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# CONSUMER



**Consumers  
Talk About  
Labeling**

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## This Month

**T**he development of a new drug is a lengthy and complex procedure involving many elements of the American economic and medical systems. This month FDA CONSUMER presents a simplified view of how a new drug is added to the medical arsenal, from the first steps—the discovery of a chemical—to the final one, use by a patient. The story, “A Primer on New Drug Development,” also describes FDA’s role in the process.

In addition to its regulatory control of drugs manufactured in the United States, FDA also is concerned with those made abroad and imported into this country. In the past 8 years, FDA consumer safety officers have traveled to 30 countries on five continents to help overseas manufacturers assure that drugs they export to the United States meet American standards. The story beginning on page 8 discusses how this important FDA program works.

“Consumers Talk About Labeling” reports on an FDA survey which sought to find out how consumers perceive the labels on foods, prescription drugs, and over-the-counter medicines. The survey is part of FDA’s ongoing efforts to make sure that the information on labels meets consumer needs.

With this issue, FDA CONSUMER, formerly FDA PAPERS, enters its eighth year of publication. The response to the new direction this magazine has taken since July 1972, when it was renamed FDA CONSUMER, has been encouraging. During the next year, we hope to continue to provide a service to the public by presenting articles about the products and issues in which consumers are most interested. We encourage you to speak out as well, through Consumer Forum (page 2).

# Consumer Forum

## DES and the Law

On page 5 of the July-August 1973 issue of the FDA Consumer, P. B. Hutt states, "And in most instances where they (the anticancer clauses in the statute) have been an issue the matter has been resolved using sound scientific judgment based on general principles of food safety before it was necessary to even consider invoking them."

On page 7, after discussing the unreliability of animal tests, the author states, "As a matter of practical necessity, therefore, we often regulate more out of fear of the unknown than out of respect and appreciation of the known." And again, "... today's decisions on the safety of food and drugs will therefore inevitably be made on the basis of incomplete scientific information." Also, "... the significance of much of the animal safety testing today is poorly understood, and the widely variable results obtained are subject to different interpretations. Its usefulness in the design of sound public policy under these circumstances is unfortunately limited."

Consider the quotes from these two pages. One wonders how sound the judgment can be when it may be based on fear of the unknown, tests of which the significance is poorly understood, or inevitably, on incomplete scientific information.

The page 5 quotation continues on, "As a practical matter, therefore, the anticancer clauses are a relatively insignificant factor in the daily administration of the safety provisions of the law."

It has been estimated, on the basis of experimental and practical observation, that feeding previously prescribed levels of DES to beef cattle affected the production of 10 percent more finished weight on a given amount of feed. On the basis of recent beef production data, and allowing only a conservative retail value, the ruling which forbids the use of DES is costing a far from insignificant billion dollars per year.

Any system which permits the administration of DES to women in a total dosage over a

5-day period of 250 mg. as a morning-after contraceptive, and at the same time decides that it is unsafe for these same women to consume beef liver containing perhaps 20 micrograms of DES per kg., has some serious flaws. That specific part of the law that leads to such a situation obviously is ridiculous and should be changed.

W. Donald Graham, Ph.D.  
Director  
Product & Process Research  
Farmland Industries  
Kansas City, Missouri

*The thrust of the Federal Food, Drug, and Cosmetic Act and indeed of most consumer protection laws is in favor of public health protection. Agencies such as FDA are legally and morally required to act conservatively, and thus to take whatever measures enhance public health in light of the admittedly incomplete scientific information available.*

*The Delaney anticancer clause to which you refer was not invoked in disapproving DES in animal feed and animal implants. When residues were found in beef cattle, the Commissioner concluded that such residues had not been proved to be safe and thus, under the law, could not be permitted. This determination was made under the general safety provisions of the law, not under the Delaney clause.*

*The use of DES as a post-coital contraceptive on a single occasion, to make an abortion unnecessary, has entirely different public health ramifications than the continuous consumption by the entire American public of low levels of DES residues in beef livers. The two are obviously not comparable. DES is used as a post-coital contraceptive with the patient's informed consent, but the consumer has no way of knowing whether DES is in the liver she buys. Use of DES as a post-coital contraceptive is in lieu of an abortion, whereas DES in animal liver is intended for no human therapeutic use whatever.*

---

**Caspar W. Weinberger**  
Secretary, U.S. Department of  
Health, Education, and Welfare

**Charles C. Edwards, M.D.**  
Asst. Secretary for Health

**Alexander M. Schmidt, M.D.**  
Commissioner of Food and Drugs

**John T. Walden**  
Acting Asst. Commissioner  
for Public Affairs

---

**Wayne L. Pines**/Editor

**Harold C. Hopkins**/Editorial Director

**Jesse R. Nichols**/Art Director

**Joan M. Galloway**/Managing Editor

**Frederick L. Townshend**/Production Mgr.

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**FDA CONSUMER** was previously known as **FDA PAPERS**.

Section 705 [375] of the Food, Drug, and Cosmetic Act:

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

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

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# Consumers Talk About Labeling

*FDA conducted a survey to find out how consumers read food, nonprescription drug, and prescription drug labels. Here is what FDA found.*

by Charles A. Nicholls  
and Margaret Morrison

Going to the supermarket is as much a part of the routine with American families as driving the car or looking at television. Almost all the necessities of life, and many of the luxuries, can be found in either the supermarket or the super drugstore, and we now have more products to choose from than people would have dreamed of a half-century ago.

In so vast a marketplace, one of the best ways to be sure of getting the product you really want and need is to read the labels — on foods, cosmetics, drugs, or any product you plan to take home and use. Reading labels is especially important when the product affects your or your family's health.

The Food and Drug Administration is the Federal agency that is responsible for making sure the information on labels of foods and drugs is useful, honest, and accurate. To help determine how it might plan more effective policies regarding labeling, FDA last year conducted a survey of consumers to learn their understanding and acceptance of labeling on foods, over-the-counter drugs, and prescription drugs.

FDA is now engaged in several programs to upgrade the labeling of foods and medicines. The Agency has promulgated far-reaching regulations to make the information on food labels uniform,

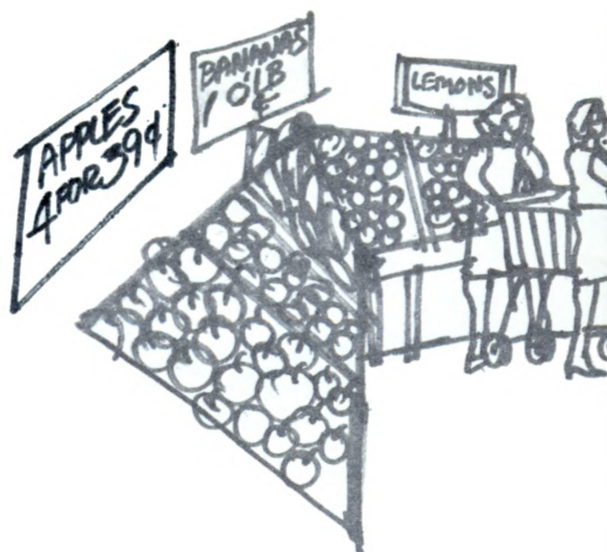
understandable, and useful. One aspect of this program, which has been announced over the past year, is nutrition labeling (see *FDA CONSUMER*, September 1973). FDA also is engaged in an extensive study to assure more accurate and uniform labels on nonprescription drugs.

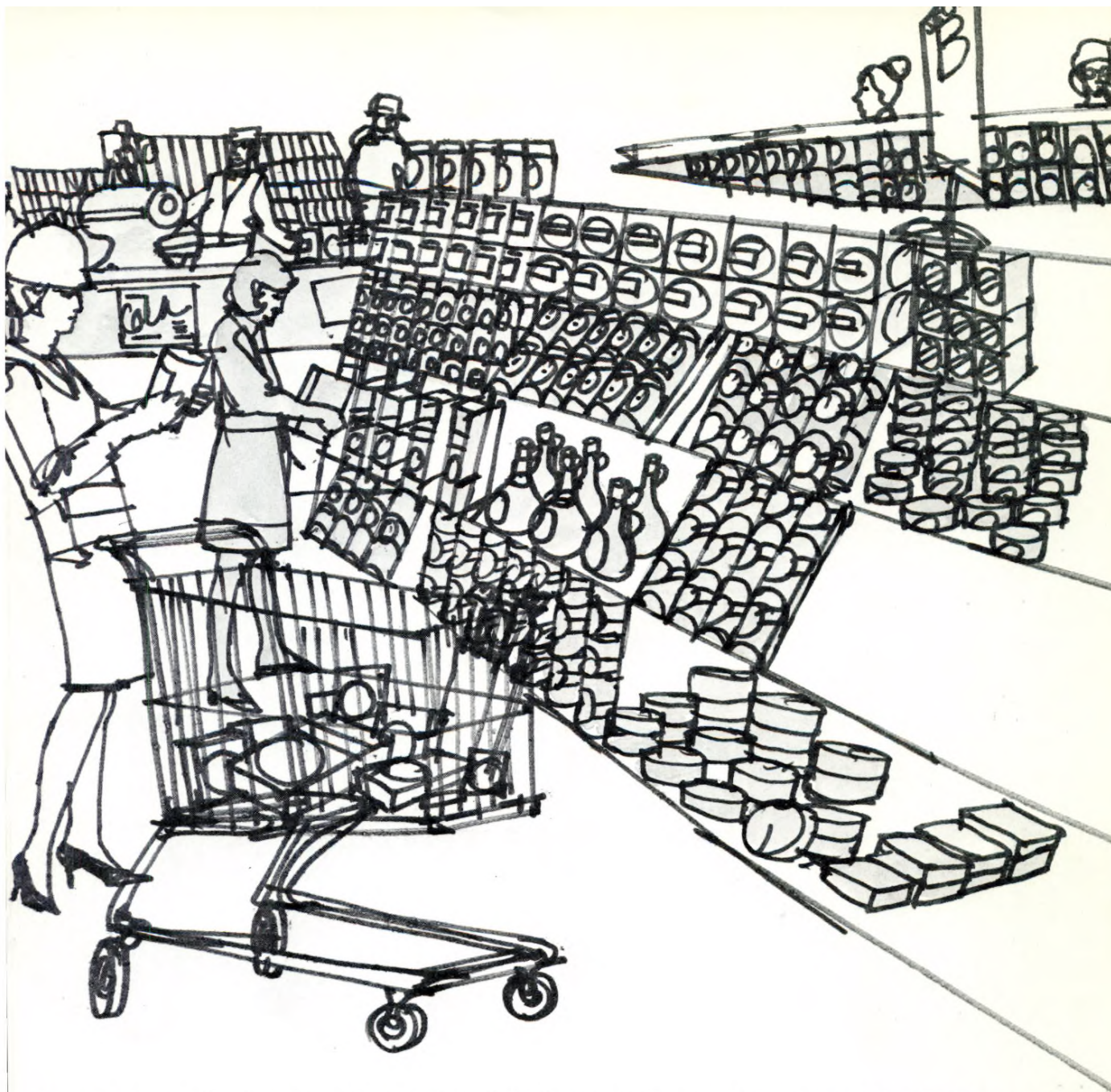
The information from the survey also influences FDA's planning of its consumer education programs. The data provide an insight into what areas of labeling are most confusing to consumers, and what types of information they expect to

see. FDA is now developing mass media public service campaigns to educate the public on the reading of nutritional labeling on foods and labels on nonprescription medicines.

## How the Study Was Made

An "area probability sample" was used in this study of consumers' understanding of labels. The total United States was divided into a large number of sampling areas, and one hundred of these areas were selected to be included in the national sample. The sampling included both urban and rural areas;





consumers questioned were 18 years of age or older, either male or female; and the study was conducted so that results are projectable to a population base of 136.1 million adults, which was the civilian noninstitutional population of the continental United States in the winter of 1973.

#### **Food Labeling**

With so many new food products being introduced each year, today's shoppers often are in a situation where they select a product they have not used before. When buying

a packaged food product for the first time, two-thirds of all shoppers say they are concerned about economic factors, such as price, volume, or weight. One-third of the shoppers buying a food product for the first time look for a listing of ingredients. Only 5 percent of these shoppers look for a list of additives, and another 5 percent look for nutrient content, such as minerals, vitamins, fats, carbohydrates, and calories.

Ingredients have been listed on food labels for at least the past 50 years, and apparently consumers

have come to take this for granted. When buying a food product for the first time, consumers believe and expect that a label will contain more information than they actually look for. For example, while 33 percent of shoppers look for ingredients on a food package, 62 percent believe the ingredients are listed there.

Members of the household who do more than half of all food shopping tend to read labels to a greater extent than other members of the household. About 30 percent of these "heavy shoppers" read prac-

tically all food labels on products purchased for the first time.

The survey found that young people tend to read labels more than older ones. However, among people over 65 years of age, a paradox exists. This age group has the highest percentage of those reading almost all the labels, as well as those reading none of the labels. One explanation may be that one segment of the population may be highly concerned with ingredients, for dietary purposes, and another segment may not even do any food shopping.

When asked to compare a less expensive food to a more expensive one, in terms of nutritional value for the money, slightly more than half of the consumers felt that the less expensive food has better nutritional value; about 25 percent believed it has poor nutritional value; and only 6 percent believed it has the same value. In FDA's view, there is no established relationship between price and nutritional value.

The survey showed two-thirds of the consumers understand that there is a difference between *ingredient* labeling and *nutritional*

labeling, but one-third believe the two words mean the same. This is one of the reasons for FDA's developing an educational program on nutritional labeling.

When the meaning of ingredient labeling was explained, 84 percent of the consumers said they thought they could do a better job of evaluating products if *all* products carried ingredient labeling.

About three out of five consumers want all the ingredients listed on the label. Of this group, more than half would like to see percentages for each ingredient. About 13 percent prefer to have only those ingredients in excess of 1 percent listed on the label. The more educated segments of the population want only the major ingredients listed, while the less educated want all ingredients listed.

Of the information items on the label, only one—selling price per unit—is related to income. As would be expected, the higher the income the less concern with the price.

The better educated consumers (those with at least some college) differ from the less educated in at least two respects: (1) they look

for more things on a label, and (2) they are more sensitive to economic information and description of contents.

Advertising through the various media is the largest source from which consumers obtain information about packaged foods they buy for the first time; nearly three out of five consumers cited advertising as a source. Labels on the package or wrapper were mentioned by 28 percent, and store displays by 11 percent. About one-fifth of the consumers buy on information they receive from friends and relatives.

### Labeling of Nonprescription Drugs

American consumers are buying millions of dollars worth of over-the-counter medicines every year. FDA wanted to learn what factors influence their selections most, when buying a new OTC drug.

Advertising was mentioned most frequently as the source of information. Recommendations of friends, relatives, druggists, and doctors were also major sources, while the label was ranked fifth.

When buying a nonprescription drug for the first time, consumers said the most significant parts of the label were what the medicine is used for and the trademark.

About 50 percent of the consumers read *almost all* the label on over-the-counter drugs, and 18 percent usually do not read *any* of them. Reading of labels is closely correlated with the presence of young children in the household.

When consumers who said they did not read labels were asked, "Why not?", 42 percent stated that they were already familiar with the products they buy. When those who do read drug labels were asked what specifically they look for on a label, the most frequently given answers were:

1. What it treats, relieves, cures, or prevents
2. Directions for use, dosage, when to stop using
3. Specific mention of active ingredients, side effects, and cautions (who should not take it)

Approximately 80 percent of the





consumers say that nonprescription drug labels are clearly or fairly understandable. Only 5 percent say they are not understandable at all.

When those who felt that nonprescription drug labels were not clearly understandable were asked what they found difficult to understand, the most frequently mentioned things were the nature of the words (i.e., the words were too long, too technical, medically or chemically oriented), and the names of the ingredients were difficult to read.

When asked whether they believed more information should be made available regarding OTC drugs, slightly less than half of the consumers said "yes." In general, those who wanted more information were younger, better educated, had young children, and were on a diet at the time.

Those who said they would like more information most frequently wanted it on side effects, ingredients, and what the medicine is supposed to do.

When these same people were asked how this additional information should be made available, 86 percent stated that the information should be in a written form that could accompany the medicine, written in a way they could understand. About 20 percent said that they would like to have this additional information presented on TV or in magazines and newspapers.

The survey found that the main purchasers and decision-makers in nonprescription drugs are women.

Among the 17 different types of nonprescription drugs commonly used in the home, not a single one was considered by most users to provide a cure. For 15 of them, it was felt by a vast majority of people that they provided relief. However, for "cold remedies," 20 percent believed that the medicine provided a cure for their cold. FDA believes consumers should understand that nonprescription drugs are capable of relieving symptoms, that they should not be taken to cure diseases.

### **Labeling of Prescription Drugs**

Prescription drug labeling has traditionally been limited to physicians and pharmacists. In 1971, increased consumer demand for information on oral contraceptives, and the special circumstances needed for their safe use, convinced FDA that labeling for this class of prescription drugs should be made available to consumers. In the future, FDA may consider making available to the public the labeling of other special types of prescription drugs if the Agency believes such labeling is needed.

The most frequently mentioned items that people thought were on prescription labels were directions for use, doctor's name, and who the medicine is for. More than twice as many people recalled "Directions for use" than the next most mentioned item, "Doctor's name."

Two out of three individuals believed that most prescription labels were clearly understandable. The others had some difficulty in understanding them. One out of 12 consumers said the labels were not understandable at all.

When those who did not feel that most prescription labels were clearly understandable were asked why, they most frequently mentioned that labels do not have enough information (31 percent), the use of technical language (26 percent), and that ingredient listing is not understandable (19 percent).

When consumers were asked whether they believed more information should be made available regarding prescription drugs, slightly less than half said "yes." The demographics of those wanting additional prescription information is identical to those wanting additional nonprescription drug information.

Those who said they would like more information on prescription drugs most frequently wanted it on:

1. Names/quantities of ingredients (36 percent)
2. What the medicine is for (29 percent)
3. Adverse side effects, cautions to take, and whether or not it is habit forming (24 percent)

When these same people were asked how this additional information should be made available, 84 percent stated "in a written (form) that comes with the medicine but in a way you can understand."

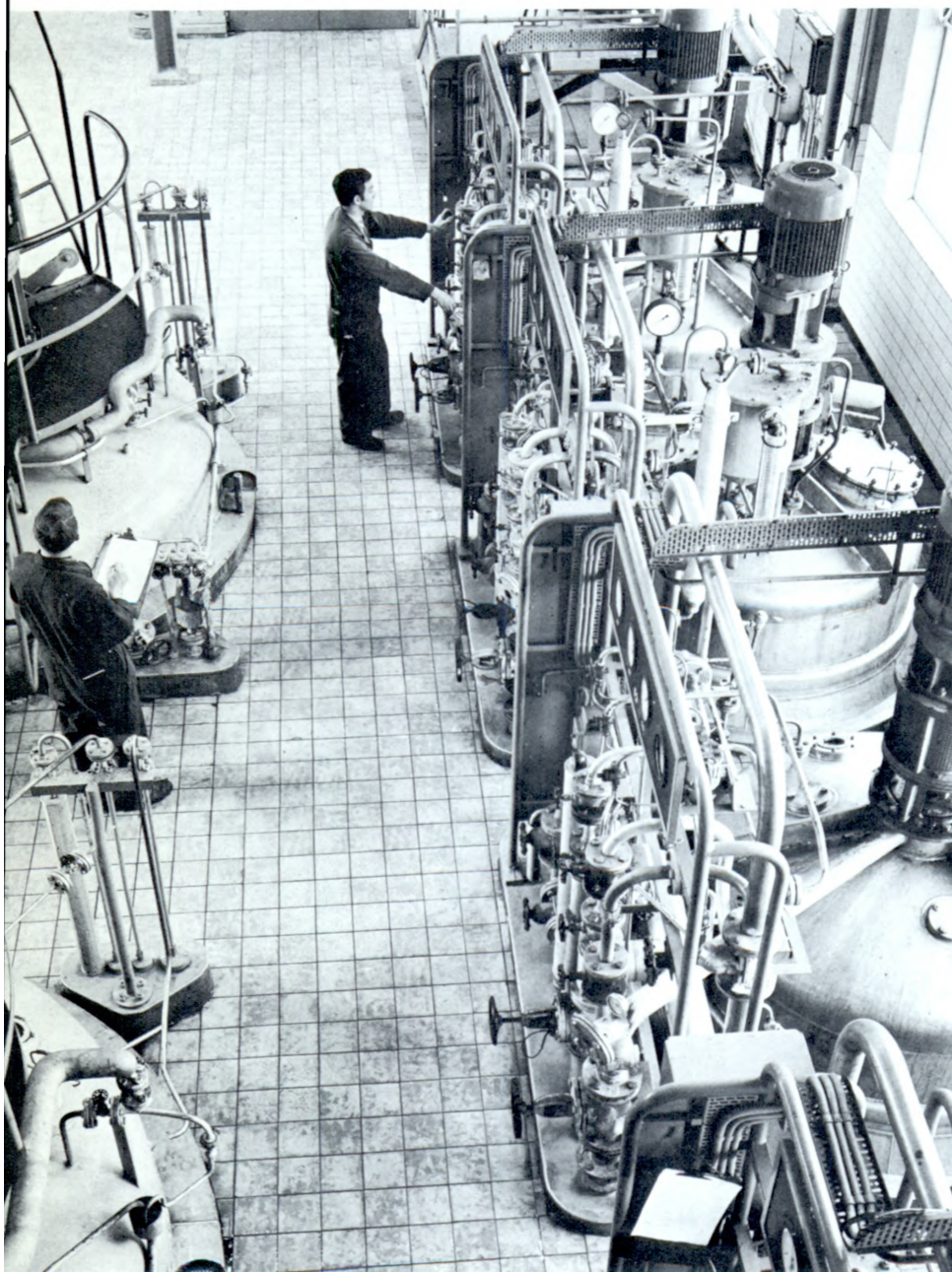
### **In Conclusion**

FDA regulations and programs are based on the Agency's responsibility to assure that the American food and drug supply is safe for use and honestly labeled—and in the case of drugs, effective. Making sure food and drug labels provide adequate and full information is a vital part of this mission. With a better knowledge of consumers' understanding of labels, and consumers' needs in regard to labeling, the Agency can move forward with programs to assure the kind of information on labels that will be the most useful to all segments of the population.

