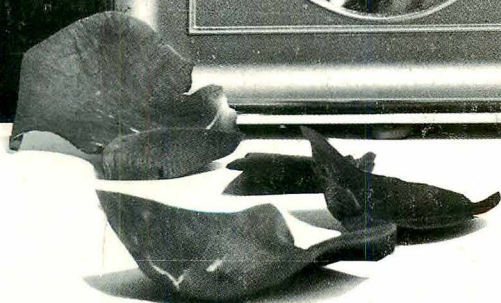


FDA **CONSUMER**

APRIL 1976



Women and Estrogens





This Month

Who speaks for the consumer?

Consumers speak for themselves, of course, when they make a purchase, register a complaint, or tell a merchant of some alteration or improvement they would like to see made in a product. But when it comes to speaking out on regulatory policy that affects the things they buy, consumers may have a bit more difficulty in making their voices heard. Most FDA regulations begin as proposals and are published in the *FEDERAL REGISTER* with a certain time period specified for any interested party to comment. Consumers can and do comment on proposed regulations.

The best way to have an impact on policy, however, is to be in on the discussions that precede regulatory proposals. To assure that the consumer viewpoint is heard in these deliberations, consumer representatives serve on more than 30 of the advisory committees and panels that help set policy on the wide range of important products FDA regulates. This month we take a look at these consumer representatives—what they do and how they see their role—as well as some other ways FDA is *Getting the Word From Consumers*.

Communicating with consumers is a two-way street. FDA must listen, but it also has a responsibility to inform, especially on matters that affect the public health. Estrogens are such an issue. The use of these drugs has increased tremendously in recent years, sometimes in ways that might be detrimental to the user's health. Dr. J. Richard Crout, director of FDA's Bureau of Drugs, discusses the benefits and risks of estrogen therapy in an interview entitled *Estrogens and Women*.

Few consumer issues have come in for more discussion in recent months than Red No. 2, the widely used and controversial coloring that FDA recently banned from food, drugs, and cosmetics. Despite the outpouring of news reports about Red No. 2, there is still some misunderstanding of FDA's action. We try to put the picture in perspective in *Why FDA Banned Red No. 2*.

Inside Front Cover Photo: Mary Plaska, of the American Public Health Association, is the consumer representative on FDA's Advisory Panel on Dentifrices and Dental Care Agents. The discussions sometimes get quite technical, she says, with panel members disagreeing as to the effectiveness of a product. "I feel I must remind them that if the product is marketed, the public will buy it in good faith, believing that it will do what it says it will do."

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

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

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

Cover Design: Jesse Nichols
Photography: Dan O'Toole

Consumer Forum

Why We Need Food Additives

I read with interest Mrs. Ruth C. Adams' misconceptions about food additives published in your February 1976 Consumer Forum, and as a fellow consumer I felt someone should set her straight.

First, confidence in the American food supply is not failing, as any trip to one's nearest supermarket should prove. This is a myth perpetuated by food faddists using sensationalism to promote sales of special foods and pop nutrition books. Per capita consumption in most food categories is up from previous years. The safety, variety, and low cost of the U.S. food supply relative to other nations can be verified by asking any foreign visitor to the United States or by visiting another country yourself.

As to her claim that for "millions of years human beings have delighted in the taste, texture and color of wholly natural foods" I suggest that she reread her history books. Written history began only about five thousand years ago, and if she knows how human beings lived even one million years ago, she must be the archaeological genius of the century! Furthermore, as few as 75 to 100 years ago some families in northern parts of the United States made it through the winters on moldy apples, sprouted potatoes, rancid salt pork and wormy cornmeal—all wholly natural foods, and all as disguised as it was possible to do. Curry powder and chili powder very nicely disguise the wholly natural flavor of less-than-fresh meat in tropical climates. The whole development of civilization has been dependent on man's ability to preserve and conserve food. He preserves it in the summer for use in the winter; in years of plenty to tide him over the years of famine; in regions of abundance to be transported to regions where adequate food cannot be produced. And additives are important to help preserve food—salt, sugar and vinegar being three commonly used by Mrs. Adams' grandmother, I'm sure.

Now, Mrs. Adams may view vinegar as a "natural" food and acetic acid as not natural. In fact, acetic acid is the substance in vinegar that does the preserving. Most food additives have been developed because they were in a natural food. Chemists were able to isolate the active substance and simply use it by itself.

I cannot believe that Mrs. Adams never adds anything to food to disguise its natural taste. I cannot imagine a sane person relishing the taste of unsweetened cranberries or enjoying the texture of a wholly natural old mushy spotted apple.

Betty Bartlett
Columbus, Ohio

Wine and What's in It

This is in reference to your News Highlights, page 25 of the (February) FDA CONSUMER, in which there is a noticeable error in your article, *Alcoholic Beverages Must List Ingredients*. The article states, "The two label requirements that will most affect alcoholic beverages are those that require ingredients to be listed, and those that require a food that claims to have a specific flavor (such as apple wine) to state prominently when artificial flavors are used." Apple wine must be made from the juice of apples and has no artificial or natural flavors added. Special natural wines, which are, in essence, formula wines, also may not have artificial flavors added. Therefore, the implication of your paragraph is entirely erroneous as related to wine labeling.

You also state, "The label will also have to declare whether artificial colors or preservatives are used." Since this follows the sentence related to wine, but which evidently relates to all alcoholic beverages, I would hasten to add that artificial colors are not permitted in wine.

Harvey Posert
Public Relations Director
Wine Institute
San Francisco

What Are Food Additives?

Ruth Adams writes in Consumer Forum, February 1976:

"How can any sane person justify the continued use of *any* food additive . . . ?"

Much misunderstanding about food additives arises from considering them as a *class* of substances. They are not. They are a *use* to which numerous unrelated substances are put. These include many ingredients of natural foods, even vitamins and essential minerals. It is just as illogical to condemn all food additives as to say that all of them are inherently beneficial.

The use of sodium propionate as a food additive slows mold growth in foods. Some molds produce carcinogens. Sodium propionate is present in Swiss cheese, and has nothing in common with Red. No. 2, which has been banned.

Thomas H. Jukes
Professor of Medical Physics
University of California
Berkeley, California

Women And Estrogens



The use of estrogens in post-menopausal women has increased dramatically over the past few years, as women seek to be "feminine forever." Now new evidence indicates that estrogens may cause cancer of the uterus, and FDA intends to provide this and other information to physicians and patients with a view toward reducing the uses of estrogens for prolonged periods. In this interview with Wayne L. Pines, FDA deputy assistant commissioner for Public Affairs, Dr. J. Richard Crout, director of FDA's Bureau of Drugs, discusses the proper uses of estrogens, the new evidence, what FDA is doing about it, and what women should know. This is the first of a two-part interview with Dr. Crout on estrogens. Birth control pills will be discussed in a future issue.

"... there has been a growing feeling, to some almost a mythology, that estrogen treatment during the post-menopausal period will stave off aging ..."

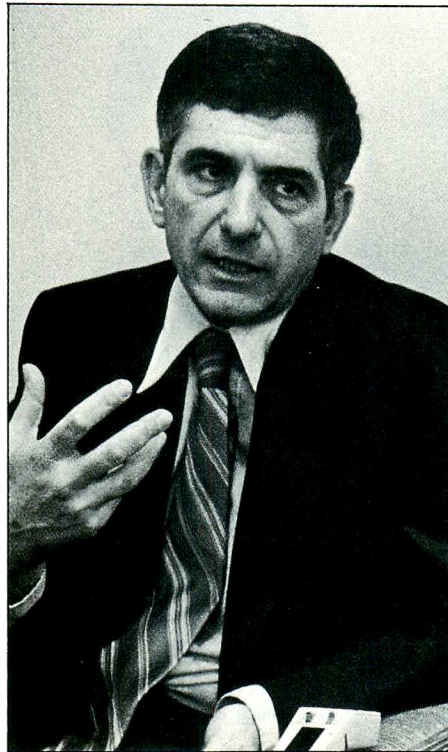
Q. *Dr. Crout, there have been a lot of newspaper articles in the past few months about estrogens and about birth control pills which contain estrogen. What are estrogens?*

A. Estrogens are female hormones. There are two fundamental types of female hormones, estrogens and progestins. Estrogens, in essence, are what make femaleness. They promote secondary sex characteristics, give women the appearance that makes them women, and control the menstrual cycle. They have a variety of medical uses that derive from the hormonal action.

Q. *What are some of those medical uses?*

A. First and foremost, estrogens are used as replacement therapy in women who have an estrogen deficiency. There is a time in midlife called the menopause when the ovaries lose their function and fail to produce estrogen. In the post-menopausal period this can result in "hot flashes" and, later on, in a few women, an atrophy of the vagina. Problems of this sort classically have been treated by physicians with estrogens. In recent years, there has been an enormous use of estrogen in younger women in the form of oral contraceptives, or birth control pills. These are really the two major uses for these drugs. There are some rare uses—for example, in patients who have their ovaries removed prematurely, or in certain kinds of genetic disorders. Also, one very interesting and important use is treating cancer of the prostate in men.

Q. *There's been a substantial increase over the past few years*



in the use of estrogens for medical purposes. To what do you attribute this?

A. The answer goes to the heart of our societal values. Let's limit this to post-menopausal use; the reasons for the growing use of contraceptives are self-evident.

Post-menopausal use of estrogen has just ballooned in recent years. It relates to a couple of things—there has been a growing feeling, to some almost a mythology, that estrogen treatment during the post-menopausal period will stave off aging, maintain youthfulness, prevent wrinkles, and so on. So there has grown an enormous desire on the part of women for that sort of thing. It's been widely popularized in magazines. Among segments of the medical

profession, there has been a growing feeling that estrogens may stave off deterioration of the bones in menopausal women, a problem called osteoporosis. Those two things combined—consumer demand and physician hope that some of the problems of aging might be staved off—have been the major causes for the proliferating use of estrogens in post-menopausal women.

Q. *How many post-menopausal women in the United States would you estimate are taking estrogens today?*

A. Many millions of women take them. The best survey on this, published a few years ago, suggested that half of all women past the menopause took estrogens. Half of these women took estrogens for longer than ten years—that is, the median time period for taking it was ten years. These chronic users tend to be middle and upper income women, the kind of people who go to doctors and the kind of people who would most value the most-longed-for youthful appearance. It's an interesting example of the poor being spared, if you will, some of the adverse effects of estrogens that are now coming to the fore.

Q. *Is estrogen use in post-menopausal women today excessive?*

A. Given the new evidence on cancer, and given the lack of evidence that these major uses are really effective, the answer to that is clearly yes.

Q. *So there is no evidence that estrogens have any benefit in helping women look and feel young?*

"These chronic users tend to be middle and upper income women, the kind of people who go to doctors and the kind of people who would most value the most-longed-for youthful appearance. It's an interesting example of the poor being spared, if you will, some of the adverse effects of estrogens that are now coming to the fore."

A. There is a good deal of testimonial evidence, but there really are no controlled studies or any objective evidence to indicate that estrogens have any of this effect.

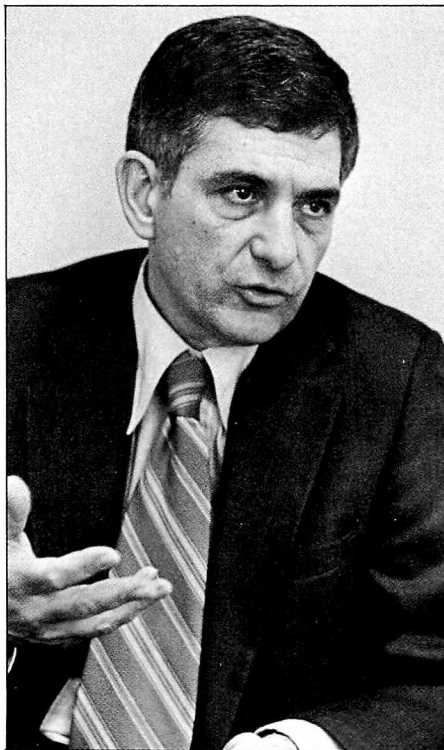
Q. *Can you describe the new evidence about the relationship between cancer and the use of estrogens in post-menopausal women?*

A. There have been some major discoveries recently about the adverse effects of estrogens in humans. The most important of these are the recent studies on endometrial cancer—cancer of the uterus. Two articles were published in the *NEW ENGLAND JOURNAL OF MEDICINE* in December, along with some editorials, and there have been other reports. These articles make quite clear that the long-term use—for more than a year or so—of estrogens in post-menopausal women is associated with an increased risk of cancer of the uterus.

Now, there are factors other than estrogens that increase the risk of cancer of the uterus, such as overweight, high blood pressure, or never having had children. But the major cause, and it seems to be increasing the rate of uterine cancer in this country, according to one survey at least, is estrogens. The newly-reported data are high enough to put endometrial cancer in the same ball park as breast cancer, in terms of risk in post-menopausal women taking estrogens.

Q. *You are saying, then, that a large part of the increase in cancer of the uterus appears to be directly related to the dramatic increase in the use of estrogens?*

A. Yes. The association between use of estrogens and this form



of cancer is quite high. Studies show that women who have taken estrogens are 4 to 7 times more likely to get endometrial cancer than are women who have not taken estrogens. The risk appears to increase the longer the woman uses estrogens. The increase in uterine cancer has been more pronounced in recent years among white women, who are more likely than black women to take estrogens, at least according to one study. This further suggests an association between estrogens and uterine cancer.

Q. *How do you explain to a woman who has been taking estrogens for 15 years that only now we are learning that she has been exposed to an increased risk of cancer?*

A. One explains that the way you explain all new discoveries. Bad news comes in many forms. There was a time when we learned that cigarettes increase one's risk of lung cancer. We're learning that certain dietary habits in this country are very important in increasing the risk of heart disease. So I don't have any problem with telling people that something new has been discovered. People expect that new things will be discovered. What I think would be unconscionable is the alternative—that embarrassment over a new discovery would lead to hiding the truth. It's important that we simply face up to new scientific discoveries.

Q. *Now that this new evidence has been accumulated, what does FDA intend to do about it?*

A. There are two things that are most important from our point of view. One is, we will revise the labeling for estrogens—the labeling that goes to doctors. The second thing is, we're going to require a package insert especially for patients to explain the risks, as well as the benefits, of estrogens, and the need for regular physical checkups for women using estrogens. The use of estrogens post-menopausally is an example of a situation where patients should be able to choose among alternatives in light of the risks. It is appropriate for patients to share in the decision to use estrogens. Until now, we've required patient labeling only for one prescription drug, namely birth control pills. Now people will be seeing patient information about estrogens.

Q. *What changes will be made in the labeling for doctors?*

"... the labeling will clearly state that evidence is lacking that post-menopausal estrogens are really effective for this thing called 'feeling of well-being' or for prolonging an appearance of youthfulness."

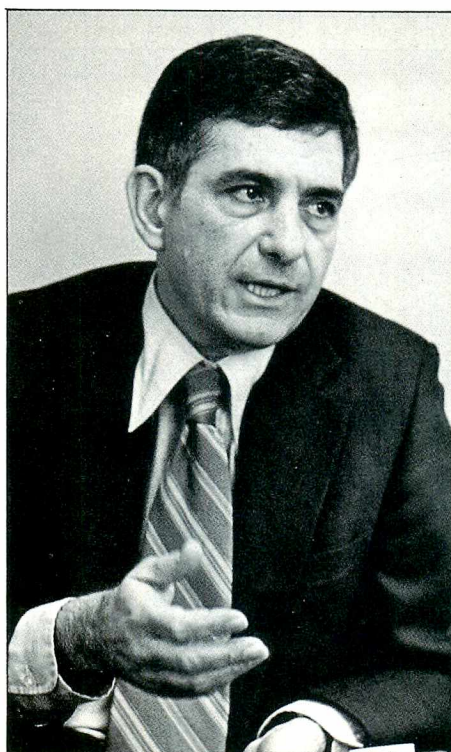
A. We'll redefine quite carefully the menopausal syndrome. We'll emphasize that the menopausal syndrome is a problem that occurs as a transient when women lose the ovarian function. It's not something that goes on for 20 years and requires prolonged therapy. We will urge that the use of estrogens be reevaluated periodically, and discontinued occasionally to evaluate the need for them. We also will urge that the lowest dose be used at all times.

We are also evaluating the research on osteoporosis to see whether there is really evidence that estrogens are effective for that use. If there is, that will be in the labeling. If there isn't, then estrogen manufacturers will not be permitted to recommend these drugs to treat osteoporosis. Also, the labeling will clearly state that evidence is lacking that post-menopausal estrogens are really effective for this thing called "feeling of well-being" or for prolonging an appearance of youthfulness.

Q. *What does FDA intend to do to make sure there actually is a reduction in the number of women who receive estrogens?*

A. We make the assumption that when a major new danger from a drug appears, and people are informed of the danger and are encouraged to reappraise use of the drug with their doctors, then a natural decline in use will occur. That's what our job is—to see that a reappraisal is made by doctors and patients. Our role is to see that both of them know the effects of **drugs**. This knowledge should lead to a decreased use of these drugs.

Q. *What should a woman who is now taking estrogens or who is*



now going through a menopausal change do?

A. She should discuss with her physician whether she needs to take or remain on estrogen. There are still some very valid uses for estrogen. Treatment of menopausal symptoms—particularly "hot flashes"—for a period of months is clearly a common and acceptable practice. Certainly the treatment of atrophic vaginitis is perfectly appropriate. But beyond that, a woman is taking a risk of cancer for a false promise of maintaining youthfulness. That is clearly a practice that ought to be reappraised.

Q. *In other words, you would say that for a number of conditions the benefits of taking estrogen still can*

outweigh the risks. But you would question its prolonged use.

A. That is correct. I'd add one other factor—that is, if a woman does not have a uterus then she obviously is not at risk for endometrial cancer. The risks we're talking about apply to women who have not had a hysterectomy.

Q. *We've just learned about the risk of cancer of the uterus. What other research is now going on which might reveal new risks for the use of estrogens? What is now suspected that is not yet proven?*

A. That's an important question, because the data on cancer of the breast are not yet in. From a biological point of view, there's every reason to think that estrogens could also increase the risk of cancer of the breast. They certainly do so in lower animals. Studies on this are now going on. I suspect that there will be new information on cancer of the breast within the next two or three years. I'm not implying that it will be adverse. I'm just saying that there are a number of studies going on that we expect to get the results of within two or three years. Up to this time, data in regard to breast cancer has been reassuring. But it is always possible that there may be bad news at some time in the future.

Q. *One particular estrogen has been singled out for special attention, and that's diethylstilbestrol, or DES as it is commonly known. What medical purpose does DES serve?*

A. DES is a synthetic estrogen and it serves all of the medical purposes that I've described. It's not the most commonly-used estrogen in post-menopausal women today, but DES

"There are still some very valid uses for estrogens. Treatment of menopausal symptoms—particularly 'hot flashes'—for a period of months is clearly a common and acceptable practice."

was the first inexpensive orally absorbable estrogen ever made. This was back in the early 1940's. Through the years it's been the estrogen our population has been exposed to the longest. DES has achieved a certain notoriety in the public mind because of its association with vaginal cancer and because it's the estrogen that is used to promote growth in animals and, therefore, enters the food supply in very minute amounts. That notoriety does not derive from any special property of DES. It's merely that it is a common and widespread estrogen, one that has been used for many years.

Q. *In 1971, it was reported that there was an increase in vaginal cancer among daughters of women who had taken DES to prevent miscarriages during the late 1940's and early 1950's. Have those studies been confirmed, and what has FDA done to preclude the possibility that a woman today would take DES during pregnancy?*

A. Use of DES for this purpose has waned, and did so some years ago. Its use during the 1940's and 1950's in pregnant women was one of those unfortunate examples of a well-meaning attempt to help people. The medical profession, without good studies, used DES to treat women who had had repeated miscarriages in the hopes that it would allow them to carry babies. It turned out that the effect of estrogen later expressed itself as cancer of the vagina in daughters. The great lesson of that episode is that therapies ought not to be introduced unless they are known to be effective. That's what Congress decided in 1962, and because of the 1962 Drug Amendments, drugs now are evaluated for effectiveness.



Q. *DES has been used on college campuses in very large doses as a "morning-after" contraceptive pill. What is FDA's view on this?*

A. DES has been used for this purpose simply because it is a popular estrogen. There is every reason to believe that any estrogen used in a proper dose will prevent pregnancy. After intercourse, a woman would have to take large doses of estrogen for five days. The woman normally gets nauseated, so there is really no popularity for estrogens as a form of "morning-after" contraception. Nevertheless, when it is needed, in cases of rape or incest or other emergencies, it is a medically useful alternative to abortion or doing nothing. So, we feel this use is a valid one for emergency situations. But DES should not be used repeatedly for this purpose. Our problem has been to get control of the sit-

uation and to see that the medical profession limits its use to the times when it is necessary.

Q. *What risk does a woman face using the "morning-after" pill?*

A. She exposes herself to a dose of estrogen which is hundreds of times what she would get in a standard birth control tablet. So "morning-after" pills are a potentially dangerous approach to contraception. A woman exposes herself to a large dose of estrogen, and some of the things we have discovered about these drugs recently are less than reassuring. At the present time there is no proven long-term harm from taking a large dose of estrogen for a short period. On the other hand, no one can say that a risk of cancer of the breast or the vagina or uterus wouldn't come out in the future. We have warned doctors through our DRUG BULLETIN that DES should not be used routinely as a "morning-after" pill, but only in emergency situations.

