Laetrile: The Making Of A Myth
This Month

The camel, it has been said, owes its shape to the fact that it was designed by a committee. The message in this theory seems to be that if responsibility is shared the job doesn’t get done, or it gets done haphazardly. But there are responsibilities that almost demand sharing — for instance, assuring the sanitation of food served or prepared outside the home. There are some 600,000 food service establishments in this country, and the day-to-day regulation of their sanitary practices must be handled by local agencies. Virtually all the food served in these places, however, has traveled in interstate commerce, and thus comes under FDA’s jurisdiction. FDA’s role in Improving Food Service Sanitation is one of the topics that gets our attention this month.

Although they’ve never claimed credit for the camel, committees are an important aspect of FDA’s decision-making process. Advisory committees on food and drugs meet regularly to review technical and scientific data and to discuss policy questions. The recommendations of these groups, many of which include consumer representatives, are an integral part of the development of Agency regulations. In the past, advisory committee meetings often were closed to the public. Now, virtually all committee sessions will be open. The new rules are outlined in an article beginning on page 19.

Most of our Federal laws are the result of a legislative process that relies heavily on the committee system. One of the more recent products of this system is the Toxic Substances Control Act, a new law that, among other things, calls for an end to the use of polychlorinated biphenyls (PCB’s). But it is considerably easier to pass a law forbidding the use of these chemicals than it is to eliminate them from the environment, as we point out in PCB’s — Coping With the Indestructible Pollutant.

No committee can decide the type of treatment a seriously ill individual will seek and accept. Although competent medical advice is almost always available, the ultimate decision is a personal one. Cancer patients faced with such a decision sometimes are persuaded to take a substance called Laetrile. It cannot be said that these people are putting their faith in an untested remedy, because Laetrile has been tested repeatedly without ever producing any evidence that it is effective against cancer. There’s a report on the development and promotion of Laetrile—and the tragic consequences of its use—beginning on page 5.

Inside Front Cover Photo: FDA Food Service Specialist Arthur Banks prepares to check the water temperature in the dishwasher at a high school cafeteria by attaching a thermometer to a glass that will be washed in the machine. Joining Banks in the cafeteria inspection is Robert Karches, a New York State health sanitarian. For more on how FDA works with State and local governments to see that food in restaurants, schools, nursing homes, and similar places is prepared and served under sanitary conditions, turn to page 10.
Update and Consumer Forum

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FDA Issues Vitamin-Mineral Regulations

For a number of years, FDA sought to restrict the maximum dosage and the combinations of vitamins and minerals that could be sold to supplement the nutrients people get in their normal diet. FDA argued that consumers were entitled to economic protection against the marketing and promotion of vitamins and minerals in dosages far above the levels that the body needs or can use. But earlier this year, Congress enacted a law prohibiting FDA from setting limits on maximum dosages of vitamins and minerals unless they pose a health hazard. The new law and the long controversy over FDA efforts to regulate dietary supplements were the subject of an article entitled Regulating Vitamins and Minerals, in the July-August 1976 issue of FDA Consumer. Here’s an update.

The Food and Drug Administration has issued final regulations governing the labeling and composition of vitamin and mineral products used as dietary supplements.

Under the regulations, FDA will:

- Require minimum potency levels for vitamins and minerals in dietary supplements, thus ensuring that vitamins and minerals are contained in these products in nutritionally significant amounts.
- Limit the composition of certain dietary supplements on the basis of safety. For example, high potency preparations of vitamins A and D, which are not safe for use except under the supervision of a physician, will continue to be regulated as prescription drugs. The amount of the vitamin folic acid which may be used in a dietary supplement will also continue to be limited.
- Restrict the composition of combination vitamin/mineral products offered for use by infants, children, or pregnant or lactating women. Vitamins and minerals in dietary supplements offered for infants, children, or pregnant or lactating women are subject to maximum as well as minimum potency requirements.
- Require that each vitamin and mineral in a dietary supplement be listed on the label in terms of both U.S. Recommended Daily Allowance (U.S. RDA) and another specified unit of measure, such as milligrams.
- Require the listing on the label of all ingredients in the product, including the natural source or chemical form of each nutrient. For instance, if the product includes vitamin C, the ingredient list would name the ingredients that supplied it, such as rose hips (a natural source) and sodium ascorbate (a chemical form). The label also must list all substances which are not vitamins or minerals (such as rutin, other bioflavonoids, or para-aminobenzoic acid), in descending order of predominance by weight.
- Consider misbranded any dietary supplement whose label or advertising claims that the product has therapeutic benefit or makes another false and misleading claim.
- Seek seizure and injunction sanctions when appropriate if the advertising of a vitamin/mineral preparation is misleading. Under the law, FDA must first notify the Federal Trade Commission of a suspected advertising violation, and if no action is taken by FTC within 90 days, FDA may take its own action.

The effective date of the revised regulations has been set for January 1, 1978, to allow time for the relabeling that will be required as well as for some reformulations of dietary supplements for use by infants, children, or pregnant or lactating women.

The regulations are in accord with the vitamin-mineral legislation enacted April 22, 1976, by Congress. The regulations were published in the October 19, 1976, Federal Register.

Canners to List Solid Weight on Label

How much solid food is in a can of fruit or vegetables? That is a hard question for consumers to answer because most canned fruits and vegetables list only the net weight, which includes the water, syrup, or other liquid in which the product is packed, on the label. FDA has proposed a regulation requiring that the drained weight—the weight of the solid food after the packing liquid has been drained—be shown on the label of most canned fruits and vegetables. FDA’s proposal, and the arguments of consumer groups and industry for and against it, were discussed in an article entitled Labels That Spill the Beans in the February 1976 issue of FDA Consumer. Here’s an update.

The National Canners Association has announced a new program whereby its member companies would voluntarily declare on the label the “solid content” weight of canned fruits and vegetables. NCA said some food canners would adopt the voluntary program with 1977 production.

Under the program, the label would continue to list the net weight of the contents of the container, including liquid. Companies that adopt the program would list also the solid weight of the food before liquid was added and the food was processed. This is called “fill-in” weight.

For example, a label for corn might read: “Net Wt. 16 oz. (1 lb.), Weight of corn 10¼ oz.”, with an explanation that “weight of corn means weight
before addition of processing liquid.”

FDA has proposed that the labels on canned fruits and vegetables list the “drained weight” of the product. This is the weight of the solid content of the food after the water, syrup, or other liquid in which it has been packed and processed has been drained.

FDA has previously stated that it would be difficult for the Agency to check on the accuracy of the fill-in weight claimed on a product without a look at the processor’s records, which is not authorized under existing law. A product may weigh more or less when it comes out of a can than it did when it went in because some fruits and vegetables absorb water and other substances from the liquid in which they are packed and thus gain weight, while others lose water and nutrients to the liquid and lose weight. Because of these factors, the “fill-in weight” and the “drained weight” of a product may differ.

NCA contends that the weight labeling program it offers would cost consumers $10 million per year as compared to $104 million per year for the FDA plan. FDA has encouraged NCA to collect data necessary to evaluate the cost and usefulness of the NCA program.

FDA made its drained weight labeling proposal in response to a petition filed by Consumers Union asking that the Agency require all processed fruits and vegetables, canned and frozen, to carry a label statement giving the weight of the solids when the liquid they are in is drained off. FDA limited its proposal to canned foods because it said there is not enough technical information available now on the drained weight of frozen foods to make a drained weight labeling requirement for these products practicable and enforceable.

FDA published its drained weight proposal in the November 7, 1975 Federal Register. Interested parties were given until May 6, 1976, to submit comments on FDA’s proposal. These comments are now being reviewed by FDA.

FDA said that it considers the NCA voluntary program to be a step in the right direction of improved consumer information, but the Agency will proceed with evaluation and final regulatory decisions on its own “drained weight” plan.

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**Mobile Labs Used in 1938**

I read with a great deal of interest the article in the October issue of FDA Consumer on the mobile laboratories now being operated by the Food and Drug Administration.

I feel it is unfortunate, however, that even I get an impression that the FDA was not developing and using this mode of operation in sound enforcement until 1950, when they were given a loan from the Army of two defunct army World War II trailers pulled by tractors.

I was Chief Inspector of the FDA Atlanta office from 1938 to 1942, and later Assistant Chief in the New York Eastern District office.

The first mobile laboratory used by FDA was developed by the Bacteriological Division back in 1938. It consisted of a “covered wagon” shell with specially designed equipment pulled by a passenger car which was bought for this sole purpose. The interior was fitted out in Washington by the Bacteriological Division and then sent south to the Atlanta Station to conduct a “crabmeat” campaign. This was in the winter and spring of 1939.

Inspectors collected official samples from carriers after delivery and brought them to the trailer laboratory. We were able to develop information as to the presumptive E. coli contamination overnight. Our procedure was to wire the receiving station, which could be Atlanta, Philadelphia, Washington, or even New York, at the time specific shipments were sampled if they were from a plant in which inspectional evidence had shown contaminating conditions. Upon completion of the presumptive test, early in the morning, the station was again wired to embargo on State or city authority the shipment in question, pending confirmatory tests. As soon as these were received, a direct reference seizure was made. This was a very effective procedure.

The laboratory was left at the Atlanta station for the remainder of the year after the close of the crabmeat project and was used for the training of new inspectors. The trainees sometimes would bring in samples to the mobile trailer unit for such things as “short weight,” “deceptive packaging,” and violations that could be detected readily in a trailer laboratory. Seizure reference was not only made more quickly, but the chief purpose of this operation was to train inspectors and analysts in simple procedures.

Unfortunately, World War II came along and other interests intervened, but it must have been because of this favorable early experience that FDA went into borrowing these laboratories from the Army when they were presumably offered as surplus.

Edward L. Holmes
St. Louis, Missouri

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St. Louis, Missouri
Repeated tests have failed to produce any evidence that Laetrile is effective in the treatment of cancer. But that has not stopped its promoters from urging cancer victims to forego conventional treatment in favor of Laetrile. Patients who do may pay with their lives.

Cancer is an ugly word. It evokes a picture of pain, prolonged and discomforting treatment, and possibly disfigurement. Some people equate the disease with sure death. Only a few years ago cancer was hardly discussed above a whisper and few people who had it would openly discuss their illness.

But the picture is changing. As people learn more about cancer, the myths are disappearing. People are learning that many cancer victims can lead normal lives, and that significant progress is being made in saving and extending the lives of its victims through early detection, improved surgical techniques, x-ray treatments, and new drugs. Detected early and treated properly, cancer no longer means certain death.

Yet among some people, a myth persists that there are effective but suppressed remedies for cancer—remedies that responsible physicians cannot provide. For years some
people have put their faith in unproven treatments whose backers promise something they can't possibly deliver—quick, painless, sure cures. Twenty years ago promoters tried to persuade the public that a substance called Krebiozen could cure cancer. Today, it has been replaced by Laetrile.

Laetrile is the chemical amygdalin, which occurs naturally in the pits of peaches, apricots, and bitter almonds, and in other plant material. In its 25-year history Laetrile has developed from the brain child of a father-son team in California into big business on an international scale.

Ernest T. Krebs, Sr., a California physician, was the first to try apricot pits as a cancer treatment in 1920. But the substance he used was highly toxic. His son, Ernest T. Krebs, Jr., a biochemist, claimed to have developed a purified form of Laetrile, safe for injection, in 1952. Krebs, Sr. joined his son in advocating the purified form as an effective treatment for cancer.

Krebs, Jr., theorized that Laetrile works by seeking out a substance which is found in cancer cells but not in normal cells. This substance, he contended, causes Laetrile to release hydrocyanic acid which destroys the cancer cell. Normal cells, Krebs said, contain a substance that protects them from the hydrocyanic acid. Later, Krebs changed the theory, claiming that cancer is caused by a deficiency of vitamin B₁₂, and that Laetrile is vitamin B₁₂. Some Laetrile advocates now claim that it prevents as well as cures cancer.

Scientists never have been able to find any valid basis for either of the Krebses' theories. Laetrile is not a vitamin. No evidence has ever been found that it has any effect on cancer. The Cancer Commission of the California Medical Association investigated Laetrile and declared it ineffective in 1953. Ten years later, the California State Department of Public Health, acting on a report by its Cancer Advisory Council that Laetrile was of no value in the diagnosis, treatment, alleviation, or cure of cancer, issued a regulation prohibiting its use in that State.

Undeterred by this decision, the Krebses continued to produce Laetrile. But they had more to reckon with than State laws. During the 1960's they were repeatedly charged in Federal courts with shipping Laetrile and other unapproved drugs in interstate commerce. After one conviction, leftover supplies of Laetrile were distributed by FDA for investigational use to U.S. physicians and to the McNaughton Foundation in Montreal, headed by Andrew R. L. McNaughton. The McNaughton Foundation had been established as a non-profit organization to fund independent and unorthodox research. McNaughton and his Foundation are now among the leading proponents and distributors of Laetrile.

Neither the U.S. Food and Drug Administration, the Canadian Food and Drug Directorate, the National Cancer Institute, the American Cancer Society, nor any other reputable organization has found any evidence to substantiate the use of Laetrile in the treatment or prevention of cancer. Laetrile may not be sold in the United States and Canada because both nations have laws requiring that drugs be proved effective before they can be marketed. It is available in some other countries because their laws do not prohibit the marketing of unproven drugs.

In the United States, proof of safety and effectiveness must be demonstrated by precise and thorough testing. Initial tests are made in animals, and if these tests show that the drug holds promise, the sponsor can file an Investigational New Drug (IND) application with FDA. This application must summarize the results of the animal tests (and any human testing done outside the United States) and describe the sponsor's plans to test the drug in human subjects.

If FDA approves the application, clinical testing with human volunteers can proceed. If these tests demonstrate to FDA the drug's safety and effectiveness, and other requirements of the law are met, the drug is approved by the Agency for marketing. If not, approval of the application is withheld and the drug may not be shipped in interstate commerce.

Several attempts have been made by promoters of Laetrile to get FDA approval to distribute the drug. The last was by the McNaughton Foundation of California which in 1970 submitted an application to test Laetrile in humans. FDA found the application inadequate and rejected it. Proponents of Laetrile claimed FDA was prejudiced. To assure objectivity, an independent panel of cancer experts reviewed the application and interviewed Andrew McNaughton. They concluded that the evidence was not adequate to justify testing the drug on humans.

This is not just the opinion of one committee of experts. From the beginning, Laetrile has been tested and found...
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The "evidence" presented by Laetrile supporters has consisted of testimonials from people who believe Laetrile has cured them of cancer, prolonged their life, or reduced pain. How is it possible to have such testimonials and still no scientific proof that Laetrile is effective? Part of the answer lies in the nature of the disease. Cancer is not a single disease, but a combination of about 100 different clinical entities, each following its own natural and sometimes erratic course. Skin cancer, for example, is different in its development, effects, and treatment than lung cancer. Patients sometimes have remissions—periods when certain symptoms disappear. If they take Laetrile during a remission, it will appear as if Laetrile helped them. In other cases, patients have taken Laetrile while also getting effective forms of treatment and may believe that the Laetrile was at least partially responsible for relief of symptoms.

Many people who claim Laetrile has helped them are sincere in their belief. But objective evidence to support their opinion has never been developed. One foreign doctor, Ernesto Contreras of Tijuana, Mexico, was asked by FDA to provide the most dramatic examples of success with Laetrile. He submitted 12 case histories. Of nine patients whose records FDA and the National Cancer Institute could obtain and review, six had died of cancer, one still had cancer that had spread since Laetrile had been taken, one had used approved drugs and radiation therapy, and one had died of another disease after having had the cancer removed surgically.

Despite all efforts by cancer researchers and the Federal Government to give Laetrile a fair hearing, its advocates maintain that the medical profession, the American Cancer Society, and the Federal Government conspire to suppress Laetrile because they are bound to conventional treatment by profit or other motives. Yet FDA has been on record for years as being prepared to approve human tests of Laetrile if experts in cancer found evidence to justify them. And the National Cancer Institute is committed to pursuing any evidence that may provide a basis for clinical trials in human patients.

Lack of Federal approval has not stopped promotion of Laetrile, which is carried out primarily by four organizations. One is the National Health Federation, a promoter of health foods. Another is the International Association of Cancer Victims and Friends (IACVF). This group publishes the CANCER NEWS JOURNAL. An offshoot of this organization is the Cancer Control Society, which publishes CANCER CONTROL JOURNAL. The fourth group is the Committee for Freedom of Choice in Cancer Therapy. It was founded by Robert Bradford, a physicist who regards efforts to regulate Laetrile and similar unproven remedies as an invasion of privacy and an unwarranted interference with individual freedom.

