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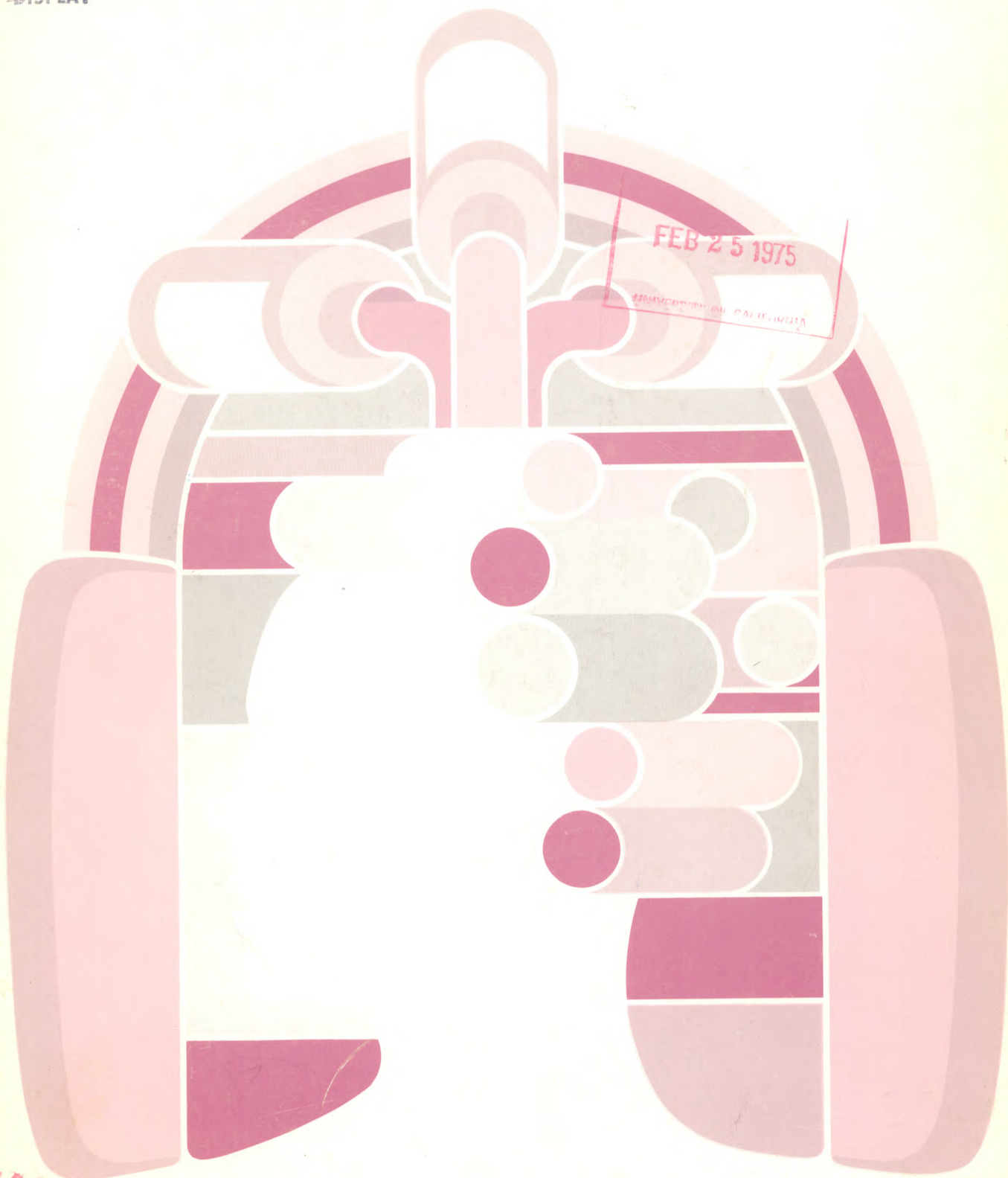
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# FDA CONSUMER

If You're Coloring Your Hair

November 1974

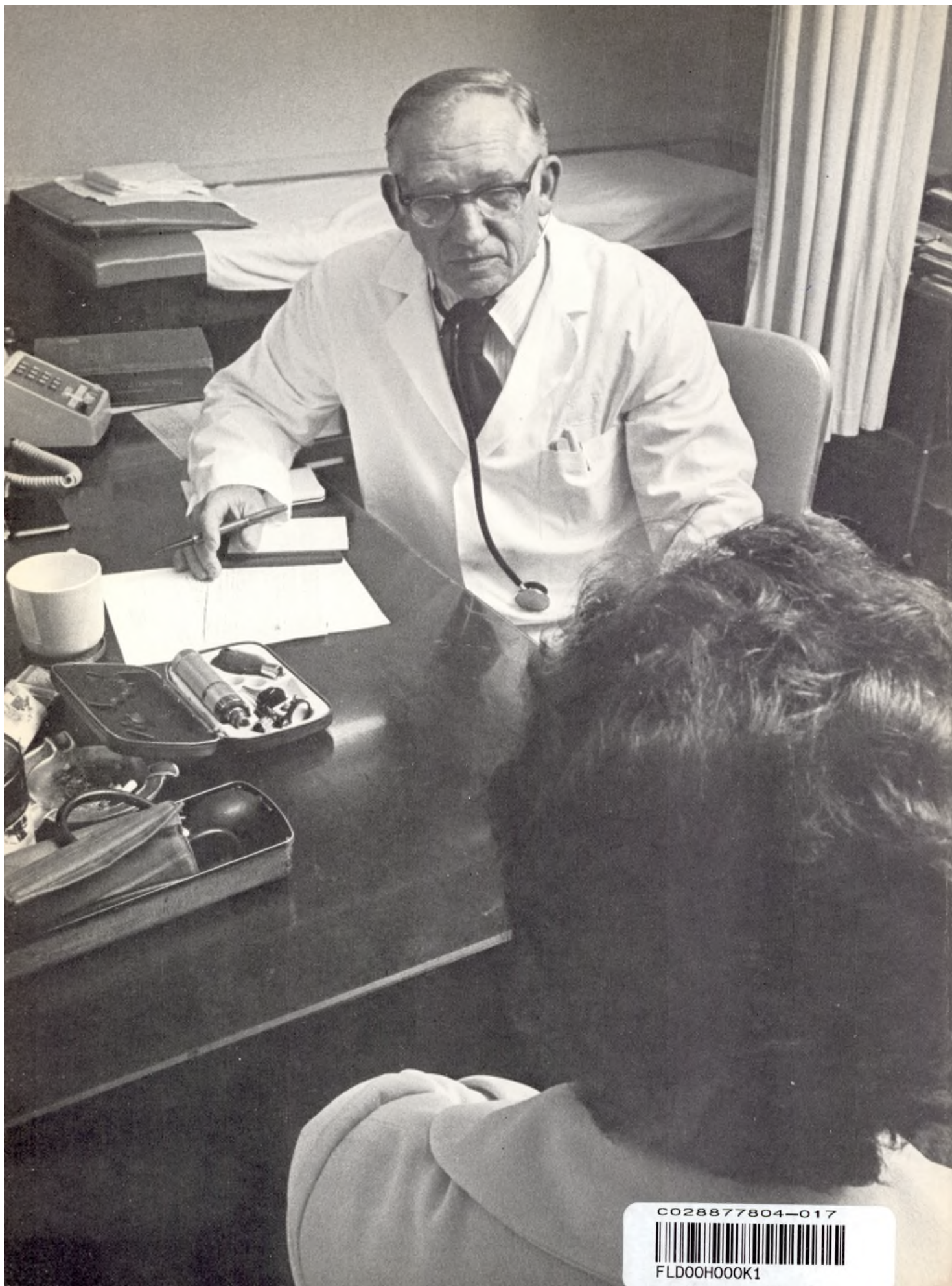
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## This Month

**T**he Food, Drug, and Cosmetic Act assigns to FDA the responsibility to assure that all prescription and nonprescription drugs are safe, effective, and properly labeled. Over the years, FDA has come to interpret this authority to mean more than just making sure that drugs meet standards of quality and potency. For drugs to be truly safe and effective, the patient must receive the right drug at the right time. Of course, the doctor examining the patient has to be the best judge of which drug is suitable. But in FDA's view, the patient has the right to participate actively with the physician in the selection of a drug, if one is needed. This month, FDA CONSUMER describes what the role of the patient should be in his own health care. Our conclusion is that the patient's role should be central. Separate articles discuss the current use of one important class of drugs, antibiotics, and what FDA is doing to improve the use of medicines.

FDA usually expresses its regulatory views through the issuance of regulations. Most FDA regulations are written by the office of FDA's General Counsel. This month, FDA CONSUMER presents a behind-the-scenes look at how regulations are developed in an interview with the General Counsel, Peter Barton Hutt. Mr. Hutt describes how he perceives his role as the General Counsel and the direction he sees in the future for FDA.

We have two color stories this month. One discusses what consumers should know about molds on foods. Molds can be dangerous, and shoppers should be careful when buying foods. The second color story is about hair dyes. If you use hair dyes, you ought to read this story to learn how they work, what they can do for you, and what precautions you should take. Safety of hair dyes is less of a problem today than it once was; still, safety should be uppermost in the consumer's mind when using these products.

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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.



# Consumer Forum

## DES Controversy Again

I wish to reply to Dr. Marvin E. Royce's letter in the May issue of FDA CONSUMER.

It's true that feeding DES to cattle can affect total beef production to the tune of 10 percent more finished weight on a given amount of feed. What actually happens though, is that individuals or groups of cattle are usually fed to the same weight regardless of whether or not they have been fed DES. Thus, what occurs when cattle are fed DES is a 10 percent savings in feed. This feed savings can be used to either feed more cattle and thus increase the supply of beef or be used to feed humans (in the case of corn and soy).

A review of scientific literature reveals that DES has a protein anabolic effect compared to cattle fed to the same weight without DES. Thus, there is a little less intramuscular fat (marbling) deposited in the lean of cattle fed DES. On a percentage basis, then, this means a small increase in protein and moisture of the lean. This reason as well as the previously mentioned reason certainly seem like a "... justifiable reason on a human nutritional basis for adding DES to animals. ..."

Concerning splattering of meat juices, I submit that any meat (with low or high fat content) will splatter if one has the temperature of the pan too high while frying! It is true that meat with a higher fat content will have less problems in this regard. However, many consumers are selecting meat with less fat and thus should adjust cooking procedures accordingly—namely lower temperatures. It is common biological knowledge that the percent fat and percent moisture of the lean portion are inversely related.

Finally, I hardly suspect that one could blame the "repeated round-after-round of meat price increases we've been treated to over the past two years" to the practice of feeding DES. In fact, the number of cattle fed DES in the last two years has decreased because on December 9, 1972, the FDA Commissioner revoked the use of DES in feeds (effective January 1, 1973). Later, on January 29, 1974, the U.S. Court of Appeals for the District of Columbia Circuit vacated the above order. However, feeders are currently cautious about using DES in view of the existing legal uncertainties. In other words, DES has been fed to cattle since 1954—not

just in the last two years! Incidentally, my figures show a 100 percent rise in the cost of meat to the consumer from 1947 to 1973 compared to a 182 percent rise in the cost of medical care! Yes, I do believe that someone "must have certainly compensated someone adequately by now."

Richard J. Epley  
Associate Professor  
Department of Food Science and Nutrition  
University of Minnesota  
St. Paul, Minnesota

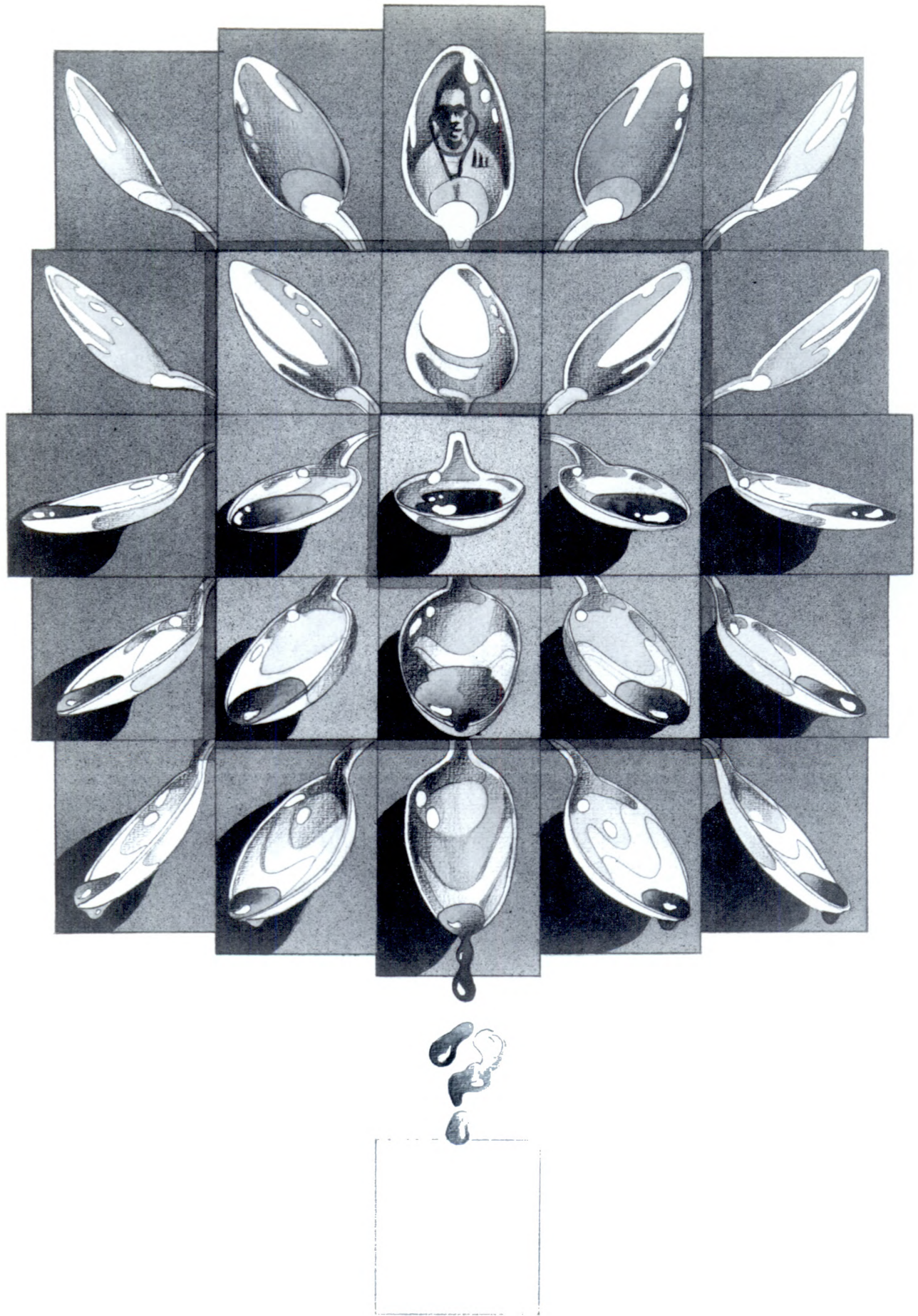
## Safe X rays

In September's issue from an article about radiation hazards, we learn that 90% of all exposure to man-made radiation is from diagnostic X-rays. The FDA now has regulations reducing the size of X-rays in newly manufactured X-ray equipment, but does the FDA have inspections to insure that old equipment already in operation meets standards of safe X-ray emissions? Is the public reduced to relying solely on the conscientiousness of doctors and dentists to maintain minimum X-ray emissions and prevent X-ray leakage in their equipment?

Maureen E. Cote  
Sandusky, Ohio

*Virtually all State health agencies have radiation protection programs which regularly check medical and dental x-ray equipment produced before the FDA standard took effect to ensure that they are safe. Equipment made before the standard took effect does not have to meet the standard, but consumers can generally be assured that such equipment has been updated and fixed if necessary to meet State safety requirements.*

Consumer Forum is an opportunity for the readers of FDA CONSUMER to express their views. Short, to-the-point letters are most acceptable for publication. Please address letters to Consumer Forum, FDA CONSUMER, HFI-20, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.



# Patients As Partners In Health Care

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*One of the greatest concerns of the Food and Drug Administration today is the proper use of medicines, by both physicians and patients. It is especially important that patients know about and accept responsibility for the proper use of medicines in achieving optimum health.*

by Arthur Ruskin, M.D.,  
and Margaret Morrison

Most people in America have grown up with the idea that when they get sick they can see their doctors and get a prescription, and very soon be well again.

This is a kind of "presto chango" syndrome—if something is wrong, there's a medicine that can right it, and quickly—which has grown out of our unquestioning faith in the knowledge and ability of the physician, and in the infallibility of medicines.

There is some reason for this

faith. Undoubtedly, the availability of professional medical attention and safe and effective medicines has given the people of this country one of the highest standards of health care in the world. Diseases that just a few years ago were debilitating and even fatal can now be alleviated or cured with good medical care and proper medication.

But this blessing is not without its problems and abuses. There is increasing concern among health professionals, in Government agencies such as FDA, and among the general public about the health care practices in our country today. FDA's particular concern is with respect to the proper use of medicines.

The person most vitally concerned with the proper use of medicines should be the patient. After all, it is the patient's health, even his life, that may be at stake.

Not only do patients have a right to know about the medicines that

are prescribed by physicians, but they should begin to recognize that they can actively participate in the proper prescribing and use of medicines for their own health care.

The proper use of drugs means selection of the right drug for the right patient, in the right amounts, at the right times. But it also includes avoiding overuse of drugs, and avoidance of all drugs at certain times, when an illness may be treated best by proper diet or hygiene, or simply by rest and "waiting." Time very often is the physician's greatest ally. It is also often the patient's.

When a physician prescribes a drug, his selection must depend on a number of factors: correct diagnosis, through evaluation of the patient's medical history, the physical examination, and laboratory tests; a knowledge of the history of the disease; knowledge and experience with other forms of treatment, both drug and nondrug, and their bene-



fits and hazards; knowledge of the drug selected—how it acts, when to give it, how to adjust the dose properly, how long to give it, how to recognize possible adverse reactions, and what precautions to take in using it; and knowledge of the costs of various medicines, so that unduly expensive drugs which offer no special advantage can be avoided. Furthermore, the physician should make sure the patient understands the drug—its purpose, its possible hazards or side effects, and any essential precautions.

Too often, patients have left all of this to the physician, thinking it was not their “business” to ask about what was being prescribed for them, or perhaps not thinking about it at all. But the patient should not be afraid to ask questions, and to learn why a drug is being prescribed and what he can expect from it. It is the patient’s right to ask such questions as:

*Is this or any drug really necessary?*

*How much should I take?*

*Exactly at what times, and for how long, should I take the drug?*

*What activities, foods, or other things must I avoid?*

*Are there possible side effects I should be aware of?*

*When should I report back, by telephone or in person, and for what reasons?*

*What are the drug’s benefits and risks?*

*Can I take a nonprescription drug while I’m taking this one?*

*If more than one drug has been prescribed, what does each do?*

*Will a less costly drug, prescribed by the generic (common) name rather than trade name, do the job as well?*

A consumer who has never asked such questions of his doctor may feel hesitant at first. But the physician should usually be willing to answer a patient’s questions as fully as possible. On occasion, the physician may decide full disclosure might harm a particular patient by creating unnecessary fears. But this

is unusual. At a November 1973 FDA consumer meeting, a respected Louisiana physician publicly said that, in general, if a patient does not get answers to his questions, he should change doctors.

One possible reason patients have not asked questions in the past is that they were not aware of the problems involved in the proper use of drugs. They assumed that their physicians had a full understanding of the medicines they prescribed, and used these drugs with dedication to the principles of good medical practice. For most doctors, this is true. Unfortunately, however, there is evidence that inappropriate prescribing practices do occur.

One of the most common errors is *drug overuse*, or use of a drug when it is not needed. Certain classes of drugs are particularly subject to overuse. Antibiotics probably are the best studied of these (see accompanying story).

Just as serious as drug overuse is *drug underuse*. This can be the fault of either the physician or the patient.

A physician may fail to prescribe medication strong enough or for long enough periods of time to be effective. For instance, antibiotics often are prescribed in doses that are not sufficient in the individual case. This can result in relapse or recurrence of the illness. One example is the use of penicillin for less than the necessary 10 days in the treatment of “strep” throat.

Often, however, it is the patient who, when he begins to “feel better,” stops taking a medication that has been prescribed for a longer period of time. This reduces the effectiveness of the medicine, making a relapse more likely.

Another problem which occurs in the prescribing of medicines involves inadequate attention to a diagnosis on the part of a physician and a consequent failure to use medication when it is needed, or lack of attention on the part of a patient to the fact that regular medical checkups are desirable.

This is perhaps best illustrated by the inadequate treatment of high blood pressure (hypertension) in our country today. High blood pressure is a major underlying cause of cardiovascular disease. Yet, too frequently, it goes undiagnosed and untreated because the patient often has no discomfort and thus is not aware of the problem.

Studies have shown that treatment with antihypertensive drugs can prevent or reduce deaths due to heart failure, stroke, and kidney disease. Yet only about half of all people in the United States with high blood pressure have had it diagnosed. Only about half of these have been treated. And half of the cases treated are not treated adequately.

Still another problem is that of *multiple drug use*. Sometimes, effective treatment for a single disease requires the use of more than one drug. And often, with concurrent diseases, more than one drug is needed. But there is reason to believe that unnecessary prescribing of multiple drugs is not uncommon. This can be costly and hazardous. It has been reported that one-fourth of all adverse drug effects result from one drug interacting with another.