Charles A. Nicholls was on the Consumer Safety Statistics Staff in the office of the Assistant Commissioner for Planning and Evaluation, Food and Drug Administration. He is now with the Consumer Product Safety Commission.

Margaret Morrison is a writer on FDA's Consumer Education and Information Staff.

# Making Sure Imported Drugs Meet American Standards



*FDA inspects foreign manufacturers to make sure that drugs exported to the United States meet American standards. The aim is to assure that all drugs available in the United States meet the same rigid standards for safety.*

by Margaret Morrison

**I**n the past 30 years, unprecedented advances in medicine and drugs have resulted in greatly improved medical care for most people of the world.

Each year, American pharmaceutical companies produce millions of dollars worth of drugs, to supply the country's tremendous demand. Consumers expect these products to be of high quality and safe for use, and one of the responsibilities of the Food and Drug Administration is to see that they are.

As foreign manufacturers have expanded into our markets with other products, so, too, have they become increasingly active in producing drugs for export to the United States. With varying manufacturing standards prevailing in other countries, how could FDA assure that foreign-made products were being produced properly?

Part of the answer has been the on-site inspection of foreign facilities producing pharmaceutical products for export to the United States.

*Gist-Brocades, a biochemical plant in Delft, Holland, exports products to the United States.*

In the past 8 years, FDA inspectors have been invited to 30 countries, on five continents, in a program to assure that drugs being sent to the United States meet American standards.

This program enforces the section of the Food, Drug, and Cosmetic Act which requires that antibiotic drugs be certified by FDA, and regulations which require companies that want certification, and whose manufacturing plants are outside the United States, to undergo an annual inspection of their facilities, for which they pay.

In addition, foreign firms that want to market a new drug product in the United States must submit to FDA—as do domestic firms—a New Drug Application (NDA); and firms that want to clinically test an Investigational New Drug (IND) must also obtain FDA approval. The regulations apply also to companies that supply ingredients to the manufacturers whose drug products are being sold in the United States.

It was in 1955 that the first foreign firm began using FDA's certification services. Later, others became interested; and in the early 1960's, the inspection program increased considerably, after the Department of Defense began a policy of buying both antibiotic and non-antibiotic drugs from qualified foreign manufacturers. The accompanying chart shows how the foreign inspections program has grown during the 19 years since it began. During fiscal year 1973, 88 foreign firms were inspected, in 23 countries.

The office in FDA with the responsibility for foreign inspections is that of the Executive Director of Regional Operations (EDRO). The inspections are performed through the Foreign Inspection Program of EDRO's Field Investigation Branch. This office selects, from FDA's District Offices, the most highly qualified consumer safety officers who want to participate in the foreign program.

The planning of each trip begins many weeks before the consumer

safety officers are to depart. FDA's Bureau of Drugs requests the inspections. For example, the Bureau may request the inspection of a firm in a foreign country which has submitted a New Drug Application (NDA) for a product to be sold in the United States. Or, the Bureau may request up-to-date inspection of a plant in a neighboring country which has held an NDA approval for a number of years. The request may be for inspection of a firm that was denied NDA approval on a first inspection, but which says it has now completed corrective work to bring its facilities up to U.S. standards.

The Foreign Inspection Office coordinates these requests for inspection and formulates a travel plan that will make possible the inspection of a number of firms on one trip. Funding for the trip comes from an FDA budget for foreign travel. Usually, two categories of funds are used: funds deposited in advance by the antibiotic manufacturers who have requested the inspection; and FDA funds allocated for the inspection of drug firms other than antibiotic manufacturers.

One or two consumer safety officers from District Offices are then chosen for the projected trip. They are brought first to FDA's Rockville, Maryland, headquarters for a briefing. Staff members of the Bureau of Drugs talk with them about the planned inspections and about any particular areas they want checked. The officers review previous inspection reports on the firms they will visit.

An inspection trip in May and June of 1973 is rather typical of the program. Charles M. Edwards and Philip Brodsky, both in FDA's Philadelphia office, were selected to inspect eight manufacturing plants in France, Germany, and Spain. Departing from Dulles International Airport outside of Washington, D.C., they flew directly to Paris, where they were to inspect several plants in the suburban Paris area.

One of these was the first inspection of an antibiotics plant.

Others were reinspections of plants which had previously been inspected and found acceptable. One plant, which had been approved for production of antibiotics, was inspected on this trip for the production of an ingredient for export to an American manufacturer. Other inspections were carried out in Mannheim, Germany, in the town of Leon in northern Spain, and in Madrid.

Between inspections, the officers prepare reports on each inspection. Frequently, the officers have to use their ingenuity in adjusting to changes from the original travel plan and arranging for transportation from one place to another.

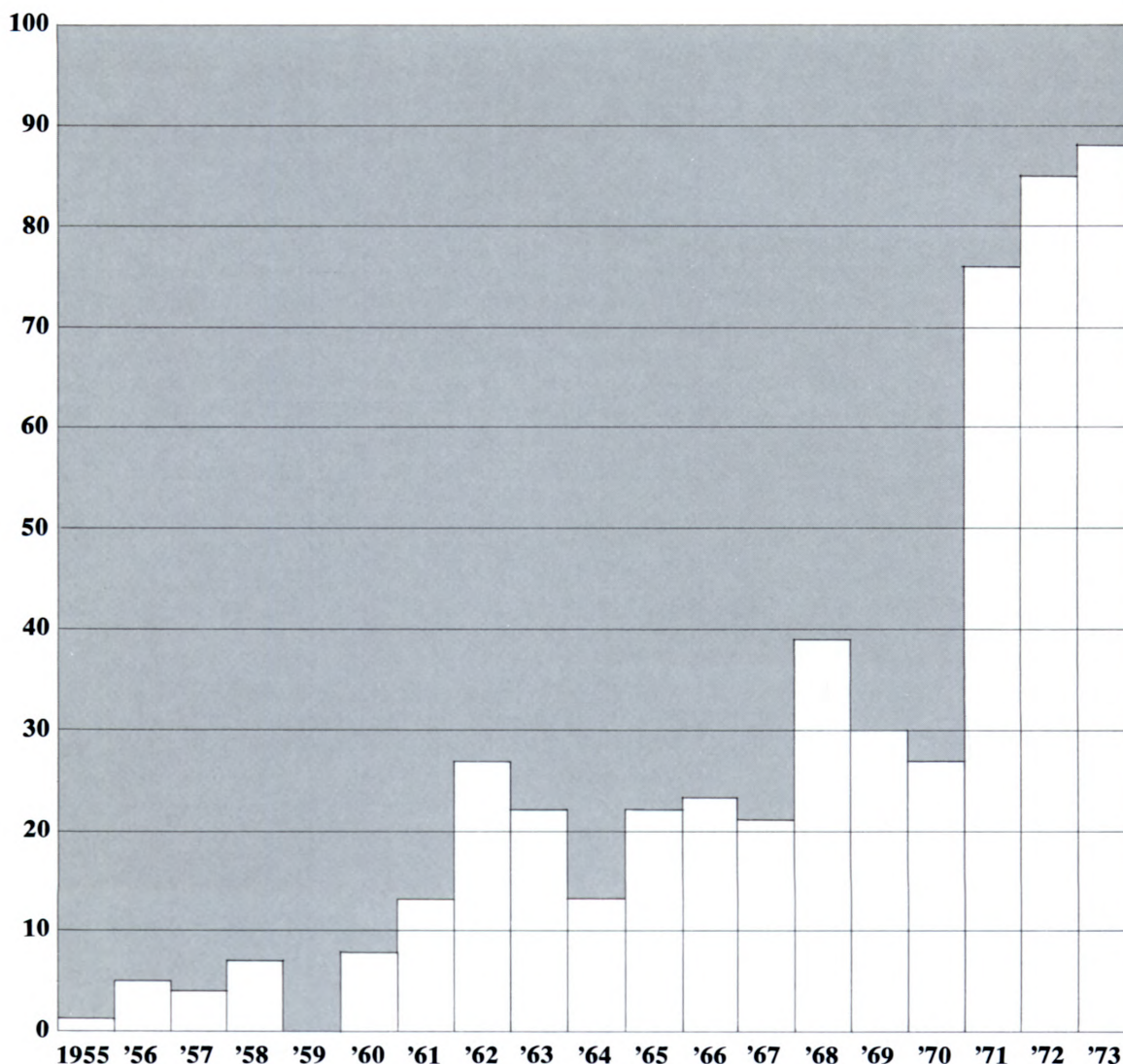
On other recent trips, Mr. Edwards had visited plants in countries behind the Iron Curtain: Bulgaria, Romania, Czechoslovakia, Poland, and Yugoslavia. Mr. Brodsky had traveled to Argentina, Brazil, Mexico, and Canada. About the time this article goes to press, Mr. Edwards will be on an inspection trip to Canada, to be followed by a trip to Japan and Korea.

Often the plants to be inspected are not those that make a product in the form in which it is sold to the consumer. In fact, the majority of foreign inspections are of plants which manufacture or produce one or more of the *ingredients* in a finished product. The ingredient may be shipped in bulk to a plant in the United States, where the final product will be made, in the form of tablets, capsules, etc. Chemists in FDA's Bureau of Drugs receive the inspectors' reports on *both* operations, foreign and domestic, and make their recommendations as to whether the standards have been met so the final product can be sold in this country.

The criteria by which all pharmaceutical operations are judged are derived from the Current Good Manufacturing Practice Regulations derived from the Food, Drug, and Cosmetic Act. As their name indicates, these regulations outline the rules to be followed to insure that a pharmaceutical product will have the proper safety, identity, strength, quality, and purity.

(continued)

**Number Of Plants Inspected**



When inspecting foreign plants, FDA consumer safety officers apply these rules, just as they do when inspecting domestic firms. Inspection procedures cover 13 general areas: buildings; equipment; personnel; raw materials; manufacturing records (such as the name and amount of each active ingredient, copy of the labeling, and other vital information); production and control procedures; product containers; packaging and labeling; laboratory controls; distribution records (including the name and address of each customer); stability controls (under what conditions is the prod-

**This chart shows how inspections of foreign firms exporting drugs to the United States have increased in the past few years, with 88 plants inspected in FY 1973.**

uct kept, and how long does it maintain its potency?); expiration dating, based on stability tests; and complaint files (written or oral complaints received by the firm).

Speaking of the inspections, Mr. Edwards says, "Every detail of the operation is investigated."

For example, when inspecting equipment, the officers make sure that the surfaces which come in

contact with the drug will not add anything to or take anything away from the drug, nor in any other way affect or change the drug. Since many mechanical devices are used, especially motors, inspection officers are careful to make sure no lubricants can work their way from the motors into the drug products and contaminate them.

They also examine machines adjacent to the ones in which the drug products are being made, to be sure there is no chance of contamination from other potent substances. They also look into clean-up procedures in the plant and the



*Consumer safety officers inspect a pharmaceutical factory in Seoul, Korea.*

possibility of contamination of the drug from other sources, such as careless spraying of pesticides in the plant, or lack of adequate screening of air intakes.

Such detailed and thorough investigation is made in each of the major areas of production. At the conclusion of the inspection, the consumer safety officers discuss their findings in each area with the management officials of the firm.

"We try to be very helpful during this phase," Mr. Edwards says, "pointing out what we observed, explaining FDA's interpretation of the manufacturing regulations, and indicating, where necessary, steps the firm can take to bring its operation up to acceptable standards."

Not all plants are given approval on first inspection. Sometimes a company must rebuild or change parts of its production facility or procedure. At other times, FDA has taken action to stop or prevent exporting from certain plants because of poor conditions or lack of cooperation in correcting defects. Usually, however, foreign manufacturers seeking to sell their products in the United States are serious business men and have obtained considerable knowledge of FDA requirements before requesting the Agency's approval.

For example, in June 1972, FDA made its first inspection in Romania, with an inspection of the "Factory of Drugs Bucharest." The first inspection showed certain conditions which were not fully acceptable, and approval was denied.

The Romanian pharmaceutical industry is nationalized under the Ministry for Chemical and Petroleum Industry. The officials in Bucharest were eager to improve their operation, and FDA consumer safety officers discussed with them the Current Good Manufacturing Practice Regulations, quality control, sterile operation, and other factors pertinent to U.S. production standards.

In November 1972, a second inspection was made, at the company's request, and it was evident the officials had spared no effort to meet fully the U.S. requirements. They had spent more than a million dollars in new construction and equipment and had transformed the production to a totally acceptable operation.

On a visit to Bucharest in July 1973, Richard McDermaid, chief of the Foreign Inspection Program, was invited to visit the plant to see the further improvements. By early 1974, they expect to have completed upgrading the Bucharest

plant, and by mid-1975, they expect to have seven other drug factories in compliance with U.S. standards. During Mr. McDermaid's visit, Romania's Minister of Health expressed his appreciation for the assistance his country had been given by FDA.

There is by no means complete inspection of all foreign manufacturers of products over which FDA has surveillance. But the program does cover all of the foreign producers of antibiotics, some pharmaceutical firms which have applied to investigate a new drug or want to submit a New Drug Application (NDA), as well as some suppliers of active ingredients (or component parts, in the case of medical devices) to firms that are applying for approval to sell their products in the United States.

How well the inspection program works to keep drug manufacturing standards high can be seen in the improvement pattern among participating firms. On a first inspection, there are nearly always some areas of production which do not measure up. When deficiencies are pointed out, officials usually are quick to adopt the recommendations which will improve their operation. Plants that have been inspected on a regular basis over a period of years almost always show high levels of competence in their operations.

FDA's inspection of foreign drug manufacturing plants, along with FDA's regular examination of drugs arriving at U.S. ports of entry, is an important consumer protection activity of the Agency. With many important pharmaceuticals now being manufactured abroad, the task of assuring that they can be used with confidence by the American public is an increasingly vital one for FDA.

Margaret Morrison is a writer on FDA's Consumer Education and Information Staff.

# A Primer On New Drug Development

by Wayne L. Pines

*The development of a new drug product is a long, complex process that can begin in many places—a drug manufacturer's laboratory, a chemical company, research at the National Institutes of Health—and that hopefully will end with benefits to the public.*

*By the time a new medicine becomes available to the general public, it has been thoroughly tested in both animals and humans under carefully controlled circumstances, and information has been approved for physicians to help them prescribe the drug correctly.*

*The Food and Drug Administration is responsible for approving the marketing of all new drugs that are sold in the United States, and for monitoring their use after approval.*

*This primer provides a simplified view of how a new drug is developed and approved for general marketing. Much of this applies only to prescription drugs, although some parts could apply to nonprescription medicines.*

## **The First Step**

The first step in the development of a new drug is research into the chemistry or anatomy of a disease, or the discovery of possible drug effects for a chemical. Recently, most drugs have been developed in the laboratories of pharmaceutical companies.

The chemical is subjected to screening tests and to testing in animals. Initial animal studies are performed to see whether the chemical has any desired drug effects. If it does, additional testing is done to determine what effects it might have, what dosage levels are poisonous, what the safe dosage range might be for humans, and whether there is a reason for testing the chemical in humans.

FDA initially requires that sufficient animal studies be performed to show it is reasonably safe to begin human testing. Additional animal tests are required as the human tests progress.

FDA does not monitor animal tests. But if they indicate the drug can be safely tested in man and that the chemical may be useful therapeutically, the drug sponsor will then proceed to the next step, which does involve FDA. This step makes the drug an Investigational New Drug (IND), which means the sponsor wants to test it in humans.

Before human tests can start, the sponsor must submit to FDA a form known as a "Notice of Claimed Investigational Exemption for a New Drug." The sponsor must tell FDA the complete composition of the drug, its source, and how it is made.

In addition, the sponsor must

submit the results of all animal studies to document that enough testing has been performed in animals to indicate that the drug shows promise of being useful in humans, and that no test subject will be exposed to an unreasonable risk.

The IND also contains a detailed outline, called a protocol, describing the planned testing in humans. The sponsor must wait 30 days after submitting the IND to enable FDA to review the materials to make sure patients are not being subjected to unwarranted risks.

Before testing is done on humans, FDA requires that, at the institution where the drug is to be tested, a committee composed of a broad spectrum of disciplines such as physicians and clergymen review the protocol to assure that patients' rights are adequately protected.

Human testing is divided into three phases.

## **Phase I**

The first phase of human testing is directed at determining what chemical actions a drug has, how it is absorbed into the body, how it should be given (by mouth or injection, for example), and what the safe dosage range is. These tests involve a small number of patients—usually fewer than 10.

The basic approach during Phase I is to begin with doses one-tenth or less of what might be expected to be useful, and gradually increase the dose with the patient carefully watched. Much of this testing is done in normal, healthy volunteers.

The safety record of such research is excellent. FDA knows of no volunteer patient who has been

permanently harmed as a result of Phase I testing of hundreds of new compounds under the FDA procedures established in 1962. Some patients do become ill as the dosage is increased.

The main things investigators are looking for during Phase I studies are to see that the chemical does act in the body, that it is safe, and that further testing can continue. Once Phase I studies are completed successfully, Phase II studies can start.

### **Phase II**

Phase II studies involve human testing on a limited number of patients for treatment or prevention of a specific disease. The number of patients depends on the nature of the drug.

This is the time when investigators evaluate the effectiveness of the drug. Additional testing usually continues on humans or animals to indicate the drug's safety.

If the Phase II tests show the drug may be useful in treating a disease and the long-term animal testing indicates no unwarranted harm, then the sponsor proceeds to Phase III.

### **Phase III**

This is by far the most extensive testing. Phase III studies are intended to assess the drug's safety, effectiveness, and most desirable dosage in treating a specific disease in a large number of patients. As with earlier human studies, these tests are carefully controlled—that is, the investigator must have a basis for determining that the drug itself is causing the desired effect,





*"No matter what system we set up, as technical knowledge grows, presently acceptable procedures and systems will appear inadequate. This is part of scientific progress."*

rather than other variables or chance.

In Phase III, the drug is used the way it would be administered when marketed. Once Phase III is completed and the sponsor believes the drug is safe and effective under specified conditions, the sponsor applies to FDA for approval to market the drug. This application is called a New Drug Application (NDA).

### **The New Drug Application**

By the time an NDA is submitted, a drug usually has been studied in several hundred to several thousand patients. An NDA contains all the information the sponsor knows about the drug. Often the NDA runs into thousands of pages.

The NDA is reviewed by the division in FDA's Bureau of Drugs responsible for evaluating that category of drug. There are six divisions: cardiopulmonary-renal, neuropharmacological, metabolic-endocrine, anti-infective, oncology-radio-pharmaceutical, and surgical-dental.

Each division is composed of physicians, pharmacists, chemists, and other professionals experienced in evaluating new drugs. FDA makes extensive use of advisory committees composed of experts from outside the Agency.

The NDA is reviewed by a team who determine whether the drug is safe and effective and whether the drug sponsor can manufacture the drug properly and consistently, batch after batch.

Among the information submitted in the NDA are: chemical structure of the drug, scientific rationale and

purpose the drug is to serve, all animal or laboratory studies, and all tests in humans.

FDA reviews the entire NDA to determine whether the benefits of the drug when used properly outweigh the risks. This is the crucial determination in evaluating a new drug.

If a drug is indicated for a cancer patient, for example, a relatively high degree of risk and adverse reactions may be tolerated if some benefit may ensue, because the alternative to use of the drug might be death. If a drug is used as a minor tranquilizer, then a much lesser degree of risk would be acceptable.

The benefit-risk judgment that goes into approval of a new drug is one of the hardest anyone can make. It involves not only medical but also societal considerations. How much risk is the public willing to take to obtain the benefits of a new drug, when no drug is completely free from risks?

Very often manufacturers of drugs—who may have spent considerable sums to develop a drug—complain that the review process for an NDA takes longer than it should. Legally, once an application is filed, FDA has 180 days to review it. In many cases, the application is not approved in the initial review, and the review period is extended.

