, excitement, strain, exhibited by impulsive physical activity such as 'packing', cannibalism and the like. In the vernacular, the flock is 'off their feed.' There is no known way that minerals can affect stress inasmuch as they are not tranquilizers. Accordingly, as to F4C-60, there is misbranding in that the label is false and misleading in its representation as to effectiveness against stress.

"As to all five articles, there are no controlled published studies and no scientific data of *in vivos* tests of their safety and effectiveness. Contemporaneous or subsequent to this seizure, some tests have been undertaken seeking to demonstrate both safety and effectiveness of these or similar products. However, the results as yet are inconclusive, undistributed, and unknown except to the researchers and Naremc themselves. The completeness and validity of such tests are also open to question. A representative group of qualified research veterinarians, nutritionists, clinicians, pathologists, and microbiologists have never heard of the products by name and have never read or heard of the safety or effectiveness of the ingredients in the combinations formulated in these products. A number of poultry and swine servicemen and salesmen believe from field experience that the products are safe and effective for the uses intended. The current researchers also share this belief from *in vitro* tests and the limited *in vivo* tests underway.



"The factual findings in relation to these articles may be summarized as follows:

| Article | Components shown to be safe | Combination shown to be safe and effective | Recognized body of research data on safety and effectiveness | Misleading label |
|--------------------------|-----------------------------|--|--|------------------|
| Mycotrol P | Yes | Yes | No | No |
| Entrol S | Yes | Yes | No | No |
| Entrol P | Yes | Yes | No | No |
| F4C-60 | Yes | Yes | No | Yes |
| Myconox-LF (Safety only) | Yes | Yes | No | |

Conclusions of Law

"Were it not for a series of recent Supreme Court decisions construing the 1962 amendments to the Food and Drug Laws, this case would be most difficult to resolve. As seen, the court has determined that claimant's products are safe and effective. More properly stated, it has not been shown by a preponderance of the evidence that they are unsafe and ineffective. While it is apparent that the advertised need for the products is largely illusory, the court is persuaded that their use will not result in any harm and could help in isolated instances. While their need might be compared to the proverbial utility of a 'wart on a toad-frog,' such considerations are not the purpose of the present inquiry and no greater harm is seen to the public from their use than from several celebrated tonics and remedies now legitimately pushed on the market for humans.

"However, in view of the important purposes behind the Food and Drug Laws, the statutory scheme, as approved by the courts, does not admit approval of such products on the evidence at hand. In all respects, it reasonably requires a satisfactory accounting of reliability before-the-fact or, in this instance, 'substantial evidence' of reliability upon seizure. The need for such restrictive tests is obvious. Indeed, it is difficult now to police the marketing of drugs and foods which can be changed in name and form by instantaneous simple variations in composition and label, a practice apparently followed by this manufacturer over a period of years with its gentian violet remedies.

"Under such circumstances, the Congress has prescribed a precise method to attest to product reliability by the application procedure before marketing. Indeed, if claimant's beliefs are as strong as professed, it is unclear why it does not proceed to get about the business of securing proof sufficient to obtain approval. In the absence of such action, a claimant is rightfully required to negate a showing of the absence of general recognition of reliability by a showing of the same preciseness.

"Quite properly, it is simply not enough to show that some people, even experts, have a belief in safety and effectiveness. A reasonable number of Americans will sincerely attest to the worth of almost any product or even idea. To remove the aberrations in uniformity which can result from a well-staged 'swearing match,' the law requires more. Indeed, it has been heretofore held that the purpose of the normal inquiry is not to determine safety and effectiveness at all, but to ascertain the drug's general reputation in the scientific community for such characteristics. . . . It is certain that a conflicting reputation is insufficient to establish general recognition. . . .

"Therefore, what is required is more than belief, even by an expert; it is a general recognition based upon substantial scientific evidence as delineated in the regulatory guidelines. 21 CFR § 130.12. *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609(1)(1973). There is no reason to differentiate the holding in *Hynson* between human drugs and animal drugs. . . . Public health considerations are similar. Further, logic would dictate no lesser standard after-the-fact than in securing an application. Indeed, the reasoning of the Supreme Court appears to be that 'the reach of scientific inquiry' is the same whatever the forum. *Weinberger v. Bentelex Pharmaceuticals, Inc.*, 412 U.S. 645(b)(1973).