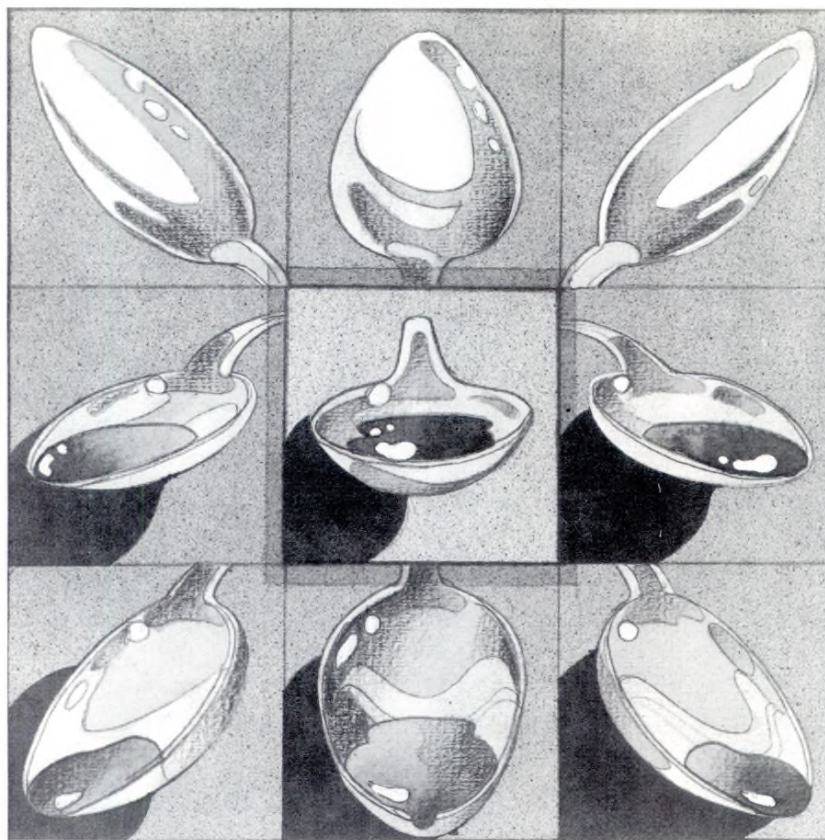
The patient may ask at this point, why do drug overuse practices occur? Why doesn’t the doctor “know better”?

But both the physician and the patient are responsible.

Patients in the United States have come to expect their physician to prescribe medication every time they see him. Apparently, many patients feel they’re not getting their money’s worth if their doctor doesn’t prescribe a drug.

Also, patients want “miracle drugs” that will cure their ills “in a hurry.” This is the way we have come to think about drugs.

By the same token, it is easier for the pressured physician to prescribe a drug rather than take the time to explain why a drug is unnecessary or unwise.



Another problem for physicians in the proper prescribing of drugs is the time required to evaluate the overwhelming amount of drug information they receive. A physician receives prescribing information in six major ways: the detail man (pharmaceutical salesman), pharmaceutical advertising in professional journals or through the mails, scientific papers in medical journals, consultation with colleagues, medical meetings, and printed matter included with the drugs he uses. In addition, of course, he gains important personal experience with drugs in his practice.

Today, more than 35,000 prescription drug products, many with similar active ingredients but with different trade names, compete for the physician's attention. Pharmaceutical firms often flood his office with promotional materials and advertisements. Firms spend about \$4,000 on medicine promotion for every physician in the United States

each year. This leads to a situation in which the physician is deluged with material, much of which is educational, but some of which is not.

For patients, the problem may be a lack of sufficient information, but more often it is a matter of their not seeking the information that is available to them. One area in which consumers seem to be particularly ill-informed is in the occurrence of adverse or undesirable drug reactions or side effects.

All prescription drugs are powerful. While they are relieving a distress, they can also disturb the normal delicate balance of brain and body. Sometimes the effects are so minor as to be unnoticed. At other times, the effects can be mildly irritating. And sometimes they can be very serious, or even fatal.

The more drugs used at the same time, the greater the risk of undesirable effects. Also, certain foods and alcoholic drinks may interact with

drugs to produce harmful reactions. Many cases involving suicide and deaths from accidental overdose are attributable to interaction with alcohol. Among the combinations that require extreme caution are sedatives, tranquilizers, or antidepressants plus alcohol.

Just as many patients do not realize that drugs have a potential for causing adverse side effects, neither do they generally understand that drugs are judged "safe" within the concept of "benefit versus risk." The concept of safety is a relative one. When the benefits of a drug outweigh the possible risks, then the drug is considered safe for use.

A drug that is safe for one person may not be safe for another. Some people have allergic reactions—which may be minor or severe—to certain drugs which may be perfectly safe for others. Patients can help to avoid allergic drug reactions by asking questions.

Patients should make sure their physician knows the details of their present and past illnesses, the prescription and over-the-counter drugs they are taking, and any allergies, including drug allergies. In fact, it's a good idea for patients to take their medicines with them when visiting the doctor's office. And they should not be hurt if the physician advises them to discard most of the medicines—a good doctor uses only those drugs that are necessary.

It is the physician's role to understand the uses of drugs and their proper application to his patient's problems. But patients should remember that they, too, must participate in using drugs to protect their health rather than harm it. It's a good thing to keep in mind the next time you start asking for medicine or a "miracle cure."

Arthur Ruskin, M.D., is assistant to the director of the Bureau of Drugs for Medical Communication. Margaret Morrison writes for FDA CONSUMER. (continued)



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## WHAT FDA IS DOING

In an effort to assure the proper use of drugs by physicians and patients, FDA is involved in a number of programs in the areas of research, education, and regulation.

For example, FDA has collected information on adverse drug reactions for many years and recently joined with the National Institutes of Health to support programs of monitoring adverse reactions in hospitalized patients.

Another activity recently undertaken by FDA is the development of a system to assess how drugs are used in the treatment of disease. One purpose of the system is to determine whether use of specific drugs is suitable for the purpose given, based on what we know about how many people should be taking them for a specific disease.

FDA's educational programs are directed toward both the consumer and the physician. Informative and easy-to-read fact sheets and brochures on the subject of proper use of prescription drugs are available to consumers through consumer affairs officers in the various FDA Regional and District offices, or by

writing directly to FDA.

FDA also is involved in supplying better information to physicians. Printed material accompanying prescription drugs, including the package insert, is an important source of information for the physician. FDA is now beginning a program to update all package inserts, which will contain more explicit information on when the drug should be used, limitations on its use, correct dosage, and vital data on adverse reactions. New guidelines for package inserts will be made available for public comment in the near future.

This is really a continuation of the broader program begun after enactment of the 1962 Drug Amendments, which called for drugs to be assured effective as well as safe. FDA conducted an extensive study of the efficacy of prescription drugs. Already the results of this study have been seen in removal of some drugs from the market, the reformulation of others, and the changing of package inserts to provide more practical information based on solid scientific evidence. It is expected that soon all package inserts will be of more value as guides for the proper use of drug products.

FDA has begun the development of a drug compendium as a further aid to better prescribing practices. The compendium will increase the physician's familiarity with the official names of drugs and point up the many drug choices that are available.

The *FDA Drug Bulletin*, first published in April 1970 as "FDA Current Drug Information," represents a significant effort on the part of FDA to communicate with physicians. The Bulletin reaches more than 600,000 physicians, dentists, pharmacists, and other health professionals. It has been used to announce significant new drug approvals, explain important FDA policies, and describe newly recognized hazards. An FDA-sponsored survey indicated that most physicians value this information and make use of it in their practice.

Appropriate prescribing of medications and their proper use are vital elements in overall health care. The failure of a physician to prescribe a drug properly, or a patient's failure to use it properly, can result in patients being denied the benefits of drugs, or in being subjected to needless hazards and side effects.

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## ANTIBIOTICS

Antibiotics is one of the "miracle" words that became a part of our vocabularies in the 1940's, as these drugs began to revolutionize the treatment of infectious disease everywhere.

Because of antibiotics, infectious diseases that were formerly incurable can now be cured, and many patients who once might have spent months in the hospital or been confined to their homes today can continue their normal activities with little interruption. Use of these drugs has meant that the death rates for certain diseases such as pneumonia, meningitis, rheumatic fever, and syphilis have declined.

No wonder these drugs have been used so extensively, and their benefits established so firmly in the minds of patients as well as physicians. But recent studies indicate there are serious problems in their excessive use.

FDA figures show that from 1964 to 1971, the estimated number of new and refilled prescriptions for antibiotics went from 100 million a year to 170 million. Use of these drugs has meant that the death rate for certain diseases such as pneumonia, meningitis, rheumatic fever, and syphilis has declined.

But at the same time, incidents of adverse reactions to antibiotic drugs have increased. And there is evidence that certain organisms are growing continually more resistant

to antibiotics, thus rendering these important drugs less effective.

Recent studies showing the increase of antibiotic use—and a corresponding increase of problems—have generated a great deal of discussion as to what can be done to assure their proper use.

The suitable use of antibiotics requires, in general, the same discipline among doctors and patients as when prescribing or using other medicines: selecting the right antibiotic, using it in the correct dosage, and using it for the appropriate length of time. In this case, suitability must be determined by the kind of organism that is causing the infection (or determination that there is, indeed, an infection present), knowledge of the way various



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antibiotics work, the possibility of a patient's reaction to particular antibiotics, and the judgment and preferences of the physician.

In short, use of antibiotic drugs should be carefully tailored to the patient's individual need.

FDA has reviewed a number of reports concerning the problems that exist in the prescribing of antibiotics. One of these is an article by Andrew W. Roberts and Dr. James A. Visconti in the *American Journal of Hospital Pharmacy* for October 1972.

As reported in this study, of 1,045 hospital patients who were monitored, 340 received antimicrobial drugs. Only 13 percent of these uses were judged to be suitable by the physicians and pharmacists making the study; 65 percent were judged unsuited; and 22 percent were considered questionable.

In another study, presented in the October 1973 issue of *Annals of Internal Medicine*, three investigators reported that more than half the antibiotics used in hospitals were not needed, incorrectly chosen, or used at an improper dosage. This, they said, resulted in needless adverse reactions, unnecessary expense, and, in the long run, a decrease in effectiveness of the drugs prescribed.

The hospital environment is not the only one in which overuse, or inappropriate use, of antibiotics may occur. One area in which misuse appears likely is in the treatment of coughs, sinus infections, post-nasal drips, and symptoms connected with the "common cold."

Although antibiotics have not been shown to prevent or cure a cold, a recent survey indicates that 31 percent of the patients who consult a physician for a cold are given a broad or medium spectrum antibiotic (such as tetracycline or erythromycin), and 22 percent are given penicillin. Involved in this situation is the belief by the patient that antibiotics cure a cold and that his physician will give him something to produce this cure.

Aside from the unnecessary expense to patients, and the risk of adverse side effects, one of the greatest concerns today is that the overuse of antibiotics may be causing their effectiveness to "run out."

Each antibiotic affects only certain bacteria. If such drugs are used indiscriminately, e.g. too often, at too low a dose, or for too brief a period of time, bacterial resistance to these drugs may develop, and thereby reduce the possibility of their being effective when used at a later date.

While there are increasing numbers of reports indicating widespread misuse of antibiotics, there are also dissenting voices.

In an address before the Pharmaceutical Manufacturing Association in April 1974, Richard M. Furlaud, chairman of the board of Squibb Corporation, denied that antibiotics are overused in this country. "It is not clear that the use of antibiotics has in fact accelerated the development of resistant strains of bacteria," he said. "On the contrary, several long-term studies conducted in the U.S. and abroad indicate that the incidence of bacteria resistant to commonly used antibiotics has decreased rather than increased."

Mr. Furlaud also countered the idea that antibiotics are overused in the treatment of colds. He quoted statistics which show that of all Americans who contract "common colds" each year, fewer than four million, or 1.7 percent, receive antibiotics.

Also, it is not unreasonable, he said, to assume that, to the physicians who prescribe antibiotics, these are *uncommon* colds, in patients with more severe symptoms, patients with complicated diseases such as chronic bronchitis or other bacterial infections that pose a real hazard.

FDA is very much concerned with the issues surrounding this question. In 1972, the Agency's Anti-Infective Drug Products Advisory Committee recommended

establishment of a National Task Force on the Clinical Use of Antibiotics. A number of organizations, including the American Medical Association, the American College of Physicians, the American College of Surgeons, and the American Academy of Pediatrics were contacted and invited to participate in the planning of this undertaking.

Subsequently, the American Medical Association established an antibiotic usage committee to consider the problem and gather more detailed information.

While there is widespread discussion concerning the possible inappropriate use or overuse of antibiotics, there are not yet sufficient definitive conclusions based on enough hard data.

FDA is now studying methods to establish guidelines and obtain adequate scientific data on which these questions can be resolved.

What can the patient do about the problem?

First of all, he should not make the physician feel that he expects an antibiotic prescription and will be resentful if he doesn't get it. This kind of pressure from patients may be the cause of much improper prescribing.

When an antibiotic is prescribed, the patient can ask his doctor what the medicine is for and the reasons for his decision to prescribe that particular drug. To determine whether the bacteria causing the illness can be affected by an antibiotic, the patient may ask that a culture be taken before using any antibiotic. It is especially important for patients to tell the physician about allergies and about any previous bad experience with antibiotics.

It is not likely the patient can diagnose his own illness, nor deal with all the elements involved in the appropriate use of antibiotics. But he can bring to the physician's attention the fact that he does not want to use antibiotics indiscriminately, and thus spur the physician to be more cautious in his diagnosis and his prescribing practices.

# Behind FDA's Regulations



*The role of the FDA General Counsel is central to the efficient and vigorous protection of the American consumer. The General Counsel provides the Agency with legal advice and recommendations and plays a key role in the development of new regulations and new regulatory approaches. Since September 1971, FDA's General Counsel has been Peter Barton Hutt, whose work with FDA has brought numerous high awards including the FDA Award of Merit, the Department of HEW Distinguished Service Award, and the Arthur J. Flemming Award as one of the 10 outstanding young men and women in the Federal Government. In this interview with the editor of FDA CONSUMER, Mr. Hutt discusses the laws enforced by FDA, what new legislation is required, how he perceives his and others' influence over FDA decision-making, and the future he sees for food and drug law.*

**Q.** *Mr. Hutt, it might be well to begin this interview by discussing the scope of FDA's legal responsibilities. How many laws does FDA enforce, and what are they?*

**A.** The principal statute enforced by the Food and Drug Administration is the Federal Food, Drug, and Cosmetic Act, which was enacted by Congress in 1938 and has been amended some 30 times since then. This law prohibits the adulteration or misbranding of any food, drug, cosmetic, or device, and requires premarket approval by FDA of any food additive, color additive, new drug, or new animal drug.

FDA also enforces the Fair Packaging and Labeling Act, which governs truthful labeling of the products subject to FDA's jurisdiction. In addition, the Agency is responsible for implementation of three important aspects of the Public Health Service Act—the Radia-

tion Control for Health and Safety Act, which protects consumers from harmful exposure to radiation from consumer products; the Biologics Act, which requires FDA approval of all biological drugs intended for use in humans, such as vaccines; and the communicable disease provisions, which authorize FDA to control products like shellfish and milk which, if unregulated, could spread communicable disease throughout the country.

There are other minor statutory provisions subject to FDA's jurisdiction, but those are the major provisions on which the Agency spends the vast majority of its time and resources.

**Q.** *What is the role of the FDA General Counsel in enforcing these laws?*

**A.** My office is responsible for providing all legal advice to the Food and Drug Administration, for review of all regulations, and

for forwarding to U.S. attorneys and assisting them with all recommended court actions.

**Q.** *Many people may not understand the distinction between a law and a regulation. Can you explain this?*

**A.** A statute or law is enacted by Congress. It contains, for the most part, general principles, although in some instances, it also contains specific requirements. For example, the Federal Food, Drug, and Cosmetic Act states generally that no food labeling may be "false or misleading in any particular." It also specifically requires that the name and address of a manufacturer shall appear on the label.

In both instances, it is necessary for the Food and Drug Administration to issue implementing regulations that will inform industry and the public exactly how those provisions will be applied. For example, FDA recently issued a regulation stating exactly where on the label, and in what type size, the name and address of the manufacturer must appear. Industry has to comply with these regulations, which means in effect that an executive agency of the Government is applying in practical day-to-day terms what Congress intended.

**Q.** *Under what authority does any agency such as FDA issue regulations? Do they really have the force of law?*

**A.** The FD&C Act contains two specific provisions authorizing FDA to issue regulations. One of those provisions broadly authorizes FDA "to promulgate regulations for the efficient enforcement of this Act."

In my opinion, all of the regulations issued by the Agency are enforceable in the courts. The basic issue in any enforcement action is whether the regulations are "reasonable," and are not "arbitrary and capricious." There have been exceptions, but most of our regulations have been upheld in the

courts as being reasonable and thus have been enforced as legal requirements.

**Q.** *How does FDA decide when to issue or change a regulation? What participation does the public have in this process of interpreting the intent of Congress?*

**A.** Ideally, the Agency will issue a regulation whenever it arrives at a policy decision that directly affects the public or the regulated industry. Federal law requires that every regulation, except procedural regulations, must be published as a proposal in the *Federal Register* for public review and comment before it is promulgated in final form. FDA ordinarily allows at least 60 days, and in some instances even 90 days, for the public to review a proposed regulation and write the Agency to give their comments and suggestions.

After these comments are received, the Agency analyzes them and prepares a detailed preamble to the final regulation which states the nature of each type of comment received and explains the reasons for the Agency's decision. In one instance, the preamble contained 98 separate, numbered paragraphs, each dealing with a specific type of comment received on the proposed regulation. Upon final promulgation, the regulation is then enforceable in the courts.

The public is thus encouraged to comment on all of our proposed regulations, and is assured that those comments will be considered and directly dealt with in the final regulations.

I have long believed that the procedures for proposing and promulgating regulations represent a major protection for the public. As long as the Government is required to state its proposals in the *Federal Register*, to consider and answer all comments, and to defend its position in the courts, we need not fear arbitrary or unreasonable action.

**Q.** *The charge is often made that in reviewing the com-*

*ments submitted on proposed regulations, industry's comments are given more attention than those of "ordinary" consumers. Can you comment on that?*

**A.** I have never heard that charge made before, and I know of no basis for it. I would suggest that anyone who is concerned about this consult any of the preambles to our final regulations published in the *Federal Register* during the past 3 years. I think you will find that every comment sent to us is dealt with, regardless of the source.

There is no distinction whatever made between comments on the basis of the source. When the documents reach the review level, indeed, we cannot determine whether the comment was made by a member of the public or by a representative of the regulated industry. All are dealt with fairly and fully.

**Q.** *You mentioned before that one function of your office is to recommend court actions to U.S. attorneys. Many people don't understand that FDA itself does not handle court cases directly. Why doesn't it?*

**A.** Under Federal law, the Attorney General of the United States is charged with the representation of the U.S. Government in all court actions. This authority has, of course, been delegated to the U.S. attorneys, who handle the specific cases in Federal courts throughout the country.

Accordingly, the first step in any court action consists of a letter from me to a U.S. attorney recommending that the action be brought, and enclosing the papers to be filed in the court. This applies to seizures of an illegal product, an injunction against illegal action, or criminal prosecution for illegal activity. Once the case is filed, members of my staff cooperate closely with the Department of Justice and the U.S. attorneys in the preparation and presentation of the case. In many instances, our staff has handled the entire case.



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*"The public is thus encouraged to comment on all of our proposed regulations, and is assured that those comments will be considered and directly dealt with in the final regulations."*

**Q.** *You listed before the laws that FDA enforces. In general, are these laws sufficient to afford what you would consider to be an adequate level of consumer protection?*

**A.** FDA is in need of two types of additional legal authority. First, and most important, we need new investigative and enforcement authority. Except for prescription drugs and new drugs, FDA presently has no authority to require that a manufacturer of a product subject to the Agency's jurisdiction provide us with any records relating to the manufacture of that product.

This means that when we conduct a factory inspection of a food plant, we are not entitled to look at any of the records showing how the food was manufactured, or the ingredients it contains, or any other similar records that directly bear upon our enforcement responsibilities. Other Federal agencies have

had this authority for years. It is essential that this aspect of the law be changed.

Similarly, we have no authority to subpoena individuals or company records relevant to an agency hearing. We have no authority to require companies or individuals to answer questions or to provide information relevant to our enforcement activities. As long as we lack these important investigative and enforcement tools, our ability to protect the consumer remains diminished.

There are additional substantive authorities relating to specific products which we regulate that also need modernization. Our present authority over both medical devices and cosmetics is extremely limited. New legislation providing additional regulatory controls over devices has been pending in Congress for some time and hopefully will be enacted. New cosmetic legislation is also being considered.

With respect to foods and drugs, legislation is pending to sharpen and refine some of the present provisions in the law. Perhaps the most important provision under consideration would permit FDA to remove unsafe or ineffective drugs from the market immediately, rather than waiting for an often protracted and lengthy public hearing.

**Q.** *Looking further down the road, say for the next 10 years, what directions do you see food and drug law taking? Do you think that eventually there will be a need for much more stringent legal controls over the food and drug supply?*

**A.** I have never believed that the Federal Government should take over the industries it regulates. The job of a regulatory agency is to monitor the way in which these companies do business, to assure that they meet all legal requirements. We must be certain that adulterated and misbranded products do not reach the consumer. But it is not our responsibility, and never should be, to tell any indus-

try how to conduct the details of its business.

Our job of monitoring the regulated industries must increasingly be spelled out in clear and concise regulations. Those regulations must, in turn, be backed up with the type of investigative and enforcement authorities I have just discussed. Thus, we should be responsible for setting the standards required of industry, and then for inspecting industry to make certain that they live up to those standards.

**Q.** *Is this the way that FDA's always looked at its regulatory authority?*

**A.** When the Agency was much smaller, and the issues much simpler, the law was enforced primarily by direct court action on a case-by-case basis. With the increased complexity of modern methods of manufacture and distribution, and the far more subtle health and safety issues that now arise, we have learned that enforcement of the law must begin with the development of explicit policy through regulations. Once that policy is articulated in the *Federal Register*, with time for comment by all interested persons, and is promulgated in final regulations, we are then in a very sound position to proceed with court action to prevent or punish violations. In the future, we will see far more regulations than we have ever thought possible in the past.

**Q.** *Could you give a few specific examples of what some of these industry-wide regulations are and how they differ from the way in which the law might have been enforced in the past?*

**A.** Our food labeling regulations immediately come to mind. A section of the law states that the information required to appear on the label must be placed "prominently" and "with such conspicuousness" in order to make it likely to be read and understood by the ordinary consumer.

Until 1973, there was no attempt to define exactly how compliance with this requirement would be undertaken. In 1973, we issued a regulation, after allowing time for public comment, requiring that every food package must have all required information on the principal display panel or on an "information panel" immediately to the right of the principal display panel, and that all of the required information must be in at least 1/16th-inch type unless exempted by further regulation. The consumer will therefore know exactly where to look for this information on food labels, and we can be certain that it will appear in sufficiently large type that it can readily be read and understood.

This is just one example of hundreds of specific regulations that have already been promulgated or are now being proposed, and there are hundreds more that will be considered in the next few years.

In the past, FDA instituted a number of court actions, or wrote letters to manufacturers, objecting to specific food labels which contained information that was not sufficiently prominent or conspicuous. This was done on an ad hoc basis, whenever the Agency noticed a food label that did not seem to meet the general statutory standard. It was never done on a systematic basis, however, and there was previously no attempt to set an objective standard of the type that is now applicable to all food labels under the new regulations. As a result, labeling practices varied widely within the food industry.