Among other promotional efforts, Laetrile advocates hold conventions open to the public where speakers extoll the virtues of unorthodox cures and printed material is readily available. They hope that growing popular support will force the Government to accept Laetrile.

Exploiting the demand created by the advocates of Laetrile, manufacturers and distributors have attempted to market amygdalin or products containing it with labeling designed to circumvent the law against the sale of unapproved drugs. The labeling has described the products as food or food supplements and has avoided any claims that the products are useful in the treatment of disease. One company tried distributing amygdalin in a milk shake mix called Seventeen. The product's package featured a picture of a bee with the word "Seventeen" (B17). The company claimed that the product was a food. In May 1975, U.S. District Court Judge Malcolm Lucas barred further distribution of the product after ruling it was an unapproved and misbranded drug.

Less than a year later, Judge Vincent P. Biunno of the U.S. District Court for the District of New Jersey enjoined distribution of a product called Seventeen, a powdered form of amygdalin to be mixed with milk or other drinks, on the grounds that it was an unapproved and misbranded drug. Apricot kernels, which contain amygdalin, are sold in some health food stores.
“Bitter Food Tablets.” This product was supposedly intended to cut the sweet taste of fruit drinks. Judge Biunno found that calling amygdalin a bitter flavor was a “patently absurd and transparent attempt to avoid the drug labeling provisions of the Federal Food, Drug, and Cosmetic Act,” and said its sale for any food or drug use constituted a fraud on the public.

Such legal actions stop some but by no means all of the distribution of amygdalin or Laetrile in its various forms. Pills and capsules made from amygdalin, or defatted apricot pits, sometimes are available in health food stores. They may be displayed openly, or kept under the counter.

The smuggling of Laetrile into the United States has become big business. On the black market, Laetrile sells for 600 to 700 percent above the manufacturer’s cost. A month’s treatment in Mexico can cost more than $1,000. U.S. Customs officials have made more than 20 major seizures and secured the conviction of a physician charged with smuggling amygdalin from the country to Mexico. In May 1976, a Federal grand jury in San Diego indicted nine Americans, six Mexicans, and a Canadian for running a Laetrile smuggling ring. Included in the 16 were Andrew McNaughton of the McNaughton Foundation, Robert Bradford, president of the Committee for Freedom of Choice in Cancer Therapy, and Dr. Contreras.

Laetrile also finds its way into the United States via the luggage of cancer victims who have sought help in clinics in those countries where the drug is legal. The most popular and most accessible clinic to Americans is just across the California border in Tijuana, Mexico—the Centro Medico del Mar, operated by Dr. Contreras.

Thousands of Americans have come to Tijuana, some from as far away as Alaska. Many are in the last stages of their illness, still seeking hope and relief from pain. Others have forms of cancer that could be controlled by early, effective treatment. In many cases their journey south is arranged by the International Association of Cancer Victims and Friends or the Committee for Freedom of Choice in Cancer Therapy. The Laetrile administered to them is produced by Cyto-Farma, a Tijuana company owned at one time by Andrew McNaughton and one of the major sources of Laetrile in the Western Hemisphere.

A basic argument advanced by many Laetrile advocates is that patients have a right to choose the therapy they are to have. “Freedom of choice” has become the rallying cry of many Laetrile supporters. Much like the hucksters of old who promoted their patent medicines with patriotic pictures, Laetrile supporters have made the drug a symbol of alleged Government suppression.

How much “freedom” is involved in choosing Laetrile over conventional therapy is open to question. Cancer victims rarely decide to use Laetrile entirely on their own. They are persuaded to demand it by false claims that it is effective in controlling cancer. Slick sales techniques used at conventions readily convince the frightened, sick, and the gullible that Laetrile is not only a cure but a preventive measure as well.

Another argument made in favor of lifting the ban on Laetrile is that there can be no harm in allowing terminally ill people to have a seemingly harmless—though worthless —substance if it makes them feel better psychologically. But the line between the terminally ill and the patient who may benefit from effective therapy, or from new approaches to treatment that have genuine promise, cannot be so finely drawn as to reliably separate the terminally ill from the treatable. And once an unproven substance is made legal for one group of patients, there would be no way to prevent access by others. Patients who have cancer in an early and controllable state could be putting their lives on the line by taking a worthless substance instead of seeking an effective treatment. Indeed, Laetrile now is being promoted as a treatment for cancer in its early stages.

There is some question, as well, about the claims that Laetrile is harmless. Laetrile is amygdalin, and amygdalin contains cyanide, one of the most toxic substances known. Some health food advocates eat seeds and kernels containing amygdalin, and there have been reports in scientific literature that these kernels have produced symptoms of toxicity.

To allow the importation and interstate distribution of any unapproved substance could have far reaching effects on laws which were designed to protect consumers against drugs that are of no value in treating illness. If one such product could be sold, untold numbers of others would appear, their promoters claiming immunity from the law on the same basis as Laetrile. The result would be chaos in medical care, with no one able to distinguish a valuable medicine from a worthless but well-promoted substance.

Despite the success of a number of regulatory efforts, cancer quackery is on the rise. One reason is that the promoters of Laetrile and similar products have been able to develop and exploit much more effective means of reaching their potential victims than have those who are concerned with protecting the public from the dangers of unproven “cures”.

These promoters prey on the real and understandable fear of cancer victims, fear not only of the disease itself but of the effects of surgery, radiation, or chemotherapy that may be a necessary part of effective treatment. Under these circumstances it is not hard to understand the appeal of painless, nonsurgical, nontoxic “remedies”. The problem is they are not effective remedies, and they are not harmless. When they delay or interfere with swift diagnosis and prompt treatment they are potentially lethal.

As long as there are diseases that are frightening, and that resist fully effective management or cure, people will turn to those who traffic in false hope. And there will always be someone to turn to. It may be a huckster at home, a psychic surgeon abroad, or a cancer clinic in Mexico. There is no way to measure the cost of such quackery—in human terms or dollars and cents. Anyone who is concerned about cancer should turn for help to a physician experienced in treatment of the disease.

For its part, FDA—along with other Government health agencies and responsible health professionals—will continue to try to bring the facts about cancer and its treatment to the public. And as the Agency responsible for approving drugs FDA is firmly committed to assuring that any new discovery that meets proper scientific standards will become available to all Americans.
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Less than a year later, Judge Vincent P. Bihunno of the U.S. District Court for the District of New Jersey enjoined two other companies from marketing amygdalin labeled as
“Bitter Food Tablets.” This product was supposedly intended to cut the sweet taste of fruit drinks. Judge Biunno found that calling amygdalin a bitter flavor was a “patently absurd and transparent attempt to avoid the drug labeling provisions of the Federal Food, Drug, and Cosmetic Act,” and said its sale for any food or drug use constituted a fraud on the public.

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Thousands of Americans have come to Tijuana, some from as far away as Alaska. Many are in the last stages of their illness, still seeking hope and relief from pain. Others have forms of cancer that could be controlled by early, effective treatment. In many cases their journey south is arranged by the International Association of Cancer Victims and Friends or the Committee for Freedom of Choice in Cancer Therapy, and Dr. Contreras.

A basic argument advanced by many Laetrile advocates is that patients have a right to choose the therapy they are to have. “Freedom of choice” has become the rallying cry of many Laetrile supporters. Much like the hucksters of old who promoted their patent medicines with patriotic pictures, Laetrile supporters have made the drug a symbol of alleged Government suppression.

How much “freedom” is involved in choosing Laetrile over conventional therapy is open to question. Cancer victims rarely decide to use Laetrile entirely on their own. They are persuaded to demand it by false claims that it is effective in controlling cancer. Slick sales techniques used at conventions readily convince the frightened, sick, and the gullible that Laetrile is not only a cure but a preventive measure as well.

Another argument made in favor of lifting the ban on Laetrile is that there can be no harm in allowing terminally ill people to have a seemingly harmless—though worthless—substance if it makes them feel better psychologically. But the line between the terminally ill and the patient who may benefit from effective therapy, or from new approaches to treatment that have genuine promise, cannot be so finely drawn as to reliably separate the terminally ill from the treatable. And once an unproven substance is made legal for one group of patients, there would be no way to prevent access by others. Patients who have cancer in an early and controllable state could be putting their lives on the line by taking a worthless substance instead of seeking an effective treatment. Indeed, Laetrile now is being promoted as a treatment for cancer in its early stages.

There is some question, as well, about the claims that Laetrile is harmless. Laetrile is amygdalin, and amygdalin contains cyanide, one of the most toxic substances known. Some health food advocates eat seeds and kernels containing amygdalin, and there have been reports in scientific literature that these kernels have produced symptoms of toxicity.

To allow the importation and interstate distribution of any unapproved substance could have far reaching effects on laws which were designed to protect consumers against drugs that are of no value in treating illness. If one such product could be sold, untold numbers of others would appear, their promoters claiming immunity from the law on the same basis as Laetrile. The result would be chaos in medical care, with no one able to distinguish a valuable medicine from a worthless but well-promoted substance.

Despite the success of a number of regulatory efforts, cancer quackery is on the rise. One reason is that the promoters of Laetrile and similar products have been able to develop and exploit much more effective means of reaching their potential victims than have those who are concerned with protecting the public from the dangers of unproven “cures”.

These promoters prey on the real and understandable fear of cancer victims, fear not only of the disease itself but of the effects of surgery, radiation, or chemotherapy that may be a necessary part of effective treatment. Under these circumstances it is not hard to understand the appeal of painless, nonsurgical, nontoxic “remedies”. The problem is they are not effective remedies, and they are not harmless. When they delay or interfere with swift diagnosis and prompt treatment they are potentially lethal.

As long as there are diseases that are frightening, and that resist fully effective management or cure, people will turn to those who traffic in false hope. And there will always be someone to turn to. It may be a huckster at home, a psychic surgeon abroad, or a cancer clinic in Mexico. There is no way to measure the cost of such quackery—in human terms or dollars and cents. Anyone who is concerned about cancer should turn for help to a physician experienced in treatment of the disease.

For its part, FDA—along with other Government health agencies and responsible health professionals—will continue to try to bring the facts about cancer and its treatment to the public. And as the Agency responsible for approving drugs FDA is firmly committed to assuring that any new discovery that meets proper scientific standards will become available to all Americans.
Perhaps the most tragic aspect of Laetrile is that some people who have been told that they have cancer in an early, treatable stage decide to try Laetrile and in so doing put off effective therapy until it is too late. One such person was "Mary," described in Dr. William A. Nolen's book about his investigations of miracle cures, Healing: A Doctor in Search of a Miracle. Mary (not her real name) was married, 35, had three children, and taught a class for retarded children. When Dr. Nolen first saw her she had cancer of the uterus in a very early stage. He wanted to put her in the hospital and start treatment promptly. But he was unable to do so. Mary's husband later explained to Dr. Nolen what happened:

"When Mary first came home from your office and told me she had cancer, I told her to get back to you as quickly as possible. I called my mother right away and she agreed to come out and help with the kids for a couple of months. Everything was set to go.

"Then Mary talked to a friend of hers who had, supposedly, had the same thing Mary had—cancer of the cervix. She had gone to Mexico for treatment, to a clinic just below the Texas border where they use something called Laetrile (the basic ingredient is made from apricot pits) to treat cancer. According to Mary's friend this cleared everything right up, without radiation or surgery or anything else.

"Mary insisted she wanted to try this first. She was a sensible woman, but the idea of either surgery or x-ray to her uterus bothered her—more, I guess, than I ever expected it would. I argued with her every way I knew how, but it didn't do any good. 'Just let me try it,' she said. 'If they don't cure me, I can always have an operation.' Finally, I had to let her go.

"For a while, after she got back from Mexico, it did seem that she was getting better. The spotting stopped, but it never had been very heavy. We spent three thousand dollars on medicines over a three-month period, and I guess we both wanted to believe she was cured. It wasn't till six months had gone by, and she was bleeding every day and losing strength fast, that I could convince her the damn Laetrile wasn't worth anything. Finally, she came back to you; but as we both know, it was too late."*

When Mary returned to Dr. Nolen's office he found that the cancer of the cervix had grown out to the walls of the pelvis on both sides, had infiltrated the bladder from the front, and the rectum from behind. There was no longer any effective treatment available. She died within a month.

* From Healing: A Doctor in Search of a Miracle, Copyright 1974 by William A. Nolen, M.D. Reprinted by Permission of Random House, Inc.
Improving Food Service Sanitation

Americans eat more than 150 million meals a day outside the home. Making sure this food is prepared and served under sanitary conditions is a massive responsibility that can be handled effectively only by State and local governments. But FDA plays an important role. It is seeking to make food service sanitation regulations more uniform throughout the country and is helping local governments establish and enforce effective consumer protection programs.

by James Greene

“A man hath no better thing under the sun than to eat, and to drink, and to be merry.”

Apparently, millions of Americans agree with this ancient scripture. In 1975, consumers spent over $70 billion eating food served or prepared outside their homes. One of every three food dollars is spent in restaurants and other food service facilities, for meals which vary from a Coke, hamburger, and french fries under the Golden Arches at around $1, to full-course meals in restaurants such as one in New York City where the minimum price for dinner for one is $60 plus a 30 percent tip. These and the approximately 600,000 other restaurants, taverns, fast-food shops, and other facilities, including schools, nursing homes, hospitals, and prisons, serve over 150 million meals a day.

FDA’s authority to regulate food includes all these establishments as well as food served on planes, buses, ships, and trains. From the moment food begins to be processed to be entered in interstate commerce until it ends up as a meal on a customer’s plate it is subject to FDA regulation. But FDA recognizes that the regulation of restaurants and institutional food service facilities is best left to State and local governments. FDA could neither inspect nor regulate more than an insignificant number of these establishments. Instead, FDA concentrates its money and manpower on assuring the safety and sanitation of food up to the time it reaches the retail level.

However, the rapid increase in chain-operated restaurants, especially fast-food eateries, has accelerated the need for more uniform food service sanitation regulations. The adoption of uniform regulations by local and State governments would help food service chains in complying with sanitary requirements, and would also result in better protection for consumers against foodborne illnesses resulting from insanitary conditions in restaurants and other food service facilities.

Over the past 40 years the Federal Government has attempted to provide that uniformity by designing a food service sanitation ordinance that local and State governments can use as a model in setting up their own regulations. The model ordinance was updated in 1962 and was eventually adopted by over 30 States and 255 local governments.

FDA now is in the final stages of approving an updated version of the ’62 ordinance. It will be used by State and local governments to update their own food service sanitation programs and, in some cases, to establish new ones. Eight States—New York, Mary—

As part of his training for certification by FDA as a State Food Service Evaluation Officer, Robert Karches accompanied Arthur L. Banks, an FDA senior food service specialist, on a round of inspections of restaurants, school cafeterias, and other places that prepare or serve food. Here, Karches (in plaid jacket), a senior health sanitarian for the New York State Department of Health, and Banks inspect a hotel restaurant and bar in Corning, New York. A complete inspection includes an examination of the dinnerware, bar equipment, kitchen utensils and equipment, food handling and storage, garbage and trash disposal facilities, and much more. After completing the inspection, Karches and Banks compare their findings.
land, Tennessee, Kentucky, Illinois, Mississippi, Rhode Island, and Alaska—already have adopted regulations based on FDA’s proposed new Food Service Sanitation Ordinance.

States seeking improvement and uniformity in their food service sanitation programs can count on continued FDA help, including training for their State inspectors.

Robert L. Karches, a 30-year-old former Navy officer, is a good example of how FDA and a State government can work together to improve food service sanitation.

As a senior health sanitarian for the New York State Department of Health, Karches spent the last three years routinely inspecting food service establishments in Steuben County, south of Rochester. Karches recently began a new phase of his career, being certified by the Food and Drug Administration as a State Food Service Evaluation Officer.

His new duties are twofold: to train local health inspectors in proper use and interpretation of New York’s recently enacted Food Service Sanitation Code; and to evaluate the effectiveness of food service sanitation programs conducted by local governments.

Karches is one of five New York State health sanitarians who have completed the FDA certification program. The State Department of Health will soon have one food service evaluation officer for each of its six regions and two for the central office in Albany. These officers will be responsible for training local health inspectors and surveying local government food service sanitation programs which have regulatory authority over 70,000 food service establishments in the State. Karches’ area of responsibility is the seven counties south of Rochester, which include approximately 3,000 food service establishments.

As part of his certification, Karches underwent a week of intensive training by Arthur L. Banks, the senior food service specialist in FDA’s New York regional office. Karches was taught FDA’s method of evaluating local government food service sanitation programs and how to interpret and apply New York State’s new sanitary requirements for food service establishments which, of course, are based on FDA’s new model ordinance.