Q. *Just to summarize our discussion of estrogens, you would say that doctors and patients alike should now view all estrogens with much greater caution than they have in the past, and that the patient herself has to be aware of some of the risks that she is exposing herself to?*

A. Yes. And I would add also that the major uses, to some extent, involve personal choices as to what form of medication people use. Women now have to choose whether they want to take certain risks for alleged benefits. We intend to provide information so that women themselves can exercise their right to engage in personal choices.

Getting The Word From Consumers

by Phyllis Lehmann



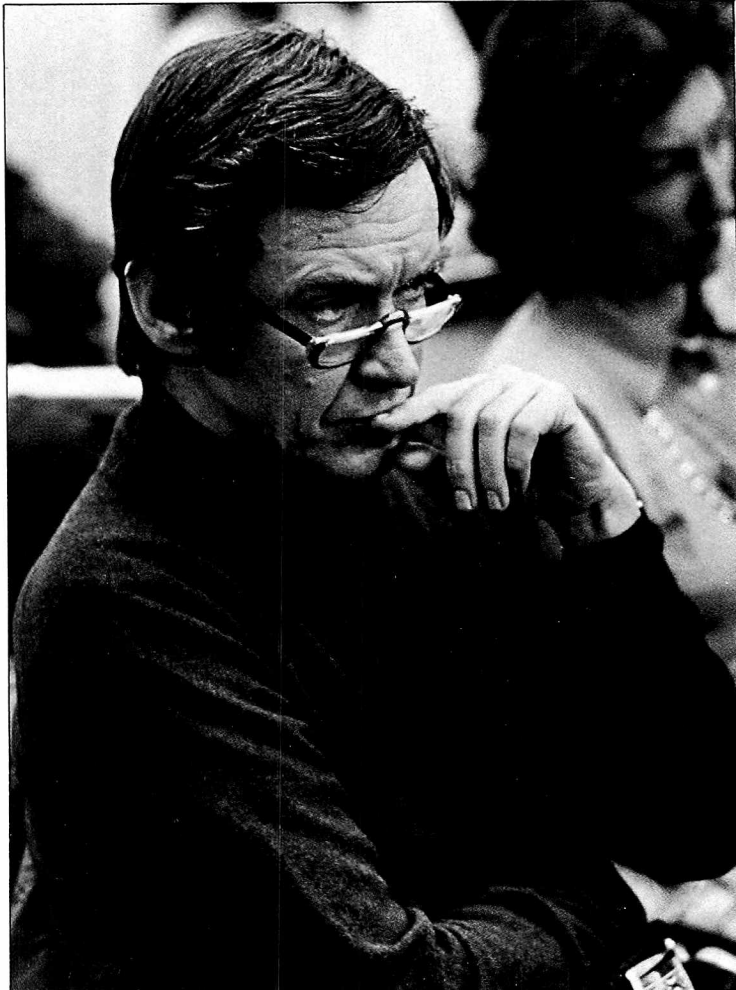
Assuring that consumers' views come through loud and clear is a matter of top importance at FDA. Consumer representatives serve on more than 30 FDA advisory panels and committees. Consumer activists and FDA's top officials get together in an open monthly meeting for a free-swinging exchange of opinions. And, by 1978 FDA hopes to be holding four "Meet-the-Commissioner" meetings a year to give consumers in various parts of the Nation an opportunity to question FDA officials directly on what the Agency is doing and why.

Protecting consumers from unsafe, ineffective, and falsely labeled products is what the Food and Drug Administration is all about. So it's only logical that the consumer's voice should be heard loud and clear by the agency that makes decisions about what we put in, on, and through our bodies.

Consumers often need look no further than the nearest newspaper headline or the nightly television news to find apparent cause for concern. Food additives such as Red No. 2 may cause cancer. Oral contraceptives and IUD's

Monthly ad hoc meetings in Washington bring together consumer representatives and activists and top FDA officials for a freewheeling discussion of topics that often reflect the latest headlines. At the January 1976 meeting, the agenda included a discussion of FDA's ban on the color additive Red No. 2.

may cause a wider range of health problems than women or their doctors ever thought. Even pet turtles—which can carry *Salmonella*—represent a health menace! Increasingly, consum-



Frequent participants in the ad hoc consumer representatives meetings include Nancy Chasen of Consumers Union (above); Robert Choate of the National Council on Children, Media, and Merchandising; and Ruth Desmond of the Federation of Homemakers.



ers are beseeching FDA to right these wrongs. FDA, of course, must dispassionately consider all the evidence and listen to all sides. But to make sure the consumer viewpoint is adequately presented, the Agency has provided a number of ways for consumers to express their opinions.

Consumers, individually or as a group, have the right to petition FDA to make or change a regulation. And FDA has a nationwide network of some 55 consumer affairs officers whose primary job is to listen to and to help inform consumers.

But more important to many consumer groups is direct access to the policymakers, the people who ultimately make the decisions. It is in this area that some important changes have taken place over the past five years.

In 1971, then Commissioner of Food and Drugs Charles Edwards began meeting regularly with a handful of Washington consumer activists, such as outspoken attorney Jim Turner, a former "Nader's Raider" and author of *THE CHEMICAL FEAST*. From these early meetings evolved three important links between FDA and consumer groups: consumer representation on FDA's advisory panels and committees, monthly ad hoc consumer representative meetings, and regional "Meet-the-Commissioner" meetings.

Since FDA constantly seeks advice from experts outside the Government, it seemed only fitting also to invite consumer representatives to participate on the Agency's various advisory panels. The National Food and Drug Advisory Committee, established in 1974 to review Agency programs and offer guidance on FDA policy matters of national significance, includes consumer representatives (referred to as public members in this group) as full voting members. Consumer representatives also now serve along with industry representatives as nonvoting members of many of the public advisory panels and committees that deal with specialized subjects. These groups help set policy on everything from antiperspirants to vitamins.

Of FDA's 61 advisory panels and committees, 35 deal with issues of sufficient public interest that they now have or soon will have consumer representatives. They include such varied groups as those that review non-prescription cold, cough, and allergy drugs; contraceptives; dental devices;

vitamins and minerals; and devices used in performing surgery.

When there is an opening for a consumer representative FDA alerts the public by publishing a notice in the *FEDERAL REGISTER*. During the following 30 days any interested person or organization may nominate someone to serve on a specific committee or for consideration as a member of any committee that has an opening. Nomination letters, which must include information on the nominee's qualifications and background, should be sent to the Director, Office of Consumer Programs, Office of the Assistant Commissioner for Professional and Consumer Programs, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.

At the end of the nomination period, FDA invites all persons and groups who have submitted nominations, as well as all other bonafide consumer groups, to vote on the nominees. Currently, some 85 organizations are offered the opportunity to vote for consumer representatives.

Nominations for consumer representatives also can be sent to FDA at any time—not just when a *FEDERAL REGISTER* notice appears. These letters are filed by the Office of Consumer Programs, which then contacts the nominee when a committee needs a representative.

Consumer representatives come from all over the country and represent a wide range of organizations—from the Ragweed Eradication Program (a natural for the Panel on Review of Allergenic Extracts) to the Consumer Federation of America. They can attend all meetings of the advisory panels of which they are members, usually about six a year, and participate fully in all discussions, but—with the exception of the public members of the National Food and Drug Advisory Committee—they cannot vote. As advisory committee members, consumer representatives or public members are appointed as special Government employees and receive a consultant fee for attending meetings and travel and living expenses.

To help prepare the consumer representatives, FDA provides background information on the work of the panel and the issues under consideration. The representatives, in turn, convey information on the panel's deliberations back to their respective

groups. For some, this is a problem. "Many consumer representatives simply don't have the resources that industry representatives have, and it's difficult for them to get important information out to their organizations," says Alexander Grant, director of FDA's Office of Consumer Programs. "We are now considering providing some kind of staff support to help them do this part of their job better."

How do the representatives themselves see their role?

"We try to alert the panels to areas of public interest—safety, effectiveness, and clear, accurate labeling," says Jim Turner, who represents the National Consumer League on the Panel on Review of Bacterial Vaccines and Bacterial Antigens.

Mary Plaska, who represents the American Public Health Association on the panels that review dentifrices and dental care agents (denture cushions, adhesives, toothache drops) and oral cavity drug products (mouthwashes, cold sore ointments), says that sometimes the consumer representative must make sure the panel sees the forest through the trees.

"Sometimes the discussion becomes very scientific and technical, and the members seem to forget that the product they're discussing will be sold to the public," she says. "Half the group may think it's effective, and the other half may think it isn't. I feel I must remind them that if the product is marketed, the public will buy it in good faith, believing that it will do what it says it will do."

As for labeling, the representatives believe they must insist that products live up to the claims on the labels and that labels are not misleading.

The consumer representatives don't pretend to have a great deal of technical knowledge in their panels' specialties. One of the newest representatives is Dianne F. Foote, assistant to the dean of nursing at the Florida State University School of Nursing, who recently was named to the Panel on Review of Dental Devices. The group is concerned with such products as tooth implants, sealants used to prevent decay, and the use of ultraviolet light for such things as hardening sealants and repairing tooth fractures. Foote believes her lack of experience in dentistry is an asset rather than a handicap. "I'm not going to try to get too deeply into the scientific matters," she

Commissioner of Food and Drugs Alexander M. Schmidt (center) responds to a question at the ad hoc consumer representatives meeting. Flanking Schmidt are Sherwin Gardner (left), deputy commissioner of Food and Drugs, and William Whitehorn, assistant commissioner for Consumer and Professional Programs.



says. "I'm here as a consumer, and I think it's better that I react as a consumer."

What do the other panel members—who *are* experts—think of their consumer colleagues? "We don't make any particular differentiation with the consumer representatives," says Dr. John Walter Stanford of the American Dental Association, who chairs the Panel on Review of Dental Devices. "Even those of us with a scientific or professional specialty consider ourselves consumers. We're all consumers here." But, he adds, the consumer representatives do raise important issues about the safety and effectiveness of the products in question.

Quite different from the workaday world of the advisory panels are the monthly ad hoc meetings in Washington where many consumer activists besides those who serve on panels come face to face with the FDA Commissioner and other top Agency officials. The early meetings between the Commissioner and a few consumer representatives were so successful, says Dr. William Whitehorn, FDA assistant commissioner for Consumer and Professional Programs, "that we decided to enlarge the group and turn the sessions from criticism of past FDA actions to looking constructively at the future."

The first ad hoc meeting in 1972 consisted of seven consumer representatives facing 11 FDA people, but the sessions have since expanded into free-

spirited give-and-take between some 25 consumer people and an equal number of FDA staffers. When there's an especially "hot" issue, the monthly meeting is jam-packed.

FDA sees these monthly get-togethers as providing "a two-way channel of communication." Jim Turner puts it more bluntly: "We talk about what an awful system it is and tell the Commissioner the things that are troubling us and what we think the FDA should do about them. He tells us what he thinks FDA is doing right."

The agenda for each meeting reflects changing concerns in a world of fast-breaking developments. In early spring of 1974 it was those *Salmonella*-infested turtles. In early 1975, it was ingredient labeling of alcoholic beverages, drugs and the pregnant woman, and possible hazards of baby food. In January 1976, it was Red No. 2 and improvement in the printed information patients receive (called patient labeling or patient package inserts) in packages of oral contraceptives. Though the specifics may change, there has been continuing interest in the general areas of food additives, more informative labeling of food products, patient package inserts with drugs, and the role of consumer views vs. industry views in FDA decisionmaking.

The ad hoc meetings also give the Commissioner a chance to get a few things off his chest. At the January 1976 meeting, at least half the session was devoted to FDA's decision to ban

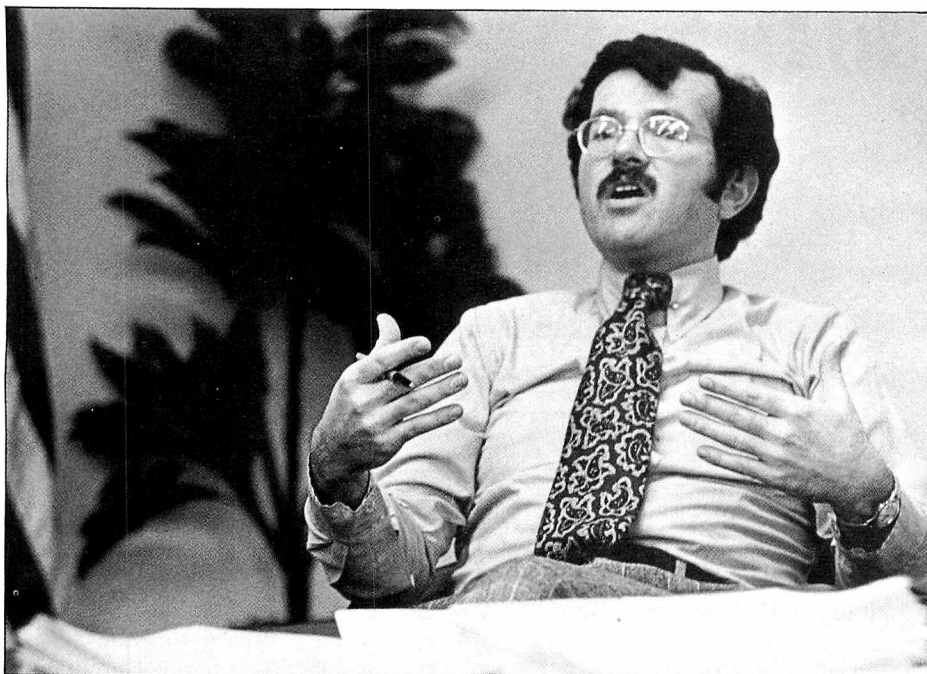
Red No. 2 and a judge's restraining order delaying publication of the ban in the *FEDERAL REGISTER*.

Commissioner of Food and Drugs Alexander M. Schmidt discussed how he and the FDA often are caught between public demands and the law. "People say to me, 'You just dillydally around and fool with people's lives when you really should ban product X.' When I explain that the evidence is not conclusive, our critics say, 'You should take action and then argue the question. Otherwise, people are at risk while you're arguing.' But as the law now stands, a judge can overrule us, and as in the case of Red No. 2, order that the product stay on the market while the argument goes on." (After further court action, the ban went into effect February 12, although the court directed that a hearing be held on the merits of FDA's action.)

Schmidt added: "We just can't do everything we'd like to do or that you people would like us to do."

But, asked Nancy Chasen of Consumers Union, shouldn't the legal burden of proving a product's safety be on industry rather than on the public? An FDA attorney explained that the Delaney Clause (a key section of the law of food additives) simply says that no substances shown to be cancer-causing may be added to food, but it doesn't say how to go about proving something is safe, or who should do it.

While the questioning is often hard and pointed, there are also examples of



Richard Merrill, FDA's general counsel, explains the legal issues involved in removing a food additive from the market.

Government-consumer cooperation. At the January meeting, Chasen outlined a supermarket survey that consumer groups plan to conduct to determine whether consumers want foods to be labeled by drained weight—that is, by the weight of the food minus the liquid it is packed in. FDA agreed to consult with and assist the consumer groups in developing the questionnaires and tabulating the results.

The discussion gave both sides a chance to offer views on the kind of information the survey should seek. For instance, FDA officials stated that they needed specifics—such as how drained-weight labeling would affect buying decisions.

There is also probing to find out how FDA can keep consumers better informed. Do the consumer groups want special meetings or some type of formal contact with industry people as had been implied at a previous meeting? No, nothing special. “I just think it would be valuable for consumers and industry people to occasionally be in the same room at the same time,” Chasen explained.

The ad hoc meetings also give FDA an opportunity to report on its own studies that bear on consumer issues. At the January meeting, Heinz Eiermann, director of the Division of Cosmetic Technology, discussed a three-month study of adverse reactions to cosmetics among some 35,000 people. (There were 589 adverse reactions confirmed by dermatologists to have

been related to cosmetics.) Eiermann also showed data on consumer complaints about cosmetics received from other sources and listed the top offenders—among them eye and face makeup products, deodorants, shampoos, depilatories, moisturizers and other face creams, and hair colors and bleaches. He explained that the most common types of injuries are skin irritations or allergic reactions. He told the consumers that FDA now is trying to determine which brands of the various products have the highest complaint rates and what ingredients may be the cause of adverse reactions.

The face-to-face meetings between the Commissioner and consumer leaders in Washington have proved so valuable that FDA has launched “Meet-the-Commissioner” meetings in key metropolitan areas of the country. Since these take a great deal of planning and coordination, only one has been held so far—in New Orleans, in November 1974. The second is slated for Philadelphia late this month. FDA hopes that such regional sessions will be held four times a year by 1978.

For the Commissioner and the top officials who accompany him, the regional meetings mean a grueling schedule of press conferences and television interviews, visits to local medical schools, meetings with local officials, and open forums at which State and local consumer leaders can quiz the Commissioner and sometimes bend his ear about their favorite issues.

The issues raised often reflect local concerns that would not come up at Washington meetings. In New Orleans, someone wanted to know why FDA didn't invoke the Delaney Clause to shut down food processing plants that use allegedly cancer-producing water from the Mississippi River. (Answer: The Delaney Clause does not apply, because the substances in the water are not considered food additives.)

A regional meeting is a hard day's work requiring many months of preparation, but FDA believes it's worth it. In New Orleans, some 400 people were directly involved in face-to-face meetings with top FDA officials, and countless more read newspaper stories or saw the Commissioner and his staff on prime time television.

As a result of their increased contacts, consumer groups and the FDA realize that basically they are working for the same things. The Agency has a better handle on what concerns the public, and consumer activists understand better the legal and scientific boundaries within which the FDA must act.

At a time when, as Commissioner Schmidt put it recently, “Just about everything this Agency has ever approved is coming into question,” there will be reason for consumer groups and the Government to work ever more closely to better protect the constituency they both represent.

Phyllis Lehmann is a freelance writer.

Using X Rays To Detect Breast Cancer

Mammography often is effective in diagnosing early breast cancer that might be overlooked by other methods. But because mammography involves radiation, and radiation itself is dangerous, FDA is gathering information on the equipment and techniques that will produce quality x rays with the minimum exposure.

by Annabel Hecht

Of all the ills the flesh is heir to, none is more greatly feared by women than breast cancer. And little wonder. It is a leading cause of death for women and the treatment often is physically disfiguring and emotionally disturbing. Moreover, there has been little reduction in the mortality rate from breast cancer in the past 40 years.

When the news broke that the wives of the President and the Vice President had undergone breast surgery, women by the thousands rushed to physicians and clinics for examinations. Cancer experts applauded these women for taking a positive step that could save their lives. As these experts have long been saying, the best chance for long-term survival and cure of any cancer is to find it in its earliest and most treatable stage.

One method for early detection of breast cancer is mammography, examination of the breast by x ray. This is considered to be a very effective diagnostic technique when done by qualified personnel using proper equipment. Unfortunately, such is not always the case. Surveys have shown that the radiation exposure received from mammography varies widely among the

hospitals and clinics performing this procedure, and that some women are getting unnecessary radiation due to use of improper techniques or equipment.

Concerned that large numbers of women may be getting more radiation than is good for them, the Food and Drug Administration is taking a serious look at mammography in its present-day applications. A special internal task force in FDA's Bureau of Radiological Health is gathering information on the equipment and techniques being used to take mammograms, the skill and training of the technologists and the factors which contribute most to radiation in mammography.

No one knows for sure the magnitude of the possible radiation risks from mammography since widespread use of the technique is relatively new and the effects of too much radiation may not become apparent for 10 to 20 years. FDA experts point out that current conventional mammographic techniques result in a higher dose than is often given to other parts of the body.