**Q.** *This industry-wide regulatory approach is generally considered to be your most significant overall contribution to FDA since you've been General Counsel. Would you agree?*

**A.** Yes. It has appeared to me to be a more fair and more efficient method of enforcing the law. It is fair because it informs everyone ahead of time exactly what legal requirements exist and how

compliance can be achieved. It is efficient because it obviates court action that might be required if the requirements of the law are not spelled out in detailed terms.

I might add that the United States Supreme Court specifically endorsed this general approach to regulatory activity in an FDA case handed down just over a year ago.

**Q.** *Another major change that's occurred in FDA since you came here has been with respect to the "openness" of the Agency. What specific regulations have made FDA a more open and accessible agency?*

**A.** I strongly believe in the openness of any regulatory agency and indeed in the openness of all government. It is the right of a citizen to know what his government is doing, and how it will affect him. At the same time, the need of the Government to conduct its deliberations in private, before announcing them to the public, must be respected. Similarly, the rights of individuals to privacy, and the right of industry to protect trade secrets from its competitors, must be considered.

Before 1972, these competing considerations were overbalanced on the side of secrecy. We have estimated that, at that time, FDA would release only about 10 percent of the material in its files, and would hold the remaining 90 percent confidential. Beginning with the publication of our proposed Freedom of Information Regulations in May 1972, we reversed that position. We now are willing to make available for public inspection about 90 percent of the information contained in our files, and retain as confidential only the remaining 10 percent.

In the past few years, we have experimented with a number of other procedural mechanisms to guarantee greater public access to the Agency, and participation in its decisions. We have opened many of our meetings to the public; we have encouraged petitions for new regulations from the public; we

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*"FDA is in need of two types of additional legal authority. First, and most important, we need new investigative and enforcement authority. . . . Similarly, we have no authority to subpoena individuals or company records. . . ."*

have added consumer and industry representatives to advisory committees; and we have established a public calendar of meetings and events in which the public might be interested. We have, in short, attempted to permit those in the public who are interested to contribute to the work of the Agency.

All of this is now being set out in new procedural regulations that are designed to lay out in public view all of the different ways that FDA goes about its work. I am aware of no other agency, anywhere in the world, that has attempted to lay out all of its operating procedures in detailed regulations of this type.

**Q.** *Making FDA an open agency meets certain informational needs of the public and satisfies those who are seeking information, but does it really lead to better regulation of the products FDA is concerned with?*

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*"The job of a regulatory agency is to monitor the way in which . . . companies do business, to assure that they meet all legal requirements. . . . But it is not our responsibility . . . to tell any industry how to conduct the details of its business."*

**A.** I believe it does. In many situations, I have seen information made available to the Agency by members of the public that has drastically changed our preconceived ideas.

I distinctly remember one situation that should be a lesson to all of us. For many years, we have received complaints about unsolicited samples of potentially hazardous products through the mail. Concerned parents have written us objecting to this type of distribution, for fear that small children might open the mail and be harmed by sampling the products involved.

Shortly after enactment of the Poison Prevention Packaging Act, a woman wrote me asking why we couldn't use that statute to handle this problem. I will be the first to admit that this possibility simply had not occurred to me. We immediately set to work drafting a proposal, which was subsequently published in the *Federal Register*

for comment. The enforcement of that law has now been transferred to the Consumer Product Safety Commission.

Besides cases like this, far more petitions for new regulations have been submitted by consumer advocates now that we have made it clear that they will not only be received but that we actively solicit and seriously consider them. The number of detailed and meaningful public comments on regulations has dramatically increased as a result of our policy to publish in the preamble to the final regulation specific responses to all of the points made.

The interest in our review of over-the-counter drugs and biological products remains very high, in my opinion, as a result of our inclusion of consumer representatives on the review panel.

In short, the availability of FDA to the public has unquestionably meant that the public has increasingly come to us, rather than remaining at a distance.

**Q.** *From an historical perspective, how did it come about that an agency such as FDA came to be closed to the public?*

**A.** The major human resource is time. The amount of time that it takes any individual to do his work is directly proportional to the number of interruptions that occur. There is no question but that FDA and any other agency can do its job faster—but not necessarily better—without any interruptions at all by members of the public or the regulated industry.

There is therefore a natural inclination for any busy person, with major responsibilities and truly inadequate resources, to avoid the type of interruptions that will slow down what he believes to be necessary work. It is, I think, primarily this concern that led to many agencies becoming relatively inaccessible to the public.

Accessibility also increases controversy. The more that is known about an agency's decisions, the more questions can be raised. The

more secret Government is, the fewer questions can be asked. This is a significant incentive towards closed Government. Secrecy to hide controversy is abhorrent, but it has occurred in the past, and without vigilance on both our parts, will continue to occur in the future.

On the other hand, public participation merely for the sake of public recognition and ego satisfaction must also be guarded against. If Government officials must spend all day long on trivial matters merely for the sake of public appearance, in order to establish good press and congressional relations, we would soon reach the stage where we would have an illusion of progress but not a sound regulatory program.

**Q.** *The initiatives to open FDA to the public were made while other parts of the Federal Government were being charged with undue secrecy. This raises the question of how much influence other elements of the Federal Government such as HEW, the White House, and Congress have on FDA activities.*

**A.** As the principal governmental regulatory agency charged with the protection of the public health, it is essential that FDA be functionally independent. The Department of Health, Education, and Welfare has recognized this fact. For the past 4 years, each Secretary of HEW has given his word to the Commissioner of Food and Drugs that regulatory decisions by FDA must be made on the basis of sound science and good law, and that political considerations are not to be considered. As a result, FDA Commissioners have been able to exercise their responsibilities to the public in an environment that has been remarkably free of outside interference.

As with any governmental agency, we must advise others of our decisions, and we must be prepared to defend them. I am not aware of any instance during my tenure where any undue outside influence



was exercised, or indeed where any serious attempt was made to dissuade FDA from its regulatory decisions.

**Q.** *As you're aware, there are advantages and disadvantages to an agency such as FDA being responsive to "politics." The disadvantages are the ones that you describe—that is, that regulation has to be determined primarily by sound science and good law. The advantage is that FDA is a public agency, and politics is the way the public expresses its desires and concerns. Could you comment on this?*

**A.** The desires and concerns of the public are adequately reflected, in my opinion, in the statutes that govern our activities. We also hear these genuine public concerns every day in the comments we receive on proposed regulations, in the hundreds of letters that reach our desks, in newspaper accounts, and in many other direct and indirect ways. I see no need to inject the other form of politics, which might lead a legislator to request favorable treatment for a constituent, into a public regulatory body such as FDA.

**Q.** *Hearings on Capitol Hill have been in the news much recently as they relate to FDA. What should the proper relationship be between the Congress and a Federal regulatory agency such as the Food and Drug Administration which has to base its decisions, as you said before, on science and the law?*

**A.** I certainly have no objection to congressional oversight. That is indeed one of the principal purposes of Congress, and is properly the way that the public at large can assure surveillance of a regulatory agency.

My principal objection to the oversight conducted by some committees has been that it has dealt with trivia, rather than with the important issues of the day, and that at times it has been conducted

in an unbalanced and unfair way. We have been asked on occasion, for example, to appear at a public hearing to answer charges that have been made for the first time either that morning or the day before. The national media then carry the charges and cannot understand why we cannot answer them off the top of our heads. This type of procedure is clearly improper.

It seems obvious to me that if Congress is interested in conducting a truly useful oversight function, it should first investigate the issues in detail; it should then apprise FDA of all of the charges made and provide us with a documentation for them; it should provide us with the same amount of time to track down these matters as it took the committee to track them down; it should ask us for a full report on the matter; and then, and only then, it should conduct a public hearing to lay out the entire matter.

I repeat, that I would not wish to stifle or run away from criticism directed at FDA. Not everything we do is perfect, and we will never reach that millennium. Constructive criticism can substantially improve the work of the Agency, and on many occasions in the past that has happened. Destructive criticism, on the other hand, which is designed only to embarrass the Agency or enhance the reputation of a public figure, can do much to harm the Agency and the public interest which it represents.

**Q.** *In the June issue of FDA CONSUMER, we conducted an interview with Cathy Sultzberger, the executive director of Consumer Action for Improved Foods and Drugs, who described how groups such as hers try to influence FDA. What influence do consumer advocate-type groups that are centered in Washington have on FDA decision-making?*

**A.** I think these groups do have, and properly should have, a significant influence on FDA. I would say the same about professional groups and industry groups.

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*"I strongly believe in the openness of any regulatory agency and indeed in the openness of all government. It is the right of a citizen to know what his government is doing, and how it will affect him."*

All segments of the public should be well-represented before the Agency, and should have an opportunity to make their views known.

The major difficulty presently faced by consumer groups, from my viewpoint, is that they do not have sufficient resources to be adequately prepared and represented on all of the significant issues that face the Agency today. There unquestionably is truth to the charge that industry is better prepared and better represented. There is, moreover, nothing that the Food and Drug Administration could do to prevent this or change it. It is simply a fact of economic life.

What we are doing to make certain that this overbalance of representation does not overwhelm the Agency is to take affirmative action to assure consumer representation on important issues. We meet monthly with consumer groups, a mechanism that we do not afford to industry groups. We have included

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*"FDA obviously represents the interest of the entire public taken as a whole. Industry is part of that public. So are individual consumers. . . . We cannot represent or favor one over the other."*

a consumer representative on our new regulatory advisory committees reviewing the safety and effectiveness of over-the-counter drugs and biologics, and indeed Ms. Sulzberger is a representative for the consumer interest on one of those panels. In this way, we are doing everything we can to assure that the consumer advocates do participate in our decisions and are heard within the Agency.

Of course, no outside representative of any particular interest can control our decisions, nor should that ever be permitted. The final decision must be an independent judgment of the Agency, based upon the best information available to us.

**Q.** *FDA is often seen as being an agency in the middle, being tugged on the one side by consumer advocates and on the other side by industry. When FDA was established, it was construed*

*by Congress to be strictly a representative of the public. Do you see FDA as being an agency "in the middle?"*

**A.** FDA obviously represents the interest of the entire public taken as a whole. Industry is part of that public. So are individual consumers, and professional associations and teachers, and consumer advocates and congressional representatives, and all other special interest groups. We cannot represent or favor one over the other.

For that reason, I think that the issue is largely one of semantics rather than reality. It is in the interest of all members of the public, including industry, to eliminate unsafe and ineffective drugs from the market, to guarantee proper labeling of foods, to assure that adulterated cosmetics are not available, and to set standards for the safety and effectiveness of medical devices. I think we could reach a consensus on that with little difficulty if we could possibly get all these diverse interests into one room to discuss it. I, for one, am totally unwilling to fractionate the American public into uncooperative and bickering partisans.

**Q.** *Moving to another area, the people who have observed FDA activities have often commented that the FDA General Counsel because of his policy influence is really "running the Agency." How do you see your relationship to the policy-making procedure?*

**A.** I have been privileged to work with three extraordinarily fine, dedicated, strong Commissioners—Charlie Edwards, Sherwin Gardner, and Mac Schmidt. It would be ludicrous to suggest, if one looks back on the past 3 years, that I have even come close to "running the Agency."

Dr. Schmidt has frequently said to me that we work in an absolutely necessary partnership. The Commissioner is responsible for decid-

ing public policy within the statutory framework, for publishing all regulations, for forwarding to me all requests for court action, and, even more important, for all of the other daily work of the Agency. His responsibilities are obviously enormous. I must, for legal reasons, approve all regulations issued by the Agency, and must forward all court actions to the U.S. attorneys. Without both of these functions, FDA could not undertake its major responsibilities.

There is unquestionably a close relationship between the Commissioner and the Agency's General Counsel. If there were not, the Agency could grind to a halt. This is the great strength of the arrangement, however, and not a defect. The progress that has been made in the past few years speaks more strongly to that effect than any testament that I could give.

Technically, of course, I am not an official of the Food and Drug Administration. My title is Assistant General Counsel of the Department of Health, Education, and Welfare, for the Food and Drug Division. My immediate superior is the General Counsel of the Department, who in turn reports directly to the Secretary.

As a practical matter, on the other hand, my staff and I obviously spend all of our time working immediately and directly with the Food and Drug Administration. It should be no other way.

**Q.** *Except for Mr. Gardner, who was Commissioner only on a temporary basis, all the other Commissioners over the past 8 years have been physicians. Before that, there had been a long history of FDA Commissioners being trained more in the regulatory and compliance area, although none of them was a lawyer. Do you think we've come to the point now where the Commissioner of Food and Drugs has to be a physician?*

**A.** I think it extremely important that either the Commissioner or his deputy be a physician.

Many of the important issues facing the Agency directly involve medical questions, and I believe that a physician can best communicate with the American public about these issues. The credibility and persuasiveness of the Agency is, after all, as important as the correctness of the decisions themselves.

**Q.** *Over the past few years, as you've mentioned, there has been a significant increase in the number of new regulations that have been proposed and promulgated. Has there been a corresponding increase in the size of your own staff of attorneys?*

**A.** Just 3 years ago, my staff consisted of a total of 18 lawyers, including myself. We have now reached a size of 30 lawyers, and will be adding an additional 10 this fall.

Recently, FDA did a so-called "Zero Budget" for my office, to determine the Agency's real needs in terms of legal advice. The study showed that, at the present moment, the Agency needs roughly 75 lawyers, and that by next year, it will need 85. There are literally hundreds of court cases that are not brought, or regulations that are not prepared, because of this lack of resources. I am hopeful that, within the next few years, this will be remedied.

**Q.** *You've been with FDA now for 3 years, and you've said publicly that you don't intend to spend your entire career in the Federal Government. Do you have any plans for the immediate future?*

**A.** When I took this job, I said that I would be here between 3 and 5 years. Sometime within the next 2 years, therefore, I will be leaving.

I specifically placed this limitation on my tenure because I believe very strongly that Government officials should not become encrusted in important positions. If I cannot bring to this agency or any other job whatever contributions I may

have to offer within 3-5 years, then I could not do so if I were to stay here 10 or 20 years. I am also afraid that the longer one stays in a job of this type the more one is inclined to defend past decisions rather than to seek out new and innovative programs.

I have laid down a rule that I will not consider my future plans until the day after I have left this job. I believe that it would be unethical for me to do otherwise.

**Q.** *The job that you held before you came to the Food and Drug Administration was as an attorney primarily representing industry interests with respect to food and drug law. How do you think that this particular background as an industry attorney has influenced your performance as FDA General Counsel?*

**A.** There was, of course, a substantial amount of controversy about that when I first took the job. Senator Moss, who conducted a hearing on my appointment, later wrote me to say that he was satisfied that I was conducting myself in an entirely proper manner. I have certainly tried very hard to do so.

I think it would be impossible for anyone adequately to undertake this job without knowledge of food and drug law. It would probably take some 3 or 4 years of on-the-job training for someone who was not familiar with this area of the law to assimilate not only the technical legal background—that is, the cases, the legislative history, and the statutory provisions—but, perhaps more important, the history and traditions that have shaped this agency's actions. To be useful to FDA, the General Counsel must understand everything that is going on in the Agency now, and most of what has happened in the past.

The fact that I once represented the regulated industry is, in my opinion, largely irrelevant to my work at FDA. A lawyer is trained to represent his present client to the best of his ability.

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*"Government officials should not become encrusted in important positions. . . . the longer one stays in a job of this type, the more one is inclined to defend past decisions rather than to seek out new and innovative programs."*

When it was announced that I would be appointed to this position, in the summer of 1971, Morton Mintz of the Washington Post telephoned me to ask the same question that you have asked, and I gave the same response. He then asked who my client would be, and I replied, without hesitation, that it would be the public, through the Food and Drug Administration.

I have taken my duties very seriously in this job. I have worked most nights and weekends, and have made many personal sacrifices, because I believe so strongly in the work of the FDA. What is more important, I believe that I have adequately represented the public and the Food and Drug Administration, and am very proud of the many things that have been accomplished during my tenure.

Wayne Pines is editor  
of FDA CONSUMER



# Please Don't Eat The Mold

by Jane Heenan

*If you subscribe to the theory that a little mold never really hurt anybody, you may be setting yourself up for a variety of problems—some of which can be fatal!*

In these days of fad diets, there's another you can add to the list: A family in South America has reached a ripe old age eating almost nothing but mold. They cultivate mold farms with the aid of rare caterpillar fertilizer and are surrounded by peers who believe as they do in the merits of mold diets.

They can get away with that sort of thing. They're ANTS!

But for human beings, mold in food should be avoided.

## **The Hazards**

Mold is a growth of minute fungi forming on vegetable or animal matter. It commonly appears as a downy or furry coating, and is associated with decay.

As food molds grow, they can produce compounds called mycotoxins. Some of these have been proven to cause cancer in animals, although the question remains open concerning human health.

Of equal concern are the hazards posed by the fungus itself. Certain species can cause serious and possibly fatal human and animal infections involving such body areas as the sinuses (often caused by sniffing mold in spices and other foods), eyes, ears, and the respiratory tract. At least one recorded human fatality resulted from a mold-induced sinus infection entering the spinal fluid. There also are reports of permanent blindness from molds.

One problem related to mold-induced infections is that they are not easy to diagnose. The symptoms do not differ from those for other types of infections. Accurate diagnosis is especially important because mold-induced infections are treated best by specific drugs such as griseofulvin.

Another cause for concern is allergic reactions to molds. Reactions occur in the form of hay fever, rashes, or other typical allergic symptoms.

This then should put aside the idiom many consumers have heard: "It's just a little mold; it can't hurt you." But less obvious are the precautions to be taken against mold

contact and the ways to recognize possible hazard.

## **What to Look For**

Virtually all foods are susceptible to mold. But moisture and storage temperatures generally determine the opportunity for mold growth. For instance, high moisture foods such as fresh produce, bakery products, and cheeses that were never intended to be veined with mold are most subject to showing signs of mold at time of purchase.

Less apt to show signs of mold are nonseasonal, high-turnover items such as meats, shipped fresh and under constant refrigeration.

Chances are virtually nil that a consumer could ever detect mold in such items as processed and hermetically sealed canned goods. The consumer must rely on Government inspections of manufacturing plants and imports to see that adulterated food isn't sold. In a processing plant, FDA consumer safety officers check conditions at each stage of processing to determine if decomposed fruits and vegetables are being used. A final sampling of the packaged product determines the presence of resultant toxins.

The final inspection, of course, must always be performed by the consumer, who is the only one who can check every item before it's placed on the dinner table.

Careful selection of food purchases is the first step in mold prevention. The opportunity for the greatest discretion will usually be at the fresh produce section, where items are offered at various periods of the growing seasons and at various stages of ripeness.

The first point to remember is that the fluffy cottony substance laymen can readily identify as mold need not be in evidence for mold to have started growing. The "fluff" is actually the "bloom" of the mold—and where there is bloom, there are roots, sometimes deep and spread throughout the food. So even a small spot of mold should be your signal to steer completely clear.

Since mold spores, present throughout the air, usually must find





some entry into the food before growth begins, the careful shopper should check produce for nicks and bruises and pay particular attention to the area where an item was attached to a stem. This is an easy place for mold to find entry. If you look very closely at the stem area on, for instance, cherry tomatoes, you may sometimes find that what appears at first to be ripe healthy fruit is actually harboring mold.

In selecting produce that will be stored several days, it's wise to stagger the ripeness. A few plums or tomatoes, for instance, that appear too "green" for immediate consumption should be just right in a few days after some of the riper ones have been used.

In other areas of the grocery store, the consumer's task won't be quite as easy. When packages preclude inspection of contents, the best clues to quality are open dating and package condition. In other cases, with see-through packaging and special windows, a partial inspection is possible.

Don't take for granted that any foodstuff is immune from mold. For instance, although moisture is required for mold growth, dried foods infected by mold before the drying process began can still carry the fungus. Spices, dried beans, nuts, and popcorn are just a few more examples that should pass review before purchase.

#### **A Word About Cheeses**

Some cheeses—such as Roquefort and Bleu—are expected to be veined with mold. They're carefully processed with the kind of mold similar to those from which penicillin is produced. And this species of mold, used for centuries with apparent safety, is not believed by scientists to be toxic. So there is no reason to avoid these types of cheese.

A practice consumers do need to change, however, is that of buying moldy cheese that is not normally expected to show signs of fungus. There's no reason to assume such mold is safe simply because it's on cheese and there's no harm for the

layman to distinguish between safe and harmful mold. There are literally hundreds of species that can appear on any consumer commodity, in almost every color. And there's no rule of thumb as to which colors indicate "good" molds or "bad."

The particular molds with a long history of safe use in curing and other processes add flavor to cheese. But consumers should avoid a chunk of cheese with cottony spots on the surface. And even with Roquefort and Bleu, extra mold that's not obviously part of the veining is suspect.

As with all other foods, merely trimming the mold off is not a safe practice. The roots may still be present. So the wisest course is to steer clear of all moldy items—and then to report such problems to the store manager. A consumer who finds mold in items just after taking them home should report it also to the FDA. In the case of meats, the U.S. Department of Agriculture should be notified.

#### **What Happens in Your Kitchen**

It's as foolish to handle and store foods carelessly as it is to buy food already in poor condition.

Here is a check list of kitchen tips about mold:

1. First, last, and always, remember that it isn't safe to scrape off mold and eat the remaining food. The whole item should be destroyed.
2. In cooking, mold itself disappears, but the toxin it produced isn't always destroyed. So don't rely on cooking the hazard away.
3. Freezing prevents mold growth, but it won't kill what's already present.
4. Since mold spores are present throughout the air, they're also in your refrigerator. The little black spots that sometimes appear inside the refrigerator are mold—or, as the consumer often calls it, mildew. Periodic and thorough cleaning—washing and drying—will keep this problem in check. The drying is particularly important; otherwise, mold remains.
5. Mold does grow at refrigerator temperatures although somewhat

slower than at room temperatures. Therefore, consumers should always take advantage of expiration dating and not rely exclusively on refrigeration to maintain freshness.

6. Musty odors are a tip-off of mold presence, but it's dangerous to rely on sniffing out the problem, especially when fine loose particles of food are involved. For example, a few healthy sniffs of a suspect spice could easily send spores directly into the respiratory tract. In fact, the age-old sniffing test is a far more prevalent and direct hazard than the problem of consuming and digesting a potential carcinogenic mold. The idea is that it apparently takes far less mold to cause respiratory infections and also that people are less apt to actually consume apparently moldy foods.

7. High moisture foods and grains are most apt to have the most hazardous types of molds. Therefore, pet owners, while revising storage and handling practices in the kitchen, should not forget the pet food. Most of the "dry" pet foods are made of grains and should be stored safely in cool, dry areas and should be reclosed carefully to seal in freshness. It's also wise to buy small amounts at a time if the food isn't consumed rapidly.