In evaluating local food sanitation programs, FDA considers a number of factors. They include:

- The program’s conformity to FDA standards.
- Enforcement policy and practices.
- Emergency planning in case of a serious food health hazard, such as an outbreak of Salmonella poisoning resulting from contaminated food served in a restaurant or other food service establishment.
- The adequacy of resources and staff in the local food service sanitation program.
- How the local program relates to the public it protects and the industry it regulates.

Karches’ training also included accompanying Banks on inspections of 25 food service establishments. Each man used FDA’s Food Service Report form to rate the establishments on 44 items involving sanitation. The inspections covered sanitary handling and serving of food; cleanliness of personnel, food, equipment, and utensils;
Karches and Banks pay a visit to a church to check on the preparation and packaging of luncheon baskets to be delivered to elderly people as part of a "Meals-on-Wheels" program.

quality of the water; reliability of the plumbing and the garbage and refuse disposal facilities; proper control of insects and rodents; and proper use and storage of toxic products.

Each item is given a point value from one to five. More important items such as food cleanliness count five points, while the storage of clean tablecloths is rated as one. A perfect score is 100. All violations are subtracted from 100 and a score of 69 or less could be grounds for administrative action to require the closing down of an establishment.

After each inspection, Banks and Karches discussed inspection techniques and the interpretation and application of the State code. After completing all 25 inspections, Banks compared his findings of violations with those checked by Karches. This helped to pinpoint Karches' strengths and weaknesses in using the FDA inspection report form.

Karches returned to his regular State job after finishing the week of training and spent the next several months inspecting food service establishments in his home territory of Steuben County, using the FDA inspection report form and the techniques he learned from Banks. Then Banks and Karches again inspected 25 food service establishments, but this time without comparing inspection reports. To obtain FDA certification, Karches' findings had to agree with those of Banks 80 percent of the time on 42 of the 44 sanitation items, and his total average rating score for the 25 establishments had to come within five points of Banks' total average rating score.

To be certified, Karches also had to evaluate the administrative aspects of a local government's food service sanitation program. This entailed completing a questionnaire covering the same factors considered by FDA in rating a local program. A sliding point scale, similar to the one used in rating food service establishments, is used. A local government's effectiveness in enforcement policy and practices, for example, rates 14 points, while the government's working relationship with the local food service industry, counts two points. A score of 59 or lower indicates the local program is not adequate to meet public health needs in food service protection. From this evaluation, Karches was required to prepare a written report identifying the major weaknesses of the food service sanitation program and recommend ways the local government could correct them. After successfully completing this evaluation Karches was certified by FDA.

Once FDA puts the finishing touches on its new Food Service Sanitation Ordinance, the Agency will be prepared to certify State sanitation officers in each State that adopts the model ordinance. The senior food service specialist in each of FDA's ten regions will handle the certification of State officers, following a program similar to the one Banks used to certify Karches.

The close working relationship between FDA and the States in certifying State food service officers is carrying over into related programs. FDA has cooperated with several States to make available courses in food sanitation to industry managers and other personnel who supervise the preparation and handling of food in restaurants and other
Community colleges in a growing number of States are offering courses in food sanitation to supervisory personnel from restaurants and other food service establishments. FDA played a key role in the development of such programs. Here, Martha Marshall (center), assistant professor of food management technology at Montgomery College in Rockville, Maryland, discusses proper storage of kitchen utensils with two students as others examine the kitchen equipment used in the course.

Food service establishments. Over the last three years Virginia, Ohio, Maryland, Vermont, and Colorado have been given contracts by FDA to develop and test courses in food sanitation. Information derived from these contracts was used to develop FDA recommendations for the material such a course should include.

FDA's contract with Maryland ran from September 1975 to June 1976 and was typical of the programs carried out in the other States. The tuition-free course called for 14 hours of classroom instruction in four major areas of food service followed by a written test. The course covered food-borne disease and food protection; facilities, equipment, utensils, and non-food supplies; personal hygiene and operational procedures for food handlers; and management techniques conducive to proper food protection. Students who successfully completed the course were given a certificate.

The nine-month program, administered by the State at a cost of about $45,000 to FDA, resulted in the certification of 392 of the 436 candidates who enrolled in the 16 separate classes, most of which were held in community colleges across the State. The majority of the persons taking the course were supervisory personnel from restaurants — including several national chains — cafeterias, schools, nursing homes, and hospitals.

Although FDA funding of the program ended last June, two community colleges have continued the course, and two others have shown interest in incorporating it into their curriculum. Tuition for the course at the two schools now offering it is low, and most companies pick up the cost of their personnel who take the course.

Since 1973, FDA has spent about $300,000 on contracts with the five States that have developed and tested training programs for food service managers. This Federal-State cooperation is paying off handsomely, well beyond the borders of the five States directly involved. Illinois has a mandatory training and certification program conducted by its junior college system and all food service managers in the State are expected to be certified by July 1978. The District of Columbia has a mandatory certification program and has agreed with Illinois to reciprocally recognize each other's certifications. At last count, 24 States had initiated either voluntary or mandatory certification programs for food service managers.

The great increase in State food sanitation training efforts can be attributed in large measure to FDA's pilot programs, which proved that the food service industry and local, State, and Federal agencies can work together to train industry personnel and improve sanitation conditions. FDA is continuing to promote such training although it is no longer funding State programs. Detailed information about FDA's Food Service Manager Training and Certification Program can be obtained by writing the Division of Food Service, Food and Drug Administration, 200 C Street, S.W., Washington, D.C. 20204.

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If you know the shorthand, and can decipher the doctor's handwriting, there's no mystery about reading a modern-day prescription. But it wasn't always so. In the Middle Ages physicians used alchemic symbols to keep patients in the dark about the medicines they were taking.

by Annabel Hecht

If the prescription you take to the pharmacist to be filled is all Greek to you, think what it would have been like in the Middle Ages when the practice of medicine was greatly influenced by astrology and alchemy. In an effort to keep the knowledge of medicine and pharmacy from the general public, physicians used strange alchemic symbols to designate the materials and processes to be used in compounding medications. "The effect on the appearance of the prescription may be readily imagined," one medical historian has written, "and it is evident that the physician succeeded perfectly in making his preparation a mystery to the patient."

Keeping the patient in the dark and creating an aura of mystery and magic are precisely the reasons given by medical historians to explain the use of Latin in prescription writing even as late as 1900. There were more practical reasons as well, however. Latin was a universal language, understood throughout the world. Being a "dead" language it was not likely to be altered or changed. And it was exact and definite in its meanings. Thus, there could be no question about what the writer of the prescription intended.

There is no mystery about a modern-day prescription once you learn to read it. Written on a preprinted form of standard size, it will contain the physician's name and address, your name, the date, the name of the drug being prescribed, the dosage form, strength of the dose, amount to be dispensed, directions for use, and the number of times the prescription can be refilled, if at all. The physician's signature appears at the bottom of the form.

Since virtually all drugs come ready-made from pharmaceutical manufacturers, a physician does not need to list an assortment of ingredients. Instead, he writes the name of the drug being prescribed, using either the manufacturer's trade name or the generic or common name. The dosage form, if there is a choice, will be indicated by an abbreviation such as "cap" for capsule or "tab" for tablet. Liquids usually are denoted as "el," "sy," or "sol" for elixir, syrup, or solution. Dosage
strength is now commonly given in metric measures such as "50 mg," meaning 50 milligrams.

If the drug is to be taken 3 times a day for 7 days, the physician will write "#21" or "21." Refill information probably will be indicated in an abbreviated form, such as "Refill 2 x," meaning the patient can obtain the same amount of the drug two more times without obtaining a new prescription.

The only place on the prescription where Latin still is used is in the directions for use. This is done only as a matter of convenience—a kind of medical shorthand—not as a way of hiding information from the patient, since the physician usually explains when the drug is to be taken at the time he writes the prescription and the pharmacist translates the Latin abbreviations into English on the label he puts on the drug container.

One symbol from the past that probably will never change is the "Rx" which has come to mean "prescription." The origins of this symbol are given variously as an abbreviation of the Latin word "recipe," meaning "take thou" or "you take," or as a representation of the sign of Jupiter. It was the custom, in ancient times, to invoke the blessings of a deity on remedies by inscribing a formal prayer at the beginning of a prescription. In the interest of saving time, physicians eventually reduced the prayer to the symbol popularly assigned to a particular god. It is believed that the symbol for Jupiter, which resembled an "R" with a line across the extended right leg, evolved into the "Rx" we know today.

For those who regularly use the same pharmacy for all their drug needs, it may not be necessary to understand the hieroglyphics on the prescription form. But for those who wish to compare drug prices in various stores, knowing how to read the product name, dosage form, and dosage strength can be important. The Supreme Court recently declared unconstitutional a Virginia law barring the advertising of prescription drug prices. This ruling apparently opens the way for pharmacies all over the country to make their prices known to consumers, if they so choose.

Surveys of a number of communities have shown that prices charged for the same drug product can vary substantially from one pharmacy to another, depending in some cases on the services provided. Knowing how to read a prescription and "shopping around" can help consumers save money on prescription drugs.

Annabel Hecht is a staff writer with FDA's Office of Public Affairs.
FDA moves to open to the public virtually all of the meetings of the advisory committees that play an important part in the Agency's decision-making process. Meetings will be routinely closed only when the discussion involves trade secrets, information that would invade the privacy of some person, or files concerning investigations for law enforcement purposes.

Practically all the deliberations of FDA's approximately 60 advisory committees will be open to the public by the beginning of 1977 as FDA continues to elaborate on its expanding programs to let consumers know what the Agency is considering doing and the basis of its actions before they happen.

Final regulations now being drawn up will open most FDA advisory committee meetings to the public before or by January 1, 1977, some ten weeks before the effective date of the new Government in the Sunshine Act, which among other things will impose similar requirements for advisory committees in this and other agencies of the Federal Government. The Sunshine Act goes into effect next March 12.

Under the new FDA regulations, members of the public not only will be able to watch as an FDA advisory committee hears and discusses all the evidence, but also will be permitted to see and hear the committee's deliberations leading up to its recommendations to the Agency.

This means the public will be able to witness those parts of an advisory committee meeting that in the past were behind closed doors, where the committee participants review and evaluate the facts, consider the alternatives, speculate about whether any given line of FDA action may turn an industry or the economy on its ear, agonize, and finally decide what they will recommend to FDA. Those interested consumers who can't be on hand to watch will be able to read about it afterward, because the new regulations also will require that a transcript be made of all advisory committee meetings. Transcripts of open portions will be available for public inspection.

FDA's advisory committees deal with everything from overall Agency policy (National Advisory Food and Drug Committee) to various categories of products. There are some 40 committees dealing with drugs and

One of FDA's newest advisory groups is the Toxicology Advisory Committee, shown here in session at an open meeting.
The discussions may get quite complex when groups such as the Panel on Review of Dentifrices and Dental Care Agents talk about the effectiveness of certain ingredients or other technical matters that they are asked to consider. Technical matters will be reviewed in open session, however, unless the discussion involves trade secrets or might result in premature disclosure of recommendations for regulatory action.

more than a dozen on medical devices. Each committee is composed primarily of experts on the subject with which the committee deals. Consumer representatives and industry representatives also serve on many of the committees. The Agency has come to rely increasingly on advice or recommendations from its advisory groups in planning and carrying out its regulatory programs.

Essentially, the new regulations will deny advisory committees the option or discretion they have had in the past of closing a meeting to the public to enable members to formulate their advice to FDA without the public looking on. Generally, the regulation will require that all meetings be open unless the subject discussed covers trade secrets, information that would invade the privacy of some person, or other material specifically exempted from disclosure under the Freedom of Information Act.

FDA no longer will permit a meeting to be closed simply because the subject under discussion would be treated as an internal Agency memorandum if it were reduced to writing. The Freedom of Information Act had permitted internal Agency memos to be kept confidential, but the closing of meetings under this exemption had been increasingly criticized prior to enactment of the Sunshine Act.

FDA is expressly prohibited by law from disclosing trade secrets. Thus, meetings which may result in disclosure of trade secrets must be closed. Also to be closed ordinarily under the new regulations are meetings during which personnel files, including medical files, and files concerning investigations for law enforcement purposes are discussed. Otherwise meetings may not be closed except in the rare circumstances where discussion of a particular matter, if public, would disclose Agency information prematurely and thereby significantly frustrate implementation of a proposed Agency action.

Another instance in which meetings can be closed—but only if closing can be said to be essential—is the review and evaluation of specific products where recommendations for regulatory action may be forthcoming.

Under the regulations, the concerned FDA bureau will make the initial determination to close meetings only when appropriate. The agendas for advisory committee meetings will also be checked by the FDA committee management office and FDA's general counsel before the agenda is sent to the Commissioner of Food and Drugs for approval. Decisions to close any portion of an advisory committee meeting will thus be subjected to close internal and public scrutiny.

An FDA advisory committee meeting may have as many as four separate portions: open public hearing; open committee deliberation; closed presentation of exempted (trade secret) data; and, rarely, closed committee deliberations such as the consideration of trade secrets or private medical records. Every meeting must have an open hearing portion in which the public can participate through oral and written presentations, with questioning and general discussion. A committee chairman, if he desires, may conduct an entire meeting as an open public hearing with all persons present permitted to participate.

In open committee discussion or deliberation the public may observe but may not participate. The chairman is responsible for maintaining order and if it cannot be maintained the committee's executive secretary is authorized to end the meeting.

Harold Hopkins is editorial director of FDA Consumer
Although polychlorinated biphenyls have been used for almost half a century, it wasn't suspected until a decade ago that they may be endangering the public health. Use of PCB's is declining now, and a new law will end their production and distribution in the United States in about two years. But FDA will continue keeping a close watch on PCB levels in food, because once this chemical gets into the environment it stays there for a long time.

by Annabel Hecht

It is, as one scientist has put it, an example of toxicology being unable to keep pace with technology. For nearly 50 years, a toxic chemical has been imposed on our environment, yet it is only in the last decade that anyone realized the public health implications of the widespread use of this ubiquitous pollutant with the polysyllabic name—polychlorinated biphenyls, or more simply, PCB's.

PCB's, a distant relative of the pesticide DDT, are a class of industrial chemicals derived from benzene, a highly flammable colorless liquid used in motor fuels, detergents, nylon, pesticides, and other products. First synthesized in Germany in 1881, PCB's were not commercially available until about 1930. Since then, they have been manufactured in the United States by one firm, Monsanto Company, as well as by companies in Europe and Japan. By 1970, U.S. production accounted for about half the world output of PCB's.

The recently enacted Toxic Substances Control Act calls for an end to PCB production and distribution in the United States over a two and one-half-year period. A few days before the law was signed, the Monsanto Company announced that it would stop producing PCB's by October 1977. While this will reduce direct contamination from PCB's in the United States it will not bring an instant or total solution to the problem. Some PCB's from products already in use in the United States undoubtedly will find their way into the environment. PCB's from products used in other countries also will get into the environment and over a period of time may "migrate" to the United States in the atmosphere or ocean currents.

Another reason that halting production will not end the problem is that PCB's are virtually indestructable.
Lake Ontario fishermen who reel in coho salmon like these can mount them as trophies but have been warned not to eat their catch because of high PCB levels.

Employees of the New York State Department of Environmental Conservation (center) trap fish in the Hudson River for analysis and measurement of PCB levels. Although now halted, discharge of PCB's from industrial plants into the Hudson has created a major environmental problem for New York State.

Domestic sales of PCB's now are limited to use in "closed" electrical systems such as this station transformer (bottom) used by a large power-generating company.
They do not decompose in water, acid, or alkalis, and require temperatures up to 650°C (1,200°F. for complete destruction).

Because they are chemically stable, fire resistant, and do not conduct electricity, PCB's have been widely used as insulating fluids in electrical transformers and capacitors, in heat transfer systems, and in hydraulic fluids where the ability to resist high temperatures is required.

PCB's also have been used in consumer goods. They have been used to make plastic more workable and flexible. They have been put into adhesives, sealants, caulking, paints and varnishes, insulating tape and protective lacquers, lubricants, materials used for waterproofing and fireproofing, fluorescent light starters, printing inks, for waterproofing and fireproofing, sives, sealants, caulking, paints and resins, used in adhesives, and require temperatures up to 650°C (1,200°F. for complete destruction).