Mammography involves a low energy x-ray beam to get the best contrast between normal tissue and a lump or mass in the breast. This means that less radiation reaches the film and relatively more is absorbed by the body. Exposure time, the type of film used, the type and condition of the equipment, plus the skill of the technologist are all factors in determining how much radiation an individual gets. Checks of x-ray facilities have turned up machines and techniques which are exposing patients to as much as 15 times the radiation produced at other

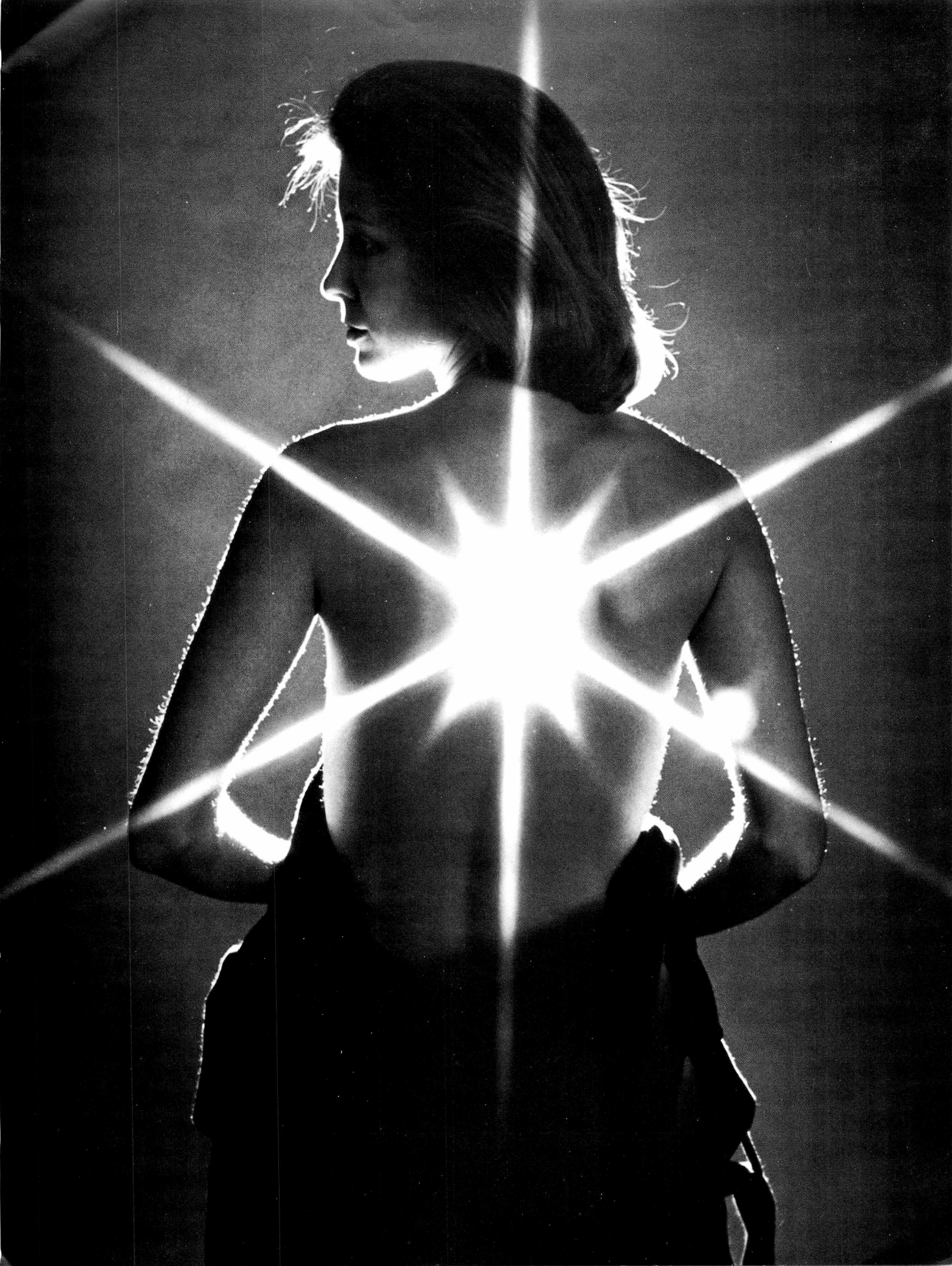
institutions. With two or more films used for each breast, this can add up to a considerable amount of radiation.

In order to assure that women getting mammography won't, at the same time, be getting excessive radiation, FDA has developed an action plan that will not only minimize patient exposure but will provide valuable information on current mammographic practices in the United States.

Already underway is a Mammography Quality Assurance Program. Pilot testing has been started in the District of Columbia and in Pennsylvania to lay the groundwork for an educational program that may eventually become a State-Federal cooperative effort. In the pilot test, each facility doing mammography will be mailed a card that can be used to measure x-ray exposure. The card is to be exposed to the x-ray beam according to standard procedures used by each facility and returned to the State radiological health agency along with information on the numbers and ages of patients who are getting mammography.

State personnel will visit those facilities whose cards show unusually high exposures and recommend corrective action. Rechecks after six months will determine how well the recommendations are followed. While FDA has no control over how x-ray equipment is used, some States do have authority to require facilities to correct deficiencies that result in overexposure.

As yet, radiology experts don't know which imaging systems will be most successful in detecting early breast cancer. FDA is conducting tests to determine the equipment that will pro-





"In order to assure that women getting mammography won't, at the same time, be getting excessive radiation, FDA has developed an action plan that will not only minimize patient exposure but will provide valuable information on current mammographic practices in the United States."

vide the best diagnostic information on an x ray of the breast with the least radiation exposure. This work is expected to lead to guidelines for the type of equipment and techniques which should be used for mammography. When these guidelines are formulated, FDA will make this information available to radiologists, x-ray technologists, and equipment manufacturers.

FDA is also supporting research to determine the long-term effects of radiation and whether age at the time of exposure influences the development of tumors later in life. This study, being carried out at the Harvard School of Public Health, is based on an evaluation of the medical histories of women and adolescent girls who had repeated fluoroscopic x-ray examinations during tuberculosis treatment.

More information on the role of mammography in the detection of early breast cancer will be forthcoming from a national breast cancer screening demonstration project now underway under the joint sponsorship of the National Cancer Institute, a research arm of the Department of Health, Education, and Welfare, and the American Cancer Society. The project involves 270,000 women, enrolled in 27 centers throughout the country, who will have five annual examinations including a physical exam, mammography, and thermography, a technique that records heat patterns on the surface of the skin. The purpose of including thermography is to determine whether it can add anything to the detection of early breast cancer. In addition, the women are taught breast self-examination.

The screening project was initiated in 1973 on the basis of encouraging results from a project carried out ten years earlier by the Health Insurance Plan of Greater New York (HIP). Among the 62,000 women involved in the HIP study, those who were screened by both physical examinations and mammography had one-third fewer

breast cancer deaths over a five-year period than their counterparts who had only their regular comprehensive health care.

Still to be determined is the age at which mass screening with mammography can do the greatest good. Since there is good evidence that a higher incidence of breast cancer occurs in humans exposed to radiation, the FDA Task Force wants to find out at what age in a woman's life the benefits of this procedure outweigh any possible risk.

A panel of experts convened by the American College of Radiology has already recommended that mammography should not be used routinely on women under 35 who have not had breast cancer and who have no complaints or physical findings and no family history of the disease. The reason is two-fold: breast cancer is uncommon in women under 35, and mammography is not very effective in detecting early tumors in the firmer and more fibrous breast tissue of young women. This does not mean, however, that mammography should not be used if a young woman has evidence of a lump in her breast.

What then of women between the ages of 35 and 50 who have neither symptoms nor a positive family history of breast cancer? Should they have routine mammography screening? The American College of Radiology's expert panel noted that the matter is still in question and calls for additional research. The *MEDICAL LETTER*, a nonprofit publication on drugs and therapeutics, reported: "Women over the age of 50 years are the only ones for whom it is now known that screening with mammography decreases mortality from breast cancer . . ."

Several FDA researchers have constructed a life-table model using data from the HIP and other studies and concluded that mass screening of symptom-free women derives its maximum potential for saving lives when begun

at age 50. They base their conclusion, in part, on the fact that the increased survivals among women in the HIP study were observed in the over-50 age group, while death rates for those under 50 were about the same whether or not they were screened. Still another cancer expert would push the minimum age for routine mammography screening to 60 or 65.

But a spokesman for the National Cancer Institute points out that times have changed and much of the data from the HIP study is already outdated. Thanks to improvements in technique and equipment, women in the national screening program are getting considerably lower doses of radiation than did women in the HIP study, the Institute says. Aware that exposure of large segments of the population to ionizing radiation must be made with caution, the Institute still feels the benefits of mammography far outweigh its risks.

Even though the screening program is barely past its midpoint the Institute believes it already has shown encouraging results. Approximately 42 percent of the cancers detected to date were found by mammography alone. Of those found in women under 50, about 73 percent had no involvement of the lymph nodes, the Institute says. In other words, the cancers were found in an early and consequently more easily treatable stage.

The national breast cancer screening demonstration projects still have several years before they are completed. Until the final results are in from this endeavor and from investigations by FDA and other organizations, no one can say for certain if and at what age mammography should be used for routine screening of women for breast cancer.

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

Why FDA Banned Red No. 2

FDA's decision to ban Red No. 2 from food, drugs, and cosmetics has been one of the most widely reported stories of 1976, yet there is still some confusion about why FDA acted. Here's the Red 2 story, from its first use in food some 80 years ago to the legal and scientific considerations that led to FDA's recent action.

by Emil Corwin and Wayne L. Pines

Red No. 2 holds a unique place in the history of color additives used in this country.

- It is the most studied color additive ever, yet scientists cannot reach a consensus whether it is hazardous to people.

- It has been the most widely used color additive—having been in soda pop, ice cream, gelatin, even drugs and cosmetics—yet some companies had changed to alternative colors long before the Food and Drug Administration recently banned it.

- FDA's decision to ban Red No. 2 has been one of the most widely reported news stories of 1976, yet many people still misunderstand the reason behind FDA's action. For example, many people apparently believe Red No. 2 has been conclusively demonstrated to cause cancer. It has not.

The Red No. 2 story started late in the 19th century, when it was first used to color foods. Then known by its common name of amaranth, FD&C Red No. 2 (its official name assigned by FDA) was one of the first seven colors approved for use in foods and drugs by the Bureau of Chemistry in the Department of Agriculture, the predecessor to today's FDA.

Colors were the first products subject to premarketing approval and testing in FDA laboratories. Use of colors that were toxic was one of the major problems leading to the original 1906 Pure Food and Drugs Act. Only

a few of the hundreds of "coal tar" or "aniline" dyes then on the market could be used safely in food. Continuous testing was needed to insure that colors were safe.

In 1907 the first list of approved colors was selected and a system established to certify that each batch had passed the required tests.

The Federal Food, Drug, and Cosmetic Act of 1938 required that listed colors be "harmless," but in the 1950's reports of illness resulting from excessive use of certain colors prompted an FDA review of all the certified colors. Several were banned when it was found they could not be considered "harmless" when consumed in quantity. In 1958, the U.S. Supreme Court upheld FDA's interpretation that the term "harmless" meant that a color could not be used if it would cause harm at *any* level, even if it was not harmful at the level actually used.

In 1960, the Congress enacted the Color Additive Amendments to permit the use of colors if they were safe at the level used. The Amendments said that industry must bear the burden of proving that a color is safe.

The Amendments established a system called "provisional listing," to permit the continued use of all color additives that were in commercial use when the law was passed on July 12, 1960. This provisional listing was to be in effect for two and one half years, until January 1963, to permit the collection of data to show that the color was safe for its intended uses. If the data could demonstrate safety, then the color additive could be "permanently" listed. If there was no data demonstrating safety, the color was to be removed from the provisional list, thus prohibiting its use.

The 1960 Amendments permitted extension of the provisional listing of an additive beyond the original two and one half years if the extension was

necessary to complete the investigations necessary to determine whether to list it permanently. This extension could be terminated if no longer justified by ongoing investigations, among other reasons. The Amendments also provided that the Commissioner could terminate the provisional listing of a color immediately "whenever in his judgment such action is necessary to protect the public health."

The original placement of a substance on the provisional list did not require any showing of safety, but simply evidence that it was in use as a color additive when the Amendments were passed. There were 133 color additives on the first provisional list published in October 1960. The current provisional list contains 82 color additives. FDA has said it will make a final decision by September 30, 1976, either to permanently list or terminate the provisional listing for most of these colors.

The safety data for provisionally listed color additives have been reviewed periodically to assure that their continued use does not pose any hazard. When questions of safety have been raised, action has been taken to terminate or restrict the use of the color additive. Since 1960, ten color additives have been delisted or had their use restricted because of safety questions.

Thirteen certifiable color additives have been permanently listed for use in food, drugs, or cosmetics. The number of permanent listings has been low due to changes in the requirements considered necessary to show the safety of the color additives under their intended conditions of use. In addition, the cosmetics industry disagreed with FDA over the interpretation of the 1960 Amendments, and took the disagreement to the courts. It was not until 1969 that the courts clarified what the Amendments required. Until then,

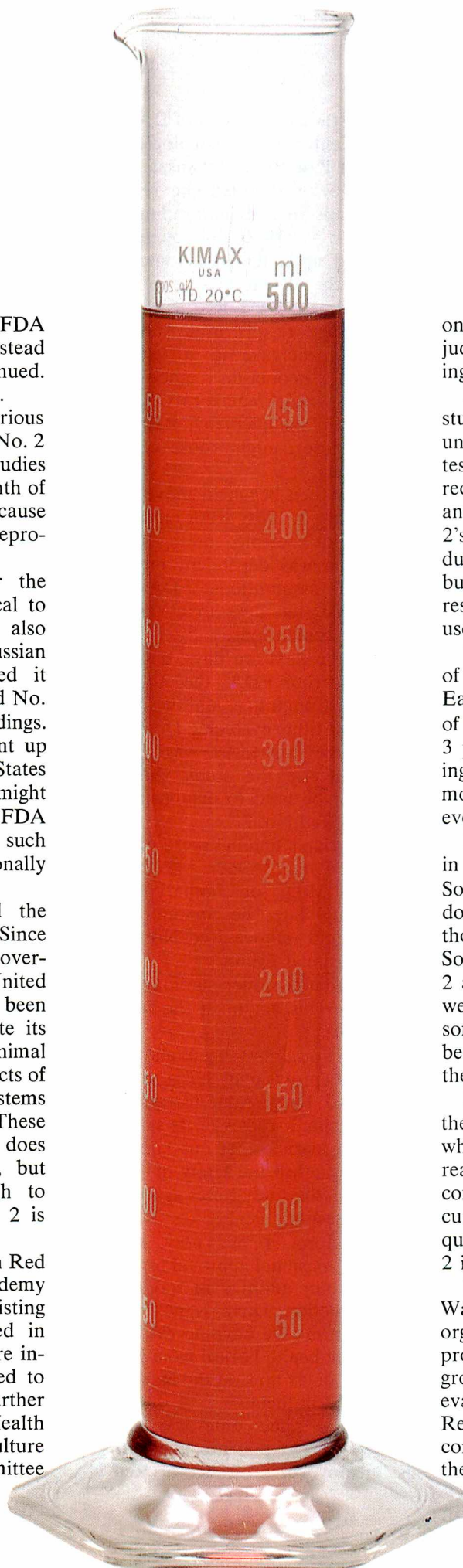
very little action was taken by FDA to list colors permanently, but instead their provisional listing was continued. Such was the case with Red No. 2.

In 1970, reports raising serious questions about the safety of Red No. 2 were received. Reports of two studies conducted in Russia on an amaranth of unknown purity showed it to cause cancer, and to be harmful to the reproduction system of animals.

FDA was uncertain whether the color used in Russia was identical to that used in this country, and also questioned other aspects of the Russian studies. FDA, therefore, decided it could not take action against Red No. 2 on the basis of the Russian findings. But the Russian studies did point up the lack of studies in the United States on the effects color additives might have on reproduction systems. FDA then required companies to start such studies for all colors still provisionally listed, including Red No. 2.

The Russian studies marked the turning point for Red No. 2. Since then, it has been the most controversial color additive used in the United States. Many animal studies have been conducted since 1970 to evaluate its potential hazard, including animal feeding studies to examine the effects of Red No. 2 on the reproduction systems and over the lifetime of animals. These studies indicated that Red No. 2 does not pose a hazard to humans, but neither did the studies establish to FDA's satisfaction that Red No. 2 is safe.

FDA sought outside opinion on Red No. 2, asking the National Academy of Sciences to review all the existing studies. The Academy concluded in 1972 that the Russian studies were inconclusive, and could not be used to evaluate Red No. 2, and that further study was needed. The World Health Organization/Food and Agriculture Organization Joint Expert Committee



on Food Additives deferred a final judgment on Red No. 2's safety pending completion of further studies.

In 1973, FDA initiated its own study on Red No. 2. FDA took the unusual action of conducting its own tests on a color additive because it recognized the need to resolve, once and for all, the question of Red No. 2's safety. FDA normally requires industry to conduct such tests, since the burden for proving a color's safety rests, by law, on those who wish to use it.

The FDA study involved the feeding of Red No. 2 to five groups of rats. Each group received a different dosage of the additive, ranging from zero to 3 percent of the diet. The rats receiving the highest doses received much more Red 2 than any consumer could ever get from food.

During this study, a mixup occurred in the rations fed to some of the rats. Some that were to receive the highest doses were inadvertently mixed up with those receiving somewhat lower doses. Some that were to receive no Red No. 2 at all were mixed up with some that were to receive small amounts. Also, some of the rats in the study could not be adequately examined to see whether there were any adverse effects.

Even though FDA knew of flaws in the study, it completed the study to see whether any conclusions could be reached. While the study was being completed, two other events were occurring which would raise further questions about the safety of Red No. 2 in the public mind.

The Health Research Group, a Washington-based consumer advocacy organization, petitioned the Agency to prohibit further use of Red No. 2. The group concluded on the basis of its own evaluation of previous studies that Red No. 2 could cause cancer. (FDA considered the assumptions used by the health group to be invalid.)

Meanwhile, at the request of Senator Gaylord Nelson, who long has been interested in the safety of food and color additives, the General Accounting Office (GAO)—the investigatory arm of Congress—conducted an investigation of FDA's handling of Red No. 2. In a report issued October 20, 1975, GAO noted that FDA had permitted the use of Red No. 2 for 15 years—since enactment of the 1960 Amendments—without making a final determination of its safety. GAO said:

"FDA has repeatedly extended the interim period for using Red No. 2 in food, drugs, and cosmetics on the basis of requests from manufacturer or industry associations to allow time to complete scientific investigations concerning its safety. In some cases, however, the requests did not identify investigations underway or indicate when they were to be completed."

GAO also pointed out that since 1970 some studies had raised questions about the safety of Red No. 2. "Permitting its continued use for an extended period while questions concerning its safety remain unresolved results in unnecessary risks to the public health," GAO concluded.

GAO recommended that FDA "act promptly to establish the safety of Red No. 2 or take appropriate regulatory action to prevent its use in food, drugs and cosmetics."

Even before the GAO report was issued, FDA decided that in view of the wide public interest in Red No. 2, it would seek non-FDA advice on whether use of the color posed any hazard. It decided to make Red No. 2 the first task for the newly-formed Toxicology Advisory Committee, established to advise FDA on the safety of chemicals used in foods, drugs, cosmetics, and medical devices. The Committee met November 20 and 21, 1975, reviewed the data, and concluded on the basis of its initial evaluation that there was no evidence that continued use of Red No. 2 posed a health hazard.

However, the Committee asked that three analyses be done, among them a biostatistical analysis of the data from FDA's own recently-completed study. This analysis was conducted by Dr. David W. Gaylor, principal bio-

logical statistician with FDA's National Center for Toxicological Research in Pine Bluff, Arkansas.

Dr. Gaylor reported the results of his analysis in a memorandum dated December 31, 1975. He concluded:

"Based upon the pathological findings of the recent study, it appears that feeding FD&C Red No. 2 at a high dosage results in a statistically significant increase in a variety of malignant neoplasms among aged Osborne-Mendel female rats." In other words, he concluded that Red No. 2, at high doses, might cause cancer in female rats.

Events then began to move swiftly. On January 8, 1976, FDA made public Dr. Gaylor's memo, noting that his conclusion was dependent on certain biological assumptions. FDA said it would take ten days to evaluate Dr. Gaylor's conclusions.

Over the next ten days, a group of scientists from FDA, the Toxicology Advisory Committee, and the National Cancer Institute evaluated Dr. Gaylor's work. One consensus was reached: Whatever else the study showed, it could not be used to demonstrate the safety of Red No. 2.

The group's findings were presented to FDA Commissioner Alexander M. Schmidt, M.D., on January 16 and three days later he announced that FDA would remove Red No. 2 from the provisional listing.

The Commissioner summarized the reason for his action in the following statement:

"Red No. 2 has been allowed for use on a provisional basis while the Food and Drug Administration conducted animal studies of its safety. We have just learned that our latest study cannot establish the safety of Red No. 2. Indeed, the study raises again certain safety questions.

"Therefore, I am now revoking FDA's provisional approval for all uses of this color additive in foods, drugs and cosmetics. There is no need for public alarm. We have no evidence of any public health hazard from foods or other products now on the market with Red No. 2 in them.

"At the same time we have no studies in sight that are likely to give us unequivocal assurance of Red No.

The use of Red No. 2 in food dates back some 80 years, when it was known by its common name of amaranth. Amaranth is a rust-colored powder that can be mixed with water to produce various shades of red for use as a coloring agent. Over the years, Red No. 2 has been used in a variety of products, but it was most widely found in sweets and snack foods.





Among the products in which Red No. 2 has been used are candy; carbonated and noncarbonated drinks; cookies, cupcakes, and similar baked goods; imitation jelly; gelatin; ice cream; hot dogs; and cold-pack cheese with wine. Although FDA has banned the use of Red No. 2 in food, its use is still permitted in a number of countries, including Canada.

2's safety. Consequently, under the law, there is no longer a justification for continued provisional approval of the color.

"The burden of proof clearly belongs with those who claim that Red No. 2 has a safe and useful place in our food supply and in our drugs and cosmetics."

The Commissioner said that, effective with publication of a notice in the *FEDERAL REGISTER*, no food, drug, or cosmetic could legally be formulated using Red No. 2. Any product made with Red No. 2 after publication of the notice would be considered by FDA to be adulterated, and subject to legal action.

That notice was scheduled to be

published January 28, but three companies that make or use Red No. 2—Warner-Jenkinson of St. Louis, H. Kohnstamm & Company of New York, and Monarch Nugrape of Doraville, Georgia—plus a trade association, the Certified Color Manufacturers Association, took FDA to court. They said FDA had not followed the proper administrative procedure in banning Red No. 2, and that the action was not necessary to protect the public health.

The court stayed the ban while the case came before the U.S. District Court for the District of Columbia, and then the U.S. Circuit Court of Appeals. The Appeals Court ruled on February 11 that the ban could take effect, and that it would hear arguments on the

Questions of What and Why

What consumers most often ask FDA about Red No. 2 is the identity of the products that contain this color. The law does not require manufacturers to tell FDA what colors they are using in food. Neither does the law require that the specific color used in a food be named on the label. Therefore, there is no list of foods containing Red No. 2.