#### **The Brighter Side**

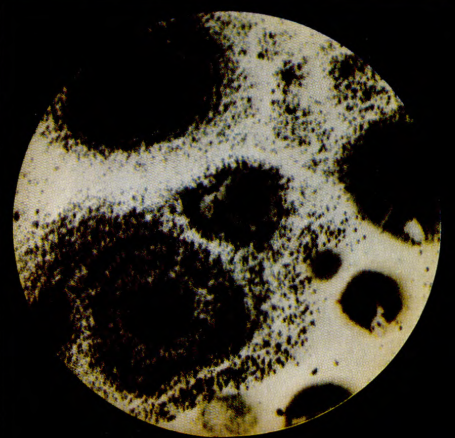
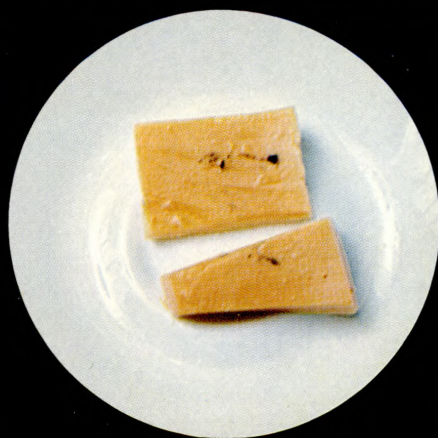
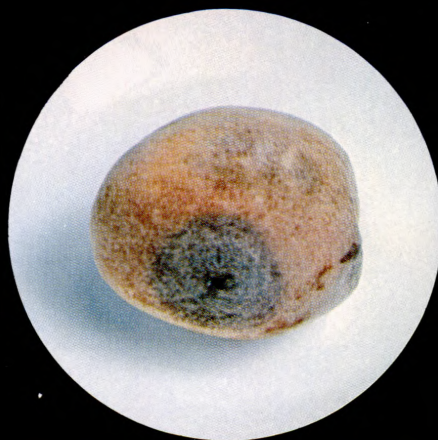
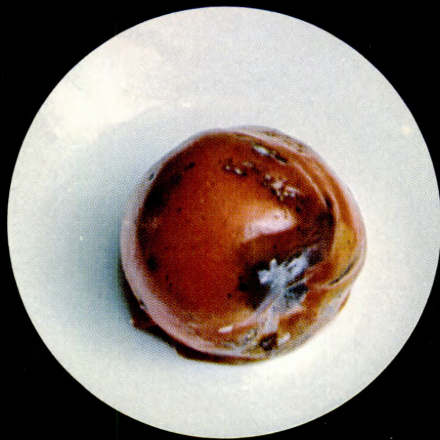
Throughout history, certain molds have been used safely in curing some meats to add flavor, as yeasts for bread, and as fermentation agents in liquor. They are also used to produce soy sauce, organic acids, and most of our antibiotics.

And despite the disease-producing potential of some varieties of molds, modern agriculture continues successful progress in developing mold-resistant strains of crops.

Even so, consumers will always have the responsibility for careful selection and storage of foods, for clean storage environment, reasonably quick use of perishables, and notification of proper authorities when store-handling practices are unsatisfactory.

Jane Heenan writes for  
**ED & COOKING**





*Very moist products can easily mold. But consumers should also check dried spices, being careful not to inhale mold spores. These are some examples of molds appearing on food—upper level, left to right, tomato, peach, and sage. Lower level photos show, left to right, mold on bread and cheese and, at far right, a sample of moldy sage in a Petri dish.*

# If You're Coloring Your Hair

by Jane Heenan



*Safety of hair dyes is less of a problem today than it once was. But consumers should know how to choose a hair coloring product and what they can expect from it.*

If you have healthy hair and scalp, generally good health, follow directions precisely, and don't expect miracles—you should be safe, and possibly happy, with coloring your hair.

If this sounds like a long list of qualifiers, consider what you're apt to find on the label of most hair dyes today:

*Caution—This product contains ingredients which may cause skin irritation on certain individuals and*

*a preliminary test according to accompanying directions should first be made. The product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.*

This is hardly the sort of wording that annually entices more than 20,000,000 Americans—women AND men—to change their hair color. But these facts are just a few of many that people who are considering such a step, or even who've practiced it for years, should keep in mind.

## **Carousel of Confusion**

Four thousand years ago, during the Egyptian Third Dynasty—at the time of the first recorded use of



hair dyes—people had neither the advantages nor the confusion that consumers face today in choosing hair coloring. The Egyptians, Persians, Hebrews, Greeks, Romans, Chinese, and Hindus used mostly plant and mineral products available in nature. And until the beginning of the 20th century, there was little progress toward the more natural and predictable shades that are easier to apply and more versatile than the primitive colors.

Today, advances in hair coloring chemistry, probably the most difficult and specialized field of cosmetics, have resulted in a diversity of products for which consumers spend more than 200 million dollars a year. Yet, just as the Egyptian princess wasn't always pleased with the dye results, neither do today's consumers always find satisfaction—or safety.

Consumers considering coloring their hair are faced with terms they've never heard of, warnings they often ignore, and information they'd just as soon let a hairdresser decipher. Yet, whether they do the coloring themselves, or turn to a friend or a professional, there's a much better chance for acceptable results if they understand what will be happening on top of their heads.

#### **Temporary Colors**

Temporary colors are rinses. They can be used by people who

want to try out a new color, or who need to be tided over between permanent coloring.

Rinses add highlights and brightness to natural color, improve shades of gray hair, and blend unevenly colored hair. But they will not lighten hair color.

Rinses are resistant to water, but since they do not penetrate the hair shaft, they are completely removable with one shampooing.

Rinses are easy to use. They are applied to the roots and combed to the ends.

The disadvantage is the color sometimes rubs off on pillows or clothes and may begin to run in water or perspiration.

#### **Semipermanent Treatments**

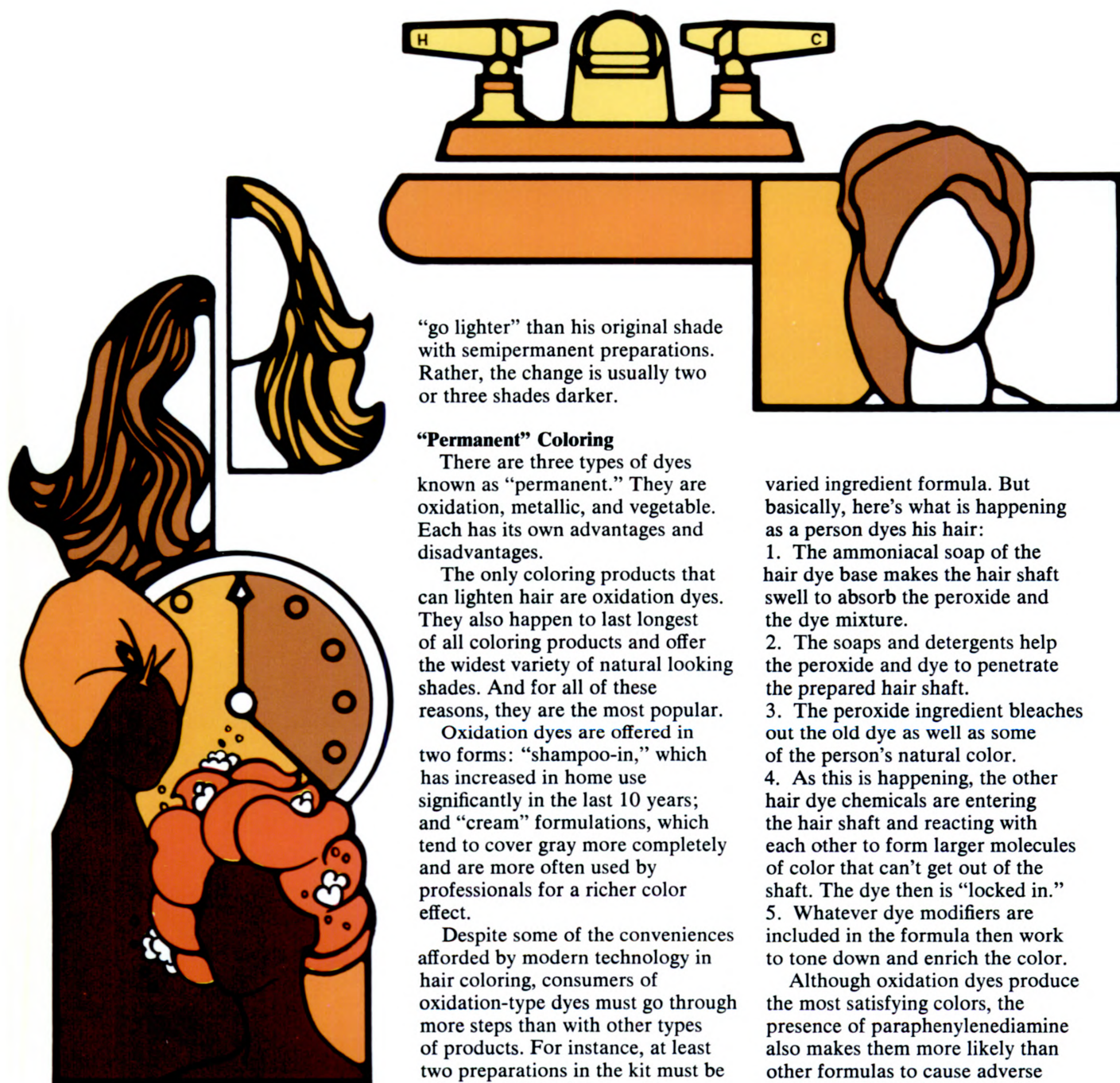
For a person who doesn't want the bother of frequent reapplication or wants a deeper color effect, a semipermanent product might fit the bill. These preparations last through about four shampoos, but do wear off eventually.

Semipermanent coloring is often used to blend streaked hair and to improve white or gray. It's also useful in adding highlights to natural blond hair.

The dye is applied directly and worked in like a shampoo. Color penetrates each hair shaft. And although there's no rub-off, some loss of color occurs with each shampoo. *(continued)*







“go lighter” than his original shade with semipermanent preparations. Rather, the change is usually two or three shades darker.

#### “Permanent” Coloring

There are three types of dyes known as “permanent.” They are oxidation, metallic, and vegetable. Each has its own advantages and disadvantages.

The only coloring products that can lighten hair are oxidation dyes. They also happen to last longest of all coloring products and offer the widest variety of natural looking shades. And for all of these reasons, they are the most popular.

Oxidation dyes are offered in two forms: “shampoo-in,” which has increased in home use significantly in the last 10 years; and “cream” formulations, which tend to cover gray more completely and are more often used by professionals for a richer color effect.

Despite some of the conveniences afforded by modern technology in hair coloring, consumers of oxidation-type dyes must go through more steps than with other types of products. For instance, at least two preparations in the kit must be mixed shortly before use. If a great deal of lightening is desired—for instance, from medium brown to light blonde—hair must first be bleached, and in some cases completely stripped of color and then redyed.

The permanent effect of oxidation dye requires a long and

varied ingredient formula. But basically, here’s what is happening as a person dyes his hair:

1. The ammoniacal soap of the hair dye base makes the hair shaft swell to absorb the peroxide and the dye mixture.
2. The soaps and detergents help the peroxide and dye to penetrate the prepared hair shaft.
3. The peroxide ingredient bleaches out the old dye as well as some of the person’s natural color.
4. As this is happening, the other hair dye chemicals are entering the hair shaft and reacting with each other to form larger molecules of color that can’t get out of the shaft. The dye then is “locked in.”
5. Whatever dye modifiers are included in the formula then work to tone down and enrich the color.

Although oxidation dyes produce the most satisfying colors, the presence of paraphenylenediamine also makes them more likely than other formulas to cause adverse reactions. To minimize this risk, some consumers choose permanent metallic or, rarely, vegetable dyes.

Metallic dyes, used for centuries, are making a small comeback, particularly with men, by advertising the special advantage of *gradual* color change and easy application. However, their description as “hair

Because no chemical reaction takes place during application as in permanent dyes, these colorings are usually milder and often chosen by people who are sensitive to permanent dyes.

Even though a complete range of colors is available, a person cannot



color restorers" gives the false impression that gray hair mysteriously resumes its original natural shade. Here's what really happens:

1. A small amount of the formula is combed in each day.
2. The metallic salt, mostly lead acetate and occasionally silver and bismuth compounds, reacts chemically on the head to produce metal sulphide pigments that coat the hair. The resulting color is often unnatural looking.
3. The process is repeated daily until the hair is as dark as desired. However, it's most important to discontinue or taper off using the product until more color is desired. Otherwise, the metallic ingredients build up to the extent that merely pushing the comb along may cause hair breakage and loss.

Metallic dyes cannot be removed and are incompatible with other coloring products—especially oxidation dyes—that a person may consider using to correct the color.

On healthy scalps, metallic dyes are apparently safe and cause no allergic reaction. But there are unresolved fears of toxic absorption of lead on abraded scalps.

As for vegetable dyes, there has also been a small ripple of interest lately in henna, a natural product that has been used for centuries. But its disadvantages are outstanding: a bright unnatural orange red, and stiff, brittle hair.

Generally, henna is applied as a pack containing ground leaves and



stems of the plant made into a paste with hot water and left on the hair for various lengths of time.

### **Bleaching**

Bleaching, as a sole means of color change, is rarely seen today, except for the purpose of lightening hair by one or two shades. Usually it's merely the first step in other dyeing procedures.

Although all bleaching causes some hair damage, undesirable results can be minimized if three things are kept in mind:

1. Bleaching should if at all possible be limited to once a month, which should be sufficient to hide new growth of dark roots.
2. Curling, teasing, and any other kind of punishment to the hair should be minimized.
3. Conditioners and other products formulated especially for bleached or dyed hair should be used to maintain softness, luster, and manageability.

### **When It's Not What You Wanted**

The most common problems in changing hair color are that the results are too red, too dark, or flat looking.

Many people who are pleased with their new color the first day find a short time later it's begun to turn red. Professional hairdressers can sometimes minimize this problem, but the best preventive is to be certain the product is good and to avoid prolonged direct sunlight exposure.

The reddening is caused by gradual decomposition of the dye as it is exposed to ultraviolet light; this happens to all dyes eventually and more quickly to colors that are less light-stable. During this process, the touches of natural red, present in almost everyone's hair and extremely difficult to remove completely, are also beginning to show through. This little bit of coloring is the part the bleaches and dyes affect least. (*continued*)



Color results that are darker than expected often stem from a misconception about what dyes actually can do. Unless hair is first stripped, the dye goes on top of the original color—and the new shade will then be darker than what the consumer saw on the advertising model. So, if you want, for instance, to achieve the same shade or a shade darker than your present color, you may have to use one shade lighter than your own hair color.

Another problem with which many consumers are familiar is the flat “shoepolish” look. This is less of a problem today than in previous years when the cause was often a deficient dye. Today, it more often results from improper use of the product or from an inferior product.

#### **And Once Again**

To avoid these problems and to increase the chance of overall satisfaction, the consumer's best bet is to follow directions precisely, to start out with generally good health and healthy scalp and hair, and to remember the patch test before each coloring.

Also, if you're not sure which type of hair dye you may be using or considering, you can try to find out about individual brands by writing the manufacturers. If you can't find the facts you want, it's wise to err on the side of safety and simply not use the product in question.

#### **A Word About Safety**

Although adverse reactions to hair coloring products today are few and far between, one point cannot be overstressed: Follow the directions precisely. When they call for a patch test, make one.

Furthermore, no matter how long a person has been using a particular product, if the patch test is indicated on the directions, it's important to make one before each application. A person can very gradually become sensitized to a product and should never assume that no adverse reaction will take place because of a history of satisfactory results.

The patch test requirement alerts consumers that the product can be more irritating or cause more allergic reactions than products without such labeling. The instructions for the test normally say to apply the product to a small area of skin—behind an ear or inside the elbow—and leave it for 24 hours. If any redness or swelling results, the product should never be used by that person.

Once a person develops an allergy to a type of dye, he remains allergic to it for life. There may

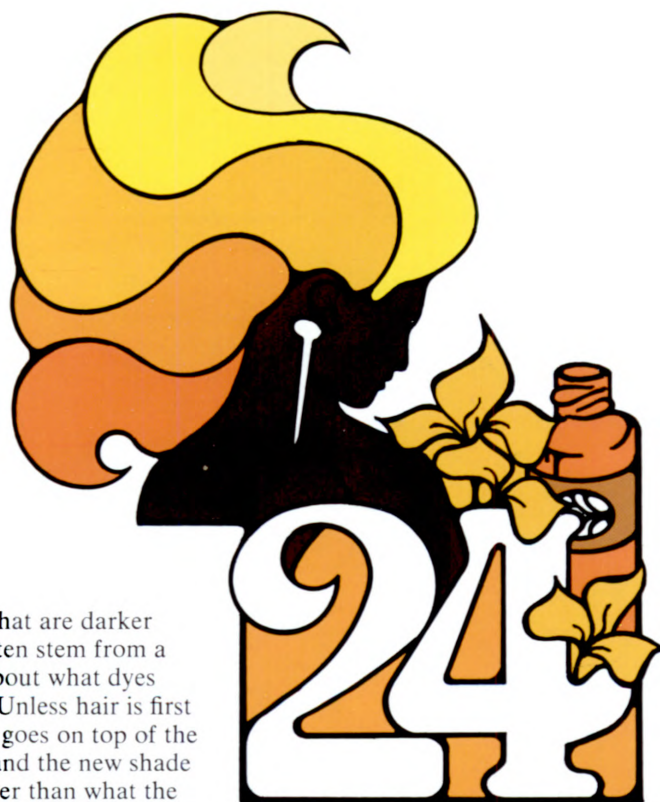
be other types he can use, but his safest course to determine alternatives is to consult a dermatologist.

Hair coloring products requiring a patch test and carrying the label warning quoted at the beginning of this article are not regulated by the Food and Drug Administration. They were specifically exempted from the Federal Food, Drug, and Cosmetic Act of 1938 by Congress after industry persuasively argued that the dyes could not meet safety standards of the Act but should nonetheless be sold to meet popular demand.

Even so, adverse reactions—itching, swelling, severe discomfort—are not often seen today because of improved techniques in formulation, greater purity of ingredients, and more extensive toxicological testing by manufacturers.

All such reactions should be reported to a physician as well as to the manufacturer and the FDA Division of Cosmetics Technology.

Jane Heenan writes for  
FDA CONSUMER.



## **Hair Coloring Terms**

### ***Accelerator:***

Peroxide in powder form added to peroxide bleach mixtures to increase bleaching effect. Also called "activator" or "booster."

### ***Bleaching:***

Removal of some or all of the hair color, whether natural or previously applied. Also called "lifting" or "lightening."

### ***Bleach Lotion or Oil:***

See Lightener Lotion.

### ***Conditioners:***

Ingredients in color lotions, or applied independently to the hair, to improve its sheen, softness, and manageability.

### ***Creme Colors:***

An oxidation hair dye product that forms a thick creamy lotion when mixed with developer. It is applied to new growth by "parting and sectioning" and is then combed through the hair tips.

### ***Creme Rinses:***

A rinse applied after coloring and shampooing to restore the initial condition of the hair, i.e., its normal acidity, softness, manageability.

### ***Developer:***

Hydrogen peroxide (usually 20 percent volume which equals 6 percent strength) supplied either as a clear liquid or cream lotion and used either to bleach hair or to develop the color of an oxidation dye.

### ***Double Process:***

Two-step process by which the hair is first bleached, usually drastically, and then re-dyed with a toner.

### ***Frosting:***

Bleaching and toning the entire length of random strands of hair over the entire head.

### ***Gentle Lightener:***

Mild peroxide formula which provides only a light bleaching effect.

### ***Lightener Lotion:***

The vehicle to which developer (peroxide) and accelerator are added to produce an effective bleach mixture. It is usually an ammoniacal soap solution and is often called "oil bleach."

### ***Metallic Dye:***

A hair dye product which contains metallic salts, usually lead acetate, as the active ingredient.

### ***Oxidation Hair Dye:***

A dye containing paraphenylenediamine and other hair dye intermediates that must be mixed with a peroxide developer just prior to application to the hair in order to develop the color.

### ***Para Dye:***

A hair dye product containing paraphenylenediamine as the primary hair dye intermediate. See Oxidation Dye.

### ***Patch Test:***

A test on the forearm, bend of the elbow, or behind ear to detect allergic sensitivity; by law it is required that a warning to perform such a test before each application of a hair color (unless the product contains only colors approved by FDA for cosmetic use) appear on the product labeling.

### ***Permanent Color:***

See Oxidation Dye.

### ***Prebleach:***

Bleaching the hair before application of a hair color or toner.

### ***Progressive Dye:***

A dye that colors the hair gradually during repeated application; a metallic dye.

### ***Restorer (Hair Color Restorer):***

Euphemism for a metallic dye.

### ***Retouching:***

The process of bleaching or dyeing the new growth (roots) with a permanent dye; it requires parting and sectioning of the hair; subsequently the applied bleach or dye is combed through the entire hair.

### ***Rinse (Color Rinse):***

A temporary hair color of low strength which is in the form of a rinse. It is removable by one shampooing.

### ***Semipermanent Color:***

Color that lasts through several shampoos. Usually a nonoxidation-type hair dye product.

### ***Shampoo-in Hair Color:***

Permanent dyes of the oxidation type that are applied like a shampoo. Also called color shampoo.

### ***Single Process:***

Bleaching and re-dyeing the hair in one step, as in the oxidation hair dyeing process.

### ***Streaking:***

The application of hair bleach to predetermined or random sections of hair.

### ***Stripping:***

Total removal of all natural and artificial color from hair with a soapy peroxide solution.

### ***Temporary Color:***

Color that is removed by the first shampoo.

### ***Tipping:***

Bleaching of predetermined or random tip ends of the hair.

### ***Toner:***

A light hair color applied to prebleached hair, usually an oxidation dye.

### ***Vegetable Dye:***

A color formed by applying only natural plant products, usually from the henna plant.



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## News Highlights

### **FDA to Set New Criteria For Antimicrobial Ingredients**

With publication of a report by a panel of expert advisors, FDA has taken a major step toward setting new regulatory criteria for assuring the safety and effectiveness of bacteria-killing ingredients (antimicrobials) in deodorant soaps, medicinal soaps, and first-aid products. The report concluded a 2-year review by a committee of non-FDA scientists.

The full report, as received by FDA from the committee, was published for public information and comment. FDA will evaluate the report and all comments on it before issuing a final regulation.

The antimicrobial review panel evaluated hundreds of ingredients which have been marketed and promoted for their germ-killing effectiveness. These ingredients range from iodine to pine tar.

