

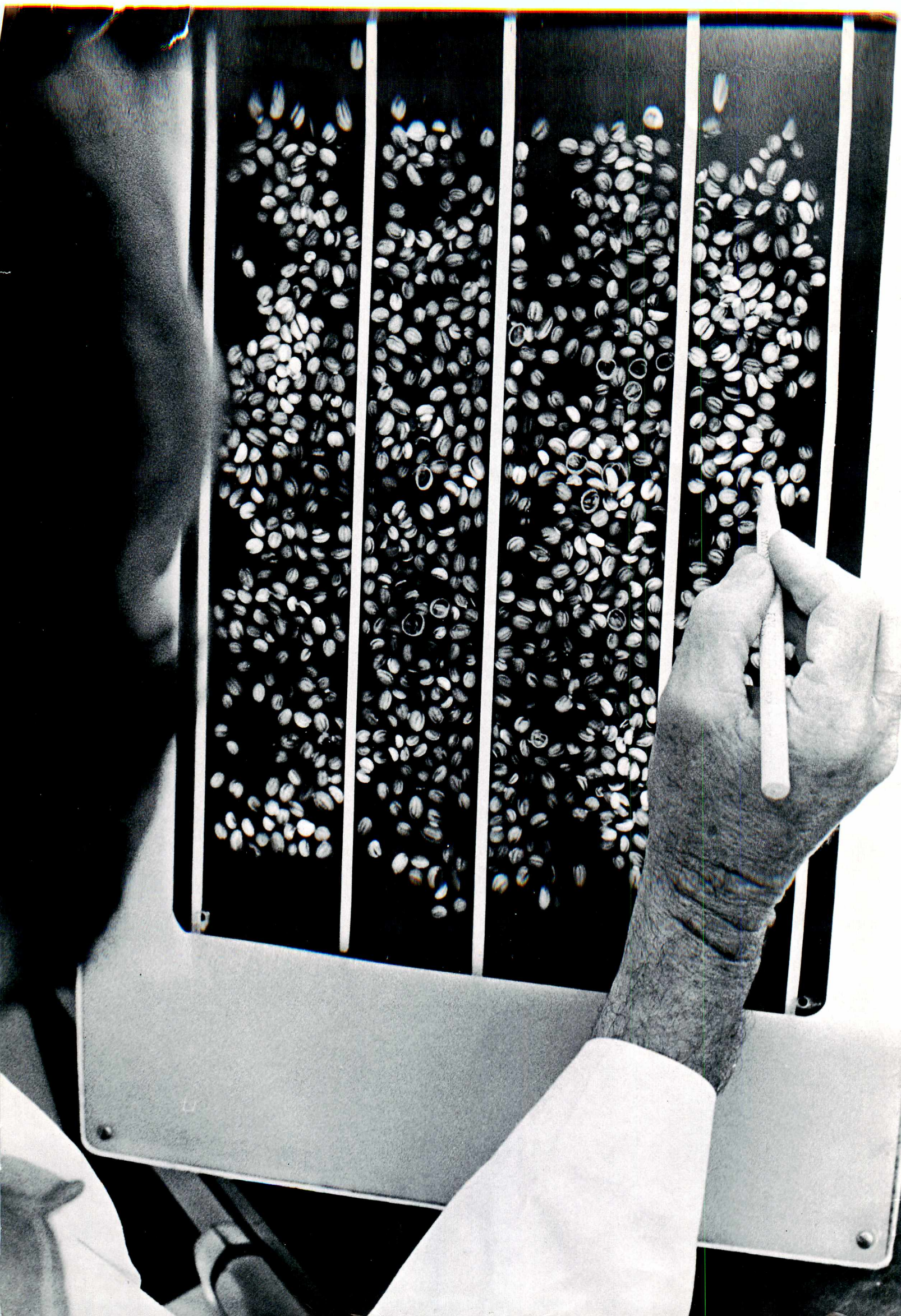
# FDA CONSUMER

September 1977

Painkillers:  
Their Uses  
And Dangers









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# This Month

**D**r. Doolittle talked to animals. That feat may be beyond the capability of the scientists who work with laboratory animals, but the animals sometimes have a message for us. Their reactions to certain tests tell us that some of the substances we eat or drink or that are in the air we breathe can cause cancer in people. The controversies over Laetrile and saccharin are just two recent issues that have increased public interest in the use of animal tests. This month, in an interview with Dr. Richard Bates, newly appointed Associate Director for Carcinogenesis Research of the National Cancer Institute, we explore some of the questions people are asking about *Animal Tests and Human Health*.

Pain is a type of communication. It's the body's way of telling us that something is wrong. For millions of people, pain and aspirin go together like peanut butter and jelly. Aspirin and other nonprescription analgesics can alleviate pain, and because they can some people have fallen into the habit of popping a couple of aspirin at the drop of a symptom. That's a bad habit; even familiar drugs should be used with discretion. An FDA advisory panel has studied the safety, effectiveness, and labeling claims of the ingredients that go into the thousands of pain-killing products that can be purchased without prescriptions. There's a report on the panel's findings and recommendations beginning on page 6.

Nonprescription drugs are required to carry information on their labels on how they should be used and what they should be used for. There is no such requirement for most prescription drugs. Patients must get this information from their doctors or pharmacists. A few prescription drugs, however, are required by FDA to be accompanied by so-called patient package inserts, which are brochures or leaflets written in simple language to advise patients about potential side effects and provide them with other information they should have. The idea may sound simple, but putting it into practice isn't, as we point out in *Developing Drug Information for Patients*.

Also in this issue is a look at what FDA is doing to see that when consumers buy coffee the insult of contamination isn't added to the injury of high prices.

**Inside Front Cover Photo:** *FDA experts can "read" x rays of coffee beans in much the same way that doctors read x rays of their patients. The coffee bean x rays are examined for evidence of insect tunneling. The amount of coffee being detained at U.S. ports because it is contaminated has increased substantially in recent years. Why this is so and what FDA is doing to deal with the situation are explained in Detentions Compound Coffee Problem.*

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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.

**Cover Design:** Thomas Teague



# Update

## Top Health Official Cites Laetrile Dangers

*Over the years there has been a series of worthless cancer treatments that claimed to offer painless, nontoxic cures. An article in the July-August 1977 FDA CONSUMER entitled Cancer Quackery: Past and Present examined some of the more vigorously promoted and highly publicized of these, including the Koch and Hoxsey treatments, Krebiozen, and the latest unproved drug, Laetrile. Here's an update.*

Julius Richmond, M.D., assistant secretary for health of the U.S. Department of Health, Education, and Welfare, has cautioned cancer victims who are buying Laetrile that they may not be getting what they are paying for and may be getting a dangerous and contaminated product.

In a statement issued at a Washington press conference, Dr. Richmond cited "disturbing new information" about the safety and content of Laetrile. He called this new information "particularly important" because some terminally ill cancer victims are legally obtaining Laetrile under a court order issued by the U.S. District Court for the Western District of Oklahoma.

Laetrile (sometimes called amygdalin) is a cyanide-containing substance derived from apricot and other fruit kernels. Its proponents say that it is effective in the prevention, cure, or control of cancer, and that it has no toxic side effects. Dr. Richmond disputed the accuracy of both these claims.

"As our experiences with Laetrile grow, we are finding that it is not harmless," Dr. Richmond said. "Quite to the contrary, we are finding that Laetrile is a potentially dangerous substance, especially in its oral form. Enzymes present in the human digestive tract can break down the drug to release deadly cyanide."

He cited testimony at a Congressional hearing by Dr. Joseph F. Ross, professor of medicine at the UCLA School of Medicine in Los Angeles, which documented 37 cases of poisoning and 17 deaths from Laetrile and cyanide-containing fruit kernels. One of the cases was that of a 10-month-old girl in Attica, New York, who died after ingesting up to five of her father's 500 milligram Laetrile tablets. Her death was listed by the medical examiner as "due to amygdalin ingestion."

Dr. Ross testified that Laetrile, in addition to possibly causing acute toxic effects, may also result in chronic poisoning, such as neurological degenerative disease.

Dr. Richmond also called attention to a recent report by four doctors at Georgetown University of

adverse reactions to Laetrile. He said that the Georgetown physicians reported that one cancer patient who resorted to Laetrile developed fever, skin rash, and abdominal pain, while a second developed difficulty in eye movement and weakness in the arms and legs.

"When Laetrile was discontinued," Dr. Richmond said, "the symptoms disappeared in both patients. In one patient the Laetrile was resumed and the symptoms returned. The other patient did not resume Laetrile."

Dr. Richmond said these reports on Laetrile toxicity "may be just the tip of the iceberg," and that this information "demonstrates once again how critical are our laws that require that drugs be adequately tested before they are sold."

There are also serious questions about the content and quality of the Laetrile now being sold to cancer victims, Dr. Richmond noted. Laetrile is produced in factories not registered with the U.S. Government nor inspected by FDA. Because of this, Dr. Richmond explained, there is no way a prescribing physician can assure the quality and purity of Laetrile, whether it is being imported under the current court order or is being imported illegally.

Tests conducted by FDA, the Stanford Research Laboratory, and other laboratories show that the Laetrile now being bought in the United States, whether imported from Mexico or made elsewhere, varies widely in its ingredients, quality, and purity, the Surgeon General said. He cited these examples:

- Tablets of Laetrile seldom meet their declared strength. Tablets have been found to vary in content from 42 to 450 milligrams.
- Actual content of amygdalin in the injectable form has been found to vary from 14 to 87 percent. No injectable product has been found to contain 100 percent of its declared potency. On closer examination, these vials were found to contain two different isomers of the drug, which are likely to vary widely in their effect on the body.
- Impurities have been found in some samples. Some producers of injectable Laetrile are using isopropyl alcohol instead of ethyl alcohol in the production process. Isopropyl alcohol may cause a more painful injection and, if high levels are used, may be a hazard in itself.
- A very recent analysis of ampules of amygdalin from Mexico revealed evidence of microbial contamination visible to the naked eye. Microbial contamination could lead to serious illness and death if the substance is injected into the bloodstream.
- Recent analyses of these same samples from Mexico revealed serious problems with the seals on



the ampules so that leakage could occur. This permits microbial contamination.

Dr. Richmond said that on the basis of all the information available he has concluded that "Laetrile not only is an ineffective cancer drug, but that cancer victims who buy it are not even getting what they are paying for, and in fact may be buying a dangerous and contaminated drug."

Dr. Richmond charged that the use of Laetrile diverts cancer patients from proven therapy. He called this the drug's "major hazard," and said that the new information on toxicity and quality "compounds that hazard."

"I urge cancer victims who are now taking Laetrile, whether legally or illegally, and those who may consider it, to be fully alert to these new hazards we are just now starting to identify," Dr. Richmond said.

"Further, I would urge all cancer patients, their relatives, and their friends to avoid the use of this dangerous, fraudulent drug and to seek effective treatment through their family doctors and the specialists they recommend. Those who persist in the use of Laetrile should limit the amount taken by mouth and should under no circumstances drink the injectable form because of its higher concentration. They should be prepared to seek prompt medical attention in case of any unexpected effects of Laetrile and should be aware of the possibility of chronic cyanide poisoning as well as acute toxicity which can result in sudden death."

In another development involving Laetrile, Commissioner of Food and Drugs Donald Kennedy announced that FDA has completed and presented to a Federal court an exhaustive new review of Laetrile. The review reaffirmed previous evaluations that Laetrile is not an effective cancer drug, and, further, has concluded that use of this substance poses a "genuine public health problem in the United States."

Dr. Kennedy and the FDA staff reviewed more than 5,500 pages of written material submitted by the proponents and opponents of Laetrile, as well as testimony presented by 47 witnesses at a two-day hearing in Kansas City.

The formal administrative proceeding was ordered by the U.S. District Court for the Western District of Oklahoma in the case of an individual seeking to obtain judicial permission to import Laetrile.

Dr. Kennedy said: "We have made every effort to obtain all available information about Laetrile, and to review it carefully and objectively. Our review affirms strongly our previous position that Laetrile is not generally recognized among qualified experts as being a safe and effective cancer therapy, and that it is not exempt from regulation under the Federal Food, Drug, and Cosmetic Act."

"Further, our review has demonstrated that Laetrile constitutes a genuine public health problem. Thousands of Americans are being persuaded to

stay away from proven therapies; they not only are wasting their money, but their very lives are at stake."

Dr. Kennedy continued: "In this evaluation, we have looked at the reasons that cancer victims and their families turn to unproven remedies and we find that Laetrile is no different in its attraction than previous unproven and fraudulent cancer treatments."

"Cancer victims over the years have been particularly susceptible to exploitation by the promise of an easy, painless cure for cancer," said Dr. Kennedy.

The administrative record has been submitted to Oklahoma District Court Judge Luther Bohanon. It was printed in the *FEDERAL REGISTER* August 5, 1977.

## Consumers Assured on Ice Cream Quality

*Because ice cream is a "standardized food"—a food made according to a specific recipe—it is exempt from the regulations requiring that ingredients be listed on the label. In an effort to accommodate numerous consumer requests that the ingredients be listed on the label, FDA decided to permit manufacturers to use a wider range of ingredients to meet the standards for ice cream. This would make the ingredients optional and FDA then would have authority under the law to require that they be listed on the label. The revised regulations and their effect were explained in the July-August 1977 FDA CONSUMER in an article entitled Inside Information on Ice Cream. Here's an update.*

Donald Kennedy, Commissioner of Food and Drugs, has assured consumers that pending new FDA rules governing the ingredients that may be used in ice cream are designed to reduce consumer costs without reducing ice cream quality, including flavor, body, texture, appearance, or nutrient value.

Commissioner Kennedy said that in addition, the new rules will require full ingredient labeling of ice cream and related frozen desserts and will, for the first time, allow consumers to know exactly what they are paying for.

The new regulations provide for the use of all "safe and suitable ingredients" in ice cream—with ingredient labeling. The regulations state that a "safe and suitable" ingredient must serve a functional purpose and must not change the basic character of the product.

The new standards replace the old requirement for a specific minimum of 10 percent total nonfat milk solids with a minimum for nonspecific protein from *milk-derived ingredients*—not, as has been reported, artificial "chemical substitutes." The new standards merely remove previous limits on the amount of such milk-derived ingredients as casein and whey.

The pending new standards are opposed by the National Milk Producers Federation (NMPF), which



claims that the changes would adversely alter the nutritional and physical characteristics of ice cream. The producers are preparing arguments for an evidentiary hearing on their claim that the nutritional quality will be affected.

While the new FDA regulations are opposed by the milk producers, they are likely to benefit the ice cream manufacturing industry. Calculations by the U.S. Department of Agriculture indicate that the new standards will permit a significant reduction in manufacturing costs.

The same estimates show that a part of such savings will be passed on to consumers in the form of a predicted 2.5 percent decrease in retail cost.

In testimony before a subcommittee of the House Agriculture Committee of the U.S. Congress, FDA Commissioner Kennedy said that in no case can FDA refuse to issue or amend a food standard that is in the consumer's interest "merely because it could cause adverse impact on a particular producer group.

"We cannot be influenced," said Commissioner Kennedy, "by transfers between economic sectors if such transfers are not germane to the interest of consumers."

The FDA Commissioner questioned the milk producers' argument that the new rules would result in a lower quality ice cream. He said that the new standards—in addition to consumer savings and ingredient labeling—would "guarantee product quality just as well as the old recipe approach."

Concluded the Commissioner: "It should hardly be necessary to point out that ice cream manufactured under the old standard is variable in quality. It may be possible to produce poor ice cream under the new standard; but the range of quality will, we believe, be no different from the present range."

In response to objections from the milk producers, FDA has stayed parts of the new regulations in order to allow additional data and information and, if justified, will grant a formal hearing.

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## Consumer Forum

### Price Shopping for Prescription Drugs

Joseph Fink's reply in April's Consumer Forum to the article entitled *On Reading Prescriptions* is an insult to any intelligent shopper. It seems he is very intent on trying to dissuade consumers from "shopping around." I wonder if he fears that such consumers would become outraged at pharmacists for their easily-discovered arbitrary pricing of drugs. Every study done of drug pricing has shown that consumers can save considerable amounts by comparative shopping.

Mr. Fink is correct in warning consumers about the dangers of "potentially serious drug-drug interactions," but he has failed us in not offering another very simple way to avoid such interactions—viz., every person should have a list of drugs they are consuming, and this list can be shown to any pharmacist at the time of purchase. In short, consumers can protect themselves against price-gouging and simultaneously be served by the pharmacist's expertise while "shopping around" and getting the most for their money.

Jack Litewka  
Research Assistant  
Cooperative Extension  
University of California  
Berkeley, California

### Jacobson's Sugar Views Disputed

It is unfortunate that Dr. Michael Jacobson used the recent interview in *FDA CONSUMER* (May 1977) to take every possible opportunity to make misleading and inaccurate statements regarding sugar.

It is extremely puzzling that Dr. Jacobson consistently chooses to ignore the conclusions of the most recent scientific evaluation of the health aspects of sugar. We refer to "Evaluation of the Health Aspects of Sucrose as a Food Ingredient," prepared for the FDA by a Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology (FASEB). This committee of highly qualified scientists reviewed the available evidence in this four-year study and concluded that aside from its involvement as one factor in dental caries, sugar is safe at present levels of consumption.

It should also be noted that when the FASEB Committee held a public hearing in May 1976 for the purpose of receiving additional evidence concerning its evaluation, Dr. Jacobson did not appear. One can only conclude he had no substantiated evidence regarding the detrimental effects of sugar to offer this scientific body.

In light of the assessment from the scientific community that sugar is safe, we hope Dr. Jacobson will give more careful thought to his comments on sugar in the future.

Sarah Setton  
Assistant to the President  
The Sugar Association  
Washington, D.C.



# Painkillers: Their Uses And Dangers

*An FDA advisory panel has looked into aspirin and other nonprescription painkillers and concluded that those little pills shouldn't be taken lightly. The panel cautioned against the use of over-the-counter analgesics for rheumatism and arthritis except under the supervision of a doctor. And it warned against the use of aspirin by people who have upset stomachs and by women in the last months of pregnancy.*

by Annabel Hecht

“Take two aspirin and call me in the morning.”

That “line” is always good for a laugh in a comic routine, but to the pill-taking public it is no joke. Americans swallow some 19 billion aspirin a year, making it the most widely used nonprescription drug on the market. Aspirin and other painkillers, however, are not something to be taken lightly, a panel of experts has warned, especially for self-treatment of such diseases as rheumatism or arthritis.

The panel also cautioned against the use of any product containing aspirin by people who have upset stomachs, even if the aspirin is intended to relieve a headache that occurs at the same time as the stomach distress.

The group of experts, called together by the Food and Drug Administration to look at ingredients in internal analgesics (pain relievers), is one of 17 such panels which have been studying the safety and effectiveness of drug products that can be purchased over the counter. For purposes of the review nonprescription drugs have been divided into product categories, such as antacids, laxatives, and cough-cold remedies. The internal analgesics panel is the seventh to make its recommendations to FDA on standards for the ingredients and labeling of the group of drugs it was asked to review.

FDA has issued final regulations for

over-the-counter antacids and is expected to do so for laxatives before the end of the year.

The internal analgesics panel reviewed 15 ingredients to determine whether they are safe and effective as painkillers (analgesics), fever reducers (antipyretics), and inflammation reducers (antirheumatics). Seven of the ingredients contain salicylic acid and eight do not.

Both salicylate and nonsalicylate painkillers have a long history of use. For centuries the bark and leaves of the willow, poplar, spirea, and other plants were used to ease pain and cure fevers. The active ingredient that made these early remedies effective—salicylic acid—was isolated in the early 19th century. Methods for making salicylic acid in the laboratory were developed in 1874 and its potential for the treatment of rheumatic conditions and gout was realized soon after. Aspirin, by far the most widely used salicylate today, was developed in 1853 but not used medically until 1899.

Nonsalicylate painkillers derived from coal tar came into use in the 1850's. Acetanilid appeared in 1852 but it was not until 1886 that its fever-reducing properties were discovered accidentally by two Austrian physicians. A search for less poisonous drugs led to the development of acetaminophen in 1893. Oldest of all the nonsalicylate pain relievers are quinine and codeine, which date to the 17th and 19th centuries respectively.

Six of the ingredients are safe and effective as painkillers and fever reducers, the panel said. Five are salicylates—aspirin, calcium carbaspirin, choline salicylate, magnesium salicylate, and sodium salicylate. The sixth is acetaminophen, a nonsalicylate frequently used as an aspirin substitute. Analgesic products with these ingredients should be permitted to claim only that they are “for the temporary relief of occasional minor aches, pains, and

headache,” the panel recommended. Fever-reducing products containing these ingredients should be limited to the claim that they are “for the reduction of fever.” Too many claims would be confusing, the panel said, and the term “minor pain” is sufficiently broad to cover all types of pain that can be effectively treated with these ingredients.

Iodopyrine was found by the panel to be neither safe nor effective as a painkiller or fever reducer, and four ingredients—acetanilid, codeine (codeine phosphate and codeine sulfate), phenacetin, and quinine—were judged effective but not safe for nonprescription use. The panel recommended that all five of these nonsalicylates be taken off the over-the-counter market.

There was insufficient evidence to determine whether aluminum aspirin, antipyrine, salicylamide, and salsalate (antipyrine and salicylamide are nonsalicylates) are safe and effective, the panel said. It recommended that FDA continue to permit the use of these ingredients in nonprescription pain and fever medicines for up to three years if manufacturers conduct tests to establish their safety and effectiveness. A minority of the panel felt there were enough questions about the safety of antipyrine to warrant its removal from over-the-counter drugs.

The fact that some of the ingredients studied have been used for as long as 100 years does not mean they are without side effects, the panel said in calling for strong warnings on product labels.

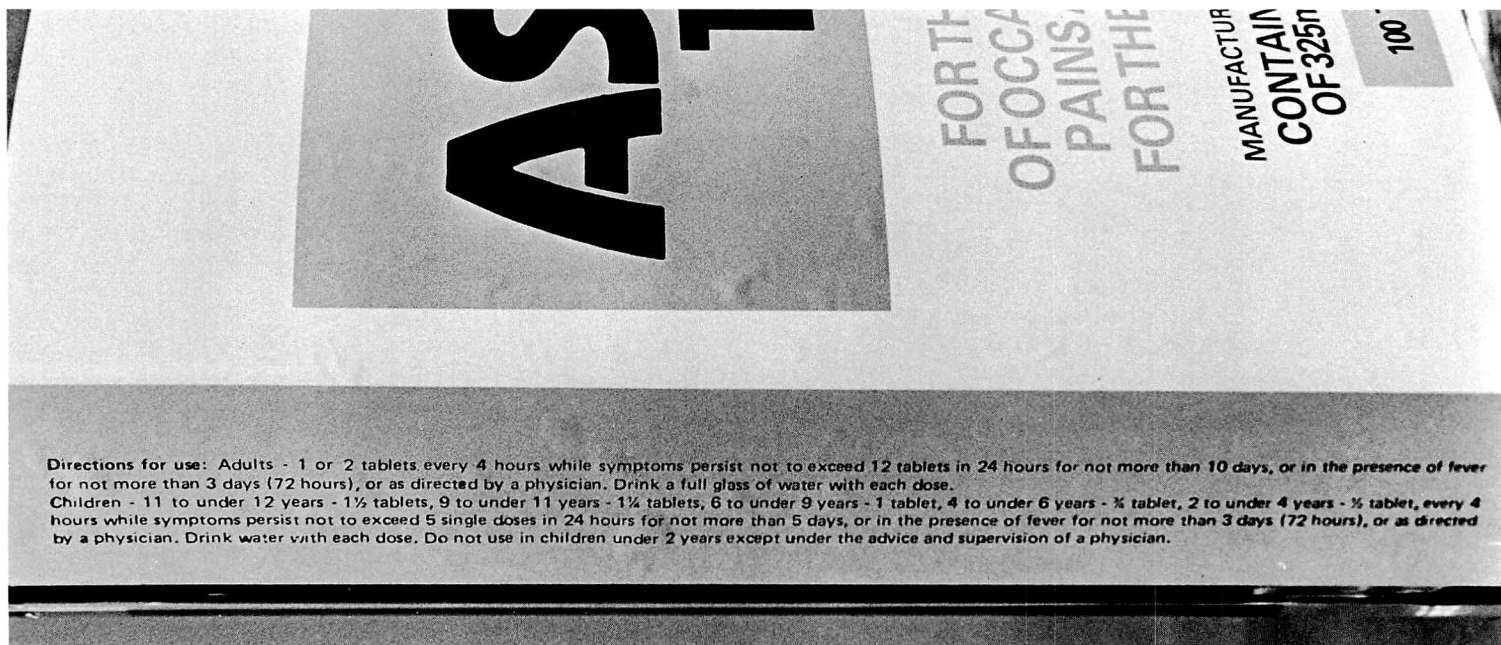
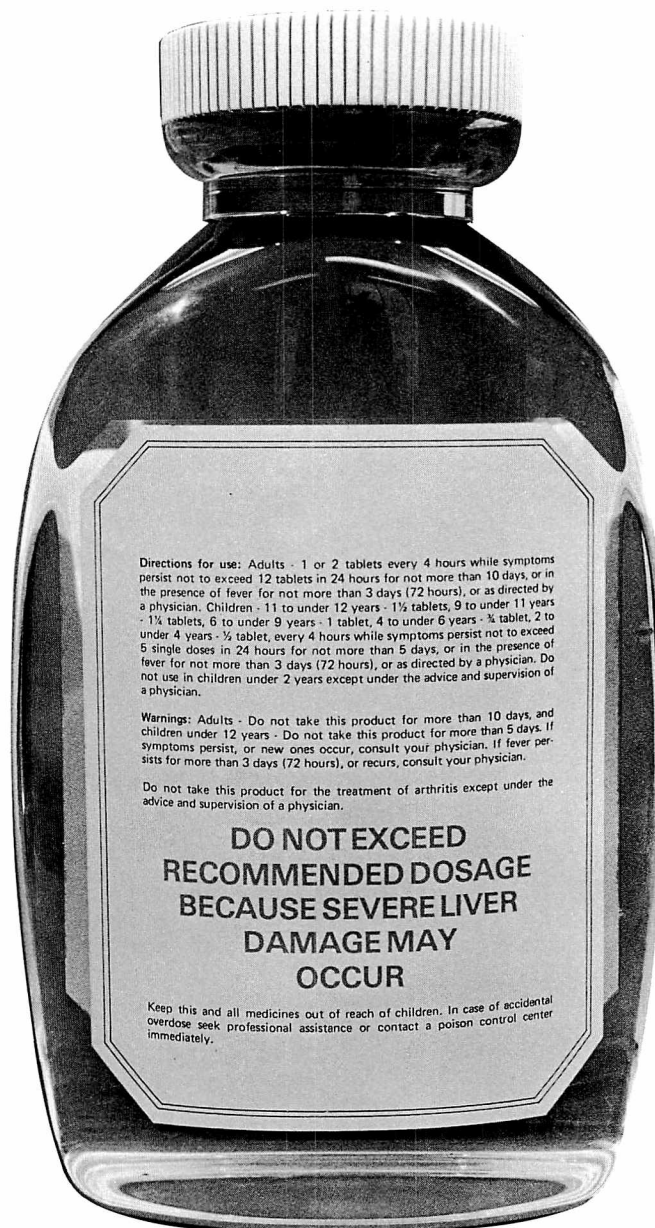
For instance, the panel pointed out that aspirin interferes with blood clotting and if taken in the last three months of pregnancy can prolong pregnancy and labor and cause bleeding before and after delivery. The labels on products containing aspirin should warn that they should not be taken by people who are allergic to aspirin, have asthma, or are in the last three months







*Labeling claims for over-the-counter painkilling drugs should be limited to one all-encompassing statement, according to an FDA advisory panel on internal analgesics. But, as these mock-up bottles show, consumers would get much more information on how to take these drugs, if the panel's recommendations are adopted by FDA.*



of pregnancy, the panel said. Labels on chewable aspirin and aspirin-containing gum also should advise against use for seven days after tonsillectomy or oral surgery.