"Measured by this standard, the absence here of qualifying tests or investigations to determine the safety or efficacy of the articles

renders a conclusion of general recognition impossible. Even if the current tests were viable (and the court thinks not), in the absence of generally accepted literature, the most claimant would have is a conflicting reputation insufficient to establish general recognition. In any event, it is clear that general recognition is not established to the extent required by law.

"Accordingly, it is concluded that Mycotrol P, Entrol S, Entrol P, and F4C-60 are new animal drugs under 21 U.S.C. § 321(w) and, being without approval, are adulterated within the meaning of 21 U.S.C. § 351(a)(5). It is likewise concluded that Myconox is a food additive under 21 U.S.C. § 321(f) and, being without approval, is adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C). . . .

"Ordered and adjudged that such articles be condemned pursuant to 21 U.S.C. § 334, and that said articles under seizure be destroyed by the United States Marshal, and all costs of this action be assessed against the claimant, Naremcro, Inc. 21 U.S.C. § 334(e)."

The claimant appealed. The court of appeals affirmed the judgment of the lower court, saying:

"The District Court held that all four drugs and the food were adulterated and that one drug was misbranded within the terms of the applicable statutes. It therefore ordered the items condemned and destroyed pursuant to 21 U.S.C. § 334(e).

"Stated somewhat baldly, the federal food and drug laws prohibit from interstate commerce drugs which are not safe and effective for their intended use, and food additives which are not safe for their intended use. This policy is effectuated by requiring the approval of the Secretary of Health, Education and Welfare of any new drug or any food additive prior to its shipment in interstate commerce. One seeking to introduce a new animal drug into interstate commerce must secure from the Secretary approval of a new animal drug application for that drug under 21 U.S.C. §§ 355(b)-(d). One seeking to introduce a food additive into interstate commerce must do so pursuant to a regulation formulated under 21 U.S.C. §§ 348(b) and (c).

"The touchstone of both paths of regulation is safety and, for drugs, effectiveness as well. Section 355(d) requires the Secretary to refuse approval of a new drug application when it finds 'that . . . (2) the results of such tests [submitted by the drug's proponent] do not show that such drug is safe for use . . . [or] (5) evaluated on the basis of the information submitted . . . there is lack of substantial evidence that the drug will have the effect it purports or is represented to have' Similarly, § 348(c)(3)(A) requires the Secretary not to issue a food additive regulation where the data submitted 'fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe' Thus in either case those who seek to market a drug or food additive in interstate commerce have some burden of proving the safety and, for drugs, the effectiveness of their product. See *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609, 613, 617-618, 93 S.Ct. 2469, 2476-2478, 37 L.Ed.2d 207, 214, 216-217 (1973).

"The alternative route for drug or food additive manufacturers is to market their products without approval and to let the Secretary take the initiative, as here. The test then is a different one, going to 'general recognition' of safety or effectiveness rather than actual safety or effectiveness. This is the route selected by the manufacturer in the case before us.

"In the new animal drug application context the effectiveness evidence which the manufacturer must bring forward includes 'adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved' from which such experts could reasonably conclude that the drug would be effective as claimed, § 355(d); *Weinberger v. Hynson, Westcott & Dunning*, *supra*, 412 U.S. at 617, 93 S.Ct. at 2477, 37 L.Ed.2d at 216.