Of the hundreds of antimicrobial ingredients evaluated, the panel identified 19 with some evidence of antimicrobial activity. Five of these were judged by the panel to have been shown safe and effective. They are: benzalkonium chloride, benzethonium chloride, methyl benzethonium chloride, hexylresorcinol, and tincture of iodine.

The first four were judged to be safe and effective as skin-wound cleansers; iodine was found safe and effective for patient preoperative skin preparations. The remaining ingredients (those not related to tribromsalan were found safe for some skin uses, but the panel recommended research to firmly establish effectiveness.

The panel also evaluated labeling claims for antimicrobial products and suggested that a number of current claims be prohibited because they mislead the consumer. Included are claims, not supported by scientific evidence, that a product speeds or aids healing, that it sanitizes, sterilizes, or disinfects the skin, that it ensures bacterially clean skin or that it controls infections.

On the basis of the panel's findings, FDA proposed that one antimicrobial, tribromsalan (TBS), and closely related chemicals, be prohibited from future use in nonprescription drugs as well as cosmetics.

The proposed FDA action against TBS is based on FDA's concurrence with the panel's concern that the ingredient can cause skin inflammation in some users after exposure to sunlight. While such an adverse reaction, called photosensitivity, is rare, it can be disabling or disfiguring and can persist for months or years.

One of the largest uses of TBS had been in antibacterial soaps. Most of these products were reformulated when the panel initially questioned the safety of the ingredient some months ago. FDA is unaware that any other chemicals in the TBS family have ever been used in nonprescription drug or cosmetic products.

If the FDA proposal on TBS is made final, it would be the second antimicrobial product to be removed from general use since this panel began its deliberations. FDA consulted with the panel before removing hexachlorophene from nonprescription use in mid-1972.

Antimicrobials is the second class of products evaluated for FDA by outside experts as part of an unprecedented program to assure safety, effectiveness, and proper labeling of all nonprescription drugs.

From these evaluations will come standards for each of 27 basic classes of nonprescription drugs. Each standard will constitute a kind of official "recipe book" specifying safe and effective ingredients, formulations, and labeling. The first monograph already has been issued for antacids. Premonograph reviews are also underway, and scientific reports are expected this year on analgesics, eye products, sleep aids, and laxatives.

Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, emphasized that the antimicrobial report has been prepared independently of the Food and Drug Administration and does not necessarily reflect the Agency's position on any matter.

Commissioner Schmidt cautioned, "The conclusions and recommendations of the panel must be read and evaluated carefully to differentiate theory from proven facts. Substantial controversy has already emerged with respect to the statements that use of antimicrobial bar soaps may kill harmless skin bacteria, resulting in a possible increase in harmful skin bacteria.

"This theory is not yet a proven scientific fact.

"The report is being published as a vehicle for further comment and criticism by industry, by consumers, and by the scientific peers of those on the review panel," said Commissioner Schmidt.

The FDA Commissioner assured that: "All points of view will be fully considered before the FDA takes final action."

The panel's report also recommended that some antimicrobial ingredients found in cosmetics be banned. On this basis, FDA will propose regulations to apply to cosmetics the same safety and labeling standards as are proposed for drugs containing antimicrobial ingredients.

Interested persons may comment in writing on the proposal. All comments should be sent to the Office of the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20852.



### **Survey Seeks Information On Cosmetic Injuries**

FDA and the American Academy of Dermatology (AAD) have cooperatively launched a 3-month survey among a nationwide sample of cosmetic users to determine the number, severity, and kinds of injuries caused by cosmetic products.

This is the first attempt by a Government agency to obtain valid cosmetic-related injury statistics from a general cross-section of the population.

This unique research effort, which began in September, involves 10,000 households and approximately 36,000 participants. All adverse reactions reported by participants in the survey will be verified by dermatologists. Contributing AAD dermatologists will examine persons referred to them during the

study at no cost to the Government or the individual.

Prior to this effort, FDA's principal source of information on cosmetic-related injuries has been a limited number of complaint letters from consumers. These letters often fail to give a medical diagnosis, lack sufficient detail, or are received too late for successful investigation of the reported injury.

Preliminary analysis of the survey results is expected to be completed in the spring of 1975. In addition to establishing the total number of cosmetic injuries in the sample population and the types of products causing these injuries, the survey is expected to show cosmetic use patterns by age, sex, family, community size, and geographic location.

The survey, being conducted by a data collection firm under a \$250,000 contract, is part of FDA's regulatory program for cosmetic safety.

### **Schmidt Urges Action On Rail Shipment Sanitation**

Dr. Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, warned September 10 that a persistent and "intractable" problem of protecting food from contamination during rail shipment must be met. He said the choices are voluntary, cooperative, and preventive measures, involving industry and Government, or a unilateral FDA program of increased seizures and prosecutions.

Speaking at a Railroad Car Sanitation Conference in Washington, Dr. Schmidt called on food shippers, railroads, and concerned Government agencies to develop a "plan of action" to eradicate insanitary conditions on railroad cars used to ship foods. He urged participants to develop programs for self-inspection, specifications, and standards for railcars and good transportation guidelines.

Commissioner Schmidt cited recent steps taken by FDA to improve sanitation in the Nation's food plants and in warehouses. This improvement involved an 8 million dollar effort made possible by money made available by Congress following a critical report of insanitary conditions in food plants and warehouses. The 1972 report was prepared by the General Accounting Office.

"FDA cannot be indifferent to conditions in food transportation which we would not tolerate in food processing or in storage," said Dr. Schmidt, adding: "A railcar is not different from a warehouse. We must regard it as a warehouse on wheels."

The FDA Commissioner asserted that FDA would take strong legal action if necessary, but said that "massive seizures of food, court injunctions, and other 'after-the-fact' activities seem a poor substitute for preventing the insanitary conditions in the first place."

The Railroad Car Sanitation Conference was sponsored by FDA and the Food and Drug Law Institute. More than 200 representatives of shippers, receivers, the railroads, and Government agencies attended.

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# Regional Reports

## REGION I

FDA's **Boston Field Office** reports that three New England companies were involved recently in two court actions charging the companies with holding food under insanitary conditions.

In a Federal court in Concord, New Hampshire, Francoeur Baking Co., Nashua, New Hampshire, and Fernand G. Francoeur, president, pleaded nolo contendere to one count of a criminal prosecution. The bakery was charged with adulterating flour by putting it into an insect-infested flour conveyor system. Magistrate William Barry accepted the pleas and fined the defendants a total of \$1,500.

C. Pappas Co., Inc., and Gloria Packing Corp., Boston, along with John C. Pappas, Jr., vice president and treasurer of Pappas and president of Gloria, and John Chrysakakis, general manager of both companies, were arraigned in a Federal court in Boston before U.S. Magistrate Willie Davis. The defendants were charged with three counts of storing food in a building infested by insects and rodents. Both companies pleaded guilty to the three counts, and the two individuals pleaded nolo contendere to a single count, the others being dismissed. The court accepted the pleas, found all defendants guilty, and fined them a total of \$2,150.

## REGION II

An attorney representing the Purdue Frederick Co., Westchester, New York, informed FDA's local resident post that the firm had recently purchased approximately 2,000 gallons of PVP (polyvinylpyrrolidone) iodine from a broker, only to learn later that the iodine was from an embargoed 3,272-gallon lot which was being held on a freight car at Frank's Parcel Service, Inc., Yonkers. The New York State Board of Pharmacy had embargoed the lot because it had been exposed to a fire at the warehouse, and the embargo had never been lifted. The contents of the freight car belonged to the U.S. Defense Supply Agency.

At the request of the State, FDA's **New York District** assisted in locating the remainder of the embargoed lot of iodine, some of which had been sold outside the State's jurisdictional area to a wholesaler in Fitchburg, Massachusetts, and some to a wholesaler in New York City. The State reembargoed the product at Purdue Frederick and at the New York City wholesaler.

American Roland Corp., New York City, has voluntarily destroyed 51 cartons of flat fillets of anchovies because of decomposition. The product, imported from Spain, was the subject of a consumer complaint to FDA's New York District. FDA officials found in a follow-up inspection at the wholesale source of supply that the lot contained a significant number of swollen cans. When the product was sampled, it was found to be decomposed. The firm arranged for the destruction in concurrence with District officials.

USV Pharmaceutical Corp., Tuckahoe, New York, has destroyed a return shipment of prescription drugs that had been damaged in transit by battery acid and water while enroute to the company's warehouse in Dallas. An FDA inspector from the **Westchester Resident Post** witnessed the burial at a dump site of 48,000 25-mg and 48,000 50-mg tablets of Chlor-Pz, 252,000 5-mg tablets of Varnail, and 190 two-ounce units of Pantho F Cream.

C. H. Coward, Byron, New York, a grain-storage facility, is making a special effort to correct violative conditions on its premises, for it is in trouble with the FDA for the second time in a year.

During the summer of 1973, FDA's **Buffalo District** obtained an injunction against the company prohibiting the storage of grain under gross insanitary conditions. Rodents had regular pathways, and birds had free access to the building because of holes in the structure. During the summer of 1974 and prior to the grain harvest, investigators from the Buffalo District returned to Byron and found the company's storage facilities in very poor condition and in violation of the injunction. The struc-



ture should have been rodent-free prior to receipt of the 1974 harvest. Again the company had to undertake special efforts to restore its status as a receiver of wheat grown in the State of New York for interstate shipment.

FDA's Buffalo District has obtained seizure in Rochester, New York, of an alleged medical device called Thermoscribe II valued at \$1,100. Literature, shipped with the device from Murdoch Engineering Co. of San Leandro, California, mislabeled the device as being effective for diagnosing a patient's sick, well, acute, chronic, and crisis patterns. It supposedly could provide nerve-pressure analysis and detect nerve interference. The device has been proved inadequate and ineffective for such purposes, and the labeling therefore is false and misleading.

Judge Lawrence A. Whipple of the U.S. District Court for the District of New Jersey at Newark signed a recent court order decreeing that condemned Bon Vivant Soup products under seizure in the various FDA Districts must be destroyed under the supervision of and in the manner prescribed by FDA offices responsible for each District. U.S. marshals are to contact local FDA offices for guidance in effecting the destruction. FDA's **Newark District** forwarded all Districts a copy of the court order and a memo from the Environmental Protection Agency listing approved sites of incineration and instructions as to how the product should be destroyed. FDA headquarters officials and EPA had determined that the only acceptable means of destruction would be total incineration.

Multiple seizures took place throughout the country in 1971 of Bon Vivant Soup and other products canned under private labels by Bon Vivant, Inc., Newark. The move came after the death of a man in New York State and the severe illness of his wife from botulism caused by eating the contents of a can of vichyssoise soup canned by the company. Analysis had revealed botulin toxin in that can and in four others of the same coded lot of the soup, as well as underprocessed and leaking or swelled cans among others of the company's products.

Consumer Affairs Officer Marta Knowlton in FDA's Newark District office has arranged with Elaine Goldin,

director of New Jersey's Somerset County Office of Consumer Affairs, for participation in a film series to be used in various consumer education classes in that county. Each 25-minute segment will feature a specific State or Federal agency and its role in consumer protection. FDA's segment will be an overview of the Food, Drug, and Cosmetic Act, complaint procedures, and consumer input into the FDA regulatory mechanism. The film series will be produced by the Office of Consumer Affairs in conjunction with the Somerville, New Jersey, High School and the Somerset County Audio Visual Aids Department.

Consumer Affairs Officer Minerva Sanchez, FDA's **San Juan District** office, collaborated with the Department of Consumer Affairs of Puerto Rico and other State agencies involved with consumer protection and information in preparation of a 28-page illustrated booklet in Spanish titled "Alimentos," recently published by the State department. FDA's input was on nutritional labeling and food labels.

"Alimentos" will be widely distributed throughout Puerto Rico, and will be channeled to home economics teachers, schools, consumer group leaders, and consumers in general. The publication will acquaint the user with good nutrition, proper food selection, food labeling, nutritional labeling, proper food storage at home, and the prevention of foodborne illness. Consumers or groups interested in bulk quantities can contact their nearest FDA consumer affairs officer.

Victor M. Barreto, FDA San Juan District investigator, assisted a U.S. marshal in accomplishing seizures of 340,000 pounds of flour valued at \$40,000 at Borinquen Macaroni Corp., Yauco, Puerto Rico; and 10,500 pounds of macaroni valued at \$2,500 at Almacenes Rivera, San Sebastian, Puerto Rico. Both lots were insect infested.

### REGION III

When FDA **Philadelphia District** officials started to make a routine inspection of Milford Packing Co., Milford, Delaware, recently, they found the doors closed





and a notice stating the contents would be sold at a sheriff's sale one week later. District officials contacted the sheriff, who allowed them to enter the building, where they found peppers, pickles, and sauerkraut in various stages of processing and in finished containers. A large number of the products were adulterated due to insects, rusted cans, and so forth. The FDA officials referred the matter to the Delaware Department of Health, which has the responsibility for sampling the articles and for declaring them adulterated.

#### REGION IV

Consumer Safety Officer Norman Miller, of the **Chattanooga Resident Post** in FDA's Nashville Section, recently witnessed the destruction of 14 cases of "Nut-Me-Ta" sandwich filler. The manufacturer, Tennessee Hills Foods, Inc., Dunlap, Tennessee, voluntarily destroyed the goods because of the swollen condition of many of the cans.

#### REGION V

Lilyan Goossens, consumer affairs officer at FDA's **Indianapolis Resident Post**, spoke on vitamins and minerals as they relate to nutrition labeling at nine recent statewide workshops sponsored by the Indiana State Department of Public Instruction. Over 3,000 food service workers of the department's Food/School Lunch Division attended the workshops.

#### REGION VII

Lorena Meyers, consumer affairs officer at FDA's **Kansas City Field Office**, participated in the Region VII American Indian Council at St. Mary's, Kansas, acquainting approximately 25 Indian agencies with FDA's current activities. Educational materials and visual aids were discussed with the group for use in

Kansas, Iowa, Nebraska, and Missouri. The Region VII American Indian Council represents approximately 60,000 Indians.

#### REGION VIII

When FDA's **Denver District** office learned recently that the City and County of Denver was preparing to auction off fall-out shelter supplies which the Emergency Preparedness Office had kept in storage for over 10 years, it became a matter of concern, for the supplies include medical supply kits along with the survival food items. FDA Investigator John Vodneck and Drug Enforcement Agency officials persuaded the City and County Purchasing Department and the Emergency Preparedness Office to remove all drug items from the kits before selling them. The kits contained such items as penicillin, phenobarbital, sulfadiazine, and aspirin.

#### REGION IX

FDA's **San Francisco District** recently supervised the destruction by disposal as garbage of approximately 25 cartons of moldy pistachio nuts valued at \$794. The nuts, adulterated while held for sale after shipment in interstate commerce, were seized at Bezzerides Co., Pacheco, California.

#### REGION X

Macaroni products processed under insanitary conditions and contaminated by insect fragments before shipment in interstate commerce cost the Porter-Scarpelli Macaroni Company, Portland, Oregon, and Ernest M. Scarpelli, president and general manager, a total of \$2,000 in fines, resulting from investigation by FDA's **Seattle District**. Each defendant pleaded guilty to two counts in the U.S. District Court for Oregon, Portland. Mr. Scarpelli was placed on probation for one year under instructions by the court to see that the company's manufacturing facilities and equipment are cleaned up.

A Seattle food manufacturer and two of its officers have entered into a consent decree of permanent injunction requiring them to discontinue misbranding practices for a flour mix. Under the terms of the decree, Sterling Food Company and Werner H. Horn, president, and P. Reginald Banks, secretary-treasurer, must destroy all existing labels of the company's product labeled as Soyacaroba (or Soya Carob), recall all outstanding products, supply a copy of the decree to all its customers who received the product, and submit revised labeling to FDA for review and approval prior to resuming distribution of the product. The Government's complaint filed in the U.S. District Court for the Western District of Washington, Seattle, after investigation by FDA's Seattle District, said the product had been promoted for use by persons allergic to wheat flour but that it, in fact, contained substantial amounts of wheat flour.



## **FDA Hires New Consumer Affairs Officers**

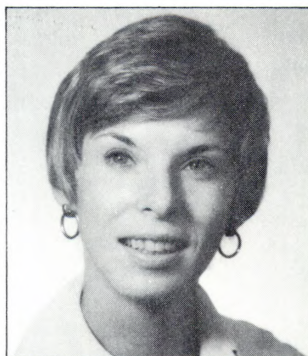
On this page are pictured some of the newer consumer affairs officers hired by the Food and Drug Administration to work with consumers and consumer groups across the country. FDA now has 52 consumer affairs officers serving the public, more than double the number just two years ago. Photographs of the other consumer affairs officers appeared in the September 1972 and June 1973 issue of FDA CONSUMER.



**Mary Groome**  
Region III—Pittsburgh  
(412) 644-2859  
(Pennsylvania, Delaware, Maryland, Virginia, West Virginia, District of Columbia)



**Barbara Ann Banks**  
Region IV—Nashville  
(615) 749-5851  
(Kentucky, Tennessee, North Carolina, South Carolina, Georgia, Alabama, Mississippi, Florida)



**Cynthia Wasson**  
Region IV—Atlanta  
(404) 526-3162  
(Georgia)



**Kathy Jones**  
Region IV—Orlando  
(904) 377-2282  
(Florida)



**Sandra Simmons**  
Region V—Grand Rapids  
(616) 456-2340  
(Michigan, Illinois, Indiana, Ohio, Minnesota, Wisconsin)



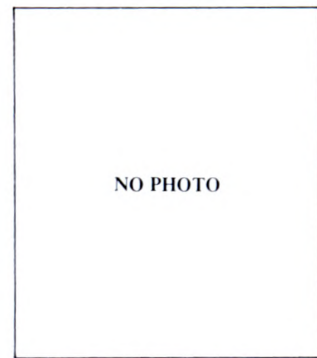
**Winn Dekoski**  
Region V—Minneapolis  
(612) 725-2121  
(Minnesota)



**Catherine M. McDade**  
Region V—Chicago  
(312) 353-7126  
(Illinois)



**Gordon Bourgin**  
Region V—Cincinnati  
(513) 684-3500  
(Ohio)



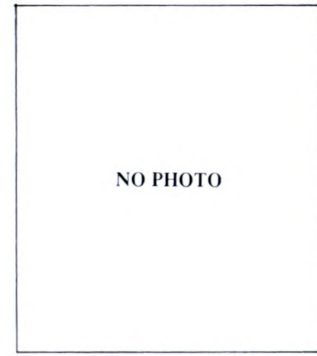
**Margaret O. Steen**  
Region II—Albany  
(518) 472-6045  
(New York, New Jersey, Puerto Rico)



**Frances Brysson**  
Region VI—New Orleans  
(504) 589-2420  
(New Mexico, Oklahoma, Arkansas, Louisiana, Texas)



**Grace Paavola**  
Region VIII—Denver  
(303) 837-4917  
(Colorado, Utah, North Dakota, South Dakota, Montana, Wyoming)



**Bernadette Simon**  
Region III—Baltimore  
(301) 962-3396  
(Maryland)



**Camilla Gray**  
Region IX—San Francisco  
(415) 556-2062  
(Nevada, Hawaii, California, Arizona)



**Ellen M. Miller**  
Region X—Seattle  
(206) 442-5258  
(Washington, Oregon, Idaho, Alaska)



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## State Actions

### Chemical/Nutrient Mix-up

All divisions of the Michigan Department of Agriculture with responsibility for consumer protection have been involved since last spring in a massive investigation regarding the contamination of animal feeds with a fire-retardant chemical. Although the State officials were aware of problems with a few dairy herds as early as mid-1973, they had been unable to determine the cause until after extensive laboratory testing and research were performed by State, USDA, FDA, and private laboratories.

Farm Bureau Services, Battle Creek, Michigan, unknowingly had blended poly-brominated biphenyls into various animal feeds, primarily dairy feeds, in place of the nutrient additive magnesium oxide. Farm Bureau apparently received bags of the fire retardant mixed with bags of magnesium oxide from Michigan Chemical Co. in St. Louis, Michigan.

To safeguard the public health, the Michigan Department of Agriculture quarantined over 30 herds of cattle totaling nearly 3,000 animals and three flocks of chickens by the end of last May. Tons of milk from quarantined dairy herds have been destroyed. State officials have also seized lots of butter and cheese containing the polybrominated biphenyls.

FDA's Detroit District assisted in the overall investigation and in running assays of the hundreds of samples of feeds and animal products generated by the investigation. The Michigan Department of Public Health is investigating the possible effects of the biphenyls on human health.

### Labeling for Salvaged Food

Any salvaged food sold in Oregon in the future would have to be clearly labeled as such under regulations proposed by the Oregon

Department of Agriculture.

The proposed regulations would implement that section of the Oregon Food Law stipulating that the term "salvaged" be used on food reconditioned, repackaged, relabeled, cleaned, or cut as a result of damage or adulteration from fire, storm, flood, water, smoke, chemicals, radiation, or commercial transit accidents.

As proposed, the word "salvaged" would be required to be in approximately the same area of the label as the product name of the food item. In the case of bulk sales, a placard could be used which would have to be prominently displayed and be immediately adjacent to the food.

Other required information would include the name and complete business address of the salvager in lieu of the name and business address of the manufacturer, packer, or distributor. The salvager would be given the option of using information on the type of salvage operation, such as "repackaged," "reconditioned," or "relabeled."

The regulations, which the State department of agriculture proposes to implement October 25, would also require that both labels and placards on "salvaged" foods be easily read by the consumer. Failure to comply with the regulations would be a violation of the Oregon Food Law.

### Open Date Labeling

Lenience in enforcing the Oregon Department of Agriculture's Open Date Labeling regulations ended the week of September 15. State Director of Agriculture Irvin Mann, Jr., said, "Our lenience, particularly on poultry products, has ceased. Products not in compliance are now subject to seizure."

Director Mann added, "Certain segments of the food industry experienced some difficulties at first,

and we offered what assistance we could to help them comply. There has been a particular problem getting out-of-State fryers labeled with slaughter dates as required in Oregon's regulations."

The Open Date Labeling regulation has been in effect since July 1. It requires that certain perishable foods sold in Oregon be marked with dates indicative of the freshness of the product.

The U.S. Department of Agriculture recently adopted regulations calling for voluntary compliance with its own open dating guidelines. In response to this, the Oregon Department of Agriculture has adopted by administrative order temporary regulations slightly modifying the Oregon Open Date Labeling regulations to comply with those of the Federal Government. The temporary order requires the poultry industry to post either the slaughter date, as previously required, or a pull date, called a "sell by" date in the USDA regulations. The temporary order became effective September 16, and a permanent order will be sought later in the year.