Because aspirin and other products containing salicylic acid can cause stomach distress, increased bleeding, and even ulcers, labels on these products should warn that they are not to be used by persons who have stomach distress, ulcers, or bleeding problems, the panel said. The label also should warn against use by persons who are taking prescription drugs for anticoagulation (thinning the blood), diabetes, gout, or arthritis except under the supervision of a physician.

Fortunately, salicylates have a built-in early warning system. Overdosing will cause a ringing in the ears. Thus the panel recommended that the label caution consumers to stop taking the drug if this ringing occurs.

While acetaminophen is free of most of the side effects caused by salicylic acid, an overdose can result in serious liver damage. The panel called for labels on acetaminophen products to contain this warning: "Do not exceed recommended dosage because severe liver damage may occur."

No painkiller should be taken for longer than 10 days by adults or 5 days by children, the panel said, and the time limit for self-medication with fever reducers should be 3 days.

Nonprescription analgesics often are used to relieve joint pains and aches due to diseases such as arthritis and rheumatism. The five salicylates deemed safe and effective as painkillers also were considered by the panel as "acceptable" for use in reducing inflammation. But although these drugs can reduce inflammation, the panel expressed concern about their use for this purpose without medical supervision. The recommended nonprescription dose of these drugs may relieve the pain of arthritis or rheumatism but

it may be insufficient to treat the disease that causes the inflammation. To reduce inflammation, the panel said, in most cases larger doses of these drugs are needed for long periods of time, and such doses should be used only under a doctor's supervision.

The panel raised serious questions about the promotion of over-the-counter analgesics for rheumatic diseases. The labeling and advertising now used can mislead consumers into thinking that these are minor ailments that can be self-diagnosed, the panel contended. Pain is the only symptom mentioned, the panel noted, and the consumer is never told that improperly diagnosed and treated rheumatic diseases can lead to crippling and even permanent disability.

Analgesic advertisements which suggest that arthritis is a minor disease or that alleviation of pain with "extra strength aspirin" will control the disease could delay proper diagnosis and treatment, the panel said. To prevent this, it recommended that nonprescription analgesics be prohibited from making any claims relating to the treatment of rheumatic diseases. Terms such as "arthritis," "rheumatism," "minor pain of arthritis or rheumatism," "arthritis strength," and "arthritis pain formula" should be removed from nonprescription products, including brand names, the panel said. Labeling for salicylate painkillers should indicate that the product is to be used to treat arthritis only under the supervision of a physician.

Acetaminophen, the only nonsalicylate ingredient rated safe and effective by the panel for the relief of pain, does not reduce inflammation and was rated not safe and effective for this purpose. The panel said acetaminophen should be labeled with the warning: "Do not take this product for the treatment of arthritis except under the advice and supervision of a physician."

The panel also found acetanilid, cod-

eine (codeine phosphate and codeine sulfate), iodopyrine, phenacetin, and quinine not safe and effective as inflammation reducers and urged that their use for that purpose in nonprescription drugs be prohibited. Salicylamide was found to be ineffective in reducing inflammation. The panel said there was not enough information available to determine whether aluminum aspirin, antipyrine, and salsalate are safe and effective for reducing inflammation. These drugs should be permitted to remain on the market for the treatment of inflammation for up to three years if their manufacturers conduct tests to establish their safety and effectiveness, the panel said. But, as with other nonprescription inflammation reducers, the panel recommended that these drugs be used only under the guidance of a physician.

The panel said it is important to establish a safe, standard dosage for aspirin and the other salicylates because overdose can lead to salicylate poisoning and even death. Consumers who follow the rule of thumb—"take two aspirin"—run the risk of serious toxic effects if they take a product with a larger amount of aspirin per tablet than is found in most nonprescription drugs.

The panel strongly recommended establishment of a standard tablet containing 325 milligrams (mg), which is the same as 5 grains, for the three most commonly used pain and fever medicines: aspirin, acetaminophen, and sodium salicylate. Tablets containing different dosage units should be labeled to show that they are more or less than the standard, the panel said.

The recommended adult oral dosage schedule for aspirin should be 325 milligrams (5 grains) to 650 milligrams (10 grains) every 4 hours not to exceed 4,000 milligrams (60 grains) in 24 hours. The same schedule would apply to acetaminophen and sodium salicylate. The panel also proposed a sched-



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**Table I****Recommended Adult Dosage Schedule for Nonstandard Aspirin Tablets**

<b>Amount of Aspirin Contained in One Tablet</b>	<b>Number of Tablets That Can Be Taken Initially</b>	<b>Number and Timing of Tablets That Can Be Taken After Initial Dose</b>	<b>Total Number of Tablets That Can Be Taken in 24 Hours</b>
400 milligrams (6.15 grains)	1 to 2	1 after 3 hours	9
421 milligrams (6.48 grains)	1 to 2	1 after 3 hours	9
485 milligrams (7.46 grains)	1 to 2	1 after 4 hours or 2 after 6 hours	8
500 milligrams (7.69 grains)	1 to 2	1 after 3 hours or 2 after 6 hours	8
650 milligrams (10 grains)	1	1 after 4 hours	6

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**Table II****Recommended Aspirin Dosage Schedule for Children**

	<b>Children's Tablets <sup>1</sup> (80 milligrams—1.23 grains)</b>	<b>Standard Adult Tablets <sup>1</sup> (325 milligrams—5 grains)</b>
<b>Age</b>	<b>Number of Tablets That Can Be Taken Every 4 Hours</b>	<b>Number of Tablets That Can Be Taken Every 4 Hours</b>
Under 2 <sup>2</sup>		
2 to under 4	2 (160 milligrams)	$\frac{1}{2}$ (162.5 milligrams)
4 to under 6	3 (240 milligrams)	$\frac{3}{4}$ (243.8 milligrams)
6 to under 9	4 (320 milligrams)	1 (325 milligrams)
9 to under 11	5 (400 milligrams)	$1\frac{1}{4}$ (406.3 milligrams)
11 to under 12	6 (480 milligrams)	$1\frac{1}{2}$ (487.5 milligrams)

<sup>1</sup> Not to exceed five single dosages in 24 hours or to be used for more than five days except under the advice and supervision of a physician.

<sup>2</sup> No recommended dosage except under the advice and supervision of a physician.

ule for nonstandard tablets which would limit the total daily dosage to 4,000 milligrams or less (see Table I).

The panel found that there is no single recognized recommended aspirin dosage schedule for children. The doses recommended on the labels of products now on the market are too low, according to the panel. This could cause overdosing, one drug manufacturer told the panel, because if the drug isn't having the desired effect a parent might give a child too much at one time or repeat dosing before the recommended time interval.

The panel recommended an aspirin dosage schedule for children which starts out with an adequate dose and repeats it every four hours (see Table II). The panel also recommended that the standard tablet for children's aspirin be 80 milligrams (1.23 grains). This would mean that one-half of a standard adult tablet would be equal to two standard children's tablets. These recommendations also apply to standard children's doses of other pain and fever drugs. There should be no recommended children's dosage for non-standard tablets, the panel said.

No more than two active analgesic ingredients should be permitted in a nonprescription pain or fever drug, the panel said. It raised no objection to products that combine a nonsalicylate painkiller with an antacid for "temporary relief of occasional minor aches, pains, and headache, and for the reduction of fever, and for acid indigestion."

But the panel called "irrational" the combination of aspirin or other salicylates with an antacid for the treatment of heartburn, sour stomach, or acid indigestion. Aspirin in any form can cause bleeding and stomach distress, the panel said, including highly buffered aspirin that is intended to be dissolved in water and which is claimed to be safe for use by people who have an upset stomach along with a headache.

There is evidence that highly buffered solutions will reduce the side effects of aspirin, but they will not eliminate them, the panel contended. In fact, such products may increase the risk of bleeding because they deliver more pure aspirin to the system than regular aspirin products. The group expressed concern that alcohol and stress, factors which most frequently "prime" the gastrointestinal tract for massive bleeding, are also the factors which most frequently cause upset stomach and headache at the same time.

To prevent the public from being misled into thinking that highly buffered aspirin is the safest aspirin product to take for both headache and upset stomach, the panel recommended that all products containing aspirin be required to carry the following label warning: "Do not take this product if you have stomach distress, ulcers, or bleeding problems except under the advice and supervision of a physician."

The panel did not object to the use of buffered aspirin. It said studies have shown that the addition of alkaline buffers makes aspirin dissolve more quickly, speeding up its absorption into the system. This reduces but does not eliminate the irritating effects of aspirin on the stomach. The panel expressed concern about the labeling of such products, however, since there have been no well-controlled clinical studies to prove that buffered aspirin goes to work faster or is more effective than plain aspirin. In addition, not all brands of buffered aspirin dissolve at the same rate and not all dissolve faster than plain aspirin.

The panel recommended that statements suggesting that buffered aspirin is superior to plain aspirin be limited to: "Faster to the bloodstream than plain aspirin," and "Provides ingredients that may prevent the stomach distress that plain aspirin occasionally causes but should not be taken by certain individuals with stomach disor-

ders as cautioned elsewhere on the label." The use of even these claims should be halted after three years unless the manufacturers of buffered aspirin can prove they are valid, the panel said, and any other claims of fast action or gentleness to the stomach should be removed from buffered aspirin labels.

The panel said aspirin should not be combined with drugs used for the treatment of asthma (bronchodilators), and no pain-killing ingredient should be combined with laxatives or vitamins. Combining painkillers with nighttime sleep-aids should be permitted if the manufacturers of such products can define a "target population" in need of such a combination, the panel said. It recommended that if such products are permitted they be labeled for the temporary relief of minor aches and pains, reduction of fever, and "for the relief of occasional sleeplessness."

Reports of all the FDA panels on over-the-counter drugs are advisory in nature. FDA publishes the reports to give interested persons an opportunity to comment on specific recommendations. The report of the Panel on Review of Internal Analgesics Including Antirheumatic Drugs was published in the July 8 FEDERAL REGISTER. Comments may be sent to the FDA Hearing Clerk, 5600 Fishers Lane, Rockville, Md. 20857 until November 5.

These comments will be carefully considered by FDA in developing final regulations on the acceptable ingredients, dosage, and labeling for nonprescription internal analgesic products. Although it may be many months before final regulations are published, consumers may see changes in some familiar products as manufacturers alter formulations or labeling in anticipation of new regulations.

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



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# Animal Tests And Human Health

*One of the most controversial questions being discussed today concerns the significance to human health of information obtained from tests with animals. Dr. Richard Bates, until recently FDA's Associate Commissioner for Science and now the Associate Director for Carcinogenesis Research of the National Cancer Institute, deals with many of the questions consumers are asking in this interview with Timothy Larkin, special assistant to the Commissioner of Food and Drugs.*

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**Q.** *Dr. Bates, when FDA was questioned about why rats were fed an equivalent of 800 bottles of diet drink a day to test whether saccharin causes cancer, one response was that this is the way science routinely tests chemicals for cancer. A great many people, including members of Congress, have said, in effect, that if this is scientific routine, then there's something wrong with the routine. As FDA's top science advisor, how would you reply to that point of view?*

**A.** I think any useful and convincing reply has to start with another question: "Why not test in man?" Before I tell you why we don't test in humans, I should point out that what we are talking about is food additives, not human drugs. Human drugs must be and are tested in people, but only after tests in animals have shown that the drug can be tested in humans without posing unreasonable risks.

The testing of food additives in people involves both ethics and practical impossibilities. Let's deal first with the ethical question. Testing any chemical in humans involves some risk. With drugs, a reasonable risk is justified because if the drug proves effective the potential benefits can be great. But the benefits of a food additive are seldom as significant as those conferred by drugs. So the law requires that if tests in animals raise any questions about an additive's safety it can't be used in food.

As to the practical question, the key to a scientific experiment is to *measure just one thing*. If you want to see if a certain chemical causes cancer, you have to set up an experiment in which you know you are measuring the impact only of that chemical and not other chemicals or other factors. So, you must isolate the experimental animals from those other chemicals and place them in a uniform, controlled environment. That way, if the animals lose weight, or stagger around, or their organs show evidence of cancer, you are sure it is only the chemical you are testing that is producing these effects.

Even with rats that isn't easy to do. For example, FDA's National Center for Toxicological Research uses special rooms that are sealed off from any known contaminants. The air the animals breathe is filtered to keep out anything larger than three-tenths of a millionth of an inch in diameter, and the animals' water, feed, bedding, and cages, are uniform and sterile. Obviously, you can't subject humans to this kind of control.

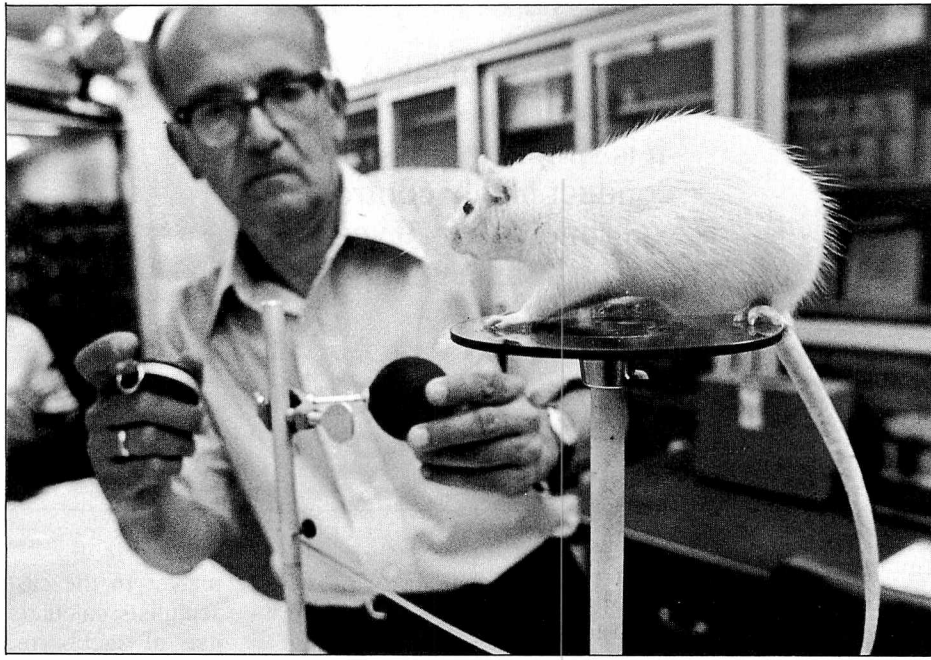
**Q.** *Why is that so obvious? I'm sure some people would be willing to volunteer to live under sterile conditions if important scientific information could be gathered in this way.*

**A.** Perhaps for a week, or a month. But if we were to get such volunteers and feed them a normal dose of a chemical for a short

period, unless it were a poison, in which case testing on humans would be out of the question, we wouldn't learn very much. Cancer often takes 20 or more years to show up. The period between first exposure to high levels of asbestos and the lung cancer it often causes is sometimes more than 30 years. So aside from all the other considerations—of ethics, of the need to sacrifice experimental animals so autopsies can be performed before they die of apparently natural causes—it is simply impossible to conduct highly controlled experiments for 20 years or more on human volunteers.

**Q.** *How about the mass of statistics we constantly gather on what's going on in real life such as those which established the relationship between smoking and lung cancer or between estrogens and cervical cancer? Can't we gather statistics on people who use a particular chemical—such as saccharin—and see if cancer has increased in that population?*

**A.** We can and we do. But while we do have an incredible amount of statistics, the statistics on general populations do not have the kind of precision that lets us identify substances that might cause a relatively few cases of cancer. For example, data clearly showed the enormous rise of lung cancer beginning about 1930. And after many studies it was possible to demonstrate that cigarettes were the



cause. But the tests of saccharin in animals suggest that the risk of bladder cancer in humans who consume moderate amounts of saccharin may be increased by only 4 percent above the present levels. To detect in the general population such a small increase in human cancer would require very detailed study of a large number of individuals who had been exposed to the chemical for several decades.

We know that bladder cancer is on the increase. There are about 30,000 new cases a year in this country. But we also know that no single chemical causes all of these cases; many individual substances may cause bladder cancer. If a chemical is responsible for only three or four percent of the total number of cases it would be very difficult to identify that chemical as a cause of bladder cancer merely by examining the statistics on the disease. The connection between that chemical and bladder cancer would have to depend on well-controlled animal studies or on the existence of some special situation such as intensive study of a group of bladder cancer victims who had, over a period of years, ingested significantly greater amounts of the particular chemical as compared with the cancer experience of a similar group which did not ingest the chemical.

**Q.** *Even if tests in animals are necessary, isn't it a big leap to use information from rat tests to say what may happen in humans? Rats*

*and man, other than being mammals, differ in important ways. What meaningful information can we learn from rat studies?*

**A.** A lot. We human animals share basic biological mechanisms with other animals, and apparently one of those basic biological mechanisms involves getting cancer. Insects get cancer, fish get cancer, plants get cancer. And cancers in laboratory animals are essentially the same as cancers in human beings. Also, with the possible exceptions of arsenic and benzene, all substances known to cause cancer in people also cause cancer in laboratory animals. We can't purposefully set up an experiment to see if substances known to cause cancer in animals also cause cancer in humans, but it would be foolhardy to assume they won't.

Rats and humans have similar genetic mechanisms and generally similar enzyme mechanisms to deal with foreign chemicals such as those associated with cancer. Even bacteria have genetic mechanisms so similar to humans that they are being used in a new test for chemicals. If a chemical causes the bacteria to mutate, there appears to be a strong possibility that the chemical may be cancer-causing.

**Q.** *Isn't it a fact, though, that if you overload any animal's system with a chemical, you are going to find cancer? Isn't it just commonsense that too much of anything will give you cancer?*

**A.** It's commonsense that the world is flat too. And this business about too much of anything giving you cancer is like a flat world; it won't hold water. Thousands of substances have been tested in huge amounts in animals. Too much will kill the animal. But only cancer-causing substances cause cancer. Other things will poison an animal or a human, but won't cause cancer. A study sponsored by the National Cancer Institute tested 120 pesticides and industrial chemicals in mice at high doses. Only 11 were found definitely to cause tumors. And these chemicals were not randomly selected. The majority of them were picked because they already were suspected of causing cancer. Despite this, and despite the very high doses fed the mice, most of these suspected cancer-causing chemicals did not cause cancer. Other studies have supported these findings that high dosage alone will not cause cancer.

**Q.** *But why feed these animals so much? It just seems that giving them such extraordinarily large amounts can't produce findings useful to humans.*

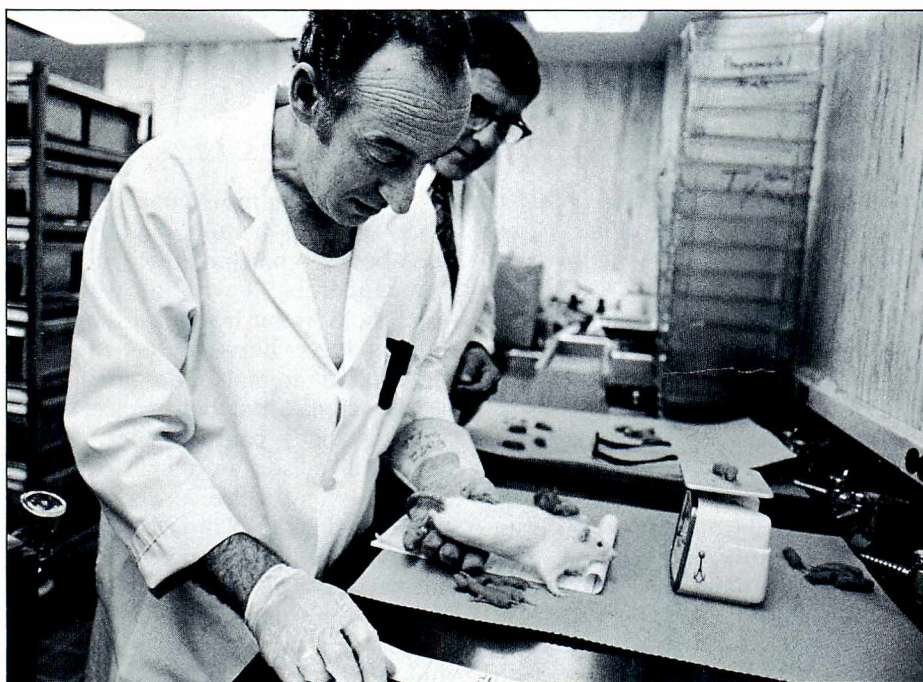
**A.** Using high doses is the only really practical way to determine if a substance will cause cancer in a small proportion of the people who use it. You see, if we assume that a low dose of a chemical might cause cancer in one out of every 100,000 humans or animals, then a test



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“Cancer often takes 20 or more years to show up . . . it is simply impossible to conduct highly controlled experiments for 20 years or more on human volunteers.”

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to detect this one cancer could take as many as 100,000 animals, even more. Now I realize that one in 100,000 sounds like an insignificant number, but that works out to 2,000 cases of cancer in our total population of more than 200 million.

Obviously, a test with 100,000 animals would be impractical. There aren't enough animal breeders, tissue examiners, time, or money for that kind of job. What scientists can do, however, is use a smaller number of animals and increase the dose of the chemical being tested. Roughly speaking, if you use ten percent of the numbers of animals that would give meaningful results at a low dose, then you must increase the dose by ten times to make up for the smaller num-

ber of animals and get results that are statistically meaningful. This gets results faster and at an acceptable cost. The method works because of the shorter lifespan of a rat—about 2 years—and the faster rate at which animals metabolize and excrete a substance in comparison to man.

**Q.** *But how can these animal tests using large doses of a chemical be relevant to humans who use much lower doses of something like saccharin?*

**A.** It is true that there is no way of predicting, exactly, on the basis of animal tests, how many humans will develop cancer from using a given product, but there are methods by which scientists can make esti-

mates. In the case of saccharin, FDA scientists calculate that even moderate use of saccharin over a lifetime by every American might lead to the possibility of up to 1,200 additional cases of bladder cancer a year. With thousands of Americans dying from cancer every day, this additional risk is one we can do without.

There is something else that should be kept in mind. That is that experimental animals get a special kind of treatment, something humans do not. Only healthy animals are used in laboratory tests; they live in a protected environment and are well fed. They are usually exposed to only one suspect chemical.

Most humans, on the other hand, do not live in sheltered environments, without stress and with a guaranteed snug bed and nutritious three squares a day. Our population includes the ill and the weak—people who would be comparatively more susceptible to cancer than test animals. And we are exposed to not one, but many environmental dangers, some of which may interact to multiply our risk of cancer. So this is another reason to pay careful attention when we find that any chemical, regardless of dose, causes cancer in test animals.

**Q.** *You say “regardless of dose,” but I still can’t keep from thinking that there is a relationship between the dose of a chemical and its ability to trigger a cancerous reaction.*

**A.** To a degree it does depend on how much. If you decrease the size of the dose of a cancer-causing substance to which people are exposed, fewer of them will get cancer.



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“... with the possible exceptions of arsenic and benzene, all substances known to cause cancer in people also cause cancer in laboratory animals.”