Another question asked about the ban on Red No. 2 is why FDA permits the use of any color, when the sole purpose is to enhance a product's appeal to the consumer's eye. The decision that color additives should be permitted in products was made not by FDA but by Congress. FDA's role, as assigned by Congress, is to assure that colors are safe for their intended purposes, and that they do not cover up damage or inferiority in a product or otherwise deceive the consumer. In banning Red No. 2, FDA is carrying out this responsibility, just as it carries out this responsibility in approving the use of a color if adequate data are submitted to demonstrate its safety.

Red No. 40 Being Studied

The Food and Drug Administration announced February 28 that it is evaluating new information which raises questions about the safety of Red No. 40, an artificial color used in food, drugs, and cosmetics. Red No. 40 is the principal alternative to Red No. 2.

The new data was presented to FDA February 25, 1976, by Allied Chemical, which holds the patent on Red No. 40. The data shows that after 41 weeks of a 78-week feeding study involving 400 mice, six of the animals had developed premature and unexpected malignant lymphomas.

FDA asked Allied to move as quickly as possible to sacrifice additional mice from the study to determine the significance of these highly preliminary findings. The work will require a minimum of 30 days.

The study is being conducted for Allied by Hazleton Laboratories of Vienna, Virginia.

The Agency cautioned that no conclusions about the safety of Red No. 40 could be reached on the basis of the interim report.

Allied undertook the study at the request of the World Health Organization, the Food and Agriculture Organization, and the Canadian government, which has not approved Red No. 40 for use in that country.

merits of the industry's case April 15. A last-ditch appeal by the industry groups to U.S. Chief Justice Warren Burger to permit continued use of the color while the case was being argued in the courts was turned down. The ban took effect February 12.

While the case was in court, the Canadian government announced that it would not take similar action in that country. Canada concluded "there is insufficient evidence available at this time to justify removal of the food color." The Canadians had previously concluded that Red No. 2 was safe, and therefore, clear evidence was needed of its lack of safety for that government to take action. FDA, on the other hand, is required by law to seek a

clear determination that Red No. 2 is safe.

The issue of whether Red No. 2 causes cancer appears to be the main source of confusion about the ban. When scientists evaluate a study to determine whether a substance causes cancer, they look for many things. They look to see whether the study turned up an increase in tumors among the animals that received the highest doses, when compared to the low-dose group. They also search for any unique or unusual tumor sites—whether there was an increase in tumors in any particular organ—and whether the tumors discovered were unusual for that species of animal.

The group that evaluated Dr. Gay-

lor's analysis said there was a statistically significant increase in malignant tumors among the female rats that received a high dose of Red No. 2. This would tend to implicate Red No. 2. But the group observed that there are four reasons to suspect that Red No. 2 does not cause cancer: There was no statistically significant increase in malignant tumors among male rats; there were no unusual or unique tumors observed; there was no increase in tumors in any particular organ among the high-dose animals; and, if the malignant and benign tumors were combined, there was no statistically significant difference in number of tumors between the high-dose and low-dose rats.

Similar observations were made by Canada in concluding that the FDA study does not demonstrate that Red No. 2 caused cancer. The Canadians pointed out in a public statement that Red No. 2 is similar in chemical structure to other dyes that have been shown not to cause cancer, and is different from dyes that have been shown to cause it. The Canadians also pointed out that almost all substances known to cause genetic mutations also cause cancer. Since studies showed that Red No. 2 does not cause genetic mutations, it is not likely to cause cancer, Canada concluded.

The best that can be said is that the evidence on Red No. 2 as a cancer-causing agent is equivocal. There is some reason to suspect that it may cause cancer, but also considerable evidence to suggest that it does not. What is important is that in order for FDA to act it did *not* have to conclude that Red No. 2 was a hazard. The FDA ban was based on a law that requires a color additive to be established as safe for its intended use. So, as long as the evidence on Red No. 2 is equivocal, by law it cannot be permitted in the American food, drug, and cosmetic supply.

So rests the Red No. 2 story. If it is to be added again to the American food, drug, and cosmetic supply, its safety must be demonstrated by those who wish to use it.

Emil Corwin and Wayne Pines are in FDA's Office of Public Affairs.

News Highlights

X-ray Operators' Self-Study Plan Developed

X-ray technologists will have an opportunity to upgrade their education through a self-assessment program developed by the American Society of Radiologic Technologists (ASRT) under contract with FDA.

The training program consists of:

- A self-evaluation test of 293 questions divided among 10 subject matter categories.
- A report from either the ASRT or the educational program administering the test providing the technologist with his or her score in each subject area and the correct answer to each question.
- A bibliography of educational materials for each category.

By using this program, x-ray technologists will be able to determine their areas of weakness and select educational materials that may help correct deficiencies. The program was tested on 200 x-ray equipment operators and their overall response to this method of continuing education was highly favorable.

The ASRT is evaluating the self-evaluation test for inclusion in its larger Evidence of Continuing Education (ECE) program through which x-ray technologists receive credit for participating in various educational activities. FDA also is exploring other means of making the materials available to as many medical x-ray machine operators as possible.

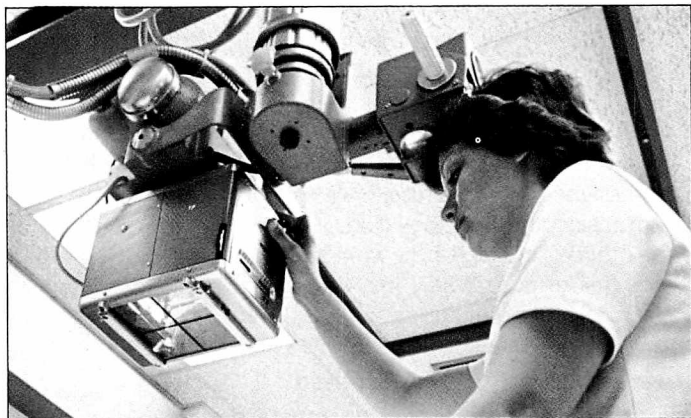
FDA Seeks End to Use of Four Animal Drugs

FDA has proposed to withdraw approval of the use of four antibacterial drugs used in chickens, turkeys, and swine to fight disease and promote growth. The drugs—all of which are nitrofurans—also are used to treat mammary gland infections in dairy cattle.

The nitrofurans affected by the FDA proposal are nitrofurazone, furazolidone, nihydrazone, and furaltadone.

FDA first proposed to withdraw approval of the four nitrofurans in 1971. In response to that proposal, the drug manufacturers requested a hearing. They submitted additional scientific data in support of their request, and also conducted new safety studies which resulted in further, extensive submissions of data. FDA has now evaluated all the additional information submitted by the manufacturers. The revised proposal to withdraw the drugs is based on a review of all pertinent information available to the Agency.

The proposed ban will be based on a determination that no adequate test exists for detecting residues of the drugs that may remain in edible animal tissue after slaughter. Under the law, a cancer-causing drug may be used in food-producing animals only if it can be shown that no residues will be detected by an adequate test method approved by



FDA. Nitrofurans have been found to cause cancer in laboratory animals.

FDA said that there is no evidence that other antibacterials pose the same problem.

FDA is required to give manufacturers of the drugs 30 days to request a hearing. If no hearing is requested, the ban will be made final after the 30-day period. If a request for a hearing is made and justified to FDA, the Agency will hold the hearing as quickly as possible.

Cancer Unit Submits Report on Cyclamate

The National Cancer Institute (NCI) has concluded that present evidence does not establish the cancer-causing potential of cyclamate in experimental animals, but NCI could reach no conclusion about cyclamate's cancer-causing potential in humans.

These findings are contained in the final report to FDA from NCI's special committee reviewing the cancer-causing potential of cyclamate. This review was undertaken at FDA's request after Abbott Laboratories petitioned FDA to allow a return of the sweetener to the American market.

NCI said a definitive assessment of cyclamate's cancer-causing potential for humans is not now possible because of "state-of-the-art problems we have had and will continue to have with compounds that at worst *may* be weakly carcinogenic in animals."

FDA will evaluate the NCI report along with all other information on cyclamate. This includes data on its possible relationship to hypertension and on effects reported on the reproductive system of test animals. After a complete evaluation of all available data, FDA will decide whether to allow cyclamate to be marketed as an artificial sweetener.

FDA to Act Against PCB's in Fish

FDA has announced that it will act against all fish shipped in interstate commerce that are found to contain poly-

chlorinated biphenyls (PCB's) in excess of 5 parts per million (ppm).

This is one of a series of decisions on PCB's announced by FDA. The Agency also said it:

- Has confirmed the problem of PCB contamination and supports the recent New York State action to ban commercial fishing, except for shad, from the Hudson River, and to advise sportsfishermen to restrict their consumption of fish caught in the Hudson and salmon caught in Lake Ontario.

- Is investigating the extent of the PCB problem in freshwater fish in other areas of the country, and will encourage and support other States in taking action similar to New York's wherever significant problems of fish contaminated with PCB's exist. Fish shipped intrastate is a State responsibility.

- Is considering lowering the present tolerance levels for PCB's in fish and other foods as a result of recent studies which indicate that PCB's may be more toxic than previously believed.

PCB's are toxic industrial chemicals which are widely used in a variety of manufacturing processes and products. Because they are highly stable, and because their industrial applications have, in the past, been largely uncontrolled, PCB's have become a persistent environmental contaminant that in some cases has reached the food supply.

The known toxic effects of PCB's in humans include an acnelike skin eruption, pigmentation of the skin and nails, excessive eye discharge, and swelling of eyelids.

Since FDA first proposed tolerances in 1972, levels of PCB's in the American diet have decreased markedly. The problem of PCB's in freshwater fish remains a concern, however, because of continued industrial discharges of PCB's into lakes and rivers. Most fish intended for human consumption come from salt waters, which have not been found to be contaminated with PCB's.

For several months, FDA has been working with New York to determine the extent of the PCB problem in the Hudson River and Lake Ontario. FDA's evaluation of test results for fish caught in the Hudson River showed that 53 out of 68 samples contained PCB's in excess of the current FDA tolerance level of 5 ppm, with an average PCB level of 31.3 ppm. Samples of salmon taken from Lake Ontario ranged from 2.1 to 24.6 ppm PCB's. Since past analyses of shad had shown low PCB levels, the New York ban does not include shad. FDA has offered to assist New York in monitoring the 1976 spring run of shad for PCB levels.

FDA recognizes that the contamination of fish with PCB's will persist unless controls are initiated to curtail pollution of the environment with PCB's. Therefore, the full scientific resources of FDA continue to be available to the Environmental Protection Agency to assist that Agency in its efforts to control PCB discharges into the environment.

Sequential Birth Control Pills Discontinued

All three U.S. manufacturers of sequential birth control pills have notified the FDA they are discontinuing marketing of these products.

It is estimated that 5-10 percent of the 10 million women taking birth control pills in the United States are taking sequentials.

The products to be withdrawn from the market are: Ora-

con, made by Mead-Johnson and Co., Evansville, Indiana; Ortho-Novum SQ, made by Ortho Pharmaceuticals, Raritan, New Jersey; and Norquens, made by Syntex Laboratories, Palo Alto, California.

Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, said: "We asked the makers of sequentials to withdraw their products because they pose an unnecessary potential risk compared with other marketed birth control pills. I believe the companies have acted responsibly in voluntarily taking the withdrawal actions."

"Women who are taking sequentials should finish out their cycles and contact their physicians for a prescription for a different birth control pill, or select another method of contraception," Dr. Schmidt said.

Sequential birth control pills contain an estrogen alone for most of the pill-taking cycle, and an estrogen and progestin for the remaining part of the cycle. The other birth control pills, known as "combination" pills, combine estrogen and progestin for the entire three-week cycle.

FDA decided that sequentials should be removed from the market after concluding:

- They are somewhat less effective than combination birth control pills.

- They are associated with a higher risk of blood clotting than the combination pills.

- They appear to have the potential for a higher risk of cancer of the uterus than the combination pills.

In late December, FDA asked the three U.S. manufacturers of sequentials to submit information identifying which women are likely to benefit from taking sequentials compared to the combination pills. All three companies submitted data but did not prove to FDA's satisfaction that the sequentials meet a unique requirement for any group of women.

FDA informed the companies of its conclusion and asked that the products be withdrawn. The three companies then notified FDA they will take the voluntary withdrawal action.

FDA did not ask the companies to recall existing stock because there is only about two-months supply of sequentials on the market.

Meeting to Review Handling of Poison Data

Toxicologists and those interested in information about toxicology are invited to attend a Symposium on the Handling of Toxicological Information to be held May 27-28, at the National Institutes of Health, Bethesda, Maryland. Sponsored by the Toxicology Information Subcommittee of the Department of Health, Education, and Welfare, the symposium will provide a forum for those in industry, academic institutions, and government who collect, manage, or use information on poisonous substances. The two-day program, will survey current methods of handling toxicological information and predict needs for new services.

There are no registration fees, but since attendance is limited by the size of the auditorium advance registration by May 15 is required. The meetings will be held in the Masur Auditorium of the Clinical Center, National Institutes of Health. Additional information on the symposium and on registration can be obtained by writing to George J. Cosmides, National Library of Medicine, National Institutes of Health, 8600 Rockville Pike, Bethesda, Maryland 20014.

Regional Reports

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

REGION I

FDA's **Boston District** detained several lots of food products offered for import from Hong Kong when laboratory analyses found they contained insect fragments, whole insects, and animal hairs, or were in violation of the Fair Packaging and Labeling Act. The products, valued at over \$48,000, included soup mix, wet bean curd, and fried carp. Also detained for similar reasons were lots of mango pickles and frozen frog legs valued at approximately \$2,500 and offered for import from India. Other products detained included sharp brie cheese tarts offered for import from West Germany and valued at \$2,475 because of decomposition; swordfish offered for import from Japan because of excessive mercury content; frozen langostinos (small lobsters) offered for import from Chile and valued at \$30,000 because of contamination by bacteria, *E. coli*; and finally \$15,000 worth of frozen frog legs offered for import from Bangladesh because of the presence of *Salmonella* micro-organisms.

REGION II

A U.S. marshal seized all food products stored at J. Raphael & Sons, Inc., a spice grinder and repacker at

Brooklyn, New York, after a routine inspection by FDA's **New York District** found rodent infestation, including live and dead mice, in the lots of food, valued at approximately \$50,000.

FDA's **Buffalo District** denied entry into the United States of 960 cases of canned mushrooms, stems and pieces, valued at \$11,000, because of adulteration by cat hairs. In addition, the labeling failed to declare that ascorbic acid was used as a preservative and the product did not meet the standard for fill of container. The mushrooms were offered for import from the Dominican Republic.

Famous Overseas, Inc., Hoboken, New Jersey, a repacker and distributor of imported food products, has been ordered by a court injunction not to receive or distribute any food products until the firm eliminates extensive rodent and insect infestations discovered during a routine inspection by FDA's **Newark District**. Investigators also found numerous lots of food products contaminated. The permanent court injunction granted by Judge Herbert J. Stern in the U.S. District Court for the District of New Jersey also requires that all food products stored at the firm be inspected by FDA before they can be sold.

REGION III

A routine inspection by FDA's San Francisco District at Contadina Foods, Inc., Riverbank, California, led to Government seizure of 1,344 cases of tomato sauce in possession of Carnation Co., Mechanicsburg, Pennsylvania, because of mold contamination. Investigators discovered insanitary packaging conditions at the California plant, which had shipped a lot of the sauce to the Pennsylvania firm. FDA's

Philadelphia District, informed of the possibly contaminated lot, collected a sample and returned it to San Francisco where laboratory tests confirmed the presence of mold.

REGION IV

The North Carolina Department of Agriculture and North Carolina State University, in conjunction with FDA's Philadelphia and **Atlanta Districts** and the U.S. Department of Agriculture, recently sponsored three feed workshops designed to alert the North Carolina feed industry to potential problems involving medicated feeds. The workshops covered use and misuse of drugs in feed, residues of drugs in animal tissues used in foods, labeling of medicated feeds, pesticide residues, and requirements established by FDA Good Manufacturing Practice Regulations. A total of approximately 220 feed mill operators attended workshops in the North Carolina towns of Goldsboro, Statesville, and Harpers Cross Roads.

The Federal Government has seized 34,000 eight-ounce packages of frozen flounder stuffed with crabmeat, packed by Singletown Packing Corp., Tampa, Florida. Investigators for FDA's **Orlando District** observed insanitary conditions during a routine inspection of the company plant. This prompted them to collect samples for laboratory analysis which revealed the presence of harmful bacteria. The packing company has requested FDA's approval to recondition the fish, valued at approximately \$33,900. In addition, the firm voluntarily destroyed 5,676 15-ounce packages of frozen deviled crabmeat that also was found to contain harmful bacteria.

The municipally owned warehouses at the Port of Pensacola, Florida, are



operating again after eliminating rodent infestations in several lots of rice in one warehouse and insanitary conditions in general discovered by Orlando District investigators during a routine inspection. Following the inspection, the State of Florida embargoed over 90,000 bags of rice destined for export. The rice was eventually reconditioned by the owners, Continental Grain, under supervision by the U.S. Department of Agriculture. FDA's inspection resulted in withdrawal by the Department of Agriculture of its grading service without which the Port facility could not operate. A week later, the Agriculture Department surveyed the warehouse area and reinstituted the grading service, after finding all rodent and rodent harborage points in the dock area had been eliminated.

REGION VI

The U.S. marshal for the Northern District of Oklahoma seized approximately 140 one-pound bags of rodent-infested pecans in possession of Safeway Stores, Inc., Tulsa, after a routine inspection by FDA's **Dallas District**.

The Government seized 103 120-pound bags of black peppercorns and 37 100-pound bags of Michigan navy beans in possession of Arrow Industries, Carrollton, Texas, after a routine inspection by Dallas District investigators revealed rodent defilement in the bags. Some of the goods were reconditioned under FDA supervision. A planned follow-up seizure of popcorn and pinto and navy beans by the Government at the same warehouse failed when U.S. marshals discovered the contaminated goods had already been moved.

Inspections by investigators from FDA's **Houston District** office revealed

that the Blue Ribbon Rice Mills, Inc., Houston, processed rice under insanitary conditions and shipped it in interstate commerce. The company was found guilty on three counts and was fined \$1,500 by U.S. District Court Judge John V. Singleton, Jr., for the Southern District of Texas, Houston Division.

Harold M. Falik, president of Sidney Myers, Inc., Houston, entered a no contest plea before U.S. District Court Judge H. Lingo Platter for the Southern District of Texas for holding several lots of rodent-defiled food in the company's warehouse. Falik was fined \$25 by Judge Platter. In an earlier court action, prompted by a routine warehouse inspection by FDA investigators, the corporation and two other executives pleaded guilty to the same charges.

A follow-up investigation of a consumer complaint to FDA's **New Orleans District** led to the voluntary destruction of \$3,400 worth of assorted candies by Pelican Tobacco Co., Alexandria, Louisiana. The consumer reported insects in a candy bar, which led investigators to the retail store where the candy was bought. Finding no evidence of insect contamination there, investigators traced the candy to the wholesale supplier, Pelican Tobacco Co., where the live insect activity was discovered. Further investigation revealed the problem came from the firm's practice of placing goods that had been returned because of insect damage in the candy storage area which resulted in insect contamination of new candy.

REGION VII

The Government seized over \$2,000 worth of unpopped popcorn, manufactured by TNT Food Products,

Lawrence, Kansas, after an inspection and sample examination by FDA's **Kansas City District** revealed the presence of whole adult insects, larvae, insect excreta, and webbing in the popcorn. The inspection was prompted by a consumer complaint to FDA's Kansas City District office which also resulted in Government seizure of additional lots of infested popcorn at dealer firms in Massachusetts, Maryland, California, Alabama, and Missouri.

During a routine inspection of Quality Plus Products, Fort Dodge, Iowa, a Kansas City District investigator discovered the firm's Neo-Oxy, an animal feed premix, was adulterated and misbranded with the antibiotic chlortetracycline. The firm immediately recalled the product at the wholesale level.

Dai-Moore Pharmaceutical Co., Mission, Kansas, voluntarily destroyed approximately \$1,200 worth of human and veterinary drugs after a Kansas City District investigator found, during a routine inspection, that the drugs had outdated expiration dates and were stored on the same shelves with other drugs being held for sale.

REGION VIII

Inspections by FDA's **Denver District** revealed that the Bennett Distributing Co., Denver, Colorado, a repacker and distributor of candy and nuts, was exposing food to contamination by insects and rodents. The company and its president, Albert W. Bennett, were found guilty on three counts by U.S. District Court Judge Fred W. Winner. The company was fined \$500 on each of two counts, and Bennett was fined \$250 on one count. Three other charges against the company, and four others against the president were dismissed.



Inspections by Denver District investigators resulted in criminal conviction of the Little Dutch Boy Bakeries, Inc., Draper, Utah, for making, packing, and storing cookies under insanitary conditions, and for using ingredients which were exposed to contamination. The corporation pleaded guilty to seven counts and was fined a total of \$2,100 by U.S. District Court Judge Willis W. Ritter. Charges against the two absentee owners were dismissed by Judge Ritter, who also instructed the jury to find the plant manager not guilty of similar charges if it decided the Government did not prove intent in the case. The verdict was not guilty.