The reason for most delays in the past has been that the data submitted to FDA were inadequate. Studies were not well controlled or there were not enough. In a large number of cases there was inadequate information about the manufacturing and quality control.

In making an important decision such as authorizing the sale to the public of a potent new chemical, it is imperative that FDA make sure the drug's benefits outweigh the risks and that the product will be made properly.

In the past, too, there may have been some unnecessary delays in the approval of a new drug. The Bureau of Drugs has taken steps, such as computerization, the use of project officers, and the use of advisory committees, to try to reduce the time delay. All the problems have not been solved, but the Bureau is working on them.

One of the final steps in the approval of an NDA is the review of the package insert or labeling. This is a detailed explanation of what the drug is, how it works, what it has been proven useful for, adverse reactions, means of administration, dosages, and other pertinent information.

The package insert must accompany the drug whenever it is shipped in interstate commerce. It also serves as the basis for all information on the drug disseminated by the manufacturer. The company may not make any claim for the drug which is not in the approved labeling.

A summary of many package inserts appears in the Physician's Desk Reference, a widely distributed book to which physicians often turn for information about prescription drugs.

Once an NDA is approved, the company is required to keep records relating to production methods for the drug and its safety and effectiveness. Any information in-

These are the forms that sponsors of Investigational New Drug (IND) and New Drug Applications (NDA) must fill out. The forms explain what types of information are required for each application. The information submitted in support of the application is considerably longer.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
ROCKVILLE, MARYLAND 20852

Form Approved  
OMB No. 57-R0003

NEW DRUG APPLICATION (DRUGS FOR HUMAN USE)  
(Title 21, Code of Federal Regulations, § 130.4)

Name of applicant \_\_\_\_\_

Address \_\_\_\_\_

Date \_\_\_\_\_

Name of new drug \_\_\_\_\_

Original application (regulation § 130.4).  
Amendment to original, unapproved application  
(regulation § 130.7).  
Abbreviated application (regulation § 130.4(f)).

The undersigned submits this application for a new drug under the Federal Food, Drug, and Cosmetic Act. It is understood that when the drug will be prescribed, recommended, or suggested in part of this application; and if the article is a new drug, it furnishes or purports to furnish information for use of the drug will contain the same information as to methods, and frequency and duration of administration, effects, and precautions, as that contained in the label (21 CFR 1.106(b)). It is understood that all required information is approved supplement to the application provide provisions of § 130.9 of the new-drug regulations.

Attached hereto, submitted in the form described in part of this application are the following:

1. Table of contents. The table of contents shall specify the volume number and the page number in which the complete and detailed item is located and the volume number and the page number in which the summary of item is located (if any).

2. Summary. A summary demonstrating that the application is well-organized, adequately tabulated, statistically analyzed (where appropriate), and coherent and that presents a sound basis for the approval requested. The summary should include the following information:  
a. Chemical structural formula or description for new-drug substance.  
b. Relationship to other chemically or pharmacologically related drugs.  
c. Description of dosage form and quantitative composition.  
d. Scientific rationale and purpose the drug is to serve.  
e. Reference number of the investigational drug notice(s) under which this drug was investigated and of notice, new-drug application, or master file of which contents are being incorporated by reference to support this application.  
f. Preclinical studies. (Present all findings including all adverse experiences which may be interpreted as incidental or not drug-related. Refer to date and page number of the investigational drug notice(s) or the volume and page number of this application where complete and reports appear.)  
g. Pharmacology (pharmacodynamics, endocrinology, metabolism, etc.).

FD FORM 356H (4/71) PREVIOUS EDITIONS ARE OBSOLETE.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

Form Approved  
OMB No. 57-R0030

NOTICE OF  
CLAIMED INVESTIGATIONAL EXEMPTION  
FOR A NEW DRUG

Name of Sponsor \_\_\_\_\_

Address \_\_\_\_\_

Date \_\_\_\_\_

Name of Investigational Drug \_\_\_\_\_

Commissioner  
Food and Drug Administration  
Bureau of Drugs (BD-26)  
5600 Fishers Lane  
Rockville, Maryland 20852

Dear Sir:

The sponsor, \_\_\_\_\_, submits this notice of claimed investigational exemption for a new drug under the provisions of section 505(i) of the Federal Food, Drug, and Cosmetic Act and § 130.3 of Title 21 of the Code of Federal Regulations.

Attached hereto, in triplicate, are:

1. The best available descriptive name of the drug, including to the extent known the chemical name and structure of any new-drug substance, and a statement of how it is to be administered. (If the drug has only a code name, enough information should be supplied to identify the drug.)

2. Complete list of components of the drug, including any reasonable alternates for inactive components.

3. Complete statement of quantitative composition of drug, including reasonable variations that may be expected during the investigational stage.

4. Description of source and preparation of, any new-drug substances used as components, including the name and address of each supplier or processor, other than the sponsor, of each new-drug substance.

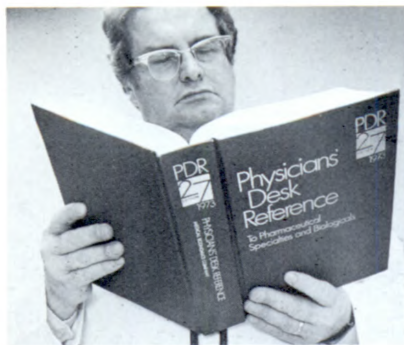
5. A statement of the methods, facilities, and controls used for the manufacturing, processing, and packing of the new drug to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to clinical investigations made with the drug.

6. A statement covering all information available to the sponsor derived from preclinical investigations and any clinical studies and experience with the drug as follows:  
a. Adequate information about the preclinical investigations, including studies made on laboratory animals, on the basis of which the sponsor has concluded that it is reasonably safe to initiate clinical investigations with the drug. Such information should include identification of the person who conducted each investigation; identification and qualifications of the individuals who evaluated the results and concluded that it is reasonably safe to initiate clinical investigations with the drug and a statement of where the investigations were conducted and where the records are available for inspection; and enough details about the investigations to permit scientific review. The preclinical investigations shall not be considered adequate to justify clinical testing unless they give proper attention to the conditions of the proposed clinical testing. When this information, the outline of the plan of clinical pharmacology, or any progress report on the clinical pharmacology, indicates a need for full review of the preclinical data before a clinical trial is undertaken, the Department will notify the sponsor to submit the complete preclinical data and to withhold clinical trials until the review is completed and the sponsor notified. The Food and Drug Administration will be prepared to confer with the sponsor concerning this action.  
b. If the drug has been marketed commercially or investigated (e.g. outside the United States), complete information about such distribution or investigation shall be submitted, along with a complete bibliography of any publications about the drug.  
c. If the drug is a combination of previously investigated or marketed drugs, an adequate summary of pre-existing information from preclinical and clinical investigations and experience with its components, including all reports available to the sponsor suggesting side-effects, contraindications, and ineffectiveness in use of such components: Such summary should include an adequate bibliography of publications about the components and may incorporate by reference any information concerning such components previously submitted by the sponsor to the Food and Drug Administration. Include a statement of the expected pharmacological effects of the combination.  
7. A total of three copies of all informational material, including label and labeling, which is to be supplied to each investigator: This shall include an accurate description of the prior investigations and experience and their results pertinent to the safety and possible usefulness of the drug under the conditions of the investigation. It shall not represent that the safety or usefulness of the drug has been established for the purposes to be investigated. It shall describe all relevant hazards, contraindications, side-effects, and precautions suggested by prior investigations and experience with the drug under investigation and related drugs for the information of clinical investigators.

8. The scientific training and experience considered appropriate by the sponsor to qualify the investigators as suitable experts to investigate the safety of the drug, bearing in mind what is known about the pharmacological action of the drug and the phase of the investigational program that is to be undertaken.

FD FORM 157I (5/71) PREVIOUS EDITIONS ARE OBSOLETE.

FDA Consumer / February 1974 / 15



*A summary of many package inserts appears in the **Physician's Desk Reference**, a widely distributed book to which physicians often turn for information about prescription drugs.*

dicating that the drug may pose an unexpected hazard must be reported.

A manufacturer must report to FDA every 3 months during the first year after approval, every 6 months in the second year, and once a year after that. Immediate reports are required in cases of drug mixups or contamination, or when unusual or especially severe adverse reactions are reported.

For some drugs, FDA requires more than recordkeeping. FDA can require additional studies to test the long-term effects of the drug. For example, FDA is requiring long-term studies for levo-dopa, a new and powerful drug used for Parkinson's disease.

### **"Me-Too"**

If a drug has previously been marketed, another company's version is called a "me-too" drug. In some cases, it is unnecessary for a company wanting to market a "me-too" drug to go through the same type of extensive testing required of the original drug. FDA therefore has established an Abbreviated New Drug Application (ANDA). Depending on the nature of the drug, FDA requires varying amounts of information from a manufacturer who wants to make the drug.

In the same vein, it is important to note that FDA does not issue patents for drugs. They are issued by the U.S. Patent Office and last for 17 years. If a firm develops a new drug, it can get a patent and take legal action against any company that tries to market the identical drug during the 17-year period. Once the original patent ex-

pires, any other company can market a "me-too" version of the drug under its "generic" name or under a new trade name if the drug meets all the requirements of the law.

### **Changes in the NDA**

Whenever a company wants to change any part of the procedure for making a drug, it must seek FDA approval. This is because even what appears to be a minor change in the manufacturing process can affect the final product. This type of approval, which is sought frequently, is called a supplemental New Drug Application.

The same applies to labeling. Very often after a drug has been in use for some time, new information develops about it. Perhaps there are new purposes for which it can be prescribed, or new warnings that need to be included. Any change must be approved by FDA.

### **Withdrawing NDA Approval**

If an approved drug is found to produce an unexpected side effect or to be less safe or effective than anticipated, FDA can seek to withdraw approval. FDA gives the firm an opportunity to present its views. In some cases, this may involve a hearing.

In landmark rulings in five "drug effectiveness" cases June 18, 1973, the U.S. Supreme Court supported FDA's authority to be the final judge of whether a drug is safe and effective, and to deny a hearing to a company that cannot show that significant facts are at issue.

### **Labeling for Patients**

In 1970, FDA took a major step to

provide information about prescription drugs directly to patients. The Agency decided that manufacturers of oral contraceptives—"The Pill"—must include in all packages received by patients a statement summarizing the potential risks of the drug. Physicians were provided with brochures listing the benefits and risks of the drug in greater detail.

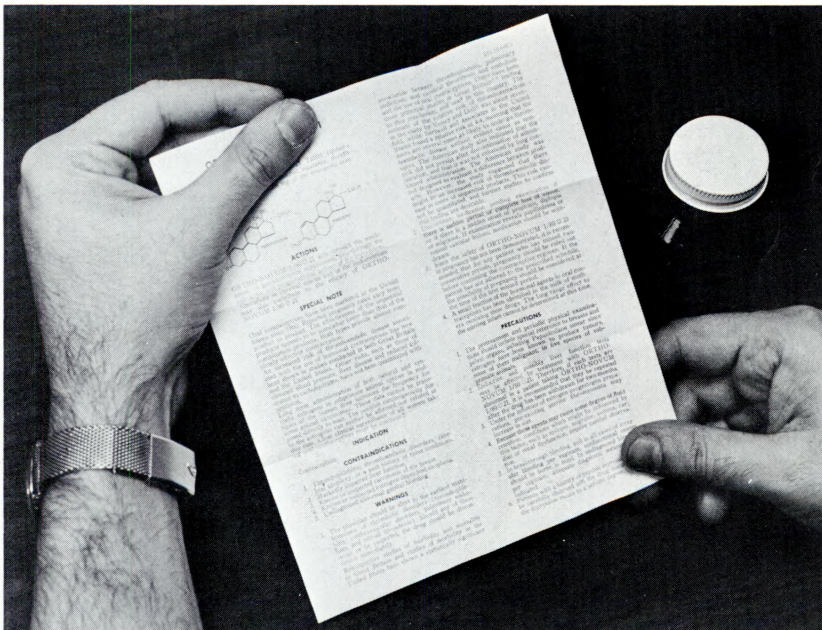
The reason for this decision was that FDA believed women should participate in the decision on whether to take "The Pill." Drugs used for contraception are different from others in that they are given to healthy women, not to treat disease, and there are nonchemical alternatives.

In 1973, FDA decided that information should be provided directly to patients on two other contraceptive drugs, diethylstilbestrol (DES) as a "morning after" pill and Depo-Provera as a long-acting injectable contraceptive. Information may be provided directly to patients on other prescription drugs in the future.

### **Patient Consent**

Increasing concern has been expressed in recent years about the use of prisoners and other institutionalized people for drug studies. People in institutions are the most convenient volunteers for some studies because they are in controlled environments.

However, FDA does not believe that any person should be required to participate in a study involving investigational drugs, or duped into taking a drug he does not need. The law requires that before using investigational drugs on humans,



*The package insert must accompany the drug whenever it is shipped in interstate commerce. It also serves as the basis for all information on the drug disseminated by the manufacturer.*



*In 1970, FDA decided that manufacturers of oral contraceptives must include in all packages received by patients a statement summarizing the potential risks of the drug. This has become known as a "patient package insert."*



*To help improve medical communications, FDA publishes a Drug Bulletin for all physicians, dentists, pharmacists, and other health professionals.*

the physician must obtain the person's consent. That consent must be informed—that is, the patient must know what the risks are. The only exception is when consent is not feasible or when in the physician's judgment it is contrary to the best interests of the person.

#### **Drugs for Pregnant Women and For Children**

FDA is concerned about the use of drugs by all persons, but especially about drugs being taken by pregnant women and by children. A drug can have a very different effect on the fetus than on the mother, since the fetus is particularly sensitive to biological change.

Investigators who believe a drug may be useful in pregnant women have to be extra careful in testing them. Most drugs have not been tested in pregnant women, and the labeling is required to indicate that. However, extensive testing is required in pregnant animals.

Thus, many physicians know which drugs pass through the placenta to the fetus. In treating a pregnant woman, physicians have to make a delicate benefit-risk decision.

The same problem applies to drugs for children. Many drugs available for adults are also prescribed for children. Some labeling and standard charts provide guidance for the physician.

However, FDA believes that drugs to be used in children should be tested in them under very carefully controlled circumstances. The only children who would ever receive a drug in a test situation are those who need it for a disease.

This area is now receiving considerable attention at FDA.

#### **Certification**

The law provides that two types of drugs—antibiotics and insulin—must not only be approved generally for marketing by FDA, but must be certified batch-by-batch. The manufacturers pay for this service. FDA tests random samples from each batch for purity and potency. The manufacturer may not release the batch until FDA certifies it.

#### **Advertising**

One of the most significant sources of information about prescription drugs is information supplied by the drug manufacturers to physicians, through advertising in medical journals, direct mail, or salesmen known as "detailmen."

The law requires that information supplied to physicians about prescription drugs be truthful, fully informative, and fairly balanced. Claims for a drug's effectiveness must be balanced with information on its side effects.

FDA extensively regulates prescription drug advertising and mail promotion. Whenever material is found misleading, FDA can seek to seize the drug on the grounds that it is "misleading." In virtually all cases, however, FDA seeks alternatives that have proven more effective. Among these are remedial ads required by FDA to be placed by the drug company in the journals in which a misleading ad appeared, or remedial letters sent to physicians.

It is generally acknowledged that the prescription drug information

system in the United States needs improvement, so that physicians are assured of having accurate and complete information. FDA publishes a Drug Bulletin for all physicians, dentists, pharmacists, and other health professionals which reports significant new regulatory developments. FDA is developing further systems to try to provide physicians with the best information about drugs.

#### **What Consumers Can Expect**

The system of new drug development and control in the United States is far from perfect. Admittedly, improvements are needed.

No matter what system we set up, as technical knowledge grows, presently acceptable procedures and systems will appear inadequate. This is part of scientific progress.

But despite the defects in the system, consumer exposure in the United States to drug products of unproven safety and effectiveness is minimal. This does not mean that patients are never exposed to unnecessary hazards from prescription drugs. All medicines have the potential to harm as well as benefit, and despite all precautions, prescription medicines at times are misused or misunderstood.

Looking beyond FDA's responsibilities in the regulation of drugs, ultimately it is up to the "three P's"—physicians, pharmacists, and patients—to make sure that drugs are used wisely and that FDA's regulatory efforts result in true benefits to the public.

Wayne L. Pines is editor of FDA CONSUMER.

A white plastic jug of Deer Park Mountain Spring Water. The label features a deer head logo with antlers. The text on the label reads: "DEER PARK Mountain Spring Water", "Purified and bottled at the spring", and "NET 100 FLUID OUNCES (1 GALLON)". The jug has a white screw-on cap.



**. . . They are all made under  
FDA's Cooperative Quality  
Assurance Program.**

## **Food Safety: A New Look At Corporate Responsibility**



*FDA is seeking to expand its inspection dollar through a program with the food industry to assure that food products will be made safely 365 days a year.*

Many different items in your grocery cart may have more in common than you think. An increasing number are being made in food processing plants that have quality control programs developed specifically for them.

The development of the quality control procedures for individual plants makes it unnecessary for FDA to spend large amounts of time or money to inspect those plants, thereby freeing the Agency to devote greater effort to other consumer protection problems.

These special quality control procedures are developed under FDA's new Cooperative Quality Assurance Program for processors across the Nation who want to assure consumers of continuous high quality products. More than 50 processing plants in the United States have joined the voluntary program, begun by FDA in 1971.

Under the program, FDA sets detailed safety and quality specifications to guard consumer health and see that wholesome products come from the plant. The program re-

**"Since joining the program, none of the companies has had to recall a product from consumer channels."**

quires that the company report to FDA about its day-to-day operations, and that any deviation from agreed-on procedures be reported to FDA.

There are many reasons why a company would want to enter into such an agreement with FDA.

The first is that the company has a greater assurance of consistently producing a quality product. Today, when recalls in all industries are so frequent and when an increasingly knowledgeable consuming public is more concerned than ever about food quality, any step a company can take to assure quality products is a step in the right direction.

This is just good business. Since joining the program, none of the companies has had to recall a product from consumer channels. Problems were either prevented or caught in advance and corrected.

There are other reasons why companies are joining the program. To

get in, a company must review its entire processing and quality control systems. This effort, which FDA reviews, provides greater assurance that the company is on the right track in making a safe product.

In addition, there are benefits to be derived from making FDA more familiar with a plant's operations. When a company needs technical advice on safety or quality, it can get that information more quickly when FDA is familiar with the plant and the products made there.

To begin the program, a formal agreement is signed by the food processor. This agreement requires the processor to prepare foods under certain quality specifications which are tailored to operations of the individual plant.

The specifications govern the food being processed as well as the processing conditions. Safety for the consumer guides development of each specification. For example: When a chocolate company purchases ingredients for its confectionery line, it assures FDA that the nuts, powdered milk, cocoa beans,

**"For the first time, FDA can have a good idea of what is going on in a plant on a year-round basis."**

and other materials do not contain harmful bacteria. Similarly, biscuit makers, jelly processors, and all other companies having selected plants in the program have agreed to have their quality assurance systems reviewed by FDA's food specialists.

When FDA screens a company's quality assurance system, the Agency checks to see that four requirements are fulfilled:

1. The company must consistently practice good sanitation. The specifications list the requirements for maintaining a clean operation, covering everything from care of utensils and equipment to maintenance of storage areas. Proper handling of the food itself is also prescribed, with particular attention to perishable ingredients.

2. The company must check material ingredients for safety. Ingredients must be free of all micro-biological, chemical, and physical

#### **Companies With Plants in Cooperative Quality Assurance Program**

##### **Category I\***

Green Giant Co.  
Skinner Macaroni Co.  
Pillsbury Co.  
Refrigerated Foods Co.

##### **Category II\*\***

General Foods Corp.  
Calumet Plant, Chicago, Illinois  
General Mills, Inc.  
Purity Oats Plant, Minneapolis, Minnesota  
Hershey Foods Corp.  
Oakdale, California Plant  
San Giorgio Macaroni Co., Lebanon, Pennsylvania  
National Fruit Product Co.  
Timberville, Virginia  
Winchester, Virginia  
Nestle Co., Inc.  
Deer Park Spring Water Co.  
Pet, Inc.  
Funsten Nut Division, Muskogee, Oklahoma

Pillsbury Co.

Grocery Product Division:  
Grand Forks, North Dakota  
Terre Haute, Indiana

Rohm and Haas Co.

Warren-Teed Pharmaceuticals, Inc.\*\*\*\*

Smucker Co., J.M.

H. B. DeViney, Inc., New Bethlehem, Pennsylvania

Hanover Brands, Inc., Bloomsburg, Pennsylvania

##### **Category III\*\*\***

Libby, McNeil & Libby, Kokomo, Indiana  
Mountain Valley Spring Co., Hot Springs, Arkansas

\*Companies having all their plants in CQAP.

\*\*Companies with one or more plants in CQAP.

\*\*\*Companies expected to be in CQAP by Jan. 1, 1974.