"The crux of appellant's argument on appeal is that the test for general recognition of safety and effectiveness—to determine whether an animal drug is a new animal drug and whether a substance is a food additive—is not to be based on the same kind of scientific evidence that is required for testing safety and efficacy of drugs and additives for new animal drug applications and food additive regulations, §§ 348(b)-(d) and 355(b)-(h) and 21 C.F.R. § 130.12. This is because drugs 'used in medicine since long before science reached the point of engaging in 'adequate and well-controlled investigations'' had passed tests of safety and efficacy by trial and error. The Supreme Court has already rejected this



view in a dictum in *Weinberger v. Hynson, Westcott & Dunning, supra*. The Court quoted with approval an argument of the Solicitor General that drugs on the market "will have mustered the requisite scientifically reliable evidence of effectiveness long before they are in a position to drop out of active regulation by ceasing to be a "new drug," 412 U.S. at 631, 93 S.Ct. at 2484, 37 L.Ed.2d at 224. In a companion case decided the same day the Court restated this and said that "the reach of scientific inquiry under both § 505(d) [21 U.S.C. § 355(d), *supra*] and § 201(p) [21 U.S.C. § 321(p)] is precisely the same," *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 652, 93 S.Ct. 2488, 2493, 37 L.Ed.2d 235, 241 (1973). The pertinent provisions here in question of § 321(w), which defines new animal drugs, are identical to § 321(p), which defines new drugs except new animal drugs.

"Just prior to this observation the Court carved out a limited but indefinite exception. It said, 'It may, of course, be true that in some cases general recognition that a drug is efficacious might be made without the kind of scientific support necessary to obtain approval of an NDA [new drug application].'*id.* The three drugs [Mycotrol P, Entrol S, & Entrol P] and the food additive [Mycnox-LF] challenged in this case are potentially within that exception since they all have as their active ingredient gentian violet, a drug long used and well recognized as a safe and effective fungicide and bactericide in man. The District Court so found, 372 F.Supp. at 918. But new combinations of well-known drugs constitute new drugs for purposes of the Act exactly because the effects of drugs in combinations are often not the sum of their parts. If reliance on a single well-known active ingredient like gentian violet lowers the test for general recognition of efficacy and safety (as appellant argues it should and as the Court hinted it might in *Bentex Pharmaceuticals*), it does not lower it to the level necessary on the facts of this case to change the result.

"The United States need only show the lack of the proper reputation for safety and efficacy of the drugs and for safety of the food additive among the appropriate experts, or that what reputation there is, is not based on adequate studies. It is not enough to show merely a conflict in the evidence of general recognition, for even properly conducted studies may produce disagreement. What is required is not unanimous recognition but general recognition.

"In the case before us, the United States has shown that there are no reports of *in vivos* tests published in recognized scholarly journals concerning the effectiveness of the drugs or the safety of the food additive, no professionally informed opinions of disinterested qualified research veterinarians or pathologists as to these products' safety or effectiveness based on adequate, controlled studies of the effectiveness of the drugs or the safety of the drugs or food and, indeed, no completed adequate studies of any kind on any of these products. 372 F.Supp. at 919. This showing not only establishes that there is not general recognition but that there is no recognition of the safety or effectiveness of these products at all.

"Even allowing for the general recognition accorded gentian violet, as suggested by the dictum in *Bentex Pharmaceuticals, supra*, we think the District Court could not hold that these combinations including gentian violet are generally recognized as safe or effective in the absence of any adequate, well-controlled, completed test of the safety or efficacy of any of the combinations here challenged.

"The trial court's opinion suggests that any conflict in the expert testimony is sufficient to prove the lack of a general reputation for safety or effectiveness. 372 F.Supp. at 920-921. So broad a statement of the rule is not necessary to this case where there was in fact no bona fide conflict among experts with each side basing its conclusions on adequate, well-controlled studies, and we do not pass on its correctness. The government's witnesses testified that they knew of no studies upon which any expert opinion could be based. The manufacturer responded with irrelevant or incomplete studies, expert opinions based on these tests or clinical experience (as opposed to clinical studies), and the interested opinions of commission salesmen. Whatever test is applied, the United States showed that there is no recognition of these products for safety or effectiveness.

"As to the misbranded drug, [F4C-60] the question is solely whether the court's finding of fact was clearly erroneous. The evidence here was similar to that in the other issues of this case, and the court's conclusion was not clearly erroneous." (F.D.C. No. 57514; S. No. 22-853 E et al.; N.J. No. 29)

Dimethylsulfoxide fluid in unlabeled jugs, at Aiken, Dist. S.C.