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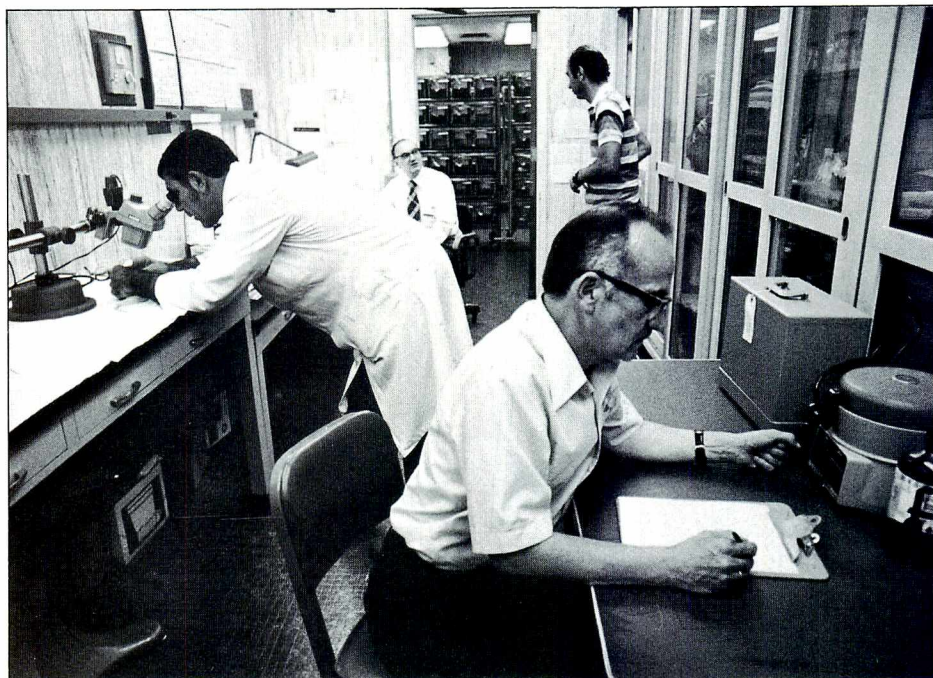
The rub is we can't guarantee that even if we keep lowering the dose no one will get cancer. When you are dealing with cancer-causing substances science has yet to find a dose small enough—what might be called a no-effect dose level—that we are certain that no cancer will be caused.

**Q.** Which means what?

**A.** It means that although it may seem logical that a threshold should exist below which even the most potent cancer-causing substances would be harmless, there is simply no theoretical or experimental basis to support this theory. Life would be much simpler for those of us who seek to determine the relative hazard of chemicals and to devise regulations if there were firm no-effect levels for cancer-causing agents. But there simply are not.

**Q.** Well, if you use a high dose, then, and no cancer shows up, haven't you proved that the substance being tested obviously does not cause cancer?

**A.** That seems logical too, but unfortunately the situation is a bit more complex. A negative finding in one species does not prove that the substance is harmless for all species. Let me give you an example. A chemical being developed as an insecticide, 2-acetylaminofluorene, was tested on guinea pigs and found to be harmless. In contrast, rats given the chemical developed cancer. It was found that the chemical needed to be metabolized (broken down in the body) in a certain way in order to cause cancer. Rats metabolize it in this way; the guinea



pig has another way of metabolizing it. It should also be noted that man metabolizes this chemical in the same way as the rat.

Now, if those testing the chemical had been content to rely on one species, the guinea pig, this really potent substance would have been given a clean bill of health. Thus, when we hear that saccharin doesn't appear to cause cancer in some primates, we cannot take this information and say it proves that the substance will not cause cancer in man.

**Q.** Are animals more susceptible to cancer than humans?

**A.** Given the great variety of species of animals and of types of cancer as well, it would be impossible

to give a simple yes or no answer to that question. There is no doubt, however, that cancer is one of our most serious human health problems. Dr. David Rall, director of the National Institute of Environmental Health Services, says the fact that 385,000 people are dying from cancer a year is telling us something. It is telling us that, for many people, the body's ability to deal with and eliminate or neutralize cancer-causing chemicals is being overwhelmed. There are too many of them. They overload the body's defense mechanisms.

So, all these points, together with others I mentioned earlier, add up to the fact that we must not take it lightly if we find that any chemical causes cancer in test animals.





# Developing Drug Information For Patients

*FDA is committed to expanding the use of package inserts that tell patients about the potential side effects and other important information they should know about prescription drugs. But many questions remain to be answered, such as what drugs should be required to contain package inserts, exactly what information should be included, how should the inserts be distributed, and by whom.*

*by Annabel Hecht*

“**O**ur daughter before age eight received medication from one of the tetracyclines. The result of her taking this drug is that she now has discolored teeth. If we had known the effects of this drug we would have asked the doctor to give her different medication.”

“(My son) has permanent gum hyperplasia (increased growth) from Dilantin. We were not told to institute a vigorous gum brushing regimen until it was too late . . .”

These and hundreds of similar reports of personal experiences were received by the Food and Drug Administration after the Agency asked for comments on a petition requesting that certain prescription drugs carry warnings for consumers.

The petition, filed on behalf of a number of consumer groups by the Center for Law and Social Policy, asked FDA to require that prescription drugs carry labels listing their most serious side effects. In addition to the label listing, the petition asked that more detailed information be included

in a package insert that would be given to patients using these drugs.

Finding out what consumers think is just one of the steps FDA has taken to answer questions about patient package inserts such as who should receive them, what the inserts should say, and how they should be given to the patient. Since late 1974 the Agency has been gathering information through meetings and discussions with medical, pharmacy, and consumer groups. A survey was made of users of oral contraceptives, one of the four prescription drugs for which patient package inserts are now required, and a controlled study is under way to determine whether information about prescribed medication will make a difference in patients' knowledge and attitude about their treatment.

Over 1,000 letters were received in response to the consumer groups' petition. Consumers commenting on the petition were overwhelmingly in favor of giving patients more information about drugs and many of them explained why in detailed accounts of unexpected reactions they, their relatives, or friends had experienced.

In some cases these reactions were transitory, disappearing when the drug was discontinued; in others, the reactions were serious and long lasting. Some drugs produced physical symptoms such as rash, swelling, severe headache, nausea, or vomiting. Others had a mind-bending effect leaving the patient feeling “like a Zombi,” acting “addled,” or having hallucinations.

Several people told of getting severely sunburned after taking tetracycline,

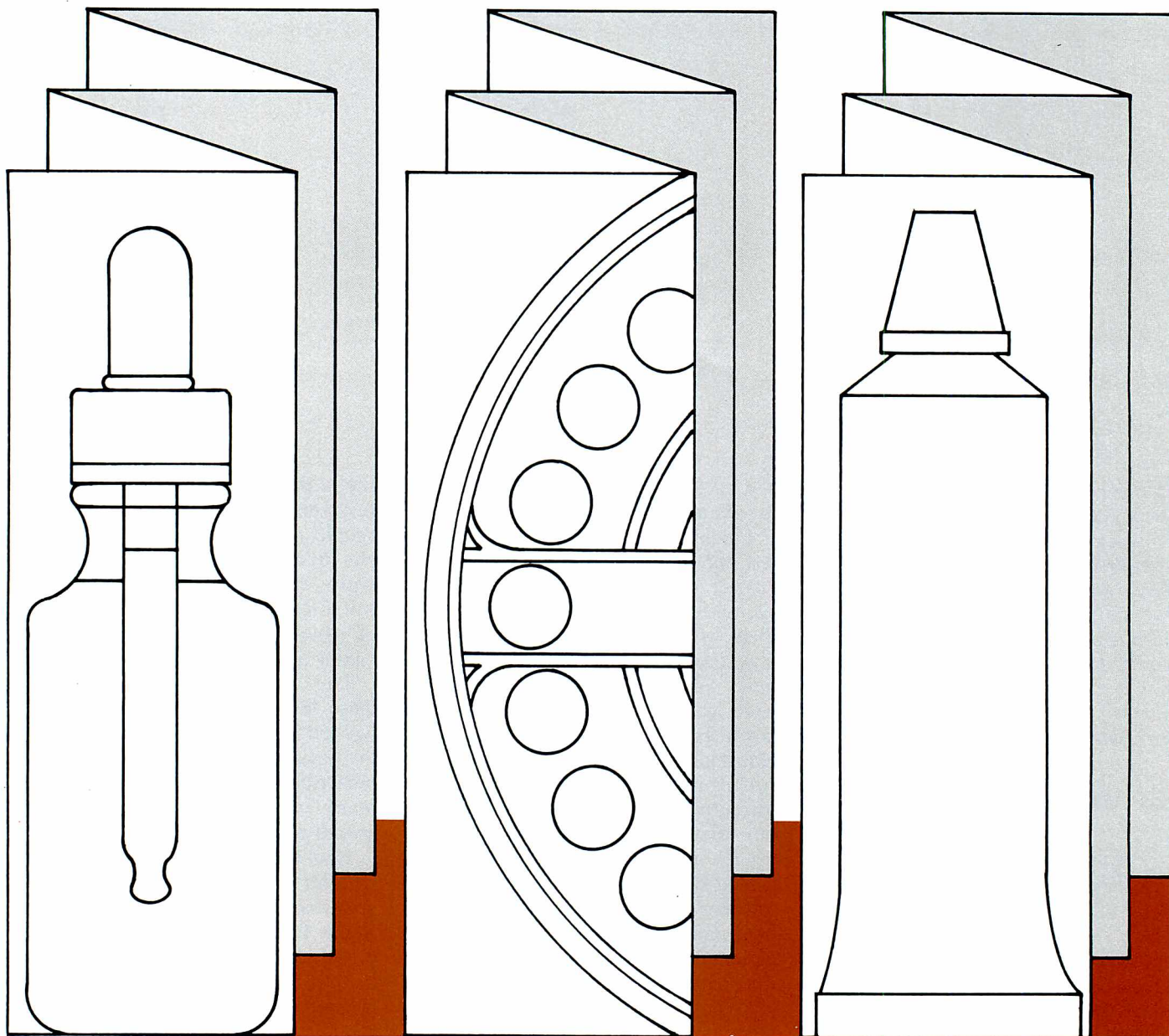
a drug known to make the patient very sensitive to sunlight. A number of people reported they nearly had serious accidents because they didn't know the drugs they were taking would make them drowsy. Others told of severe illness that resulted from mixing alcohol with medicine.

The common thread throughout these letters is the claim that no one warned the patients or their families of the possible side effects from the drugs prescribed for them. Had they known, many wrote, they could have been spared much anguish.

Health professionals, representing a smaller proportion of the total responses, were fairly evenly divided. Some favored the inserts, some opposed them, and some took a “wait-and-see” attitude. Their comments expressed concern that giving the patient too much information could have undesirable effects. Such information would be confusing and bewildering, some said, and would alarm patients, who already are under stress as a result of their illness. Neurotic patients would imagine they had the symptoms they saw listed as side effects in the patient labeling.

Some opponents suggested that patient package inserts could lead to the abandonment of prescribed medication, leaving the field open to quacks. Others claimed that the information would interfere with the doctor-patient relationship, reduce the amount of time doctors spend with their patients, and increase the cost of prescription drugs. One respondent suggested that the quality of care would go down because doctors would simply stop prescribing





drugs in which a patient package insert is included.

Some of the letters touched on questions that will have to be ironed out if patient package inserts do become widely used. Everyone agrees that the inserts should be written in simple, easy-to-understand language. But how much and what kind of information should be included? Should the patient get all the information the physician gets, or just a few specifics on how to take the medication, warnings against drinking and driving when on drugs, and directions for proper storage?

Then there is the question of how such information should be given to the patient. Some say it should be up

to the physician to decide whether the insert is appropriate for a particular patient. Under this system, the physician could help patients who get the inserts understand what to expect by going over the information with them. Others who commented on the petition said pharmacists should give the inserts to patients because they are most knowledgeable about drugs and drug reactions.

In addition to the comments on the consumer groups' petition, the topic of patient package inserts was examined at a symposium jointly sponsored by FDA, the American Medical Association, the Pharmaceutical Manufacturers Association, and the Drug Informa-

tion Association, an independent professional group concerned with drug information.

Although the majority of the principal speakers and panel participants at the symposium were in favor of patient package inserts, most urged a cautious approach. The Pharmaceutical Manufacturers Association (PMA) called the insert a concept "whose time has come." But PMA spokesman John G. Adams said that since there is little evidence of the effectiveness of inserts careful and controlled pilot studies should be conducted before they are used extensively.

The American Medical Association (AMA) favors inclusion of patient in-



formation with selected drugs if it will help the patient understand the importance of taking the drug as prescribed. The insert also should warn patients not to use other drugs at the same time that may produce adverse reactions and lessen the effectiveness of the prescribed drug, William Barclay, M.D., of AMA said. He said inserts should be used with a limited number of drugs that can be monitored to determine the impact of the information.

The American Pharmaceutical Association (APhA) favors patient education, just as other groups do, said Pierre S. Del Prato. The problem, according to Del Prato, is that each group wants the inserts developed in its own way and no one has answered the crucial question of what they really want the inserts to do. "If there is one basic recommendation that APhA can make to the FDA, consumer groups, and other health professions," he said, "it is that we should 'get our act together' lest we design a program which confuses everyone, costs too much and, tragically, serves no one."

The need for continued research and evaluation and "deliberate progress" in the development of patient package inserts was echoed by speakers who addressed panel discussions on specific aspects of the issue.

Representatives of two hospital organizations agreed that education is an important part of patient care and that patients must have information to take medication safely. The problem, said Elizabeth Lee of the American Hospital Association, is determining what should be taught and who should teach it.

Mary Jo Reilly of the American Society of Hospital Pharmacists said her organization favors package inserts when used as a part of a comprehensive patient education system but they should not be given to hospitalized patients. The treatment of hospital inpatients is carefully monitored by the pharmacist, nurses, and physicians, so there is no need for patient labeling in institutions, she said. This viewpoint was shared by Lawrence Fleckenstein, a pharmacist and director of the Drug Information Service at Alta Bates Hospital, Berkeley, California. Reilly and Fleckenstein noted that responsibility for providing patient information lies with the pharmacist. Marien Evans, a Boston attorney, pointed out that

many State statutes require pharmacists to provide information about the drugs they dispense.

On the other hand, Mary Ann Swain of the University of Michigan School of Nursing suggested that nurses should have a comprehensive role in counseling patients and therefore should distribute drug information to them.

The patients' right to know about the drugs they take was stressed by Joseph Onek, representing the Center for Law and Social Policy, and primary author of the petition calling for patient package inserts. Onek said the inserts will help patients achieve their right to be part of the decisionmaking process. The right to have this information is basic even though some patients will not read it, Onek contended. Patient package inserts are not "end all and be all," he pointed out, but the beginning of a dialogue between the doctor and the patient.

Communication between the practitioner and the patient is essential, several speakers said, to be sure that the patient understands the information in the package insert. Other symposium participants said physicians and pharmacists should have the option of not giving a patient such information if they feel it might be harmful.

Limitations on the kind and the amount of information to be given patients were suggested by Don Harper Mills, M.D., of the University of Southern California School of Medicine. Mills said the inserts should tell patients specific circumstances in which particular drugs should be avoided, drug combinations that should be avoided, and the kinds of activities that should be avoided when certain drugs are used. Although he supported the idea of patient package inserts, Mills cautioned that "nothing should appear thereon which would require the patient to exercise medical judgment."

Other speakers urged that patient package inserts include information on major adverse reactions, their symptoms, and what to do if they occur; foods and drugs to avoid; directions for preparation and administration of the drug; what to do when a dose is missed; what to do in event of an overdose; and instructions on storage and refills.

Although the ultimate goal of the

Center for Law and Public Policy is labeling for all drugs, Onek gave first priority to drugs with the most serious side effects and those used by patients who are least likely to be under continuous medical care. Other priorities suggested by symposium speakers were: drugs used by the chronically ill; those most frequently prescribed; those most likely to be abused; those for which the outcome of therapy depends on proper administration; and those that pose hazards for particular populations, such as pregnant women.

Alexander Schmidt, M.D., then Commissioner of Food and Drugs, in his keynote address, underscored the educational aspects as well as the right of consumers to know about the medicines they take. The patient package insert should not be "a compendium of complex negative information," he said, but should emphasize the positive. Inserts can strengthen communication only if they explain why it's important to take a drug, why it should be taken as directed, why it shouldn't be discontinued without the physician's advice, what to avoid and what side effects should be reported. By requiring such information, FDA can contribute to better medical practice, Schmidt said.

FDA now requires patient package inserts with four types of prescription drugs: isoproterenol inhalation preparations, oral contraceptives, the postcoital contraceptive diethylstilbestrol, and the estrogen drugs. Package inserts will be required for intrauterine contraceptive devices (IUD's) effective November 7, 1977. The Agency has announced plans for patient labeling for the progestin drugs and metronidazole (Flagyl).

The Agency is committed to expanding the package insert program but, as the diverse opinions expressed at the symposium indicate, many questions remain to be answered. To help answer these questions, and to respond to the consumer petition calling for inserts, FDA plans to propose a system for developing package inserts. The proposal will be published in the *FEDERAL REGISTER* later this year and interested persons and organizations will have an opportunity to comment on it.

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

# Detentions Compound Coffee Problem



*Price isn't the only problem with coffee these days. The amount of coffee beans detained at U.S. ports by FDA inspectors because the product is contaminated also has risen substantially in recent years. One factor in the increase in detentions apparently is an effort by some producers to cash in on high prices by trying to sell almost anything that answers to the name of coffee.*

*by Harold Hopkins*

When I was an undergraduate at Tulane University in New Orleans right after the second World War, I

had a love affair with the sights, sounds, tastes, and smells of that exotic port city. At night I would awaken to the sound of distant boat whistles carving holes in the fog that lay thick on the Mississippi, in the subtropical morning the neighborhood quiet would be pierced by a babble of strange accents with fruits and vegetables, hot tamales, even brooms for sale, and in the evening I could walk several blocks or ride a streetcar called you know what and hear jazz as played before its rediscovery. There were sights to match, and the ways of the city's gastronomic artists with the catch from the bayous and the gulf and the harvest

from the ricefields have been twice and thrice told.

But what really ensnared me, as it hung in the humid air over the entire commercial district of this gateway to Latin America, was the tantalizing aroma from the bean of *Coffea arabica* arising from several downtown roasting houses. Once I got the scent in my nostrils it was impossible to concentrate on anything else, and invariably I surrendered and stepped into a restaurant, oyster bar, or coffee stand and drank a cup of chicory blend, French dark roast, cafe au lait, or the standard light roast coffee.

Whatever the kind, one thing was



certain: there was lots more where that came from. A walk along the city's wharves took you past what seemed to be miles of stacked bags of green coffee stamped with the names of practically every tropical country you had ever heard of.

Coffee is this country's largest food import, its second largest import of any kind. The rising sun and the morning java signal the day's beginning for the majority of adult Americans. Many Americans look upon coffee as nothing short of a magic potion that gets them organized in the forepart of the day and wipes their eyes and mind clear at other critical times when they're fighting sleep or trying to concentrate.

The United States is the best customer of the coffee-producing countries of Latin America. Over the years this commercial relationship has had its ups and downs. For our part we have always hoped for an adequate supply at low cost and, beginning with enactment of the first Federal Food and Drug Act of 1906, have sought to protect the American consumer from getting coffee that is moldy, contami-

nated, water stained or damaged, contains harmful residues of pesticides or other chemicals, or contains filler that looks like coffee but isn't. The coffee-producing countries, on the other hand, have been concerned with getting a better price for their product, with keeping their good neighbor to the north as their best customer, and with meeting U.S. standards for imported food.

A minor crisis overtook the relationship in July 1975 when the coffee growing regions of southern Brazil were struck by two nights of devastating frost. The resulting chill has crept into every part of the United States and into just about every pocketbook for, although we import coffee from many countries, Brazil is the world's largest coffee producer and the leading exporter to this country.

The frost destroyed 60 to 75 percent of Brazil's anticipated 1976-77 crop of reportedly 28 million bags. Millions of trees were killed or extensively damaged and the planting of new seedlings was required for continued production. Seedlings do not begin to produce

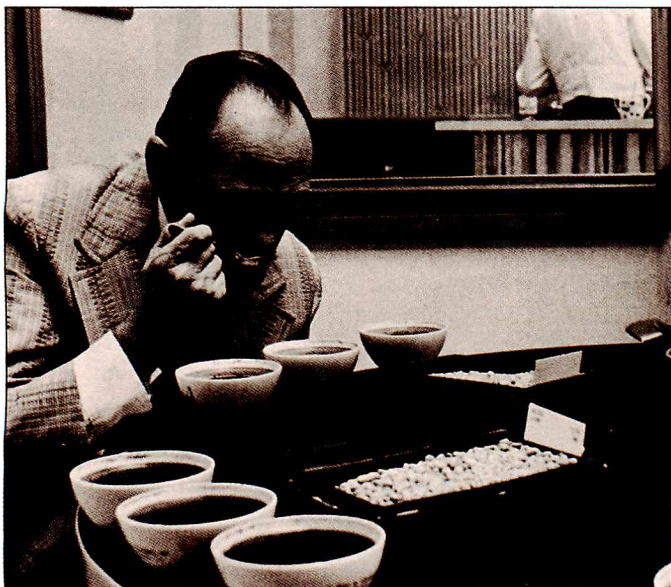
beans until they're three years old; thus the effects of the frost will last for a few years. The coffee produced in Brazil and other Latin American countries, derived from the species *Coffea arabica*, is the one preferred by most Americans and brings a better price than that from *C. robusta* and *C. liberica*, the two species grown mostly in Africa. Practically all our coffee is imported in bulk in unroasted or green form. The green beans then are roasted, blended, and ground to suit various tastes.

The Brazilian frost was only the worst of a series of developments affecting the supply and price of coffee, some dating back to the mid-1960's when surpluses reached a postwar high because of growers' response to demands that followed World War II. The excess of coffee stocks depressed prices and Brazil, which had been expanding production, decided to downgrade coffee in its total agricultural program. Since then stored coffee stocks in Brazil and many other countries have declined sharply so the frost and other events have substantially de-

*A shipment of coffee, transferred to barges from an ocean-going ship anchored upstream in the Mississippi, is discharged at the Port of New Orleans, which handles about 20 percent of U.S. coffee imports tonnage.*





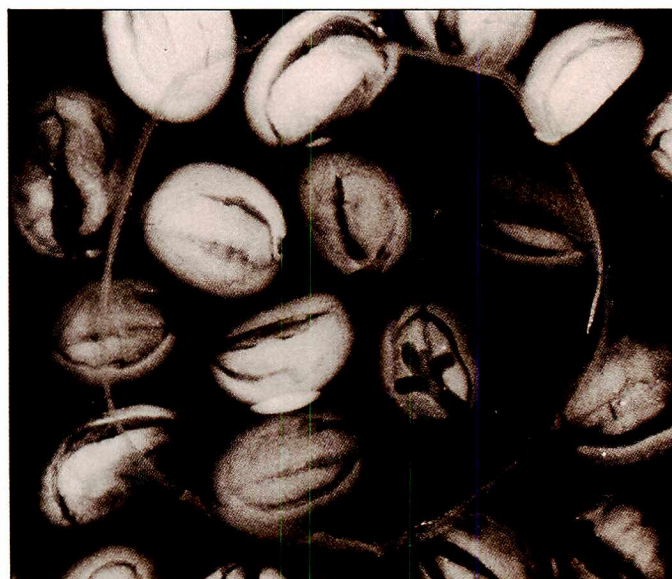
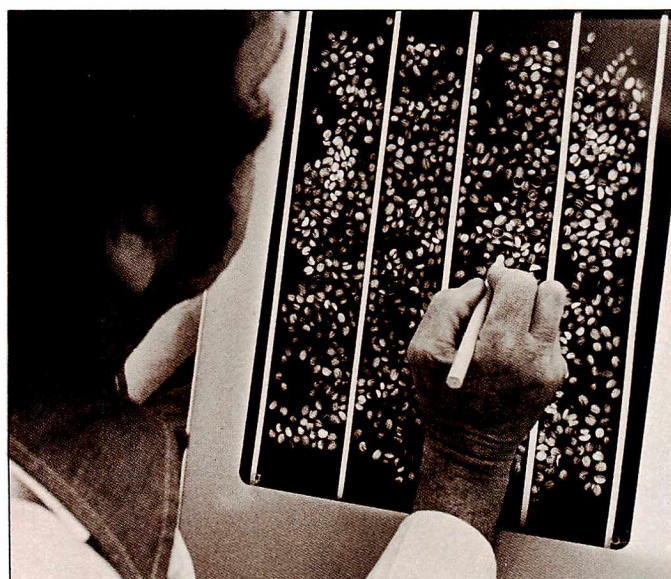


*At buying houses such as this one in New Orleans, experts examine samples of various types of coffee offered from countries all over the world. The examination includes grading and tasting (above) after the various samples are roasted (above right), ground, and brewed. The coffee tradesmen use the same grading system for buying that FDA uses to determine if import entry should be denied because of adulteration.*

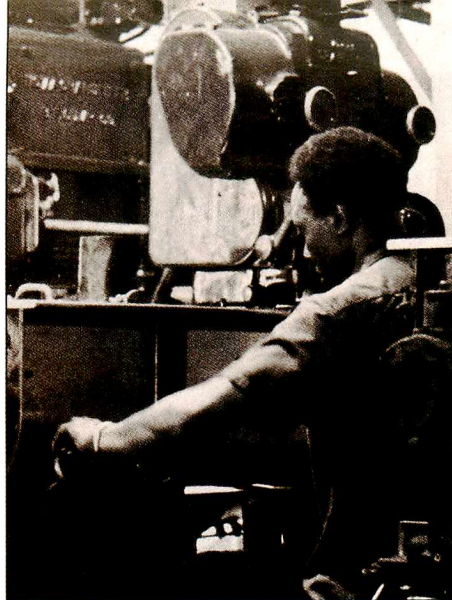
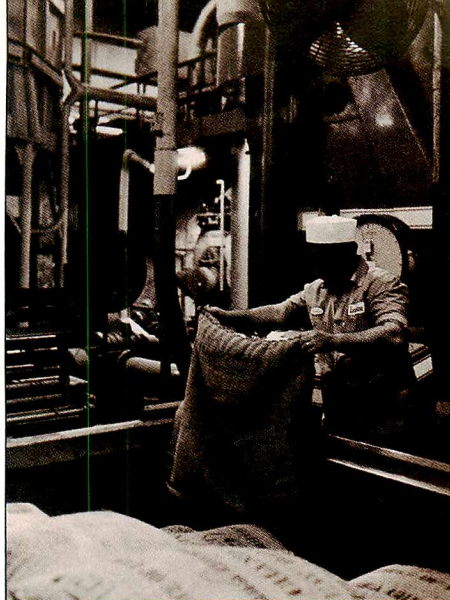


*FDA Analytical Entomologist Bud Freeman (below) reviews x rays taken of coffee beans to detect insect tunneling, using a marker to circle damaged beans on the photo plate for tallying. In closeup of x-ray photos an insect-bored bean is shown in the marked circle, the tunneling here suggesting a cross.*

*At FDA's New Orleans District laboratory, decomposed coffee beans are shown at left and good beans at right.*







*In a coffee roasting plant, an employee slices open bags of green coffee and dumps them into a vat. They then go to the roaster, where an employee tends the machine to control time and temperature.*

pleted remaining stocks and created a tight market. Some other recent contributing factors have been civil war or economic unrest in Angola, Ethiopia, and Zaire, all African producers, and poor weather or growing conditions in some Central or South American countries.