REGION IX

Luminex International, Inc., Las Vegas, Nevada, a manufacturer of

prosthetic intraocular lenses, voluntarily recalled 446 vials of a contaminated neutralizing solution used to sterilize the lenses, which are surgically implanted in the eyes of cataract patients. The manufacturer issued recall letters to 160 consignees following an investigation by the California Department of Health, Food and Drug Division, that revealed several complaints of injury and one loss of eyesight due to the presence of a mold introduced into the eyes from the solution. The State unit notified investigators from FDA's **Los Angeles** and **San Francisco Districts** who, in turn, visited over 150 consignees to assure the effectiveness of the recall. The 446 vials were returned to the manufacturer and subsequently destroyed under FDA supervision. An additional 50 vials were destroyed by a physician when the problem first became known. The

firm has also requested return of the remaining lots of intraocular lenses for reesterilization with ethyleneoxide gas, which eliminates the need for the neutralizing solution.

REGION X

A total of 33,445 pounds of insect-adulterated food products, including flours, bread and pastry mixes, powdered milk, nuts, and raisins, was voluntarily diverted to animal food use by Ruth Ashbrook Bakeries Corp., Seattle, Washington, following a routine inspection by FDA's **Seattle District**. Investigators discovered live insect infestations in the firm's basement where raw materials were stored.

State Actions

Prison Cannery Inspected

The Colorado Department of Health sought the assistance of FDA's Denver District office to inspect Colston Products, a cannery operated by the State, at the State Penitentiary in Canon City. Consumer Safety Officer Nicholas Nance made a joint inspection of the plant with the State Department of Health which showed that the cannery had virtually no controls over its food processing. Products of this cannery include low-acid canned vegetables which are used in many State-supported schools and institutions. No distribution is made to private consumers. FDA furnished a detailed report of deficiencies to the State Health Department.

Soft Drink Bottler Fined

Squirt Vernors, Buffalo, Inc., a bottler of soft drinks, was fined \$700 by the New York State Department of Agriculture and Markets after a routine State inspection revealed in-

sanitary conditions at the bottling plant. State investigators discovered insects, mold, broken glass, and chipped paint in and around the beverage production area. The firm was also ordered to improve its pre-wash procedure and to destroy 70 pounds of the chemical preservative sodium benzoate, which had been exposed to a container of hydrated lime. The State inspection had been conducted under contract with FDA. The company bottles Pepsi Cola, Crush, Squirt, Vernors, and Schweppes Ginger Ale and Hires Root Beer.

Cooperative Workshop

A five-day Federal-State Laboratory Workshop on identification of insect fragments in food was held at FDA's Kansas City Laboratory. Laboratory personnel from the Nebraska Agriculture Laboratory, the Kansas Division of Public Health, the Missouri Division of Health, and the Iowa State Chemical Laboratory, joined FDA chemists from the Kansas City Laboratory in a

training course for microscopic identification of insect fragments in food. The course was conducted by FDA's Bureau of Foods.

Metal Poisoning Traced

The State of Louisiana investigated a mild case of metal food poisoning in one public school resulting from a student drinking a soda from a carbonated beverage vending machine. State Health officials discovered copper was apparently leaching from the machine into the carbonated drink. A follow-up investigation by FDA's New Orleans District revealed that the machine, distributed by Artic, Inc., and manufactured by Freeze King of Chicago, was a soft ice cream machine converted to a carbonated beverage "slush" machine by Artic, Inc., an adaptation not intended in the original design. FDA investigators discovered that the agitator in the machine, a metal device containing 60 percent copper, was reacting with the carbonic acid in the drink and causing the copper poisoning.

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 37 actions to remove from the consumer market products charged to be violative was reported in February. These included 32 seizures of foods: 1 involved charges concerning poisonous and deleterious substances, 29 involved charges concerning contamination, and 2 involved charges concerning economic and labeling violations. Other seizures included 2 of food additives, and 3 of drugs.

PRODUCTS, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD/Poisonous and Deleterious Substance		
Wheat, bulk/Ammon, Idaho 10/30/75	Returned to Iona, Idaho from Salt Lake City, Utah.	Contains the added poisonous and deleterious substance mercury.
Contamination, Spoilage, Insanitary Handling		
Baking mix, white cake mix, cereal/ St. Louis, Mo. 10/21/75	Dolgin Grocery & Tobacco Co., Inc./ St. Louis, Mo. (D)	Held under insanitary conditions; insect contaminated.
Butter, milk fat, American cheese/ Seattle, Wash. 8/1/75	Consolidated Dairy Products Co./ Seattle, Wash. (M,D)	Decomposed.
Candy pacifier, Lic-A-Nip/Mount Dora, Fla. 7/14/75	Pico Plastic Excl. Ravico/Brussels, Belgium, (M); The Paul Spitz Co., Inc./Bronx, N.Y. (S)	Unfit for food; presents choking and aspiration hazards to infants and small children.
Chicken breeding/Dallas, Tex. 12/17/75	Al Semtner Drug Depot/Dallas, Tex. (D)	Held under insanitary conditions; insect and rodent contaminated.
Cocoa/Raleigh, N.C. 10/22/75	Van Dutch Products Corp./Bronx, N.Y. (M,S)	Insect contaminated.
Coffee beans/St. Paul, Minn. 9/16/75	New York Tea Co./St. Paul, Minn. (D)	Held under insanitary conditions.
Nashville, Tenn. 10/2/75	A.C. & Leon Israel Coffee Co./New Orleans, La. (S)	Held under insanitary conditions; rodent contaminated.
Crabmeat, canned/Seattle, Wash. 8/19/75	Taisin International, Inc./Taipei, Taiwan (S)	Rodent and insect contaminated; decomposed.
Flounder, stuffed with crabmeat/ Tampa, Fla. 12/12/75	Tampa Cold Storage/Tampa, Fla. (D)	Contains <i>E. coli</i> and bacterial filth; prepared and packed under insanitary conditions.
Fruitcake/Davenport, Iowa 8/29/75	Bonnie Bakeries, Inc., Davenport, Iowa (M,D)	Moldy.
Grain, salt, barley, and misc. items of food/Atlanta, Ga. 9/25/75	Nelson Brokerage Co./Atlanta, Ga. (D)	Held under insanitary conditions.
Green pepper strips, sliced, canned/ S. Boston, Mass. 11/19/75	Imported from Yugoslavia.	Swollen and leaking cans.
Ice cream cone mix/Chattanooga, Tenn. 12/22/75	Specialty Mix Co./New Orleans, La. (M,S)	Prepared, packed, and held under insanitary conditions.
Mushrooms, marinated/Laredo, Tex. 9/16/75	Imported from N. Laredo, Mexico.	Jars with swollen and leaking lids.
Orange soda and Coca Cola/Wichita, Kans. 8/29/75	Wichita Coca Cola Bottling Co./ Wichita, Kans. (D)	Prepared and packed under insanitary conditions; moldy.
Peaches, canned/Kirkwood, Mo. 12/1/75	Contadina Foods, Inc./Riverbank, Calif. (M,S)	Prepared and packed under insanitary conditions; contains <i>Geotrichum</i> mold.
Peanut butter/Minneapolis, Minn. 9/26/75	Sunstar Foods, Inc./Sioux City, Iowa (M,S)	Prepared and packed under insanitary conditions; insect contaminated.
Pinto beans, kidney beans, red beans/ Owensboro, Ky. 10/27/75	Shipped from Minn., Mich., and Idaho, respectively.	Held under insanitary conditions; rodent contaminated.
Pistachio kernels, almonds, peanuts/ Milwaukee, Wis. 12/18/75	Milwaukee Cold Storage Co./ Milwaukee, Wis. (D)	Held under insanitary conditions.
Popcorn/St. Louis, Mo. 12/17/75	TNT Food Products, Inc./Lawrence, Kans. (M,S)	Insect contaminated.
Los Angeles, Calif. 1/15/76	Flash Steak Co./Los Angeles, Calif. (D)	Insect contaminated.
Rice/Boston, Mass. 11/19/75	Port Terminals Inc./Boston, Mass. (D)	Held under insanitary conditions; insect contaminated.
Seafood coating mix/San Bruno, Calif. 7/28/75	Shipped from Millstadt, Ill.	Insect contaminated.
Sesame seeds/Cambridge, Mass. 11/19/75	Imported from Guatemala.	Held under insanitary conditions.

PRODUCTS, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Soda, Seven-Up/No. Kansas City, Mo. 9/10/75	The 7-Up Bottling Co. of No. Kansas City/No. Kansas City, Mo. (D)	Prepared and packed under insanitary conditions; moldy.
Tapioca flour/Houston, Tex. 12/5/75	Dixie Cone Manufacturing Corp./ Houston, Tex. (D)	Held under insanitary conditions; rodent contaminated.
Tomatoes, canned/San Antonio, Tex. 8/19/75	Imported from Spain.	Moldy.
Tomato sauce/Hopkins, Minn. 1/7/76	Contadina Foods, Inc./Riverbank, Calif. (M,S)	Prepared and packed under insanitary conditions; contains <i>Geotrichum</i> mold.
Whitefish steaks, breaded/Louisville, Ky. 12/29/75	Fish Processors, Inc./Louisville, Ky. (D)	Prepared and packed under insanitary conditions; contains <i>E. coli</i> and bacterial filth.

Economic and Labeling Violations

Shrimp, breaded/San Antonio, Tex. 9/29/75	Singleton Packing Corp./Tampa, Fla. (M,S)	Fails to conform to definition and standard of identity for breaded shrimp (contains less than 50 percent of shrimp material).
Spread (margarine)/Mount Kisco, N.Y. 1/7/76	Standard Brands, Inc./Pennsauken, N.J. (M,S)	Label fails to bear common or usual name; false and misleading claims.

FOOD ADDITIVES

Dairy powder, chocolate/Bridgeton, Mo. 9/16/75	Consolidated Flavor Corp./Granite City, Ill. (M,S)	Contains nonconforming food additive saccharin.
Onion rings/Old Monroe, Mo. 8/18/75	Sun Ring Foods, Div. of Tamara Foods, Inc./Old Monroe, Mo. (D)	Contains nonconforming food additive iodine.

DRUGS/Human Use

Viro-Zyme injectable/Dallas, Tex. 1/14/76	Marcen Laboratories, Inc./New Rochelle, N.Y. (M)	New drug without effective approved New Drug Application.
Kirkwood, Mo. 12/23/75 & 1/13/76	"	"
Gadsden, Ala. 1/14/76	"	"

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

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

- October 24, 1975: **International Laboratories**, P.O. Box 41-4176, Miami Beach, Florida 33141. Advertising and sale through the mail of an unnamed product representing the ability to grow hair and end scalp problems.
- October 29, 1975: **Jobbers Distributing Co., Inc.**, P.O. Box 1863-M, Durham, North Carolina 27702. Advertising and sale through the mail of the product "Korean Ginseng," representing the ability to instill an insistent and compelling need for immediate sexual satisfaction in females.
- November 14, 1975: **Original Cosmetic Products, Inc.**, P.O. Box 480, New York, New York 10029. Advertising and sale through the mail of the products "Song of Passion Tablets," "Instant Erection Oil," "Sugar Ginseng Tablets," "Jungle Passion Caps," "Spanish Fly Imitation," "All American Booster Caps" with Vitamin "E," and "Authentic Turnera Aphrodisiaca Caps," all representing the ability to increase and prolong sexual virility and potency.
- November 18, 1975: **Sundown Products**, P.O. Box 60-1051, N. Miami Beach, Florida 33160. Advertising and sale through the mail of the product formula "Vitamin Diet," representing the ability to effect substantial weight loss.
- November 18, 1975: **Roger's Laboratories, Inc.**, 15383 N.W. 7th Avenue, Miami, Florida 32903. Advertising and sale through the mail of the product "Prostaïd," representing the ability to effect treatment and cure in problems of urination, loss of sexual function, groin and back pains, and to relieve symptoms of benign chronic prostatitis.

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

- August 25, 1975: Against **Charles Laboratories**, P.O. Box 22546, Sacramento, California 95822. Advertising and sale through the mail of the product "Beautylift," representing the ability to remove blemishes, sagging skin, pimples, acne, wrinkles, dry skin, and other skin-related ailments.
- October 30, 1975: Against **Palafax-Knight Pharmaceutical Labs**, Drawer 460, Anthony, New Mexico/Texas 88021. Advertising and sale through the mail of the product "Pepso Pacific," representing the ability to cure and relieve constipation, ulcers, and other chronic digestive problems.
- November 14, 1975: Against **Joe Weider**, 21100 Erwin Street, Woodland Hills, California 91364. Advertising and sale through the mail of the product "Slimgard," representing the ability to cause profuse perspiration and break down cushions of fatty tissue for a considerable weight loss.

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Almonds, shelled, at Jacksonville, M. Dist. Fla.

Charged 9-11-75: when shipped by Valley Almond Growers Co-op., Winters, Calif., and while held for sale, the article contained the added poisonous and deleterious substance aflatoxins; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 60464; S. Nos. 76-43-801, 76-43-806; N.J. No. 1)

FOOD/Contamination, Spoilage, Insanitary Handling

Bean sauce, canned, at New York, S. Dist. N.Y.

Charged 4-21-75: while held for sale, the article was unfit for food, since it was in swollen cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60255; S. No. 44-743 H; N.J. No. 2)

Candy and gum in banks, at Memphis, W. Dist. Tenn.

Charged on or about 1-3-75 and amended on or about 1-17-75: when shipped by Old Dominion Peanut Corp., Norfolk, Va., the article, labeled in part "National Kidney Foundation Candy Bank . . . Manufactured . . . by Old Dominion Peanut Corp. . . . Norfolk, Virginia," was unfit for food by reason of containing metal fragments; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60163; S. Nos. 60-842/3 H; N.J. No. 3)

Candy pacifiers, Lic-A-Nip, at Mount Dora, M. Dist. Fla.

Charged 7-14-75: when shipped by the Paul Spitz Co., Inc., Bronx, N.Y., the article was unfit for food because it was prepared in a manner and a shape which presented choking and aspiration hazards to infants and small children; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60391; S. No. 4-200 H; N.J. No. 4)

Cheeses and other food stocks, at New York, S. Dist. N.Y.

Charged 6-26-75: while held by Krinos Foods, Inc., New York, N.Y., some of the articles contained rodent filth, and the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 60401; S. No. 46-061 H et al.; N.J. No. 5)

Filberts, shelled, at Brooklyn, E. Dist. N.Y.

Charged 11-15-74 and amended 2-25-75: when shipped by Harborside Terminal Management Co., Inc., Jersey City, N.J., and while held for sale, the article was held under insanitary conditions; 402(a)(4). The article was claimed by the shipper who denied the charge. The Government served written interrogatories on the claimant. Subsequently, a consent decree authorized release to the claimant for salvaging. (F.D.C. No. 60046; S. No. 43-671 H; N.J. No. 6)

Kidney beans, chick peas, and horsebeans, at Newark, Dist. Del.

Charged 3-25-75: While held for sale, the horsebeans contained rodent filth, and all the articles had been held under insanitary conditions by American International Specialties, Inc., Wilmington, Del.; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60294; S. Nos. 35-545 H, 35-548/9 H; N.J. No. 7)

Lentils, dried beans, puffed rice, and various other foods in bags, cartons, and bales, at Baltimore, Dist. Md.

Charged 12-18-75: while held by Sadana Bros. (Inder R. Sardana), Baltimore, Md., the articles were held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60571; S. No. 76-03-209 et al.; N.J. No. 8)

Lima beans, dried, at Tupelo, N. Dist. Miss.

Charged 11-4-74: when shipped by Arrow Food Products, Inc., Dallas, Tex., the article, labeled in part "Hyde Park . . . large lima beans . . . distributed by Malone & Hyde, Inc., Memphis, Tenn.," contained insect filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60051; S. No. 60-829 H; N.J. No. 9)

Milk, sweetened, condensed, canned, at Oklahoma City, W. Dist. Okla.

Charged 10-2-75: while held for sale, after having been involved in a train wreck in which some of the shipment was submerged under swamp water, the article was contained in swollen, leaking, rusted, pitted, and dented cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60494; S. No. 76-15-068; N.J. No. 10)

Mustard seed, crushed, at Muskogee, E. Dist. Okla.

Charged 9-10-75: while held by Griffin Manufacturing Co., Muskogee, Okla., who had crushed the mustard seed for use in manufacturing prepared mustard, the article contained insects, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the manufacturer for salvaging. (F.D.C. No. 60476; S. No. 76-14-956; N.J. No. 11)

Peppercorns and navy beans, at Carrollton, N. Dist. Tex.

Charged 9-30-75: while held for sale, the navy beans contained rodent filth and both articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Arrow Industries, Carrollton, Tex., for salvaging. (F.D.C. No. 60484; S. Nos. 76-15-446, 76-15-449; N.J. No. 12)

Pistachio kernels, shelled almonds, and shelled peanuts, at Milwaukee, E. Dist. Wis.

Charged 12-18-75: while held by Milwaukee Cold Storage Co., Milwaukee, Wis., the articles were held under insanitary conditions; 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 60566; S. Nos. 76-31-442/4; N.J. No. 13)

Sesame seeds, at San Juan, Dist. P.R.

Charged 12-20-74: while held by Nieves Hermanos, Inc., San Juan, P.R., 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. 60081; S. No. 25-014 H; N.J. No. 14)

Soda, Seven-Up, at North Kansas City, W. Dist. Mo.

Charged 9-4-75: while held by 7-Up Bottling Co. of North Kansas City, North Kansas City, Mo., who manufactured the article using beet sugar shipped in interstate commerce, the article contained mold and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for destruction of beverage and salvaging of the bottles. (F.D.C. No. 60448; S. No. 76-115 H; N.J. No. 15)

Soups of various kinds, Bon Vivant and Ancora, 2 seizure actions, at Jericho, E. Dist. N.Y., and Lake Ronkonkomo, E. Dist. N.Y.

Charged 2-7-75 and 2-11-75: when shipped by Bon Vivant Soups, Inc., Newark, N.J., the articles were unfit for food in that some cans of the Jericho lot were defective and abnormal, and in that the manufacturing procedures used for the articles did not assure proper sealing of the cans or adequate heat treatment of the sealed cans to prevent contamination and spoilage, and the articles had been prepared, packed, and held under insanitary conditions whereby they may have become contaminated with filth or whereby they may have been rendered injurious to health; 402(a)(3), 402(a)(4). Default decrees ordered destruction. (F.D.C. Nos. 60204/5; S. Nos. 70-209 G, 70-206 G; N.J. No. 16)

Spaghetti, at New York, S. Dist. N.Y.

Charged on or about 11-14-74: while held by Fred Day Co., New York, N.Y., the article contained insect filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60076; S. No. 53-346 H; N.J. No. 17)

Tomato sauce, Contadina, at Hopkins, Dist. Minn.

Charged 11-18-75: when shipped by Contadina Foods, Inc., 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. 60550; S. No. 76-29-810; N.J. No. 18)

FOOD/Economic and Labeling Violations

Bread, enriched, Schmidt's Blue Ribbon, at Baltimore, Dist. Md.

Charged 7-11-72: when set apart in the bakery of Schmidt Baking Co., Inc., Baltimore, Md., ready for delivery to Schmidt Baking Co., Inc., Distribution Center, Tasley, Va., the article's label statements, "Here's What Blue Ribbon's Powerful Energy Protein can do for you and your family Everybody needs protein. Needs it every day. Children need it for growth. Children and adults need it for repair and maintenance of muscles and other tissues in the healthy body. Bread has traditionally been a source of protein. But now the Blue Ribbon bakers have found a way to 'beef up' the protein in Blue Ribbon, to give you a better protein that the body can make more use of. It's called P.E.P. . . . Powerful Energy Protein." and "Blue



Ribbon also gives you Extra B Vitamins and Iron," were false and misleading in representing and suggesting that there is a general need for more protein in the diet; that the main function of protein is to supply energy; that the protein in the article had been significantly improved and would satisfy dietary needs of protein; and that the article supplied more B vitamins and iron than ordinary enriched bread—403(a); and the article was also in violation of the Fair Packaging and Labeling Act, since the principal display panel of the article lacked a statement of the identity of the article, i.e., enriched bread—15 U.S.C. 1453(a)(1). The baker claimed the article. Consent order authorized donation of all of the article, except 18 loaves, to a public institution. The claimant denied the charges. The parties served written interrogatories on each other. The Government moved for summary judgment. The court ruled against the Government saying:

"Plaintiff's motion for summary judgment sets out five allegedly false and misleading representations or suggestions. First, plaintiff contends that the label on the seized bread 'represents and suggests to the consumer that there is a general need for more protein in the diet.' Clearly, there is no direct statement on the label that there is a general need for more protein in the diet. Thus, it is necessary to determine whether the label would, taken as a whole, represent or suggest to the consumer such a need for more protein in the diet. To this end, the Court will evaluate the label in terms of its effect upon the 'often unthinking and gullible consumer.' See *United States v. Article . . . consist. of 216 Carton Bot.*, 409 F.2d 734 (2nd Cir. 1969); *United States v. Article of Drug*, 47 shipping cartons . . . , 331 F. Supp. 912 (D.Md. 1971). Applying this standard, yet keeping in mind the difficult burden which must be borne by a movant under Rule 56, this Court cannot conclude that there is no genuine dispute as to whether the label in question suggests or represents a need for more protein in the diet.