Charged 4-1-77: when shipped in bulk drums from Cahoka, Ill., by Vet Aid Laboratories, Aiken, S.C., who repackaged the article into

jugs, the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to the use or intended use of the article as a veterinary liniment; the article lacked the name and place of business of the manufacturer, packer, or distributor; the article lacked a quantity of contents statement; and the labeling of the article lacked adequate directions for use; 501(a)(5), 502(b)(1), 502(b)(2), 508(f)(1). Default decree ordered destruction. (F.D.C. No. 61132; S. No. 77-01-499; N.J. No. 30)

NF-180 Concentrate furazolidone medicated premix, at Russellville, E. Dist. Ark.

Charged 8-12-77: when shipped by Rhodia, Inc., Hess & Clark Div., Ashland, Ohio, the article was a new animal drug and it failed to conform to an approved New Animal Drug Application; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 61283; S. No. 77-79-143; N.J. No. 31)

MEDICAL DEVICES

Antimicrobial sensitivity test panels for *in vitro* diagnostic tests and their antibiotic components, at Wheat Ridge, Dist. Colo.

Charged 4-21-77: the test panels (which were being manufactured by Pasco Laboratories, Inc., Wheat Ridge, Colo., using various combinations of antibiotic components including antibiotics from Pearl River, N.Y., and Indianapolis, Ind.) lacked a label bearing the name and place of business of the manufacturer, packer, or distributor, and lacked a label bearing an accurate quantity of contents statement—502(b)(1 & 2); the labeling lacked adequate directions for use (i.e., lacked the intended purposes of the devices, and the warnings and storage instructions adequate to protect their stability—502(f)(1); and the articles were composed wholly or partly of a certifiable antibiotic or certifiable antibiotic derivatives, were devices for human use which on the enactment of the Medical Device Amendments of 1976 were subject to certification, and no certificate, release, or exemption was in effect for such articles—502(l). Consent decree initially authorized release to the manufacturer of the panels for bringing into compliance. Subsequently, an amended consent decree ordered the articles destroyed. (F.D.C. No. 61193; S. Nos. 77-24-646/51; N.J. No. 32)

Thermoscribe II thermocouple graphical recorder, at Rochester, W. Dist. N.Y.

Charged on or about 7-29-74: when shipped by Murdoch Engineering Inc., San Leandro, Calif., the article's accompanying introduction booklet contained false and misleading claims for being a research device and for determining a patient's sick patterns, well patterns, acute patterns, chronic patterns, and crisis patterns, and as an aid in determining the treatment of choice and effectiveness in individual cases; and the article's accompanying instruction booklet contained false and misleading claims for obtaining correct nerve pressure analyses and detecting nerve interference or impingement—502(a); and the article's labeling lacked adequate directions for use for the article's intended purposes, since adequate directions for use could not be written for lay use and adequate information for use by licensed practitioners could not be furnished—502(f)(1). The article was claimed by the shipper. Pursuant to stipulation, the action was transferred to the Central District of California. The parties served written interrogatories on each other. Pursuant to stipulation, a postseizure sampling of the article was effected by the Government's withdrawal of the article from the U.S. Marshal's control for FDA examination and testing. Return of the article to the U.S. Marshal at least 20 days prior to the trial was also stipulated. The parties pursued discovery. Ultimately, the claimant withdrew its claim, pursuant to stipulation; and a default decree of condemnation was entered. The default decree authorized FDA to retain the article (which had been released to it as a postseizure sample) to be used only for testing and exhibit purposes, or to be destroyed. (F.D.C. No. 59851; S. No. 92-322 G; N.J. No. 33)

COSMETIC/BEAUTY PRODUCT

Eye-Lift eye makeup remover, at Los Angeles, C. Dist. Calif.