The result has been a sharp and steady rise in coffee prices since the fall of 1975. From most accounts things are going to get worse. At this writing, U.S. coffee importers report green coffee is bringing \$3 a pound at the pier, and they fear it's headed for \$4. At this price the jolly green bean would be worth, pound for pound, more than Cadillac. No relief is likely before late 1978, according to the experts, some of whom believe coffee by that time may be even higher.

As the price spirals the mutters on these shores become more irritable and irrational. Some say that the shortage comes as much from deliberate withholding of coffee by Brazil and other exporting countries as it does from bad weather and other uncontrollable factors.

The question of whether there's still an awful lot of coffee in Brazil is important to a large part of our adult population. Because Americans are such devoted coffee drinkers a great many of us are going to resist being weaned to some other drink by anything short of a price spiral that goes completely out of sight.

We've been so busy staring in disbelief at the supermarket cash register we've failed to notice or forgotten that scarcity and high prices aren't the only problems that can plague coffee drinkers. But FDA has had a nervous eye for some time on a situation that concerns the quality of America's favorite

beverage. The Agency's import inspectors have been stopping an ever increasing number of shipments of green coffee at dockside because the product is, for various reasons, unfit to drink.

With green coffee at around \$400 a bag, now is obviously the worst of all possible times for secondary complications. What's been happening to coffee imports? Why?

FDA charts show that the total poundage of green coffee detained by import inspectors increased from about 20 million in 1972 to 83.5 million pounds in 1975, then declined somewhat to about 71 million in 1976. Detentions thus have risen from less than 1 percent of total coffee imports in 1972 to over 3 percent in 1975 and slightly less in 1976.

The high detention rates are new but the reasons for detention are the same perennial troublemakers we've had since coffee has been unloaded at these shores. Live and dead insects among the beans accounted for 52 percent of the detentions in 1976. Damage to the bean itself from insect chewing, boring, and tunneling accounted for 3 percent. Bird excreta and rodent excreta and urine were responsible for 12 percent of 1976 detentions; mold for 26 percent; oil and water stains for 5 percent; and contamination by various foreign substances such as dirt, trash, pier sweepings, and various chemicals from other cargoes for 2 percent.

These have been the traditional causes of green coffee contamination year after year. Have they suddenly begun to increase? And have the current high prices of coffee tempted coffee producers and shippers to discard their quality standards or to abdicate their responsibilities for the sake of a quick profit?

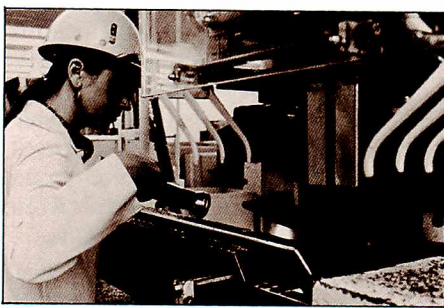
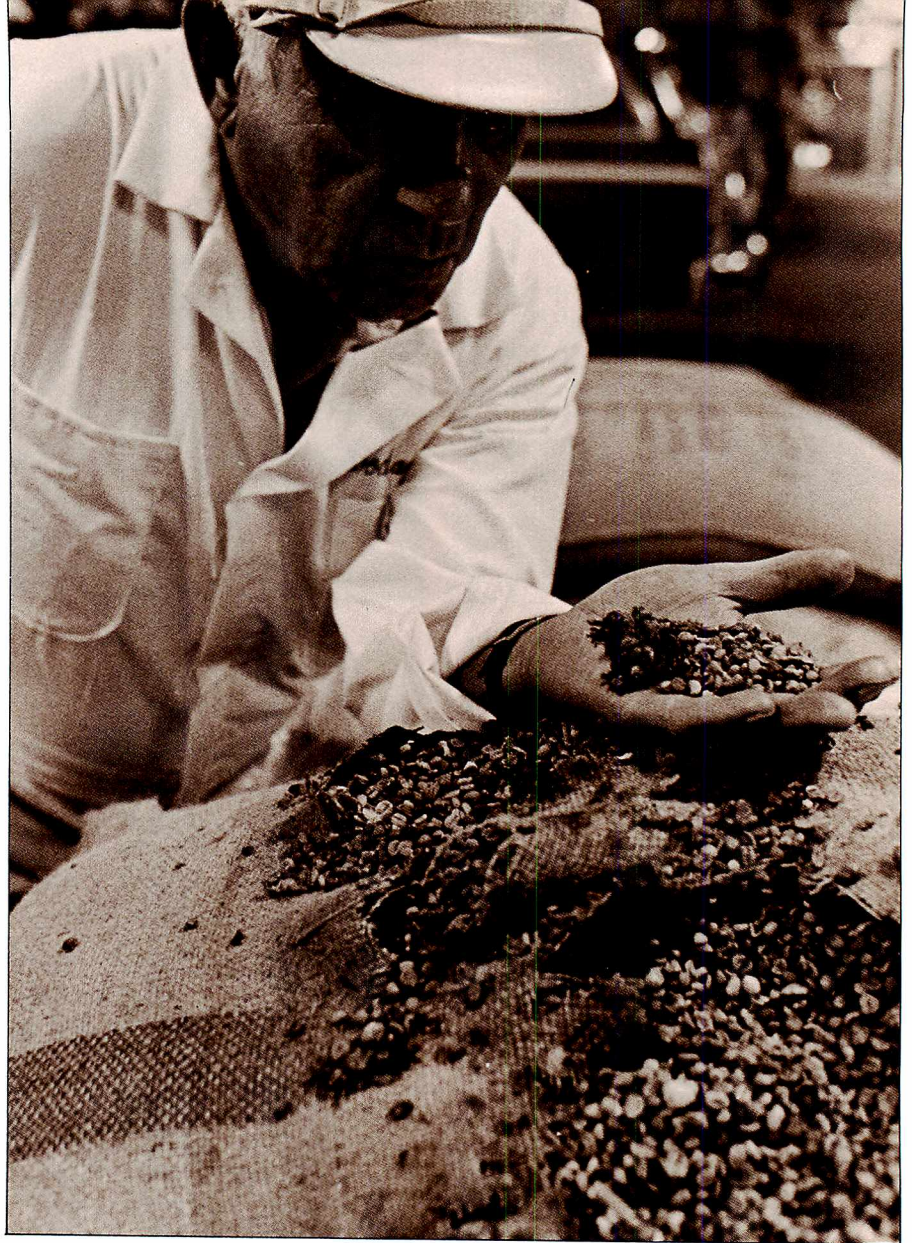
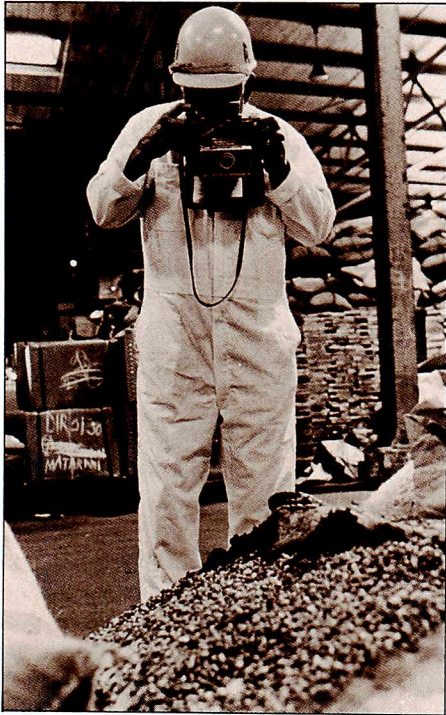
The answer to both questions is, to an extent, yes. It should be stated that FDA has been inspecting foods and food processors much more thoroughly in the past two years than earlier because the public and Congress have been expressing increased concern about food contamination. The large rise in coffee detentions has coincided with a correspondingly large increase in FDA's force of inspectors. This added staff has enabled the Agency to pay more attention to filth and contamination problems involving coffee as well as other foods, domestic or imported. This would have happened whether coffee prices increased or not. Even with this closer scrutiny, however, FDA still detains only a small percentage of the total supply of coffee and detentions have not had a significant effect on prices.

But many of the contaminations that brought increased detention may have occurred because of rises in coffee prices. A producer or exporter or shipper, anxious to make a quick profit, may be tempted to take shortcuts, use inexperienced help for critical work, and fail to take adequate measures to assure that the product is kept free of contamination. Coffee now being removed from long storage may present greater insect and mold problems than new crops, so the drain on stocks can thus affect quality.

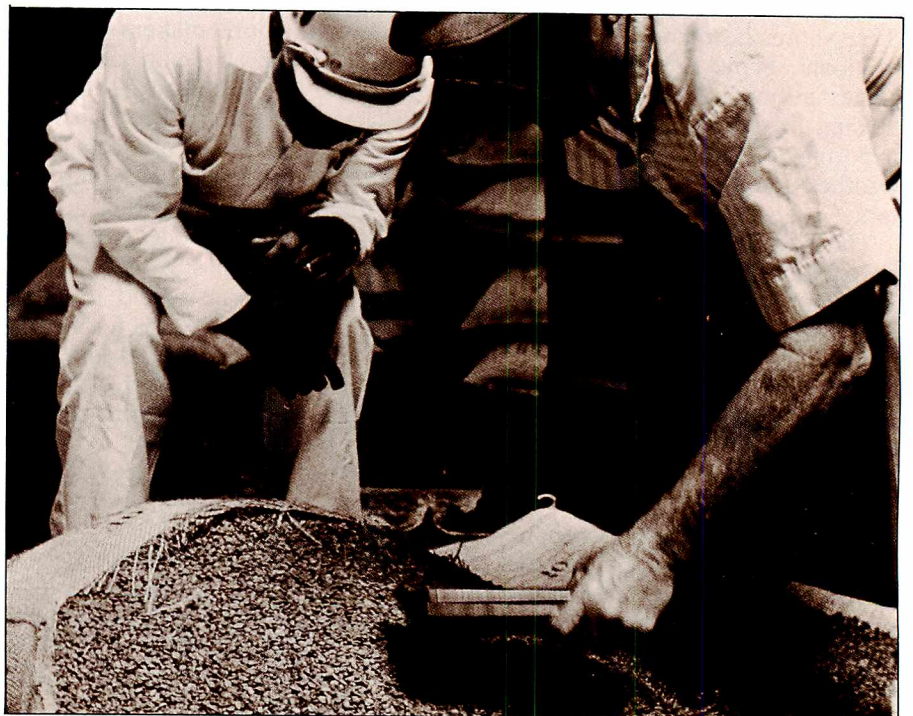
High prices may tempt unscrupulous persons to sweep up spilled coffee along with dirt and trash and try to market it or "blend" it into cleaner lots. FDA investigators have encountered some import shipments of coffee that sometime in the past were deliberately contaminated with chemicals when prices were low as a method of reducing supplies through rendering



*During an inspection of a coffee imports warehouse, FDA Inspector Leo Lacoste photographs contaminated coffee to support a detention decision, examines a lot of ruptured bags (right) containing rotting or moldy coffee, and watches closely (bottom right) as a warehouse employee reconditions a partially contaminated bag of coffee by skimming off the spoiled beans so the remaining good ones can be sold.*



*FDA Investigator Hilda E. Orraca monitors the reconditioning of contaminated coffee. Reconditioned beans must meet all FDA standards before they are permitted to be marketed.*







*These bits of metal were removed from detained bags of green coffee during reconditioning. The metal is removed by emptying the beans into a sieve topped hopper that contains a magnetic device.*

them unfit for use as food. Such coffee may not be salvaged and normally is diverted to use as fuel or some other nonfood product. The shipments that FDA detained apparently were smuggled out of a large producing country and reshipped to the United States from a smaller country and offered as good coffee by unethical interests.

The high prices also have drawn inexperienced persons into coffee production in countries where little coffee has been grown before and where unfavorable climates or other conditions, such as lack of seaports (requiring long overland transportation) make the production and transport of a good product almost impossible. Demands for increased production have simply been more than many producers with limited resources can handle.

The highest detention rates have involved coffee produced in African and Asian countries. Of coffee imports offered from African countries, 1.2 percent was detained in 1974, 5.7 percent in 1975, and 5.4 percent in 1976. Of imports offered from India, Indonesia, and New Guinea as a group, 6.4 percent was detained in 1974, 9.5 percent in 1975, and 12.2 percent in 1976.

When green coffee is detained it can become expensive to the exporter. He must pay for re-exporting unacceptable coffee or for reconditioning insect-infested coffee to salvage his investment. U.S. coffee importers estimate that the cost of removing insects from infested green coffee is about \$6 per 132-pound bag. This and expensive inconveniences to the importer add a total of about \$9 to the cost of a bag of coffee that has been reconditioned.

FDA, to help foreign food producers and processors and their governments understand the standards imported

foods must meet, conducts a number of programs, some general and some concerning specific products. One kind of Agency program that has proved useful and effective in helping overseas industries bring their exported products up to our standards is the seminar/workshop for specific food products. These meetings are scheduled usually at the request of exporters whose products have had high detentions at U.S. ports.

FDA experts on the Agency's requirements and how to meet them make presentations covering major problem areas and may, at the request of foreign companies and their governments, inspect overseas operations to point out specific deficiencies.

In response to the coffee detention problem FDA conducted a 10-day International Green Coffee Seminar/Workshop in Dallas and Houston last January. Representatives from 18 coffee-producing countries heard an FDA team of 11 experts discuss various aspects of the subject. Other presentations were made by five executives representing the U.S. coffee importing industry.

John Zaic of FDA's Office of International Affairs led the FDA group. Most of the overseas representatives, Zaic said, had been "totally unaware of the FDA requirements for imported green coffee, and were equally in the dark as to our procedures for sampling and analysis and our specific guidelines for compliance." One big FDA objective was to give the foreign representatives information they could take home and pass on to their countrymen engaged in producing coffee. The coffee seminar/workshop included visits to FDA's Dallas District laboratories and field trips to coffee roasting plants and

to docks and warehouses at the Port of Houston.

FDA also has recently cooperated with the National Coffee Association of the U.S.A., Inc., in the publication of a booklet to be distributed to coffee exporters setting forth the principles and specifics for "Health and Safety in the Importation of Green Coffee Into the United States."

The first Federal assessment of problems concerning marketed coffee and protection of the U.S. consumer was issued in 1891 from the U.S. Department of Agriculture by Dr. Harvey W. Wiley, chief chemist, who was to become the "father" of the first Federal Food and Drug Act of 1906. At the time there was no Federal law to protect the consumer. Dr. Wiley was worried about the deceptive adulteration of coffee with worthless or harmful substitutes before and after importation. "The practice of adulterating coffees is widespread, and the consumer has little protection," he concluded. He pointedly emphasized how much better off was the tea drinker because of economic protection afforded by the Tea Importation Act passed some years earlier.

Today, Federal law protects the consumer not only from economic deception but also from any food product unfit for consumption for any reason. Although FDA has no control over weather and economic or other factors that bring fluctuations in the supply of coffee and its price, it does have some say-so in making sure that when the consumer spends his money for the golden bean, the drink he gets will live up to his expectations.

*Harold Hopkins is editorial director of FDA CONSUMER.*



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# News Highlights

## Plan Set to Distribute Epilepsy Drug

FDA and Abbott Laboratories have agreed on a plan to broaden distribution of sodium valproate, a drug used to control seizures in epileptics.

Special arrangements are required for the drug's distribution because it has not yet been approved for general use in the United States. Abbott is in the process of completing the studies and submitting the information required by law before FDA can approve the drug for sale in the United States.

Abbott's supply of sodium valproate is very limited, and under the plan worked out with FDA the company is making the drug available to physicians who have one or two patients who need it. Physicians seeking the drug must apply to Abbott and agree to follow a plan for studying its use.

Physicians considered qualified to use the experimental drug would include neurologists, pediatricians with special neurology training, neurosurgeons, and internists with neurological training.

FDA has told Abbott that sodium valproate is likely to be a therapeutic advance for the treatment of epilepsy and that the Agency will give approval of this drug priority consideration. But FDA can do no more to speed any drug's approval than to work with the drug sponsor to cut approval requirements to a minimum. FDA cannot force any private company to provide any given drug to the American market; neither can it dictate the research or marketing priorities of such companies.

Although sodium valproate has been available overseas since the late 1960's, no company in the United States showed any interest in marketing it until Abbott started research in 1975. FDA has made clear it will accept foreign data on the safety and effectiveness of this drug. There are, in fact, no known areas of disagreement or misunderstanding between Abbott and FDA about the data required or about FDA's interest in expediting an approval decision.

In a letter to Commissioner of Food and Drugs Donald Kennedy, the Epilepsy Foundation of America thanked FDA for the "positive steps" it has taken to accelerate its evaluation of sodium valproate.

The letter said:

"The Foundation and the two million persons with epilepsy whom we represent, greatly appreciate your sensitivity to the need for FDA's evaluation of sodium valproate in the shortest feasible time frame. We, in turn, are deeply cognizant of the necessity for reliable verification of this drug's safety and efficacy before it can be made generally available in the U.S."

## Partial Ingredient Labeling Suggested

The Office of Management and Budget (OMB) has notified FDA that the Bureau of Alcohol, Tobacco and Firearms (BATF) in the Department of the Treasury has adequate authority under the laws it administers to require ingredient labeling of alcoholic beverages and is the appro-

priate agency to do so if such labeling is required.

The OMB finding that BATF is the appropriate agency to handle alcoholic beverage labeling came in response to an FDA request that the Justice Department appeal a U.S. District Court decision which held that FDA lacks authority to require the listing of ingredients on alcoholic beverages. The Justice Department is responsible for court litigation in FDA's enforcement of the law.

OMB said that neither FDA nor BATF had adequately explored alternatives to complete ingredient labeling of alcoholic beverages in terms of both cost and benefit to consumers. It requested that BATF and FDA jointly develop a proposed partial labeling requirement with special focus "on assuring that consumers are made aware of hidden and potentially harmful ingredients (such as preservatives, colors, and clarifiers) and on reducing the economic burden on manufacturers (and ultimately consumers) of providing such data."

No deadline was set but OMB asked the agencies to "move quickly."

FDA announced in November 1975 that manufacturers of alcoholic beverages would have to meet statutory requirements of the Food, Drug, and Cosmetic Act for ingredient labeling of their products. FDA's labeling requirements would have taken effect January 1, 1978. Previously, FDA had not established labeling requirements for alcoholic beverages because of an agreement under which FDA deferred to BATF responsibility for enforcing labeling requirements for such beverages.

Nine distilleries and three trade associations filed suit in March 1976 claiming that BATF had exclusive jurisdiction over labeling of alcoholic beverages. Judge James F. Gordon of the U.S. District Court for Western Kentucky upheld their contention, and FDA then asked the Justice Department to appeal Judge Gordon's decision.

## Task Force to Study Lead Glazes on Glasses

The Environmental Protection Agency, the Food and Drug Administration, and the Consumer Product Safety Commission have formed an interagency task force to investigate more fully the safety of glasses decorated with lead-containing glazes.

The concern about these glazes results from recent evidence discovered by Dr. Thomas Spittler, an EPA scientist, that lead from these glazes can leach out, particularly on glasses that have been through repeated dishwashing cycles. Dr. Spittler's preliminary tests were conducted at the request of the State of Massachusetts. They confirmed that lead was present in the decorative glazes on the outside of the glasses. Additional tests on glasses that were subject to repeated washings show that this increased the amount of lead leached from the decorative designs.

Although tests conducted to date by FDA have shown no evidence that the lead from the decorative glazes can contaminate food or liquid inside the glasses, FDA and EPA urge care in the use of these glasses by small children until the task force can investigate other avenues of human

exposure, especially exposure to the outside of the glasses by young children.

The three agencies will determine how much of the lead from these glazes can leach out and be ingested by humans, and what the toxicological effects of this ingestion would be, particularly in children. A determination will be made as to what are the most effective corrective or regulatory actions that should be taken by any or all of the agencies.

### **Automated X-ray Data Systems Developed**

Three automated systems developed under contract to FDA and designed to improve the use of information from radiological examinations and to cut down on unnecessary x rays are being adopted by medical centers throughout the country.

The new systems are a diagnostic x-ray reporting system, an x-ray scheduling and film tracking system, and a nuclear medicine reporting system.

The automated x-ray reporting system, developed jointly by the Johns Hopkins Hospital and FDA's Bureau of Radiological Health, allows the radiologist (the doctor who reads or interprets the x ray) to produce a printed copy of his diagnostic report at the time he reads the x ray. This eliminates delays in sending the radiologist's report to the physician who ordered the x ray and reduces duplicate examinations that occur when a physician reorders an x ray because he has not received the radiologist's report.

The x-ray scheduling and film tracking system, designed by the Massachusetts General Hospital, uses a computer to maintain a schedule of all patients' x-ray examinations. This information is used to detect possible duplicate or similar examinations which would expose the patient to unnecessary radiation. The film tracking part of the system makes use of a computer to store information about the location and content of each patient's x-ray folder.

The nuclear medicine reporting system, developed at the Cincinnati General Hospital, involves creation of a fixed set of 200 statements (called a lexicon) which describe the results of nuclear medicine tests and their interpretation. The system provides a simple and accurate format for reporting the results of such tests to the physician, for writing clinical reports, and for storing this information. The lexicon can be used with or without a computer.

Nuclear medicine tests usually involve injecting a radioactive drug into a patient and tracing it through the body to obtain diagnostic information.

### **Diabetics Advised on Phenformin Action**

Commissioner of Food and Drugs Donald Kennedy has advised diabetics who are taking the drug phenformin, and who are concerned about recent reports that it will shortly be phased out of general use, to consult their doctors so they can be switched to other therapy.

Dr. Kennedy said phenformin will remain available for general use until October 23 so that there can be an orderly transition by patients to other therapy.

Dr. Kennedy warned that diabetics should not discontinue taking phenformin without consulting their physicians.

Withdrawal of phenformin from general use was announced July 25 by Secretary Joseph A. Califano, of the

Department of Health, Education, and Welfare (HEW). His action was based on a recent study conducted by FDA which showed that lactic acidosis, an uncommon but serious side effect, occurs at an estimated rate of .25 to 4 per 1,000 phenformin users each year, and that about half who develop lactic acidosis die.

FDA has mailed to all physicians and other health professionals in the United States a DRUG BULLETIN providing the details of the phaseout.

The DRUG BULLETIN states: "A 90-day transition period is provided so that all patients now on phenformin can be evaluated by their physicians. By the end of this time, however, phenformin should be removed from the treatment program of essentially all patients now taking the drug."

It adds: "FDA and HEW recognize that a decision of this type causes public concern and imposes a special burden on diabetic patients and their physicians. We are attempting to minimize alarm and confusion by sending this special issue of the DRUG BULLETIN to all health professionals."

The BULLETIN points out that phenformin may continue to be prescribed and dispensed during the phaseout period.

It further says that there are a small number of patients in whom phenformin may continue to be used, even after the phaseout ends. These are patients who meet specific conditions set forth in the BULLETIN.

FDA has been meeting with the two manufacturers of phenformin, Ciba-Geigy, which sells the drug under the trade names DBI and DBI-TD, and USV Pharmaceuticals, which sells it under the name Meltrol, and with medical and pharmacy professional societies to develop a tightly restricted distribution system for those few patients who may still need phenformin.

Details of the distribution system will be announced when they are made final.

### **Seized Laetrile Valued at \$300,000**

Continuous efforts by the Food and Drug Administration against the controversial drug Laetrile have resulted in a number of recent enforcement actions. The total amount of Laetrile seized since May has a value of almost \$300,000.

In late July, the largest clandestine manufacturer and distributor of Laetrile in the United States was closed by a preliminary injunction handed down by a Federal court in response to a complaint by FDA.

U.S. District Court Judge John W. Reynolds ruled July 29 in Milwaukee, Wisconsin, that U.S. Pharmaceuticals, Inc., of Mosinee, Wisconsin, and the firm's officers may no longer manufacture and distribute Laetrile and must forfeit all products and materials used in its manufacture to FDA. The firm's officers were also barred from any future association with production of the illicit drug.

Action against U.S. Pharmaceuticals began May 16 when U.S. marshals and FDA investigators served a search and seizure warrant at the firm's Manitowoc, Wisconsin plant, an old dairy products plant partially converted for processing Laetrile from apricot pits. At that time, Federal officers seized extracted amygdalin crystals and empty capsules with a value of about \$100,000. (Amygdalin is a substance similar to Laetrile.)

On July 29, in a followup action based on the court-



ordered forfeiture, marshals and FDA investigators seized additional materials at the Product Distributors Company in Hales Corners, Wisconsin, a business operated by an officer of U.S. Pharmaceuticals, Inc. There, Government officials found 10,000 amygdalin tablets worth more than \$10,000 and several hundred pieces of literature promoting Laetrile as a cancer cure.

In issuing the preliminary injunction, Judge Reynolds found that Laetrile is a "fraud on the consuming public," and that testimonials about cancer cures by laymen and by physicians with no training as cancer specialists are useless as proof of safety and effectiveness of a cancer drug. In addition, Judge Reynolds found that:

- Laetrile is unsafe.
- Laetrile is ineffective.
- Laetrile is not, according to medical experts, a substance that is generally recognized as safe.
- Laetrile is unfit for consumption as a food due to its cyanide content.
- Laetrile is not manufactured at the Mosinee plant in conformance with FDA's Current Good Manufacturing Practice Regulations.
- There are no assurances that Laetrile is manufactured at the Mosinee plant under sanitary conditions.
- Laetrile is not a vitamin and there is no vitamin B-17, a name ascribed to Laetrile by its proponents.
- Laetrile is a drug and not a dietary supplement.