Fortunately for U.S. citizens, the Food and Drug Administration had started the wheels moving to protect the Nation's food supply from PCB contamination even before the Japanese misfortune. In 1967, FDA began a project to devise a means of separating PCB's from chlorinated pesticides encountered in the analysis of food. In July 1969, FDA laboratories throughout the country were provided instructions for the new analytical method, and by November 1970, analysis for PCB's was routinely included in both FDA's pesticide surveillance program and total diet studies. Under these programs, samples of fresh fruits and vegetables, dairy products, shell eggs, grains, fish, animal feeds, and processed foods were analyzed for a variety of chemical contaminants.

In 1971, the U.S. Department of Agriculture began sample testing of meat and poultry for PCB's and both that department and FDA have kept a close watch for PCB contamination in food during their regular inspection activities.

West Virginia was the site of one of the first documented cases of PCB contamination of food in the United States. In July 1969 FDA scientists found PCB's in milk from several dairy farms near Martinsburg. The source of contamination was traced to used transformer fluid that had been used as a base for an herbicide which had been sprayed near the cattle grazing areas. Advised that FDA would not permit interstate shipment of the contaminated milk, State officials halted marketing from the affected farms.

Within the next 2 years, seven more incidents of avoidable PCB contamination of food were investigated by FDA, the Agriculture Department, and State officials. In one case, chickens had been fed rations containing ground bread cartons and wrappers which may have contained PCB's. In another case, heat transfer fluid leaked into fishmeal which, in turn, was fed to poultry and catfish. This was probably the most serious incident of PCB contamination of the food supply and led to recall or seizures of poultry, eggs, fish, and feeds in a 10-State area by FDA and the Agriculture Department.

In several other cases, PCB's in paint and sealant used inside silos migrated into cattle feed and ultimately were detected in milk. This situation occurred again in 1976 when PCB's in two samples of milk were traced to silos coated with PCB-contaminated sealant.

FDA analysis of food samples during 1969-1971 indicated that PCB levels were relatively low in all foods except fish, milk, cheese, eggs, and by-products used in animal feeds. No PCB's were found in cereal grains and fresh fruits and vegetables. For the most part, PCB's in animal feeds were traceable to isolated industrial accidents and were not a widespread problem. PCB's in milk, however, were caused by their presence in paint or other coatings used in silos and this was a problem of wider magnitude.

PCB's were found in fish samples collected throughout the country, however, with the highest levels found in fish caught in waters near industrial and metropolitan centers. Early in 1970, FDA established an interim regulation—called an "action level"—forbidding the interstate shipment of any fish that contained more than 5 parts of PCB's per million parts in the edible flesh of fish.

The complexity of the PCB problem was only beginning to be realized. In July 1971 a new source of PCB contamination was revealed when low level residues of the chemical, found in breakfast cereal samples, were traced to the package the product came in. The manufacturer of the packaging material had used about 95 percent recycled paper, including carbonless copy paper which contained PCB's. A nationwide survey undertaken by FDA later that year showed that 36 percent of food packages sampled had PCB residues ranging up to 338 parts per million and that there was a definite correlation between the presence of PCB's and the number of contaminated packages.
The use in silos of paints or sealants containing PCB's has been identified as one of the causes of PCB contamination of milk. The chemical can migrate into the feed and then turn up in the milk of cows that eat the contaminated food. FDA now prohibits the use of paints or other materials containing PCB's in animal feed storage areas.

In a number of instances chickens have become contaminated with PCB's by eating feed that contained the chemical. Most of the occurrences of PCB's in animal feeds have been caused by isolated industrial accidents.

PCB's in the packaging and the use of recycled paper in the packaging material.

To strengthen the Government's efforts to protect the public from actual or potential harm, a task force was established in September 1971 composed of representatives of the Federal agencies most concerned, including FDA. The report of the task force, published in May 1972, recommended restrictions on the use of PCB's, rather than an outright ban, based on the belief that such restrictions and better housekeeping during manufacture, use, and disposal of PCB's and products containing them would gradually eliminate these chemicals from the environment.

Even as the task force worked, FDA was preparing regulations to set temporary tolerances for indirect PCB contamination of food, animal feed, and packaging. Taking into account the average daily intake of food that might contain PCB's and the levels of PCB's found in surveillance programs, the Agency set tolerances which would provide an adequate margin of safety for the public and at the same time minimize the economic impact on the food and feed industries. Published in 1973, the temporary tolerances were as follows:

- 5 ppm (parts per million) in the edible portion of fish and shellfish.
- 5 ppm in the fat of poultry.
- 2.5 ppm in the fat of milk and manufactured dairy products.
- 0.5 ppm in eggs.
- 0.2 ppm in finished animal feed.
- 2 ppm in animal feed components of animal origin.
- 0.2 ppm in infant and junior foods.

The regulations also prohibited the use of PCB's in new equipment or machinery used by the food, food packaging, or animal feed industries and in coatings or paints for use in animal feed storage areas. To preclude accidental PCB contamination, manufacturers of food-packaging materials, human food, and animal feed were required to replace heat exchange fluids containing PCB's with fluids that did not contain this chemical. They also were required to eliminate, wherever possible, equipment, machinery, and materials containing PCB's that could contaminate packages, food, or feed.

An action level of 10 parts per million was set for PCB's in paper food-packaging material except where there is a barrier through which PCB's cannot pass between the package and the food. This action level was established pending a public hearing on the issue.

Because of FDA's efforts and com-
pliance by the affected industries, there have been no “PCB accidents” involving food or feed in interstate commerce since 1972, other than the two silo incidents. Except for fish, the rate of occurrence of PCB’s in samples of various types of food analyzed by FDA had dropped to less than 1 percent by 1975. Samples of meat and poultry checked by the Agriculture Department also showed a significant decline in PCB occurrence.

Fresh water fish remain a problem, though not a major one in terms of the Nation’s total diet. In 1971, Monsanto Company, sole U.S. producer of PCB’s, limited its domestic sales of the product to use in “closed” electrical systems such as hermetically sealed transformers and capacitors. Monsanto’s restrictions helped reduce, to some extent, the amount of PCB’s entering rivers, lakes, and streams, but it did not eliminate the PCB’s already there. PCB’s have a nasty way of accumulating in the flesh of fish (and other animals and humans) that eat them. In some instances the PCB levels in fish have been found to be hundreds of thousands of times higher than the PCB levels of the water in which they were caught. Thus, even a low level of PCB contamination in water can lead to high levels of the chemical in fish and other aquatic life. This is particularly true of older, larger, oily fish.

While the overall percentage of fish containing PCB’s has declined, the percent with more than the permissible 5 parts per million has remained about the same. Areas where these high level fish have been found include the Hudson, Mississippi, and St. Lawrence Rivers, and Lakes Michigan, Ontario, and Onandaga. Coho and chinook salmon, steelhead trout, striped and smallmouth bass, carp, eel, rock bass, and catfish are among the species most affected. It should be stressed that these are fresh water fish which represent a very small part of the national fish diet, although in some areas fresh water sport fish are a significant part of the local diet.

The problem is not just a local one, however. Lake Michigan carp have been used to stock private fishing lakes in Illinois, Ohio, Indiana, and Missouri. Migratory fish, such as striped bass and shad, spawn in the Hudson, then go out to sea, and Great Lakes salmon, loaded with PCB’s, have been seized by FDA inspectors on the West Coast where they had been shipped for processing.

In February 1976, FDA endorsed a decision by New York State to ban commercial fishing—except for shad—in the Hudson River and to advise the public not to eat Hudson River fish or salmon from Lake Ontario. Michigan also has warned the public against eating sports fish caught in Lake Michigan. A two-year study, funded by FDA, revealed that people who eat Lake Michigan fish have more PCB’s in their blood than people who do not. But no adverse health effect could be identified in the study population.

Laboratory studies have shown that commercial PCB mixtures can cause damage to test animals. PCB’s affect the reproductive ability of mink and monkeys. Liver damage has been produced in chickens, rabbits, quail, and rats. Monkeys fed PCB’s developed reproductive problems, liver disease, acne, eye inflammations, weight loss, and loss of hair. Of particular concern is the finding that PCB’s produced liver tumors in mice and rats.

Except for people who have been exposed to high concentrations of PCB’s on the job or who have consumed large quantities of PCB-contaminated fish, the population at large has had minimal exposure to these chemicals. Still, PCB residues have been found in human fat tissue.

It has been estimated that 51 percent of the population has detectable levels of the chemical in their bodies. Preliminary findings from a national study of insecticides in human milk revealed that 65 of 67 women were found to have measurable amounts of PCB’s in their milk. A group of experts in pediatrics and toxicology who studied the findings to date agreed that women should not be advised against nursing their babies. No illness has been reported in the United States, other than from occupational exposure, that can be directly connected with PCB’s, although what long range effect they will have on human health is yet to be determined.

While Congress debated the merits of the Toxic Substances Control Act, efforts were being made on a number of fronts to prevent future pollution from the diehard chemical. The American National Standards Institute issued guidelines for industry on the use, disposal, and labeling of PCB’s. The Department of the Interior now prohibits the use of PCB’s in offshore oil drilling equipment.

The Environmental Protection Agency (EPA), which is charged with protecting the Nation’s waterways from pollution, has issued regulations to prevent spills of hazardous substances, including PCB’s, and has proposed regulations that would prohibit practically any discharge into waterways of industrial wastes containing PCB’s. These regulations would apply to manufacturers of PCB’s and manufacturers of transformers and capacitors that use PCB’s.

Earlier this year, EPA recommended carefully controlled incineration as the best method for the disposal of industrial wastes containing PCB’s.

A number of States have enacted or are considering legislation limiting use of PCB’s to closed electrical systems, including Michigan, Minnesota, Indiana, Wisconsin, Illinois, and New York.

An assessment of the effects of PCB’s on health has been made by a task force of the U.S. Department of Health, Education, and Welfare made up of representatives from FDA, the National Cancer Institute, Center for Disease Control, National Institute for Occupational Safety and Health, and National Institute for Environmental Health Sciences. In its report, issued in July 1976, the group called for more research on the chemical components of PCB residues and on the effects of these chemicals on man and animals. Specifically recommended were long-range health studies of people who consume substantial amounts of fresh water fish which have high levels of PCB’s.

FDA will conduct an expanded surveillance program for PCB’s in fish and other foods and continues to encourage other Federal and State agencies to step up their efforts to control the entry of PCB’s into the environment. And although the use of PCB’s is declining, their tenacity in clinging to the environment means that all responsible agencies will have to devote considerable resources to the control of PCB’s for years to come.

Annabel Hecht is a staff writer with FDA’s Office of Public Affairs.
News Highlights

Evaluations of Four Food Ingredients Released

FDA has released evaluations conducted by an outside group of scientists of four substances on the list of food ingredients generally recognized as safe (GRAS). The evaluations were made by the GRAS Review Panel of the Federation of American Societies for Experimental Biology (FASEB), which for several years has been evaluating all GRAS List substances under an FDA contract. Thus far, FASEB has provided FDA with about 200 such evaluations.

The four recently-released evaluations were on glutamates, protein hydrolyzates, caffeine, and BHT. The report on BHT is final and, based on it plus recent studies, FDA is preparing a regulatory proposal. The other three reports are tentative; that is, FASEB has not yet completed its own work on them, and will hold a hearing on them before presenting them to FDA as final reports.

Following, is a summary of the four evaluations:

• Glutamates: Present levels of glutamates are acceptable for adults except for monosodium glutamate (MSG), a substance used as a flavor enhancer. The panel said additional studies are needed to justify continued use of MSG in adult foods, though there is no evidence that it poses a hazard at current levels of use. Because of reported adverse effects of glutamates in experimental animals, the use of these substances in baby and junior foods is not recommended, the panel said. Baby and junior food manufacturers a few years ago stopped using MSG.

• Hydrolyzed vegetable or plant proteins: These have been used since the late 19th century as flavor enhancers and sources of meat-like flavor for a variety of food products. These substances are not recommended for baby and junior foods because of reported adverse effects in experimental animals. The panel said additional studies are needed to justify continued use of vegetable and animal protein hydrolyzates in adult foods. One particular ingredient, enzymatic casein hydrolyzate (protein derived from milk), was deemed by the panel to be acceptable for both adult and infant use.

• Caffeine: The panel was concerned solely with the addition of caffeine to nonalcoholic cola-type beverages. The panel was divided on the degree of potential hazard resulting from caffeine in cola beverages. Some members recommended its prohibition because animal studies indicate it has a potential for adverse effects, particularly in young children. Other members recommended that use could continue while additional studies are conducted.

• BHT: Butylated hydroxytoluene (BHT) is a synthetic compound used in foods since 1949 to prevent most fats, oils, and fat-containing foods from turning rancid. The panel recommended that BHT be studied further. The panel further recommended that its present uses in food could continue while the studies are being conducted.

After FDA receives final evaluations from FASEB, it has several regulatory options. It could affirm a substance's place on the GRAS List; establish specific limitations under which the substance can be safely used; or prohibit its use. If further studies are needed, FDA specifies what those studies are and, if no hazard is posed, generally permits the continued use of the substance at current levels while the studies are carried out by industry.

Studies May Bring Action on Amphetamines

The Food and Drug Administration has told Congress that if current studies document a continuing and serious abuse of amphetamines, a class of drugs widely used to help people lose weight, then FDA would either withdraw approval for use of the drugs in treating obesity or remove them from the market altogether.

Testifying before a Senate hearing chaired by Senator Gaylord Nelson, Dr. J. Richard Crout, director of FDA's Bureau of Drugs, said that FDA anticipates that information being developed by the Drug Enforcement Administration (DEA) will provide the legal evidence of abuse necessary to support future FDA regulatory action.

The most common medical use for amphetamines, often called "pep pills," is in short-term programs of weight reduction. Less common uses are for the treatment of narcolepsy (a rare condition of uncontrollable sleepiness) and for minimal brain dysfunction (hyperactivity) in children. Other drugs are available for these uses.

Dr. Crout said that FDA and the National Institute of Drug Abuse (NIDA) are cooperating with DEA in its efforts to document the abuse problem.

Dr. Crout said removal from the market of approved drugs, such as amphetamines, on the basis of widespread abuse, rather than safety risk to individual patients, "would be an innovative position for which there is little legal precedent."

He added, however, that "we believe such a position is legal and we are prepared to defend it."

FDA has, for a number of years, supported strong controls on the amphetamines. In 1972, an expert advisory group to FDA determined that the amphetamines made only a "trivial contribution" to weight-reduction programs and FDA immediately tightened physician labeling requirements to reflect this judgment and also to highlight the potential of the drugs for abuse.

With FDA concurrence, the DEA has for five years listed the amphetamines in the most restrictive category available under the Controlled Substances Act.

This category, Schedule II, is reserved for medically useful drugs that have known potential for abuse. Morphine and and other opium products are in this schedule. Production, distribution, and sale of Schedule II drugs is strictly limited. Prescriptions may not be refilled and manufacturers must limit production according to DEA-established quotas.

These scheduling and labeling regulations have resulted in an 80 percent reduction in annual use of amphetamines compared to the peak year of 1965.

Evidence indicates, however, that the amphetamines remain the most seriously abused of all anorectic (appetite suppressant) drugs.
Nutrition Labeling Approved for Carry-Outs

In an effort to encourage fast-food restaurants to provide nutritional information to their customers, the Food and Drug Administration has given the go-ahead for such restaurants to post signs giving the nutritional content of a meal or a combination of foods, such as a hamburger, french fries, and a milk shake.

The sign would have to be in the form of a nutrition label and tell how many calories are in the meal, as well as the amounts of protein, carbohydrates, and fat; and the percentage of the U.S. Recommended Daily Allowance for seven vitamins and minerals.

The policy statement on nutrition labeling of fast-food-restaurant foods is in response to a petition from McDonald’s Corporation. The statement appeared in the Federal Register, November 19, 1976.

Breast Cancer Linked to X-ray Treatments

Repeated exposure to x rays during treatment 20 to 40 years ago resulted in an excessive number of breast cancers among women who had been patients in two tuberculosis sanatoriums, according to a study conducted by the Harvard School of Public Health. The project, sponsored by the National Cancer Institute and supported by the U.S. Public Health Service, was designed to investigate the long-term effects of x-ray exposure to the chests of adolescent girls and adult women to determine whether there is a relationship between breast cancer risk and radiation dose and whether later development of breast cancer is related to age at the time of the x-ray exposure.

A followup of 1,047 women who had been exposed to an average of 102 fluoroscopic examinations of the chest in the course of therapy revealed that 41 developed breast cancer whereas only 23 would have been expected to do so. A control group of 717 women who also had tuberculosis but who had been treated by other procedures did not have an unusually high incidence of breast cancer. All the women had been patients between 1930 and 1954.