Charged 6-22-77: while held by Beauty Aids, Inc., Los Angeles, Calif., who manufactured the article using FD&C Yellow No. 5 which had been shipped in interstate commerce, the article was not a hair dye and it contained the nonconforming color additive FD&C Yellow No. 5, in that the use and intended use of such additive was in the area of the eye—601(e); the labeling claim "non-allergenic" was false and misleading in representing that the article might be used by anyone at any time without potential for allergic reaction—602(a); the label of the article lacked a quantity of



contents statement—602(b)(2); and the article was also in violation of the Fair Packaging and Labeling Act, since the box label lacked the article's identity (i.e., eye makeup remover) on the principal display panel—15 U.S.C. 1453(a)(1). Default decree ordered destruction. (F.D.C. No. 61294; S. No. 77-77-405; N.J. No. 34)

NOTICE OF JUDGMENT on Criminal Action FOOD

Barnett & Sons Salvage, Ltd., of Opelousas, La., **Jesse P. Barnett, Jr.**, secretary & treasurer, and **Billy D. Hicks**, of McGehee, Ark., Tunica, N. Dist. Miss.

Charged 5-23-77 by grand jury: that the defendants conspired to ship in interstate commerce, with intent to defraud and mislead, cottonseed products which were adulterated and misbranded, and in furtherance of such conspiracy committed overt acts such as: a meeting by Hicks at Tunica, Miss., and an agreement that a Tunica firm would acquire poison-treated cottonseed, would process it into meal for fertilizer, chemical, and other industrial uses, and would deliver it to a railroad agent at Tunica, Miss.; a contract by Barnett and his corporation for the sale of 1,000 tons of cottonseed meal to a Memphis, Tenn. feed ingredient company; the shipment of railroad cars of cottonseed meal to feed companies at Macon, Miss., Starkville, Miss., and Mobile, Ala., and elsewhere; the telling by Jesse P. Barnett that the warnings "Fertilizer Use Only" (placed on the bills of lading for two railroad cars of cottonseed meal) should not appear on the bills of lading because the cottonseed meal was 41 percent prime cottonseed meal for feed use; the delivery of various lots of poison-treated cottonseed by Hicks to Tunica, Miss., for processing into cottonseed meal; and the redelivery of cottonseed meal processed from such poison-treated cottonseed for shipment to various interstate consignees—18 U.S.C. 371; when shipped from Tunica, Miss., with intent to defraud and mislead, to Mobile, Ala., (3 lots), and to Okeechobee, Fla., (1 lot), bulk cottonseed meal contained the added poisonous and deleterious substance mercury, and contained the nonconforming food additives pentachloronitrobenzene (a fungicide) and diethyl-S-2-(ethylthio) ethyl phosphorodithioate (an insecticide)—402(a)(1), 402(a)(2)(C); and, with intent to defraud and mislead, 1,000 tons of cottonseed meal (processed from poison-treated cottonseed which had been shipped in interstate commerce) were offered for sale and the documents accompanying such meal failed to reveal that the meal was poison-treated and unfit for food use—403(a).

The defendants pleaded not guilty. After trial before the court and jury, the jury returned verdicts of guilty. The court fined the corporation \$1,500. Jesse P. Barnett, Jr., was sentenced to 6 months imprisonment, 3 years probation, and a \$6,000 fine. Billy D. Hicks was sentenced to 3 years imprisonment and a \$6,000 fine. In addition, the individuals were directed to pay the costs of prosecution (\$5,945). Barnett and his corporation moved for a new trial, or in the alternative, moved that the verdict be reduced to a misdemeanor. In denying such motion, the court said:

"In this case, the jury returned a verdict of guilty on all felony counts against the moving defendants, Jessie Barnett, Jr. and Barnett & Sons Salvage, Ltd., as well as the co-defendant Billy D. Hicks. The jury verdict was returned on October 31, 1977. By Rule 33, F. R. Crim. P., a motion for new trial must be made within 7 days after verdict or finding of guilty or within such further time as the court may fix during the 7-day period. The only exception for the 7-day limitation is the assignment of the ground of newly discovered evidence. In this case, movants' motion for new trial was filed November 11, 1977, or 4 days after the 7-day period expired on November 7. During the 7-day period, no application was made to the court for enlargement of the 7-day period, nor does the motion of moving defendants assign as ground for new trial newly discovered evidence. Under these circumstances, the motion for new trial cannot be entertained because of untimeliness. *United States v. Granza*, 427 F.2d 184, 186 (5 Cir. 1970). Defendants misconceive that the 7-day period provided by Rule 33 commences to run from date of imposition of judgment. It is beyond peradventure of doubt that the 7-day period commences to run upon the return of the jury verdict of guilty in a jury trial or upon a finding of guilty in a nonjury trial.