On August 5, 1977, U.S. marshals and FDA investigators seized from Henderson's Pharmacy in Baltimore, Maryland, and from proprietor Robert Henderson's residence 3,000 injectable ampules and 15,000 tablets of Laetrile valued at approximately \$45,000. The Laetrile was allowed to be imported from Mexico under a preliminary injunction issued by the U.S. District Court for the Western District of Oklahoma which permits terminally ill cancer patients to obtain a limited quantity of the drug for their personal use. The court decision requires an affidavit certifying that the patient is terminally ill and specifying the amount of Laetrile that can be ordered by the patient. The Laetrile in Henderson's possession was imported by Henderson as agent for 33 persons for whom he had affidavits.

FDA investigations have revealed that many of the affidavits in Henderson's possession are fraudulent in several respects. Among other things, the patients named in the affidavits did not order Laetrile or the order was substantially less than the amount specified in the affidavit. Investigations further reveal that Henderson is using the cover of legal importation to accumulate a personal supply of Laetrile. He then sells this fraudulently imported Laetrile to persons not entitled to import or receive the drug.

FDA sought and obtained release to the patients who actually ordered Laetrile under court-authorized affidavits the small amounts of the drug they ordered. FDA regards the great bulk of what was seized as contraband and asked a court to order its condemnation and destruction.

FDA will not interfere with the receipt of Laetrile shipments by terminally ill patients with legitimate affidavits. But when FDA discovers that shipments are being carried out without affidavits, under false affidavits, or in excess of the amount requested by legitimate consignees, it will take appropriate enforcement action.

On July 25, U.S. marshals and FDA investigators seized

Laetrile and other products from a dealer in Fort Worth, Texas. Executing Federal search and seizure warrants, they seized 5,000 Laetrile tablets made at the Mosinee, Wisconsin firm.

Additional Laetrile seizures were made on July 14 at West Palm Beach, Florida, and near Cincinnati, Ohio.

In West Palm Beach, search and seizure warrants were executed at three locations operated by Metabolics, Inc. The materials seized had an estimated value of over \$100,000.

In Ohio, search and seizure warrants were executed at the A.O. Medical Supply Company of Hebron, Ohio, and a house trailer office in Buckeye Lake, Ohio. Approximately \$25,000 worth of amygdalin and other unproven cancer remedies were seized.

## **Selection Factors Reduce Skull X Rays**

Use of a list of patient selection criteria can reduce the need for skull x rays in injury cases by 40 percent with no adverse effects on patient care, according to a study sponsored by FDA.

The study, carried out by the University of Washington Hospital in Seattle, involved a list of selection factors, including symptoms such as unconsciousness and discharge from the ear, which would increase the likelihood of obtaining useful information from an x ray. During the study, physicians at the University Hospital could order skull x rays only if one or more of these factors were present.

As a result of this policy, the number of skull x rays ordered was reduced and the rate at which useful information was obtained from the examination improved. When the selection factors were used, evidence of injury was found in one of every 28.6 cases in which a skull x ray was ordered. Records from a hospital not using the selection factors showed evidence of injury in only one of every 44.6 cases in which a skull x ray was ordered. In addition, the number of skull x rays ordered at the hospital not using the selection factors increased, compared to a decline at the hospital using the selection criteria.

## **Regulatory Units Plan Cooperative Reforms**

The heads of the Food and Drug Administration, the Environmental Protection Agency, the Consumer Product Safety Commission, and the Occupational Safety and Health Administration have announced seven cooperative initiatives to reform the regulatory process and improve protection of workers and public health.

FDA Commissioner Donald Kennedy, EPA Administrator Douglas M. Costle, CPSC Chairman S. John Byington, and Assistant Secretary of Labor for OSHA Eula Bingham said: "The President during the campaign promised the American people that waste and duplication in the Federal Government would be eliminated wherever possible. He is committed to improving the management of the Government. Our agencies often deal with many of the same issues and the same industries, and they often have the same research, regulatory and enforcement objectives. It's time we planned and worked together to streamline our regulatory processes and maximize our resources."

As a first step, the agency heads have directed their field

staffs across the country to develop common action plans to meet this goal. The staffs have been told to develop plans to share facilities, laboratories, vehicles, libraries, and other resources, as well as to examine the possibilities of increased cooperation in compliance and enforcement and alternative ways to reduce the burden on the regulated industries.

The joint agency initiatives announced by the four agencies include:

- Development of compatible testing standards and guidelines to determine what criteria should be used in deciding whether testing is needed, what tests should be run, what amount and type of data is necessary for determining safety, and how data should be interpreted.
- Risk and safety and health assessments to decide what data each agency needs to determine a "risk," what methods will be used, and how the results will be announced.
- Information sharing to include use of each agency's current systems and to determine if a national information system on toxic substances is needed and if so how it can be developed.
- Research planning to include a review of each agency's research needs, and a determination of the cost and effectiveness of cooperative research.
- Regulation development to include improved cooperation among the agencies in the development of regulations.
- Compliance and enforcement to include a review of how field personnel can jointly contribute to the mission of all four agencies, and whether laboratory as well as other facilities could be shared.
- Interagency communication and public education on the regulation of toxic substances to examine the possibilities for joint exchange of information with the public and industry through publications, seminars, conferences, and hearings.

In a letter to President Carter, the agency heads said: "We have concluded that within our collective legislative mandates there are significant and exciting opportunities—acting as a team—to effectively control hazardous materials for the protection of public health. We have agreed to examine, assess, and redesign, if necessary, the processes by which we collectively regulate the chemicals which impact upon people and the environment. We are particularly sensitive to the need to minimize duplicative (Government) requests for information from industry . . . . Our goal is to make the regulatory processes more efficient for our agencies, for industry, and for the public."

EPA, FDA, and CPSC already have developed a cooperative plan to ban the nonessential aerosol uses of chlorofluorocarbons that may be depleting the earth's protective ozone layer. Other cooperative efforts among the agencies to date include actions to limit the exposure of workers and the general public to vinyl chloride, and proposals to do the same for benzene.

## **Intraocular Lenses Recalled**

FDA has announced a recall of an estimated 7,700 Surgidev Style 8 Anterior Chamber Intraocular Lenses. The action was necessary because of reports received about adverse reactions including increased intraocular

pressure requiring surgical removal of some of these lenses.

Intraocular lenses are small plastic lenses which are implanted to replace the natural lens of the eye in patients who have undergone cataract operations. The Surgidev Style 8 lens is one of many types of intraocular lenses used for such operations.

The manufacturer, Surgidev Corp., Santa Barbara, California, at the request of FDA on June 16 ceased distribution of these lenses and on June 24, notified, by certified letter, approximately 650 physician and hospital consignees advising them to discontinue further implantations and to closely monitor patients in whom the lenses have been implanted.

FDA asked Surgidev to request medical personnel to discontinue implantations of the Style 8 lenses, but did not ask the firm to have the lenses returned to the manufacturer because the reason for the problem has not been definitely established.

FDA is reviewing reports of injuries to gather additional information on experience with this type of lens and checking similar lenses of other manufacturers to determine the reason for the complications reported to date.

The firm estimates that about 1,200 of 7,700 lenses distributed have been implanted. FDA will check with all recipients of lenses to be sure they have been notified.

## **FDA Completes Action on Zirconium Ban**

The Food and Drug Administration has completed its formal actions to remove zirconium from aerosol antiperspirants and other drugs and cosmetic aerosols.

In anticipation of FDA's action, the manufacturers of these products announced voluntary cessation of the production of zirconium products as of May 1976.

Under the formal action, published in the August 16, 1977, *FEDERAL REGISTER*, zirconium may not be used in aerosol antiperspirants or other drug and cosmetic aerosol products until manufacturers develop evidence demonstrating its safety.

Zirconium has been used as a perspiration inhibitor. An FDA advisory committee, in a report issued in 1975, found that zirconium compounds have caused lung disease and other toxic effects in animals. Based on that report, FDA proposed the removal of zirconium from aerosol products until safety data could be developed by the manufacturers, and the manufacturers proceeded to remove it from their products.

## **Radiation Test Device Patented**

A U.S. Patent has been assigned to the Department of Health, Education, and Welfare for a device that can be used in laboratory experiments to determine how much radiation a person might absorb from medical x rays or other sources of radiation.

The device is the result of studies done by Harry Levine and Marvin Rosenstein of FDA's Bureau of Radiological Health and William L. McLaughlin of the National Bureau of Standards.

Designed to simulate the radiation absorption characteristics of human muscle or tissue, the device (called a dosimeter) contains a dye that changes color when exposed to specific levels of radiation.



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# Regional Reports

*"Regional Reports" consists of important information on inspections, product seizures, court proceedings, and other regulatory and administrative actions initiated by FDA's regional and district field offices across the country to provide protection to consumers under Federal laws. "State Actions," the section immediately following "Regional Reports," consists of similar information about the consumer protection activities of State and local governments.*

## REGION I

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

Sneider Sales Corp., Biddeford, Maine, was fined \$1,000 by Magistrate Seymore Nathanson in the U.S. District Court for the District of Maine following guilty pleas on a three-count information charging that food held by the firm was adulterated by rodents. The legal action resulted from inspections of the firm's warehouse by FDA's **Boston District** which showed it was infested with rodents and the food was contaminated with rodent filth.

A U.S. marshal seized over 1,000 pounds of fish deceptively labeled as flounder and valued at over \$1,000 from the manufacturer, Massachusetts Coastal Seafoods Inc., Magnolia, Massachusetts. The seizure occurred after an analysis of samples collected by Boston District investigators during an inspection of the firm revealed the fish was greenland turbot and not flounder as indicated on the label.

Astra Pharmaceutical Products, Inc., Worcester, Massachusetts, voluntarily recalled nine lots of Xylocaine HCl with epinephrine because of subpotency. The drug, which is used for anesthesia, was contained in 20 and 50 milliliter multiple dose vials. Inspection of the firm by the Boston District, and a followup review by the firm of records, showed a degradation in epinephrine content that brought the drug below labeled strength. FDA originally

was notified of the problem by a hospital pharmacist who reported the subpotency through the Agency's Drug Defect Reporting System.

The Boston District detained a variety of products offered for import and worth over \$350,000 at the Port of Boston after they were found in violation of FDA regulations. Some of the major detentions included: canned mushrooms from Taiwan for misbranding; chopped clams from Canada for bacteriological contamination; frozen shrimp from India for decomposition and *Salmonella* contamination; and Muenster cheese from Germany for decomposition and labeling violations.

## REGION II

*New Jersey, New York, Puerto Rico, Virgin Islands*

Dell Laboratories, Teaneck, New Jersey, its president, Jack R. Lyons, and chief chemist, Gerald Nacht, signed a consent decree in the U.S. District Court in Newark which prohibits the shipment of any drugs manufactured at the facility until it complies with FDA's Current Good Manufacturing Practice Regulations. The action resulted from a routine inspection by FDA's **Newark District** which revealed the firm, which makes injectable drugs, had not tested the effectiveness of its sterilizing equipment and had failed to fill the drug containers aseptically in conformance with acceptable clean room techniques.

Investigators from FDA's **San Juan District**, accompanied by a U.S. marshal, supervised the destruction of nearly 1,500 cases of canned tuna, valued at more than \$32,000, that had been seized by U.S. marshals at the Neptune Packing Co., Mayaguez, Puerto Rico. The tuna was buried in the Mayaguez city dump and completed an action begun in 1974 when FDA investigators collected samples from the processing plant that were shown by laboratory analysis to be decomposed. The seizure, which took place in 1975, was contested by the

firm. Finally, in 1977, after having samples of the fish analyzed by private laboratories, the company withdrew its objections and acknowledged that the tuna was decomposed by entering into a consent decree in the U.S. District Court of Puerto Rico at San Juan. The company further agreed to pay the cost incurred by the U.S. marshal in the destruction.

## REGION III

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

Approximately \$12,000 worth of raw materials and partly processed and finished products, including antibacterial soaps, medicated skin lotions, foot powders, and ointments was seized by the Federal Government in the possession of Gordon Laboratories, Upper Darby, Pennsylvania. The 77 finished products and additional raw materials were found, during a routine inspection by FDA's **Philadelphia District**, to be in violation of FDA's Current Good Manufacturing Practice Regulations. Investigators found the firm failed to test incoming drug ingredients and finished products; to maintain adequate inventory and quality controls; and to provide adequate labeling for one product. In addition, investigators found the firm was manufacturing three animal drugs which had not been approved by FDA.

Joint action between FDA's Los Angeles and Philadelphia Districts resulted in a seizure by the Federal Government of 266 cases of chopped ripe olives at D. Westerveldt, Inc., Hanover, Pennsylvania. The Los Angeles District had inspected the processor of the olives, Early California Foods, Inc., Los Angeles, and found they were short in weight. Investigators then notified the Philadelphia District that a shipment had been made to the Hanover-based warehouse. Subsequent examination of samples collected by the Philadelphia District at the warehouse confirmed that the canned olives were misbranded because they were more than 11 percent

short in weight. The olives were valued at \$4,500.

The Federal Government seized 624 cartons of Sulfacet HC lotion in the possession of Dermik Laboratories, Inc., Fort Washington, Pennsylvania, because it was not manufactured in accordance with FDA's Current Good Manufacturing Practice Regulations. The lotion, which is a skin ointment used in the treatment of acne, was adulterated in that it contained less of the drug hydrocortisone than was declared on the label. The lotion was valued at \$1,200. Each carton contained one bottle of lotion, one tube of color blender, and one vial of powder.

A lot of 50 100-pound bags of mung beans, valued at \$1,500, and offered for import from Thailand, was detained at the Port of Baltimore by FDA's **Baltimore District**. Investigators discovered during a routine import inspection that the beans contained excessive residues of the pesticide endrin. The beans were imported for a firm in Columbia, Maryland, and were from Oriental Food Co., Ltd., Bangkok, Thailand.

Approximately \$14,000 worth of dried chili peppers was detained at the Port of Baltimore by the Baltimore District after investigators found them infested with insects. The peppers were offered for import from Taiwan.

A lot of 180 dozen earthenware mugs, offered for import from Japan, was detained by the Baltimore District at the Port of Baltimore after laboratory tests revealed they contained excessive leachable lead. Investigators had collected samples for analysis during a routine import inspection at the port. The mugs, valued at over \$500, were embossed with a scene depicting the Smoky Mountains and the design of a black bear.

A shipment of 5,800 dozen porcelain cups and saucers, valued at over \$10,000, was detained at the Port of Baltimore after laboratory tests conducted by the Baltimore District revealed they contained excessive leachable lead. Samples of the porcelain, offered for import from Hong Kong, had been collected by investigators during a routine import inspection.

## REGION IV

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

B. C. Tanner Pecan, Inc., Mobile, Alabama, and its president, B. C. Tanner, Jr., were fined \$500 and \$250 respectively in the U.S. District Court for the Southern District of Alabama. The convictions resulted from a series of inspections by FDA's **Atlanta District** which revealed the firm was operating under insanitary conditions conducive to bacterial contamination of shelled pecans. Samples collected by FDA investigators on the plant's shelling line and in interstate commerce were found to contain *Escherichia coli* bacteria. The firm has a history of sanitary violations dating from 1968.

Southwestern Plasma Center, Inc., a corporation with blood plasma collection centers in Tampa and Lakeland, Florida, was fined \$27,000, by a Federal court in Tampa, Florida, for conspiring to violate the Federal Food, Drug, and Cosmetic Act; for intentionally misbranding and adulterating plasma; and for providing false information to FDA. Three company officials also received prison sentences following a five-week jury trial. Alfred E. Smith, president, was sentenced to three years; William P. Dorn, vice president, was sentenced to 18 months; and Dr. Marvin W. Johnson, medical director, was sentenced to two years. During the trial, Government witnesses testified that the company officials authorized and directed the falsification of donor records, overbleeding of donors, and the mixing of hepatitis-contaminated plasma with uncontaminated plasma. Evidence showed that Dr. Johnson presigned physical examination forms to mislead FDA investigators into believing that donors had been examined as required by Federal regulations. The criminal action was brought against the firm after several inspections by FDA's **Orlando District** and FDA's Bureau of Biologics revealed illegal and dangerous practices at the centers. The plasma centers have been under Federal injunction and out of business since 1975.

Famous Bakeries, Inc., Orlando, Florida, and its president, Max Zeidwerg, were fined a total of \$1,500 by

Magistrate Donald Dietrick in the U.S. District Court for the Middle District of Florida for holding insect- and rodent-contaminated flour for sale under insanitary conditions. The corporation pleaded guilty to three misdemeanor counts and was fined \$1,000 on each count. The fines for two counts were suspended and the corporation placed on probation for five years. Zeidwerg was fined \$500. Two other corporate officers and an employee pleaded no contest to one count. The two corporate officers were placed on five years unsupervised probation. The prosecution was based on three inspections of the bakery by FDA's **Orlando District** from 1972 to 1975, which revealed insanitary conditions.

## REGION V

*Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin*

A woman in Minneapolis recently recovered from a serious case of cyanide poisoning from eating a concentrated dose of apricot kernels, source of the controversial drug Laetrile. She had learned that she had an intestinal polyp and was afraid it was malignant. On the advice of a friend who persuaded her that apricot pits could cure her condition, she bought a one-pound bag of the kernels at a local health food store. She found the kernels were too hard and bitter to eat, and decided to grind them up. About 20 minutes after eating a small portion the woman became extremely nauseated and dizzy. She was hospitalized and found to be suffering from cyanide poisoning. While she was in the hospital the intestinal polyp was removed and found to be benign.

The Federal Government seized over one million plastic pouches containing red dye valued at about \$325,000, at a warehouse in Ohio. The distributor claimed the dye could be used to prevent food poisoning. The product, Food Cheks, was seized at Midwest Marketing in North Baltimore, Ohio. The seizure resulted from an intensive investigation by FDA's Cincinnati and Dallas Districts which included issuance of a letter to the firm warning that claims made for the product were misleading. According to their claims, the red liquid was supposed to turn yellow when harmful levels of bacteria are present in food.



FDA lab tests in Cincinnati found that the liquid, which was packaged in postage stamp-size pouches, remained red even when the food being tested contained an enormous amount of *Clostridium botulinum*, the most dangerous of all food poisoning organisms. Further tests proved Food Cheks couldn't even detect *Salmonella* or staphylococci in numbers far over the safe level. Additional seizures also were made in Michigan. A newspaper in Corpus Christi, Texas, set the investigation in motion when a reporter called the FDA office in Houston and questioned the claims made for the product.

U.S. Customs officials in northern port cities are on the lookout for a product called Tatex Tattoo Remover which is being mailed into this country by its manufacturer, The Atlanta Co., Pickering, Ontario. The product has been found to cause acute inflammation, burns, and secondary infections when applied on the skin. FDA's Cincinnati District had been notified about the product by Bethesda Hospital in Cincinnati, which had treated a patient who will probably need skin grafts after suffering from third degree burns on his legs, caused by this tattoo powder remover. The firm, which is not allowed to sell the product in Canada, has been trying to promote mail order sales in this country. U.S. Customs officials, who normally handle mail shipments from Toronto and Ottawa, have been alerted to notify FDA of any shipments that pass through their offices. Consumers should not use the product if they receive it in the mail.

## REGION VI

*Arkansas, Louisiana, New Mexico, Oklahoma, Texas*

A mass seizure of contaminated dried foods, valued at about \$65,000, was made by the Federal Government at Bennett Institutional Foods, Inc., Dallas, following an inspection of the warehouse by FDA's Dallas District. Investigators found the food, including dried lima beans, black-eyed peas, potato flakes, enriched rice, and flour, was grossly infested with rodents and birds. Investigators discovered numerous lots of rodent-defiled food and observed birds flying through the warehouse. The firm began reconditioning

of the seized goods under FDA supervision when investigators discovered that the company had distributed or otherwise disposed of about \$8,000 worth of the dried foods, an action that was in defiance of or contrary to the terms of a court order. As a result, the firm was compelled to forfeit a bond worth over \$11,000 covering the cost of merchandise plus profit.

Progressive Seafoods Inc., Brownsville, Texas, reconditioned 76,000 pounds of *Salmonella*-contaminated frozen frog legs at a cost of over \$3,300. The reconditioning was done under the supervision of FDA's Houston Section. The frog legs, imported from Mexico, were then released to the firm, which had contested the seizure in court for six months. The firm signed a final order and agreed judgment in the U.S. District Court for the Southern District of Texas, and forfeited \$15,000 in penalties to U.S. Customs and paid \$6,600 court costs incurred during the litigation. The frog legs had been discovered by the Houston Section at the Brownsville firm following a tip from the U.S. Customs Service in Dallas, which originally had refused their entry into the United States. The firm had previously been fined \$25,000 in a criminal case brought by FDA based, in part, on similar evidence. Of the \$25,000 fine, \$10,000 was levied against Manuel Sanchez, owner of the firm, who was also given one year supervised probation pending payment of the total fine.

FDA's Houston Section detained nearly \$7 million dollars worth of coffee at the Port of Houston because of insect damage and mold contamination. The coffee, offered for import from the Ivory Coast, came from three shippers and was consigned to a food corporation in New York.

A U.S. marshal seized all foodstuffs at the Forrest City Grocery Co., Forrest City, Arkansas, after an inspection by FDA's New Orleans District revealed poor warehousing practices and extensive rodent infestations. The estimated value of the dried goods, which included cornmeal, flour, beans, and rice, was placed at \$134,000. In addition, the Arkansas State Health Department embargoed \$4,000 worth of similar goods not under FDA jurisdiction. The firm plans to attempt

reconditioning of the foodstuffs under FDA and State supervision.

## REGION VII

*Iowa, Kansas, Missouri, Nebraska*

A consumer complaint to FDA's Kansas City District about coffee with abnormal odor and taste led to seizure by the Federal Government of nearly 7,000 2-pound cans of coffee at the Old Judge Coffee Co., St. Louis. The investigation by the Kansas City District revealed the firm had a warehouse fire and investigators found rusted, swollen, and scorched cans of coffee. Samples collected at the firm were brewed in the FDA laboratory in Kansas City and findings confirmed that the coffee had a burned flavor and smoke-like odor. The District instituted seizure of the coffee, valued at about \$50,000, after the firm expressed intentions to remarket the product by blending it with good coffee.

Private Formulae Inc., St. Louis, and its president, Hans F. Jacoby, and production manager, John Hampton, have agreed to discontinue the manufacture of drug products until the firm can comply fully with FDA's Current Good Manufacturing Practice Regulations. A consent decree of permanent injunction was filed in the U.S. District Court for the Eastern District of Missouri, and was based on a series of inspections at the firm by the Kansas City District in late 1976 and early 1977. Laboratory analysis of several pharmaceuticals including nitroglycerine and estrogen tablets and potassium sulfate, revealed subpotency of active ingredients and failure to meet requirements for content uniformity and disintegration. The legal action resulted from the firm's continued violation of the GMP's despite previous warnings from FDA.

## REGION IX

*Arizona, California, Guam, Hawaii, Nevada*

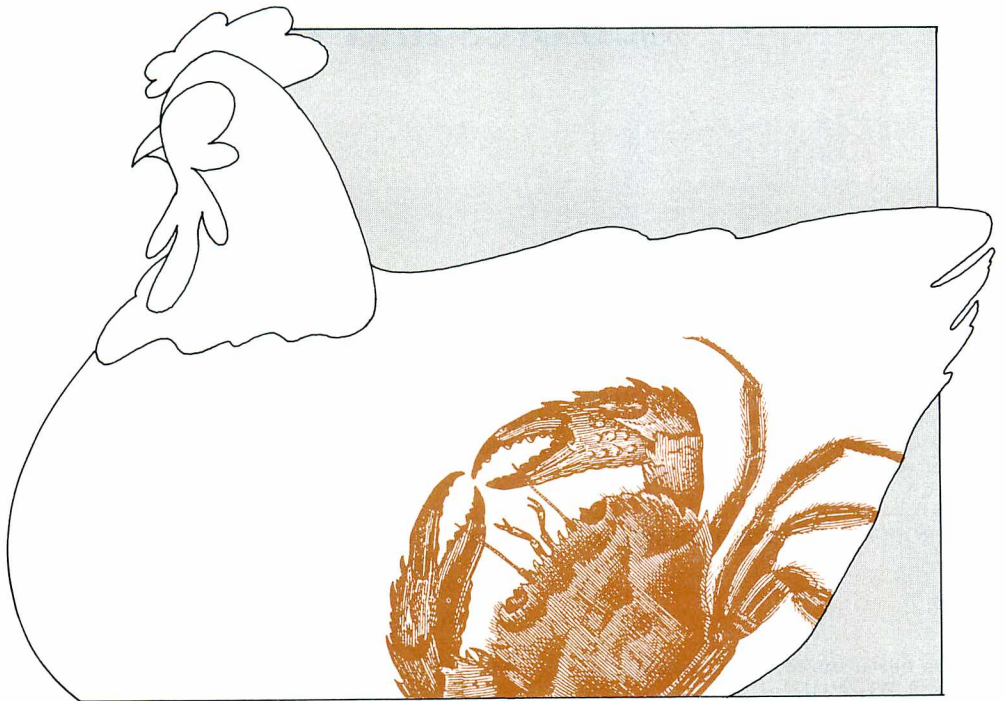
U.S. marshals seized 260 cases of Asiatic ginseng capsules, valued at over \$46,000, at Banner Gelatin Products Corp., Chatsworth, California, because of adulteration and mislabeling violations. An investigator from FDA's Los Angeles District, acting on information received from FDA's Orlando District in Florida, collected a sample

at the manufacturer in Chatsworth. Laboratory tests found the capsules were adulterated since they contained ginseng, an unapproved food additive, and also found the capsules were misbranded in that they consisted of more than two ingredients and not all of these were listed on the label. The only ginseng products generally recognized as safe are the whole, powdered, or ground forms used as tea.