\*\*\*\*Makers of chemically defined foods (serving special dietary needs).

hazards. For instance, the company must check to see that ingredients being received are not decomposed—an obvious consideration, but one problem that can sometimes be easily masked in some ingredients by grinding or blending unsatisfactory portions with good materials. An example of this practice is use of insect-infested or moldy foods. Companies in the Cooperative Quality Assurance Program check for these problems, and most have laboratories to screen raw materials. Others arrange to use the services of private labs.

3. The processor must have direct control of all processing operations and submit the methods for such processes as cooking times and temperatures to FDA for approval. For instance, if a canned product is bulky and dense, like stew, it requires longer cooking than a broth. Loose controls over cooking processes have been for years a leading cause of problems that result in

product recalls or seizures.

4. Before a finished product is distributed, a representative sample must be checked in the laboratory. With products such as milk chocolate, where skim milk powder is used, tests for *Salmonella* or bacteria counts are required. Net weight and formula composition are also checked.

In addition to furnishing agreed-on information, participants have also voluntarily supplied current information about their industry that helps the FDA in its regulatory function.

For example: A chocolate manufacturer advised FDA of the presence of DDT in imported cocoa beans. This information was relayed to other FDA offices so that imports would be scrutinized for this problem.

Other information of this type has been used to alert FDA.

FDA checks up on participants in the program in several ways.

First, the Agency continues to audit the company's product. Second, it inspects the plant at statistically determined intervals to make sure that the quality assurance specifications are being followed. Third, through self-monitoring, the company reports to FDA any administrative or processing operations that deviate from agreed-upon specifications. Finally, the company reports its consumer complaints that involve the safety, wholesomeness, or quality of its products.

In turn, FDA lets the firm know of any consumer complaints it has received. For the first time, FDA can have a good idea of what is going on in a plant on a year-round basis rather than solely on the day it makes inspections.

The Cooperative Quality Assurance Program brings together the food industry and the special food safety experience of the FDA to serve a common cause: consumer protection.

#### **Types of Products With 10 Percent or More of Their Total U.S. Production Covered by Cooperative Quality Assurance Program**

<b>Product</b>	<b>Percent of Market</b>
Canned Peas	28.8
Canned Corn	26.0
Canned Asparagus	19.0
Chocolate Products	12.0
Macaroni & Noodles	11.2
Dehydrated Potatoes	10.0

Other items covered representing less than 10 percent of their market include shelled pecans, canned green and waxed beans, canned lima beans, canned mushrooms, frozen vegetables, bottled water, peanut butter, chemically defined foods for special dietary needs, dessert mixes, gravy and sauce mixes, baking powder, pectin, syrups, and home baking supplies.

By the summer of this year, both canned corn and peas produced under the program are expected to exceed 30 percent of total U.S. production for these types of products, chocolate should top 50 percent, bottled water should reach 10 percent, and probably as much as 80 percent of refrigerated dough products will be produced in accordance with the program.



## Aflatoxins: Stopping Trouble Before It Starts

**T**here's one problem these days that is becoming LESS of a problem. For that reason, you may never have heard of the word "aflatoxin."

"Aflatoxin" is a naturally occurring toxic product of a common mold. There is usually no visual evidence of its presence. It has been found in greatest amounts in peanuts, tree nuts, corn, and products manufactured from these commodities. It has been shown to cause liver cancer in some test animals and has been a suspected, but unproven, cause of liver cancer in certain African and Asian countries where high amounts of these toxins have been detected in foods normally consumed.

In the United States, liver cancer

is rare, accounting for less than 1 percent of all cancers detected. The evidence indicates there is probably no causal relation to aflatoxin in this country.

The problem is that increasingly refined methods of detection have revealed the presence of small amounts of aflatoxin, primarily in peanut products, cottonseed, and corn in the United States. But science has not yet provided a foolproof means to *prevent* the mold damage from occurring. As far as we have come in that regard is to develop methods to cut down on the chances of mold damage and to prevent contaminated products from reaching consumers.

As a starting point for controlling the problem, FDA began investigating aflatoxin

contamination in peanuts in 1963. Since then, the potential for aflatoxin contamination has been clearly demonstrated for cottonseed and cottonseed meal, corn, copra, and tree-nut products. And since most of these commodities or their byproducts are also frequently used in the rations of food-producing animals, there was also obviously a need to check for aflatoxin transmission to animal products.

Product surveys are continuing. None of the results from surveys conducted in 1973 was alarming to FDA scientists, who have set 20 parts per billion (ppb) as the action guideline for aflatoxin in food. Beyond that level, the Agency will move against the product to see it does not reach consumers.

A survey of 320 samples of cottage cheese curd, nonfat dry milk, and evaporated milk products showed that 7.5 percent of the samples were made from milk that contained between .05 and 0.4 parts per billion. A survey of 140 peanut butter samples found 25 percent with detectable levels of aflatoxin, including 4 percent slightly above the guideline. And a survey of 220 samples of unground (salted or confectionery) peanuts revealed 10 percent with detectable levels, including 2 percent above the guideline.

Scientists regard these statistics as an encouraging achievement in reducing human exposure to the naturally occurring contaminant. Refined methods of detection and identification, along with means developed by industry to reduce the presence of aflatoxin, have allowed FDA to reduce its original guideline of 50 parts per billion, set in 1964, to 30, and then to the present level of 20.

Total elimination of contamination by mold toxins is probably not possible, but

considerable improvement can probably be achieved by research aimed at determining how contamination occurs in order to develop preventive measures.

Behind the research, the surveys, and the development of methods to control the problem are cooperative efforts by the FDA, the United States Department of Agriculture, and industry. Foreign countries that export to the United States also have been helpful.

Since becoming aware that aflatoxin could occur naturally in peanut products, USDA and the peanut industry have cooperated, with FDA guidance and approval, to set up an extensive control program. In 1964, a procedure was started to have all raw shelled peanuts analyzed for aflatoxin by a USDA-certified laboratory. FDA surveys of finished peanut products have confirmed the general effectiveness of the program.

Following FDA's survey of milk products, State governments that had not already acted took steps to prevent contaminated cottonseed meal from being fed to food-producing animals.

Looking into the possibility of aflatoxin residues in liver and muscle tissues of food animals, scientists fed extremely high levels of contaminated feed to experimental laboratory animals. They found even smaller residues in these tissues than in milk from animals fed the same level of contaminated feed.

Aflatoxin in Brazil and pistachio nuts has come under control in the last 6 years since exporters were convinced to refine their sorting methods, and importers have agreed to a voluntary certification system on arrival of lots of nuts in this country. Aflatoxin is a worldwide problem. Cooperation between scientists in attacking the problem has been worldwide. Part

of this cooperation is the worldwide distribution of the extensive bibliographic information system for mold toxins developed by FDA.

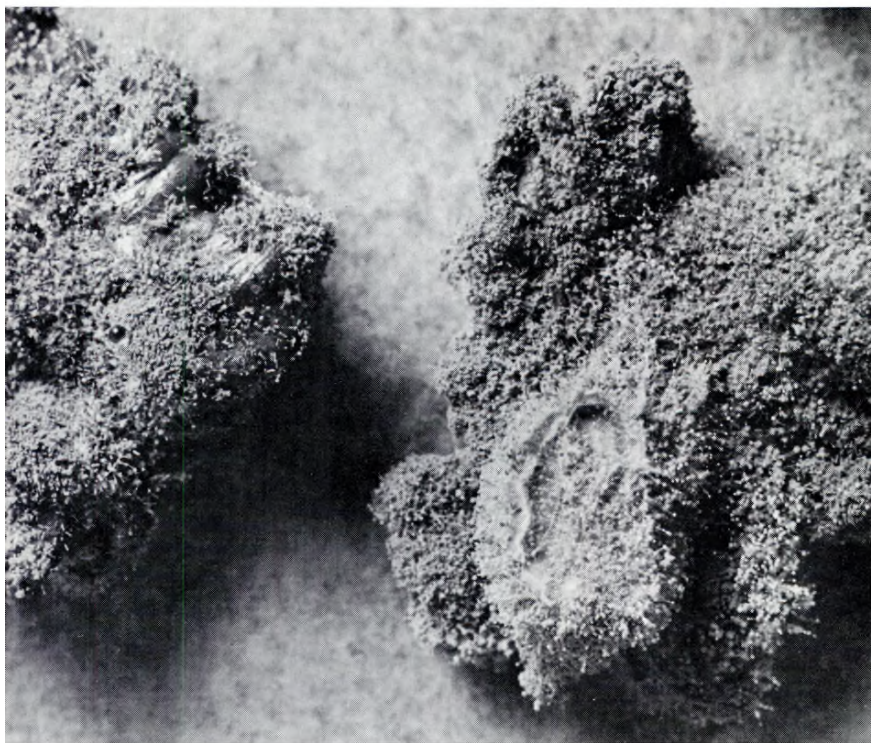
In the meantime, in this country, farmers, distributors, and processors have been urged to take precautions to help control aflatoxins, such as preventing mold by proper drying and storage of crops, removing damaged material before storage or processing, and providing adequate moisture and humidity control of stored feedstuffs.

One other precaution is the use of insecticides to keep down insect infestations, since insect damage often precedes mold damage. These pesticides must comply with food additive regulations of the Food, Drug, and Cosmetic Act.

Beyond these measures, spraying cottonseed and cottonseed meal to destroy contamination is now being tried with some success in areas where the potential for aflatoxin contamination is greatest.

As research continues, FDA is evaluating results to determine what other actions may be needed to further protect the consumer. Speaking to the press last November, FDA Deputy Commissioner Sherwin Gardner explained:

"Such actions would take into account the extent to which aflatoxin contamination is unavoidable and would only be taken after full opportunity is provided for public and industry participation in the decision-making process. The Agency's procedure for any formal action would afford an opportunity for anyone who has data or opinions to make them a part of the public record. Only through such involvement can we achieve the kind of public and industry understanding we increasingly need to resolve issues of this type."



*These walnut meats show a heavy contamination by *Aspergillus flavus*, the mold species which produces aflatoxin, grown under ideal conditions in the laboratory. Aflatoxin is one of a number of toxins, called mycotoxins, produced by various molds. Not all molds produce toxins, and some are useful in food processing, such as the mold used to produce Roquefort cheese. Other molds are used to produce antibiotics.*



*Several foods are subject to contamination by aflatoxin under conditions conducive to growth of the mold *Aspergillus flavus*. Among them are peanuts, tree nuts, corn, and cottonseed. These filbert shells shown growth of *A. flavus* in the laboratory.*

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## News Highlights

### **FDA Asks Public to Comment On Drained Weight Labeling Petition**

FDA on December 4, 1973, called for public comment on a Consumers Union petition to require the listing of drained weight on processed fruits and vegetables.

Consumers Union contended in its petition that "drained weight labeling is essential to avoid confusion of consumers and to enable value comparison at the consumer level."

Presently, most labels on such foods list net weight, which is the weight of the fruit or vegetable, plus the fluid in which it is packed. The C.U. petition would require that the drained weight of only the fruit or vegetable also be listed.

In publishing the petition for comment, FDA determined that information it currently has available is not adequate to determine if the proposal should be adopted. The FDA action is designed to stimulate the submission of all available information and views from consumers, industry, other government agencies, and the academic community.

Some of the specific issues are:

- How much does variation in size, shape, maturity, climatic conditions, or the geographic region in which the product was grown affect the drained weight?
- How much variation is there from container to container or lot to lot and how much deviation for labeling would be necessary?
- What is the best way for drained weight to be stated on the label? Should it be actual drained weight? Or, should a minimum drained weight be established for each form of each food in each size container?
- What additional costs would be involved in preparing a variety of labels and holding unlabeled containers until the drained weight could be determined?
- Would the information be worth the additional cost to the consumer?

### **FDA Acts to Clarify Conditions For Prescription Drug Price Disclosure**

The Food and Drug Administration has proposed regulations to clarify and define conditions for public disclosure, including advertising, of prices charged by retail pharmacies for prescription drugs.

Price disclosure, as part of drug labeling and advertising, has been subject to FDA regulation since 1962, but the precise requirements have not been widely understood.

A number of States have laws banning the posting of prescription drug prices in retail pharmacies or the advertising of such prices in newspapers or on radio and TV.

Since 1962, bans on price posting have been overturned or open drug pricing has been otherwise upheld by the courts in at least nine States. In January 1974, two States went one step further and now require posting of drug prices in retail pharmacies.

FDA Commissioner Alexander M. Schmidt, M.D., said that for FDA the principal question is not whether such advertising should be allowed, but how to insure that such advertising, wherever practiced, will provide consumers with all information needed to make meaningful price comparisons.

"It is our desire that when open pricing of prescription drugs occurs, it be done in a sensible and uniform manner," stated Dr. Schmidt, adding, "Contrary to wide misunderstanding, the Food, Drug, and Cosmetic law in no way inhibits prescription drug price advertising. We do have an obligation to insure fairness and accuracy in such advertising."

The new rules would spell out more clearly already existing regulations on prescription drug advertising as these regulations affect price disclosure.

The rules would provide that the posting or advertising of prescription drugs must state all charges to the customer, including cost of the drug, professional fees charged by the pharmacist, and handling and mailing costs, if any.

The FDA proposal further spells out mandatory as well as optional rules providing for the listing of brand as well as generic names, quantity of each active ingredient, name of manufacturer or distributor, dosage form (tablets, liquid, etc.), and price according to number of doses in the unit advertised.

The new price advertising policy would extend to all materials intended to provide consumers with price information. These materials include price lists and catalogues, whether mailed, posted in a pharmacy, printed in a newspaper, or aired on radio or television.

### **FDA Proposes Safety Standard For Use of Laser Products**

The Food and Drug Administration has proposed a safety standard to prevent unnecessary human exposure to radiation from laser products.

The proposed standard would also require user warnings for all of the light-amplifying devices that have a potential for biological damage.

Publication of the proposed standard in the *Federal Register* December 10, 1973, followed surveys that showed serious shortcomings in laser safety practices. Animal research indicates that the more powerful laser beams can cause human eye and skin injuries.

Lasers have important medical and research applications. They also are increasingly used in the construc-

tion industries for leveling and alignment, and in high schools and colleges to demonstrate scientific principles. Major expansion in new uses of the devices is expected, for example, in grocery store package checkout systems.

The proposed standard would require that laser products sold for science instruction, art displays, and other demonstration purposes must be low-powered devices to minimize the hazard to eyes or skin. Laser products sold for construction and surveying also would be limited to the less hazardous classes of devices.

Many medical laser products would be required by the standard to be capable of accurately delivering the minimum radiation necessary for effective treatment.

Protective housing and safety interlocks would be required to prevent user exposure to laser emissions in excess of the lowest levels at which products could perform their intended functions. Laser systems, other than those in the least hazardous class, would have to be equipped to warn operators when ready for use. Such systems also would have to incorporate safety devices for reducing beam levels. High-powered lasers could be turned on only with keys.

### **FDA Warns About Potentially Dangerous Dietary Supplements**

The Food and Drug Administration on November 27 warned consumers about two products which are derived from apricot kernels and contain potentially dangerous levels of hydrogen cyanide. The two products, Aprikern and Bee-Seventeen, are sold nationally as special dietary supplements, primarily in health food stores.

The distributor, General Research Laboratories, Van Nuys, California, refused an FDA request to recall the products from the market. FDA will initiate appropriate legal action to halt future interstate shipments.

According to Dr. Alexander M. Schmidt, Commissioner of Food and Drugs, "Complete withdrawal of these products is hampered by two facts. They are sold nationally in thousands of retail outlets and each outlet usually carries small quantities. In addition, the manufacturer has refused to release distribution records. For these reasons, FDA must rely in great part on public action to help get the products out of distribution channels."

In its request for a recall, FDA said that the Aprikern capsules were found to contain an average of 2 milligrams of hydrogen cyanide per capsule. FDA scientists estimate that ingestion of five such capsules could result in cyanide poisoning and be fatal to a child. Twenty capsules could be fatal to an adult. Oral toxicity studies performed on rats at the University of Arizona School of Pharmacology support these figures. FDA estimates that two packets of the Bee-Seventeen product contain enough hydrogen cyanide to cause cyanide poisoning in a small child.

On November 15, 1973, the State of Arizona requested a court injunction prohibiting distribution or

sale of the Aprikern product in Arizona. That action is now pending before the court.

In the interest of public safety, FDA advised consumers and retailers to destroy any supplies of the two products.

### **FDA Establishes Standards And Proposes Guidelines for Bottled Water**

The Food and Drug Administration has established minimum product quality standards and proposed specific manufacturing guidelines for bottled water.

FDA's standard of quality for bottled water sets bacteriological, physical, chemical, and radioactivity limits.

The standard is based on the current Federal Drinking Water Standard developed by the U.S. Public Health Service in 1962. The Environmental Protection Agency has responsibility for establishing and updating the PHS Federal Drinking Water Standard, and an extensive revision of that standard is currently underway. FDA will review and revise its bottled water standards to keep them compatible with any changes EPA may make in general drinking water standards.

Bottled water not meeting the FDA standards may still be marketed but must carry a label stating that it is below quality. Examples of what such a label would state are: "Contains Excessive Bacteria," "Contains Excessive Chemical Substances," or "Excessively Radioactive."

FDA's proposal to establish a Good Manufacturing Practice (GMP) Regulation for bottled water was the fourth in a series of such guidelines for specific industries. It defines criteria to be used in determining whether the facilities, methods, and controls used in bottled water plants are adequate to assure a safe and sanitary product.

### **FDA Warns Against Use Of Defective Aerosol Inhaler**

The Food and Drug Administration has advised consumers not to use a silver-metal aerosol inhaler with a blue-and-white label to relieve attacks of asthma or other bronchial distress.

No product name appears on the can. However, the name, "Metermatic Aerosol," and the distributor's name, "USV Pharmaceutical Corp.," or "Fison's Corp.," are listed on the accompanying instruction sheet which is given to the consumer.

The product is sold by prescription, principally to asthmatics. The active ingredient is isoproterenol. Inhalers sold since 1968 can be more specifically identified by one of the following numbers printed on the container label: 52447, 50894, 48388, 47507, 47250, 46792, 46356, 52446, 48389, 47976, 47506, 46082, 46355, 51077, 47974, 47975, 47103, 46791.

Consumers who have such inhalers should contact their physician or pharmacist to obtain a replacement.

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# Regional Reports

## REGION I

A Massachusetts dairy received the maximum fine of \$4,000 in the U.S. District Court at Boston after pleading guilty to charges of causing its milk to be adulterated through reuse of plastic bottles which previously held gasoline or kerosene.

It was theorized that consumers used the plastic milk bottles to store gasoline and then returned them to retail stores for a cash refund and reuse by the dairy. Normal washing does not remove all gasoline or kerosene odors from the bottles. Magistrate Willie Davis imposed the fine on Cumberland Farms Dairy, Inc., Canton, after the company changed its plea from not guilty to guilty. The charges had been filed almost 2 years earlier after several consumer complaints to FDA's **Boston Field Office** that the company's milk, distributed through Cumberland Farms Stores, Canton, had a gasoline-like odor.

Storage of food under insanitary conditions and its subsequent contamination by filth from rodents, insects, birds, and cats resulted in fines of \$7,000 against a Massachusetts warehouse corporation and \$1,500 each against two company officials. The charges were made against First National Stores, Inc., Somerville; Arthur Silk, vice president; and Thomas Murphy, base manager for the warehouse. The fines were imposed by Judge Arthur Garrity in the U.S. District Court at Boston after the company changed its plea from not guilty to guilty on eight counts and its officers did the same on four counts each. The charges were based on investigations by FDA's Boston Field Office.

## REGION II

Approximately five tons of unfit drugs was destroyed in a landfill in New York City as a result of an alert from FDA's **New York District**. When the American Pharmaceutical Co. of the Bronx went into bankruptcy, all its finished goods were purchased by a new corporation, the American Pharmaceutical Co. of New Jersey, Inc. FDA advised the New York State Board of Pharmacy and the New York City Department of Health that the new company intended to abandon all quarantined, rejected, and recalled drugs because it didn't want to assume responsibility for the products. But a New York City ordinance prohibits the casual abandonment of drugs. The company was advised of the ordinance and arranged for destruction of the pharma-

ceuticals under the supervision of the New York City Department of Health. The products included antibiotics, sulfa drugs, cortisone, digoxin, quinidine, rauwolfia, stilbestrol, and pentaerythritol tetranitrate.

Combe, Inc., an "own label" distributor in White Plains, New York, voluntarily destroyed 3,278 pounds of Delila Smoothee Leg Lotion, totaling 3,895 bottles. This product was withdrawn from the market after the company found it was contaminated with *Pseudomonas* bacteria. The destruction was witnessed by an inspector from the Westchester Resident Office. FDA is investigating the possibility of other products being contaminated.

A final judgment of consent prohibits Costa Apple Products, Highland, New York, from adulterating its cider by using apples which are in part rotten. The judgment, filed in the U.S. District Court for the Southern District of New York, resulted from charges by FDA's **Buffalo District** that the company was producing and distributing adulterated cider in interstate commerce.