"With respect to the alternate motion for correction of the jury verdict by reducing the verdict of guilty from conviction of felony counts to that of misdemeanor counts, the court is of the opinion

that there was an adequate basis for the jury to find that the moving defendants were guilty of the felony counts beyond a reasonable doubt. (F.D.C. No. 60777; S. No. 76-00-154 et al.; N.J. No. 35)

Burdine Industries, Inc., t/a **Lone Star Donut Co.**, and **Calvin E. Burdine**, president, and **James C. Rader**, vice president, Dallas, N. Dist. Tex.

Charged 11-10-76: special cake donut mix, and parsley flakes were held in a building accessible to rodents and insects, and were contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (F.D.C. No. 60515; S. Nos. 88-874 H, 76-15-785; N.J. No. 36)

Independent Wholesale Grocery Co., and **H. G. Blackwelder, Jr.**, president, and **J. Ken Sechler**, general manager, Kannapolis, N. Dist. N.C.

Charged 7-5-77: nonfat dry milk, cake mix, and flour were held in a building accessible to rodents and/or insects and were contaminated with rodent and/or insect filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Nolo contendere pleas by individuals to count involving nonfat dry milk; fine suspended and probation. (F.D.C. No. 62028; S. No. 76-02-276 et al.; N.J. No. 37)

Leavitt Corp., and **James T. Hintlian**, president & treasurer, Everett, Dist. Mass.

Charged 4-14-77: Pik-Nik peanut butter (count 1) and Teddie peanut butter (counts 6, 7, and 8), which (except for count 8) contained insect filth and which had been prepared and packed under insanitary conditions, were shipped to Salem, New Hampshire, (counts 1, 6, and 7), and Bronx, N.Y., (count 8)—402(a)(3), 402(a)(4); fancy handpicked peanuts (count 2), shelled Spanish peanuts (count 4), and filberts (count 5), were held in a building accessible to rodents and insects and were (fancy handpicked peanuts only) contaminated by rodents and insects—402(a)(3), 402(a)(4); fancy handpicked Virginia peanuts (count 3) were held under insanitary conditions in a building accessible to rodents and insects and were prepared and packaged, under insanitary conditions, into bags labeled "Teddie Fresh Roasted Peanuts In The Shell . . . The Leavitt Corporation, Everett, Mass.," thereby resulting in the article containing rodent and insect filth—402(a)(3), 402(a)(4). Guilty pleas; fines. (F.D.C. No. 60780; S. No. 107-957 H et al.; N.J. No. 38)

B. Rothstein & Co., Inc., and **Hyman Rothstein**, president, and **Howard Rothstein**, treasurer, Dorchester, Dist. Mass.

Charged 4-14-77 by grand jury: rye chops, semolina flour, spring flour, corn cones, rye flour, and high gluten flour were held in a building accessible to rodents and birds and were contaminated with rodent filth; 402(a)(3), 402(a)(4). The defendants moved to dismiss, moved to sever, moved for a bill of particulars, and made more than a dozen other motions. Subsequently, the corporation pleaded guilty to all six counts and was fined \$12,000; and the individuals (three counts only) were each fined \$1,500. (F.D.C. No. 60909; S. No. 76-06-695 et al.; N.J. No. 39)

Sneider Sales Corp., Biddeford, Dist. Maine.

Charged 5-13-77: candy, navy beans, and donut topping were held in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (F.D.C. No. 60779; S. Nos. 76-06-723, 76-06-725/6; N.J. No. 40)

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

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

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

Donald Kennedy, *Commissioner of Food and Drugs*
Washington, D.C., February 1, 1978

If it's cold, keep it cold!