"The affidavits of claimant's experts, Drs. Britt and Twedt, state that the label on the seized bread neither suggests nor represents to the consumer that there is a general need for more protein in the average diet. In the opinion of the Court, these affidavits raise a factual dispute as to whether or not the label suggests or represents to even the gullible or unthinking consumer that there is a need for more protein in the diet. Plaintiff's motion for summary judgment cannot be granted on this point.

"Plaintiff alleges that the label on the seized bread 'represents and suggests that the main function of protein is to supply energy.' Claimant has presented the Court with the affidavits of two Professors of Marketing. These authorities state that the label in question does not suggest to the consumer that the main function of protein is to supply energy. In the opinion of the Court, these affidavits create a factual dispute as to whether the label suggests or conveys an overall impression to the gullible consumer that the main function of protein is to supply energy. For this reason, summary judgment as to this point is inappropriate.

"Plaintiff also alleges that the seized bread is 'misbranded in that the label represents and suggests to the consumer that the article will satisfy dietary needs for protein.' Since the Court is again dealing with the highly subjective questions of inference, suggestion, and impression upon a gullible consumer, within the context of a motion for summary judgment, it is necessary to conclude that such a summary disposition would not be warranted at this time. The affidavits of Drs. Twedt and Britt squarely dispute plaintiff's allegation concerning the nature of the representation or suggestion allegedly conveyed by the label on the seized bread. Therefore, the Court must conclude that summary judgment cannot be granted on this issue.

"Plaintiff next contends that the seized bread is misbranded in that it 'represents and suggests to the consumer that the protein in the article has been significantly improved.' Here the government's contention 'is based upon the plain and obvious meaning of the labeled statement, 'But now the Blue Ribbon Bakers have found a way to 'beef up' the protein in Blue Ribbon to give you a better protein that the body can make more use of. It's called P.E.P. . . . Powerful Energy Protein. And Blue Ribbon gives you this new improvement at no extra cost.'"

"In the opinion of the Court, the statement on the label

does represent and suggest that the protein in the seized bread has been significantly improved. However, for the government to sustain its burden on this motion for summary judgment, it must also demonstrate that there is no genuine dispute that such representation on the label is false or misleading. 21 U.S.C. § 343. Thus, the affidavit of Dr. Simon S. Jackel, a biochemist and nutritionist, states that '[t]he quality of the protein in the Schmidt's P.E.P. Bread is improved compared (1) to the previous bread Schmidt was making and (2) compared to the enriched white bread marketed in Baltimore by the other leading bakers. . . .' Consequently, the Court must conclude that there is a genuine dispute as to whether the label is false and misleading in representing that the protein in the seized bread has been significantly improved, and plaintiff's motion on this point cannot be granted.

"Finally, the plaintiff alleges that the seized bread is 'misbranded in that the label represents and suggests to the consumer that Schmidt's Blue Ribbon Enriched Bread supplies more Vitamins and Iron than ordinary enriched bread.' The government indicates that this contention rests upon the 'plain and obvious meaning of the bald faced statement, 'Blue Ribbon also gives you Extra Vitamins and Iron.'"

"Although the label of the seized bread clearly indicates that this bread supplies more vitamins and iron, it does not clearly indicate whether a comparison is drawn against the bread produced by competitors, the bread formerly produced by claimant, or some other standard for evaluating enriched bread. Despite the conclusion of plaintiff's affiants, Drs. Johnson and Perloff, that in the mind of the consumer such comparison is made with ordinary enriched bread, it does not appear to the Court that such conclusion is the only one that the consumer could reasonably reach. According to Dr. Twedt, the statement on the label 'specifically compares past and present formulations of the product [Schmidt's Blue Ribbon Enriched Bread] with respect to their satisfaction of minimum daily requirements for essential food substances.' Thus, there exists a genuine dispute as to the conclusion which may be drawn from the statement on the label and therefore, claimant's motion for summary judgment on this point must be denied."

Subsequently, the claimant moved to withdraw from the action. The court denied the motion, saying:

"Pursuant to the Federal Food, Drug and Cosmetic Act, the Government seized from the Schmidt's Baking Co., Inc. an undetermined number of loaves of Schmidt's Blue Ribbon Bread awaiting shipment to Tasley, Virginia on grounds that each loaf was misbranded within the meaning of 21 United States Code, Section 343(a) of the Act. The Bakery then filed a timely claim for the bread and requested leave to defend against the Government's seizure. Thereafter, the Bakery answered the original complaint, denying the allegations that the labeling of the bread was either false or misleading and demanded a jury trial. Following extensive discovery by both parties, the Government moved for summary judgment, which this Court refused in a Memorandum and Order dated July 31, 1973. The decision was based on affidavits submitted by Schmidt's nutritional experts that presented, in the Court's view, genuine issues of material fact about the comparative protein content of Blue Ribbon Bread, the effect of the labeling on the consumer, and the quality of the protein in the libeled bread. The parties then engaged in further discovery until January 4, 1974, when the Claimant filed the present motion to withdraw its claim.

"In support of this motion, the Bakery contends that the bread label has now been altered, rendering moot the allegations of the complaint, and that the substantial cost of presenting an adequate trial defense justifies authorization of the withdrawal by this Court.

"The Plaintiff, United States, opposes the motion, claiming that voluntary withdrawal or dismissal is governed by the provisions of Rule 41(a) of the Federal Rules of Civil Procedure, which makes no mention of Defendants. Alternatively, the Government asserts that the Claimant, as a Plaintiff, must satisfy Rule 41(a)(2) forbidding voluntary dismissal without prior court approval, which is seldom granted if the Defendant will suffer prejudice. According to the Government, prejudice is unavoidable in this case because of the advanced stage of the litigation.



"The plain language of Rule 41 supports the argument of the United States that only a Plaintiff may seek a voluntary dismissal. In this action, the issue is whether the Bakery, as a Claimant, is a Defendant or a Plaintiff, for purposes of a voluntary dismissal under Rule 41(a). Although the Claimant differs from a Defendant appearing pursuant to a summons because it intervened voluntarily to protect a property interest, this distinction vanishes once it enters an appearance in the action. Like the ordinary Defendant, the Claimant is now subject to the in personam jurisdiction of the Court, *Hippolite Egg Co., v. United States*, 220 U.S. 45, and voluntary dismissal is controlled by the terms of Rule 41(a). Furthermore, voluntary intervention by the Bakery was initially compelled by the seizure of its bread and the threat of subsequent action by the Plaintiff if the same labels remained in use. And a default judgment favoring the Government against the res, the bread, would result in pecuniary loss to the Plaintiff, similar to the loss suffered after a default judgment in a nonfictional civil suit.

"Confirmation of this analysis is found in the Federal Food, Drug and Cosmetic Act, the Federal Rules of Civil Procedure, and judicial decisions interpreting those rules. First, 21 United States Code, Section 334(b) states that 'the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty.' By an amendment to Rule 1 in 1966, admiralty suits are now governed by the Federal Rules of Civil Procedure, with one major exception. According to the Supplemental Rules for Certain Admiralty and Maritime Claims 'these rules also apply to the procedure in statutory condemnation proceedings analogous to maritime actions in rem, whether within the admiralty or maritime jurisdiction or not. The general Rules of Civil Procedure are applicable to the foregoing proceedings except to the extent that they are inconsistent with these Supplemental Rules.'

"This extension by congressional Act of the old admiralty rules to statutory actions analogous to maritime proceedings is repeated in Supplemental Rule C(1)(b). In *United States v. \$5,372.85 United States Coin and Currency*, 283 F. Supp. 904 (S.D.N.Y. 1968), Judge Wyatt declared that the Supplemental Rules govern forfeiture proceedings where applicable, but that the other rules generally control the action.

"Here, Supplemental Rule C(6) requires that a claim be verified on oath and state the interest in the property by virtue of which the Claimant demands restitution and the right to defend the action. Two recent decisions involving forfeitures under statutes similar to 21 United States Code, Section 334 also conclude that a Claimant is, indeed, a party Defendant. While denying a Claimant's motion to reopen a default judgment against the seized property, Judge Kalbfleisch indicated that he must apply to intervene in the action as a party Defendant within the 10[-]day limitation provided by Rule C(6). Similarly, a Claimant was granted his motion to intervene as a party Defendant in *United States v. Two Hundred and One, Fifty Lb. Bags*, 52 F.R.D. 222 (D. N.Dakota 1971), an earlier decision of Judge Kalbfleisch, which I just cited, which was *United States v. One Buick Electra 225*, found in 57 F.R.D. 185, and this construction comports with the interpretation given to old admiralty rule 25 in the *Two Marys*, 12 F. 152, and the *Antoinetta* in 49 F. Supp. 148. Both of these decisions characterized an intervenor under this direct predecessor of Supplemental Rule C(6) as a defender of his interest in the libeled property.

"A final reason for treating the Bakery as a party Defendant is that the Government carries the burden and will suffer any penalty of not going forward with its evidence. *United States v. 4 Cases of Slim Mint Chewing Gum*, 300 F. 2d. 144; *United States v. 60 28 Capsule Bottles Labeled Unitrol*, 211 F. Supp. 207. Once the Bakery answers, the Plaintiff must demonstrate by a preponderance of the evidence that the bread was deceptively labeled and failure to meet this standard will result in a direct verdict for the Claimant.

"Moreover, this Court finds little merit in the reasons presented in support of this motion to withdraw. The issues in this suit are not rendered moot by a mere change in labels, since the Claimant is free to return to the earlier packaging at any time, and its argument that the new labels are used in good faith should be weighed against the fact of an 18[-]month delay in making these simple alterations. If, on the other hand, the Bakery is a party to a judgment on the merits favoring the

Government, then the effect of res judicata will prevent a return to misbranding and the necessity of a second lengthy lawsuit by the Plaintiff. *United States v. 14 Bags of Blake's Mineral Compound*, 118 F. Supp. 837. Second, the Claimant was well aware of the legal expenses when it intervened to defend against the seizure of the bread. This change of labels relied upon by the Bakery occurs after extensive discovery, the recruitment and, presumably, use of experts by both parties, and a denial of Plaintiff's motion for summary judgment following a full hearing before this Court.

"In short, the Government has already incurred substantial and avoidable expenses as a result of this intervention in an effort to secure a ruling which would bind the Bakery. To permit the Claimant to withdraw at this late stage of the litigation would prejudice the Plaintiff and violate, in the Court's judgment, the expressed terms of Rule 41(a). If the Bakery was concerned about the cost, it could have allowed the Government a default against the res alone. Now, further expense is inevitable unless the Claimant defaults, which will result in a judgment binding in future litigation involving the same issues and the same parties.

"For the reasons just stated, the Claimant's motion to withdraw in the case must be denied."

After additional litigation the Government moved for and was granted partial summary judgment. The court said:

"A preliminary matter before the Court is raised by the claimant's motion requesting the Court to authorize oral testimony at the hearing on the government's renewed motion for summary judgment. The grounds for this motion, as stated by claimant are as follows: The government contends that the affidavits of Dr. Jackel, one of claimant's experts, were misleading and untrue. Dr. Jackel has reviewed his affidavits and stands by his initial opinion that the protein in the bread baked with the PEP formula was superior to the protein in the bread baked with nonfat dry milk. Rather than continue to attempt to sift through affidavits and depositions to arrive at the truth, it would seem that the most economical, expeditious and reliable way of arriving at a determination as to whether or not there is a factual issue to be decided is to present Dr. Jackel in court and allow him to state his opinion and subject him to cross examination by the government attorneys. The Court would then be in a better position to determine if the case should go to trial. In addition, since the government has accused Dr. Jackel of misleading the Court and being untruthful, Dr. Jackel should be afforded the opportunity to respond in person to the accusations.

"While the Court appreciates the reasons for claimant's motion, it finds that no useful purpose will be served by allowing oral testimony to expand further an already voluminous and adequate record. The Court agrees with the government that Dr. Jackel has already had two and one-half years, two affidavits, and a lengthy deposition to make his position clear and to present his opinion that the protein of the later bread was superior to that of the first formula. If Dr. Jackel could support his position, he should have done so in supporting the memorandum in opposition to the government's renewed motion for summary judgment. Because the Court thinks that the claimant need be provided with no more opportunities to present its case, it will deny the claimant's motion to allow Dr. Jackel to present oral testimony.

SUMMARY JUDGMENT ON PROTEIN IMPROVEMENT

"The crucial issue before the Court is raised by the government's motion for summary judgment. In its previous opinion, the Court found that the statement on the label does represent and suggest that the protein in the seized bread has been significantly improved. Although the Court did not specify its points of comparison, it is clear that the Court was referring to the government's contention that the label suggested that the quality of the P.E.P. formula bread was improved over the previously-baked bread. Thus, the claimant's position that the Court has not previously ruled on this issue is not persuasive. Therefore, the sole issue is whether or not the P.E.P. formula did in fact improve the quality of the protein in the claimant's bread over that previously baked.

"The government suggests that in ruling on the motion for summary judgment, the Court should not consider the affidavits prepared by claimant's expert, Dr. Jackel. It contends that the



affidavits were not made on personal knowledge as required by Rule 56(e) and should be disregarded, thus leaving the testimony offered by the government's affiants uncontroverted and entitling the government to summary judgment. The Court finds it unnecessary to reach that issue because it finds that, even if Dr. Jackel's affidavits are not stricken, the government is entitled to summary judgment since the affiants do not raise any genuine issue of material fact.

"In the pretrial order, paragraph 5, the parties agreed to the formula of the bread seized and the previously-baked bread. The only factors that could account for a significant increase in the quantity and quality of protein in the seized bread over the previous bread are milk blend and wheat gluten. (pretrial order, paragraph 6.) The amount of wheat gluten was increased from 0 pounds to 4 pounds 8 ounces, and the amount of milk blend was decreased from 27 pound[s] to 18 pounds. The Court has had the benefit of affidavits from several experts in interpreting these figures. * * *

"Through these affidavits, the government has shown that 27 lbs. of any of the possible mixtures used prior to 'P.E.P.' provides a better quality of protein than that provided by the seized article. . . .

"The question then is whether the claimant has set forth specific facts showing that there is a genuine issue for trial. As noted at the start of this opinion, the claimant has had adequate opportunity to present affidavits in support of its position and has in fact presented two affidavits by its expert, Dr. Jackel. The court, therefore, sees no need for oral testimony from Dr. Jackel and will decide the issue on the affidavits and depositions now before it. * * *

"Dr. Jackel bases his conclusion that the protein was of improved quality on the general concept that balanced protein is 'better' protein and the P.E.P. formula provided balanced protein. He sets forth no specific facts as required by Rule 56(e) but concludes that, because in general balanced protein is better, the specific P.E.P. balance is better. This conclusion, without a basis in specific facts, cannot overcome the conclusion of Dr. Forbes, quoted above, that the general concept of balanced protein does not hold true in the specifics of this case. (affidavit, paragraph 13.)

"Further, in his supplementary affidavit, Dr. Jackel did not state that P.E.P. bread was superior to that previously baked. He stated in paragraph 12:

Schmidt is making a nutritionally improved loaf compared to what they are required to make by Federal Standards of Identity, Title 21, Chapter I, Part 17, Section 17.2. Schmidt is also making a nutritionally improved loaf compared to the other leading white enriched breads in their market area.

"This supplementary affidavit was submitted because at oral argument on the government's first motion for summary judgment the Court found that Dr. Jackel's initial affidavit did not comply with the personal knowledge requirements of Rule 56(e) and granted claimant leave to file a second affidavit to overcome this deficiency. The Court notes that in this supplementary affidavit Dr. Jackel does not repeat his prior position that the P.E.P. bread was superior to the prior bread.

"In addition, Dr. Forbes stated that a total yield of 188.95 grams of lysine is found in the P.E.P. blend, while 339.0 grams of lysine were present in the previous blend. (affidavit, paragraph 12.) Although it was not admitted by claimant in the pretrial order that the quality of protein in any particular bread made principally of wheat flour is directly related to the amount of lysine in that bread (5(a)(4)), the claimant has not refuted that conclusion with any specific facts but has simply repeated its general statements about the importance of 'balanced' protein. There thus appears to be no genuine issue as to the importance of lysine in determining protein quality.

"Dr. Jackel testified that during the years 1961-69 claimant used five percent, four percent, three percent and two percent non-fat dry milk in its enriched breads which added 565, 451, 338 and 225 grams of lysine respectively. (Tr[anscript] 40 and 78.) All of these amounts of lysine are greater than that of the seized bread. (The government in its memorandum states that the lysine in the seized bread was 208.52 grams rather than the 188.95 grams computed by Dr. Forbes. Whichever figure is used, it is clear that the amount of lysine is lower than that of the previous breads.)

"When confronted with the above facts, Dr. Jackel admitted their truth but added:

A: I think that is incomplete. I think you have to show 1 percent and zero percent. There is actually bread on the market with one percent non-fat dry milk, and they were contemplating going to zero.

Q: But we are talking about breads actually baked.

A: One percent were actually baked. (Tr. 84)

"Even if the claimant did bake a one percent bread (with 112.8 grams of lysine), it did not bake this bread immediately prior to P.E.P. The bread baked then contained 338.9 grams of lysine. It is the bread baked immediately prior to P.E.P. that is significant in terms of the claim that P.E.P. was an improvement.

"Nor did claimant ever bake bread with zero percent, as claimant admits:

Q: If we talk about zero percent of bread that they could have baked, Schmidt's is better than that just as General Motors has said we will put a car out with three wheels, when the four wheel car is better because wheels are going up now and we can only afford three wheels.

A: I disagree with that analogy because the federal standards for enriched bread, such a bread would meet the requirements fully.

Q: They could have baked one with zero. It's something they could have done.

A: Well, bakers have. Many bakers have baked it without.

Q: I'm talking about Schmidt's.

A: It would have been silly for them to do that. To satisfy you they could have. If they knew that was your point of view, they would have. (Tr. Jackel, p. 85)

"To review, the government contends that the amount of lysine in bread is the significant factor in determining the quality of protein and has shown that the lysine of P.E.P. bread was inferior to that produced immediately prior to the seized bread. The claimant does not accept the government's contention as to the significance of lysine but has not presented facts in support of their position that the protein *balance* of P.E.P. is improved over the previous bread.

"Although the Court has not reached the issue of whether Dr. Jackel's affidavit should be excluded for lack of personal knowledge, it has evaluated Dr. Jackel's testimony in terms of his familiarity with the Schmidt formula. There are several instances in which Dr. Jackel admits he lacks personal knowledge of certain critical elements. Although the contents of the formula used prior to P.E.P. is the crux of the issue before the Court, Dr. Jackel admits his lack of personal knowledge of that formula. . . .

"Further, when asked if he had any personal knowledge of what the bread was comprised of after 1961, Dr. Jackel stated that he did not. (Tr. 53)

"In sum, the claimant's expert, Dr. Jackel, attempts to establish two facts: one, that the bread baked after P.E.P. was a better quality protein bread than a water bread, and two, that the bread baked after P.E.P. was a better quality protein bread than that baked prior to P.E.P., because it was a better balanced protein. (Tr. 73). The first fact is irrelevant to the instant inquiry. What is important is not the protein in a hypothetical water bread but the protein in the bread actually baked prior to P.E.P. The second fact is significant, but the claimant has been unable to establish any basis for its statements that the protein balance was better in P.E.P., and the government has produced an expert, Dr. Forbes, who states specifically that the protein balance was inferior in the P.E.P. bread. Therefore, the Court finds that no genuine issue of fact exists and summary judgment should be granted for the government.

"MORE B VITAMINS AND IRON REPRESENTATION"

"The government contends that it is entitled to summary judgment on the mislabeling as to the amount of B vitamins and iron in the P.E.P. bread. The Court agrees with the claimant that the government elected to abandon this issue in paragraph 4(c) of the pretrial order and therefore will not consider it.

CONCLUSION

"On the single issue remaining in this lengthy litigation, the comparative protein qualities of the breads, the Court finds that the protein quality of the P.E.P. bread was not improved over the protein quality of the previously-baked bread. The claimant



has produced no evidence on this motion for summary judgment that raises a genuine issue of material fact. Therefore, the Court will grant the government's motion for summary judgment."

Ultimately, the Government moved for dismissal of the action as to the remaining charges, for the following reasons: 1) the charges that the bread would satisfy dietary needs of protein, that it supplied more B vitamins and iron than ordinary enriched bread and that it was in violation of the Fair Packaging and Labeling Act had been abandoned in the pretrial order; 2) the court had granted the Government summary judgment on the charge involving the quality of the protein; 3) the only remaining issues were those concerning the general need for more protein in the diet and the main function of protein as supplying energy; 4) the claimant had ceased using the label which was the subject of the complaint, and the two remaining issues were moot. Accordingly, the court dismissed, without prejudice, those remaining issues. (F.D.C. No. 58123; S. No. 8-938 F; N.J. No. 19)

Pineapple juice, at Brooklyn, E. Dist. N.Y.

Charged 10-31-75: when shipped by Excess Inventory Exchange, North Brunswick, N.J., the article, labeled in part "1 Litro Ananas Only . . . [on side panel of label] Fresh Pineapple Juice . . . Itapemirim, Espirito Santo Brasil," was in violation of the Fair Packaging and Labeling Act, since the article lacked a statement of identity on its principal display panel, lacked a quantity of contents statement within the bottom 30 percent of the principal display panel, and the quantity of contents statement was expressed as "1 Litro" instead of "Net 32 fl. oz. (1 qt.)." Default decree ordered destruction. (F.D.C. No. 60509; S. No. 76-39-983; N.J. No. 20)

FOOD/COLOR ADDITIVES

Cherries, maraschino, at Gretna, E. Dist. La.