### Contaminated Peas

A canner of peas in Wisconsin recently voluntarily destroyed, by burying, 10,959 cases of peas, each case containing 24 cans, from the July 23, 1973, pack, because of possible contamination by broken glass. Inspector J. M. Gabor, Division of Food Standards, Wisconsin State Department of Agriculture, and Inspector R. D. Mier, U.S. Department of Agriculture, witnessed the destruction. USDA had discovered an accident involving glass at the plant which could possibly have contaminated the peas, the State department of agriculture maintained surveillance over the lot, and none of it reached the consumer.

# 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 52 actions to remove from the consumer market products charged to be violative was reported in September. These included 26 seizures of foods: 1 involved charges concerning a poisonous and deleterious substance, 25 involved

charges concerning contamination. Other seizures included 8 of drugs, 2 of medical devices, 1 of prophylactics, and 15 of cosmetics.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>FOOD/Poisonous and Deleterious Substances</b>		
Oats/Cedar Rapids, Iowa 6/17/74	Walsh Grain Co./Minneapolis, Minn. (S)	Contain a mercurial compound, an unsafe pesticide chemical.
<b>Contamination, Spoilage, Insanitary Handling</b>		
Beans, pinto, split/Mesa, Ariz. 9/10/74	Hansen Elevators, Hansen, Idaho (M); Prusse Sales Co., Denver, Colo. (S)	Contain dirty beans, animal excreta, insect-damaged beans, and rocks.
Brazil nuts/Los Angeles, Calif. 6/25/74	Imported from Brazil.	Insect contaminated; contain decomposed, rancid, and moldy nuts.
Federal Brew Conditioner/Bufalo, N.Y. 8/9/74	Royale Rolls, Inc./Buffalo, N.Y. (D)	Insect contaminated.
Buttermilk powder/St. Louis, Mo. 9/5/74	Universal Flavors of Missouri, Inc./St Louis, Mo. (D)	Held under insanitary conditions.
Corn husks in bales/Denver, Colo. 9/11/74	El Molino Foods, Inc./El Paso, Tex. (S)	""; rodent contaminated.
Crabmeat, canned/Honolulu, Hawaii 5/24/74	Imported from Taiwan, Angel Trading Co., Ltd./Osaka, Japan (S)	Decomposed.
Foster City, Calif. 8/7/74	Imported from Taiwan	Insect contaminated.
Foster City, Calif. 8/22/74	Lein Mou Food Factory Ltd./Kaoshiung, Taiwan (M,S)	"
Creecy greens (dry land cress)/Salem, Va. 7/26/74	Monticello Canning Co., Inc./Crossville, Tenn. (M,S)	Contain cockleburrs which may render article injurious to health; no accurate statement of quantity of contents.
Filberts, Spanish peanuts, peanuts/Everett, Miss. 9/11/74	The Leavitt Corp./Everett, Mass. (D)	Insect and rodent contaminated.
Flour/Trenton, N.J. 6/26/74	Landolfi Food Products/Trenton, N.J. (D)	Held under insanitary conditions.
Yauco, P.R. 7/23/74	Porinquen Macaroni Corp./Yauco, P.R. (D)	""; insect contaminated.
Seattle, Wash. 8/22/74	Oscar Lucks Co./Seattle, Wash. (D)	"
Food products, various/New Orleans, La. 9/17/74	George W. Groetsch Wholesale Grocer/ New Orleans, La. (D)	""; rodent and insect contaminated.
Milk/San Juan, P.R. 8/31/74	Almacenes Maritimos Inc./San Juan, P.R. (D)	Decomposed.
Spanish peanuts/Brooklyn, N.Y. 6/13/74	Banner Candy Manufacturing Co./Brooklyn, N.Y. (D)	Rodent contaminated.
Pecans, canned, shelled/Charleston, S.C. 5/22/74	Finer Foods Sales Co., Inc./Richmond, Va. (M,S)	Insect contaminated; not in conformity with the Fair Packaging and Labeling Act.
Rice/South San Francisco, Calif. 8/7/74	Oriental Trading Co./South San Francisco, Calif. (D)	Held under insanitary conditions; rodent contaminated.
soybeans/Columbia, Md. 9/20/74	Japan Food Corp./Columbia, Md. (D)	"
Sable fish, King Salmon/Brooklyn, N.Y. 4/16/74	National Cold Storage/Brooklyn, N.Y. (D)	Decomposed.
Sodium acid pyrophosphate/Monte Vista, Colo. 7/24/74	Nonpareil Processing/Monte Vista, Colo. (D)	Held under insanitary conditions.
Spaghetti/San Sebastian, P.R. 7/26/74	Almacenes Rivera/San Sebastian, P.R. (D)	""; insect contaminated.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>Contamination, Spoilage, Insanitary Handling (cont'd)</b>		
Sugar, cane/Oklahoma City, Okla. 9/12/74	Woody Candy Co./Oklahoma City, Okla. (D)	Held under insanitary conditions.
brown, cane, citric acid anhydrous/ Colorado Springs, Colo. 8/8/74	Adams Syrup Co., Inc./Colorado Springs, Colo. (D)	''; rodent contaminated (brown sugar).
Walnut kernels, black/Nashville, Tenn. 7/9/74	Block Bros., Inc./Nashville, Tenn. (P,S)	Prepared, packed, and held under insanitary condi- tions; rodent contaminated.
<b>DRUGS/Human Use</b>		
Amodril Spancap (levamphetamine succin- ate)/Miami Beach, Fla. 7/1/74	North American Pharmacal/Dearborn, Mich. (S)	Article misbranded in that labeling lacks adequate directions for use; new drug without effective ap- proved New Drug Application.
Dex-Amobarb #1 et al/Lancaster, Pa. 5/ 17/74	Manufacturers unknown; various shippers.	Articles misbranded in that labeling lacks adequate directions for use; new drugs without effective ap- proved New Drug Applications.
Digitoxin tablets/Muskegon, Mich. 8/16/ 74	Generic Drug Co./Muskegon, Mich. (M); Darby Drug Co./Inwood, N.Y. (S)	Quality and strength below U.S.P. standard.
Nan Lien Herbal Pill/Berkeley, Calif. 9/6/ 74	Nan Lien Pharmaceutical Co./Hong Kong, China (M); Shey Fon Trading Co./Hong Kong, China (S)	Label fails to bear established name of each active ingredient, dangerous to health when used as di- rected; new drug without effective approved New Drug Application.
Potassium chloride injection/Columbus, Ohio 8/16/74	International Medication Systems, Ltd./ So. El Monte, Calif. (M,S)	Not in conformity with good manufacturing prac- tice.
Sanorex tablets/Baltimore, Md. 9/13/74	Sandoz Pharmaceuticals, Div. of Sandoz- Wander, Inc./East Hanover, N.J. (M,S)	Article misbranded; lacks adequate directions for use.
Sterile silicone/Hot Springs, Ark. 9/5/74	Dr. D.B. Stough, III./Hot Springs, Ark. (D)	Failure to bear name and place of business of manu- facturer, packer, or distributor and accurate state- ment of net quantity of contents; fails to bear established name of drug; inadequate directions for use.
Uripin tablets/New Orleans, La. 8/1/74	Pan American Laboratories/New Orleans, La. (D)	Fails to disintegrate within the time required for the disintegration of enteric-coated tablets.
<b>MEDICAL DEVICES</b>		
Diapulse/Raymondville, Tex. 6/11/74	Diapulse Manufacturing Corp. of America/ New York, N.Y. (M)	False and misleading claims to be effective for speci- fied conditions; inadequate directions for use.
Thermoscribe II/Rochester, N.Y. 7/29/74	Murdock Engineering Co./San Leandro, Calif. (M,S)	False and misleading labeling to be effective in diagnosing sick, well, acute, chronic, and crisis patterns through nerve-pressure analysis.
<b>Prophylactics</b>		
Prophylactics/Council Grove, Kans. 9/3/74	M&M Rubber Co./Kansas City, Mo. (M,S)	Defective quality.
<b>COSMETICS</b>		
Long nails/Houston, Tex. 8/21/74	C.E.B. Products, Inc./Chicago, Ill. (M,S)	Article contains a poisonous and deleterious sub- stance (liquid methyl methacrylate monomer), which may render article injurious to users under such conditions of use as are customary or usual.
Houston, Tex. 8/23/74	''	''
Gary, Ind. 8/28/74	''	''
Highland Park, Mich. 8/29/74	''	''
Memphis, Tenn. 8/29/74	''	''
Toledo, Ohio 8/30/74	''	''
Henderson, N.C. 9/10/74	''	''
Hayward, Calif. 9/11/74	''	''
San Francisco, Calif. 9/12/74	''	''
San Jose, Calif. 9/12/74	''	''
Dallas, Tex. 8/28/74	''	''
Cincinnati, Ohio 9/3/74	''	''
St. Louis, Mo. 9/10/74	''	''
Buffalo, N.Y. 9/19/74	''	''
Cheektowaga, N.Y. 9/19/74	''	''

(cont'd)



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**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 (30 U.S.C. 3005) as reported by the Chief Postal Inspector.

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

- July 10, 1974: Against **Dena of Denmark**, 7471 Melrose Avenue, Los Angeles, California 90046. Advertising and sale by mail of Supreme Natural Essence Bosom Creme represented to be effective for enlargement of the bosom.
- July 19, 1974: Against **Smoking Withdrawal Program**, 6300 Wilshire Boulevard, Suite 10001, Los Angeles, California 90048. Advertising and sale by mail of the Kicker Kit represented to be effective for breaking the smoking habit.
- July 29, 1974: Against **International Health Establishment BBC #55**, Vesterbrogade 208, 1800 Copenhagen, Denmark and Postfac 6072, 2011 Malmö #6, Sweden. Advertising and sale by mail of the Swedish Reducing Capsule represented to enable the user to lose up to 60 pounds in 6 weeks.

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

- July 3, 1974: **Porter and Dietsch, Inc.**, 2453 University Avenue, St. Paul, Minnesota. Advertising and sale by mail of X-11 Reducing Plan represented as an effective means for the user to lose 25 pounds or more without changing eating habits.
- July 18, 1974: **Impact Diets**, P.O. Drawer 5128, Winston-Salem, North Carolina 27103. Sale and advertising through the mails of a diet plan designed to enable the user to lose 12 pounds in 12 days.
- July 22, 1974: **Cosvetics Laboratories**, 1030 Windsor Parkway, Atlanta, Georgia 30319. Advertising and sale through the mail of a Vitamin E Shampoo represented to aid in scalp conditioning and in promoting vasolary circulation and vasodilation, and Vitamin E Capsules represented as being effective for healing stretch-marks and for helping to make the body beautiful from the inside out.
- July 24, 1974: **Northwest Plaza Drive**, Dallas, Texas 75225. Advertising and sale through the mail of an electronic board designed to cure all ills.
- July 26, 1974: **Tray Laboratories and Tray Laboratories Mail Orders**, P.O. Box 174, at Wenonah, New Jersey 08090. Advertising and sale by mail of Naturaid represented as an effective remedy for male impotency.
- August 2, 1974: **Nutri-Diet**, 22028 Ventura Boulevard, Woodland Hills, California 91364. Advertisement and sale by mail of multivitamin tablets represented to be effective for weight loss.
- August 6, 1974: **Comfonics Corp.** and P.O. Box 1132, Weston Branch at Westport, Connecticut 06880. Advertising and sale by mail of the "revolutionary" new Youth Mask represented as equivalent to the effect produced by a miniature surgical face-lift (mini-lift).

# Notices of Judgment

## NOTICES OF JUDGMENT on Seizure Actions FOOD/Poisonous and Deleterious Substances

### Frog legs, frozen, at Chicago, N. Dist. Ill.

Charged 1-28-74: when shipped by E. J. Kozins Co., Chicago, Ill., from Rotterdam, Holland, the article, labeled in part "ACE Brand Frog Legs Processed and Packed for Sawant Fisheries . . . Bombay Product of India," contained the added poisonous and deleterious substance *Salmonella* micro-organisms; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 59630; S. No. 26-398 G; N.J. No. 1)

### Swordfish, frozen, 3 seizure actions, at Newport Beach, C. Dist. Calif.; Los Angeles, C. Dist. Calif.; and Wilmington, C. Dist. Calif.

Charged 1-15-71, 3-24-71, and 3-30-71: when shipped, the articles, which in whole or in part were from fish caught in waters outside the State of California, contained the added poisonous and deleterious substance mercury; 402(a)(1). Approximately half of the fish at Newport Beach, Calif., was claimed by Madel E. Kingston, t/a Bayside Fish Market, Newport Beach, Calif., who denied the charge. The remainder was subsequently the subject of a default decree which ordered that remainder destroyed. Holly Seafood Co., Los Angeles, Calif., claimed the fish seized at Los Angeles, Calif., and denied the charge. Pete Dragich, Redondo Beach, Calif., claimed the fish seized at Wilmington, Calif., and denied the charge. The Government served written interrogatories on the claimants. After the interrogatories were answered, the Government moved for summary judgment and for consolidation of the actions. The court granted partial summary judgment, ruling that the articles had been shipped in interstate commerce. Pursuant to stipulation, the consolidated actions were continued for some time to await the completion and availability of the results of up-to-date studies concerning mercury contamination. Ultimately, the claimants withdrew their claims and answers, and default decrees ordered the articles destroyed. (F.D.C. Nos. 56825, 57074, 57106; S. Nos. 51-419 D, 51-760 D, 66-644 E, 66-648 E, 67-046 E; N.J. No. 2)

## FOOD/Contamination, Spoilage, Insanitary Handling

### Barley, malted, at Santurce, Dist. P.R.

Charged 5-29-74: while held by Cerveceria Corona, Inc., Santurce, P.R., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for conversion into animal feed. (F.D.C. No. 59784; S. No. 23-428 H et al.; N.J. No. 3)

### Cornmeal and dried pinto beans, at Mountain Grove, W. Dist. Mo.

Charged 2-15-74: while held by Richards Bros., Inc., Mountain Grove, Mo., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59659; S. Nos. 47-048/9 G; N.J. No. 4)

### Flour, at East Carondelet, E. Dist. Ill.

Charged 5-22-74: while in transit in a river barge, the article had been held under insanitary conditions, since the barge had partially sunk in the Ohio River; 402(a)(4). Consent decree authorized release to Midwest Commodities, Inc., Mulberry Grove, Ill., for industrial use. (F.D.C. No. 59788; S. Nos. 94-202/3 H; N.J. No. 5)

### Flour, at Phoenix, Dist. Ariz.

Charged on or about 3-14-74: while in interstate commerce, the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Atchison, Topeka & Santa Fe Railway Co., Phoenix, Ariz., for salvaging. (F.D.C. No. 59709; S. No. 56-023 G; N.J. No. 6)

### Flour, milk powder, and sugar, at Barberton, N. Dist. Ohio.

Charged 1-25-74: while held by Gardner Pie Co., Inc., Barberton, Ohio, the milk powder contained rodent filth, and all 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. 59620; S. Nos. 31-980/2 G; N.J. No. 7)

### Peanuts, shelled, at Brooklyn, E. Dist. N.Y.

Charged 6-3-74: while held for sale, the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59791; S. No. 42-350 H; N.J. No. 8)

### Peanuts, unshelled, at St. Louis, E. Dist. Mo.

Charged 4-19-74: while held by N. E. Friedmeyer-Sellmeyer Distributing Co., St. Louis, Mo., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree authorized release to a government commission for use as wildlife feed. (F.D.C. No. 59740; S. Nos. 79-561/3 H; N.J. No. 9)

### Pineapple slices, canned, at Miami, S. Dist. Fla.

Charged 1-25-74: while held for sale, the article was held in swollen, leaking, and rusty cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59645; S. No. 476 G; N.J. No. 10)

### Popcorn and dried black-eyed peas, at San Angelo, N. Dist. Tex.

Charged on or about 1-22-74: while held by Martin Glover Co., San Angelo, Tex., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59634; S. No. 37-284 G et al.; N.J. No. 11)

### Rice, soybeans, and hominy grits, at Chicago, N. Dist. Ill.

Charged 5-1-74: while held by Grocerland Co-Operative, Inc., Chicago, Ill., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59759; S. No. 97-001 H et al.; N.J. No. 12)

### Sage, at Denver, Dist. Colo.

Charged on or about 6-10-74: while held by P. Hicks Cadle & Co., Inc., Denver, Colo., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59812; S. No. 80-736 H; N.J. No. 13)

### Salmon, headed, dressed, frozen, at Seattle, W. Dist. Wash.

Charged 10-3-73: while held for sale, the article contained decomposed fish; 402(a)(3). Consent decree authorized release to Northern Products Corp., Seattle, Wash., for salvaging. (F.D.C. No. 59494; S. No. 97-472 G; N.J. No. 14)

### Sesame seeds, at Stockton, E. Dist. Calif.

Charged 5-24-74: while held by Stockton Port District, Stockton, Calif., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Lucidi Packing Co., Fresno, Calif., for salvaging. (F.D.C. No. 59787; S. Nos. 26-081/4 H; N.J. No. 15)

### Shrimp, canned, Bendiksen's East Point, at Kodiak, Dist. Alaska.

Charged on or about 10-22-71: when returned to the packer East Point Seafood Co., Kodiak, Alaska, after delivery to an interstate carrier, the article had been prepared and packed under insanitary conditions; 402(a)(4). The article was claimed by Queen Fisheries, Inc., Seattle, Wash., who denied the charge and denied that the court had jurisdiction, asserting that the article had not been delivered to the interstate carrier, because it had been placed in a van owned by the interstate carrier but had been removed from the van before the van was delivered to the interstate carrier. Thereafter, a consent decree authorized release to the claimant for salvaging. (F.D.C. No. 57583; S. No. 43-081 E; N.J. No. 16)

### Starch, modified, at Los Angeles, C. Dist. Calif.

Charged 5-21-74: while held by Green Boys Foods, Inc., Los Angeles, Calif., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59779; S. No. 67-311 H; N.J. No. 17)

### Stock of commingled human and animal food in containers such as bags, cartons, cans, jars, and bales, at Denver, Dist. Colo.

Charged 1-30-74 and amended 2-14-74: while held by Walk Brokerage, Inc., Denver, Colo., the articles were held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59652; S. No. 44-327 G et al.; N.J. No. 18)

### Sugar, brown, at Detroit, E. Dist. Mich.

Charged on or about 4-12-74: while held by Lakeshore Warehouse, Inc., Detroit, Mich., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59749; S. No. 84-124 H; N.J. No. 19)

### Sugar, confectioner's, at Alexandria, E. Dist. Va.

Charged 7-12-73: while held by Krispy Kreme Doughnut Co., Alexandria, Va., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59371; S. No. 10-549 G; N.J. No. 20)

### Sugar, granulated, at Memphis, W. Dist. Tenn.

Charged 9-12-73: while held for sale, the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Patterson Warehouses, Inc. (Div. of Day Companies, Inc.), Memphis, Tenn., for salvaging. (F.D.C. No. 59456; S. No. 4-232 G; N.J. No. 21)

## FOOD/Economic and Labeling Violations

### Popcorn, TNT, at Lawrence, Dist. Kans.

Charged 11-16-73: while held by T-N-T Food Products, Inc., Lawrence, Kans., the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not separated from other printed label information appearing above the declaration; and the quantity of contents statement, appearing on a principal display panel area of more than 25 square inches, was in a type size less than 3/16 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Consent decree authorized release to the dealer for relabeling. (F.D.C. No. 59549; S. No. 46-633 G; N.J. No. 22)



**Sauce for hot dogs and hamburgers, Texas Pete, at Greenville, Dist. S.C.**

Charged 3-1-72: when shipped by T. W. Garner Food Co., Winston-Salem, N.C., the labeling of the article was false and misleading, since the label vignette depicting what appeared to be ground meat on a frankfurter and the undue prominence given to the word "Chili" as part of the name "Chili Sauce" on the can label, and the word "Chili" on the case label, represented and suggested that the article contained substantial amounts of meat, when, in fact, the article contained no meat other than beef fat; 403(a). The article was claimed by the shipper who denied the charge. Thereafter, the claimant moved to have the action removed to the district of the claimant's principal place of business. The court denied such motion. Subsequently, upon consent of the parties, the action was removed to the Eastern District of North Carolina. Thereafter, pursuant to a consent decree of condemnation, the article was authorized to be donated to a charitable institution. (F.D.C. No. 57849; S. No. 94-740 E; N.J. No. 23)

**Tomato sauce, tortilla chips, and seasoning mix combination for taco casserole, at Sparks, Dist. Nev.**

Charged 1-12-73: when shipped by McCormick & Co., Inc., Salinas, Calif., the article's name "Taco Casserole" and its carton label vignette depicting a casserole containing meat falsely and misleadingly suggested and implied the presence of meat in the article, when the article contained no meat; 403(a). The article was claimed by the shipper. Pursuant to stipulation, the article was transferred to the Eastern District of Pennsylvania. Thereafter, the parties served written interrogatories on each other. The claimant moved to withdraw its claim and the Government opposed such motion. The case came on for trial. After the presentation of a number of expert witnesses by the Government, the claimant represented to the court that this product with the challenged labeling was no longer marketed by the claimant, and that the claimant would label such product in accordance with the regulations of August 2, 1973, concerning food packaged for use in the preparation of "main dishes" or "dinners" (21 CFR 102.12), and that no useful purpose would be served by contesting the charge. Accordingly, a consent decree was entered in which the claimant, denying that the article was in any respect violative, consented to the donation of the article to charitable institutions. (F.D.C. No. 58734; S. No. 74-248 F; N.J. No. 24)