## REGION X

*Alaska, Idaho, Oregon, Washington*

Alaska Wholesale, Inc., Anchorage, Alaska, and its responsible officials entered into a consent decree of permanent injunction, filed in the U.S. District Court of Alaska, as a result of an inspection by FDA's **Seattle District** disclosing that the firm was holding food under insanitary conditions in a rodent-infested facility. The corporation is a distributor of fresh produce to retail outlets and a wholesale distributor of packaged foods to the institutional trade and military bases in the Anchorage area. Under the consent decree, the firm agreed to bring its operation into compliance with FDA regulations by establishing an effective sanitation control program, eliminating vermin from its facility, cleaning and renovating its facility, repairing structural defects, and selecting a qualified



person to be responsible for the firm's sanitation work. The decree also required that all food on hand at the warehouse be examined for filth under FDA supervision and that all foods found contaminated be destroyed. If the firm fails to comply with the decree, it could be subject to closure or whatever additional remedies the court deems necessary to effect compliance with the Federal Food, Drug, and Cosmetic Act.

An investigator from the Seattle District witnessed the conversion of 100,000 pounds of contaminated crabmeat into chickenfeed by a seafood firm in Bellingham, Washington. The crabmeat, which had been shipped from Alaska, had become contaminated with leaking ammonia from the ship's freezing coils while being unloaded at the Port of Bellingham. The firm then voluntarily notified the Seattle District of the problem.

## State Actions

### Milk Firm Penalized \$10,000

The New York State Department of Agriculture assessed a civil penalty of \$10,000 against the Dairylea Corporation as the result of a milk adulteration incident which took place at its plant in Goshen, New York, in 1975. The incident occurred when a tank truck was mistakenly connected to milk pipelines that were being rinsed with water and a cleaning solution, resulting in contamination.

Instead of dumping the milk, Dairylea employees attempted to salvage it by putting it through a separator and adding skim milk. Compounding the problem, one of the storage tanks used was not refrigerated and excessive growths of bacteria occurred. The

resulting substance was used in a variety of milk products, including cheese, butter, and ice cream mix. The ice cream mix and cheese were eventually recovered and destroyed.

In addition to the cash penalty, the firm's milk dealer license was encumbered for two years, which means it must abide by unusually stringent quality control and administrative reporting requirements.

The original investigation of the incident was conducted in cooperation with investigators from FDA's New York District.

### Canning Center Opened

The State of Missouri recently established its first community canning cen-

ter under the sponsorship of the Ozark Area Community Action Corporation.

The facility, in Aurora, Missouri, will use equipment provided by the Ball Canning Co., and be available for home use only by individuals of the community who have homegrown garden vegetables and other produce to preserve. The canning facility will be under the supervision of employees provided by the community action corporation. Training in how to preserve foods by canning will be offered by the Missouri Division of Health upon request.

Ball Canning also is conducting a training course on proper operation of the equipment for supervisory personnel of the canning center.



# Seizures and Postal Service Cases

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

A total of 31 actions to remove from the consumer market products charged to be violative was reported in June. These included 22 seizures of foods: 3 involved charges concerning poisonous and deleterious substances, 13 involved charges concerning contamination, and 6 involved charges concerning economic and labeling violations. Other seizures included 2 of food additives, 1 of animal feed, 4 of drugs (including 1 of veterinary), and 2 of medical devices.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>FOOD/Poisonous and Deleterious Substances</b>		
Fish fillets, frozen, Mahi Mahi/Milwaukee, Wis. 4/11/77	M. S. Cowen Co./Miami, Fla. (S)	Contains added poisonous and deleterious histamine-like substances which might render article injurious to health; contains decomposed fish.
Boston, Mass. 5/11/77	Beaver Street Fisheries, Inc./Jacksonville, Fla. (S)	
Swordfish pieces/Manchester, N.H. 5/20/77	Great Atlantic Fish Corp./Boston, Mass. (S)	Contains the added poisonous and deleterious substance mercury, which may render article injurious to health.
<b>Contamination, Spoilage, Insanitary Handling</b>		
Figs, dried/Tallahassee, Fla. 3/1/77	Simone Fruit Co., Inc./Fresno, Calif. (M,S)	Contains dirt and insect filth, and decomposed figs.
Flour/Nashville, Tenn. 2/18/77	Capitol Foods, Inc./Nashville, Tenn. (D)	Held under insanitary conditions; rodent contaminated.
Grits/Yonkers, N.Y. 3/4/77	Central City Commodity Distributors, Inc./Yonkers, N.Y. (D)	Contains insects.
Peas, dried, and dried pink beans/San Juan, P.R. 6/7/77	Almacenes Maritimos/San Juan, P.R. (D)	Held under insanitary conditions; rodent contaminated.
Pectin, dried pinto beans, dried Great Northern beans, flour, dog food, cane sugar, and other grocery stocks/Forrest City, Ark. 5/7/77	Forrest City Grocery Co./Forrest City, Ark. (D)	Held under insanitary conditions; the Great Northern beans, dog food, and sugar rodent contaminated.
Popcorn/St. Louis, Mo. 6/8/77	United Fruit and Produce Co./St. Louis, Mo. (D)	Held under insanitary conditions; rodent contaminated.
Rice/New Orleans, La. 4/5/77	Allships Supply, Inc./New Orleans, La. (D)	Contains insects; held under insanitary conditions.
San German, P.R. 5/25/77	A. Sanchez Sucrs., Inc./San German, P.R. (D)	Held under insanitary conditions.
Sauces, oyster-flavored, ground bean, thick soy, thin soy, and Hoi Sin/Taylor, Mich. 6/13/77	Imported from Hong Kong, China.	Unfit for food, since contained in swollen and leaking cans.
Soybeans, and mung beans/Irving, Tex. 4/20/77	Yong Ho Co./Irving, Tex. (D)	Held under insanitary conditions; rodent contaminated (mung beans).
Sugar, brown/Brooklyn, N.Y. 4/14/77	Duso Food Distributors, Inc./Ellenville, N.Y. (S)	Held under insanitary conditions; rodent contaminated.
Talc for coating rice/Stuttgart, Ark. 4/2/77	Comet Rice Mills, Inc./Stuttgart, Ark. (D)	Held under insanitary conditions; bird contaminated.
Various food stocks/Dallas, Tex. 3/16/77	Bennett Institutional Foods/Dallas, Tex. (D)	Held under insanitary conditions; rodent and insect contaminated (some foods).
<b>Economic and Labeling Violations</b>		
Breakfast food, Hi-Proteen, Fruit & Nut/Bronx, N.Y. 2/3/77	Hoffman Products, Div. of York Barbell Co., Inc./York, Pa. (S)	Labeling contains a number of false and misleading claims; and required label statements are not prominently placed due to failure to place together and due to inadequate size.
Dairy powder, chocolate-flavored, Gold Standard/New Orleans, La. 6/17/77	Consolidated Flavor Corp./Bridgeton, Mo. (M,S)	Chocolate-flavored dairy powder made with cocoa and carob has been substituted for chocolate-flavored dairy powder made with cocoa.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Honey/Princeton, Fla. 2/10/77	National Papaya Co./Tampa, Fla. (M,S)	Syrup has been substituted in whole or in part for honey.
Olives, ripe, chopped, canned/Hanover, Pa. 5/5/77	Early California Foods, Inc./Visalia, Calif. (M,S)	Article is short weight.
Shrimp, breaded, frozen/Elberton, Ga. 5/24/77	Seabrook Foods, Inc./Tampa, Fla. (M,S)	Fails to conform to standard of identity for frozen raw breaded shrimp, since it tests less than 50% shrimp material.
Tomato juice/Davenport, Iowa 4/5/77	Shipped from Portland, Ind.	Unfit for food, since article contains pieces of can liner.

#### FOOD ADDITIVES

Ginseng and herb extract/North Hollywood, Calif. 6/13/77	ITO Warehouse Co. (Herman Ludwig Corp.)/Newark, N.J. (S)	Contains the nonconforming food additive ginseng; required information not prominently placed, since distributor's name and address are not on label together with ingredient statement; and lacked common or usual name of some ingredients.
L-tryptophan tablets, Trypto-Rest/Wilmington, Mass. 5/11/77	Synergy Plus/Union, N.J. (M,S)	Contains the nonconforming food additive L-tryptophan.

#### ANIMAL FEED

Skim milk, tallow, and lecithin mix/Minneapolis, Minn. 4/6/77	Morelli's Overseas Export/Kenosha, Wis. (S)	Held under insanitary conditions; rodent contaminated.
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#### DRUGS/Human Use

Ephedrine hydrochloride tablets/Denver, Colo. 5/5/77	Unknown shipper/Los Angeles, Calif. (S)	Unlabeled article lacked: name and place of business of the manufacturer, packer, or distributor; quantity of contents statement; adequate directions for use; and established name of the drug.
Mephesisin combination tablets/Denver, Colo. 5/9/77	Western Research Laboratories/Denver, Colo. (M)	Labeling fails to bear adequate directions for use, and article is not exempt since it is a new drug without an effective approved New Drug Application.
Thyroid tablets, chloral hydrate capsules, ipecac syrup, and other drug stock and drug components/Brewster, N.Y. 2/16-17/77	Consolidated Midland Corp./Brewster, N.Y. (M,P)	Circumstances of manufacture, processing, packing, and holding fail to conform with current good manufacturing practice.

#### DRUGS/Veterinary

Esmopal vet drug implant/Indianapolis, Ind. 6/14/77	Mattox & Moore, Inc./Indianapolis, Ind. (M)	Article is a new animal drug and no approved New Animal Drug Application was in effect with respect to the use and intended use of the article.
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#### MEDICAL DEVICES

Cushions with electric vibration and heating/Fort Worth, Tex. 4/25/77	All-Purpose Massager Co./Fort Worth, Tex. (D,M)	Labeling, including brochure entitled "All Purpose Massager 2 Different Massagers in One," contained false and misleading claims for various specified pains, returning invalids to work, massaging body completely, and tightening teeth; labeling fails to bear adequate directions for use for the intended purposes.
Diapulse device/Ellenville, N.Y. 2/18/77	Diapulse Corp. of America/New Hyde Park, N.Y. (M)	False and misleading claims for infections, fractures, bursitis, arthritis, low back pain, and blood flow to peripheral areas; inadequate directions for use and not exempted since adequate information for use by licensed practitioners can not be furnished for such purposes.



## U.S. POSTAL SERVICE

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

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

- April 27, 1977: **Vital Nutrients**, P.O. Box 1082, Southgate, Michigan. Advertising and sale through the mail of the product "Vanish Plus," representing the ability to remove stretch marks.
- April 27, 1977: **Vital Nutrients**, P.O. Box 1059 and 1082, Southgate, Michigan. Advertising and sale through the mail of the product "Pep Pill," representing the ability to "bring added energy and zest back into your life."
- April 27, 1977: **Carter-Ross Labs**, P.O. Box 1082, Southgate, Michigan. Advertising and sale through the mail of the product "Bio-Trim Diet Plan," representing the ability to cause weight loss.
- April 27, 1977: **Advanced Nutrient Products**, P.O. Box 1059, Southgate, Michigan; and P.O. Box 701, Taylor, Michigan. Advertising and sale through the mail of the product "Diet Cap," representing the ability to cause weight loss.
- April 27, 1977: **Supreme Products**, P.O. Box 3572, Van Nuys, California. Advertising and sale through the mail of the product "Super Pulsator and Penis Enlarger," representing the ability to enlarge the penis.
- April 28, 1977: **P. A. Distributors**, 6311 Yucca, Hollywood, California. Advertising and sale through the mail of the product "Peter Pump," representing the ability to enlarge the penis.
- May 2, 1977: **Moscattello Products Company**, 850 North Cypress Street, Orange, California, and P.O. Box 2328, Hollywood, California. Advertising and sale through the mail of a facial cream representing the ability to remove wrinkles, blemishes, acne, and other skin problems.
- May 3, 1977: **Scientific Products and Progress Products**, P.O. Box 3531; and **FDM Supply Company and Scientific Products**, P.O. Box 3572, Van Nuys, California. Advertising and sale through the mail of the product "Standard Model Vacuum Enlarger," representing the ability to increase the size of the penis.
- May 3, 1977: **Derma Diet**, P.O. Box 906, San Mateo, California. Advertising and sale through the mail of the product "Derma Diet Skin Conditioner," representing the ability to erase wrinkles, stretch marks, acne, and other skin disorders.
- May 5, 1977: **Diet Research**, 1865 Warren Way, and P.O. Box 91189, Atlanta, Georgia; and P.O. Box 91189, East Point, Georgia. Advertising and sale through the mail of the product "The Rice Diet," representing the ability to cause weight loss.
- May 9, 1977: **Parker Sales Co., Inc.**, P.O. Box 203, Forest Hills, New York. Advertising and sale through the mail of the product "Jungle Love," representing the ability to be aphrodisiac in nature, and a device representing the ability to strengthen and lengthen the muscles in the penis.
- May 10, 1977: **Slimmer**, P.O. Box 5485 and 4601, Park Road, Mobile, Alabama. Advertising and sale through the mail of a device representing the ability to cause weight loss.
- May 12, 1977: **Leasure Time Products**, P.O. Box 2206, Columbus, Ohio. Advertising and sale through the mail of the product "Vacuum Enlarger," representing the ability to increase the size of the penis.
- May 12, 1977: **P & D Distributors**, P.O. Box 35930, Los Angeles, California. Advertising and sale through the mail of the product "Penis-Stretch," representing the ability to increase the size of the penis.
- May 13, 1977: **Back To Nature Labs**, Kingston Medical Plaza, Suite 104, Drawer 16600, Fort Lauderdale, Florida. Advertising and sale through the mail of the product "Vita Skin," capsules representing the ability to remove stretch marks and acne and reduce hair loss.
- May 13, 1977: **Luciel Cosmetics**, 5300 N.W. 163rd Street, Hialeah, Florida. Advertising and sale through the mail of capsules representing the ability to cause weight loss.
- May 17, 1977: **Canyon House**, Box 8316, Charter Road, Philadelphia, Pennsylvania, and P.O. Box 4000, Rexdale, Ontario, Canada. Advertising and sale through the mail of the product, "Perma-Gone," a home electrolysis system, representing the ability to remove unwanted hair.
- May 18, 1977: **Desert Crest Products**, P.O. Box 1498, Gilroy, California. Advertising and sale through the mail of the product, "Chaparral Tea," representing the ability to cure cancer.
- May 19, 1977: **Trim Sales Co.**, 6311 Yucca St., Hollywood, California. Advertising and sale through the mail of the product, "Sauna-500" slim suit, representing the ability to cause weight loss.
- May 25, 1977: **Photografix**, P.O. Box 2051, Culver City, California. Advertising and sale through the mail of the product, "Damiana Super Blend," representing the ability to be an aphrodisiac; and "Fo-Ti-Teng," representing the ability to cause an energizing effect on nerve and brain cells.
- June 1, 1977: **Diverse Industries, Inc.**, 7651 Haskell Avenue, Van Nuys, California. Advertising and sale through the mail of the products, "Standard Vacuum Enlarger and Erection Keeper," representing the ability to lengthen and thicken the penis.

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

- May 19, 1977: Against **Eureka Products**, 1246 So. La Cienega Blvd., Los Angeles, California. Advertising and sale through the mail of the product, "Standard Vacuum Enlarger," representing the ability to lengthen and thicken the penis.
- June 2, 1977: Against **Biochem Research**, Elk Lodge Office, Route 4, Boone, North Carolina. Advertising and sale through the mail of the product, "Cellu-Gel Home Treatment Kit," representing the ability to cause weight loss.
- June 13, 1977: Against **Sans Egal**, 380 Madison Avenue, New York, New York. Advertising and sale through the mail of the product, "Sans Egal," a skin care cream, representing the ability to reduce wrinkles.

# Notices of Judgment

## NOTICES OF JUDGMENT on Seizure Actions

### FOOD/Poisonous and Deleterious Substances

#### **Fish filets, Mahi-Mahi, frozen**, at Los Angeles, C. Dist. Calif.

Charged on or about 2-24-77: when shipped by unknown shipper from Manta, Ecuador, the article, labeled in part "Inexpac Fresh Frozen Fish Product of Ecuador S.A. Mahi-Mahi," contained added poisonous and deleterious histamine-like substances; and the article consisted in part of decomposed fish; 402(a)(1), 402(a)(3). Default decree ordered destruction. (F.D.C. No. 62043; S. No. 77-77-087; N.J. No. 1)

#### **Fish filets, Mahi Mahi, frozen**, at Santa Clara, N. Dist. Calif.

Charged 12-21-76: when shipped by M. S. Cowen Co., Miami, Fla., the article, labeled in part "Mahi Mahi Fillet Sociedad Nacional de Galapagos Fresh Frozen Fish Perlita Brand M.S.C. S.P. . . . Product of Ecuador," contained added poisonous and deleterious, histamine-like substances; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 61009; S. No. 77-48-059; N.J. No. 2)

#### **Halibut, trimmed, frozen**, at Bellingham, W. Dist. Wash.

Charged 12-17-76: when shipped by Excursion Inlet Packaging Co., Excursion Inlet, Alaska, the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Consent decree authorized release to Wards Cove Packing Co., Inc., Seattle, Wash., for salvaging. (F.D.C. No. 61059; S. No. 77-70-540 et al.; N.J. No. 3)

#### **Swordfish**, at Miami, S. Dist. Fla.

Charged 8-4-76: when shipped from the Atlantic Ocean by Garcia Bros. Seafood, Inc., Miami, Fla., the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 60839; S. No. 77-43-414; N.J. No. 4)

### FOOD/Contamination, Spoilage, Insanitary Handling

#### **Black-eyed peas, frozen**, at Plymouth, M. Dist. Fla.

Charged 11-5-76: while held for sale, the article contained decomposed black-eyed peas; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60972; S. Nos. 76-64-431, 76-64-436; N.J. No. 5)

#### **Brazil nuts, dried black-eyed peas, and other warehouse stocks**, at New York, S. Dist. N.Y.

Charged 11-12-76: while held by The Graham Co., Inc., New York, N.Y., the brazil nuts contained insect and rodent filth; and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60981; S. No. 77-88-867 et al.; N.J. No. 6)

#### **Corn flour for tortillas**, at Irving, N. Dist. Tex.

Charged 2-11-77: while held for sale, the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 62053; S. No. 77-21-370; N.J. No. 7)

#### **Fennel seed**, at Garrison, Dist. Md.

Charged 3-29-77: while held for sale, the article contained rodent, insect, and other filth; 402(a)(3). Consent decree authorized release to Baltimore Spice Co., Garrison, Md., for salvaging. (F.D.C. No. 61105; S. Nos. 77-91-172, 77-60-728; N.J. No. 8)

#### **Fennel seed, ground**, at Sparks, Dist. Nev.

Charged 3-10-77: when shipped by Baltimore Spice Co., Baltimore, Md., the article contained insect filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61104; S. No. 77-74-215; N.J. No. 9)

#### **Flour and cornmeal**, at Meridian, S. Dist. Miss.

Charged 5-6-77: while held by Hasson Grocery Co., Inc., Meridian, Miss., the articles contained rodent filth, and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 61204; S. No. 77-22-541 et al.; N.J. No. 10)

#### **Flour and wheat bran**, at Atkins, E. Dist. Ark.

Charged 5-6-77: while held for sale in a railcar, the articles were held under insanitary conditions; 402(a)(4). Consent decree authorized release to Missouri Pacific Railroad Co., Little Rock, Ark., for salvaging. (F.D.C. No. 61203; S. No. 77-79-125 et al.; N.J. No. 11)

#### **Mint leaves, brown rice, shelled pistachio nuts, and mahlep**, at Brooklyn, E. Dist. N.Y.

Charged 1-26-77: while held by Sahadi Importing Co., Inc.,

Brooklyn, N.Y., the nuts and the rice contained insect filth; and the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 62015; S. Nos. 77-42-316/9; N.J. No. 12)

#### **Pecans, shelled**, at San Antonio, W. Dist. Tex.

Charged 6-24-76: when shipped by S.N.A. Nut Co., Mansfield, La., the article contained *E. coli*; 402(a)(3). Consent decree authorized release to the shipper for reconditioning. (F.D.C. No. 60781; S. No. 76-22-066; N.J. No. 13)

#### **Pepper, brown sugar, cassia, peppermint leaves, dried whey, and dried mushroom powder**, at Brownstown, S. Dist. Ind.

Charged 2-22-77: while held by Marion Kay Co., Inc., Brownstown, Ind., the articles (except the pepper and sugar) contained rodent or insect filth, and all the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 62066; S. No. 77-69-266 et al.; N.J. No. 14)

#### **Rice, rolled oats, and dried beans**, at Salt Lake City, Dist. Utah.

Charged 3-23-76: while held by Buie International, Salt Lake City, Utah, the articles had been held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60691; S. Nos. 76-16-992/4; N.J. No. 15)

#### **Rice flour**, at San Francisco, N. Dist. Calif.

Charged 3-28-77: while held by Wing Sing Chong Co., Inc., San Francisco, Calif., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61130; S. No. 77-49-117; N.J. No. 16)

#### **Salt, crackers, and cake mix**, at Ellenville, S. Dist. N.Y.

Charged 3-4-77: while held by Duso Food Distributors, Inc., Ellenville, N.Y., the articles had been held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61109; S. Nos. 77-58-116/8; N.J. No. 17)

#### **Tunafish, canned**, at Mayaguez, Dist. P.R.

Charged 6-23-75 and amended 9-5-75: when shipped from outside the territorial waters of Puerto Rico by the fishing vessel *Jacqueline Marie*, and while held by Neptune Packing Co., Mayaguez, P.R., who prepared and packed the article, the article contained decomposed tunafish; 402(a)(3). The Government's complaint sought seizure of 1,471 unlabeled cases of the article. The article was claimed, however, by the packer who denied the charge and asserted that the only can code cited in the complaint was K27A3/314G1 (which was contained in only 462 cases), and that the remaining 1,009 cases contained codes K27A4/314G1 and K27A7/314G1. The claimant moved for release from the seizure of such 1,009 cases of the article. Subsequently, the parties reached an agreement on the total number of cases involved. Although three can codes were involved, all represented the same lot of uncanned tuna. Accordingly, the complaint was amended to specify all three codes involved in the 1,471 cases. The Government served written interrogatories on the claimant. The claimant similarly served written interrogatories on the Government. Subsequently, additional sets of interrogatories were propounded by both parties. In the course of the proceedings, the Government contested an order to perform new tests on the article. As to this, the Government ultimately prevailed, since the district court said:

"By his Status Conference Report of May 28, 1976 the U.S. Magistrate ordered plaintiff to perform new organoleptic tests in presence of an independent testing laboratory who will be given a sample of any cans found contaminated for further testing. These tests to be performed in the same number of samples that were originally taken.

"In denying plaintiff's motion for reconsideration of said order, the U.S. Magistrate expresses that in order for claimant to show that in spite of positive results to the organoleptic tests, 'the can might still not be contaminated' claimant must test cans 'found to be deficient by the government expert.'

"After due consideration, we believe that the only reason for conducting new series of organoleptic tests would be to prove the accuracy of the previous tests. That purpose can be achieved by placing at the disposition of defendant a given number of batches of samples for the defendant to analyze and to report. Certainly, that can be done without the active participation of plaintiff United States of America.

"Section 304(c) of the Federal Food, Drug and Cosmetic Act, 21 USC 334(c) states that defendant has the right to move for an





order allowing said defendant to a condemnation proceeding: . . . 'to obtain a representative sample of the article seized and a true copy of the analysis . . .'

"Claimant Neptune Packing Company has not moved this Court for entry of an order granting it leave to take a representative sample from the seized canned tuna fish as authorized by Section 304(c) of the Act, 21 USC 334(c). Nevertheless, claimant retains that option, and if such a motion were made at this time, there would be no opposition from the plaintiff.

"Once these new series of tests have been conducted, defendant in this case will stand in a much better position to challenge or admit the accuracy of the testing method utilized by the government and subject to this controversy.

"Wherefore, upon consideration of the order issued by the United States Magistrate John M. Garcia on June 23, 1976, the same is hereby reversed."

Subsequently, the claimants entered into a consent decree of condemnation which ordered the article destroyed. (F.D.C. No. 60405; S. No. 23-273 H; N.J. No. 18)

**Walnut pieces, black, at Nashville, M. Dist. Tenn.**

Charged 4-14-75: while some of the walnut pieces were held by Black Bros., Inc., Nashville, Tenn., who prepared and packed the article, and while other walnut pieces were held for sale and stored for Black Bros., Inc., at a public warehouse in Nashville, Tenn., both lots of the article had been prepared, packed, and held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60328; S. No. 61-423 et al.; N.J. No. 19)

**FOOD/Economic and Labeling Violations**

**Cheese product, grated, at Indianapolis, S. Dist. Ind.**

Charged 2-10-77: when shipped by Virginia International Sales, Ltd. (t/a Amity Cheese Co.), Schenectady, N.Y., the article, labeled in part, "Delco Pizza Products . . . Parmesan Grated Cheese . . . Packed For: Delco Pizza Products, Indianapolis, Ind.," had had another substance substituted for parmesan cheese—402(b)(2); the labeling was false and misleading in claiming that the food consisted wholly of parmesan cheese—403(a); and the article failed to conform to the definition and standard for grated cheese, since the fat content of its solids were less than 31 percent—403(g)(1). Default decree ordered destruction. (F.D.C. No. 62033; S. No. 77-69-386; N.J. No. 20)

**Cheese product, grated, at Noblesville, S. Dist. Ind.**

Charged 2-10-77: when shipped by Virginia International Sales, Ltd., Schenectady, N.Y., the article, labeled in part "Dante Italian Caccio-Romano-Bianco Grated . . . Packed by Virginia International Sales, Ltd., Schenectady, New York," had had another substance substituted for romano cheese; the labeling was false and misleading in representing the article as consisting wholly of romano cheese; and the article failed to conform to the definition and standard of identity for grated cheese, since the article contained less than 31 percent of the fat content of solids; 402(b)(2), 403(a), 403(g)(1). Default decree ordered destruction. (F.D.C. No. 62032; S. No. 77-68-510; N.J. No. 21)

**Cheese, Reggiano, grated, at Andover, Dist. Mass.**

Charged 2-16-77: when shipped by J & D Sales Co., Schenectady, N.Y., the article, labeled in part "Italian Bouquet Imported Parmesan Grated Cheese . . . Dist. By: J & D Sales Co., Schenectady, N.Y.," had had Reggiano cheese substituted for the article—402(b); the labeling was false and misleading in claiming that the food consisted of parmesan cheese—403(b); and the grated Reggiano cheese was offered for sale under the name of another food (grated parmesan cheese); 403(b). Default decree ordered donation to public/charitable institution for consumption only. (F.D.C. No. 62037; S. No. 77-93-050; N.J. No. 22)

**Pecan pieces, pecan halves, and black walnut pieces, Kentucky Kernel, at Hickman, W. Dist. Ky.**

Charged 2-11-77: while the pecan pieces were held for sale by Roper Pecan Co., Hickman, Ky., who had prepared and packed the pecan pieces using pecans shipped in interstate commerce, and when the pecan halves and black walnut pieces were returned from Murfreesboro, Tenn., to the packer, the articles were short weight (approx. 1.7 to 4.3 percent)—403(e)(2); and the pecan pieces were in violation of the Fair Packaging and Labeling Act, since the quantity of contents statement did not include the term "Net Weight"—15 U.S.C. 1453(a)(3)(A)(i). Consent decree authorized release to the dealer for reconditioning. (F.D.C. No. 62009;

S. No. 77-34-331; N.J. No. 23)

**Potato chips, "fortified," Clover Club Golden, at Corona, C. Dist. Calif.**

Charged 2-15-73: when shipped by Clover Club Foods Co., Kaysville, Utah, the label statement "Now—Fortified [underlined] for Extra Nutrition" falsely and misleadingly represented that the article's nutritive value had been significantly improved and that the article had significantly greater nutritive value in a usual serving than ordinary potato chips—403(a); label references concerning nutritional value were misleading, since such references represented that 3½ ounces of potato chips was a common, usual, or average serving when the common or usual serving was approximately ½ ounce, which supplied approximately 113 calories and an insignificant amount of vitamins, minerals, and proteins—403(a); and the label falsely and misleadingly represented the article for use in reducing dental cavities—403(a). The shipper claimed the article, and denied the charges. Pursuant to stipulation, the action was transferred for further proceedings to the District of Idaho.