A Buffalo District consumer safety officer checking stored canned mushrooms—a part of FDA's nationwide investigation that followed finding of *Clostridium botulinum* in some brands of canned mushrooms—noticed birds in the warehouse of Grisfulli Brothers, Inc., Albany, New York. The consumer safety officer, Raymond Kent, and a New York State Agriculture and Markets inspector then made a sanitary inspection of the warehouse and found that dried beans and peas, matzoh meal, yellow corn flour, macaroni shells, and sugar were contaminated by bird droppings. The company voluntarily destroyed the products.

Government seizure of a quantity of gelatin dessert valued at \$2,000 was made at General Grocery Warehouse, Carlstadt, New Jersey, after an inspection by FDA's **Newark District** found the product was defiled by rodents. The goods were destroyed after FDA consumer safety officers discovered that during reconditioning, which had been permitted under a consent decree filed in the U.S. District Court at Newark, the warehouse was still infested by rodents.

An inspection of the Marriott Inlite Catering Service at the Puerto Rico International Airport, San Juan, last September by the Puerto Rico Health Department, assisted by FDA's **San Juan District**, found sanitary deficiencies, and the catering service was prohibited

from providing food to airplanes flying out of the airport pending a cleanup to correct the deficiencies. Three days later a second inspection indicated sanitary conditions had been improved and a provisional service certificate was issued to the company. Extensive improvement was noted after a third inspection, and the company has been placed on the "approved" list.

The following month an airplane arrived in the Puerto Rico airport from Lisbon, Portugal, with a large number of the passengers ill from food poisoning while the plane was in flight. The plane had been serviced by Marriott Catering in Lisbon. Samples of the meal served on board were collected by a Center for Disease Control quarantine officer and analyzed by the Puerto Rico Health Department. The department found coagulase-positive *Staphylococcus aureus* bacteria in the gelatin and cream dessert served on the flight and also in samples from the stools of eight patients who had been hospitalized upon arrival at San Juan.

### REGION III

FDA's **Philadelphia District** notified all FDA Districts of the recall by Avondale Industries, Avondale, Pennsylvania, of No. 10 cans of "Superior Brand" mushrooms packed by the company after FDA's Division of Microbiology in Washington confirmed the presence of viable *Clostridium botulinum* Type B spores in sample cans of the product taken from a warehouse in Miami, Florida. The District also provided the identities of 139 consignees of the product in various FDA Districts. The possible presence of botulinum toxin was first suspected by an inspector in the Health Department of Dade County, Florida, who noted several abnormal cans in four lots sampled. The recall involved all No. 10 cans processed by the company prior to May 3, 1973.

### REGION IV

The Government seized two lots of salt and one of flour, totaling 23 tons, at Statesville Flour Mill Warehouse, Charlotte, North Carolina, after inspection and sampling by Consumer Safety Officer Loyd W. McEwen of the **Atlanta District** established that the products were being held under insanitary conditions in a rodent-infested warehouse and that the flour contained rodent urine.

A seafood processing establishment in Florida was fined and two of its officers placed on probation after a series of inspections, carried out over 3 months by John M. Head, John R. Sears, and James A. Casey of FDA Region IV's **Orlando Section**, showed the company to be operating under insanitary conditions.

The consumer safety officers found ineffective sanitizing solutions in use, poor handling practices for cooked crabs, an overflowing septic tank, and infestation by flies and cockroaches. Samples of processed

crabmeat contained coagulase-positive staphylococci bacteria.

The company, Barwick Brothers Fish & Crab Co., Panacea, Florida, was fined \$500, of which \$200 was suspended under a 1-year unsupervised probation. Charles Barwick, Sr., president, and Augustus Barwick, secretary, pleaded guilty and were fined \$300 each, suspended under a 1-year unsupervised probation. The sentences were imposed by the U.S. magistrate at Tallahassee.

### REGION V

FDA's **Cincinnati District** detained a number of imports at Lake Erie ports as Christmas merchandise arrived and seagoing vessels rushed to clear the St. Lawrence Seaway before its waters froze. The detentions included pails of almond mix with damaged containers, misbranded crackers, canned artichokes found non-sterile, and olive oil which failed to comply with the Fair Packaging and Labeling Act.

The Skiles Co., Inc., Bluffton, Indiana, and its president, Robert M. Skiles, were fined a total of \$2,400 by Judge Jesse Eschback of the U.S. District Court for Northern Indiana, Fort Wayne, after pleading guilty to charges by FDA's **Detroit District** of operating an insanitary warehouse.

A Wisconsin company, Super Valu Stores, Inc., has been fined a total of \$2,500 on five counts charging adulteration of food in its warehouse at Green Bay. The fine was imposed by U.S. Magistrate John C. McBride in the Eastern District of Wisconsin when the company was found guilty of charges by FDA's **Minneapolis District** that during an inspection there was rodent infestation in the building, food that had been gnawed or otherwise contaminated by rodents, rodent excreta, rodent hairs, rodent nesting materials, and in some cases rodents present in the food.

### REGION VI

The Magnolia Grocery Co., Carthage, Texas, was prohibited from storing, selling, or distributing foods until corrections have been made to prevent adulteration of foods on its premises as a result of being held under insanitary conditions. The consent decree of permanent injunction was filed in the court of Judge William Wayne, Justice of the U.S. District Court for the Eastern District of Texas. The action followed convictions of the company on similar charges in 1967 and in April 1973. The new action was sought by FDA's **Dallas District** after an inspection in August 1973 showed continuing violations.

FDA's Dallas District detained two shipments of green coffee from Indonesia and Brazil—totaling 354,370 pounds and valued at \$111,920—because of insect infestation and mold. Nine shipments of coffee from

Cameroun, Ivory Coast, Guinea, and Mexico, totaling 2,140,245 pounds and valued at \$1,093,163, were detained because of insect infestation.

A New Orleans physician has been convicted on five counts of mail fraud and submission of false statements to FDA in his testing of drugs for two pharmaceutical companies. Wallace Rubin, M.D., an otolaryngologist and a member of the staff of Tulane University School of Medicine, was sentenced by Judge Alvin B. Rubin (no relation) of the U.S. District Court for the Eastern District of Louisiana, New Orleans, after entering a plea of *nolo contendere*.

The sentence called for imprisonment for 1 year on each of the five counts, but the imprisonment was suspended and Dr. Rubin was placed on 3 years' supervised probation during which time he is required under the terms of probation to contribute his time for 90 days in teaching physicians in residence at three locations in the country and in treating public patients at no charge. An additional requirement is that he violate no Federal or State laws during the probation period.

Under the probation terms, Dr. Rubin also was required to refund \$10,710 received in contract fees from two companies for the test periods running from 1967 to 1970. Dr. Rubin had already made this refund after FDA's **New Orleans District** began investigating the case about 3 years ago.

FDA began its investigations after the pharmaceutical companies involved expressed skepticism about the thoroughness of the reports submitted by Dr. Rubin. The New Orleans District's investigation indicated information on the data sheets completed by Dr. Rubin was not supported by the studies required by FDA.

## REGION VII

A Missouri wholesale grocery pleaded guilty and was fined a total of \$2,500 by U.S. Magistrate Calvin Hamilton in the U.S. District Court for the Western District of Missouri, Kansas City, on five charges of adulteration of foodstuffs stored in its two warehouses. The prosecution resulted after inspections of the two facilities of Shyrack-Given Grocery Co., Boonville, Missouri, by FDA's **Kansas City District** disclosed rodents in one facility and insects in the other and contamination of foodstuffs with either rodent or insect filth.

## REGION VIII

A North Dakota establishment, Eddie's Bakery, Grand Forks, was shut down by Lawrence Kochler, State food commissioner and chemist, after an inspection by Richard Brumfield, State laboratory inspector, and Donald Fernholz, FDA **Denver District** consumer safety officer, found the bakery extensively contaminated by insects. The plant reported spending more than \$13,000 to correct all the deficiencies found in the inspection, including disposal of flour and other ingredients valued at

nearly \$6,000. After a follow-up inspection by State inspectors, the bakery was permitted to reopen.

A total of 100,000 pounds of bulk oats seized by the Government in 1971 at Wilmar, Minnesota, because of contamination by mercury, a poisonous substance, has been destroyed by dumping and covering with a bulldozer. The oats had been returned to Farmers Grain Elevator, LaBolt, South Dakota, where the owner futilely sought a feasible method of salvage. Salvage was deemed impossible because of the mercury contamination, and the Environmental Protection Agency had objected to a plan to spread the oats on cropland because of the hazard to game birds.

## REGION IX

Government seizures as a result of charges by FDA's **San Francisco District** included 18,000 pounds of medicated feed valued at \$5,000 and containing the banned drug diethylstilbestrol, from Pelleted Feeds, Inc., Orovada, Nevada; a Diapulse device found ineffective for many conditions for which promoted, from Chester Wong, M.D., Berkeley, California; 2,400 pounds of rodent-gnawed peanuts being held under insanitary conditions, from Wing Coffee Co., Honolulu; 800 pounds of rolled oats, rodent gnawed and being held under insanitary conditions, from Robb-Ross, Inc., Fresno, California; 15,000 pounds of black-eyed peas found insect infested, at Crows Landing, California, owned by D. C. Woldert Co., Tyler, Texas; 3,700 pounds of rice contaminated by rodent urine and held under insanitary conditions, from Marbo Quality Foods, Fresno, California; 1,100 pounds of pinto beans, pancake mix, and corn starch pudding, in bags contaminated with rodent urine and being held in a rodent-infested warehouse, from Low-Temp Sales & Rental Co., Madera, California.

The Honolulu Transport & Warehouse Corp., Honolulu, was fined \$1,000, and two officers, Alvin E. Medeiros, Jr., president, and Emery Medeiros, warehouse manager, \$500 each on charges by the San Francisco District of allowing foods to become adulterated by rodent filth. The defendants were found guilty by a jury in the U.S. District Court of Honolulu, and the fines were invoked by Judge Samuel P. King, who suspended 3-month jail sentences and placed the defendants on probation for 2 years. It was the first FDA-originated prosecution in the State of Hawaii.

## REGION X

The Government seized 10,000 pounds of frozen, dressed salmon at Seattle after investigation by FDA's **Seattle District** revealed that the fish were decomposed, had been caught in Alaska, and that a portion of the lot had been exported to Europe prior to sampling by the District. FDA has notified the country to which the salmon was exported.

## FDA Halts Unsafe Products From Entering Consumer Channels

A destructive storm last spring at Joplin, Missouri, brought a team of FDA consumer safety officers to the scene within hours to prevent food and drugs made unfit by water and other damage from being channeled to consumer use.

The team, a part of the Kansas City Field Office operation, began arriving at 10 a.m. on May 11, three hours after the early morning storm struck Joplin, a city in southwest Missouri near the border with Kansas. Later classified as a tornadic cyclone, it was accompanied by a downpour of rain, along with hail a foot deep in some places. It also disrupted electric power for 24 hours. Total damages have been estimated at \$15 million.

The rain was still falling when Consumer Safety Officer Edwin S. Dee arrived from the Springfield Resident Post. He made a quick assessment of damage, met with officials of the city and the State Division of Health to reach agreement on strategy, and reported his findings to Irving Weitzman, supervisory CSO in Kansas City, along with an estimate of help needed. Two more consumer safety officers, Jan A. Longnecker and George I. Van Wey, arrived the next day.

Under the agreement, city and State officials took over monitoring of salvage operations at retail stores, and supervised voluntary destruction of 15-20 tons of food and other products from various establishments. The FDA staffers were assigned to check food manufacturing and wholesale establishments and accounted for voluntary destruction by various manufacturers, in-

cluding three bakeries, of more than 30 tons of food products.

The worst damage was sustained by a food storage warehouse, Fleming Foods of Missouri, Inc., Joplin. The roof of the warehouse was badly damaged by the wind and punctures from ventilating fans torn loose on the roof, resulting in water damage to stored products. The FDA team monitored the company's removal of 62 semitrailerloads of food and other products to an underground storage warehouse in Carthage, Missouri, and destruction of one load of food and paper products at the Joplin landfill.

The underground facility at Carthage, equipped with humidity controls, reduced humidity to 25 percent to remove much of the water and prevent rusting of canned foods. During salvage operations at Carthage late in May, an additional two tons of unfit food products was destroyed under FDA monitoring, and State officials relieving FDA people supervised the destruction of six more tons of foods, soaps, and detergents, and paper goods.

Back at Joplin, the company sustained further damage to stored products because of inadequate repair to the roof and additional rain. FDA early in June witnessed the destruction of an additional quantity of food products made unfit for use.

The Joplin storm came almost exactly 2 years after a similar storm hit the city on May 5, 1971, notes CSO Edwin Dee, who was also on the scene for FDA after the earlier storm.



Some food products packed in cardboard could not be salvaged. Here CSO George Van Wey examines some breakfast cereal that was eventually destroyed.



Damaged and thawed ice cream is loaded on carts by Dick Woods, Joplin city health inspector (left), and Earl Holstein, sanitarian, Missouri Division of Health.

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## State Actions

### Organic Food Rules

After more than a year of study and hearings, Oregon has adopted regulations establishing definitions for organic foods, to become effective October 1, 1974. Irvin Mann, Jr., director of the Oregon Department of Agriculture, said the regulations give producers, processors, and retailers a full year to bring their products and labeling into compliance. He said Oregon hopes to eliminate mislabeling of foods as organically grown when in fact they were produced in the same manner as other foods.

The standards make it unlawful to label any animal product or by-product as organically grown food. This includes meat, milk, eggs, cheese, and honey. The reasoning is that animals and bees are so mobile that their background and the chemicals to which they have been exposed cannot always be determined.

The regulations do establish as acceptable the labeling of meat and poultry products and byproducts as "produced in an organic environment" when the product meets certain criteria involving maintenance and care of the animal.

Under the regulations, "organically grown food" means food which has been grown without synthetic pesticides, fertilizers, or chemicals; in soil in which the humus content is increased only by the addition of natural matter, and in soil in which the mineral content is increased only by the application of natural mineral fertilizers or other natural matter.

There is also a definition for "organically processed food," meaning food organically grown which in the processing has not been treated with preservatives, artificial coloring, artificial flavorings, or any other artificial or synthetic additive.

One of the reasons some authorities refuse to recognize the existence

of organic foods is that certain synthetic chemicals have been in the environment so long that it would be virtually impossible to produce food that does not show at least a trace of man-made chemicals. The department deals with this problem by establishing a synthetic pesticide tolerance in organically grown foods of 10 percent of the residue allowed in other foods under standards set by the FDA.

The department has authority to require that growers, processors, or sellers of these foods prove through laboratory analyses the organic claims made for these foods.

### New York Economy

The regulatory functions of the New York State Department of Agriculture and Markets, Division of Food Control, have been increased to take in 20 inspectors who enforce State fruit and vegetable standards. This is part of a program to help cut the costs of enforcing the Agriculture and Markets Law. The plan would give one inspector the responsibility of four in the inspection of food stores. He would be responsible for the sanitation, meat labeling, food labeling, advertising claims, fruit and vegetable grade standards, egg grades and advertising, and both incoming potable water and outgoing waste water. The new plan cuts the cost of travel for four inspectors formerly conducting these same functions. The department feels this may be of interest to similar organizations concerned with cutting operations costs.

### Meat Embargo

About 1,500 pounds of meat valued at \$2,000 was embargoed by Missouri Division of Health sanitarians when they intercepted a truck at Sedalia after being informed by

FDA's Kansas City District that the meat was being transported from Kansas in an unrefrigerated van, apparently under insanitary conditions. The District had been so informed by a local Kansas health officer and in turn notified John G. Norris, chief of food processing and drug control in the Missouri division's Bureau of Community Sanitation. The sanitarians found the meat was being transported on the floor of an unrefrigerated bread truck at an unsafe temperature, exceeding 50° F. The food store chain that owned the meat was told that it could either surrender it for destruction or rendering to nonfood products or go to court. The company surrendered the meat for rendering and promised not to repeat such offenses in the future.

### Insect-Infested Foods

Voluntary destruction of 14,330 pounds of flour and 43,410 pounds of cornmeal was supervised by Mildred Jackson, an inspector in the Kansas City-Wyandotte County Health Department, after the department found the products, stored in a surplus commodity warehouse at Kansas City, were heavily infested by insects. The cornmeal had been shipped from a Nebraska mill and the flour from a mill in Kansas City, Missouri.

### Insanitary Conditions

The Food and Drug Division of the Texas State Health Department in October prosecuted Dandy Bakery, Cavazos Wholesale Candy and Produce Co., and Julian M. Trevino Wholesale Grocery, all located in Laredo. All three companies were charged with operating under insanitary conditions. The State division has a contract with FDA to inspect bakeries, warehouses, and bottling plants in Texas.

# 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 42 actions to remove from the consumer market products charged to be violative was reported in November. These included 15 seizures of foods: 2 involved charges concerning poisonous and deleterious substances, 10 involved charges concerning contamination, 1 involved charges con-

cerning economic and labeling violations. Other seizures included 1 of food additives, 1 of color additives, 12 of drugs (including 4 of veterinary and medicated feed), and 15 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 Meat/Los Angeles, Calif. 8/8/73	Imported from Ecuador. Empacadora Shayne Cia. Ltd./Guayaquil (M, S)	Contains excessive histamine.
Tuna, Dubon/Hattiesburg, Miss. 10/1/73	Fraering Brokerage Co./New Orleans, La. (S)	"; decomposed.
<b>Contamination, Spoilage, Insanitary Handling</b>		
Liquors, various/Superior, Wis. 10/9/73	Exports, Inc./Superior, Wis. (D)	Held under insanitary conditions.
Mushrooms, Four Seasons Brand/Houston, Tex. 9/14/73 and 9/14/73 (2 actions)	Container & Trailer Marrying Co./Houston, Tex. (D)	Swelled, leaky, rusty, and dented cans.
Great Lakes Brand/Houston, Tex. 9/14/73	"	"
Peanuts, Virginia Fancy/Honolulu, Hawaii 10/30/73	Wing Coffee Co. Ltd./Honolulu, Hawaii (D)	Held under insanitary conditions; rodent gnawed.
Des Moines 10/24/73	International Multifoods Corp./Omaha, Nebr. (S)	Held under insanitary conditions; insect contaminated.
Rice, extra long grain/Salt Lake City, Utah 10/31/73	Watson Warehouse & Storage Co./Salt Lake City, Utah (D)	Held under insanitary conditions; rodent contaminated.
long grain parboiled; enriched; long grain enriched parboiled; extra long grain enriched/Los Angeles, Calif. 10/11/73	Interstate Restaurant Supply/Los Angeles, Calif. (D)	Held under insanitary conditions; insect contaminated.
Salmon, frozen dressed headless/Bellingham, Wash. 10/16/73	Bellingham Cold Storage Co./Bellingham, Wash. (D)	Decomposed.
Sugar, Domino Granulated Pure Cane; cheddar cheese, rectangular chunks mild; Water Maid Quality Supreme Rice; By Golly Lolly Suckers/Nashville, Tenn. 9/5/73	Bi-Rite Food Stores/Nashville, Tenn. (D)	Held under insanitary conditions; rodent contaminated.
Vinegar, white/Kansas City, Kans. 11/8/73	Speas Co./Kansas City, Mo. (M, S)	Held under insanitary conditions; insect contaminated.
<b>Economic and Labeling Violation</b>		
Whipped topping/Bonner Springs, Kans. 9/19/73	Presto Food Products/Kansas City, Mo. (M, S)	Net quantity of contents statement not in conformity with the Fair Packaging and Labeling Act.
<b>FOOD ADDITIVE</b>		
Cornmeal, rye meal, bread flour, cake flour, mixes, bran/Phoenix, Ariz. 10/19/73	California Milling Corp./Phoenix, Ariz. (D)	Contains unsafe food additive malathion (rye meal); held under insanitary conditions; rodent and insect contaminated.
<b>COLOR ADDITIVE</b>		
Candy, Coffees, Rummies/Los Angeles, Calif. 8/8/73	Bohemian Biscuit Co./Los Angeles, Calif. (D)	False and misleading label statement; unsafe color additives, patentblue and nykockin, in products are not "U.S. Certified Colors" as stated.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>DRUGS/Human Use</b>		
Afrodex capsules/Covina, Calif. 9/25/73 Brooklyn, N.Y. 9/26/73	ICN Pharmaceuticals, Inc./Covina, Calif. (D) " (M, S)	Inadequate directions for use; new drug without effective approved New Drug Application. New drug without effective approved New Drug Application.
Landover, Md. 9/12 & 10/31/73	Manufactured for Bentex Div. of ICN Pharmaceuticals, Inc./Houston, Tex.; ICN Pharmaceuticals, Inc./Covina, Calif. (S)	"
d-Anferoid, d-Amphetamine Phos tablets; d-Anferoid with Phenobarbital tablets, Dextramindex Injection, Dexmotabs Nos. 4 & 5, Dextro-Amphetamine Sulfate and Amobarbital tablets, Amfamindex Injection, Dextrobar Lanacaps No. 2/Baltimore, Md. 10/5/73	Reyman Drug Co., Inc./Baltimore, Md. (D)	Label statements false and misleading; inadequate directions for use; new drugs without effective approved New Drug Applications.
Dextrocell tablets/Richmond, Va. 10/24/73	Jones & Vaughan, Inc./Richmond, Va. (D)	Inadequate directions for use; new drug without effective approved New Drug Application; label statements false and misleading.
Potassium Chloride Injection/Dallas, Tex. 10/17/73	Premo Pharmaceutical Labs., Inc./South Hackensack, N.J. (M, S)	Not in conformity with good manufacturing practice.
Spastol tablets/Cumberland, Md. 10/24/73	J. W. S. Delavau Co./Philadelphia, Pa. (M, S)	" ; contains a color additive, FD&C Violet No. 1, which is unsafe.
Ulcortar Hydrocortisone in Tar Extract Cream/Minneapolis, Minn. 11/1/73	Ulmer Pharmacal Co./Minneapolis, Minn. (D)	Below purported strength; false and misleading statement "Hydrocortisone U.S.P. 1%"; contains less than that amount.
<b>Veterinary/Medicated Feed</b>		
Anaparin Veterinary/Friona, Tex. 9/11/73	Seney & Co., Inc./Denver, Colo. (M, S)	New animal drug without effective approved New Animal Drug Application.
Diethylstilbestrol/Hale Center, Tex. 9/14/73	Wittney & Co., Inc./Denver, Colo. (M, S)	"
Stepticol Veterinary/Tulia, Tex. 10/1/73	Seney & Co., Inc./Denver, Colo. (M, S)	"
Stilbolsol-10 Diethylstilbestrol Premix/Kissimmee, Fla. 9/24/73	Mid State Feed Mill/Kissimmee, Fla. (D)	"
<b>MEDICAL DEVICES</b>		
"Circulatron"/Winter Haven, Fla. 9/21/73	DCA Leasing Corp./New Hyde Park, N.Y. (M, S)	Inadequate directions for safe use by laymen.
Diapulse/Commerce, Tex. 9/6/73 Shawnee, Okla. 10/3/73	John C. Weddle, D.C./Commerce, Tex. (D) Earl Carpenter, D.C./Shawnee, Okla. (D)	" False and misleading claims for treatment of infections, fractures, bursitis, etc.; inadequate directions for use.
New Boston, Tex. 10/3/73	John W. Chandler, D.C./New Boston, Tex. (D)	Inadequate directions for use.
Claremore, Okla. 10/17/73	Diapulse Manufacturing Co. of America/New York, N.Y. (M)	Misbranded; inadequate directions for use.
Berkeley, Calif. 10/29/73	Remington Rand Div. Sperry Rand Corp./New York, N.Y. (M); Diapulse Corp. of America/New York, N.Y. (S)	Inadequate directions for safe use by laymen.
North Kansas City, Mo. 10/23/73	Diapulse Corp. of America/New Hyde Park, N.Y. (M)	Labeling is false and misleading; inadequate directions for lay use.
Liberty, Mo. 10/26/73	"	"
Wichita, Kans. 10/19/73	"	"
Clearmont, Mo. 10/25/73	"	"
Pleasant Hill, Mo. 10/23/73	"	"
St. Petersburg, Fla. 11/5/73	Remington Rand Div. Sperry Rand Corp./New York, N.Y. (M)	Inadequate directions for safe use by laymen.
San Francisco, Calif. 10/9/73	" ; Diapulse Corp. of America/New York, N.Y. (S)	"
Majzlin Spring IUD/Providence, R.I. 10/18/73	Anka Research Ltd./Jamaica, N.Y. (M, S)	Dangerous to health.
Specific Adjusting Machine/Spring Valley, Ill. 9/15/73	Arden D. Zimmerman, D.C./San Jose, Calif. (M, S)	Inadequate directions for safe use by laymen; dangerous to health when used as directed; false and misleading claims for treatment of removal of pressure from the spinal cord, back pain, arthritis, ruptured disc, etc.