**VITAMINS/SPECIAL DIETARY FOODS**

**Choline tablets, multivitamin tablets, and vitamin E capsules, at Saugus, C. Dist. Calif.**

Charged 5-16-72: while held by Pacific Pharmaceutical Corp., Saugus, Calif., who manufactured the choline tablets and multivitamin tablets from ingredients shipped in interstate commerce and who had repacked the vitamin E capsules from bulk capsules shipped in interstate commerce, the article's labeling contained the following false and misleading claims: choline tablets—the false and misleading label statements "Choline from Choline Bitartrate . . . Directions: As a dietary food supplement one tablet daily," which falsely and misleadingly represented and suggested that choline was a nutrient with special dietary properties; multivitamin tablets—the false and misleading statements "As a dietary supplement, one tablet daily" and "Each Two Tablets Contain: Vit. A . . . 25,000 IU . . . Vit. D . . . 1500 IU . . . Thiamine Mono (B<sub>1</sub>) 15 mg. . . Riboflavin (Vit. B<sub>2</sub>) 10 mg. . . Vit. B<sub>12</sub> . . . 50 mcg. . . Ascorbic Acid (Vit. C) 200 mg. . . Niacinamide 100 mg. . . Vitamin E . . . 200 IU . . ." which falsely and misleadingly represented and suggested that 25,000 International Units of vitamin A, 1500 International Units of vitamin D, 15 milligrams of thiamine, 10 milligrams of riboflavin, 50 micrograms of vitamin B<sub>12</sub>, 200 milligrams of vitamin C, 100 milligrams of niacinamide, and 200 International Units of vitamin E were necessary and useful as a dietary supplement, when each two tablets of the article supplied substantial specified multiples of the minimum daily requirements for vitamins A, D, thiamine, riboflavin, B<sub>12</sub>, vitamin C, niacinamide, and E; the name, "Multi Vitamins with Vitamin E," on the label of the article falsely and misleadingly represented and suggested that there was special nutritional significance to the presence of vitamin E in a multivitamin supplement; and the label declaration of the article's vitamin content in terms of the vitamins contained in each two tablets of the article was misleading as applied to the article which was recommended for use in the amount of one tablet daily; vitamin E capsules—the label statements, "Each capsule contains 200 International Units of Vitamin E," and "One capsule per day as a dietary supplement," falsely and misleadingly represented and suggested that 200 International Units of vitamin E were necessary and useful as a dietary supplement, when the article supplied 6 2/3 times the recommended daily allowance of vitamin E for adult males; 402(a). Default decree ordered destruction. (F.D.C. No. 58018; S. Nos. 45-178/80 F; N.J. No. 25)

**Vitamin tablet and mineral tablet packets, at Dallas, N. Dist. Tex.**

Charged 7-13-72: when shipped by Automated Packaging Concepts, Los Angeles, Calif., the labeling of the article, labeled in part "Natural or Organic Vitamins and Minerals . . . 182 Vitamin Tablets 364 Mineral

Tablets . . . Formulated For and Distributed by The Nutri-Way Corporation, Dallas, Texas," contained a number of false and misleading claims, including the following: with respect to the article's composition as a mixture of certain vitamins and minerals of proven nutritive value with ingredients of no proven nutritive value (inositol, aminobenzoic acid, rutin, bioflavonoid complex, hesperidin complex, choline, alfalfa juice and powder concentrate, and traces of other nutritive factors naturally occurring in kelp, yeast, and bone flour), the article's labeling falsely and misleadingly represented and suggested that the nutritive value of the article was significantly enhanced by the presence of inositol, aminobenzoic acid, rutin, bioflavonoid complex, hesperidin complex, choline, alfalfa juice and powder concentrate, and traces of other nutritive factors naturally occurring in kelp, yeast, and bone flour, and that such ingredients had proven nutritive value; false and misleading claims that the nutritional value of the article was significantly enhanced by the presence of unsaturated fatty acids, biotin, potassium, copper, zinc, manganese, and magnesium, and that the need in human nutrition for biotin, potassium, zinc, manganese, magnesium, pantothenic acid, and folic acid was not recognized—403(a); the article's label (packet) failed to bear an accurate statement of the quantity of contents in terms of numerical count—403(e)(2); the article's label lacked required information concerning the article's dietary properties—403(j); and the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not on the principal display panel of the package—15 U.S.C. 1453(a)(2). The article was claimed by Nutri-Way Corp., Dallas, Tex., who denied the charges. The parties served written interrogatories on each other. The Government moved for summary judgment on the grounds that the pleadings, admissions, and affidavits on file with the court showed no genuine issue of material fact. Thereafter, the parties exchanged a number of proposals and counterproposals for a consent decree due to the publication of FDA's proposed regulations for nutritional labeling of foods and foods offered as health foods or dietary supplements. The claimant moved to withdraw its claim and answer, and the Government opposed such motion. The court denied the claimant's motion to withdraw its claim and answer, and ordered that the Government's motion for summary judgment be prepared for hearing. In finding for the Government and condemning the article, the court said:

"In support of its Motion, the Government submitted the affidavits of experts in food economics and marketing, food science, human nutrition, pharmacology and biochemistry concerning the true nutritive value of the seized food and the likelihood that the product's labeling would be misleading to the public. Claimant, the Nutri-Way Corporation, filed an answer to the Complaint and the affidavit of its President which sets forth the history of the action but does not offer any proof controverting the affidavits filed by Plaintiff. The pleadings and admissions on file with this Court, together with the Affidavits, demonstrate that there is no genuine issue as to any material fact and that the Government is entitled to a judgment of condemnation against the seized goods.

"The Court finds that the seized goods are in violation of 21 U.S.C. 343(a) in that the listing in the labeling of the seized food of ingredients of no nutritive value and insignificant amounts of ingredients of recognized nutritive value represents to the consuming public that the presence of ingredients of no nutritive value, in a vitamin-mineral supplement which also contains vitamins and minerals which are well-known to the layman to be of nutritive value, makes a significant nutritional contribution to the product and in fact have nutritive value, and that the presence of insignificant amounts of known nutrients in such a vitamin supplement significantly enhances its nutritional value, all of which representations are false and misleading. *United States v. An Article of Food . . . Nuclomin*, 482 F.2d 581, No. 72-1626 (CA 8, 1973) and *United States v. Vitasafe Formula M*, 226 F. Supp. 266, 278 (D.N.J., 1964), remanded on other grounds 345 F. 2d 864 (CA 3, 1965); and \* \* \*

"In addition to being misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, the Complaint alleged and Claimant admitted that the seized goods were violative of the Fair Packaging and Labeling Act, 15 U.S.C. 1453(a)(2). There is no genuine issue of material fact precluding judgment for the government with respect to this violation of law and the Court therefore finds that the seized goods are in violation of 15 U.S.C. 1453(a)(2).

"Although a violation of any one section of the Federal Food, Drug, and Cosmetic Act or of the Fair Packaging and Labeling Act subjects the seized article to condemnation, it is equally true that the government seeks not only condemnation but a judicial determination that the labeling claims complained of are false and misleading. This is inherent in the prayer for condemnation. Therefore, in light of public interest in the efficient enforcement and good administration of these statutes, the Court hereby Orders the condemnation of the seized goods for violation of all of the statutes as alleged in the Complaint. \* \* \* (F.D.C. No. 58114; S. No. 30-465 F; N.J. No. 26)

**FOOD ADDITIVES**

**Bee [vignette of bee] Seventeen powder, at Detroit, E. Dist. Mich.**



Charged on or about 12-14-73: when shipped by General Research Laboratories, Van Nuys, Calif., the article contained the nonconforming food additive amygdalin; the label vignette and statement "picture of bee" Seventeen Food for Special Dietary Use," the listing on the label of 16 vitamins and minerals along with a picture depicting fruit resembling apricots, and the label declaration concerning the article's content of apricot fruit and kernel concentrate containing 500 milligrams of amygdalin per packet, were false and misleading in representing and suggesting that apricot fruit and kernel concentrate containing amygdalin is a nutrient with special dietary properties; and the labeling lacked adequate directions for use for the article's intended purposes, i.e., the treatment and prevention of cancer; and the labeling lacked adequate warning against unsafe use; 402(a)(2)(C), 403(a), 502(f)(1), 502(f)(2). Default decree ordered destruction. (F.D.C. No. 59565; S. No. 42-210 G et al.; N.J. No. 27)

**Nu-E 100 vitamin combination tablets with taurocholic acid**, at Arlington, N. Dist. Tex.

Charged 7-16-73: when shipped by Strong Cobb Arner of California, Inc., Sun Valley, Calif., the article contained the nonconforming food additive taurocholic acid; 402(a)(2)(C). The article was claimed by Real-Life Distributors, Inc., Arlington, Tex., who denied the charge. The claimant served written interrogatories on the Government. Thereafter, pursuant to stipulation of the parties, the action was dismissed without prejudice or costs, and the article was ordered delivered to the claimant. (F.D.C. No. 59284; S. No. 38-804 G; N.J. No. 28)

**ANIMAL FEED**

**Sheep Creep medicated animal feed**, at Longmont, Dist. Colo.

Charged 5-14-74: while held by Golden West Milling Co., Longmont, Colo., who had manufactured the article using chlortetracycline shipped in interstate commerce, the article was an animal feed containing chlortetracycline and ammonium chloride, which were new animal drugs, and no approval of a New Animal Drug Application was in effect with respect to the combination of chlortetracycline and ammonium chloride as used in the article—501(a)(5); the article's label lacked a quantity of contents statement, lacked the established name of the article, and lacked the name of each active drug ingredient—502(b)(2), 502(e)(1); the article's labeling lacked adequate directions for use—502(f)(1); and the article's label lacked the common or usual name of the food and the common or usual name of each food ingredient it contained—403(i)(1&2). Consent decree ordered destruction. (F.D.C. No. 59765; S. No. 44-360 G; N.J. No. 29)

**DRUGS/Human Use**

**Afrodex methyltestosterone, yohimbine HCl, and nux vomica extract capsules**, 3 seizure actions, at Shreveport, W. Dist. La.; Brooklyn, E. Dist. N.Y.; and Dallas, N. Dist. Tex.

Charged 9-18-73 (amended 9-21-73), 9-20-73, and 11-23-73: when shipped by ICN Pharmaceuticals, Inc. (Bentex Div.), Covina, Calif., the article was a new drug without an effective approved New Drug Application; 505(a). Default decrees ordered destruction. (F.D.C. Nos. 59453, 59457, 59544; S. Nos. 67-377 G, 71-505 G, 103-518 G; N.J. No. 30)

**Beef peptone injection**, at Boise, Dist. Idaho.

Charged 8-28-73: when shipped by Sandia Pharmaceuticals, Inc., Albuquerque, N. Mex., the article was a new drug without an effective approved New Drug Application; and the accompanying package insert contained false and misleading claims for stimulating the antibody-forming and detoxifying mechanisms of the body, for the relief of pain in inflammatory neuritis, for the relief of pain and healing of lesions in herpes zoster ophthalmicus, and for the relief of pain associated with tabes dorsalis; 505(a), 502(a). Consent decree ordered destruction. (F.D.C. No. 59432; S. No. 37-512 G; N.J. No. 31)

**Chorionic gonadotropin injectable, U.S.P.**, at Chicago, N. Dist. Ill.

Charged 5-30-72: while held by Kennedy Diet Center, Chicago, Ill., the article's labeling (including the reprint "New Hope for Diet Dropouts," the book "Pounds and Inches" and the magazine article "The Rich Woman's Wonder Diet That Works") lacked adequate directions for use, and the article was not exempted therefrom, since the article was a new drug for use for obesity without either an effective approved New Drug Application or a Notice of Claimed Investigational Exemption; 502(f)(1). The article was claimed by Dr. James C. Carver, Bloomfield, N.J. The Government served written interrogatories on the claimant, and the claimant served written interrogatories on the Government. Upon the basis of the claimant's answers to such interrogatories and additional interrogatories, and the affidavits of qualified experts, the Government moved for summary judgment. Subsequently, the claimant moved to withdraw his claim and answer. The court granted the latter motion, and subsequently, a default decree ordered destruction. (F.D.C. No. 58046; S. No. 20-604 F; N.J. No. 32)

**Heparin sodium, cyanocobalamin, folic acid, choline chloride, and niacinamide combination injectable**, at Gravette, W. Dist. Ark.

Charged 11-9-73: when shipped by Medwick Laboratories, Inc., Melrose

Park, Ill., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 59534; S. No. 67-340 G; N.J. No. 33)

**DRUGS/Veterinary**

**Anchor Wound Healer liquid**, at Saint Joseph, W. Dist. Mo.

Charged 4-3-72: when shipped by Dow B. Hickman, Inc., Houston, Tex., the article, labeled in part "Anchor Wound Healer Liquid . . . Contains: Trypsin . . . Balsam Peru . . . Castor Oil . . . Anchor Serum Company . . . St. Joseph, Missouri," was a new animal drug, and there was no approval of a New Animal Drug Application in effect with respect to the use and intended use of the drug; the name of the article and other label statements contained false and misleading claims for wound healing in general, abrasions, decubital ulcers, lacerations, wire cuts, rope burns, and dehiscent and indolent wounds of dogs, cats, horses, and cattle; and the labeling lacked adequate warnings against use on deep or puncture wounds; 501(a)(5), 502(a), 502(f)(2). Consent decree ordered destruction. (F.D.C. No. 57889; S. No. 65-040 E; N.J. No. 34)

**Vitamite sulfamethazine mix**, at Oxford, Dist. Kans.

Charged on or about 12-10-73: when shipped by Neese & Sons, Inc., Ankeny, Iowa, the article's strength differed from its purported strength, since the article was approximately 1/3 deficient in sulfamethazine; the label lacked an accurate quantity of contents statement, since the bags labeled as containing 1 pound actually contained 3 pounds; and the article was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to the use and intended use of the drug; 501(a)(5), 501(c), 502(b)(2). Default decree ordered destruction. (F.D.C. No. 59569; S. No. 49-920 G; N.J. No. 35)

**MEDICAL DEVICES**

**Diapulse electromagnetic energy generator**, at Altamonte Springs, M. Dist. Fla.

Charged 10-17-73: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the article's labeling lacked adequate directions for lay use for the article's intended purposes, and adequate information for use by licensed practitioners could not be prepared, and the article failed to bear a label containing the name and place of business of the manufacturer or distributor; 502(f)(1), 502(b)(1). Default decree ordered destruction. (F.D.C. No. 59505; S. No. 3-200 G; N.J. No. 36)

**Diapulse electromagnetic energy generators**, 8 seizure actions, at Spearman, N. Dist. Tex.; Winchester, E. Dist. Tenn.; Umatilla, Dist. Oreg.; Pendleton, Dist. Oreg.; Gresham, Dist. Oreg.; St. Louis, E. Dist. Mo.; Belleville, E. Dist. Ill.; El Paso, W. Dist. Tex.

Charged 10-3-72, 9-6-72, 9-22-72, 9-29-72, 9-29-72, 10-18-72, 1-2-73, 1-18-73: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' accompanying treatment charts and leaflets contained false and misleading claims, such as claims for tissue and bone healing, infections, bursitis, diabetic ulcer of the foot, arthritis, blood flow to peripheral areas, sinusitis, and low back pain; and the articles' labeling lacked adequate directions for use for their intended purposes, and neither adequate directions for lay use nor adequate information for use by licensed practitioners for the articles' intended use could be written; 502(a), 502(f)(1). The articles were claimed, and, except in the action at Belleville, Ill., the charges were denied, and the Government served written interrogatories on the claimants. In the action at Belleville, Ill., the court granted the Government's motion for summary judgment because the charges were not denied and ordered the article destroyed. In the action at El Paso, Tex., the court granted the Government's motion for summary judgment upon consideration of the pleadings, affidavits, and memoranda, because there was no genuine issue as to any material fact with respect to the charges. Accordingly, the court condemned the device at El Paso, Tex., and ordered it destroyed. In the other actions, consent decrees authorized salvaging or destruction. (F.D.C. Nos. 58234, 58241, 58291, 58297, 58302, 58384, 58670, 58704; S. Nos. 32-577 F, 2-149/50 F, 78-753 F, 78-757 F, 79-182 F, 43-452 F, 21-607 F, 31-641 F; N.J. No. 37)

**Diapulse electromagnetic energy generators**, 14 seizure actions, at Huntington, S. Dist. W. Va.; Huntington, S. Dist. W. Va.; Commerce, N. Dist. Tex.; New Boston, E. Dist. Tex.; San Francisco, N. Dist. Calif.; Berkeley, N. Dist. Calif.; Dallas, N. Dist. Tex.; North Kansas City, W. Dist. Mo.; Wichita, Dist. Kans.; Pleasant Hill, W. Dist. Mo.; Marlinton, S. Dist. W. Va.; Morrisville, E. Dist. Pa.; Fries, W. Dist. Va.; Moberly, E. Dist. Mo.

Charged 7-9-73, 7-9-73, 9-5-73, 9-27-73, 10-2-73, 10-3-73, 10-15-73, 10-18-73, 10-16-73, 10-18-73, 11-6-73, 1-14-74, 1-16-74, 3-13-74: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the labeling of the articles lacked adequate directions for lay use for the articles' intended purposes, and adequate information for use by licensed practitioners could not be prepared; 502(f)(1). Default decrees were entered in all cases, and all the articles were ordered destroyed except for part of the device at Pleasant Hill, Mo.,





which was ordered released for salvaging of the electrical components, and the device at Berkeley, Calif., which was ordered delivered to FDA for exhibit and testing purposes. (F.D.C. Nos. 59318/9, 59435, 59471, 59493, 59506, 7, 59511, 59513, 59515, 59518, 59598, 59613, 59693; S. Nos. 13-001 G, 12-680 G, 36-457 G, 34-300 G, 90-750 G, 90-751 G, 103-424/5 G, 40-384 F, 49-938 G, 40-632 F, 10-473/4 G, 82-527 G, 14-056 G, 46-658 G; N.J. No. 38)

**Earth Board bedboards and labeling**, at Orlando, M. Dist. Fla.

Charged 7-23-73: while held by Earth Board Co., Orlando, Fla., the dealer's accompanying leaflets entitled "Some Typical Questions & Answers About Earth Boards," "Someone thought of you . . .," "Whether or not you use Earth Board," "Certificate of Guarantee," "A Memo From Phyllis V. Schlemmer PREDICTION FOR 1973," and "Instructions for use of your Earth Board," and pamphlets entitled "Let's Sleep Right to Keep Fit" contained false and misleading claims for back ailments, arthritis, acne, high blood pressure, diabetes, insomnia, hemorrhoids, Parkinson's disease, bedsores, loss of vision, fractures, sprains, tumors, nervous problems, kidney infections, strokes, cancer, aging, and emotional disturbances; 502(a). Since the bedboards had been returned to the Phoenix, Ariz., shipper, only the accompanying labeling was seized. Default decree ordered destruction. (F.D.C. No. 59326; S. No. 2-331 G; N.J. No. 39)

**PROPHYLACTICS**

**Prophylactics, rubber, Peacocks**, at Edina, Dist. Minn.

Charged 5-16-74: when shipped by Dean Rubber Co., North Kansas City, Mo., the article's quality was deficient, since the article contained holes; 501(c). Default decree ordered destruction. (F.D.C. No. 59776; S. No. 62-864 H; N.J. No. 40)

**Prophylactics, rubber, Trojan-Enz**, at Anaheim, C. Dist. Calif.

Charged 1-20-72: when shipped by Youngs Drug Products Corp., Piscataway, N.J., the quality of all lots of the article fell below that which it purported and was represented to possess, since the article contained holes; and the labeling of some lots of the article contained false and misleading claims for the prevention of venereal disease; 501(c), 502(a). The article was claimed by the shipper, who denied the charges. The claimant moved for and was granted postseizure samples of the articles. The parties served written interrogatories on each other. Thereafter, the claimant moved to withdraw its answer and that a default judgment be entered, since the law of the State of California provided that no prophylactics should be offered for sale by a wholesaler if manufactured more than 1 year previously, and the seized articles, at the time of such motion, had been manufactured more than 1 year previously. Accordingly, a default decree was entered ordering the article destroyed. (F.D.C. No. 57756; S. No. 90-349 E; N.J. No. 41)

**COSMETICS/BEAUTY PRODUCTS**

**British Royal cologne & after-shave**, at Nogales, Dist. Ariz.

Charged 2-28-73: when shipped by Saxony Products, Inc., Los Angeles, Calif., the package label of the article, which consisted of one bottle each of cologne and after-shave in each package, was in violation of the Fair Packaging and Labeling Act, since the package label lacked the name and place of business of the manufacturer, packer, or distributor, and lacked a quantity of contents declaration; 15 U.S.C. 1453(a)(1), 1453(a)(2). Default decree ordered destruction. (F.D.C. No. 58914; S. No. 45-780 F; N.J. No. 42)

**Roux lash & brow tints**, at City of Commerce, C. Dist. Calif.

Charged 3-11-68: when shipped by Roux Laboratories, Inc., New York, N.Y., the article was a cosmetic which was not a hair dye, and it contained a color additive composed of silver sulfate, silver nitrate, and pyrogallol, and its use and intended use were not in conformity with a regulation or exemption, in that it was not a previously or permanently listed or exempted color additive; 601(e). The article was claimed by the shipper who denied the charge except that the article was admittedly a cosmetic which was not a hair dye and who defended on the following grounds: that the action was in violation of an injunction obtained by the shipper and others in the case of *Toilet Goods Assn. v. Gardner* (278 F. Supp. 786) involving cosmetic diluents; that the article's listed ingredients were diluents and not color additives; that the Government was estopped from instituting and prosecuting the action; and that FDA had failed to complete the required administrative procedure of providing by regulation for separately listing color additives for use in or on cosmetics. Pursuant to stipulation, postseizure samples of the articles were obtained by the parties. The Government served written interrogatories on the claimants. The claimants moved to dismiss. Thereafter, the district court declared that this case hinged upon a regulation held to be invalid in the case of *Toilet Goods Assn. v. Gardner* (278 F. Supp. 786), and dismissed the case. The Government appealed.

Upon appeal, the court of appeals held (437 F. 2d 209, at 214): "The Toilet Goods decision did not enjoin the F.D.A. from seizing cosmetics that contain 'additives' that are unsafe because they have not been listed or exempted under the regulations. Furthermore, the district court

in *Toilet Goods* did not determine whether the ingredients silver nitrate, silver sulfate, and pyrogallol are 'additives' or 'diluents.' Therefore, the district court's reliance on *Toilet Goods* begged the controlling factual issue in this case: Are silver nitrate, silver sulfate, and pyrogallol 'additives' or 'diluents'?" Accordingly, the judgment of the district court was reversed and the case was remanded for trial on the merits. The Government served supplemental written interrogatories on the claimant and subsequently moved for an order shortening the time within which the claimant may answer. The motion for shortening the time was denied. Subsequently, the case came on for trial. The claimant moved to dismiss the complaint on the grounds that the trial evidence established that the color additive in Roux Lash & Brow Tint consisted of silver nitrate, silver sulfate, and pyrogallol; that silver nitrate and silver sulfate were metallic salts capable of coloring hair; and that the FDA Federal Register notice of December 10, 1963, provided that, because of the ambiguity concerning the status of metallic salt hair coloring products, FDA would not take any action against such color additive until further notice. At the conclusion of the Government's case, the court granted the claimant's motion to dismiss.