The parties served written interrogatories on each other, and litigated the responses to the interrogatories. The claimant subsequently filed an amended answer, a counterclaim seeking damages, and an amended counterclaim. The Government moved to dismiss the counterclaim and to strike the claimant's affirmative defenses, which concerned a previous proposed Federal seizure in the District of Montana of other potato chips of the claimant (which had been embargoed by the State of Montana on July 3, 1972) upon similar charges, and which the claimant had consented to destroy on the basis that the product would be "properly labeled in order to be marketed in Montana." The claimant also moved to amend its amended answer and to amend its amended counterclaim. The court reviewed the motions pending before it. In dismissing the claimant's counterclaim, in denying claimant's motion to amend its pleadings again, and in denying the Government's motions to strike the claimant's third, fourth, and fifth defenses, the court said:

"The United States has moved to strike from the amended answer, the Third, Fourth and Fifth Defenses, pursuant to Rule 12(F), F.R.C.P.

"A motion to strike an allegedly legally insufficient, immaterial or impertinent defense is not a favored motion by the courts. . . . The motion will be denied if the defense has any relation to the subject matter of the controversy, could be held to in any manner defeat the plaintiff's claim, or if it fairly presents any question of fact or law. . . .

"The Third Defense attacks on constitutional grounds the validity of the FDA's determination that the potato chips are misbranded. Clover Club does not contend that the Federal Food, Drug and Cosmetic Act is facially unconstitutional, but that the FDA's determination that its product is misbranded within the meaning of the Act is violative of the Fifth Amendment as arbitrary and capricious and without a rational basis. The Third Defense is related to the government's claim, is not immaterial or impertinent and cannot at this stage be said to be legally insufficient as there is no authority, pro or con, on the narrow issue which the defense raises.

"Claimant's Fourth Defense alleges that the United States is estopped to bring this action due to a binding agreement between Clover Club and the FDA following a seizure of some of Clover Club's potato chips in July of 1972 by the Montana State Department of Health pursuant to its own misbranding statutes. In substance, Clover Club contends that following the seizure in Montana, it reached an agreement with the FDA that it would change all of its future packaging but that it could use up the remaining objectionable packages which it had already printed. The government denies the existence of any agreement and contends that, in any event, the FDA official could not bind the government because he had no authority to make such an agreement.

"Clover Club's Fifth Defense alleges that the seizure in 1972 by the Montana authorities was at the request of the FDA and, therefore, this action is barred by 21 U.S.C. 334(a)(1) because the FDA has engaged in multiple seizures of its product.

"As to the Fourth and Fifth Defenses, the government does not attack their legal sufficiency so much as it attacks their factual validity. Whether an agreement was made is a question of fact which at this point is open to dispute and, therefore, not appropriately resolved on a motion to strike. And if an agreement was made, whether it is one which could bind the United States



depends upon the authority of the official, which also is a disputed question of fact at this point. The government contends that it has not engaged in multiple seizures while Clover Club asserts otherwise, thus raising substantial questions of both fact and law. The government has not demonstrated beyond mere conclusory argument that these defenses are insufficient as not being valid legal defenses to the forfeiture action, that there are no questions of law or fact, or that the defenses, if proven, would not defeat the forfeiture action.

"The United States has moved pursuant to Rule 12(b) F.R.C.P. to dismiss Clover Club's amended counterclaim against it on the grounds that the Court lacks subject matter jurisdiction and jurisdiction over the person. The counterclaim, which is asserted under the provisions of 28 U.S.C. 1346(a)(2), The Tucker Act, sets forth the same allegations contained in Clover Club's Fourth Defense in its Amended Answer.

"The government contends that the Court is without jurisdiction to consider the counterclaim because Tucker Act claims against the United States cannot be asserted by way of a counterclaim, only by an original proceeding in the manner contemplated by 28 U.S.C. 1346(a)(2). As authority it relies upon *United States v. Nipissing Mines Co.* . . . and argues that under 28 U.S.C. 1346(c) the United States may assert counterclaims in suits brought against it, but there is no reciprocal provision for counterclaims by private parties where the United States is plaintiff.

"Clover Club asserts that it is the majority and more modern view that Tucker Act claims may be asserted as counterclaims against the United States where they arise out of the same transaction or occurrence which is the subject matter of the government's claim. . . .

"As a sovereign, the United States is immune from suit save as it consents, and the terms and conditions under which it consents to be sued define the limits of any court's jurisdiction. . . .

"The Tucker Act does not expressly give the district courts jurisdiction over any counterclaim against the United States not exceeding \$10,000 in amount. However, the courts which have allowed counterclaims to be asserted under the Tucker Act have reasoned that if the United States has come into court, it has waived any immunity from assertion of the counterclaim when both claims arise out of the same transaction or occurrence. . . . But however attractive such a result may be under those circumstances, Clover Club's counterclaim does not arise in the same manner.

"In this action the United States has not come into court on a cause of action based upon the law of contracts or any other claim which is contemplated by 28 U.S.C. 1346(a)(2) as one which could otherwise be asserted against the United States in an original proceeding under that section. This is a very limited statutory procedure provided by the Food, Drug and Cosmetic Act, 21 U.S.C. 334, for the limited purpose of removing from commerce an article of food carrying an allegedly false and misleading label. It is an *in rem* proceeding to condemn the articles and Clover Club appears not as a defendant but as the claimant of the goods.

"The subject matter upon which the government bases its complaint for forfeiture is very narrow. It relies upon the Food, Drug and Cosmetic Act and the administrative determination that the articles of food carry false and misleading labels within the meaning of the Act, not upon any alleged express or implied contract or agreement upon which Clover Club relies for its counterclaim. The counterclaim does not arise out of any transaction or occurrence which is the basis for the government's action. It therefore cannot be said that the government has waived its immunity from defending against Clover Club's claim in any manner other than as is contemplated by the terms and conditions of its consent under 28 U.S.C. 1346(a)(2), in an original proceeding.

"Clover Club has moved pursuant to Rule 15(a) F.R.C.P. to amend its answer for a second time to add a sixth defense and to amend its counterclaim again for a second time to add a second cause of action. The proposed sixth defense alleges that to the extent any statute or regulation relating to the labeling of defendant's product could be interpreted to prohibit any language printed on their packaging, such statute or regulation violates Clover Club's First Amendment rights to freedom of speech. The proposed second cause of action in its counterclaim is brought under the provisions of the Federal Tort Claims Act, 28 U.S.C. 2674, et seq. and alleges that the FDA has engaged in multiple seizures of its product prohibited by 21 U.S.C. 334(a)(1) and therefore the seizure of its products by this action amounted to a wrongful conversion.

"While leave to amend one's pleading is, even after a substantial period of delay, ordinarily freely granted where prejudice to another party is not shown, the Court is not required to engage in futile gestures by allowing amendments which are without legal basis or which would assert claims over which the Court does not have jurisdiction. . . .

"Clover Club's proposed sixth defense has no merit as a matter of law. Freedom of Speech does not include the freedom to violate the labeling provisions of the Federal Food, Drug and Cosmetic Act. . . .

"Clover Club argues that its proposed second cause of action in its counterclaim does not come within the exception of 28 U.S.C. 2680(c) that the Federal Tort Claims Act and 28 U.S.C. 1346(b) shall not apply to '[a]ny claim arising in respect of . . . the detention of any goods or merchandise by any . . . law enforcement officer.' The Court fails to see the distinction between the gravamen of Clover Club's proposed second cause of action in its counterclaim and the exception.

"Although Clover Club states that it is not seeking damages for the detention of their product, it prays for loss of potato chips, a loss which could only be occasioned by the detention of them, not from their seizure alone. More important, the basis for the claim is that the FDA has engaged in multiple seizures of Clover Club's product, making the instant seizure illegal. Contrary to Clover Club's argument, 28 U.S.C. 2680(c) 'is normally used to bar actions based upon the illegal seizure of goods. . . . [T]here is nothing in the language of the statute to indicate that erroneous seizure in the inception should be distinguished from improper retention or negligent handling of goods properly seized at the outset. Rather, the statute specifically bars "any claim" arising out of the detention of goods.' . . .

"In view of the holding that Clover Club's proposed second cause of action in its counterclaim is barred by 28 U.S.C. 2680(c), the Court expresses no opinion as to whether a counterclaim under the Federal Tort Claims Act may be asserted in an *in rem* proceeding such as the case at bar, or whether administrative remedies must be exhausted prior to its assertion."

Both parties moved for summary judgment, and the court denied summary judgment to both parties. The parties then submitted the case to the court for decision on the merits based on the same records presented for the summary judgment motions. Although the court found that the Government had failed to prove a number of its charges, the court found that the article was misbranded with respect to one charge and found that judgment was to be entered for the Government and against the claimant. The article was accordingly condemned and ordered destroyed. In reaching its decision the court said:

"This civil *in rem* proceeding was commenced on June 29, 1973, in the United States District Court for the Central District of California, where the plaintiff, United States of America, filed a Complaint for forfeiture and seized a quantity of potato chips. . . . After some preliminary discovery, Clover Club was permitted to file an Amended Answer and a Counterclaim for money damages. The Counterclaim has been heretofore dismissed by the Court in an Order dated March 27, 1975. That Decision appears to be correct and is herein affirmed.

"An astonishing volume of discovery has been accomplished. A survey of consumers has been carried out, and the report made a part of the record. Expert opinions and testimony have been secured and filed. Many Affidavits have been filed, accompanied by considerable volume of packaging material, including that which is subject to the misbranding charge. I have read and carefully considered all of this material, and have given such weight to each item of evidence presented as I feel is due. I am convinced that a full record, sufficient for determination of the controversy on the merits, has been considered. A Pretrial Conference Order was agreed upon and made a part of the record. This Order provides a number of agreed facts and designation of issues of fact and law to be determined. I adopt the pretrial agreed facts by incorporation herein as though fully set forth in this Opinion.

"There are some technical issues, which combine law and fact questions, which will be dealt with at the end of this memorandum.

"Preliminarily, I turn my attention to the meat of the dispute which was succinctly stated in the Pretrial Order in the following language: 'A. Whether the seized Clover Club potato chips are misbranded within the meaning of 21 U.S.C. § 343(a) in that their labeling is false or misleading in any particular.'

"The alleged allegations of mislabeling are directed at three





separate areas of the labels under attack and are set out as follows:

"(1) On the front panel label of the packages of potato chips the words 'Now Fortified for Extra Nutrition' are prominently set out.

"(2) On the back of the package appear what purport to be separate articles written by one Hod Sanders and one Clover Sanders. The Sanders are apparently husband and wife and are the producers of the Clover Club potato chips, according to the language in the articles. (Mrs. Sanders' given name 'Clover' being the source of the tradename).

"The alleged misbranding appears in the article purportedly authored by Clover Sanders and entitled 'Potato Chips Are Nutritious'. The first portion of the article under attack contains the following language which is held to be false and misleading and to constitute misbranding:

'I must confess that when Hod and I started making potato chips back in 1938 we didn't think of them in terms of their food value. All we wanted to do was to make chips that were fun to eat.

'But with the recent interest in the nutritional value of all foods, we asked Dr. Ora Smith, Director of Research for the Potato Chip Institute International and Professor Emeritus of Cornell University, to help us. He called our attention to the U.S. Department of Agriculture's Handbook No. 8 (Composition of Foods) in which the chemical composition and food values of potato chips are listed.

'Matching these USDA figures with the official "Recommended Dietary Allowances" (RDA) in the 1968 report of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, Dr. Smith pointed out that a 10 to 12 year old boy needs 2500 calories in food energy. For boys 14 to 18 this figure is 3,000 calories. "A 3 1/2-ounce package of potato chips would supply these children with 568 calories of energy," says Dr. Smith. "Or about 23 percent of the recommended energy per day for the 10 to 12 year olds and 19% for the 14 to 18 year old boy."

'In addition, the 10 to 12 year olds would obtain about 12% of their daily requirements of protein, 18% of the iron, 40% of the vitamin C or ascorbic acid, 28% of the niacin, 16% of the thiamine, 5% of the riboflavin, some vitamin A, 12% of their daily phosphorous allowance and 3% of the calcium, as well as some potassium and other minerals.'

"(3) Also in the Clover Sanders' portion of the article appears the following language, claimed to constitute misbranding:

'Dr. Smith also notes that potato chips are among foods recommended by the Department of Dentistry, University of California, as a part of a diet aimed at reducing dental cavities.'

"For convenience then, the three items of alleged false and misleading labeling may be restated as follows: (1) Claim of fortification for extra nutrition (hereinafter the 'fortification claim'); (2) Claim of nutritional quantities of calory and vitamin content (the 'nutrition claim'); and (3) Claim of value in reducing dental cavities (the 'dental claim').

#### Fortification Claim

"It appears from the evidence that some extra caloric fortification was indeed added to the potato chips in question. The amount was not great, measured on a percentage basis. The Government takes the position that the public is being misled unless the caloric addition is significant. The preponderance of the evidence shows that the average member of the consuming public does not make a judgment between extra and significant, and that the statement did not tend to mislead the public and was not factually false. The plaintiff has therefore failed to prove that the challenged advertising relative to the fortification claim constituted misbranding.

#### Nutrition Claim

"The plain reading of the language (quoted above) relative to this claim is that 3 1/2 ounces of the potato chips contain certain nutrient values. According to the evidence, these statements are essentially true. But plaintiff claims that the language is misleading because it contends that the import of the wording incorrectly suggests that 3 1/2 ounces of potato chips represents a usual or average serving. The evidence indicates that about 2 ounces of potato chips may very well be an ordinary serving. The theory of the plaintiff may have some rationality, but the evidence indicates that the consuming public generally do not so construe the language involved. The label correctly states the facts. Plaintiff has failed to prove that the public will be misled thereby. It follows that plaintiff has failed to prove misbranding in this regard.

#### Dental Claim

"Here, a plain reading of the language is that potato chips are recommended by a prominent dental school to be added to a diet

designed to reduce dental cavities. The evidence makes it clear that this is not true. The recommendation, at most, was a proposal to substitute potato chips on a diet for other foods more conducive to tooth cavity causation, such as candy bars and the like. The label tends to mislead the ordinary reasonable consumer. A preponderance of the evidence supports the plaintiff's contention that this portion of the label is false and misleading so as to constitute misbranding.

"Three other matters, combining fact and law questions, are urged by the defendant. They are (1) a claim of due process violation, (2) an estoppel claim, (3) a double seizure in violation of 21 U.S.C. § 334(a)(1).

#### Due Process Violation

"This contention of the defendant is based upon allegations that the F.D.A. brought these proceedings for improper purposes. It is contended that, because defendant dared to question [an] F.D.A. action, this prosecution ensued. Commendably, defendant concedes that direct proof is unavailable, but seeks to rely on an inference that, since competitors were using claimed nutritional values and are not usually prosecuted, this constitutes evidence of selective enforcement of the law for bad purpose. The claim is made then that this prosecution violates the defendant's due process rights. The record fails to support the defendant, and this defense must be found to have failed.

#### Estoppel

"The defense of estoppel is based on an alleged agreement between the defendant and the F.D.A., supposedly entered into after an embargo of the defendant's potato chips in the State of Montana made by state authorities. It is claimed that officers of the F.D.A. agreed with the plaintiff not to proceed against the defendant on similar grounds in other areas. Defendant claims that in reliance on this agreement, potato chips seized in the instant action were entered into commerce. Defendant has failed to prove by a preponderance of the evidence that an agreement was ever reached as alleged. I am of the view that, even had such an agreement been made, it was void as against public policy, and cannot support a defense of estoppel. It follows that there is no estoppel shown in this matter.

#### Double Seizure In Violation of 21 U.S.C. § 334(a)(1)

"This statutory provision provides for condemnation based upon a Complaint alleging misbranding of food in any United States court having jurisdiction where the misbranded article is found. However, only one action may be instituted based upon the same misbranding. (There are some limitations to this rule not pertinent here.) Defendant apparently contends that another action was pending in Montana when the instant action was begun, and that the Montana matter is a statutory bar. The short answer is that while officers of the F.D.A. and of the United States may have been somehow involved in the Montana matter, the Montana case was a state enforcement of an embargo and not a legal bar to the instant prosecution.

#### Conclusion

"I conclude therefore that as to the alleged mislabeling involving a claimed value for the potato chips in the reduction of dental cavities, the plaintiff has proved that the seized food was mislabeled. Under the statutory provision, the property was subject to seizure and further ultimate disposal by the Government. The other alleged grounds for supporting an allegation of mislabeling are not proved. The defenses of violation of due process, estoppel, and statutory bar are not proved and should be dismissed." (F.D.C. No. 58878; S. No. 49-467 F; N.J. No. 24)

**Whey and cheese condiment**, at Schenectady, N. Dist. N.Y.

Charged 4-1-77: when returned from South Gardiner, Maine, to J & D Sales Co., Schenectady, N.Y., the article, labeled in part "AG Food Stores Imported Parmesan Grated Cheese Flavored Condiment (Cheese Whey & Grated Cheese) Ingredients: Dried Cheese Whey, Swiss Cheese, Cheddar Cheese, Parmesan Cheese . . . Distributed By: Associated Grocers of Maine, S. Gardiner, Maine," had had the valuable constituent parmesan cheese omitted from the food—402(b)(1); the article's labeling was false and misleading in representing that the article contained parmesan cheese—403(a); the article's label lacked the common or usual name of the food, since none of the natural flavor used in the food was derived from parmesan cheese (whose flavor the article simulated), and (contrary to regulations) the article was neither labeled with the flavor of the product from which the flavor was



derived nor as artificially flavored—403(i)(1); and the ingredient statement lacked the common or usual name of the article's ingredient sardo cheese—403(i)(2). Default decree ordered destruction. (F.D.C. No. 62031; S. No. 77-56-761; N.J. No. 25)

#### FOOD ADDITIVE

##### **Aangamik 15 calcium pangamate tablets, at Dallas, N. Dist. Tex.**

Charged 3-17-77: when shipped by FoodScience Laboratories, Inc., Burlington, Vt., the article contained the nonconforming food additive calcium pangamate—402(a)(2)(C); the label statements identifying calcium pangamate as "Vitamin B-15" were false and misleading, since calcium pangamate was neither a vitamin nor a provitamin, there was no accepted scientific evidence which established any nutritional properties of the substance or which had identified a deficiency of calcium pangamate in man or animals, and since no medical, nutritional, or other usefulness for calcium pangamate had been established—403(a); and the article lacked the common or usual name of each ingredient, since "a minimum amount of binder and lubricant" was not the common or usual name for such ingredient—403(i)(2). Default decree ordered destruction. (F.D.C. No. 61103; S. No. 77-21-339; N.J. No. 26)

#### DRUGS/Human Use

##### **Benzthiazide tablets, N.F., at Hollywood, S. Dist. Fla.**

Charged 1-14-77: when shipped in bulk by Drummer Laboratories, Sellersville, Pa., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 60974; S. No. 77-64-507; N.J. No. 27)

##### **Quinidine sulfate tablets, U.S.P., at Dallas, N. Dist. Tex.**

Charged 10-14-76: when shipped by Vitarine Co., Inc., Springfield Gardens, N.Y., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 60946; S. No. 77-66-103; N.J. No. 28)

##### **Quinidine sulfate tablets, U.S.P., and sulfoxazole tablets, U.S.P., at Broomfield, Dist. Colo.**

Charged 9-21-76: while held for sale locally, after manufacture by Cord Laboratories, Broomfield, Colo., using active ingredients shipped in interstate commerce, the articles, labeled in part "Quinidine Sulfate Tablets [or "Sulfoxazole U.S.P. . . . Compressed Tablets"] . . . Manufactured for Geneva Generics Broomfield, Colorado," lacked adequate directions for use and were not exempted therefrom, since they were new drugs without effective approved New Drug Applications; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 60916; S. Nos. 77-73-190/1; N.J. No. 29)

##### **Reserpine alkaloid tablets, U.S.P., at Valley Stream, E. Dist. N.Y.**

Charged 12-17-75: while held for sale, the strength of the article differed from, and its quality fell below, the U.S.P. standards, since it failed the U.S.P. requirements for content uniformity; 501(b). The article was claimed by Marshall Pharmacal Corp., South Hackensack, N.J., who denied the charge. The claimant served a notice to take the depositions of certain Government employees and to produce all test reports. The depositions were subsequently cancelled upon the delivery of FDA analytical worksheets. Thereafter, there were no active pursuits of the matter by the claimant and the Government moved for a default. Default decree ordered the article destroyed. (F.D.C. No. 60558; S. No. 45-969 H; N.J. No. 30)

#### DRUGS/Veterinary

##### **Chloramphenicol solution, unlabeled, at Wakarusa, N. Dist. Ind.**

Charged 3-21-77: while held for sale, the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to its use or intended use—501(a)(5); the article lacked the name and place of business of the manufacturer, packer, or distributor—502(b)(1); the article lacked an accurate statement of the quantity of contents in terms of weight or measure—502(b)(2); it lacked the established name of the drug—502(e)(1)(A)(i); and it lacked adequate directions for use—502(f)(1). Consent decree ordered destruction. (F.D.C. No. 61121; S. No. 77-69-294; N.J. No. 31)

#### DIAGNOSTIC DEVICE

##### **Diagnostic plates containing sheep blood, chocolate, and azide differential agar culture mediums, and bottles of Transgrow medium with CO<sub>2</sub>, at St. Paul, Dist. Minn.**

Charged 2-28-77: the articles, which Diagnostic, Inc., St. Paul, Minn., had prepared using components shipped in interstate com-

merce, lacked labels containing accurate statements of quantity of contents—502(b)(2); the labeling lacked adequate directions for use as specified by regulations—502(f)(1); and the labeling of the articles containing the chocolate agar and Transgrow medium was false and misleading in incorrectly stating the identity and quantity of the ingredients—502(a). Consent decree authorized release to the preparer of the articles for bringing into compliance. (F.D.C. No. 62058; S. Nos. 77-30-237/9, 77-98-341; N.J. No. 32)

#### NOTICE OF JUDGMENT on Criminal Action

##### FOOD

##### **Famous Bakeries, Inc., Max Zeidweg, president, Edward L. Zeidweg, vice president, and Willie L. Ridley, plant engineer, Orlando, M. Dist. Fla.**

Charged on or about 11-9-76 and amended 12-28-76: first clear flour (count 1), high gluten flour (count 2), and spring wheat flour (count 3), were held in a building accessible to rodents and were contaminated with rodent and/or insect filth; 402(a)(3), 402(a)(4). The defendants initially pleaded not guilty. They filed motions for discovery and a bill of particulars. Subsequently, they changed their pleas. Guilty plea by the corporation to counts 1-3; fine and probation. Nolo contendere pleas to count 3 by the individuals; Max Zeidweg—fine; William L. Ridley—probation; and Edward L. Zeidweg—probation. (F.D.C. No. 59488; S. No. 6-629 F; N.J. No. 33)

#### NOTICE OF JUDGMENT on Probation Violation

##### **J. T. Hopkins & Sons, and Charles E. Hopkins, partner, Waycross, S. Dist. Ga.**

Charged 1-9-77 in petition for probation revocation: rice, popcorn, and flour were held under insanitary conditions in a building accessible to rodents and were exposed to contamination by rodents; and the flour was contaminated with rodent filth; 402(a)(3), 402(a)(4). After a hearing before the court, the defendants' probations were revoked. (F.D.C. No. 59491; S. No. 76-00-551 et al.; N.J. No. 34)

#### NOTICE OF JUDGMENT on Injunction Action

##### **Vita Food Products of Illinois, Inc., and Lawrence T. Schweig, president, Chicago, N. Dist. Ill., (Civil Action No. 70-C-2246) and Ewig Bros. Fish Co., Inc., and Eugene W. Ewig, president, Port Washington, E. Dist. Wis. (Civil Action No. 73-1008).**

Charged 9-11-70 and 4-15-71 in complaints for injunction: that the defendants, in Ewig Bros. action, received, after shipment in interstate commerce, fish known as chubs which contained DDT, DDT derivative, and dieldrin; that the defendants in both actions prepared such chubs as smoked chubs, and packed and distributed smoked chubs for human consumption; that, when such smoked chubs were distributed, they contained the nonconforming food additives DDT, DDT derivatives, and dieldrin in that the total amount of DDT and its derivatives in the smoked chubs was in excess of FDA's interim limit of 5 parts per million and in that dieldrin was not permitted in smoked fish; that by the introduction and delivery for introduction into interstate commerce, of such smoked chubs, and (Vita Foods action only) by the preparation, packing, and distribution of such smoked chubs while held for sale after shipment (as raw chubs) in interstate commerce, the defendants violated the law; and that the defendants in both actions were well aware that their activities were in violation of the law; 402(a)(2)(C).