## 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)

- August 17, 1973: **Crown Sales, Ltd.**, Box 5000, Northridge, California 91324. Advertising and sale by mail of "Oxford Slim Discs" containing vitamin E and represented to be effective for weight loss.
- August 28, 1973: **Princeton Diet Research**, Box 2034, Princeton, New Jersey 08540. Advertising and sale by mail of a diet plan represented to cause a weight loss of 20 pounds in 14 days.
- September 6, 1973: **New Slim Line Diet**, P.O. Box 636, Santa Ana, California 92706. Advertising and sale of "Grapefruit Diet" represented to be effective for a weight loss of 15 pounds in 1 week.
- September 12, 1973: **Crown Sales, Ltd.**, Box 5000, Northridge, California 91324. Advertising and sale by mail of "Vitamin E Oil" represented to be effective for treatment of various skin disorders.
- September 12, 1973: **Ob-lean**, 12th & Market Street, Wheeling, West Virginia. Advertising and sale by mail of a plan for losing weight.
- September 14, 1973: **Elizabeth Astor Division**, 1231 East Los Olas Boulevard, Fort Lauderdale, Florida 33301. Advertising and sale by mail of a product called "Exogen Vitamin E Oil" represented to be effective as a wrinkle and stretch mark remover.
- September 14, 1973: **United States Purchasing Exchange**, 5260 Vineland Avenue, North Hollywood, California 91601. Advertising and sale by mail of "Vitamin E Creme" represented to be effective for treatment of 12 skin problems.
- September 14, 1973: **Vita Youth Science Co.**, 7471 Melrose, Los Angeles, California 90046. Advertising and sale by mail of "Vitamin E Moisturizing Lotion" represented to be effective for treatment of skin disorders.
- September 17, 1973: **Elizabeth Astor Division** 5075, 1231 East Los Olas Boulevard, Fort Lauderdale, Florida 33301. Advertising and sale by mail of a product called "Exogen Vitamin E Oil" represented to be effective as a wrinkle remover.
- September 26, 1973: **OttaVee Herbs**, P.O. Box 335, Sparks, Nevada. Advertising and sale by mail of "Ancient Imported Herbs" represented to be effective as an aphrodisiac, treatment of male impotency, and removal of aging lines.
- October 1, 1973: **Cosmetic Laboratories**, P.O. Box 7040, Atlanta, Georgia 30309. Advertising and sale by mail of a product called "Head Start" represented to be effective in preventing baldness and, in some cases, causing new hair growth.
- October 2, 1973: **Arman Drug Co., Inc.**, P.O. Box 14191, Omaha, Nebraska 68114. Advertising and sale by mail of a product called "Vitamin E Cream" represented to be effective as a wrinkle remover.
- October 2, 1973: **Arman Drug Co., Inc.**, P.O. Box 14191, Omaha, Nebraska 68114. Advertising and sale by mail of a product called the "Armadox Plan" represented to enable the user to lose 15 pounds in 30 days.
- October 2, 1973: **Cornell Research Corp.**, 797½ North Main Street, Akron, Ohio. Advertising and sale by mail of a product called "Metab-A-Slim" represented to enable the user to lose up to 5 pounds within 24 hours, 12 pounds the first week, or 34 pounds the first month.
- October 3, 1973: **Primus and Primus International Ltd.**, 75 East 55th Street, New York, New York 10022. Advertising and sale by mail of a book entitled "Eat Like A Horse Yet Lose Up To 40 Pounds (Or More)" containing an effective program to control obesity which does not require dietary restrictions.
- October 4, 1973: **United States Purchasing Exchange**, 5260 Vineland Avenue, North Hollywood, California. Advertising and sale by mail of the "Vibro-Suction Elec. Massager" represented to be effective for massaging away fat.
- October 5, 1973: **Hanover House**, Hanover, Pennsylvania 17331. Advertising and sale by mail of a "Vitamin E Cream" to "halt and reverse the ravages of time."
- October 5, 1973: **Hanover House**, Hanover, Pennsylvania 17331. Advertising and sale by mail of "Hungrex Tablets" to cause weight loss by reducing appetite.
- October 12, 1973: **Hanover House**, Hanover, Pennsylvania 17331. Advertising and sale by mail of a chin strap to provide facial lift without surgery.
- October 12, 1973: **Paragon Products**, 939 W. Street, NW, Washington, D.C. 20001. Advertising and sale by mail of a product to relieve high blood pressure "nature's way without drugs."
- October 16, 1973: **Midwest Health Aids**, 154 East Erie Street, Chicago, Illinois 60611. Advertising and sale by mail of a product called "New Alcorem" represented to be effective as a cure for alcoholism.
- October 12, 1973: **Romar Sales Corp.**, 227 East 45th Street, New York, New York 10017. Advertising and sale by mail of "Hungrex Tablets" to cause weight loss by reducing appetite.
- October 19, 1973: **Hartford Publishing Corp.**, 79 Savage Road and P.O. Box 932, Denville, New Jersey 07834. Advertising and sale by mail of "The Digital Diet," a means of overcoming obesity through eating.
- October 19, 1973: **Ricard Chemical Distributors**, 2655 N. E. 30th Place, Fort Lauderdale, Florida 33306. Advertising and sale by mail of a product called "Preparation 38" represented to be effective as a sex stimulant.

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

- August 13, 1973: Against **Health Aids Co.**, Box 1, Brooklyn, New York. Advertising and sale by mail of products and methods to lose weight.
- August 31, 1973: Against **The Fitness Bazaar Inc.**, 90 Beacom Boulevard, Miami, Florida 33135. Advertising and sale by mail of a product represented to be effective in taking inches off the user's body.
- September 10, 1973: Against **K. Rode Corp.**, Apartado Postal 1-1970, Guadalajara, Mexico. Advertising and sale by mail of products to enlarge the bust.
- September 12, 1973: Against **Spectron Industries**, P.O. Box 17200, San Diego, California. Advertising and sale through the mail of a product represented to be an effective cure for baldness.
- September 13, 1973: Against **A.D.P.**, P.O. Box 703, Solana Beach, California. Advertising and sale by mail of "U.S. Woman's Ski Team Diet" represented to be effective for a 20-pound weight loss in 14 days.
- October 1, 1973: Against **Adarsh Ayurvedic Pharmacy**, Post Box 30, Simla (H.P.) India. Advertising and sale by mail of a booklet allegedly containing "fool-proof" cures for various illnesses and diseases.
- October 4, 1973: Against **New Slim Line Diet**, P.O. Box 636, Santa Ana, California. Advertising and sale by mail of "Grapefruit Diet" represented to be effective for a weight loss of 15 pounds in 1 week.
- October 15, 1973: Against **Institucion Internacional S.A.**, Aptdo. 1365, Monterrey, Mexico. Advertising and sale by mail by a Mexican firm of the apparatus "Hidro-Sen" to enlarge the bust.

# Notices of Judgment

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

**Alfalfa hay**, 2 seizure actions, at Corona and Ontario, C. Dist. Calif.

Charged 11-27-72 and 11-27-72: when shipped by Garin & Co., Poston, Ariz., the article contained the added pesticide chemical S,S-tributyl phosphorothioate for which there was no tolerance or exemption therefrom for alfalfa hay; 402(a)(2)(B). Default decree ordered destruction. (F.D.C. Nos. 58568/9; S. Nos. 46-704 F and 47-641 F; N.J. No. 1)

**Ladyfish, frozen**, at San Francisco, N. Dist. Calif.

Charged 7-6-72: when shipped by Anderson Seafood Co., Panama City, Fla., the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 58119; S. No. 74-140 F; N.J. No. 2)

## FOOD/Contamination, Spoilage, Insanitary Handling

**Beans, Great Northern, dried**, at Denver, Dist. Colo.

Charged 3-29-73: while held by Mountain States Bean Co., Denver, Colo., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59057; S. No. 44-924 G; N.J. No. 3)

**Beans, kidney, dried**, at San Juan, Dist. P.R.

Charged 3-8-73: while held by M. Cuebas, Inc., San Juan, P.R., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for reconditioning. (F.D.C. No. 58942; S. No. 94-694 G; N.J. No. 4)

**Beans, pinto, dried**, at Vernalis, E. Dist. Calif.

Charged 3-27-73: while held by Weston Warehouse Co., Inc., Vernalis, Calif., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59043; S. No. 92-286 G; N.J. No. 5)

**Beans, pinto, dried**, at Ventura, C. Dist. Calif.

Charged 5-4-73: while held by Ramirez & Feraud Chili Co., Inc., Ventura, Calif., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 59193; S. No. 52-793 G; N.J. No. 6)

**Beans, pinto, dried, and rice**, at Fresno, E. Dist. Calif.

Charged 9-14-72: while held by Hobbs-Parsons Co., Fresno, Calif., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 58247; S. Nos. 74-553/4 F; N.J. No. 7)

**Brazil nuts**, at San Francisco, N. Dist. Calif.

Charged 12-18-72: while held for sale, the article contained insect-infested, moldy, and rancid nuts; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 58684; S. No. 75-665 F; N.J. No. 8)

**Cashew kernel pieces**, at Chicago, N. Dist. Ill.

Charged 12-19-72: when shipped by J. F. Braun & Sons, Inc., Lake Success, N.Y., the article contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the shipper for salvaging. (F.D.C. No. 58697; S. Nos. 21-841/2 G; N.J. No. 9)

**Cereal, Jones Klean Cracked Wheat**, at St. Joseph, W. Dist. Mo.

Charged 10-31-72: when shipped by Jones Milling Co., Wichita, Kans., the article contained rodent filth, and had been prepared, packed, and held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58438; S. No. 40-740 F; N.J. No. 10)

**Cherries, canned**, at Lima, N. Dist. Ohio.

Charged 12-21-73: when shipped by USP Corp., Salem, Oreg., the article, labeled in part "Shurfine . . . Black Bing Dark Sweet Unpitted Cherries . . . Distributed by Eastern-Retailer-Owner Grocers Cooperative, Inc., New York, N.Y.," was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not within the bottom 30 percent of the principal display panel area; the quantity of contents statement was expressed as "Net Weight 1 Lb. 1 Oz." or "Net Wt. 30 Oz." instead of "Net Wt. 17 Oz. (1 Lb. 1 Oz.)" or "Net Wt. 30 Oz. (1 Lb. 14 Oz.)"; and the quantity of contents statement, appearing on the principal display panel area of more than 5 square inches, was in a type size less than 1/8 inch high—15 U.S.C. 1453(a)(4), 1453(a)(3)(A)(i), 1453(a)(3)(C)(i); and, while held for sale, the article contained mold and decomposed cherries and was unfit for food due to swollen and leaking cans, and the article failed to conform to the standard of identity for canned cherries, since the article was not sealed in a container and so processed by heat as to prevent spoilage—402(a)(3), 403(g)(1). Default decree ordered destruction. (F.D.C. No. 58699; S. Nos. 27-801/2 F; N.J. No. 11)

**Coffee beans**, at Duluth, Dist. Minn.

Charged 1-29-73: while held by Ceres, Inc., Duluth, Minn., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to Red Owl Stores, Inc., Hopkins, Minn., for salvaging. (F.D.C. No. 58843; S. No. 59-921 G; N.J. No. 12)

**Cornmeal, pumpnickel mix, rye mix, doughnut mixes, and flour**, at Worcester, Dist. Mass.

Charged 3-15-73: while held by Rudnick & Meager Cold Storage Co., Inc., Worcester, Mass., the articles contained rodent and insect filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58922; S. Nos. 91-467/9 F et al.; N.J. No. 13)

**Dextrose, cornmeal, and soy flour**, at Oakland, N. Dist. Calif.

Charged 4-6-73: while held by Domasco Bakers Supply Co., Oakland, Calif., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59092; S. Nos. 92-702/5 G; N.J. No. 14)

**Flour**, at Casper, Dist. Wyo.

Charged 1-10-73: while held by Pioneer Markets, Inc., Casper, Wyo., 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. 58765; S. Nos. 34-184/6 F; N.J. No. 15)

**Flour**, at Chicago, N. Dist. Ill.

Charged 3-22-73: while held by Baltic Bakery, Chicago, Ill., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59039; S. Nos. 23-466/70 G; N.J. No. 16)

**Flour**, at Los Angeles, C. Dist. Calif.

Charged 2-28-73: while held by Rancho Cold Storage, Los Angeles, Calif., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the county of Los Angeles, Los Angeles, Calif., for salvaging. (F.D.C. No. 58938; S. No. 47-680 F; N.J. No. 17)

**Flour**, at Mapleton, N. Dist. Iowa.

Charged 3-27-73: while held by Midwest Wholesale Grocery (John Abraham), Mapleton, Iowa, the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59067; S. Nos. 49-809/10 G; N.J. No. 18)

**Flour**, at New Orleans, E. Dist. La.

Charged 3-2-73: while held by P. A. Menard Co., Inc., New Orleans, La., 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. 58947; S. Nos. 66-902/5 G; N.J. No. 19)

**Flour**, at Sault Ste. Marie, W. Dist. Mich.

Charged 11-30-72: when shipped by Pillsbury Co., Minneapolis, Minn., the article contained rodent filth; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 58610; S. No. 98-774 F; N.J. No. 20)

**Flour and sugar**, at Lebanon, M. Dist. Tenn.

Charged 12-14-72: while held by Bradley Candy Manufacturing Co., Lebanon, Tenn., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58658; S. Nos. 7-381/2 F; N.J. No. 21)

**Halibut fish, frozen**, at Everett, W. Dist. Wash.

Charged 3-6-73: when shipped, the article contained decomposed fish; 402(a)(3). Consent decree authorized release to Everett Fish Co., Everett, Wash., for salvaging. (F.D.C. No. 58939; S. No. 96-501 G; N.J. No. 22)

**Kipper herring fillets, canned**, at New Orleans, E. Dist. La.

Charged 12-7-72: while held for sale, the article contained decomposed fillets; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 58614; S. No. 54-535 F; N.J. No. 23)

**Macaroni and cheese dinner**, Porter, at Twin Falls, Dist. Idaho.

Charged 12-7-72: when shipped by Porter-Scarpelli Macaroni Co., Portland, Oreg., the article contained insect filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58616; S. No. 79-465 F; N.J. No. 24)

**Margarine and cornmeal mix**, at Gadsden, N. Dist. Ala.

Charged 3-14-73: while held by Osborn Bros., Inc., Gadsden, Ala., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58964; S. Nos. 4-442/3 G; N.J. No. 25)

**Pancake mix, DCA**, at Weymouth, Dist. Mass.

Charged 3-22-73: when shipped by Golden Dipt. Co., Division DCA Food Industries, Inc., Melrose Park, Ill., the article had been prepared and packed under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58969; S. No. 13-427 F; N.J. No. 26)

**Peanuts, shelled**, at Silver Creek, W. Dist. N.Y.

Charged 2-2-73: while held by A. J. Petrie & Sons, Inc., Silver Creek, N.Y., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 58846; S. No. 18-161 G; N.J. No. 27)

**Peanuts, unshelled**, at Lafayette, W. Dist. La.

Charged 3-15-73: while held by Lafayette Fruit Co., Lafayette, La., the article was held under insanitary conditions; 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 58980; S. No. 67-021 G; N.J. No. 28)

**Peanuts, unshelled**, at Macon, M. Dist. Ga.

Charged 3-30-73: while held by Wilder Produce Co., Macon, Ga., 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. 59063; S. No. 5-064 G; N.J. No. 29)

**Peanuts, unshelled**, at San Francisco, N. Dist. Calif.

Charged 3-26-73: while held by Wrieth Popcorn & Nut Co., San Francisco, Calif., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59044; S. No. 91-367 G; N.J. No. 30)

**Pistachio nuts**, at Los Angeles, C. Dist. Calif.

Charged 12-27-72: while held by Service Foods, Los Angeles, Calif., the article was held under insanitary conditions; 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 58723; S. No. 46-627 F; N.J. No. 31)

**Rice**, at Chicago, N. Dist. Ill.  
Charged 1-26-73: while held by Banner Wholesale Grocers, Chicago, Ill., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 58824; S. Nos. 19-822/3 F; N.J. No. 32)

**Rice**, at Denver, Dist. Colo.  
Charged 4-3-72: while held by Granada Fish Market, Inc., Denver, Colo., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59080; S. Nos. 44-921/3 G, 44-933/8 G; N.J. No. 33)

**Rice**, at Fort Wayne, N. Dist. Ind.  
Charged 11-28-72: while held by Fort Wayne Storage Co., Inc., Fort Wayne, Ind., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58605; S. Nos. 94-347/8 F; N.J. No. 34.)