The study also showed that the younger a woman was when she first received the tuberculosis treatment the greater the risk of developing breast cancer. The high incidence of breast cancer cases developed in women whose first x-ray treatment occurred at ages 10-19 and 20-29, with the greatest risk occurring among those first exposed between the ages of 15 and 19. Women who had their first treatment after age 30 did not have a high-incidence of breast cancer. The high incidence of cancer of those exposed to x rays did not occur until 15 years after the initial exposure, but was still present at the end of 40 years of observation.

Another finding of the study was that the more frequently a woman was exposed to low dose radiation, the greater her risk of developing breast cancer.

The treatment that the women in the study had received, known as pneumotherapy, is no longer used. Present fluoroscopy units give significantly lower exposures than those in use between 1930 and 1954.

Rules Proposed on Food, Drug Safety Tests

The FDA has proposed new regulations to assure the adequacy and integrity of animal studies on the safety of new drugs and food additives for human use.

Under Federal law, such studies must be submitted by companies seeking FDA’s approval to market certain products.

The proposed Good Laboratory Practice (GLP) Regulations set standards for all aspects of animal and other laboratory studies, from facilities and equipment to personnel and recordkeeping.

Noncompliance with the regulation could result in rejection of data submitted to FDA in support of a new drug or food additive application, or withdrawal of approval of a marketed drug or food additive. If false data are submitted to the FDA, criminal prosecution also could result, as provided by other regulations governing the submission of reports to the Government.

It is estimated that the proposed regulations would affect at least 550 laboratories in this Nation, as well as foreign laboratories conducting studies to be submitted to FDA.

In proposing the new laboratory standards, Commissioner of Food and Drugs Alexander M. Schmidt, M.D., said: “Recent FDA investigations have found animal studies poorly carried out, and data which were improperly reported or not reported at all. We do not know how widespread the problem is, but we are concerned that these findings are not isolated instances. It is essential that FDA decisions about the safety of consumer products be based on valid scientific data; the Agency can accept nothing less.

“The law places the burden for supplying these data on industry, and the GLP Regulations we are proposing today should help them do the kind of research needed for good decisionmaking by regulatory agencies. The FDA intends to use the new regulations, combined with regular inspections and other compliance methods, to make certain that laboratory studies are carried out by industry and reported to FDA in such a way that both we and the American consumer can have confidence in the safety of new products entering the market.”

Dr. Schmidt has testified four times before Congress in the past 17 months on deficiencies in animal studies uncovered by FDA investigations. Congress subsequently pro-
FDA Proposes Warning Label on Aerosols

The Food and Drug Administration has proposed that the following warning be required on the labels of food, drug, and cosmetic products containing chlorofluorocarbons: "Warning. Contains a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere."

At the same time, FDA affirmed its intent to phase out all nonessential uses of chlorofluorocarbons in the products it regulates. The warning statement would be required as an interim measure until the phaseout is completed.

Chlorofluorocarbons are used as propellants in many products such as deodorants, antiperspirants, hair sprays, colognes, and fragrances.

FDA estimates that of the 2.4 billion self-pressurized containers sold in the United States annually, the proposed label warning would affect about one billion. The remainder of the containers either do not contain chlorofluorocarbons or are products not regulated by FDA.

Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, said: "The purpose of this warning is to encourage self-restraint by consumers in purchasing aerosol products containing chlorofluorocarbons and to encourage them to seek alternative products. Our goal is to reduce the use of chlorofluorocarbons in aerosols until they are phased out."

"This action is unique, and should represent the first of a worldwide series of actions by all nations to limit the release of chlorofluorocarbons into the atmosphere. Given the long-term nature of the hazard, the way in which we are going about the phaseout and warning labels on aerosols will be to the consumer's maximum benefit.

"We are giving everyone adequate notice of what we intend to do, so that no one is caught by surprise. We are providing ample opportunity for public and industry comment. We are providing sufficient time for companies to switch to other packaging or other propellants. We will make sure that essential uses of chlorofluorocarbons in drugs and devices can continue. And the phaseout and label warning will be accomplished in an orderly way at a minimum expense to consumers."

The label warning would not be required for prescription drugs or for over-the-counter drugs or devices used to treat bronchial asthma. FDA will review these products separately.

The warning statement would become effective 30 days after issuance of a final regulation. Products in retail stores or in interstate commerce before the effective date would not have to be recalled or labeled with the warning.

On October 15, 1976, FDA announced that it would propose a warning label and initiate a phaseout in response to a National Academy of Sciences (NAS) report affirming that continued release of chlorofluorocarbons into the atmosphere may harm the public health and environment by depleting the protective ozone layer in the stratosphere.

Reduction of the ozone shield, which absorbs harmful ultraviolet radiation from the sun, could lead to an increase in the incidence of skin cancer and adverse effects on the environment.

Chlorofluorocarbons are part of a family of chemicals known as halocarbons. Chlorofluorocarbons contain chlorine, fluorine, and carbon. Of all the types of halocarbons, chlorofluorocarbons pose the most serious risk of ozone depletion. FDA plans to evaluate the atmospheric effects of other halocarbons to see whether regulatory action is needed.

The proposal to require the label warning was published in the Federal Register, November 26, 1976. Comments may be submitted within 60 days to the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20857.

Dental Group Backs Plan to Reduce Radiation

The American Academy of Dental Radiology has adopted a resolution endorsing the Dental Exposure Normalization Technique (DENT) system, a program developed by FDA to eliminate excessive radiation in dental x rays. The resolution urges State radiation control agencies to implement DENT and encourages practicing dentists to cooperate in all phases of the program.

Under the DENT program each State radiation control agency sends special radiation-sensitive cards to all dentists within its jurisdiction who have x-ray facilities. The dentists expose the cards to the dosage of radiation they normally use for x rays and return them to the agency for analysis. Dentists whose cards indicate exposures above an acceptable range are visited by a radiological health surveyor who suggests ways to produce good quality x rays with low patient exposure.

Thirty-one radiation control agencies are now participating in the DENT program, which was initiated in 1970 as a Federal/State effort. Of the 6,842 x-ray machines checked thus far, 43 percent were found to exceed the acceptable exposure range. After consultation, the average exposure per film was reduced substantially.
“Regional Reports” consists of important information on inspections, product seizures, court proceedings, and other regulatory and administrative actions initiated by FDA’s regional and district field offices across the country to provide protection to consumers under Federal laws. “State Actions,” the section immediately following “Regional Reports,” consists of similar information about the consumer protection activities of State and local governments.

REGION II

New Jersey, New York, Puerto Rico, Virgin Islands

A shipment of 4,000 gallons of refined peanut oil, valued at $21,000, from World Food Program, Rome, Italy, was voluntarily destroyed by the New York Import Broker after FDA’s New York District learned that the oil had been damaged by fire while in transit on the freighter SS Mormac Bay. New York District investigators witnessed the destruction, in which the oil was dumped into a landfill.

Supervisory Tea Examiner Robert Dick of FDA’s New York District rejected 12,000 pounds of tea offered for import from Ceylon because it did not meet the standards for imported teas set by the U.S. Board of Tea Experts. Samples of the tea, valued at about $5,000, were collected by inspectors from FDA’s New York District during a routine wharf inspection at the Port of New York and then tested at FDA’s New York laboratory. Dick said that Ceylon garden teas are normally of unusually high quality and have never been rejected by the board except for in-transit damage. These two shipments, however, had dark infusions and were earthy in aroma and taste, Dick said, both of which are characteristics of poorly manufactured tea.

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Walker, Corp & Co., Syracuse, New York, has agreed not to produce any more drugs or distribute any into interstate commerce until it can comply fully with FDA’s Current Good Manufacturing Practice Regulations. In entering into a consent decree of permanent injunction issued by the U.S. District Court for Northern New York at Utica, the firm also agreed not to ship any drugs already produced until they have been tested to assure that they meet FDA quality and purity standards. The injunction was the result of an inspection by investigators from FDA’s Buffalo District, who found that the plant lacked adequate quality and dust control systems and needed general cleaning up to prevent contamination. The firm manufactures 45 drugs, including children’s drugs, estrogens, and 19 other prescription drugs.

The Federal Government seized 39 lots of food weighing more than 4,000 pounds and valued at $62,000, at Merse Bros. Trucking, a public food-storage warehouse in Bridgewater, New Jersey, because of gross insect infestation. Investigators from FDA’s Newark District found that more than 60 percent of the lots of flour, rice, and cornstarch stored there by various firms was adulterated with insects. The seizure resulted after Newark District investigators traced to their origin 31 bags of insect-infested flour found during a routine inspection of a wholesale bakery supply house in Newark.

When a Miami resident complained to a pharmacist that his isosorbide
dinitrate heart tablets did not dissolve readily under his tongue he probably never imagined that the comment would lead to a nationwide recall. But the pharmacist responded correctly by immediately reporting the problem through the Drug Defect Reporting System, operated by FDA's Bureau of Drugs and the United States Pharmacopeia (USP). Newark District investigators discovered that the distributors of the tablets, Drugs, Inc., Elizabeth, New Jersey, had purchased tablets that had been manufactured before the USP listed the drug and specified a two-minute disintegration time in July 1975. Shortly after receiving the complaint, the firm voluntarily recalled the product from all its direct accounts nationwide.

Inspectors from FDA's San Juan District witnessed the destruction of the entire contents of a warehouse of pharmaceuticals which had been exposed to fire and water damage. The pharmaceuticals, valued at over $860,000, were buried in a San Juan landfill. The destruction was undertaken voluntarily by Richardson Merrill Interamerica, Inc., after fire struck the block-long warehouse in the San Juan suburb of Puerto Nuevo.

Federal marshals seized 1,700 cases of canned crushed pineapple, valued at more than $31,000, following complaints from Puerto Rico schools to FDA's San Juan District that the product, imported from Brazil, had an "off-taste." Analysis by FDA's San Juan laboratory revealed that the lining of the cans had deteriorated causing numerous tin flakes in the pineapple.

REGION IV

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

U.S. marshals seized 12,600 pounds of turbinado sugar, valued at over $4,000, at Collegedale Distributors, Inc., Ooltewah, Tennessee. The seizure resulted from an inspection by FDA's Nashville District which revealed the sugar, held in bags, was contaminated with rodent excreta pellets and stored under insanitary conditions in a rodent-infested warehouse.

Biomedical Laboratories, Inc., Fort Lauderdale, Florida, voluntarily turned in its license to collect plasma to FDA's Bureau of Biologics. The action resulted from joint inspections of the laboratory by FDA's Orlando District and the bureau, which revealed overbleeding of donors, inadequate recordkeeping, and improper plasma storage. On three earlier occasions the firm had voluntarily suspended its license for similar deficiencies in its plasma collection operation.

Over 40,000 gallons of various fruit-flavored syrups were voluntarily recalled and destroyed by burial in a landfill, by H and H Products, Co., Orlando. The action resulted from an inspection by FDA's Orlando District which revealed the flavor concentrate used to make the syrup contained Red No. 2, a food color additive banned by FDA early this year. The firm manufactures and distributes, among other products, Hartley's brand fountain and slush syrup.

REGION V

Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin

Approximately $10 million worth of foodstuffs and empty liquor bottles were seized by a U.S. marshal at Broker's Warehouse, Minneapolis, after investigators from FDA's Minneapolis District confirmed a State investigation which found the six-room public warehouse was contaminated with residues from several chemical herbicides.

Three FDA investigators accompanied a U.S. marshal in what is one of the largest seizures—in dollar value and amount of goods—ever undertaken by the Federal Government. Among the more numerous products seized were 123 tons of raisins, over 35,000 50-pound bags of nonfat dry milk and over 50,000 cases of empty liquor bottles. The mass seizure also involved a variety of products, including coffee beans and such items as animal feeds and birdseeds.

FDA's investigation confirmed an earlier report from the Minnesota Department of Agriculture which traced a strong odor of pesticides in the warehouse to empty bottles. Subsequent tests performed by an independent laboratory at the request of the State revealed that some of the liquor bottles contained residues of the powder herbicide product Eptam 100, and another possible liquid herbicide product.

Additional lab tests and investigative work by FDA's Minneapolis District confirmed the presence of Eptam, along with two additional herbicide products, Vernam and Dyfonate, in or on the bottles and their cases and in or on samples of nonfat dry milk and coffee beans collected in the other five rooms.

The joint investigation revealed that the herbicide products, including the Eptam 100, which was stored in plastic-lined paper bags, originally had been stored in the warehouse, but had been moved to another location, also operated by Broker's Warehouse.

FDA's Minneapolis District is notifying the 160 owners of the seized products since neither the warehouse nor any large single claimant will assume responsibility for the contaminated goods. None of the products has been distributed into consumer channels.

REGION VI

Arkansas, Louisiana, New Mexico, Oklahoma, Texas

A U.S. marshal seized about 20,000 pounds of food products stored at Basic Need, Inc., Grand Prairie, Texas, after investigators from FDA's Dallas District discovered widespread insect infestation at the warehouse. Among the food items seized were
macaroni products, rice, buckwheat flour, and texturized protein. Almost all lots of food products examined during the inspection were found contaminated with insects. Investigators also observed insects flying and crawling in food storage areas. Inspectors from the Texas State Food and Drug Division confirmed FDA's findings of insect contamination and placed the food products under a State embargo, pending seizure by a U.S. marshal.

Acme Agricultural Supply, Inc., North Little Rock, Arkansas, and its president, Colvin B. Bryant, and secretary-treasurer, James Leon Bryant, have agreed to stop selling prescription veterinary drugs to lay people without requiring prescriptions or other orders from veterinarians. The agreement came in the form of a consent decree of permanent injunction which the two company officials signed in the court of U.S. District Judge G. T. Eisele of the Eastern District Court of Arkansas. FDA's New Orleans District initiated the legal action after the Arkansas Veterinary Medical Examining Board notified FDA of retail pharmacies because some of the products were not sterile. Earlier this year an inspection of the firm's ophthalmic manufacturing operations by FDA's Kansas City District disclosed questionable manufacturing practices and controls. Subsequent analysis by FDA revealed lack of sterility in one of the firm's eye lotion products, and the firm also reported finding another nonsterile lot. These two discoveries prompted FDA to request a total recall.

Approximately $4,500 worth of red food color containing Red No. 2 and intended for household use was seized by a U.S. marshal at Tone Bros., Inc., Des Moines. The color additive was packaged in bottles of one fluid ounce each. Red No. 2 was banned by FDA early this year. The seizure was the result of a routine inspection of the firm by FDA's Kansas City District.

Dolgin Grocery & Tobacco Co., St. Louis, and Eugene Dolgin, the firm's president, agreed and stipulated in the District Court for the Eastern District of Missouri to the accuracy of two criminal charges of insect contamination of stored foods and insanitary conditions at the firm's warehouse. U.S. District Judge John K. Regan then found the corporation guilty on two counts, and the president guilty on one count. The corporation was fined $2,000 and its president $500. The prosecution followed investigations by FDA's Kansas City District which revealed extensive insect activity and evidence of contamination of large lots of foods. FDA laboratory analysis revealed insects and insect filth in cake and biscuit mixes, breakfast cereal, and rice.

REGION VIII

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

A total of 1,200 cases of canned corn intended for use on several Indian reservations in South Dakota was recalled by the canner, Stokely Van Camp, Hoopstown, Illinois, because of worm and insect contamination. The recall was initiated after a complaint was lodged with FDA's Denver District by Floyd Lashly, an Environmental Sanitarian with the U.S. Public Health Service in South Dakota, which claimed that about one in every three or four cans contained worms and insect larvae. Subsequent investigation by FDA's Denver District confirmed the adulteration. The cans were all labeled for use by the U.S. Department of Agriculture Food Health Program in Government installations including Indian reservations and prisons, and were not distributed for general consumer use.

REGION IX

Arizona, California, Guam, Hawaii, Nevada

Refrigerated Foods, Los Angeles, a manufacturer of frozen foods, has spent over $35,000 to correct deficiencies in its operation which were discovered by inspectors from FDA's Los Angeles District during an earlier inspection. Among the deficiencies found corrected by inspectors during a followup inspection was the resurfacing of the firm's interior walls with a material which now provides showing evidence of rodent contamination were destroyed.
a smooth, hard surface. The walls had been lined with tile that had deteriorated to the point that it could not be cleaned satisfactorily.