The court thought that there was no doubt that the December 10, 1963, notice was intended to cover all hair colorings, including preparations for the coloring of eyelashes and eyebrows, and that, although the January 31, 1973, Federal Register notice (that rescinded the prior notice) had used (contrary to the use in the prior notice) the term "hair dye," that use of the term "hair dye" was not retroactive so as to limit the December 10, 1963, exemption to hair dyes only. Accordingly, the court said that cosmetic manufacturers of eyelash and eyebrow tints or colorations were entitled to rely on the 1963 notice, but that such notice was withdrawn or rescinded effectively by the January 29, 1973, notice.

The court found that this seizure action was a sufficient showing of prejudice against the claimant during the time that the December 3, 1963, notice was in effect, and that the claimant was entitled to his motion to dismiss. However, the court further stated there was no doubt that silver nitrate, silver sulfate, and the pyrogallol, when applied, were capable, through the actions with one another, of imparting color, and that the claimant's motion was granted only on the basis of the December 3, 1963, notice and not on the grounds that the Government failed in its proof. (F.D.C. No. 55106; S. Nos. 33-366/8 C; N.J. No. 43)

**NOTICES OF JUDGMENT ON Criminal Actions**  
**FOOD**

**DCA Food Industries, Inc., t/a Charles Dennery Co., Lazare Levy**, vice president, and Benjamin C. Mauthe, plant manager, New Orleans, E. Dist. La.

Charged 1-16-74: coconut flakes, donut mix, rice flour, and pie crust mix were held in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Nolo contendere pleas by individuals to counts involving rice flour and pie crust mix; fines. (F.D.C. No. 59249; S. No. 54-485 F; N.J. No. 44)

**Kenneth C. Evans, t/a Ken Evans Food Distributors**, Detroit, E. Dist. Mich.

Charged 6-8-73: rolled oats and brown sugar were held under insanitary conditions in a building accessible to rodents and insects and were exposed to contamination by rodents and insects; 402(a)(4). Nolo contendere plea; fine and probation. (F.D.C. No. 58997; S. Nos. 37-963/4 F; N.J. No. 45)

**Fettig Canning Corp., George T. Fettig**, vice president, and Philip E. Fettig, plant manager, Elwood, S. Dist. Ind.

Charged 11-21-73: when shipped, catsup contained decomposed tomato material and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Nolo contendere by individuals; fines. (F.D.C. No. 59352; S. No. 4-733 G et al.; N.J. No. 46)

**General Grocer Co. of Ill., Thomas E. Venker**, president & treasurer, and Carl A. Neal, vice president, Bloomington, S. Dist. Ill.

Charged 11-26-73: all-purpose flour and self-rising flour were held under insanitary conditions in a building accessible to rodents, and the all-purpose flour was contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Guilty plea by individuals; fines and probations. (F.D.C. No. 59299; S. No. 22-122 G; N.J. No. 47)

**Leemont Corp., t/a Kitcheneat Foods, Elmer L. Montgomery**, president, and Charles B. Lee, vice president, Englewood, Dist. Colo.

Charged 7-3-72: hash brown potatoes were prepared, packed, and held in a plant accessible to insects and were exposed to contamination by insects; 402(a)(4). Nolo contendere pleas; fines. (F.D.C. No. 58141; S. No. 33-991 F; N.J. No. 48)

**Liberty Cash Grocers, Inc., John W. Montesi**, president, **Joseph M. Montesi**, secretary-treasurer, and **Charles D. Pesce**, assistant vice president and general manager, Memphis, W. Dist. Tenn.

Charged 3-12-73 by grand jury: tea was held in a building accessible to rodents and was contaminated by rodent filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (F.D.C. No. 57982; S. Nos. 22-770/2 E; N.J. No. 49)



**Lock Two Grain & Milling Co., and Carl H. Kuenning**, president, New Bremen, N. Dist. Ohio.

Charged 7-25-73: when shipped, Special-Bleached-Cone flour and Ahead-of-All flour had been prepared, packed, and held under insanitary conditions; 402(a)(4). Nolo contendere pleas; fines. (F.D.C. No. 59112; S. Nos. 26-850 F, 91-229 F; N.J. No. 50)

**Raynard A. Miller, t/a Rocky Peanut Co.**, Detroit, E. Dist. Mich.

Charged 6-8-73: filberts 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. 58993; S. No. 37-995 F; N.J. No. 51)

**Nash Finch Co., John R. Mower**, branch manager, and **Jay T. Phipps**, warehouse supervisor, Lincoln, Dist. Nebr.

Charged 11-1-73: peanuts (counts 1 & 2), cheese food slices (count 3), and biscuits (count 4) were held in a building accessible to rodents, and the articles, except the biscuits, were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation to all counts; fine. Nolo contendere pleas by individuals to count 3; fines. (F.D.C. No. 59243; S. No. 47-001 G et al.; N.J. No. 52)

**Petri Home-Like Cookies, Inc., and Armand J. Petri**, Silver Creek, W. Dist. N.Y.

Charged 11-27-73: peanuts were held in a building accessible to insects and were contaminated with insect filth—402(a)(3), 402(a)(4); and when shipped, Petri "Home-Like" cookies had been prepared, packed, and held under insanitary conditions—402(a)(4). Guilty plea by corporation; fine. Nolo contendere plea by individual; fine suspended. (F.D.C. No. 59307; S. No. 18-161 G et al.; N.J. No. 53)

**Shryack-Givens Grocery Co.**, Boonville, W. Dist. Mo.

Charged 8-21-73: flours, cake mix, pizza mix, and macaroni were held in buildings accessible to insects and rodents and were contaminated with insect or rodent filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (F.D.C. No. 59119; S. No. 39-864 F et al.; N.J. No. 54)

**Rala Singh, t/a Rala Singh Farms**, Glendale, Dist. Ariz., and **Hamilton Farms**, a partnership, and **R. E. Schlittenhart**, partner, Eloy, Dist. Ariz.

Charged 9-11-73: when shipped, one lot of lettuce bore and contained the pesticide chemicals toxaphene and cryolite in excess of the prescribed tolerances, and another lot of lettuce bore and contained the pesticide chemical parathion in excess of the prescribed tolerance; 402(a)(2)(B). Nolo contendere pleas; fines. (F.D.C. No. 57320; S. No. 50-644 D et al.; N.J. No. 55)

**Skiles Co., Inc., and Robert Miller Skiles**, president, Bluffton, N. Dist. Ind.

Charged 5-26-73: breeding, Great Northern beans, pancake mix, sugar, cornmeal, all-purpose flour, and self-rising flour were held in a building accessible to rodents and exposed to contamination, and the breeding, beans, pancake mix, and sugar were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation to all counts; fine. Guilty plea by individual to count involving breeding; fine plus court costs. (F.D.C. No. 59109; S. No. 38-596 F et al.; N.J. No. 56)

#### NOTICES OF JUDGMENT on Injunction Actions

**Cowley Pharmaceuticals, Inc., and Benjamin C. Cowley**, president & treasurer, Auburn, Dist. Mass.

Charged 11-30-66 in complaint for injunction: that the defendants were engaged in the business of manufacturing, packaging, labeling, and distributing in interstate commerce various drugs, of which the names of some were recognized in the U.S.P. or N.F., and their strength differed from and their quality and purity fell below the U.S.P. or N.F. standards; of which others were not so recognized in the U.S.P. or N.F., and their strength differed from and their quality and purity fell below their own standards; of which the labeling of some of the drugs contained false and misleading claims about the drugs' identity, purity, quality, and strength; of which the labeling of some lacked adequate directions for use; that such drugs had been manufactured, processed, packed, and held under circumstances that failed to conform with current good manufacturing practice; and that the defendants were well aware that their activities were in violation of the law; 501(a)(2)(B), 501(b), 501(c), 502(a), 502(f)(1).

The defendants answered the complaint and denied the charges. Subsequently, the defendants entered into a consent decree of permanent injunction enjoining the acts complained of, ordering and enjoining the shipment in interstate commerce of defendants' drugs unless and until a number of specified methods and controls were established and administered in conformity with current good manufacturing practice.

Thereafter, the defendants moved to dissolve the decree of permanent injunction. The Government opposed the motion, and the motion was denied.

Charged on or about 2-7-69 in petition for order to show cause in criminal contempt: when shipped, Methazem tablets were represented as plain-coated tablets for oral use, but failed to disintegrate after being swallowed; the phenobarbital tablets, U.S.P., contained more than 106 percent of the labeled amount of phenobarbital; some diphenylhydantoin

sodium capsules, U.S.P., contained less than 93 percent of the labeled amount of diphenylhydantoin sodium, some diphenylhydantoin sodium capsules, U.S.P., failed the U.S.P. requirements for hard capsules with respect to variation of weight of content; digitalis tablets, U.S.P., contained less than 85 percent of the labeled potency, and dilanthin E.C. tablets failed to disintegrate after being swallowed, and the circumstances used for the manufacture, processing, and packing of the dilanthin E.C. tablets failed to conform to current good manufacturing practice; 501(a)(2)(B), 501(b), 501(c). The firm, having sold its assets, subsequently cancelled its FDA establishment registration and proceeded to dissolution. (Inj. No. 520; S. Nos. 2-567 B et al., 6-710 C et al.; N.J. No. 57)

**Ridgeway Cheese and Butter Co., Inc., Clyde Johnson**, president & treasurer, and **Harold L. Brockway, Jr.**, plant manager, Ridgeway, N. Dist. Iowa.

Charged 2-14-72 in complaint for injunction: that the defendants were engaged in the business of manufacturing, packing, holding, and distributing in interstate commerce, quantities of cheese which contained soluble insect filth and which had been prepared, packed, and held at the defendants' plant at Ridgeway, Iowa, under insanitary conditions, and that they were well aware that their activities were in violation of the law; 402(a)(3), 402(a)(4). A consent decree of permanent injunction perpetually enjoined and restrained the defendants from the acts complained of and enjoined the shipment of cheese from the defendants' plant unless and until a number of specified methods, facilities, and controls were established to assure sanitation at the plant. (Inj. No. 618; S. No. 34-825 E et al.; N.J. No. 58)

#### NOTICES OF JUDGMENT on Miscellaneous Actions

**Amphetamine combination drugs for anorectic use**, Bryn Mawr, W. Dist. Pa.

Charged 9-10-73 in suit for declaratory judgment and injunctive relief by Dr. Watson Gutowski, against the Food and Drug Administration of the Department of H.E.W. and the Drug Enforcement Administration of the Department of Justice: that a March 28, 1973, FDA order purported, in effect, to declare combination anorectic drugs (with certain exceptions) unmarketable and illegal; that the defendants had attempted to apply such order retroactively and make possession of such anorectic drugs subject to criminal penalties and seizure provisions of the Food, Drug, and Cosmetic Act, in violation of the U.S. Constitution, and had threatened the plaintiff with criminal and civil prosecution for his unlawful possession of such medications; that, if plaintiff was subjected to criminal prosecution, his reputation and ability to practice his profession would be diminished and impaired, and he would be irreparably damaged; that, if his drugs were seized, he would be prevented from professionally and adequately treating his patients and from practicing his profession; that the defendants should be enjoined from retroactively enforcing the March 28, 1973, order, in violation of the U.S. Constitution; and that plaintiff prayed the court for its order declaring that combination anorectic drugs or medications, in the plaintiff's possession prior to March 28, 1973, and lawfully obtained, were not subject to the criminal and civil sanctions of the Food, Drug, and Cosmetic Act.

The Government moved to dismiss the action on the grounds that the court lacked jurisdiction over the subject matter, and that the plaintiff had failed to state a claim upon which relief could be granted. The court dismissed the plaintiff's petition for failure to respond to the defendants' motion. Thereafter, the plaintiff moved to have his petitions reinstated on the grounds that one of the plaintiff's counsel had become ill. The court denied the motion stating that, since there was a possibility that such illness may have had something to do with the seemingly total neglect of the litigation, the court would be inclined to vacate the dismissal order, if it could conceive of any arguable merit to the plaintiff's case. The court concluded:

"Plaintiff's failure to suggest that he might have a defense to the government's dismissal motion is not surprising. Plaintiff's pleadings do not establish any basis for the assertion of jurisdiction by this Court. It seems obvious that this is not an appropriate case for the entry of a declaratory judgment, and that there is no basis whatever for injunctive relief. In the unlikely event that there is any valid reason for concluding that plaintiff should be unaffected by the March 1973 F.D.A. order, that reason can be asserted by way of defense in any action which might be taken against the plaintiff or his property.

"For all of the foregoing reasons, I decline to vacate, reopen or reconsider the dismissal order of February 11, 1974." (Misc. No. 253; N.J. No. 59)

**Peanut butter standard of identity**, 2 actions for Judicial Review in Court of Appeals, 3rd and 7th Circuits.

Petitioned 12-12-68 by Corn Products Co., New York, N.Y. (3rd Circuit), and 10-18-68 by Derby Foods, Inc., Chicago, Ill. (7th Circuit), for judicial review against the Food and Drug Administration: that the plaintiffs were manufacturers of peanut butter who would be adversely affected by an FDA order to establish a definition and standard of identity for peanut butter (21 CFR 46.1). Upon motion of FDA, the Derby Foods, Inc., action was transferred to the Third Circuit Court of Appeals. Upon review the court said:



"Corn Products Company and Derby Foods, Inc., petitioned for review of an order of the Food and Drug Administration, Department of Health, Education and Welfare, which establishes a definition and standard of identity for the food product known as peanut butter. They seek this review because their products, as they were formulated at the time of the order, fail to conform to the standard.

"The order was promulgated under Section 401 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 341. Basically, it limits the percentage by weight of optional ingredients which may be added to the peanut ingredient to a maximum of ten percent. It allows for the addition or removal of peanut oil and limits the fat content to 55 percent. The standard also identifies allowable additives and specifies certain labeling requirements.

"As originally constituted, peanut butter was composed of ground peanuts, salt, and sometimes sugar. However, this product had the disadvantages of oil separation, stickiness, short shelf-life, etc. These deficiencies have been diminished, if not eliminated, by the addition of stabilizing ingredients, hydrogenated vegetable oils. Today, peanut butter consists of the peanut ingredient, which has a solid component and an oil component, the stabilizer, and seasonings.

"Petitioners are the major producers of peanut butter. Each has enjoyed a high degree of success. In 1965 Corn Products, the industry leader, claimed 22 percent of the market for its brand, Skippy. Derby as the second leading producer had 14 percent of the market from its product, Peter Pan. Their product formulations fail to qualify under the standard since each uses in excess of ten percent of optional ingredients as these are defined by the standard, but each for a different reason.

"Both petitioners were unsuccessful in urging the Food and Drug Administration to adopt a standard which would allow 13 percent of optional ingredients, i.e., consist of 87 percent peanuts. Corn Products urges here that the adoption of the 90 percent standard was unreasonable and arbitrary and that the standard will not promote honesty and fair dealing in the interest of consumers. It also argues that the findings upon which the order is based are not supported by substantial evidence. \* \* \*

"The Supreme Court has indicated that substantiality must be determined in the light of all that the record relevantly presents; that findings must be set aside when the record clearly precludes the agency's decision from being justified by a fair estimate of the worth of the testimony of witnesses or its informed judgment on matters within its special competence or both; and, that 'reviewing courts must be influenced by a feeling that they are not to abdicate the conventional judicial function.' **Universal Camera Corp. v. NLRB**, 340 U.S. at 490.

"The Commissioner has concluded that adoption of a standard will promote honesty and fair dealing in the interest of consumers. Support for this conclusion is found in the findings. There is a general lack of information among consumers about the actual composition of peanut butter. It was found that a trend toward a decrease in peanut content has not always been in the interest of consumers. Another finding demonstrates that other ingredients are cheaper and that in some cases the reduced peanut content has resulted from competitive pressure. It was further found that some consumers and state agencies recognize a need for regulation in this area. These findings are supported by sufficient rational probative evidence to afford a sound basis for the exercise of the Commissioner's judgment to promulgate a standard of identity. See **Federal Security Administrator v. Quaker Oats Co.**, 318 U.S. 218 (1943).

"In support of its argument that the adoption of the standard requiring 90 percent peanuts is arbitrary and unreasonable, Corn Products cites its market success, market history, established trade practices, and urges that the purpose of the Act, to prevent confusion and deception among consumers, would be served by a standard which would allow its product to be sold as it is presently formulated. It is at once apparent that this argument is not aimed at debasing the findings and conclusions upon which the order is based, but is rather an argument in support of a standard which would not require Corn Products to change the composition of Skippy.

"The court's function, however, is to review the findings to determine if there is substantial evidence to support them. Because the court must consider the evidence in keeping with the normal judicial function, **Universal Camera Corp. v. NLRB**, *supra*, the issue of reasonableness would not appear to be completely beyond judicial reach. However, due regard must be given to the integrity of the administrative function. Given a range of reasonable alternatives, the administrator is given the task of selecting the one which, in his judgment, is most appropriate. In such circumstances, the court must defer to his judgment. **Federal Security Administrator v. Quaker Oats Co.**, *supra*.

"Using an affirmative approach to the order under consideration, the issue becomes whether the findings upon which the 90 percent standard is based are supported by substantial evidence.

\* \* \*  
"The surveys conducted in 1963 and 1965 support the finding that a majority of manufacturers produced peanut butter containing 90 percent of peanuts. Further, it was found that other manufacturers who then would not comply with the standard had in the past produced a 90 percent peanut product. It is noted that compliance with the standard will not require a change of equipment. Expert testimony indicates that for those presently not in compliance only an alteration of formula is necessary.

"Inferentially, petitioners contend that an 87 percent standard would satisfy the purposes of the Act, and there may be substantial evidence to support a standard which would allow their products to be marketed as formulated. Assuming without deciding that to be so, this does not militate against the conclusion that the findings are supported by substantial evidence. In addition, it does not compel the conclusion that the choice of the 90 percent level is arbitrary and unreasonable. It would simply indicate that a reasonable standard could have been established which would not require petitioners to change their formulations. Where equally reasonable alternatives are available, the court must refer to the exercise of administrative discretion. \* \* \*

"Upon a review of the record, we conclude that the Commissioner acted within his authority in promulgating the standard and definition of identity. The findings are supported by substantial evidence and the conclusions rationally follow from the findings.

"The standard reflects the practice of a number of manufacturers and to those not in compliance there will be no economic hardship in complying. The fact of exclusion of the leading producers does not make the regulation unreasonable. Products have been excluded before. See, e.g., **Federal Security Administrator v. Quaker Oats Co.**, *supra*. Skippy and Peter Pan will not be banned; merely a change in product formula will be required. '[I]t is an essence of legislation, functionally speaking, that in its immediate effect, it hurts some and benefits other members of society.' **Willapaht Oysters, Inc. v. Ewing**, 174 F.2d at 694."

Subsequently, a petition for a writ of certiorari to the Supreme Court by Derby Foods, Inc., was denied, and the definition and standard of identity for peanut butter came into effect. (Misc. Nos. 119, 120; N.J. No. 60)

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.  
Alexander M. Schmidt, M.D., *Commissioner of Food and Drugs*  
Washington, D.C., November 1, 1974



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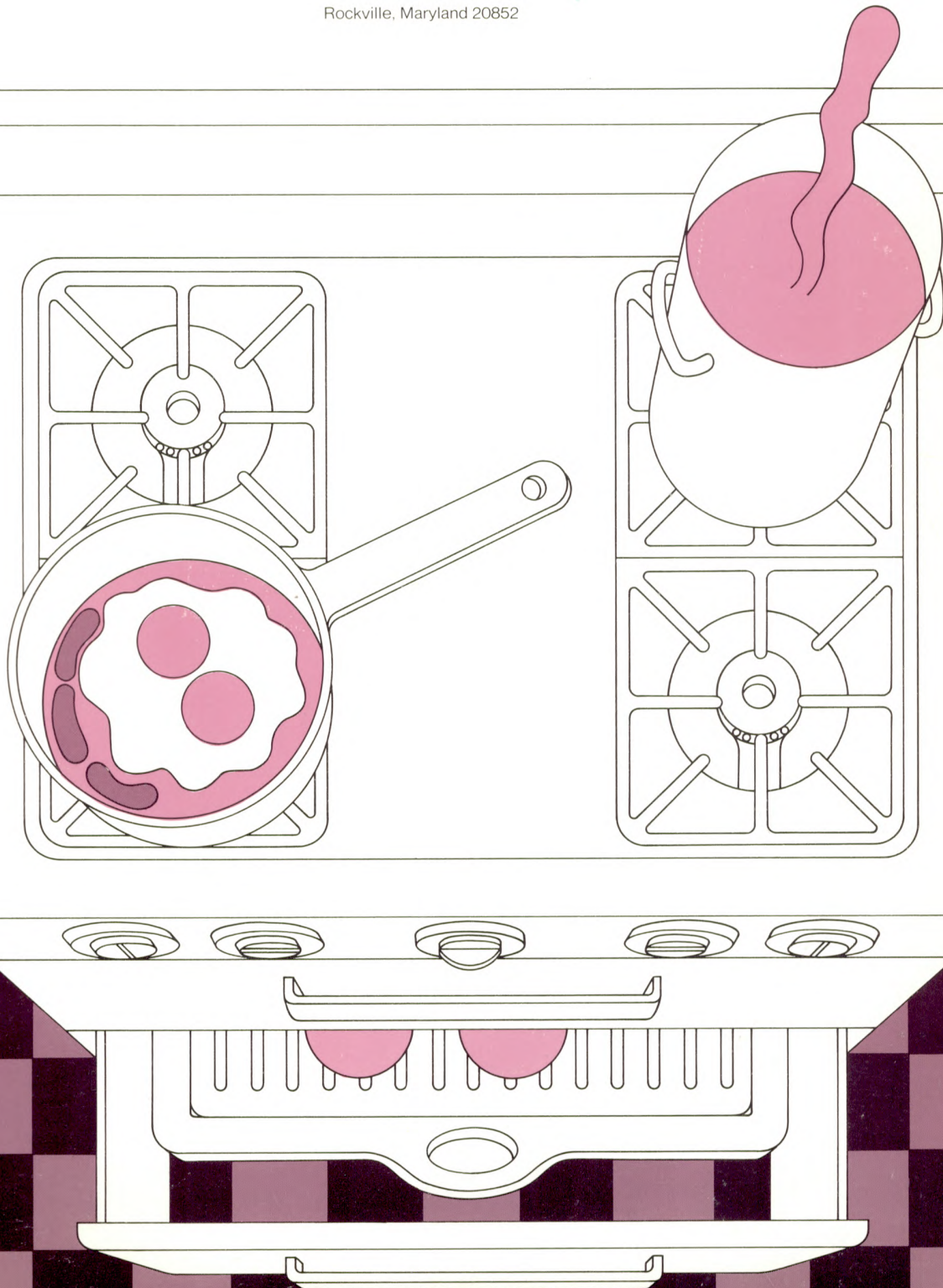
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