**Rice**, at Miami, S. Dist. Fla.  
Charged on or about 2-27-73: while held by Miavana Wholesale Co., Inc., Miami, Fla., 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. 58928; S. No. 3-222 G; N.J. No. 35)

**Rice**, at Oakland, N. Dist. Calif.  
Charged 3-7-73: while held by Veronica Foods Co., Oakland, 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. 58953; S. No. 92-225 G; N.J. No. 36)

**Rice**, at West Palm Beach, S. Dist. Fla.  
Charged 3-23-73: while held by Cheney Bros., Inc., West Palm Beach, Fla., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58978; S. No. 2-661 G; N.J. No. 37)

**Rice and flour**, at Los Angeles, C. Dist. Calif.  
Charged 3-22-73: while held by Wasserman & Lieb Enterprises, Inc., Los Angeles, Calif., the articles were held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59016; S. Nos. 52-147/8 G, 52-149 G; N.J. No. 38)

**Soy grits, low-fat, and nonfat dried milk**, at Walnut Creek, N. Dist. Calif.  
Charged 11-15-72: while held by Debco Manufacturing Co., Walnut Creek, Calif., the articles were held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 58475; S. Nos. 74-079/80 F; N.J. No. 39)

**Sugar**, at Linden, Dist. N.J.  
Charged 3-30-73: while held by Linden Motor Freight Co., Inc., Linden, N.J., the article contained wood splinters, straw, pieces of brown paper, a spider, and nondescript dirt; 402(a)(3). Consent decree authorized release to Clifford Kaufholz & Co., Inc., Lansdowne, Pa., for nonfood use. (F.D.C. No. 59078; S. No. 55-770 F; N.J. No. 40)

**Sugar**, at Prichard, S. Dist. Ala.  
Charged 8-22-72: while held by Barbour's B & W Coffee Co., Inc., Prichard, Ala., the article was held under insanitary conditions; 402(a)(4). Default decree ordered article forfeited and condemned for the use of the Government. (F.D.C. No. 58210; S. No. 639 F; N.J. No. 41)

**Sugar**, at Roseville, E. Dist. Mich.  
Charged 12-18-72: while held by Oven King Cookies, Roseville, Mich., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58657; S. No. 98-572 F; N.J. No. 42)

**Sugar, brown, and coconut, shredded**, at Los Angeles, C. Dist. Calif.  
Charged 4-25-73: while held by Arden-Mayfair, Inc., Los Angeles, Calif., the coconut contained rodent filth, and both articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59176; S. Nos. 52-843/4 G; N.J. No. 43)

**Tomato juice, Naas**, at Big Rapids, W. Dist. Mich.  
Charged 2-28-73: when shipped by Naas Foods, Inc., Geneva, Ind., the article contained decomposed tomato material; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 58937; S. Nos. 39-302/3 G; N.J. No. 44)

**Tomato juice**, at Plainfield, N. Dist. Ill.  
Charged 3-14-73: when shipped by Naas Foods, Inc., Geneva, Ind., the article, labeled in part "Cherry Valley Tomato Juice . . . Distributed by Jewel Companies, Inc., Melrose Park, Ill.," contained decomposed tomato material; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59017; S. No. 23-902 G; N.J. No. 45)

**Tomato juice, Naas**, 2 seizure actions, at Jackson and at Bay City, E. Dist. Mich.  
Charged 3-4-73 and 3-15-73: when shipped by Naas Foods, Inc., Geneva, Ind., the articles contained decomposed tomato material; 402(a)(3). Default decrees ordered destruction. (F.D.C. Nos. 58948 and 58952; S. Nos. 39-305 G, 39-424 G; N.J. No. 46)

#### FOOD/Economic and Labeling Violations

**Broth and seasoning mixes of various flavors, Maggi**, at Denver, Dist. Colo.  
Charged 11-9-72: when shipped by The Nestle Co., Inc., and Gerber Cheese Co., Franklin Park, Ill., the labels of the articles (which in the chicken-flavored and onion-flavored articles contained salt as their most predominant ingredient and in the vegetable-flavored and beef-flavored articles contained salt as the second most predominant ingredient) had false and misleading claims representing and suggesting that the articles had special dietary value as a means of restricting the intake of sodium or salt—403(a); and all the articles except the beef-flavored article were in violation of the Fair Packaging and Labeling Act, since the quantity of contents statement, appearing on the principal display panel area of

more than 5 square inches, was in a type size less than 1/8 inch high—15 U.S.C. 1453(a)(3)(C)(i). Consent decree ordered destruction. (F.D.C. No. 58513; S. Nos. 33-422 F, 33-424/6 F; N.J. No. 47)

#### Cookies, King Size T.V., at Cincinnati, S. Dist. Ohio.

Charged 12-15-72: when shipped by Imperial Baking Co., St. Louis, Mo., the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents, appearing on the principal display panels on the front and back of the package, was not duplicated on the alternate principal display panel on the side of the package; and the quantity of contents statements, appearing on the principal display panel areas of more than 5 square inches, were in a type size less than 1/8 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Consent decree authorized release to the shipper for relabeling. (F.D.C. No. 58695; S. No. 26-478 F; N.J. No. 48)

#### Flour, all-purpose enriched, Pillsbury's Best XXXX, at Chandler, Dist. Ariz.

Charged 10-30-72: when shipped by Pillsbury Co., Clearfield, Utah, the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents statement, appearing on the principal display panel area of more than 25 square inches, was in a type size less than 3/16 inch high; 15 U.S.C. 1453(a)(3)(C)(i). Default decree authorized donation to a charitable/public institution. (F.D.C. No. 58444A; S. No. 43-953 F; N.J. No. 49)

#### Muffin mixes, Shawnee, at Joplin, W. Dist. Mo.

Charged 11-13-72: when shipped by Shawnee Milling Co., Shawnee, Okla., the articles' names, "Red Raspberry Muffin Mix" and "Blueberry Muffin Mix," were false and misleading as applied to articles which contained artificially flavored and colored nuggets and did not contain red raspberries and blueberries; the articles contained potassium sorbate, a chemical preservative, and failed to state that the articles contained a chemical preservative; and the quantity of contents statement of the mix containing "artificial red raspberry flavorbursts" was not prominently placed, since the statement was printed in a color that did not contrast sufficiently with the background color; 403(a), 403(k), 403(f). Consent decree authorized release to the shipper for relabeling. (F.D.C. No. 58443; S. Nos. 39-547 F, 39-549 F; N.J. No. 50)

#### Peach halves, canned, O'Sage, at Woodruff, Dist. S.C.

Charged 3-15-73: when returned to Cherokee Products Co., Woodruff, S.C., the article's label lacked the words "Seasoned with Peach Pits" required by the definition and standard of identity for canned peaches containing the optional ingredient peach pits; and the article fell below the standard of quality for canned peaches, since the weight of the largest peach half was more than twice the weight of the smallest peach half; 403(g)(2), 403(h)(1). Consent decree authorized release to the possessor for bringing into compliance. (F.D.C. No. 59009; S. No. 27-361 F; N.J. No. 51)

#### Salt from the sea, at Culver City, C. Dist. Calif.

Charged 7-10-72: when shipped by Codisel Cie Des Salins Du Midi, Mer, France, and Campagnie Des Salinsdomid, Mer, France, the mandatory information concerning the name of the food, its weight, and the name and place of business of the manufacturer, packer, or distributor was not in terms likely to be read and understood under customary conditions of purchase and use, since such information was not stated in the English language; 403(f). Consent decree authorized release to Erewhon Trading Co., Inc., Culver City, Calif., for relabeling under bond. A subsequent court order forfeited a percentage of the bond equivalent to that percentage of the article which had been distributed in violation of the decree. The rest of the article was observed by FDA to have been satisfactorily relabeled and was released along with the remainder of the bond. (F.D.C. No. 58115; S. Nos. 44-523/4 F; N.J. No. 52)

#### Squid pieces in tomato sauce, Campanelli's, at Las Vegas, Dist. Nev.

Charged 3-2-72: while held by Madonna Italian Foods, Inc., Las Vegas, Nev., the label lacked the common or usual name of the food, and the label lacked the common or usual name of each ingredient—403(i)(1), 403(i)(2); and the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not on the principal display panel—15 U.S.C. 1453(a)(2). The article was claimed by Joseph Campanelli, Jr., and pursuant to stipulation was released to the claimant for exportation of the article. (F.D.C. No. 57847; S. No. 20-369 E; N.J. No. 53)

#### Topping, whipped, Real Whip, at Norman, W. Dist. Okla.

Charged 1-17-73: when shipped by Presto Food Products, Inc., Kansas City, Mo., the article was short weight—403(e)(2); and the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not within the bottom 30 percent of the principal display panel area and was not in lines generally parallel to the base of the article—15 U.S.C. 1453(a)(2). Default decree authorized donation to charitable institution. (F.D.C. No. 58776; S. No. 32-156 F; N.J. No. 54)

#### VITAMINS/SPECIAL DIETARY FOODS

##### Formula D vitamin and mineral tablets, at St. Petersburg, M. Dist. Fla.

Charged 4-18-72: when shipped by Brown & Brown, Hockessin, Del., the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not within the bottom 30 percent of the principal display panel area—15 U.S.C. 1453(a)(2); and the label contained a number of false and misleading claims, including the following: label statements with respect to the article's composition as a mixture of nutrients of proven nutritive value (vitamins A, D, C, B<sub>1</sub>, B<sub>2</sub>, B<sub>6</sub>, B<sub>12</sub>, niacin, iron, copper, zinc, and iodine) with ingredients of no proven value (choline bitartrate and inositol), that falsely and misleadingly rep-

resented and suggested that the nutritive value of the article was enhanced by the presence of choline bitartrate and inositol in the article, and that choline bitartrate and inositol had proven nutritive value; that 5 international units of vitamin E, 5 milligrams of magnesium sulfate, and 1 milligram of zinc sulfate are adequate and effective in supplementing the diet with vitamin E, magnesium, and zinc, when the amounts of vitamin E, magnesium, and zinc supplied by the article were insufficient as a dietary supplement; that the dietary needs of adults over 35 years of age were substantially different than adults of other age levels; and that manganese sulfate and potassium sulfate were necessary and useful in supplementing the diet—403(a). Default decree ordered destruction. (F.D.C. No. 57927; S. No. 3-014 F; N.J. No. 55)

#### **Honey, at Des Plaines, N. Dist. III.**

Charged 3-28-73: when shipped by Miller's Honey Co. (Woodrow Miller), Colton, Calif., the article labeled in part "Nature's Own Brand . . . Honey . . . Distributed by Mi-Del Products Franklin Park, Illinois" contained a number of false and misleading claims in its label to the effect that the article was of significant value in weight control diets as a means of restricting the intake of calories; that the usual or ordinary serving of honey would supply nutritionally significant amounts of many essential vitamins and minerals; and that the article had special dietary value in infant feeding—403(a); and the article was in violation of the Fair Packaging and Labeling Act, since the principal display panel lacked a quantity of contents declaration—15 U.S.C. 1453(a)(2). Consent decree authorized release to the dealer for relabeling. (F.D.C. No. 58999; S. Nos. 21-244 8 F; N.J. No. 56)

#### **Inland Sea Water, at Franklin Park, N. Dist. III.**

Charged 4-19-72: when shipped by TM Research Laboratories, Inc., Hooper, Utah, the article's label contained false and misleading claims that the article had special dietary value as a dietary supplement with respect to its composition of calcium, iron, sodium, chloride, potassium, sulfate, bromine, lithium, boron, magnesium, iodine, fluoride, strontium, bismuth, cobalt, lutetium, ytterbium, aluminum, cadmium, erbium, holmium, dysprosium, chromium, copper, terbium, gadolinium, europium, selenium, samarium, neodymium, manganese, gallium, germanium, molybdenum, nickel, nitrogen, zinc, gold, titanium, praseodymium, vanadium, and silver—403(a); the article's accompanying leaflet contained a number of false and misleading statements such as that the article contained 42 trace minerals essential in human nutrition; that the article contained rare trace elements essential to human nutrition and not found in other mineral preparations; that it was necessary to supplement the diet with minerals in order to have proper protein formation; that the article contained potassium which will help functioning of the vagus nerve and the digestive system; that it was necessary and useful to supplement the diet with potassium; that it was necessary and useful to supplement the diet with cobalt to insure utilization of vitamin B<sub>12</sub>; and that it was necessary to supplement the diet with minerals so that the minerals combined with vitamins to remove internal gaseous waste and carbon-nitrogen substances which cause damage to nerve coverings; as well as claims for diseases such as osteoporosis, osteomalacia (soft bones), retarded tooth development, fragile bones, stunted growth, rickets, cramps, spasms, heart palpitation, insomnia, and irritability—403(a); the label statement "Net Contents: 20 Fl. Oz. (1 pint)" was inaccurate and inconsistent—403(a), 403(e)(2); and the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not separated from other printed label information appearing above the declaration; and the quantity of contents statement, appearing on the principal display panel area of more than 5 square inches, was in a type size less than 1/16 inch high: 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Default decree ordered destruction. (F.D.C. No. 57883; S. No. 20-549 F; N.J. No. 57)

#### **Riddo food supplement powder, Papaya with papain tablets, and Improved Bragg Live Food Vital Concentrate capsules, at Burbank, C. Dist. Calif.**

Charged 7-18-72: while held by Live Food Products Co., Burbank, Calif., the bottle labels and accompanying labeling contained false and misleading claims as follows: Riddo food supplement powder—as an aid to health, as a laxative, and as a colon detoxifier; and that lactic acid and lactose were nutrients with special dietary properties; and that the nutritive value of the article was enhanced by the presence of lactic acid and lactose, and that 23 milligrams of lactic acid and 7.9 grams of lactose had proven special dietary value in a dietary supplement; Improved Bragg Live Food Vital Concentrate capsules—with respect to its composition as containing nutrients of proven special nutritive value (vitamins A, D, B<sub>1</sub>, B<sub>2</sub>, B<sub>6</sub>, B<sub>12</sub>, C, E, niacinamide, calcium, phosphorus, iron, and iodine) with ingredients of no proven special nutritive value in a dietary supplement (safflower oil, red bone marrow, defatted liver, hemoglobin, p-aminobenzoic acid, 40 mg protein hydrolysate, lecithin, bile salts, rutin, citrus bioflavonoids, betaine hydrochloride, inositol, and choline bitartrate), its labeling falsely and misleadingly represented and suggested that the nutritive value of the article was enhanced by the presence of these ingredients of no proven special nutritive value, and that these ingredients of no proven special nutritive value had proven special nutritive value; that the name of the product, "Vitamins and Minerals Plus Other Nutritional Factors," and the label statements, "As a dietary food supplement," "two capsules daily supply . . . D Calcium Pantothenate 2.0 mg. . . . Copper 0.02 mg. . . . Magnesium 0.2 mg. . . . Zinc 0.2 mg. . . ." and "other nutritional factors . . . biotin 0.1 mcg. . . ." falsely and misleadingly represented and suggested that 2 milligrams of D calcium pantothenate, 0.02 milligrams of copper, 0.2 milligrams of magnesium, 0.2 milligrams of zinc, and 0.1 microgram of biotin were present in nutritionally significant amounts; and that the amounts, when taken daily, would significantly supplement the dietary needs of the consumer; that the label statements,

"As a dietary food supplement" and "Two capsules daily . . . supply potassium 2 mg. . . . Manganese 3 mg. . . ." falsely and misleadingly represented and suggested that the ordinary diet needed supplementation with potassium and manganese, and that 2 milligrams of potassium and 3 milligrams of manganese were nutritionally significant; that the need in human nutrition has not been established for biotin was false and misleading, since it was contrary to fact; that the label statements, "Directions: As a dietary food supplement two capsules daily" and "Two capsules daily supply . . . Vitamin A . . . 12,000 USP Units Vitamin B<sub>1</sub> . . . 8.5 mg. . . . Vitamin B<sub>2</sub> . . . 8.5 mg. . . . Niacinamide USP 40.0 mg. . . ." falsely and misleadingly represented and suggested that 12,000 USP units of vitamin A, 8.5 milligrams of vitamins B<sub>1</sub> and B<sub>2</sub>, and 40 milligrams of niacinamide per day were necessary and useful as a dietary supplement; false and misleading claims that the article was a must for all ages for added pep, energy, and vitality; that natural-organic supplements were superior to synthetic ones; that the article was a powerful health benefit to the body, and that taking this article would help one feel, look, and do one's best; and Papaya with papain tablets—false and misleading claims that papaya powder and papain had a high potency and had therapeutic value; and that the article was necessary and useful in the digestion of protein for the ordinary individual; that the article was necessary to digest protein, and that it was adequate and effective in relieving sour stomach, bloating, gas distress, and in "sweetening up digestion"; 403(a). Patricia Bragg (Live Food Product Co.), Burbank, Calif., claimed the articles and denied the charges. Thereafter, the claimant moved to withdraw her claim. Conditioned upon the recovery from the claimant of court costs, fees, etc., the court authorized the withdrawal of the claim and authorized the destruction of the articles. (F.D.C. No. 58143; S. Nos. 44-396 F, 45-239 40 F; N.J. No. 58)

#### **Vitamin and mineral tablets, at Camden, Dist. N.J.**

Charged 12-27-72: when shipped by J. W. S. Delavau Co., Inc., Philadelphia, Pa., the label of the article, labeled in part "One Daily . . . Distributed by C. O. Truxton, Inc. . . . Camden, New Jersey . . . a dietary supplement," contained false and misleading representations and suggestions that the article's content of pyridoxine HCl, calcium pantothenate, and vitamin E significantly enhanced the nutritive value of the article, when such ingredients were present in nutritionally insignificant amounts—403(a); and the article was in violation of the Fair Packaging and Labeling Act, since the principal display panel of the label lacked a statement of the identity of the article, and the quantity of contents declaration was not within the bottom 30 percent of the principal display area—15 U.S.C. 1453(a)(1), 1453(a)(2); and while held for sale, the valuable constituent thiamine had been omitted or abstracted, and the label statement of thiamine content was false and misleading, since the article contained approximately 60 percent of the declared amount of thiamine—402(b)(1), 403(a). Default decree ordered destruction. (F.D.C. No. 58722; S. No. 68-781 F; N.J. No. 59)

#### **ANIMAL FEED**

##### **Animal feed supplement liquid, at Loveland, Dist. Colo.**

Charged 6-23-73: while held by Prescription Premix, Loveland, Colo., who manufactured the article using a concentrate which had been shipped in interstate commerce, the article contained diethylstilbestrol, a new animal drug for which no approval of a New Animal Drug Application was in effect: 402(a)(2)(D). Consent decree ordered destruction. (F.D.C. No. 58108; S. Nos. 34-063 5 F; N.J. No. 60)

#### **DRUGS/Human Use**

##### **Bacto Unidisk sensitivity test discs with antibiotics and sulfonamides, at Detroit, E. Dist. Mich.**

Charged 5-25-62: when shipped from Buffalo, N.Y., the article purported to be and was represented as a drug composed in part of penicillin, streptomycin, chloramphenicol, tetracycline, and aureomycin, and it lacked an Antibiotic Certification or Release and was not exempted therefrom: 502(i). The article was claimed by Difco Laboratories, Inc., Detroit, Mich., who denied the charge, stating that the article consisted of reagent disks for laboratory use, and praying for representative samples of the article. The Government served written interrogatories on the claimants, and the claimant served written requests for admissions. The Government moved for summary judgment. The court denied the motion, and the case came on for trial before the court on the issue of whether the article was a drug or not. After the trial, the district court concluded that the article was not a drug. This was affirmed by the court of appeals. However, upon appeal to the Supreme Court, the article was determined to be a drug; and the Supreme Court stated in its opinion the following: "Despite the renewed effort here to relitigate the public health issue, we agree with the decision implicitly made by the courts below not to base a resolution of this case on the public need for, or medical wisdom of, the Secretary's regulations requiring premarket clearance of antibiotic sensitivity discs. It is enough for us that the expert agency charged with the enforcement of remedial legislation has determined that such regulation is desirable for the public health, for we are hardly qualified to second-guess the Secretary's medical judgment. Our sole concern is whether the statute's definition of 'drug' authorizes the disc regulations contested here; and while we agree with the lower courts' limited conception of the issue, for reasons outlined below, we reverse their disposition of it."

"We need not stop to parse the language of the Act's definition of drug, for the District Court found, and the parties do not disagree here, that a literal reading of the words 'intended for use in the . . . cure, mitigation, for treatment' of disease 'clearly has application' to the

Bacto-Unidisk. Although respondent again urges that the disc itself does not 'treat' a patient in the same way an antibiotic does in terms of personal application, the disc plays at least some role in the selection of the appropriate drug. Thus, the essential question for our determination is whether Congress intended the definition of drug to have the broad coverage the courts below and the parties agree its words allow. Viewing the structure, the legislative history, and the remedial nature of the Act, we think it plain that Congress intended to define 'drug' far more broadly than does the medical profession.

"The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow. Strong indications from legislative history that Congress intended the broad coverage the District Court thought 'ridiculous' should satisfy us that the lower courts erred in refusing to apply the Act's language as written. But we are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health, and specifically, § 507's purpose to ensure that antibiotic products marketed serve the public with 'efficacy' and 'safety.'

"Furthermore, the legislative history, read in light of the statute's remedial purpose, directs us to read the classification 'drug' broadly, and to confine the device exception as nearly as is possible to the types of items Congress suggested in the debates, such as electric belts, quack diagnostic scales, and therapeutic lamps, as well as bathroom weight scales, shoulder braces, air conditioning units, and crutches. In upholding the Secretary's determination here, without deciding the precise contours of the 'device' classification, we need only point out that the exception was created primarily for the purpose of avoiding the semantic incongruity of classifying as drugs (1) certain quack contraptions and (2) basic aids used in the routine operation of a hospital—items characterized more by their purely mechanical nature than by the fact that they are composed of complex chemical compounds or biological substances. Finally, we are supported in the decision to uphold the FDA's determination that the sensitivity discs fall under the coverage of the Act and specifically under the drug provision thereof by the knowledge that the classification of these discs as drugs may not be as contrary to common medical usage as the District Court and respondent would have us believe.