Charged 10-15-75: while held by Zartarain's, Inc., Gretna, La., who manufactured the article using cherries shipped in interstate commerce, the article contained the color additive FD&C Red No. 4 in excess of the prescribed limit; 402(c). Default decree ordered destruction. (F.D.C. No. 60507; S. No. 76-37-822; N.J. No. 21)

Chubs, skinned, gutted, frozen, at Philadelphia, E. Dist. Pa.

Charged 10-21-75: when shipped by Vita Foods of Illinois, Chicago, Ill., the article contained the nonconforming food additive dieldrin for which there was no tolerance or exemption therefrom in fish; 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 60481; S. No. 35-831 H; N.J. No. 22)

DRUGS/Human Use

Napizem sodium pentobarbital capsules, at Oakmont, W. Dist. Pa.

Charged 8-20-75: while held by the Zemmer Co., Oakmont, Pa., who manufactured the article using sodium pentobarbital shipped in interstate commerce, the strength and quality of the article differed from and fell below U.S.P. standards, since the article contained excess sodium pentobarbital and failed the U.S.P. content uniformity standard—501(b); and the circumstances used for the article's manufacture, processing, packing, and holding failed to conform with current good manufacturing practice—501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 60451; S. No. 31-234 H; N.J. No. 23)

Phenobarbital tablets, at Plainview, E. Dist. N.Y.

Charged 9-12-75: while held for sale after manufacture by Columbia Pharmaceutical Corp., Garden City, N.Y., using phenobarbital shipped in interstate commerce, the strength and the quality of the article, labeled in part "Star IDE Brand Phenobarbital . . . U.S.P. . . . Tablets Manufactured for Interstate Drug Exchange, Inc., Plainview, L.I., N.Y.," differed from and fell below the U.S.P. standards, since the article contained excess phenobarbital and failed the U.S.P. content uniformity standard; 501(b). Default decree ordered destruction. (F.D.C. No. 60456; S. No. 43-370 H; N.J. No. 24)

Three Bromides ammonium, potassium, and sodium bromides elixir, at Louisville, W. Dist. Ky.

Charged 2-2-75: while held by Kentuckiana Pharmaceuticals, Inc., Louisville, Ky., who manufactured the article using bromides shipped in interstate commerce, the strength of the article differed from its purported strength, since it contained approxi-

mately 118 percent more total bromides and approximately 117 percent ammonium bromides—501(c); and the circumstances of the article's manufacturing, processing, packing, and holding failed to conform with current good manufacturing practice—501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 60202; S. No. 60-645 H; N.J. No. 25)

DRUGS/Veterinary

Dimethyltoluthionine chloride veterinary solution, at Tulia, N. Dist. Tex.

Charged 9-25-73: when shipped by Seney & Co., Inc., Denver, Colo., the article, labeled in part "Septicol Veterinary . . . contains dimethyltoluthionine chloride . . . Manufactured for AVC, Inc., Tulia, Texas," was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to its use or intended use; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 59368; S. No. 35-749 G; N.J. No. 26)

MEDICAL DEVICES

Diapulse electromagnetic energy generators, 2 seizure actions, at Salt Lake City, Dist. Utah, and Murray, Dist. Utah.

Charged on or about 3-22-73 and 3-20-73: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the accompanying treatment chart and (Salt Lake City action only) newspaper tear sheet about "Doctor Testing Device to Speed Healing" and leaflet "Effects of Pulsed Electromagnetic Energy (Diapulse) in Experimental Hematomas" contained false and misleading claims for normal bone and tissue healing, sinusitis, bursitis, rheumatoid arthritis, and blood flow to peripheral areas; and the article's labeling lacked adequate directions for use for the article's intended purposes and neither adequate directions for lay use, nor adequate information for use by licensed practitioners could be provided; 502(a), 502(f)(1). The devices were claimed by George E. Eason, D.C., Salt Lake City, Utah, and Rulon C. Allred, N.D., Murray, Utah, who denied the charges. The Government served written interrogatories on the claimants. Subsequently, the claimants requested a stay pending the outcome of an appeal from a permanent injunction entered against Diapulse Corp. of America, New Hyde Park, N.Y. The court granted such a stay and permitted that the written interrogatories not be answered until the stay was vacated. After the Supreme Court denied certiorari to Diapulse Corp. of America, the claimants conceded that the devices did not accomplish the purposes for which they were originally advertised and sold and requested the court to allow them to attempt to bring the devices into compliance with the law and to use them as conventional diathermy devices. The Government asserted that such a procedure was economically unfeasible and had yet to be accomplished by any Diapulse claimant and moved for summary judgment. Both claimants also moved for summary judgment. The court denied all motions for summary judgment on the grounds that nothing had been presented to the court which could establish a foundation that the devices were identical to or were mislabeled like other devices which had been condemned and that the claimants failed to cite statutory authority for their petition that the device be stripped of all labeling and returned to claimants to be used for whatever is safe and prudent in their professional opinions. Ultimately the claimants moved to withdraw their claims and answers. Such motion was granted and default decrees ordered the articles destroyed. (F.D.C. Nos. 58628/9; S. Nos. 33-874 F, 32-681 F; N.J. No. 27)

Electrical therapy shock generator, at Denver, Dist. Colo.

Charged 6-23-75: when shipped by Mrs. Mary F. Spencer from San Jose, Calif., and while held for sale, the article lacked a label containing the name and place of business of the manufacturer, packer, or distributor; the labeling lacked adequate directions for its intended use and was not exempted therefrom; and the labeling lacked adequate warnings against unsafe uses; 502(a), 502(b), 502(f)(1). Default decree ordered destruction. (F.D.C. No. 60387; S. No. 81-159 H; N.J. No. 28)

Iso-Tensor plastic exerciser bars; and Betty Weider's Neckline Chin/Neck bands and Betty Weider's Love Legs rubber thigh girdles, 2 seizure actions, at Woodlark, C. Dist. Calif.

Charged 6-7-74 and 6-7-74: while held by Body Persuasion Systems, Woodland Hills, Calif., the labeling of the Iso-Tensor



bars, (i.e., leaflet entitled "Betty Weider's Iso Tensor System Bustline Increaser Course . . . Body Persuasion Systems, Inc.," contained false and misleading claims concerning forming the breasts, adding inches to one's bustline, and in filling out one's breasts; and the labeling lacked adequate directions for such purposes—502(a), 502(f)(1). While held by Weider International, Inc., t/a Body Persuasion Systems, Woodland Hills, Calif., the labeling of the Neckline Chin/Neck bands and Love Legs thigh girdles lacked adequate directions for use for their intended purposes—502(f)(1); the Love Legs thigh girdles were dangerous to health when used as directed—502(j); the Neckline Chin/Neck bands' accompanying booklets and leaflets contained false and misleading claims for breaking down fat in a "double chin"; in restoring youthful resilience and skin tone; that it caused a copious perspiration which flushed fatty globules from under the skin; caused the neck to become more slender; rid the skin of dead, used up cells, toxic buildup, and fat; acted to relieve the pressure of tension in a mildly orthopedic way by helping to align the bone and muscle structure of one's body; helps remove double chin, neckline wrinkles, and mottled crepe-like skin—502(a); and the Love Legs thigh-girdles' accompanying booklets and leaflets contained false and misleading claims for shaping and contouring the thighs; supplying massage; supplying exercise; and causing unwanted inches of fatty deposits to melt down—502(a).

The articles were claimed by the dealer who denied the charges. The actions were consolidated for trial. The actions were tried by the court. The court found for the Government saying in part:

"The use of the Iso-Tensor device, in accordance with the directions in the booklet which accompanies the device and is printed for and used by claimant in the sale and distribution of the device, is inadequate and ineffective in increasing the size of female breasts, increasing the measurement of the female bustline, resculpturing and improving the contour and shape of female breasts, making female breasts rounder and fuller, or uplifting female breasts.

"The use of the Chin/Neck Band device, in accordance with the directions in the booklet which accompanies the device and is printed for and used by claimant in the sale and distribution of the device, is inadequate and ineffective in helping break down the fat in a double chin, causing fat-flushing perspiration which flushes fatty globules from under the chin and neck, or restoring a youthful chin and neckline.

"The use of the Love Legs device, in accordance with the directions in the booklet which accompanies the device and is printed for and used by claimant in the sale and distribution of the device, is inadequate and ineffective in trimming down heavy thighs and slimming, shaping, contouring, and firming the thighs through removal or redistribution of fat from the thighs.

"Wearing the Love Legs device on the thighs or performing the exercises described in said booklet while wearing the Love Legs device can impede venous blood flow from the leg and can exacerbate circulatory conditions in pregnant women and persons with circulatory problems. In certain cases it is possible that so wearing the Love Legs device or performing said exercises while so wearing the device will cause thrombophlebitis.

"The statement in the booklet accompanying the Love Legs device, 'CAUTION: Not to be used by pregnant women or those with circulatory problems without the advice of a physician,' is inadequate to prevent certain users of the device from potentially exacerbating circulatory conditions by use of the device in that there are many persons with circulatory problems who are unaware that they have such problems, some of whom may use the device."

Accordingly, the court ordered the articles condemned and destroyed. (F.D.C. Nos. 59723, 59781; S. Nos. 54-934 G; 54-932/3 G; N.J. No. 29)

COSMETICS/BEAUTY PRODUCTS

Perfume, at Shreveport, W. Dist. La.

Charged 8-13-75: when shipped by United Distributing of Texas, Inc., Dallas, Tex., the article's label statements "No. 5 Chanel Perfume," and "Chanel, Inc., New York, N.Y. 10019," and other statements suggesting that the article was such No. 5 Chanel perfume were false and misleading, since the article

was not authentic Chanel perfume; the article's bottle label lacked the true name and place of business of the manufacturer, packer, or distributor; and the article lacked any quantity of contents statement; 602(a), 602(b)(1), 602(b)(2). Default decree ordered destruction. (F.D.C. No. 60450; S. No. 54-681 H; N.J. No. 30)

NOTICES OF JUDGMENT on Criminal Actions FOOD

Thomas O. Burchinal, vice president and general manager of Marhoefer Baking Co., Inc., Altoona, W. Dist. Pa.

Charged 12-20-74 in probation revocation order to show cause; that the Marhoefer Bakery was still insanitary; 402(a)(4). Subsequently, upon consent of the parties and in view of the probation revocation proceeding, the individual's probation was extended for an additional year and the Marhoefer Baking Co., Inc., entered into a consent decree of permanent injunction. (F.D.C. No. 59403; S. No. 67-929 F; N.J. No. 31)

Walter F. Durbin, t/a **Walter Durbin Wholesale**, Atoka, E. Dist. Okla.

Charged 3-6-74: wafer cookies (count 1), chocolate-coated raisins (count 2), dehydrated potatoes (count 3), chocolate-flavored candy (count 4), and ice cream cones (count 5), were held in a building accessible to insects and rodents, and were contaminated with insect and/or rodent filth; 402(a)(3), 402(a)(4). The defendant pleaded not guilty and moved to dismiss the information on the grounds that separate notices for each FDA inspection were not issued, that no hearing was held concerning counts 2, 3, and 4, and that the notice of hearing did not contain any notice of rodent filth contamination. The court denied the motion saying:

"Defendant's interpretation of 21 U.S.C. § 374(a) as requiring a separate notice for each day of a multiple day inspection is incorrect. It is contended herein by Plaintiff that the inspection involved herein was conducted on Thursday, May 31, 1973, Friday, June 1, 1973 and Monday, June 4, 1973; that no inspection work took place on Saturday, June 2, 1973 or Sunday, June 3, 1973; that the Notice was dated May 31, 1973 and was effective until the inspection was completed and the required Report submitted. The written Report upon the completion of an inspection required by 21 U.S.C. § 374(b) covered the three days above mentioned and was submitted to Defendant by the Inspectors on the final day of the multiple-day inspection, namely, June 4, 1973. The Court finds and concludes that the three-day inspection was properly noticed and the Information should not be dismissed as requested by Defendant's Motion. Said Motion should be denied.

"Defendant's Motion to Dismiss Count Two, Three and Four for lack of a hearing thereon as required by 21 U.S.C. § 335 is without merit and should be denied. The file reflects substantial compliance with said Statute. It appears the hearing was reasonably noticed, was held, the Defendant appeared and was afforded an opportunity to present his views. This is all that is required. *United States v. Hunter Pharmacy*, 213 F. Supp. 323 (S.D.N.Y. 1963). Defendant's further Motion that all Counts be dismissed because notice of hearing did not mention rodent filth contamination is likewise without merit and should be denied. The Report of June 4, 1973 noted rodent problems in the warehouse. This was discussed at the hearing. There was substantial compliance with the Statute. Moreover, the complete lack of such a hearing is not fatal to the Information herein."

At the initial trial, the jury was unable to reach a verdict. At the second trial, the defendant was found guilty on counts 3, 4, and 5. The Government moved to tax the defendant with the cost of prosecution; and the defendant moved for another new trial. The court denied the motion to tax the costs of prosecution, stating:

"The statute makes it clear that the assessment of costs is discretionary with the Court. The Court has heard the evidence in this case in two separate trials and is of the view that it would be inappropriate to assess the costs against the defendant and in the exercise of its discretion concludes that the plaintiff's motion should be denied."

The court also denied the defendant's motion for a new trial, saying:

"1. *Inconsistent verdicts*. Defendant argues that each of the



five counts in the indictment are essentially identical with the only difference being the items of food involved. He further argues that the evidence presented for each count was essentially the same and therefore the inconsistent verdicts on counts 1 and 2 amount to reversible inconsistencies. Defendant cites several authorities for this proposition but no Tenth Circuit case is cited.

"The United States Attorney argues that even though substantially the same evidence is offered for each count, a not guilty verdict on one or more counts does not invalidate one or more guilty verdicts on other counts. . . . Furthermore, in the present case, the same evidence was not offered in each count. Each count involved a different food and the jury's finding of the degree of filth might well have been different as to each count.

"2. *The real evidence offered.* Defendant argues that the admission into evidence of the samples of food was error because it was shown that live infestation existed in one of the samples after the sample had been sealed with chloroform inside to presumably kill all insects. This was prejudicial according to defendant, because the food samples had deteriorated from the time they were first taken. * * * Notwithstanding the evidence of live insects in one of the samples, there was testimony that the samples were in substantially the same condition at trial as they were when taken. The evidence also shows an unbroken chain of possession and control of the samples from the time of their taking to the trial. The Court therefore finds that the samples of food were properly admitted under the above [*Reed v. United States*, 377 F.2d 891 (10th Cir. 1967)] test.

"3. *The demonstrative evidence.* Defendant argues that the admission into evidence of the diagram of the defendant's warehouse was error in that it was not drawn to scale and it had various 'x's' on it to represent items not mentioned in the information. It is further argued by defendant that it was error to admit into evidence the enlarged photographs because said photographs exaggerated the conditions and misled the jury and because the proper foundation was not laid for their introduction.

"Mr. Rahto identified the diagram as being a substantially correct representation of the inside of the warehouse at the time he made his inspection. It was not necessary for the purpose for which it was introduced for the diagram to be drawn exactly to scale. No prejudice to the defendant could have resulted as a result of the diagram having been drawn other than to scale. As to the 'x's' on the diagram, it was proper for the witness to indicate the approximate location of various filthy substances found and the fact that those items were not specifically mentioned in the information is immaterial since the general condition of the warehouse was a part of the charge.

"Mr. Rahto also testified that he took the photographs in question and that they substantially and accurately represented the conditions which he observed at the time of his inspection. *United States v. Hobbs*, 403 F.2d 977 (6th Cir. 1968). The photographs were therefore properly admitted.

"4. *Testimony of witness Rahto regarding food products not charged or named in the information.* Defendant contends that such testimony was improper in that it allowed the government to put on proof of other crimes which were not charged in the information. However, the information charged a violation under 21 U.S.C. § 342(a)(4) which includes the provision that adulteration exists where foods are 'held under insanitary conditions whereby it may have become contaminated with filth.' The existence of such conditions is relevant to the issue of insanitary conditions even though the same conditions may have been the basis of a different count had the government chosen to include it.

"5. *The affidavits.* Defendant challenges the admission into evidence of the affidavits signed by defendant which indicate that certain foods were shipped in interstate commerce on the grounds that defendant was not informed of his constitutional rights before signing the documents and therefore his 5th amendment rights were violated.

"The government contends that no Miranda warnings were necessary because defendant was never in custody or under arrest and that the admissions were made voluntarily. With this the Court agrees.

"6. *Search of defendant's warehouse.* Defendant argues in his

brief that the search of his warehouse and seizure of food articles were unconstitutional as being made without a search warrant and were not made incident to a lawful arrest. Defendant further argues that the search was unreasonable.

"21 U.S.C. § 374 provides for searches of food warehouses without a search warrant but requires that said searches be made at reasonable times and for reasonable lengths of time. The Court finds that the searches herein fully complied with this statute. See *United States v. Durbin*, 373 F. Supp. 1136 (E. D. Okla. 1974).

"7. *The prosecutors.* The trial of the case was conducted by attorneys for the Pure Food and Drug Administration in Washington, D.C. and the defendant claims that this was improper.

"The government states in its brief that the case was prosecuted by the United States Attorney's office and that 'staff lawyers' were used to conduct most of the trial. All pleadings by the plaintiff were signed by an Assistant United States Attorney. Without proof by the defendant to the contrary it must be presumed that the decision to prosecute and the actual supervision of the prosecution came from the United States Attorney's office. This is in substantial compliance with 28 U.S.C. § 547(1). Furthermore, the attorneys who conducted the trial for the plaintiff proceeded in a responsible and proper manner so that defendant received a fair trial in all respects.

"8. *Jury instructions.* Defendant reurges his objections to the instructions given to the jury. The Court carefully reviewed defendant's objections and authority cited prior to giving the instructions to the jury and the defendant has shown no reasons for reconsidering the prior determinations made regarding those instructions. Defendant should not be granted a new trial on this basis.

"9. *Allowance of only one character witness.* Defendant argues that such limitation was prejudicial to the defendant in that it minimized in the eyes of the jury the effect of good character and reputation.

"The limitation of cumulative evidence is within the discretion of the trial court. . . . Good character and reputation in the present case has very little relevance to the crime involved since the crime is one not requiring criminal intent. The limitation of the defense to a single character witness was not prejudicial to the defense in any way."

Thereafter, the defendant was fined \$3,000. (F.D.C. No. 59622; S. No. 36-862 G et al.; N.J. No. 32)

Lee Brothers Wholesale Grocery, Inc., Lester Lee, Jr., president, and Joe F. Gaines, warehouse manager, Elberton, M. Dist. Ga.

Charged on or about 10-21-74: flour was held in a building accessible to rodents and insects and was exposed to contamination by rodents and insects; 402(a)(4). Guilty pleas; fines and probations. (F.D.C. No. 59708; S. No. 4-517 G et al.; N.J. No. 33)

Miavana Wholesale Co., Armando A. Coronel, Jr., president, and Alexis F. Coronel, vice president, Miami, S. Dist. Fla.

Charged 6-27-74: rice was held in a building accessible to rodents and insects, and was contaminated with rodent and insect filth; 402(a)(3), 402(a)(4). Guilty pleas; fines and probations. (F.D.C. No. 59703; S. No. 2-910 G et al.; N.J. No. 34)

Reed-Harlin Co., t/a Central Cash & Carry Wholesale Grocer, James E. Hard, president, and Bobby G. Burtrum, manager, West Plains, W. Dist. Mo.

Charged 9-23-75: flour was held in a building accessible to insects and was contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (F.D.C. No. 60014; S. No. 75-193 H; N.J. No. 35)

NOTICES OF JUDGMENT on Injunction Actions

ABC Rendering of Louisiana, Inc., and Dmytro Gorczakowsky, plant manager, Lafayette, W. Dist. La.

Charged 4-30-71 in complaint for injunction: that the defendants engaged in preparing and holding at their rendering plant at Lafayette, La., and engaged in distributing in interstate commerce, dried meat scraps; that such foods contained the added poisonous and deleterious substance *Salmonella* microorganisms; that such foods were prepared and held at the defendants' rendering plant at Lafayette, La., under insanitary conditions whereby the foods might be rendered injurious to health; that FDA inspections disclosed the existence of a number of speci-



fied insanitary conditions; and that the defendants were well aware that their activities were in violation of the law; 402(a)(1), 402(a)(4). The defendants denied generally all the material obligations concerning the violations and stated: that they would show that they were in the process of taking appropriate measures to sanitize such plant and to eliminate the possibility of *Salmonella* contamination of the food; that defendants' plant and facilities were in keeping with the established and recognized standards of the rendering industry; and that the measures being taken were intended and designed to raise the standard well above the ordinary or average standard of the business.

Prior to trial, a consent decree of permanent injunction was entered that enjoined the complained of violations, and that enjoined the interstate shipment of dried meat scraps meal or any similar food prepared, packed, and held in the defendants' plant at Lafayette, Louisiana, unless and until the defendants' facilities, methods, practices, and controls were in conformity with practices assuring that such foods were not contaminated with *Salmonella* microorganisms or any other pathogenic microorganisms, including a number of specified facilities, methods, practices, and controls, and unless and until the food on hand was destroyed or shipped to a qualified rendering plant for sufficient heat treatment to destroy any *Salmonella* microorganisms which might contaminate the food. (Inj. No. 605; S. No. 77-316 D et al.; N.J. No. 36)

Dixie Industries, Inc., and Howard K. Askew, vice president, and **Hill Askew, Jr.**, plant manager, Jackson, S. Dist. Miss.