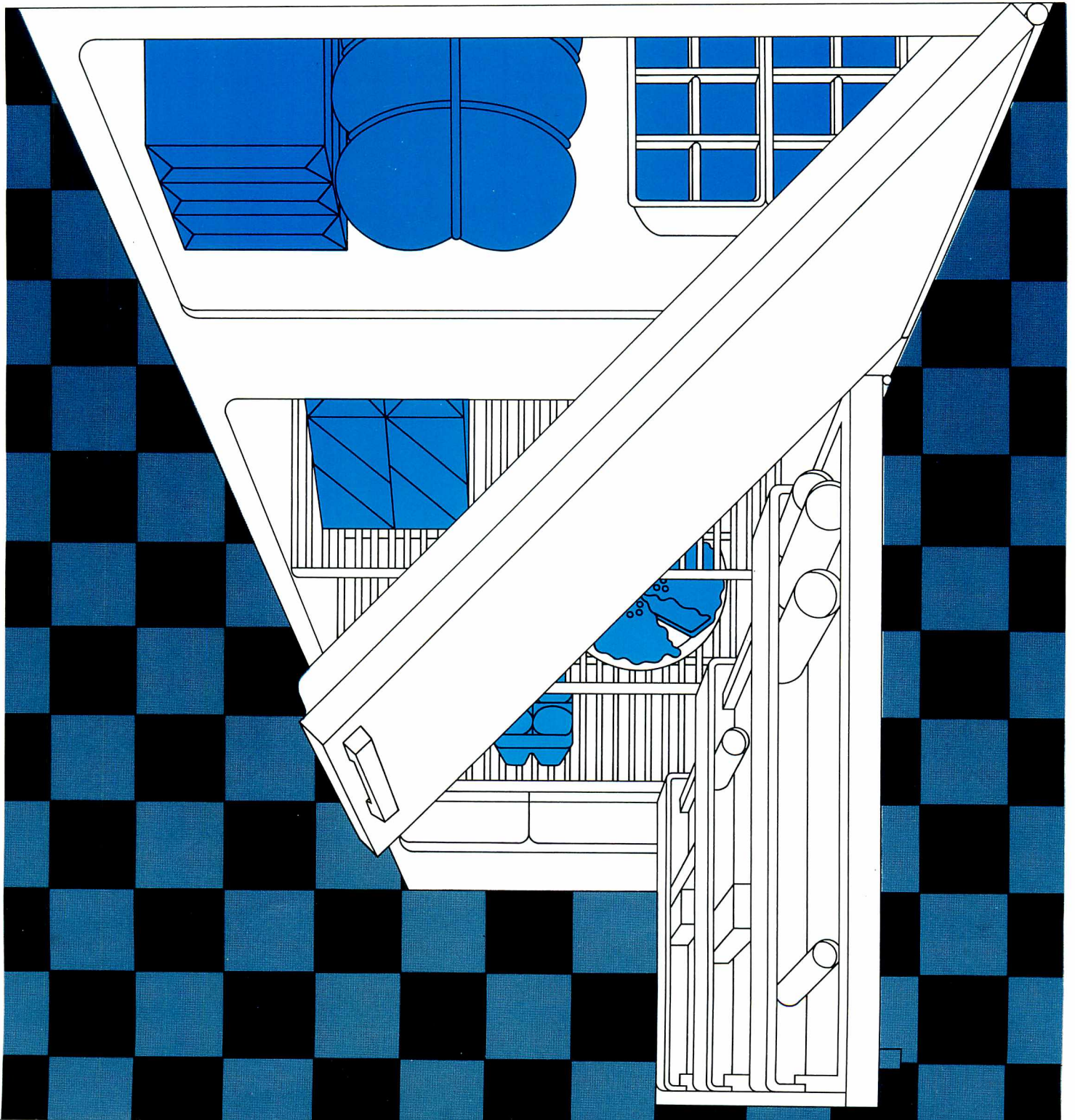
At room temperature, bacteria can multiply in food.

These bacteria can cause upset stomach. Or other illness.

To prevent food contamination—

Keep hot foods hot. Keep cold foods cold.

FDA



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