The action against the Ewig Bros. Fish Co., Inc., was consolidated for trial with five actions against distributors of raw chubs (Strege & Rousar Fish Co., et al., q.v. N.J. No. 34 of June 1977 issue of FDA CONSUMER). The Wisconsin District Court found for the Government and against Ewig Bros. Fish Co., Inc., as to enjoining the interstate shipment of smoked fish containing more than 5 parts per million DDT. After a hearing in the Illinois case, the Illinois District Court ruled in favor of Vita Food Products of Illinois, Inc., saying:

"In effect, the government's theory is that the chubs involved herein are adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C) because DDT and dieldrin are 'food additives' under the Act and second since 'their use and intended use are not in conformity with a regulation or exemption' they are 'unsafe' as a matter of law under the terms of 21 U.S.C. § 348(a).

"Defendants' position is 'that any traces of DDT and dieldrin in its smoked fish are not "food additives" within the Act', and that the government's mode of procedure 'seriously perverts the elabo-





rate statutory scheme established by Congress to ensure the safety of food and food additives and that defendants are not now and have not in the past sold any "adulterated" smoked fish.'

"Defendants contend that the government has tried to establish adulteration as a matter of law because it is unable to establish adulteration as a matter of fact and in so doing has ignored the statute.\*\*\*

"DDT is a chemical pesticide which has been used since the early 1940's to control mosquitoes and other pests. Recently, the use of DDT has been reduced by approximately 80% in the United States (tr. 219) and as of January 1, 1972, due to an order of the Environmental Protection Agency, the use of DDT will be almost eliminated. DDT and its derivatives are found in virtually all living tissue. Studies show that these concentrations (8-10 parts per million) in man . . . are decreasing. . . .

"Dieldrin is a far more mysterious substance than DDT although like DDT it finds its way into certain organisms. The most that can be said of dieldrin at this juncture is that its effect has not been fully demonstrated.

"On April 22, 1969, a 'guideline' characterizing 5 ppm as the maximum amount of DDT permissible in fish shipped in interstate commerce was issued in the form of a press release by the F.D.A.

"In ruling on the statutory basis for the F.D.A.'s authority to issue its interim enforcement guideline the Court in *United States v. City Smoked Fish Co., et al.* (E.D.Mich., Memo.Op. 33669, pg. 6, 1970) said:

'Plaintiff concedes that this guideline is neither a "regulation" which the Act empowers it to issue, nor any other species of administrative rule recognized by any relevant or pleaded statute. This guideline is not published in the Code of Federal Regulations, nor apparently in any other published compilation of administrative rules.

'Since there is no statutory authority to issue such an interim enforcement guideline, it follows that defendants' violation of law, if any, must be of the statute itself, in this case The Food, Drug and Cosmetic Act.'

"The Court therein found such violation of the statute. However, I find myself in disagreement with that decision and instead find that DDT and dieldrin are not 'food additives' within the meaning of the Food, Drug and Cosmetic Act of 1939.

"I have come to this conclusion after a careful analysis of the statute, the 1959 'Food Additives Amendment' and its legislative history and purpose.\*\*\*

"It is uncontroverted that defendants herein do not actually 'add' DDT or dieldrin to its product. The chemicals in question are introduced into the chubs by the environment. In no way have the defendants been accused of nor do they deliberately use the named substances in connection with the preparation of their product.\*\*\*

"I find myself in agreement with defendants that if, indeed, DDT and dieldrin traces found in fish are to be considered 'additives' in any sense, they must clearly be considered 'accidental' ones and as such not a 'food additive' under the Act. Thus, I am in disagreement with the government's contention that 'as components of the defendants' chub, residues of DDT and dieldrin are incidental food additives governed by the food additive provisions of the Act.'\*\*\*

"The government has attached as Ex. D to its Trial Memorandum the ruling in *United States v. City Smoked Fish, supra*, in which the Court found:

'It further appears that DDT found in raw chubs is a pesticide chemical and not a food additive within the meaning of the Act. However, the Court concludes that DDT found in smoked chubs is a "food additive", since the chubs are no longer in their raw or natural state as required by the Act.'

"I cannot agree. 21 U.S.C. § 342(a) states that a 'pesticide chemical' remains a 'pesticide chemical' within the meaning of the Act even after the 'raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating or milling.'

"For the above stated reasons, I find that any traces of DDT or dieldrin found in defendants' chubs cannot be labeled a 'food additive' within the meaning of the Food, Drug and Cosmetic Act of 1938.

"The next issue to be resolved is that of whether or not the chubs in question fall within the purview of 21 U.S.C. § 342(a)(1).

"The government has alleged as follows:

'It should be noted that smoked chubs containing residues of DDT, its derivatives or dieldrin in excess of the enforcement guidelines need not be proven injurious to health to be adulterated under the Act. In a long line of cases, the federal courts have held that foods may be adulterated regardless of whether they are injurious to health, unless the particular statutory definition of adulteration expressly requires the Government to prove such injury (citing cases). Since 21 U.S.C. § 342(a)(2)(C) does not require such proof, no injury to health need be shown to establish the adulteration alleged in this case.' . . .

"However, having found that 21 U.S.C. § 342(a)(2)(C) is not applicable, I find that injury to health must be shown in order for the government to prevail. The testimony on this issue was diverse and interesting but in the final analysis not as illuminating nor as definitive as might have been hoped. . . .

"Dr. William Deichmann, an eminent toxicologist, testified in behalf of the defendant\*\*\*

"In response to the question of whether he knew of any disease in humans attributable to DDT the witness replied:

'I have introduced this word on two occasions (DDT-itis), and I made the statement that there is no record of any DDT-itis in this country or any other country. . . .

"Again Dr. Deichmann testified:

'Nowhere in the world does this compound, and I am referring to DDT, present an "imminent hazard" to public health.' . . .

"Thus, I cannot on the basis of the evidence tendered during the course of this trial unequivocally state that DDT is a known health hazard to man.

"A great portion of the trial revolves around the issue of the reliability of the test methodology used by the government to prove that the samples of Vita's chubs involved herein contained DDT concentrates in excess of 5 ppm. The government's test method is referred to as the 'AOAC' method. Although I shall not go into a detailed analysis of the testing procedures I should like to note the following information that was gleaned from the trial testimony.

"No method of testing has been proven to be absolutely reliable. Certain discrepancies that were raised during trial and in defendant's post-trial brief have led me to conclude that the AOAC method is capable of distinguishing between concentrations of DDT in the area of 4 to 9 ppm. Thus, there is always the possibility of a margin of error and I must hold that the AOAC method, when left to be followed by testers provided by food processors in all cases and utilized by government testers only in spot checking on the continuous batch upon batch testing to be performed by the food processors, is incapable of that degree of accuracy which ought to exist to support a court judgment enjoining a food processor from proceeding on in the industry.

"Since September 1971, the American Meat Institute Laboratory (AMI) has been hired by Vita to analyze its chubs for pesticides, using the AOAC method. The AMI Laboratory also analyzes each of the samples which formed the foundation for the case herein. Its analysis showed substantially lower results than did the comparable analysis performed by the FDA chemists. Four of the seven AMI analyses showed readings below 5 ppm and the highest of those above 5 ppm read 5.35. There are numerous other examples of differences between the various methods of testing. Differences in results tended to reflect differences between individual chemists performing the tests.

"The concept 'absolute reliability', like the phrases 'unimpeachable preciseness' and 'perfect certainty', is repugnant to the scientific mind. The most that should be looked for is 'sufficient reliability'—reliability to a degree sufficient for the purpose to be served. The purpose to be served here is not served when the acknowledged degree of exactness has a coefficient of error of plus or minus 25%, and when various tests of the same samples with the same procedures performed by equally qualified persons result in readings varying over a range of one hundred percent.

"From all the relevant data one fact stands out. It is that science has not developed a system which is sufficiently reliable. The AOAC's method is not sufficiently reliable for me to find by the greater weight of the evidence and as a controlling fact that the chubs sampled by FDA in April 1972 contained DDT concentrations in excess of 5 ppm.

"There is in this case uncontradicted evidence tending to show that the level of Lake Michigan chubs generally is less than 5 ppm. Mr. Bernard Lorant, a chemist, testified that based upon all of the test results in evidence (FDA's AMI's, NMFS, and those of WARF) . . . the incidence of DDT and its analogs in Lake



Michigan chub are at or below 5 ppm. . . .

"In summary, I find that 21 U.S.C. § 342(a)(2)(C) is not applicable since DDT, derivatives of DDT and dieldrin found in Vita's smoked chubs are not 'food additives' under the Act. I find that DDT, derivatives of DDT and dieldrin as found in Vita's smoked chubs are not a known health hazard within the meaning of 21 U.S.C. § 342(a)(1). I find that the test method to be used by processors of smoked chub is not sufficiently precise for a finding of fact that the chubs sampled in April 1972 contained DDT concentrations in excess of 5 ppm.

"It should be made crystal clear that these findings do not open the gate to an area of abandonment of concern on the part of processors of food. Neither do they restrain the Food and Drug Administration from pursuing a severe program of monitoring processors of smoked fish in its effort to keep out of interstate commerce food that constitutes a known health hazard. I have been presented in this case just one matter and my findings are technical ones. By the greater weight of the evidence and by the applicable law the allegations of the complaint against these defendants have not been sustained."

The Government appealed such adverse decision in the Vita Food Products of Illinois, Inc., case.

Meanwhile, together with the five distributors of raw chubs, Ewig Bros. Fish Co., Inc., appealed. The court of appeals affirmed the injunctions against the raw chub distributors; but, because Ewig Bros. Co., Inc., was a distributor of smoked chub and that firm's case presented different issues, the Ewig Bros. Co., Inc., case was held for further oral argument and the disposition of the appeal involving Vita Food Products of Illinois, Inc.

Thereafter, the court of appeals ruled for the Government and against the distributors of smoked chub. The court of appeals said:

"There are two ways to state the principal question presented by these appeals. Narrowly, the issue is whether residues of DDT and dieldrin in smoked chubs are 'food additives' within the meaning of § 201(s) of the Federal Food, Drug and Cosmetic Act. A somewhat more disturbing way to state the same question is whether all of the fish in the Great Lakes are 'adulterated' as a matter of statutory definition. If they are, the Administrator may have, at least for the present, virtually unbridled power to eliminate all such fish from our food supply. We therefore attach special importance to the additional questions presented in the *Vita Food* appeal. That appeal, unlike the *Ewig Bros.* appeal, requires us to consider the legal significance of an 'interim guideline' announced in a press release on April 22, 1969, as well as the district court's findings that the testing methods used by the government's experts were not sufficiently reliable to demonstrate that Vita's smoked chubs contained more DDT than the guideline permits.

"A total ban on the future use of DDT would not resolve the problem presented by this case. Although the levels of DDT contamination are declining, we must assume that the chemical, or its derivatives, will survive as an ingredient of all or most foods for some time.

"Scientists seem to agree that if the DDT level is high enough, the food should not be consumed by man and, conversely, if the amount is sufficiently small, ingestion of DDT may be harmless. Danger levels have not been precisely defined. The record demonstrates, however, that in fish levels in the range of 5 parts per million are neither (a) generally recognized among qualified experts as safe, nor (b) demonstrably injurious to health or unfit for human consumption. At the levels disclosed by the record before us, the effect on human health is somewhat uncertain. \* \* \*

"In this case the government's claim that defendants' chubs are 'adulterated' is not predicated on a claim that the particular fish defendants sell contain a poisonous substance or are otherwise unfit for food pursuant to either subparagraph (1) or subparagraph (3) of § 402 of the F.D.C.A. Under those subparagraphs the government would have the burden of proving that the fish are actually harmful to man. Instead, the government's claim is predicated on § 402(a)(2)(C), under which it need only prove that 'such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use . . . ." § 201(s) of the F.D.C.A., 21 U.S.C. § 321(s).

"It is the government's position that a fair analysis of the statutory scheme Congress has enacted, including the allocation of decision-making responsibility between the agency and the judiciary, justifies proceeding under this section. For if, as the govern-

ment contends, DDT is a food additive, the Food and Drug Administration may itself decide when products containing quantities of DDT should be removed from public consumption, without having to rely upon the decisions—possibly inconsistent with one another—of different federal judges determining danger to health under §§ (a)(1) and (a)(3) on a case-by-case basis.

"The question, then, is whether DDT and dieldrin in defendants' processed fish are 'food additives' within the meaning of § 201(s). \* \* \*

"The legislative history of the 1958 Bill indicates concern about the difficulties present when dangerous substances could not be proscribed by per se rules. Since Congress used broad language in order to eliminate such difficulties, we should not construe it narrowly. The language . . . defines a food additive as *any* substance, 'the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . .' Although Congress was primarily concerned with substances used by a food processor, neither the language nor the history of the 1958 Act limits its application to such substances. The words 'the intended use of which' are not confined, as they easily could have been confined, to use in food processing.

"Vita has argued that a process, such as smoking, during which nothing new is added to a food, cannot 'transmogrify' a preexisting component of a food into an additive. But whether the food be fish, fruit, or meat, if the component is a pesticide chemical, we think that is exactly what Congress intended.

"Although it may seem odd to place the label 'additive' on a chemical substance which was a component of the raw product and which is not changed by processing, Congress' choice of that label does not result in any 'transmogrification.' Before processing, DDT is a 'pesticide chemical' on a raw product; after processing, it is an 'additive.' Since there is no tolerance for DDT on fish, both before and after processing the presence of the DDT causes fish to be adulterated without any proof that it is actually unfit as food. Defendants' contention, if accepted, would result in the anomaly that a chemical such as DDT would adulterate all raw fish, but adulteration of processed fish would be determined on an uncertain case-by-case basis. We conclude that such a construction of the statute is illogical and unacceptable. \* \* \*

"Vita Food argues, in the alternative, that even if DDT and dieldrin are food additives, we should nevertheless affirm because the government failed to prove that residues of these chemicals exceeded the limits specified in the F.D.A. interim enforcement guidelines. In its opinion the district court stated that there is never 'perfect certainty' in any scientific analysis and that the government's test methods were 'not sufficiently reliable for me to find by the greater weight of the evidence and as a controlling fact that the chubs sampled by FDA in April 1972 contained DDT concentration in excess of 5 ppm.' . . .

"Neither party has contested the applicability of the F.D.A.'s 5 ppm enforcement guideline. Nevertheless, it is clear that the government might have argued that the enforcement guideline was merely adopted as an internal standard to determine when it would be appropriate to initiate an enforcement proceeding, and that publication in a Press Release was merely intended to give industry fair notice of its internal standards. By way of analogy, a police department might adopt a policy of not enforcing a 55 mile speed limit unless a motorist's speed exceeded 65 miles per hour. Under such a policy, at a trial it would not be necessary to prove anything more than a speed in excess of 55. By comparison, the F.D.A. might as a matter of discretion withhold enforcement unless it found residues of over 5 ppm, but have no legal obligation to prove anything more than a trace to establish statutory adulteration.

"We do not so interpret the interim guidelines before us in this case; for both the language of the Press Release and the government's treatment of it in this case indicates that it was meant to operate more like a rule of general applicability than a mere prediction of how the agency would choose to exercise its prosecutorial discretion. Accordingly, even though the government was not obligated to adopt any interim guideline, and might have let industry accept the responsibility for initiating tolerance proceedings, it correctly assumed the burden of proving that appellant violated the specified limits.

"The district court considered the AOAC method of testing for chemical residues insufficiently precise for the government to sustain its burden. It is clear, however, that the enforcement guidelines must have been adopted on the assumption—shared by





government and industry—that existing methods of testing DDT were sufficiently accurate to permit meaningful administration of the limits specified therein. The AOAC method was used by both the government technicians and by the expert employed by appellant. However imprecise that method may be, the record indicates that it is the best method that can be used. Certainly the government must be permitted to use the best testing method yet devised by analytical chemists, for the enforcement guidelines must have been predicated upon that method. Therefore, without disagreeing with the district court's observation that the AOAC method falls short of perfect certainty, we cannot accept the view that it may not be used to evaluate appellants' compliance with the guidelines. The district court's contrary determination was clearly erroneous.

"Acceptance of the AOAC method as the proper standard for measuring residues of pesticide chemicals in fish leads inexorably to the conclusion that the government met its burden of proving repeated violations of the guidelines. \* \* \*

"Vita argues, however, that there really is no significant difference between DDT levels of 5 ppm and levels as high as 8 ppm. But that is an argument that should not be addressed to us; it may properly be asserted as a reason for setting a tolerance at 8 ppm or perhaps even higher. The F.D.A. need not have set its guideline limit at 5 ppm, but it did so, and industry has not seen fit to invoke the statutory procedures for establishing a different tolerance level. In these circumstances, the government has met its burden by proving that the guidelines have been exceeded repeatedly.

"The judgment in *United States v. Vita Foods* is therefore reversed and remanded for the entry of appropriate relief. In view of the nature of the case and the trial judge's familiarity with the technical materials in the record, Circuit Rule 23 shall not apply.

"The judgment in *United States v. Ewig Bros Co.* is affirmed."

In accordance with the ruling of the court of appeals, the case involving Vita Food Products of Illinois, Inc., was remanded to the district court for the entry of an appropriate injunction. Vita Food Products of Illinois, Inc., litigated the terms of the Government's proposed injunction because the defendants felt that such proposed injunction was unnecessarily broad, because the case dealt only with Lake Michigan chub and the proposed order applied to any fish, because the proposed order required the establishment of "appropriate procedures" for analysis of samples without specifying what the procedures would be, and because the proposed order applied to Lawrence T. Schweig although he had left the defendant firm. The parties also litigated matters concerning interrogatories, the taking of a deposition, and the use of postjudgment discovery.

The district court entered the Government's proposed order, saying:

"Defendants have objected to the proposed order on the ground that it is 'unnecessarily broad in that it applies to any species of fish taken from waters anywhere in the world.' While the evidence introduced at trial may not have related to all species of fish handled by the defendant company, the appellate court found the evidence to be 'uncontradicted' that the Act had been violated; in fact, the appellate court found that the government proved the legal guidelines had been 'exceeded repeatedly.' The relevant guidelines involved levels of DDT and dieldrin, and the evidence did show that all species of fish handled by the defendant company were likely to contain some residues of DDT and dieldrin. Furthermore, plaintiff's complaint did pray for an order of relief relating to all fish handled by the defendant company. And finally the defendants themselves concede that the Court has the power in a case as this 'to frame an injunction which will provide whatever relief is necessary to protect the public, including an injunction whose provisions exceed the specific acts established by the complaint or hearing.' . . .

"Finally, the defendants have objected to the inclusion of Lawrence T. Schweig within the proposed order. In part, their objection is based upon Mr. Schweig's alleged disassociation from the defendant company. Yet, such a disassociation has not been formally made part of the record. Rule 65(d) of the Federal Rules of Civil Procedure also seems relevant.

"While I have decided to enter the government's proposed order, I have also decided to stay the execution of the order for ten days to allow the defendants to move for relief from the order, if they so wish. Such a stay seems appropriate, since the defendants' objections to the proposed order were based upon alleged

relevant factual changes since the time of trial."

After the entry of the order of permanent injunction, Michael J. Tooley was substituted as a party defendant in place of Lawrence Schweig. The defendants also moved that the injunction be modified. In denying such motion, the court said:

"Pending are several motions by the defendants relating to their request for modification of the order of permanent injunction entered on June 13, 1975. Defendants contend modification is appropriate under Rule 60(b) of the Federal Rules of Civil Procedure; among other things, they argue that the record does not support the order that was entered and that the order is unnecessary for the accomplishment of the government's purposes. The government counters by asserting that the 'defendants seek to relitigate this case with respect to certain provisions of the order.'

"Although the parties disagree as to which subdivision of Rule 60(b) is applicable, it appears beyond doubt that this Court has jurisdiction to entertain the pending motions. In fact, execution on the injunctive order was stayed so as 'to allow the defendants to move for relief.' However, the stay was entered only because the defendants' earlier objections 'were based upon alleged relevant factual changes since the time of trial.'

"The substance of the pending motions concerns the appropriateness of certain provisions in the injunctive order in light of the evidence adduced at trial and of the appellate court's mandate. These motions thus essentially seek a reconsideration of the order based upon the existing record rather than upon any factual changes since trial. The defendants did note in one legal memorandum, however, that they expect 'to produce facts showing that DDT concentrations have continued to decline since trial;' yet such facts have not been forthcoming. After reviewing the existing record, I am still of the opinion that the terms of the injunctive order are proper and within the scope of the original complaint, the evidence at trial, and the appellate court decision. As noted in my earlier memorandum opinion and as recognized by the defendants, this Court has the power to frame an injunction whose provisions exceed the specific acts established by the complaint or hearing.

"Accordingly, defendants' motion for a hearing and related motions are hereby denied. This denial is without prejudice to any future modification request(s) based upon alleged relevant factual changes since the time of trial and sufficiently supported by facts demonstrating entitlement to relief. . . .

"Motions denied. It is so ordered and decreed."

The defendants in the Vita Food Products of Illinois, Inc., case filed an appeal and the defendants also moved to suspend, pending an appeal, the execution of the injunction or to modify it so as to require sampling and testing of chub only. After a hearing before the district court, the defendants requested that their appeal be dismissed. (Inj. Nos. 585 & 600; S. Nos. 89-776 C et al., 23-723 D et al.; N.J. No. 35)

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

Donald Kennedy, Commissioner of Food and Drugs  
Washington, D.C., September 1, 1977



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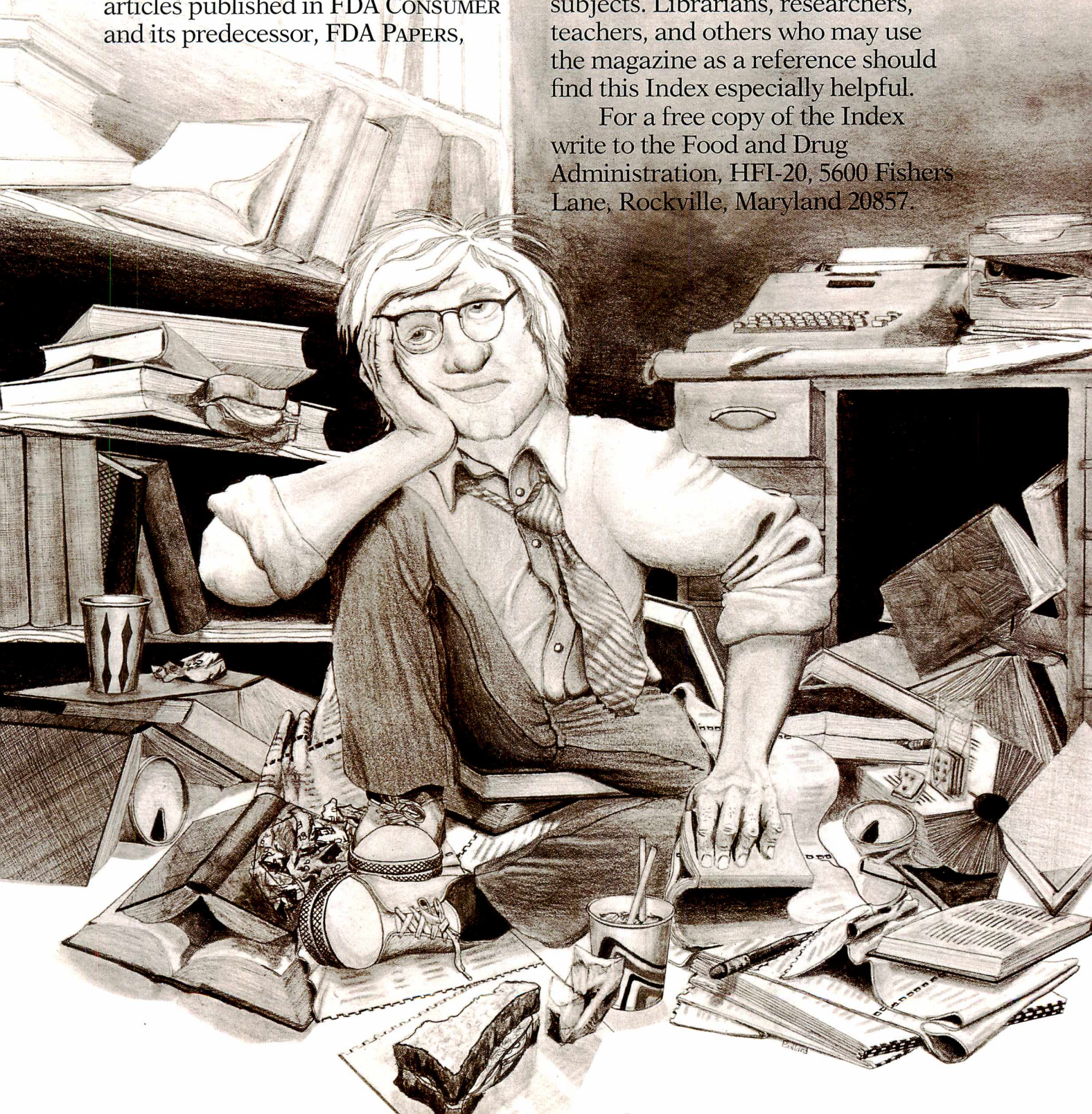
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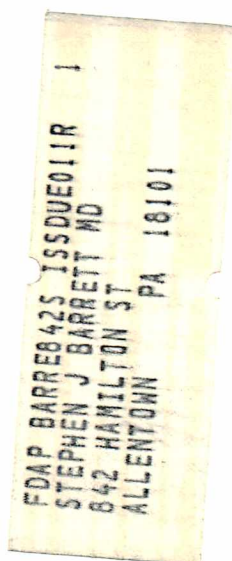




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