Charged 6-11-74 in complaint for injunction: that the defendants engaged in receiving in interstate commerce, and in holding for sale, selling, and distributing after shipment in interstate commerce, vegetable oils and animal fats for use as animal feed; that FDA samples of such foods (from a tank car in which one food was received by the defendants, from storage tanks at defendants' plant, and from a poultry grower to whom some such food had been sold and delivered) revealed that such samples contained dieldrin in excess of 0.15 parts per million; and that plaintiff believed that defendants would continue such violations unless restrained by the court; 402(a)(2)(C).

A consent decree of preliminary injunction enjoined the violations complained of, and enjoined the defendants from doing any acts with respect to shipping, and receiving after shipment in interstate commerce, vegetable oils and animal fats whose invoices and other labeling failed to restrict such articles to nonfood use, unless and until the defendants either (a) established specified procedures to sample and analyze such articles for dieldrin and other food additives and to destroy or appropriately dispose of articles found to be contaminated with nonpermitted or excess food additives, or (b) in the use of articles sold or distributed by the defendants in the same tank cars or trucks as received from defendants' suppliers, the defendant obtained a specified guaranty; and unless and until a system was established for correlated coding of each shipment of the articles received and sold by the defendants in order that proper identification could be made of such shipments with the samples collected. (Inj. No. 671; S. No. 59-712 H et al.; N.J. No. 37)

I. D. Russell Co. Laboratories, and Dan B. Russell, DVM, vice president, **John Paul Russell**, secretary-treasurer, and **William T. Russell**, Kansas City, W. Dist. Mo.

Charged 9-26-74 in complaint for injunction: that the defendants distributed in interstate commerce, manufactured, processed, packed, labeled, and held for sale, after shipment of components in interstate commerce, various drugs for animal use, including "Ferro-Vite," "Triple Wormer Tablets," "Liver Extract plus Iron," potassium penicillin G, "Russell Poultry Lift," "Di-Biotic K," "Ru-Vi-Otic," bacitracin soluble, and streptomycin sulfate soluble powder, a number of which drugs had been manufactured, processed, packed, and held at defendants' Kansas City, Mo. plant under circumstances that failed to conform with current good manufacturing practice; that FDA inspections revealed a number of specified inadequacies in the defendants' operation of their plant at Kansas City, Mo.; that a number of the defendants' drugs were new animal drugs and no approved New Animal Drug Application was in effect with respect to the use and intended use of such drugs, and (for some drugs containing antibiotics such as penicillin G; bacitracin, and streptomycin sulfate) no antibiotic certificates or

releases were in effect with respect to such drugs; and that the defendants were well aware that their activities were in violation of the law; 501(a)(2)(B), 501(a)(5).

A consent decree of permanent injunction, permanently enjoined the complained of violations, and enjoined the interstate shipment of the defendants' drugs and the manufacturing, processing, packing, or labeling of their drugs while held for sale after shipment of such drugs' components in interstate commerce, unless or until a number of specified methods, facilities, and controls were established in conformity with current good manufacturing practice, all processed drugs on hand at the defendants' plant were examined and appropriately tested, recalled if failing tests, and destroyed or otherwise brought into compliance with the law; unless and until approvals of New Animal Drug Applications for the defendants' named drugs and other such drugs were in effect with respect to their use and intended use; and unless and until the defendants' drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or derivatives thereof, were from batches with respect to which antibiotic certificates or releases were in effect. (Inj. No. 679; S. No. 74-789 H et al.; N.J. No. 38)

NOTICES OF JUDGMENT on Miscellaneous Actions

Penicillin-streptomycin combination antibiotic drug products, and penicillin-sulfonamide combination antibiotic drug products; suit for injunction to stay FDA order revoking antibiotic certification thereof, Wilmington, Dist. Del.

Charged 7-9-69 by American Home Products Corp., a Delaware corporation, against H.E.W. Secretary Robert H. Finch and FDA Commissioner Herbert L. Ley, Jr.: that the plaintiff, through its operating subsidiaries and divisions (e.g. Wyeth Laboratories, Inc.) engaged in manufacturing and selling antibiotic drugs, including Wycillin SM procaine penicillin G and streptomycin sulfate combination injections, Bicillimycin penicillins and streptomycin sulfate combination injection, Bicillin-Sulfas benzathine penicillin G and sulfonamides combination suspension and tablets, and Pen-Vee Sulfas phenoxymethyl penicillin, sulfadiazine, and sulfamerazine combination tablets and suspension; that none of the above-listed drugs of plaintiff were to be dispensed, administered, or sold, except upon a physician's prescription; that plaintiff was required by law, 502(l), to obtain an effective certificate to market any drug product containing penicillin or streptomycin; that plaintiff had, until recently, repeatedly applied for and obtained certification by FDA of such drugs; that, early in 1966, the FDA Commissioner announced he had requested the National Academy of Sciences-National Research Council ("NAS-NRC") to investigate, among other things, the efficacy of antibiotic drugs being certified pursuant to the law prior to the 1962 amendments of the law; that, on October 6, 1966, the Commissioner ordered the manufacturers of such antibiotic drugs to report certain data to FDA; that the plaintiff submitted the required reports; that on April 2, 1969, the Commissioner published *Federal Register* notices of his intention to delete plaintiff's antibiotic products, among others, from the list of drugs acceptable for certification; that the bases of the Commissioner's proposal were the opinion of panels of the NAS-NRC (the identities of whose members, except for the chairman, were unknown to the Commissioner); that FDA had not conducted any independent investigation of the plaintiff's drugs or of the bases of the NAS-NRC opinions; that the NAS-NRC reports concluded that plaintiff's combination antibiotic drugs were not relatively more effective than their individual components used separately or than other antibiotics; that those reports acknowledge the effectiveness of the simultaneous use of penicillin with streptomycin or sulfonamide for certain diseases; that although reference was made to an increased risk, it was not suggested that such simultaneous use presented an imminent hazard to health; that the NAS-NRC panels' conclusions were not materially different from views publicly expressed at least as early as 1957 by some of the leading NAS-NRC members; that, pursuant to the Commissioner's April 2, 1969, publications, plaintiff submitted data bearing on the safety and efficacy of its drug products and on the proposed delisting from certification, and requested a hearing; that on April 8, 1969, the Commissioner published certain procedural regulations concerning *Hearing Procedures for the Issuance, Amendment or Repeal of Antibiotic Drug Regulations* that provided for an opportunity for a hearing before such



order of amendment or repeal became effective, except such amendment or repeal might be effective on the date of publication, if the Commissioner found that "Such an order is necessary to deal with an imminent hazard to public health;" that, on June 13, 1969, the Commissioner published orders deleting plaintiff's products from the list of antibiotic drugs eligible for certification, asserting that plaintiff's recent submission of data bearing on safety and efficacy of its drug products did not contain "any clinical data" and did not "provide substantial evidence of the effectiveness of such combination drugs," and that there were "known hazards associated with the use of each component of such combination"; that it was clear that, unless enjoined and restrained by the court, the defendants would not grant a hearing, if at all, until after plaintiff's drugs had been removed from the market, and plaintiff was deprived of any meaningful opportunity to test or discover the evidentiary basis for such orders and would suffer irreparable harm by the removal of its drugs from the market without first having had an opportunity to be heard; that the defendant's actions and orders were in excess of their lawful authority, and arbitrarily and capriciously denied plaintiff its right to a hearing; that such a hearing was required: (a) by the Food, Drug, and Cosmetic Act, (b) by the Administrative Procedure Act, (c) by the Fifth Amendment and principle of fairness and administrative due process, and (d) by defendants' own regulations of April 8, 1969; that neither section 507 nor section 701(a) granted authority to remove antibiotic drugs from the market without a hearing; that in issuing orders of summary removal of the plaintiff's drugs from the market, the Commissioner exceeded his authority under the Act and failed to observe the required procedures; that Commissioner's order of October 6, 1966, exceeded his authority in including plaintiff's drugs to be investigated by the NAS-NRC for efficacy; that the standards of evaluation employed by the NAS-NRC panels and adopted by the Commissioner, were not in accordance with the applicable standards required by the Act; that unless enjoined and restrained by the court, the plaintiff, as well as physicians and patients, would be irreparably injured. The Government moved to dismiss or for summary judgment.

The court granted the plaintiff's motion, concluding:

"1. The amount in controversy exceeds the sum of \$10,000 and the pleadings, affidavits, briefs, and arguments, herein reflect an actual justiciable controversy between the parties. . . .

"2. The subsection of the Act . . . which authorizes judicial review in an appropriate Court of Appeals of the issuance, amendment or repeal of antibiotic regulations . . . is not exclusive in that the subsection contains a 'savings clause' which also provides: 'The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law' The 'savings clause' is to be taken at its face value, and to be read in harmony with the policy favoring judicial review in proper cases. *Abbott Laboratories v. Gardner*,

"3. The issues raised in this case are 'ripe' for judicial review under the tests laid down in *Abbott Laboratories*, . . . and in *Toilet Goods Ass'n v. Gardner*, The Court is not concerned with the final resolution of factual issues raised by the parties. It is solely concerned with the legal question of whether, and in what circumstances, plaintiff is entitled to a hearing by the Commissioner and whether the Commissioner should refrain from enforcing his Orders prior to his action on plaintiff's Objections to those Orders and Request for a Hearing.

"4. *Myers v. Bethlehem Shipbuilding Corp.*, . . . relied upon by defendants is inapposite since it involved an attempt to prevent a hearing, whereas here plaintiff is attempting to enjoin enforcement of Orders until a hearing has been provided. . . .

"5. Section 507(f) of the Act requires a hearing in cases in which 'reasonable grounds' are presented. In . . . [*Dyestuffs & Chemicals, Inc. v. Fleming*] the Court held the objections legally insufficient because the Supreme Court had recently interpreted the law so as to make the factual arguments raised as objections 'frivolous'. Here, however, no such recent and decisive resolution of the legal issues has been made. To this Court, unskilled in science or medicine, it appears that plaintiff's position, supported by affidavits and medical literature, presents meritorious factual issues to the Commissioner regarding the methods and materials used by the NAS/NRC; the philoso-

phy of the panel members as to fixed combination drugs; the merits of other medical philosophies pertaining to such drugs; the effect of the medical literature dealing with plaintiff's products; and the weight to be given the long period of clinical experience with plaintiff's products. No holding of law has made these considerations irrelevant, and none of the Commissioner's orders has yet resolved them. Thus, the holding in *Dyestuffs*, *supra*, does not apply in this case.

"6. Further, if plaintiff's objections do raise meritorious issues of fact plaintiff should be permitted to produce its evidence on the merits at a hearing. . . .

"7. While the Commissioner has not made a final determination as to whether 'reasonable grounds' for a hearing exist, it appears to the Court that the objections of plaintiff presented to the Commissioner are not 'frivolous', 'inconsequential' or 'legally insufficient'. *Dyestuffs*, *supra*.

"It appears to this Court that the Commissioner may have made the test of substantial evidence of effectiveness—the showing required to justify continued certification of the drug—the test of whether the plaintiff is entitled to a hearing. . . .

"My reading of the *Dyestuffs* case and interpretation of the statutory scheme provided by § 507(f) of the Act indicates that 'reasonable grounds' should be understood as meritorious, non-frivolous objections, which could most appropriately be resolved finally after a full hearing. Not only would a hearing provide the opportunity for the development of a more ample record, through the testimony and cross-examination of witnesses, but in light of the requirement of fundamental fairness implicit in due process, would seem to be the appropriate method to answer finally any meritorious objections to the Commissioner's decision to order removal of plaintiff's drugs from the market.

"In the present action the Commissioner, without making a final determination whether such reasonable grounds exist, has proceeded to order the removal of plaintiff's drugs from the market. This action is immediately and irreparably harmful to plaintiff and anticipates either that no hearing will be held or that the outcome of a hearing will be favorable to the defendants.

"This Court concludes from a reading of the pertinent legislative history and related portions of the Act that it was the intent of Congress, in the absence of a finding of imminent hazard to public health, that the Commissioner should proceed with appropriate respect for procedural fairness and extend to all interested parties a full opportunity to develop and present pertinent information prior to taking such drastic action. . . .

"8. Although on its face § 507(f) does not provide for an automatic stay of FDA's Orders upon the filing of objections thereto, other provisions of the Act . . . do provide for an automatic stay. In addition, although no automatic stay is specifically provided for in the regulations promulgated by the Commissioner to govern his procedure in cases such as this, those regulations appear ambiguous. . . . The Court believes, therefore, that a stay is not prohibited as a matter of law and that the principles of equity and the Administrative Procedure Act . . . may be applied to determine whether such a stay should be granted. . . .

"9. The factors to be considered by a court in deciding whether administrative action should be stayed were summarized in the often cited case of *Virginia Petroleum Jobbers Ass'n v. F. P. C.*, These factors are, in brief summary, whether petitioner will suffer irreparable damage if the stay is not granted, whether the public interest calls for denial of a stay, and whether there is a substantial indication of probable success on the merits.

"10. As to the first factor, the plaintiff has demonstrated to the satisfaction of the Court that immediate enforcement of the removal Orders will cause it irreparable harm.

"11. As to the second factor the public interest does not require this Court to permit defendants to act prior to their final determination of whether such action is proper. Indeed, it is clear to the Court that plaintiff's products had been sold and used by practicing physicians for up to 17 years; that the Commissioner took no action on the NAS/NRC reports for six months after receiving the reports, and did not mention a hazard of any kind for at least nine months; that plaintiff, until April 2, 1969, had been led to believe that information on the basis of which its drugs had been certified for many years was sufficient; and until June 13, 1969, that it would be



afforded an opportunity to present its evidence at a hearing; and that the Commissioner has never explained the precise nature of the evidence it is now demanding, being content to state that what has been presented has not been 'substantial' or 'adequate' or 'well-controlled'. Counsel for defendants suggest that plaintiff was required to and should have conducted 'well-controlled clinical tests' on a continuing basis since 1952, or at least since 1966. Yet, the record shows that the FDA never demanded such tests of plaintiff until its June 13 Orders. It will be recalled that in its April 2 Orders, FDA requested only 'pertinent data'.

"12. As to the third factor, the likelihood of success on the merits is not of itself dispositive, and must be balanced against the other equitable considerations which *Virginia Petroleum* requires the Court to consider. This Court has already found that the objections of plaintiff, adduced in support of a request for a hearing, are not 'frivolous', 'inconsequential' or 'legally insufficient'. In the exercise of its general equitable jurisdiction, the Court does not find it necessary to conclude that the plaintiffs must demonstrate a *substantial* likelihood of success on the merits before the Commissioner in order to grant an injunction at this time. The Court in *Virginia Petroleum* indicated in *dicta* that the exercise of the Court's equitable powers rested finally on a weighing of these different factors. . . . It is fully consistent with this application of a balancing principle for the Court here to require a showing of less than a 'substantial' indication of probable success' on the merits if the likelihood of irreparable injury is clear.

"Second, the context in which the test of a substantial likelihood of success on the merits was enunciated in *Virginia Petroleum* differs markedly from the circumstances of this case. . . . Here, the question is not of court interference with 'ordinary processes of administration' pending *judicial review*, but rather one of insuring the functioning of the 'ordinary processes of administration' necessary to protect the procedural rights of the plaintiff and prevent irreparable injury to him. Further, in contrast to a determination of probable success on appeal, this Court does not possess the necessary expertise to determine, in advance of a hearing before the appropriate administrative body, whether the plaintiff will have a 'substantial likelihood of success' before that body.

"13. The Court concludes, therefore, that the plaintiff should have an injunction restraining the defendants from taking any action to implement their Orders of June 13, 1969, until thirty days after the date on which the defendants have completed appropriate action on the objections filed by plaintiff on June 9, 1969 and that defendants' motions to dismiss and for summary judgment should be denied."

Subsequently, FDA published new regulations setting forth principles with regard to adequate and well-controlled clinical investigations. Subsequently, the plaintiff voluntarily withdrew from the market all of the subject antibiotic combination drugs except Wycillin SM 600 injection. In addition, plaintiff offered, at a conference with FDA, to relabel Wycillin SM 600 injection, so as to limit its indications for use to treatment of surgical infections for a period not exceeding seven days. However, FDA's evaluation of the evidence supporting plaintiff's proposed revised labeling for Wycillin SM 600 injection was that there was a lack of substantial evidence to prove that the dosage levels were demonstrably effective. Nevertheless, the parties agreed that Wyeth would have an opportunity to revise and supplement its July 9, 1969, *Objections to Orders and Request for Hearing*, so as to reflect a continuing objection and request for hearing on Wycillin SM 600 injection. However, on May 21, 1971, due to the unwarranted hazard from this fixed combination antibiotic therapy (i.e., the known hazards of deafness from streptomycin and of allergenicity from penicillin) and the lack of substantial evidence of effectiveness, FDA ordered Wycillin SM 600 deleted from the list of drugs acceptable for certification.

The plaintiff continued to strongly object to the FDA's effort to circumscribe its right to a hearing, by asking for adequate and well-controlled investigations showing that the combination drug would be effective and safe; and plaintiff continued to object to the FDA attempt to erect a standard for determining whether a hearing should be held. The plaintiff therefore requested that the Commissioner order a full and complete hearing before taking action against Wycillin SM 600, and

requested a stay of the Commissioner's order of May 21, 1971, until after a final determination on the merits or after an administrative hearing on the merits. After argument before the court, the plaintiff advised that it *did not intend* to appeal the case. Thereafter, plaintiff sent a formal discontinued product notice to all its branches and ceased manufacturing and distributing its remaining penicillin-streptomycin combination product, Wycillin SM 600 injection. (Misc. No. 125; N.J. No. 39)

Serc betahistine hydrochloride tablets and the staying of the order withdrawing approval of its New Drug Application, suit of mandamus and injunction, Washington, Dist. Columbia.

Charged 12-15-72 by Consumers Union of U.S., Inc., Mount Vernon, N.Y., against H.E.W. Secretary Elliot L. Richardson, and FDA Commissioner Charles C. Edwards, in suit to compel the implementation of the Commissioner's order withdrawing the approval of Serc's New Drug Application: that Consumers Union represented its members in proceedings of significant concern to consumers, many of whom suffered from Meniere's syndrome (a middle ear disease) and many of whom, in reliance upon defendants' approval of the marketing of Serc, had purchased and continued to purchase Serc for use as therapy for such disease; that, in 1966, FDA had approved a New Drug Application for Serc tablets filed by Unimed, Inc., Morristown, N.J.; that, in 1967, FDA learned that, as a result of untrue statements in the Serc application and defects in the efficacy studies, there was a lack of substantial evidence of the efficacy of Serc; that, in 1968, FDA published a Notice of Opportunity for Hearing on the FDA proposal to withdraw approval of Serc; that, in 1970, after a hearing, FDA issued a final order withdrawing approval of Serc; that subsequently, FDA issued a stay of such Final Order pending Unimed's petition for review in the Court of Appeals; that, in 1972, the Court of Appeals denied the petition for review and affirmed the Final Order; that, nevertheless, FDA wrote Unimed, Inc., that the matter was "being continued" pending further efficacy studies by Unimed, Inc.; that, despite repeated demands for the implementation of the Final Order, FDA refused to implement it; and that plaintiff accordingly requested a court order requiring the implementation of the Final Order.

At about the time the plaintiff's action was filed, FDA had completed its review of six studies in progress by qualified investigators of Serc, in order to identify any trend that might provide justification for the continuous marketing of Serc. FDA concluded that there was no such trend, revoked the stay of the order withdrawing the New Drug Application for Serc, and advised Unimed, Inc., that any further shipments of Serc in interstate commerce would be unlawful. Shortly thereafter, FDA telegraphed Unimed, Inc., to make clear its view that all stocks of Serc must be recalled. Since the stay was revoked and the six studies, if continued, were to be monitored under an investigational exemption, the plaintiff's action was deemed moot and the case was dismissed. (Misc. No. 208; N.J. No. 40)

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

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

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

Alexander M. Schmidt, M.D., *Commissioner of Food and Drugs*
Washington, D.C., April 1, 1976

The Index lists all articles published in FDA Consumer (and its predecessor, FDA Papers) through the December 1975-January 1976 issue. It is arranged by subject—from "Abbreviated New

For a free copy of the Index write to the Food and Drug Administration, HFI-20, 5600 Fishers Lane, Rockville, Md. 20852.

FDA has proposed to withdraw approval of the drug diethylstilbestrol (DES) as a growth promoter in cattle and sheep.

FDA previously attempted to ban DES, a potent mutagen in animals, but the U.S. Court of Appeals for the District of Columbia in 1974 overturned the ban. It concluded that the Agency had not provided manufacturers of DES adequate opportunity for comment. An industry spokesman says that DES is available in Mexico and that the U.S. is not a major importer of the drug. He says that the drug is available in the U.S. for injection and that it is used in Mexico for the treatment of cancer.

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Howard R. Roberts, acting director, Bureau of Alcohol, Tobacco, and Drug Administration, at the International Executive Association Annual Conference.

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Function Proteins required for growth and maintenance are part of the genome (DNA). They code for specific characteristics and the most essential amount of each is needed when the species undergoes rapid pregnancy and nursing activity. If there is a loss of hemorrhage, or a popular herb, the amount of each growing must be strenuously maintained. The active substances and the active substances of each type of tea, such as heat, stirring, natural elasticity and vitality at a certain level. The growth of the plant is complete with the leaf with the men are killing b

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