**REGION X**

*Alaska, Idaho, Oregon, Washington*

Amalgamated Sugar Co., Ogden, Utah, forfeited $5,000 of a $10,000 bond for failing to comply with all the terms of a consent decree of condemnation filed in the U.S. District Court for the Western District of Washington in Seattle. Under the decree more than 21,000 pounds of sugar packed in 100-pound bags and approximately 1,500 pounds of bulk sugar which had been seized at a Seattle flour mill were to be reconditioned under FDA supervision at the firm’s plant in Nyssa, Oregon. When the inspectors arrived, however, they found that the bulk portion of the sugar had been disposed of. Subsequently, the Federal Government filed a motion in the court for forfeiture of bond, which the court upheld. The sugar had been seized by a U.S. marshal at the Seattle flour mill after inspectors from FDA’s Seattle District collected samples and laboratory analysis revealed it was unfit for food because of an objectionable odor.

Swinomish Indian Fish Co., La Conner, Washington, is legally prohibited from shipping low-acid canned foods in interstate commerce until it has been granted an Emergency Permit by FDA. To obtain the permit the firm must comply with all FDA regulations for processing low-acid canned foods in hermetically sealed containers. The firm had originally objected to FDA’s contention that an emergency permit was needed to continue shipping canned salmon. After an administrative hearing was held at FDA’s Seattle District, the firm’s objections were overruled. The firm has since applied for two emergency permits but was turned down each time after followup inspections at the plant by FDA’s Seattle District found continued deviations, including improperly maintained processing and production records.

### State Actions

#### Live Snake Found

The Michigan Department of Agriculture received an unusual complaint when a consumer from Grand Rapids reported finding a small live snake inside a package of smoked sausage purchased at a retail grocery store. State investigators confirmed the consumer’s snake finding and a subsequent investigation showed the package had been tampered with either after leaving the packaging plant or at the retail store. A check at the store showed all other packages of the product to be normal.

#### Fire Damages Food

Investigators from the Texas Department of Health Resources supervised burial of contaminated foodstuffs and drugs at the Municipal Sanitary Landfill in Dallas. The merchandise, which was valued at approximately $20,000 and included flour, cornmeal, canned goods, and miscellaneous drugs, was damaged during a fire at Salvage Enterprises, a Dallas food salvage firm. The cleanup operation conducted by State investigators took more than a week.

#### Bakery Reopens

German Home Bakery, Costa Mesa, California, reopened for business after taking action to eliminate insect infestations in the shop and rodent contamination of bakery goods found by health inspectors from the Food and Drug Section of the California Health Department during two recent inspections. The company lost an estimated $30,000 worth of business during the two weeks it stopped production to make structural changes in its bakery. The first inspection resulted in the State filing a legal action against the firm in the Orange County Municipal Court in which the owners of the bakery pleaded guilty to five counts of adulteration and bakery insanitation. The firm was fined $625 and placed on three years’ probation. The followup inspection by the State showed continued violation and resulted in another legal action in the Municipal Court in which the owners were found guilty of violation of probation, and were fined an additional $1,110.

#### Grape Soda Destroyed

A consumer complaint to the North Carolina Department of Agriculture about odd-tasting grape soda led to voluntary recall and destruction of over 45,000 10-ounce bottles of grape crush soda bottled by the Pepsi Cola Bottling Co., Durham, North Carolina. Analysis of the soda by the State Department of Agriculture revealed a high concentration of yeast contamination in the product. The recall of the soda, valued at nearly $6,000, was monitored by the State, which normally inspects bottled beverage manufacturers under an FDA contract.
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 13 actions to remove from the consumer market products charged to be violative was reported in October. These included 8 seizures of foods: 1 involved charges concerning poisonous and deleterious substances, 7 involved charges concerning contamination. Other seizures included 2 of food additives, 2 of drugs (including 1 of veterinary/medicated feed), and 1 of a medical device.

<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peanut butter/Fredonia, N.Y. 9/21/76</td>
<td>Manufactured at Fredonia, N.Y., from Alabama and Georgia peanuts.</td>
<td>Contains the added poisonous and deleterious substance, aflatoxin.</td>
</tr>
<tr>
<td>Bean-paste threads, shark fins, and misc. oriental foods/San Francisco, Calif. 10/22-23/76</td>
<td>Chuck Lee's Market &amp; Warehouse/ San Francisco, Calif. (D)</td>
<td>Held under insanitary conditions; some foods were rodent contaminated.</td>
</tr>
<tr>
<td>Candy and desicated coconut/Largo, Fla. 9/13/76</td>
<td>Krueger-Satin Candy Co., Inc./Largo, Fla. (D)</td>
<td>Held under insanitary conditions; candy insect contaminated.</td>
</tr>
<tr>
<td>Cereals, oatmeal and mixed/Caguas, P.R. 10/7/76</td>
<td>Shipped from continental United States.</td>
<td>Insect contaminated.</td>
</tr>
<tr>
<td>Flour, enriched/Abilene, Tex. 9/8/76</td>
<td>Independent Grocers, Inc./Abilene, Tex. (D)</td>
<td>Held under insanitary conditions; insect contaminated.</td>
</tr>
<tr>
<td>Gelatin mixes, cornmeal, cereals, dog food, and misc. foods/Dallas, Tex. 5/17/76 and 5/21/76</td>
<td>T. L. Jeffrey Distributing Co., Inc./Dallas, Tex. (D)</td>
<td>Held under insanitary conditions; some goods were insect, mold, and/or rodent contaminated.</td>
</tr>
<tr>
<td>Pinto beans/Bayamon, P.R. 10/7/76</td>
<td>Puerto Rico Food Products/Bayamon, P.R. (D)</td>
<td>Held under insanitary conditions; insect contaminated.</td>
</tr>
<tr>
<td>Popcorn, rice, sugar, &amp; misc. foods/Detroit, Mich. 8/3/76</td>
<td>The Miesel Co./Detroit, Mich. (D)</td>
<td>Held under insanitary conditions; some goods were rodent contaminated.</td>
</tr>
</tbody>
</table>

FOOD ADDITIVES

Caldiamate calcium pangamate tablets, Aangamik calcium pangamate tablets, Calpam 15 calcium pangamate tablets/W. Palm Beach, Fla. 9/16/76

General Research Labs/Van Nuys, Calif. (M, S); Food Science Labs/ Burlington, Vt. (S); Da Vinci Labs/ Burlington, Vt. (S)

Contract Pharmacal Corp./Hauppauge, N.Y. (M)

Drugs/Human Use

Hydrogenated ergot alkaloids tablets/Farmington, Mich. 9/23/76

Riker Laboratories, Inc./Los Angeles, Calif. (M, S)

New drug without an effective approved New Drug Application.

含有的无害和危险物质

- 花生酱/弗雷多尼亚, N.Y. 9/21/76
  - 制造商在弗雷多尼亚, N.Y., 来自阿拉巴马和乔治亚花生。
- 肉豆蔻线、鲨鱼鳍和各种东方食品/旧金山, Calif. 10/12-23/76
  - 查克·李的市场及仓库/旧金山, Calif. (D)
- 糖果和脱水椰子/拉格罗,佛罗里达。9/13/76
  - 克鲁格·萨丁糖果公司, Inc./拉格罗, Fla. (D)
- 陶器,燕麦片和混合品/卡瓜斯, P.R. 10/7/76
  - 独立杂货商, Inc./阿比林, Tex. (D)
- 面粉,增强/阿比林, Tex. 9/8/76
- 凝胶混合物,玉米面,谷物,狗粮,以及各种食品/达拉斯, Tex. 5/17/76和5/21/76
- T. L. 杰弗里分销公司, Inc./达拉斯, Tex. (D)
- 红豆/贝阿蒙, P.R. 10/7/76
- 普鲁多里食品产品/贝阿蒙, P.R. (D)
- 爆米花,米,糖,以及各种食品/底特律, Mich. 8/3/76
- 独立杂货商, Inc./底特律, Mich. (D)

食品添加剂

- 卡尔迪马特钙化泛酰胺片，
- 阿那格米特钙化泛酰胺片，
- 卡尔帕姆15钙化泛酰胺片/W.棕榈滩, Fla. 9/16/76

一般研究实验室/范努伊, Calif. (M, S); 食品科学实验室/伯灵顿, Vt. (S); 达芬奇实验室/伯灵顿, Vt. (S)

合同药物公司/哈普鲍格, N.Y. (M)

药物/人类使用

- 硬脂酸钙化泛酰胺片
- 新药没有有效批准的新药申请。
Vitamin E plus Hemo Blend/Muncie, Ind. 10/1/76
Hemo-Blend Research Corp./Canton, Ohio (M, S)

New animal drug and no approved New Animal Drug Application was in effect with respect to its use and intended use.

Therapuncteur and Punctoscope/ Oklahoma City, Okla. 8/4/76
Med-E-Prise, Inc./Orlando, Fla. (M)

False or misleading therapeutic claims; fail to bear adequate directions for use.

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

September 10, 1976: World Wide, 1236 South La Cienega Blvd., Los Angeles, California. Advertising and sale through the mail of the products "Penis Enlargers and Masturbators" and "Super Pulsator and Penis Enlarger," representing the ability to tone and develop specific genital muscles that contribute to erection of the penis.

September 13, 1976: Banner Laboratories, Box 10288W, Detroit, Michigan. Advertising and sale through the mail of the product "Ultra Hair," representing the ability to stop balding and grow hair again.

September 13, 1976: Ginseng II, 1 Wolfs Lane, Pelham, New York. Advertising and sale through the mail of the product "Ginroy," capsules representing the ability to restore and increase vitality in persons of all ages.

September 17, 1976: Melville Products, Inc., P.O. Box 56, Old Bethpage, New York. Advertising and sale through the mail of the "Slim Life Plan," representing the ability to cause weight loss.

September 29, 1976: Mark Hunter, P.O. Box 2608, Sepulveda, California. Advertising and sale through the mail of a pamphlet represented as a penis enlargement technique.

September 30, 1976: Pillows 'N Potions, P.O. Box 5756, Sherman Oaks, California. Advertising and sale through the mail of the products "Yohimbe Bark," "Damiana Suprema," and "Sarsaparilla," representing the ability to be aphrodisiac in nature.

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

September 7, 1976: Against Glamourlift, Inc., P.O. Box 7945, Louisville, Kentucky. Advertising and sale through the mail of the product "Glamourlift Electron Cream," and a bust development program, representing the ability to cause enlargement of the bust in just days.

September 13, 1976: Against Omega, 72511/2 Owensmouth, Suite #6, Canoga Park, California. Advertising and sale through the mail of the "Penis Enlargement Techniques," representing the ability to increase the length of the penis.

September 21, 1976: Against Omega, 6355 Topanga Blvd., Suite 307, Dept. 1420, Woodland Hills, California. Advertising and sale through the mail of the product "New Spanish Fly Improved With Ginseng," representing the ability to increase sexual desire and help solve all energy problems.

October 7, 1976: Against Swinger Total Body Shaper, 401 Market Avenue, Dept. K-33, Canton, Ohio. Advertising and sale through the mail of the product "Swinger," representing the ability to cause weight loss without exercise or dieting.

September 4, 1976: Guaranteed Booster, Box 536-QW, Fort Payne, Alabama. Advertising and sale through the mail of a plan representing the ability to stimulate sexual desires.

October 1, 1976: C & H Labs, 516 Fifth Avenue, New York, New York. Advertising and sale through the mail of the product "Bathe 'N Shape," a bottle of fluid representing the ability to firm and tighten the skin and cause the disappearance of wrinkles, stretch marks, and loose, unwanted inches from the neck, bustline, abdomen, midriff, calves, legs, and thighs.

October 4, 1976: Guaranteed Booster, Box 536-QW, Fort Payne, Alabama. Advertising and sale through the mail of a plan representing the ability to cause weight loss.

October 9, 1976: Against American Consumer, Dept. STS-2, Caroline Road, Philadelphia, Pennsylvania. Advertising and sale through the mail of a liquid formula representing the ability to cause nail growth by penetrating the nails.

October 19, 1976: Against Doctor's Laboratories, Box 398-D, Punta Gorda, Florida. Advertising and sale through the mail of the product, "Rotasage Scalp Massager," a circular rubber device used to massage and shampoo the scalp representing the ability to increase hair growth.

October 20, 1976: Against Progressive Sales, Box 310, New Rochelle, New York. Advertising and sale through the mail of the product "Impulse Capsules," representing the ability to sexually stimulate and excite both men and women.
NOTICES OF JUDGMENT on Seizure Actions

FOOD/Contamination, Spoilage, Insanitary Handling

Charged 2-9-76: when shipped by J. F. Braun & Sons, Inc., Brooklyn, N.Y., the article contained insect filth; 402(a)(3). Consent decree authorized reconditioning. (F.D.C. No. 60632; S. Nos. 76-40-040; N.J. No. 1)

Cereals, puffed wheat and puffed rice, at Springfield, W. Dist. Mo.
Charged 7-27-76: while held by Finkbinder Transfer & Storage Co., Springfield, Mo., the puffed wheat contained rodent filth and the puffed rice was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60789; S. Nos. 76-55-153/4; N.J. No. 2)

Charged 1-6-76: while held for sale, the article contained insect filth; 402(a)(3). The article was claimed by Gene England, t/a Santa Cruz Chili & Spice Co., Tumacacori, Ariz., who denied the charge. The Government moved for summary judgment based upon the claimant’s admission that the article was a food and was shipped from Mexico, and upon the quantity of the article being held by a spice company and the affidavits of the FDA inspector and FDA analyst. The court granted the Government summary judgment. The claimant moved the court to reconsider. In denying the claimant’s motion to reconsider, the court said: “The owners have now moved this Court to reconsider its Order granting summary judgment. The Government’s response to this motion to reconsider fully reheates the unacceptable course of delay which the owners of the chiltipines have pursued. No useful purpose would be served by again detailing the course of these proceedings.

Subsequent to the time the motion to reconsider was filed, a response to the motion for summary judgment was filed by the owners’ counsel. In his response, counsel asserts that summary judgment is precluded in this case because there is a dispute over whether all the chiltipines are in fact contaminated. Even if the Court were to grant the motion to reconsider, the owners’ response fails to show the existence of any material issue of fact.

The owners attempt to create an issue of material fact by the introduction of commercial lab reports. These lab reports purportedly show that not all of the subject bags are contaminated within the meaning of Title 21, United States Code, Section 342(a)(3) (1970). However, the case for the owners in submitting these lab reports has failed to comply with Federal Rule of Civil Procedure 56(e). The reports are apparently intended to controvert the tests performed on the subject chiltipines by the Food and Drug Administration. These lab reports, however, are neither sworn nor certified as required by Rule 56(e). Accordingly, the lab reports and any reference to them in the accompanying affidavits must be disregarded by this Court. State of Washington v. Maricopa County, 143 F.2d 871, 872 (9th Cir. 1944). Indeed, neither the lab reports nor the affidavits of Mr. Gene England reflect any basis for reliability of the lab reports, i.e., where the samples came from, how they were taken, the chain of custody, etc.