"In upholding the Secretary's construction of the Act, we are not unmindful of our warning that '[i]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.' 62 Cases of Jam v. United States, 340 U.S. 593, 600, 71 S.Ct. 515, 520, 95 L.Ed. 566 (1951). Our holding here simply involves an obvious corollary to that principle, that we must take care not to narrow the coverage of a statute short of the point where Congress indicated it should extend.

"Reversed."

Pursuant to the mandate of the Supreme Court, an order of condemnation was entered ordering the destruction of the article. (F.D.C. No. 47510; S. No. 26-293 T; N.J. No. 61)

**IMS lidocaine hydrochloride for dilution, with Add-A-Jet injectors**, 19 seizure actions, at Madison, W. Dist. Wis.; Milwaukee, E. Dist. Wis.; Topeka, Dist. Kans.; Utica, N. Dist. N.Y.; Salt Lake City, Dist. Utah; Miami, S. Dist. Fla.; Holly Hill, M. Dist. Fla.; Covington, E. Dist. Ky.; Kearny, Dist. N.J.; Marlborough, Dist. Mass.; Florissant, E. Dist. Mo.; Kenton, N. Dist. Ohio; Kenosha, E. Dist. Wis.; St. Louis, E. Dist. Mo.; Nashua, Dist. N.H.; York, M. Dist. Pa.; Seattle, W. Dist. Wash.; Bloomsburg, M. Dist. Pa.; and Portland, Dist. Ore.

Charged on or about 3-13-73, 3-20-73, 3-14-73, 3-21-73, 3-14-73, 3-27-73, 3-29-73, 3-12-73, 3-21-73 (amended 3-23-73), 3-23-73, 3-14-73, 3-20-73, 3-20-73, 3-15-73, 3-14-73, 3-22-73, 3-19-73, 3-16-73, 3-23-73: when shipped by International Medication Systems, Ltd., South El Monte, Calif., the article was a new drug without an effective approved New Drug Application and without notice of claimed investigational exemption; 505(a). Default decrees ordered destruction. (F.D.C. Nos. 58977, 59002, 59004/5, 59007, 59011, 59013, 59015, 59018/20, 59027/9, 59031, 59033, 59036, 59038, 59045; S. Nos. 60-382 G, 59-266/70 G, 50-861 G, 18-741 G, 44-521 G, 683 G, 2-822/3 G, 1-008 G, 64-245 G, 15-356 G, 50-001 G, 31-177 G, 59-271/2 G, 50-002/3 G, 84-241 G, 96-703 G, 16-543 G, 85-503/4 G, 98-710 G; N.J. No. 62)

**IMS lidocaine hydrochloride for dilution, with Add-A-Jet and Flex-O-Jet injectors**, at South El Monte, C. Dist. Calif.

Charged 3-16-73: while held by International Medication Systems, Ltd., South El Monte, Calif., who manufactured the article using lidocaine base shipped in interstate commerce, the articles' labeling lacked adequate directions for use and was not exempted therefrom, since the articles were new drugs without effective approved New Drug Applications and without notices of claimed investigational exemption, and since the articles lacked adequate information for use by licensed practitioners for the purposes intended, including cardiac arrhythmia; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 59041; S. Nos. 52-230/3 G; N.J. No. 63)

**IMS lidocaine hydrochloride for dilution, with Flex-O-Jet injector**, 3 seizure actions, at Rochester, Dist. Minn.; St. Louis Park, Dist. Minn.; and Fargo, Dist. N. Dak.

Charged 3-12-73, 3-15-73, 3-19-73: when shipped by International Medication Systems, Ltd., South El Monte, Calif., the article was a new drug without an effective approved New Drug Application and without notice of claimed investigational exemption; 505(a). Default decrees ordered destruction. (F.D.C. Nos. 59003, 59010, 59034; S. Nos. 60-405 G, 59-341/2 G, 43-745/6 G; N.J. No. 64)

**Hepachol heparin sodium and choline chloride combination injection**, at Los Angeles, C. Dist. Calif.

Charged 12-19-72: when shipped by Myers Carter Laboratories, Glendale, Ariz., the article was a new drug without an effective approved New Drug Application; and the listing in the labeling of the article of heparin sodium, choline chloride, cyanocobalamin, folic acid, and niacinamide as ingredients of the article and the statement "Indications: Wherever impaired lipid metabolism exists or is suspected as in hypertension, diabetes mellitus, xanthomatosis, hypothyroidism, angina pectoris, myocardial infarction, and certain diseases of the liver and kidney associated with arteriosclerosis," represented and suggested that each such ingredient of the article was of value for the article's intended use and that there was substantial scientific evidence that the article was safe and effective under the conditions of use specified in its labeling; 505(a), 502(a). Default decree ordered destruction. (F.D.C. No. 58688; S. No. 46-469 F; N.J. No. 65)

**Prednisone tablets, U.S.P.**, at Valley Stream, E. Dist. N.Y.

Charged 2-14-72: when shipped by Marshall Pharmacol Corp., South Hackensack, N.J., the article failed to conform to the U.S.P. standard, since the article failed the U.S.P. tablet dissolution requirement, and the article's label statement "Prednisone 5 mgm. U.S.P. Tablets" was false and misleading, as to an article that failed to conform to the U.S.P. standard; 501(b), 502(a). Consent decree ordered destruction. (F.D.C. No. 57801; S. No. 96-769 B; N.J. No. 66)

**Thyroid and hormone combination tablets**, at Detroit, E. Dist. Mich.

Charged 3-30-73: when shipped by Linden Laboratories, Inc., Los Angeles, Calif., the article, labeled in part "Linden Laboratories, Inc. Subsidiary of Chromalloy American Corp., Los Angeles, Ca. . . Ship to Len-Tag Company . . . Detroit, Mich. . . Anderlen SCT Blue," was a new drug without an effective approved New Drug Application, and the circumstances of the article's manufacturing, processing, packing, and holding failed to conform to current good manufacturing practice; 505(a), 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 59064; S. No. 37-343 F; N.J. No. 67)

#### Veterinary/Medicated Feed

**Custom Beef Premix #3 diethylstilbestrol preparation for beef cattle**, at Denver, Dist. Colo.

Charged 11-27-72: while held by Feed Products, Inc., Denver, Colo., who manufactured the article using diethylstilbestrol shipped in interstate commerce, the article was a new animal drug, and no approved New Animal Drug Application was in effect with respect to the article's use and intended use; 501(a)(5). Consent decree ordered destruction. (F.D.C. No. 58519; S. No. 33-475 F; N.J. No. 68)

**Diethylstilbestrol premix**, at Port William, S. Dist. Ohio.

Charged 7-12-72 and amended 11-27-72: while held by Joe Beam & Sons, Port William, Ohio, the article was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to the use and intended use of such drug in the manufacture of an animal feed containing Terramycin (oxytetracycline); 501(a)(5). Default decree ordered destruction. (F.D.C. No. 58127; S. No. 26-345 F; N.J. No. 69)

**Diethylstilbestrol veterinary repository**, at Brush, Dist. Colo.

Charged 11-3-72: when shipped by Veterinary Laboratories, Inc., Lenexa, Kans., the article was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to the use and intended use of such drug; 501(a)(5). Consent decree ordered destruction. (F.D.C. No. 58472; S. No. 34-058 F; N.J. No. 70)

**Diethylstilbestrol veterinary repository solution**, at Fort Dodge, N. Dist. Iowa.

Charged 4-17-73: while held by Fort Dodge Laboratories, Inc., Fort Dodge, Iowa, who had manufactured the article using diethylstilbestrol shipped in interstate commerce, the article was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to its use and intended use; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 59099; S. No. 49-101 G; N.J. No. 71)

**Phenylbutazone veterinary injection**, at Teaneck, Dist. N.J.

Charged 11-14-72: while held by Dell Laboratories, Inc., Teaneck, N.J., who was using phenylbutazone shipped in interstate commerce, 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). Default decree ordered destruction. (F.D.C. No. 58512; S. No. 55-257 F; N.J. No. 72)

**Prednisolone injection, sterile estradiol suspension, and other prescription veterinary drugs**, at Dorr, Bradley, and Wyoming, W. Dist. Mich.

Charged 11-3-72: when shipped by Independent Buyers Association, Inc., Milbury, Mass., and while held by Henry Jansingh, t/a Independent Buyers Association West, Wyoming, Mich., and by Henry Jansingh's agents, Owen Fransens, Dorr, Mich., and Gary C. Henningson, Bradley, Mich., the articles lacked adequate directions for lay use and were not exempted therefrom as prescription veterinary drugs, since the articles were in the possession of persons who were not lawfully engaged in the articles' wholesale and retail distribution, and the articles were being sold without a licensed veterinarian's prescription or order; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 58453; S. Nos. 38-246/7 F; N.J. No. 73)

**Rumen bacteria boluses, diethylstilbestrol solution for poultry, and diethylstil-**

bestrol solution for cows and mares, at Albuquerque, Dist. N. Mex. Charged 4-3-73: while held for sale, the articles were new animal drugs, and no approvals of New Animal Drug Applications were in effect with respect to the use and intended use of such drugs: 501(a)(5). Default decree ordered destruction. (F.D.C. No. 59066; S. Nos. 35-103/4 G et al.; N.J. No. 74)

#### MEDICAL DEVICES

**Diapulse electromagnetic energy generators**, 17 seizure actions, at Vermilion, N. Dist. Ohio: Columbus, S. Dist. Ohio: Mount Eaton, N. Dist. Ohio: Plainview, N. Dist. Tex.: Elmo, W. Dist. Mo.: Kent, N. Dist. Ohio: Davenport, S. Dist. Iowa: Boise, Dist. Idaho: Ann Arbor, E. Dist. Mich.: Westland, E. Dist. Mich.: Detroit, E. Dist. Mich.: Detroit, E. Dist. Mich.: Tacoma, W. Dist. Wash.: Rockford, N. Dist. Ill.: Hot Springs, W. Dist. Ark.: Sylacauga, N. Dist. Ala.: Clarkston, E. Dist. Mich. Charged 10-20-72, 10-6-72, 11-2-72, 11-6-72, 11-3-72, 10-26-72, 10-18-72, 10-20-72, 10-24-72, 10-24-72, 11-21-72, 11-22-72, 11-20-72, 11-20-72, 11-17-72, 12-5-72, 11-21-72, when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' labeling lacked adequate directions for lay use for their intended purposes, and adequate information for use by licensed practitioners could not be prepared: 502(f)(1). Default decrees ordered destruction. (F.D.C. Nos. 58348, 58350, 58352, 58354, 58370, 58390, 58399, 58410, 58426/7, 58488, 58491/5, 58499; S. Nos. 25-466 F, 25-781 F, 25-468 F, 32-587 F, 40-171 F, 28-411 F, 38-916 F, 79-831 F, 35-520 F, 94-284 F, 94-286/7 F, 94-281 F, 79-829 F, 19-342 F, 53-395 F, 447/8 F, 35-519 F; N.J. No. 75)

**Diapulse electromagnetic energy generators**, 24 seizure actions, at Atlantic, S. Dist. Iowa: Omaha, Dist. Nebr.: Columbus, S. Dist. Ohio: Aurora, W. Dist. Mo.: Cherokee, N. Dist. Iowa: Rolla, E. Dist. Mo.: Davenport, S. Dist. Iowa: Bastrop, W. Dist. La.: St. Ignace, W. Dist. Mich.: Ida Grove, N. Dist. Iowa: Alcester, Dist. S. Dak.: St. Charles, E. Dist. Mo.: Cresco, N. Dist. Iowa: Holly Hill, M. Dist. Fla.: Deltona, M. Dist. Fla.: Ormond Beach, M. Dist. Fla.: Ash Grove, W. Dist. Mo.: Bridge City, E. Dist. Tex.: East Peoria, S. Dist. Ill.: Chicago, N. Dist. Ill.: Venice, M. Dist. Fla.: Geneva, N. Dist. Ill.: Streamwood, N. Dist. Ill.: Rockford, N. Dist. Ill. Charged on or about 10-11-72, 10-30-72, 10-16-72, 11-3-72, 10-31-72, 10-18-72, 10-11-72, 11-6-72, 10-18-72, 10-18-72, 10-16-72, 10-19-72, 11-7-72, 11-2-72, 11-22-72, 11-3-72, 11-8-72, 11-9-72, 11-8-72, 11-9-72, 11-6-72, 11-9-72, 11-9-72, 11-11-72: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' accompanying treatment charts and leaflets contained false and misleading claims, such as for infections, fractures, smooth muscle spasm, bursitis, arthritis, low back pain, and headaches; and the articles lacked adequate directions for their intended purposes, and neither adequate directions for lay use nor adequate information for use by licensed practitioners for the articles' intended uses could be written: 502(a), 502(f)(1). Default decrees ordered destruction. (F.D.C. Nos. 58357/63, 58369, 58371, 58383, 58392/3, 58431/3, 58435, 58441, 58454, 58457, 58459/60, 58465, 58470/1; S. Nos. 40-172 F, 39-269 F, 25-780 F, 39-540 F, 40-528 F, 40-673 F, 38-912 F, 53-672/3 F, 37-820 F, 40-529 F, 34-073 F, 43-453 F, 39-347 F, 204 F, 202 F, 203 F, 39-543 F, 29-291 F, 19-676 F, 22-326 F, 2-881 F, 22-324 F, 22-327 F, 19-343 F; N.J. No. 76)

**Diapulse electromagnetic energy generators**, 12 seizure actions at Mebane, M. Dist. N.C.: Greensboro, M. Dist. N.C.: Luverne, M. Dist. Ala.: Pecatonica, N. Dist. Ill.: Freeport, N. Dist. Ill.: Sycamore, N. Dist. Ill.: Hope, W. Dist. Ark.: Walnut Creek, N. Dist. Calif.: Lake City, M. Dist. Fla.: Quakertown, E. Dist. Pa.: Kansas City, W. Dist. Mo.: Circleville, S. Dist. Ohio. Charged on or about 1-22-73, 1-22-73, 10-3-72, 10-5-72, 10-5-72, 10-5-72, 10-2-72, 10-19-72, 10-3-72, 10-5-72, 11-1-72, 10-11-72: when shipped in interstate commerce after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' accompanying treatment charts, leaflets, and other labeling contained false and misleading claims, such as for tissue and bone healing, infections, bursitis, arthritis, blood flow to peripheral areas, sinusitis, and low back pain; and the articles lacked adequate directions for their intended use, and adequate directions for lay use and adequate information for safe use by licensed practitioners could not be written: 502(a), 502(f)(1). A consent decree in the action at Luverne, Ala., and default decrees in the other actions, ordered destruction. (F.D.C. Nos. 58239, 58317/8, 58330/1, 58332/3, 58341/3, 58347, 58351; S. Nos. 1-114 F, 1-214 F, 815 F, 19-333 F, 19-332 F, 19-331 F, 53-778 F, 75-063 F, 193 F, 68-106 F, 41-767 F, 25-775 F; N.J. No. 77)

**Electro-sedation device**, at Greensboro, M. Dist. N.C.

Charged 1-15-73: when shipped by Tri-Tronics Laboratory, Inc., Euless, Tex., and while held by Mayrand, Inc., Greensboro, N.C., the accompanying reprints supplied by the dealer and the booklet and leaflets supplied by the shipper contained false and misleading claims for soothing crippling tensions, easing stress-related illness, modifying a patient's neural reactions, bringing relief from chronic harmful tension and erasing tensions, psychosomatic illness, and insomnia, and of substantial scientific evidence of safety and effectiveness for such uses; the labeling lacked adequate directions for use by licensed practitioners, and such could not be furnished; and the labeling lacked adequate warnings against unsafe uses: 502(a), 502(f)(1), 502(f)(2). Default decree ordered destruction. (F.D.C. No. 58762; S. No. 1-216 F; N.J. No. 78)

**Oxygen spheres, face masks, and kits**, at Lansdowne, E. Dist. Pa.

Charged 7-13-72: while held by Castle Tool Specialty Co., Lansdowne, Pa., who was assembling the articles and filling the oxygen spheres, the articles, labeled in part "Sav-A-Life Oxygen Company . . . Jenkintown, Penn." and "Universal Life Enterprises . . . Oxygen . . . Lansdowne, Pa.," failed to bear adequate directions for use and failed to bear

adequate warnings against unsafe use, and the articles were dangerous to health when used as directed, since by reason of insufficient flow rate and quantity of oxygen, reliance upon their use would serve to delay or deny proper emergency measures in those life-threatening situations where an immediate adequate supply of emergency oxygen was needed—502(f)(1), 502(f)(2), 502(i); and the labeling of the articles labeled "Sav-A-Life" was false and misleading in representing and suggesting that the listed 75.5 liters of oxygen per sphere was sufficient oxygen for 30 minutes continuous emergency first aid—502(a). The dealer claimed the articles and denied the charges. The Government served written interrogatories on the claimant. Subsequently, the claimant advised that it did not intend to answer the interrogatories, to make any further defense of the suit, or to oppose or contest the Government's motion for a default judgment. Default decree ordered destruction. (F.D.C. No. 58128; S. No. 65-932 F; N.J. No. 79)

**Relaxacizor electrical muscle stimulator**, at Averill Park, N. Dist. N.Y.

Charged 3-29-73: when shipped by Relaxacizor, Inc., Chicago, Ill., the article's labeling did not and could not bear adequate directions for safe use by laymen, and its labeling lacked adequate warnings against unsafe use: 502(f)(1), 502(f)(2). Default decree ordered destruction. (F.D.C. No. 59047; S. No. 18-628 G; N.J. No. 80)

**Solarama 2' x 2' bedboard**, at Pittsburgh, W. Dist. Pa.

Charged 4-4-73: when shipped by World of Solarama, Greenville, S.C., the article's accompanying labeling (including insert entitled "Solarama Electric Bed-Board Therapy" and leaflet entitled "Greenville Man's Electronic 'Solarama' acclaimed by Users") contained false and misleading claims for pain, tension, virus infections, sleeplessness, sore muscles, arthritis, burns of all sorts, frostbite, postoperative healing, hemorrhoidal pain and shrinkage, brain tumors, back ailments, acne, high blood pressure, sugar diabetes, insomnia, nervous problems, kidney infections, Parkinson's disease, ruptured discs, paralysis, and poor circulation; and the article's label lacked the name and place of business of the manufacturer, packer, or distributor: 502(a), 502(b). Default decree ordered destruction. (F.D.C. No. 59090; S. Nos. 67-685/6 F; N.J. No. 81)

#### NOTICES OF JUDGMENT ON CRIMINAL ACTIONS

##### FOOD

**Alaskan Glacier Sea Food Co., and David P. Ohmer**, president, Petersburg, Dist. Alaska.

Charged 10-10-71: when shipped, Frigid Zone shrimp meat contained coagulase positive staphylococci and bacterial filth and had been prepared and packed under insanitary conditions: 402(a)(3), 402(a)(4). Nolo contendere pleas; fines and probations. (F.D.C. No. 57179; S. Nos. 73-938/9 D; N.J. No. 82)

**Allen County Food Distributors, and John Schmitz and Max T. Schmitz**, partners, Fort Wayne, N. Dist. Ind.

Charged 11-28-72 by grand jury: barley was held in a building accessible to insects and was exposed to contamination by insects: 402(a)(4). Guilty plea by partnership; fine. Guilty pleas by individuals: fines and probations. (F.D.C. No. 58140; S. No. 34-797 F; N.J. No. 83)

**Arrow Food Products, Inc., and Marcus Rosenberg**, president, Carrollton, N. Dist. Tex.

Charged 1-8-73: pepper was held in a building accessible to rodents and was contaminated with rodent filth: 402(a)(3), 402(a)(4). Nolo contendere pleas; fines. (F.D.C. No. 58195; S. No. 31-804 F; N.J. No. 84)

**F. W. Bryce, Inc., and Louis G. Ashby**, president, Gloucester, Dist. Mass.

Charged 12-21-71: when shipped, frozen fish, labeled in part "HADDOCK PACK BY JOB BROTHERS CO. LTD. LA SCIE NEW FOUNDLAND," bore the false and misleading statement "Haddock"; the label lacked the common or usual name of the food: the frozen fish was offered for sale under the name of another food, i.e., haddock fish, when the frozen fish consisted of fish other than haddock, and fish other than haddock had been substituted for haddock—402(b)(2), 403(a), 403(b), 403(i)(1); and codfish was repacked into cartons labeled in part "FLOUNDER BLOCKS DIST. BY F. W. BRYCE MONTREAL CANADA," which resulted in the label statement "Flounder Block" being false and misleading as to the codfish, in the label lacking the common or usual name of the food, and in codfish being substituted for flounder—402(b)(2), 403(a), 403(i)(1). Guilty pleas; fines. (F.D.C. No. 57181; S. Nos. 15-541 D, 15-544 D; N.J. No. 85)

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

Published by direction of the Secretary of Health, Education, and Welfare.  
Alexander M. Schmidt, M.D., Commissioner of Food and Drugs  
Washington, D.C., February 1, 1974

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