Hence, the Court finds no adequate reason to withdraw its Order of January 16, 1976.” (F.D.C. No. 60044; S. No. 68-122 H; N.J. No. 3)

Corn, baby, canned, at Portland, Dist. Ore.
Charged 2-17-76: while held for sale, the article was contained in jars with swollen lids and contained cloudy liquid and precipitate; 402(a)(3). Consent decree authorized reconditioning. (F.D.C. No. 60719; S. Nos. 76-33-326/7; N.J. No. 4)

Cornmeal and coffee beans, at New Orleans, E. Dist. La.
Charged 6-9-76: while held by Strachan Shipping Co., New Orleans, La., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Raymond-Hadley Corp., New York, N.Y., claimed the cornmeal and A. C. & Leon Israel Coffee Co., New Orleans, La., claimed the coffee beans. Consent decree authorized release to claimants for salvaging. (F.D.C. No. 60755; S. Nos. 76-38-907/8; N.J. No. 5)

Donut mix, at Dallas, N. Dist. Tex.
Charged 7-8-76: while held by Hol ’ n One Donut Co. of Texas, Inc., Dallas, Tex., 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. 60767; S. No. 76-15-580; N.J. No. 6)

Fennel seeds, at Denver, Dist. Colo.
Charged 4-13-76: while held for sale, the article contained animal filth; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 60702; S. No. 76-18-278; N.J. No. 7)

Flounder, stuffed with crabmeat, breaded, Singleton, at Tampa, M. Dist. Fla.
Charged 12-3-75: while held by Singleton Packing Corp., Tampa, Fla., the article contained E. coli and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). A default decree which ordered destruction was entered. The next day, the shipper moved to set aside that default, and filed a claim to the article. The court set aside that decree and extended the time for the claimant to answer the complaint. However, the claimant did not file the required claim. The Government moved for a second default decree. The court granted the Government’s motion, ordered the claimant to pay court costs and fees, and ordered the article destroyed. (F.D.C. No. 60567; S. Nos. 76-49-108; N.J. No. 8)

Flour, at Mobile, S. Dist. Ala.
Charged 7-13-76: while in transit in a railcar, the article contained roden filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Illinois Central Gulf Railroad Co., Mobile, Ala., for salvaging. (F.D.C. No. 60753; S. No. 76-11-043 et al.; N.J. No. 10)

Ginger cookies, chocolate chip cookies, shortcake biscuits, and tea finger biscuits, at St. Louis, E. Dist. Mo.
Charged 2-10-76: while held by Charles O. Bel She, Oroville, Calif., the article contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60600B; S. No. 76-48-290; N.J. No. 11)

Peppers, jalapeno, pickled, canned, at San Francisco, N. Dist. Calif.
Charged 2-26-76: while held for sale, the article was contained in leaking and swollen cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60651; S. No. 76-49-108; N.J. No. 12)

Charged 4-5-76: while held for sale, the article was decomposed and was contained in swollen and leaking cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60705; S. No. 76-49-167; N.J. No. 13)

Popcorn, rice, sugar, pancake mix, and other wholesale food stocks, at Detroit, E. Dist. Mich.
Charged 7-30-76: while held for sale by The Miesel Co., Detroit, Mich., the named articles contained roden filth and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60845; S. Nos. 77-67-415 et al.; N.J. No. 14)

Rice, chocolate coating, plain crooutons, bacon-flavored crooutons, somsae cheese, and other warehouse food stocks, at Richmond Hill, E. Dist. N.Y.
Charged 11-6-75: while held by Herbert Charles, Richmond Hill, N.Y., the named articles contained rodent filth and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 60540; S. No. 76-40-713 et al.; N.J. No. 15)

Rye chops, flour, wheat gluten, salt, dextrose, sugar, and other bakery supplies, at Dorchester, Dist. Mass.
Charged 5-6-76: while held by B. Rothstein & Co., Inc., Dorchester, Mass., some of the articles contained roden filth, and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60726; S. No. 76-06-695 et al.; N.J. No. 16)

Sugar and citric acid, at Colorado Springs, Dist. Colo.
Charged on or about 7-24-74: while held by Adam’s Syrup Co., Inc., Colorado Springs, Colo., the sugar contained roden filth and both articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer.
Tomato sauce, canned, Contadina, at Tempe, Dist. Ariz.
Charged 11-25-75: when shipped by Contadina Foods, Inc., a subsidiary of Carnation Co., Riverbank, Calif., the article contained Geotrichum mold, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60552; S. No. 76-27-462; N.J. No. 18)

Vermicelli, Chinese, at San Francisco, N. Dist. Calif.
Charged 3-4-76: while held by Orientex Imports, San Francisco, Calif., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60685; S. Nos. 76-49-186/8; N.J. No. 19)

Wheat, at Yantic, Dist. Conn.
Charged 6-5-75: when shipped by Coward Feed Stores, Stafford, N.Y., the article contained rodent filth; 402(a)(3). The article was charged by the complainant, a sample of the article was taken and examined. However, the complainant did not file any answer to the charge and the Government moved for a default decree based upon such failure to file and requested the imposition of court costs and fees and storage and other expenses. The claimant moved for permission to withdraw from the case without liability for the demurrage ($11,000) for the railcar containing the wheat. Ultimately, a consent decree was entered whereby the article was destroyed and which imposed expenses of $3,200 on the claimant. (F.D.C. No. 60380; S. No. 95-108 H; N.J. No. 20)

FOOD/Economic and Labeling Violations
Charged 11-25-75: when shipped by B&B Better Baked Foods, Inc., Westfield, N.Y., the required information as to the quantity of contents statement was not prominently placed on the label, since the statement was printed in small, thin, white type against a yellow background; and the article's label lacked the common or usual name of each ingredient, since "oxidant" and "enzyme conditioner" were not common or usual names for such ingredients; 402(a)(3). The article was held in violation of the Fair Packaging and Labeling Act, since the quantity of contents statement appearing on a principal display panel area of more than 25 square inches was in a type size less than 3/16 inch high—15 U.S.C. 1453(a)(3)(C)(i). Consent decree authorized release to shipper for relabeling. (F.D.C. No. 60544; S. Nos. 76-45-222; N.J. No. 21)

Honey mixture, at South Gate, C. Dist. Calif.
Charged 2-27-75: when the three lots of the article were shipped from Hamburg, Germany; Santos, Brazil; and Liverpool, England, each lot labeled, respectively, "Prodelmel...Natural Industrialized Bee Honey Brazil...Hammburg," "Industrialized Bee Honey Brazil," and "Industrialized Bee Honey Brazil...Liverpool England," had had invert sugar substituted in part for honey; 402(b)(2). The article was charged by South Gate Co., South Gate, Calif., that the article had been shipped in interstate commerce but denied the charge. The parties attempted to resolve the case with various proposals, such as the entry of a consent decree providing for salvaging, and such as the labeling of the article as "**Industrialized Honey...10% sucrose added." The Government moved for summary judgment. The claimant also moved for summary judgment, arguing that the seized product was a blend of honey and sugar, and that honey and sugar were natural foods, that honey and sugar contained sugar and many products on the market contained blends of various substances, and that a blend of two foods properly labeled when sold to the consumer was not adulterated. The Government opposed the claimant's motion, asserting that, although claimant stated that the article was bought from a honey broker as pure honey, all concerned recognized at the time of the sale that the honey was not pure honey but had invert sugar admixed, and that what else might have been admixed or used as a mechanism for adding the sugar was not known. After argument before the court, the court denied the claimant's motion, granted the Government's motion for summary judgment and continued the case for a hearing on the matter of whether the article was a blend of honey and sugar. "Vitamin B-15 (Sodium Pangamate)," "A Dietary Supplement," "Each tablet contains Sodium Pangamate (Vitamin B-15)...50 mg.," and "The need in human nutrition for Vitamin B-15 is not established. No dietary claims are made for this product," were false and misleading since sodium pangamate was not an identifiable substance, and was not a vitamin or pro-vitamin, since there was no accepted scientific evidence which established any nutritional property for sodium pangamate or which identified a deficiency of sodium pangamate in man or animals, and since the safety of sodium pangamate had not been demonstrated; and the article's label lacked the common or usual name of each ingredient; 402(a)(2)(C), 403(a), 403(i)(2). Default decree ordered destruction. (F.D.C. No. 60474; S. Nos. 76-39-859/60; N.J. No. 28)

Sodium pangamate tablets, at Deer Park, E. Dist. N.Y.
Charged 4-28-75 and 5-15-75: while held by High Valley Farm, Inc., Colorado Springs, Colo., who prepared the articles from pheasants and pheasants; 402(c), 402(a)(2)(C). The article was charged by the claimant. Subsequently, consent decrees ordered the articles destroyed. (F.D.C. No. 60347, 60357; S. Nos. 81-539 H, 3-724/6 H; N.J. No. 27)

FOOD/COLOR ADDITIVES
Flavoro's No. 39405 rose pink food coloring, at Tampa, M. Dist. Fla.
Charged 7-7-76: when shipped by Flavorol Laboratories, Inc., Indianapolis, Ind., the article contained FD&C Red No. 2, a color additive not permitted for use in foods; 402(a)(2)(C), 403(i)(2). Default decree ordered destruction. (F.D.C. No. 60791; S. No. 76-44-287; N.J. No. 26)

Pheasant, smoked, frozen, and canned smoked pheasant, 2 seizure actions, at Colorado Springs, Dist. Colo.
Charged 12-17-75: while held by High Valley Farm, Inc., Colorado Springs, Colo., who prepared the articles from pheasants from Pennsylvania and New York, the article bore or contained the nonconforming food additives sodium nitrate and sodium nitrite; 402(a)(2)(C). The articles were claimed by the claimant. The Government moved for summary judgment; 402(b)(2), 403(i)(2). Consent decree authorized release to Household Mfg. Co., Hawthorne, Calif., for salvaging. (F.D.C. No. 59786; S. Nos. 55-781 G et al.; N.J. No. 25)

ANIMAL FEED
Coop Plus 4 medicated feedlot supplement, at Oakland, Dist. Nebr.
Charged 2-25-77: when released for sale, after manufacture by Farmland Industries, Inc., Fremont, Nebr., using chlortetracycline shipped in interstate commerce, the animal was an animal drug, and there was no approval of a New Animal Drug Application with respect to such animal drug; and the circumstances of the article's manufacture, processing, packing, and holding failed to conform with Current Good Manufacturing Practice Regulations; 501(a)(6), 501(a)(2)(B). Default decree for analyses to determine the percent composition of the mixture for labeling purposes. Ultimately, a consent decree authorized release for a number of specified uses, including use as a bakery sweetener with an FDA-approved label under controlled conditions. (F.D.C. No. 60237; S. Nos. 69-491/3 H; N.J. No. 22)
ordered destruction. (F.D.C. No. 60679; S. No. 76-54-421; N.J. No. 29)

Feed supplements, at E. St. Louis, E. Dist. Ill.
Charged 4-16-73: while held by Ultra-1 Laboratories, Inc., E. St. Louis, Ill., the articles contained rodent filth and were held under insanitary conditions: 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging.

Charged 12-4-74 in bond forfeiture action against the dealer: that the premises were the terms of the consent decree (which required, until compliance, the return of DA, that the goods not be shipped, sold, or disposed of, that the goods be retained intact, and that the goods not be disposed of contrary to law), portions of the seized goods had been removed, interfered with, diverted, and used for the production of other goods. Judgment was granted in favor of the Government and $3,000 of the bond was forfeited. See N.J. No. 41 of this issue of FDA Consumer for a related criminal contempt action. (F.D.C. No. 59122; S. Nos. 21-643 F, 22-181 G; N.J. No. 30)

DRUGS/Use

Calcium gluconate and dimethyl glycin combination tablets, Glucon 15 and Aangamik, at Concord, N. Dist. Calif.
Charged 7-5-75: when shipped by Food Science Laboratories, Inc., t/a Da Vinci Laboratories, Burlington, Vt., and/or Food Science Laboratories, Inc., Wautoma, Wis., the articles, labeled in part “Glucon 15 Calcium gluconate and dimethyl glycine . . . The professional formula for Calcium Pangamate . . . Vitamin B-15 Each Tablet: 50 mg. . . .” Burlington, Vermont,” and “Aangamik Calcium gluconate and dimethyl glycine . . . The Russian Formula for Calcium Pangamate . . . Vitamin B-15 Each Tablet: 50 mg. . . .” Food Science Laboratories, Inc., Burlington, Vermont, were new drugs without effective and approved New Drug Applications—503(a); the articles contained the nonconforming food additives calcium pangamate and dimethyl glycin, and, with reference to dimethyl glycin, failed to comply with the regulations for use of an additive. CaMs. (2), the labeling of the articles lacked adequate directions for use for the uses claimed in the accompanying booklet, “Glucon 15 . . . Calcium Pangamate, a salt of Pangamic Acid, Vitamin B-15 For Use in Maintaining the Proper Structure and Function of the Body—502(f)(1); the Glucon 15 Tablets labels lacked the common or usual name of each ingredient, since “fillers” and “lubricants” were not the common or usual names for such ingredients—403(a); a number of specified statements concerning the nature of the articles in the labeling of the articles were false and misleading: (1) since calcium pangamate was not an identifiable substance and was not a vitamin or pro-vitamin, (2) since there was no accepted scientific evidence which established the nutritive properties of the substance, (3) since there was no accepted scientific evidence to identify a deficiency of calcium pangamate in man or other animals, and (4) since no medical, nutritional, or other usefulness for calcium pangamate had been established—403(a); and the accompanying booklet contained false and misleading statements $3,000 concerning the use of the article (which statements were false and misleading due to lack of adequate evidence based on sound scientific study) such as the following: “pangamic acid helped maintain an optimum level of blood sugar, preventing a lowering of the blood sugar level,” “pangamic acid helped maintain a healthy liver in test animals,” “It may also enhance peripheral circulation and tissue oxygenation . . . and improve myocardial oxygen availability,” “introduction of pangamic acid to old animals resulted in increased levels of basic energy source of energy activating the muscles,” “it lessened the desire for alcohol,” “an appearance of nausea at the smell of alcohol attributable to restoration of protective mechanisms which had been blocked by alcohol,” “causes improvement of psychological and physical attitude to help individuals face problems,” “helped improve sleep patterns,” “How Does Pangamic Acid Affect the Function and Structure of the Body?,” “Pangamic acid stimulates the relative production of tissue oxygen and conserves oxygen consumption and builds up the body’s functional resistance to metabolic stress,” “How Does Pangamic Acid Improve the Structure and Function of Muscles and Aid Physical Activity?,” “How Does Pangamic Acid Affect the Metabolism?,” and in some cases, significantly stimulate cerebral blood flow and oxygen intake”—502(a), Default decree ordered destruction. (F.D.C. No. 60762; S. Nos. 76-49-901/4; N.J. No. 31)

Phenmetrazine tartrate tablets, and chorionic gonadotropin injectable, at Ronkonkoma, E. Dist. N.Y.
Charged 7-16-76: when shipped by Barr Laboratories, Inc., Northvale, N.J., the phenmetrazine tartrate tablets was a new drug without an effective approved New Drug Application—502(f)(1); while held by John Ewing Co., La Salle, Colo., the article's strength differed from its quality fell below its represented strength and quality, since the article contained approximately 60 percent of the declared chlorotetracycline hydrochloride—502(e). Default decree ordered destruction. (F.D.C. No. 60790; S. Nos. 76-41-059, 76-41-312; N.J. No. 32)

DRUGS/Veterinary

Formula 707 medicated supplement for horses, at Dallas, N. Dist. Tex.
Charged 4-29-76: when shipped by John Ewing Co., La Salle, Colo., the article's strength differed from its quality fell below its represented strength and quality, since the article contained approximately 60 percent of the declared chlorotetracycline hydrochloride—502(e). Default decree ordered destruction. (F.D.C. No. 60715; S. No. 76-14-822; N.J. No. 33)

Veterinary injectables, at Fort Collins, Dist. Colo.
Charged 4-13-76: when shipped by Anthony Products Co., El Monte, Calif., Chromalloy Pharmaceuticals, Inc., Carter Glogau Labs. Div., Glendale, Ariz., DM Pharmaceuticals, Inc., Rockville, Md., or others shipped, the articles, labeled in part “Tri-Bo locic (Men让他ropin Dripionate Injection) or ‘Injection . . . Tri-Gom Oil . . . Gomelon . . . Eucalyptol . . . Iodoform . . .’ or ‘Dexamethasone Sodium Phosphate Injection’ . . .” for Tri-Bo locic Associates, Inc., Havre de Grace, Md., or Ft. Collins, Colo., were new animal drugs, and no approval of a New Animal Drug Application was in effect with respect to the use or intended use of such drugs—501(a)(5). Default decree ordered destruction. (F.D.C. No. 60710; S. Nos. 76-17-525/7; N.J. No. 34)

MEDICAL DEVICES

Familon-S low frequency electric current applicator, at Van Nuys, Cali.
Charged 4-9-76: when shipped by Hakujii Institute for Health Science Co., Ltd., Tokyo, Japan, and while held by Iomlab, Inc., Van Nuys, Calif., the accompanying brochure (used in the promotion, sale, and use of the article) contained the false and misleading representation that the article was a massager, and contained false and misleading claims for relieving pain, rupture, dislocation, and muscle spasm; cysts; gallbladder disorders; neuralgia; sciatica; arthritis; kidney disorders; sciatica; stomach disorders; arthritis; backache; pain in muscles; arthritis; diabetes; eye, sinus, and other nasal disorders; and arthritis; and misleading representations that the article was a massager, and contained false and misleading claims for relieving pain, rupture, dislocation, and muscle spasm; cysts; gallbladder disorders; neuralgia; sciatica; arthritis; kidney disorders; sciatica; stomach disorders; arthritis; backache; pain in muscles; arthritis; diabetes; eye, sinus, and other nasal disorders; and arthritis; and was an effective therapeutic agent in the treatment of obesity — 502(f)(1). Default decree ordered destruction. (F.D.C. No. 60798; S. Nos. 76-29-181; N.J. No. 35)

Solorama 17” x 19” bedboards, at Phoenix, Dist. Ariz.
Charged on or about 5-17-76: while held by Jobe W. Green, t/a Solarama of Arizona, Phoenix, Ariz., (who painted the asbestos board component with a liquid No. 60790; S. Nos. 502(f)(1); and the article was dangerous to health when used as directed in its labeling—502(f). Default decree ordered destruction. (F.D.C. No. 60798; S. Nos. 76-29-181; N.J. No. 35)

Solorama 17” x 19” bedboards, at Phoenix, Dist. Ariz.
Charged on or about 5-17-76: while held by Jobe W. Green, t/a Solarama of Arizona, Phoenix, Ariz., (who painted the asbestos board component with a liquid No. 60790; S. Nos. 502(f)(1); and the article was dangerous to health when used as directed in its labeling—502(f). Default decree ordered destruction. (F.D.C. No. 60798; S. Nos. 76-29-181; N.J. No. 35)

Solorama 17” x 19” bedboards, at Phoenix, Dist. Ariz.
Charged on or about 5-17-76: while held by Jobe W. Green, t/a Solarama of Arizona, Phoenix, Ariz., (who painted the asbestos board component with a liquid No. 60790; S. Nos. 502(f)(1); and the article was dangerous to health when used as directed in its labeling—502(f). Default decree ordered destruction. (F.D.C. No. 60798; S. Nos. 76-29-181; N.J. No. 35)
of tension by Thermal Electron Emission, healing surgery 30% faster, causing rejection of cancer virus, activating all the cells, restoring them to healthy condition, aiding the life processes, benefiting the emotional tone, enhancing the psychological vigor of human beings, and supplying the body with vital matter—502(f)(1). Default decree ordered destruction. (F.D.C. No. 502(f)(1); S. No. 76-28-473; N.J. No. 36).

Therapuncteur and Punctoscope electrical devices, at Oklahoma City, Fla., the articles' accompanying ear chart entitled “Auriculo-therapy P.F.M. Nogier M.D.” contained false and misleading representations of the functions of the articles which supports all living matter—502(a); and the labeling of the articles lacked adequate directions for use for such purposes, since the article was worthless for such purposes—502(f)(1). Default decree ordered destruction. (F.D.C. No. 502(f)(1); S. No. 76-28-473; N.J. No. 36).

NOTICES OF JUDGMENT on Criminal Contempt Actions


Charged 6-24-75 in a petition for an order to show cause why this court should not issue a writ of mandamus to compel them to cease and desist from the manufacture, processing, packing, holding, and distributing in interstate commerce various animal feeds, such as “Purina Commercial Steer Chow Yeast #2” and “Custom Premix,” and various medicated animal feeds, such as “Purina Custom #2 Steer Fatena 20” and “Purina Custom #5 Steer Fatena 20,” which articles were held for sale after shipment in interstate commerce of one or more of their components; that a number of FDA inspections of the defendants' plant revealed that the by-products of the manufacture of animal feed revealed levels of diethylstilbestrol contamination of 0.19 to 112 parts per million; that analysis of FDA samples of nonmedicated feed revealed diethylstilbestrol contamination of 0.19 parts per million; and that the defendants were well aware that the activities were in violation of the law; 501(a)(2)(B), 402(a)(2)(D). The defendants were convicted of violation of the law, the court ordered the dismissal of the action without prejudice, and the defendants are to cease and desist from the manufacture, processing, packing, holding, and distributing in interstate commerce of such nonmedicated feed.

NOTICES OF JUDGMENT on Injunction Actions

Sylvan L. Socolick professional corporation, and Sylvan L. Socolick, M.D., New York, S. Dist. N.Y.

Charged 10-10-75 that the defendants operated a methadone treatment program for narcotic-dependent persons at New York, N.Y.; that Sylvan L. Socolick, M.D., was the owner and medical director; that the defendants operated under an interim approval to receive methadone shipments; that methadone was a new drug subject to regulation for new drugs for use in the treatment of narcotic addiction; that FDA inspections revealed that the conditions for use of methadone were inadequate in a number of specific respects; and that, in violation of the law, the defendants caused Mallinckrodt, Inc., St. Louis, Mo., to ship methadone in accordance with the new drug regulation establishing the conditions for use of methadone; that, in violation of the law, the defendants failed to establish and maintain proper records; and that the defendants were well aware that their activities
were in violation of the law: 505(a), 505(j).

As the court issued a temporary restraining order, the defendant consented to a permanent injunction that perpetually enjoined the defendant from allowing methadone take-home privileges for patients unless the need was fully documented, and enjoined the defendants from accepting more patients in the defendants' program unless FDA had conducted a specified number of specified inspections, and controls and for specified reports. The defendants and administering methadone were consequently enjoined from providing such treatments.

NOTICES OF JUDGMENT on Miscellaneous Actions


Charged 7-13-73 by East Coast Healthfood Organization, Washington, D.C., and The Diet Shop, Inc., Elizabeth, N.J., against the Food and Drug Administration, in suit for mandamus, injunction, and declaratory judgment; that East Coast Healthfood Organization (ECHO), was an association of retailers of health foods, natural foods, food supplements, and nutrients; that The Diet Shop, Inc., was a retailer of health foods, natural foods, food supplements and nutrients; that FDA had published a program circular as part of its compliance program guidance manual of instructions to FDA district directors and field inspectors; that such circular determined, without any notice or hearing, that sea kelp capsules and sea kelp mixtures with nutrients were in violation of the law and subject to FDA enforcement; that ECHO members and The Diet Shop, Inc., had sold and planned to continue to sell kelp in capsules, that sea kelp in capsules was a handy way for the consumer to take whole kelp, or to save money, that sea kelp was toxic or dangerous to public health, and contained iodine, other minerals, and valuable nutrients; that the FDA circular falsely claimed that capsules implied "nutritional" or "therapeutic need"; that consumers demanded such products, and neither wanted nor needed Government protection in buying or consuming such products; that, by such circular, FDA denied freedom of choice and dictated thought control, in violation of the law, that the plaintiffs' remedies at law were inadequate, and plaintiffs prayed for declaratory judgment and permanent injunction against FDA.

Plaintiffs served written interrogatories on the defendant; the defendant moved to dismiss the action for lack of jurisdiction over the defendant and the subject matter, and for failure to state a claim upon which relief could be granted. The court dismissed the action. The defendants moved to vacate the dismissal and moved to amend their complaint by adding the allegation that jurisdiction was based upon 28 U.S.C. 1331. The court granted the defendants' motions. However, the court subsequently ruled against the plaintiffs. The plaintiffs moved that the court alter its judgment. Upon consideration of the plaintiffs' memorandum in support of its motion to alter judgment, and declaratory judgment and permanent injunction against FDA.

New Drugs, and their marketing prior to FDA approval of New Drug Applications, Washington, Dist. Columbia.

Charged 2-27-75 by Hoffmann-LaRoche, Inc., Nutley, N.J., against H.E.W. Secretary Caspar W. Weinberger and FDA Commissioner Alexander M. Schmidt in complaint for declaratory judgment and injunction: that, contrary to statute, FDA permitted the interstate shipment of a new drug without first approving a New Drug Application for it and had adopted such a policy without notice of its intention to act in the Federal Register; that the plaintiff (manufacturer of Librium brand of chlordiazepoxide) learned of this policy in connection with its effort to learn whether FDA would permit the interstate transportation of its product in connection with its marketing; that plaintiff had developed chlordiazepoxide in its research facilities; that chlordiazepoxide was widely prescribed and was among the largest selling prescription drugs in the United States, with sales of over $50 million per year; that chlordiazepoxide was marketed only after plaintiff had obtained FDA approval of New Drug Applications; that plaintiff made, and continued to make, numerous submissions and reports to FDA pursuant to FDA regulations applying to holders of approved New Drug Applications; that the plaintiff had sued Zenith Laboratories, Inc., and its subsidiary Paramount Supply Corp., alleging, in part, infringement of the plaintiff's patent on chlordiazepoxide or un infringement of the plaintiff's patent on chlordiazepoxide; that plaintiff was shipping chlordiazepoxide capsules based upon Zenith's filing in March 1973, of an Abbreviated New Drug Application; that FDA had adopted a policy which permitted such shipments prior to FDA's approval of a New Drug Application; that such policy caused plaintiff irreparable injury because other manufacturers could market drugs in competition with the plaintiff without bearing the expenses of the holders of New Drug Applications and because such policy increased the chances of ineffective or unsafe versions of such drug being marketed; that such policy threatened the public health and safety by increasing the chances of ineffective or unsafe versions of prescription drugs being marketed; that plaintiff prayed the court to declare FDA could not permit interstate marketing of prescription new drugs unless the manufacturer had obtained an approved New Drug Application, and to declare FDA must publish in proposal form, prior to adoption, policies regarding marketing without approved New Drug Applications; that plaintiff prayed for FDA to be enjoined from permitting prescription drugs which FDA found to be new drugs to be sold in interstate commerce without approved New Drug Applications, and to be enjoined from adopting regulations, policies, or procedures unless FDA had adopted such policy as a proposal. Subsequently, the plaintiff moved for a preliminary injunction.

In opposition to the plaintiff's motion, the Government maintained that the court should rule against the plaintif for failure to state a claim upon which relief could be granted. The court disallowed the motion, supplanting the interim enforcement policy. After a hearing before the court, the court granted summary judgment to the plaintiff, saying:

"This action brings before the courts again the troubled administration of the New Drug Amendments of 1962 designed to strengthen the FDA's regulation of new drugs. The Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1040, provided that new drugs introduced after 1938 be subject to regulatory clearance prior to their being sold for human consumption for administrative suspension of such clearance if thereafter required for public safety. Under the 1938 Act, a new drug was defined as any drug which was not generally recognized among experts as safe as well as effective. The New Drug Amendments of 1962 changed the definition of "new drug" to require that proof of effectiveness as well as safety, be submitted as part of a new drug application. . . ."

"The 1962 New Drug Amendments changed the premarketing clearance procedures. Under the original 1938 Act, new drug applications were deemed approved within a fixed period unless the Secretary took affirmative steps to reject the application. However, the Amendments required the FDA to affirmatively express its approval of new drug applications prior to permitting the marketing of new drugs in interstate commerce.

"21 U.S.C. §355 (1970) prohibits the introduction or delivery for introduction into interstate commerce of any new drug unless approval of an application is effective with respect to such drug. It further provides a scheme for the processing and approval of new drug applications. The required contents of a new drug application are prescribed. 21 U.S.C. §355(b) (1970). The FDA is required to approve the application within 180 days, give the applicant written notice of its final decision within 30 days of receipt of the application. 21 U.S.C. §355(c) (1970). After giving notice and opportunity for hearing, the FDA is required to either issue an order refusing to approve the application or issue an order approving the application. 21 U.S.C. §355(d) (1970). Conditions for approval may be instituted to seize drugs introduced into interstate commerce without section 353 approval. . . ."
too' drugs. Me-too drugs are drugs which are chemically equivalent to a pioneer drug for which a full new drug application is in effect. It is estimated that five to thirteen me-too drugs exist for every new drug that has an FDA approved new drug application. It is the present policy of the FDA, termed an interim policy, to require the filing of an abbreviated new drug application by the manufacturers of each me-too drug where the pioneer drug has a full new drug application approved pursuant to 21 U.S.C. §355 (1970). The FDA's position is that marketing of these drugs may be permitted without the approval of each individual new drug application.

"The FDA advances two principal arguments to justify its policy. First, it claims that its compliance resources are limited and must be concentrated primarily in those areas where a potential health threat exists. Thus, the FDA has directed its compliance activities toward those drug products which have been found ineffective rather than toward those which have been found effective. Second, for those drugs that the NAS/NRC have found effective, it is widely recognized as safe and effective and no bioavailability or special manufacturing problem is known or suspected, the need to police their distribution is minimal. Additionally, the FDA claims that it would have a difficult time in court contesting that a specific version is a new drug within the meaning of 21 U.S.C. §321(p) (1970).

"On the contrary, Hoffmann-LaRoche argues that the FDA's action is another example of its failure to follow the 1962 Drug Amendments. Like the situation condemned in the case of Public Health Assoc. v. Veneman, [349 F. Supp. 1311 (D.D.C. 1972)], the FDA is again acting contrary to the clear statutory directives of section 355. Plaintiff contends that the plain meaning of section 355 dictates that once the FDA requires a new drug application to be filed, then the approval process must be completed before such drug can be marketed. . . . It argues that the Congressionally expressed interest in public health and safety mandates no other choice. . . . Further, it claims that the position of the FDA Division of Generic Drug Monographs, demonstrates that no undue administrative burdens would be imposed by such a requirement.

"To understand how the present state of affairs has arisen, it is necessary to chronicle some of the administrative actions taken in the implementation of the 1962 amendments with respect to me-too drugs. On January 24, 1968, at a government industry conference, the FDA announced that it would apply the applicable effectiveness findings from the National Academy of Sciences-National Research Council studies to all drugs, identical, related, or similar drug products. All opinions previously given to the effect that a drug was no longer a new drug would have a difficult time in court contending that a specific version is a new drug within the meaning of 21 U.S.C. §321(p) (1970). However, the argument that the FDA lacks the administrative resources to insure compliance with section 355 cannot be permitted to postpone to some indefinite future date the implementation of the required preclearance approval of new drug applications.

"The Court gives particular weight to the fact that the amicus curiae is the Pharmaceutical Manufacturers Association whose members numerically would favor me-too companies, but said views are not representative of the entire industry. The FDA Division of Generic Drug Monographs, demonstrates that no undue administrative burdens would be imposed by such a requirement.

"Certainly it has the power to promulgate regulations that adopt a monograph procedure for human prescription drugs similar to that adopted for over-the-counter drugs whereby a drug or drugs may be declared to be no longer new drugs. . . . The FDA can regulate the bioequivalence and special manufacturing procedures through its general rule-making power, 21 U.S.C. §371 (1970). However, the argument that the FDA lacks the administrative resources to insure compliance with section 355 cannot be permitted to postpone to some indefinite future date the implementation of the required preclearance approval of new drug applications.

"Preliminarily, the FDA suggests that Count One of plaintiff's complaint is moot because the FDA approved the new drug application of Zenith Labs on March 7, 1975, during the pendency of this litigation. Count One challenges the FDA's policy as violative of 21 U.S.C. §355 (1970). This general policy continues in operation with respect to whole generic classes of drugs. Voluntary cessation of the alleged wrongful conduct in one instance, while it continues in all other areas, has not conveniently mooted this portion of plaintiff's complaint. . . . Reaching the merits of plaintiff's statutory argument, the Court holds that the FDA's policy of permitting new drugs to be marketed without an approved new drug application contravenes the clear statutory requirement of preclearance mandated by 21 U.S.C. §355 (1970). The FDA's choice of policy is not within the interpretative discretion granted by section 355 of the Drug Amendments and the legislative scheme they embody. . . .

"Further, the action of the FDA in permitting such marketing of large classes of me-too drugs violates its own regulations. . . . The implication that the FDA seeks to find in the language of the July 14, 1970 notice is an impermissible one. The Court recognizes that the FDA is to be given the administrative flexibility to make regulations and to determine the new drug status of individual drugs or classes of drugs. . . . Certainly it has the power to promulgate regulations that adopt a monograph procedure for human prescription drugs similar to that adopted for over-the-counter drugs whereby a drug or drugs may be declared to be no longer new drugs. . . . The FDA can regulate the bioequivalence and special manufacturing procedures through its general rule-making power, 21 U.S.C. §371 (1970). However, the argument that the FDA lacks the administrative resources to insure compliance with section 355 cannot be permitted to postpone to some indefinite future date the implementation of the required preclearance approval of new drug applications.

"The Court gives particular weight to the fact that the amicus curiae is the Pharmaceutical Manufacturers Association whose members numerically would favor me-too companies, but said views are not representative of the entire industry. The FDA Division of Generic Drug Monographs, demonstrates that no undue administrative burdens would be imposed by such a requirement.

"The Court gives particular weight to the fact that the amicus curiae is the Pharmaceutical Manufacturers Association whose members numerically would favor me-too companies, but said views are not representative of the entire industry. The FDA Division of Generic Drug Monographs, demonstrates that no undue administrative burdens would be imposed by such a requirement.

"Summary judgment will therefore be entered for the plaintiff. Defendants will be permanently enjoined from implementing its policy which permits the introduction into interstate commerce without an approved new drug application of prescription drugs which the FDA has previously declared to be new drugs within the meaning of 21 U.S.C. §321(p) (1970)." (Misc. No. 291; N.J. No. 45)

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

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If you're deep into calorie counting, we've got something that will help you figure out how to keep tabs on your figure.

The nutrition label that now appears on many foods tells you exactly how many calories are in each serving of the food. With this information it's much easier to keep track of the total calories you consume in a day. And nutrition labels also show proteins and vitamins and minerals—so you can control the nutritional value of the calories you do consume.

That's why we say weight watchers ought to be label watchers. It figures.