FDA'S DRUG BULLETIN

The Current Status Of Food Regulation

REDUCING INJURIES FROM EYEGlasses
"We are carefully to preserve that life which the Author of nature has given us, for it was no idle gift."

Harvey W. Wiley, 1844-1930
Father of the Federal Food and Drugs Act of 1906
From his commencement address
"Life and the Coming Time"
Hanover College, 1867

The soldier fighting a war waits until it’s over before he writes about it for one or both of these reasons: (1) he’s too busy fighting to write; (2) hindsight, if he survives, gives him time to make the case that all his decisions were logical.

Now comes the tape-recorded interview, a handy if sometimes tricky journalistic mechanism for catching a busy official in motion and putting his thoughts into print—in his own words—while the shooting is still going on. It asks him to describe and synthesize his whole operation in a few extemporaneous sentences. Its usefulness depends on the importance of the subject covered, the substance of what the interviewee says, and his ability—off the cuff—to get through clearly to the reader.

That’s asking a lot, but we think Virgil O. Wodicka, director of FDA’s Bureau of Foods, comes off creditably in telling what his Bureau has been doing and where it’s headed in its mission of consumer protection (see page 10). We hope in future issues to find other FDA officials just as able to shoot from the hip—and just as accurate.

(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 the 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.

Advisors to the Editor*

H. Nelson Fitton, Department of Agriculture; George Crew, Department of Housing and Urban Development; William J. Cottin, Post Office Department; Henry Scharer, Department of Commerce; Dr. Milner B. Scheeler, Department of the Interior; Dr. Sam Kaim, Veterans Administration; Dr. Peter V. Sager, Federal Aviation Agency; Dr. Spofford G. English, United States Atomic Energy Commission; Dr. Harve J. Carlson, National Science Foundation; Howard J. Lewis, National Academy of Sciences; Arthur Settle, Bureau of Customs.

*The Food and Drug Administration is solely responsible for the contents of FDA PAPERS. The Advisors to the Editor are consultants on matters relating to the functions of the Federal Departments and Agencies listed.
4 Closing the Communications Gap: FDA's Drug Bulletin
Relaying new and important information about drugs to the busy physician.

8 Reducing Injuries From Shattered Eyeglasses
Better protection is promised by new rules requiring that lenses be resistant to impacts.

10 The Current Status of Food Regulation
Major problems and undertakings facing FDA's biggest bureau and the underlying consumer protection philosophy.

17 Field Reports
22 Product Safety Report
24 News Highlights
28 State Actions
29 Seizures and Postal Service Cases
32 Notices of Judgment
CLOSING THE COMMUNICATIONS GAP:
FDA'S DRUG BULLETIN
by Henry E. Simmons, M.D., M.P.H.
FDA's Drug Bulletin, put out by the Bureau of Drugs, is designed to remedy one of the most intriguing and important problems facing the Agency's drug regulatory efforts—how to communicate up-to-date, objective, and useful information on drugs to the overworked American physician.

The problem stems from events that have taken place in the drug producing and medical communities since World War II. After the war, the “Golden Age” of drug development began. New products representing significant advances in therapy were being developed continually. According to figures compiled by Paul de Haen, a New York City pharmaceutical consultant, more than 400 new drug products and new dosage forms were introduced in every year from 1948 through 1960.

As a result of the rapid increase in the number of new drugs developed after the war, many physicians found it difficult to keep abreast of advances in drug therapy. Drug manufacturers stepped in to perform the vital function of keeping physicians informed of the development and availability of new products. The drug industry became the primary providers of drug prescribing information.

The system had its benefits as well as its drawbacks. Physicians were being kept abreast of new developments in drug therapy. Significant increases in the numbers of prescriptions written each year attest to that. But at the same time, physicians were not being made aware of drugs’ side effects, dangers, or contraindications. An imbalance in drug information came about. Today, we would call that imbalance a “communications gap.”

FDA and the Congress undertook several measures during the 1960's in an attempt to close the “communications gap.” In 1961, FDA promulgated a regulation aimed at providing the physician with more balanced information about prescription drugs. The regulation provided for the package insert. It required that labeling bear adequate directions for use, including indications, effects, dosages, hazards, side effects, precautions, and routes, methods, and frequency of administration.

A year later, in October 1962, Congress enacted the Kefauver-Harris Drug Amendments. The most publicized amendment was the one that required drug manufacturers to prove the effectiveness as well as the safety of their products. But one amendment also dealt with the difficult problem of drug advertising. That amendment vested in FDA the sole responsibility for regulation of advertising and other descriptive printed material for prescription drugs. (For an account of FDA’s implementation of the advertising amendment, see FDA PAPERS, February 1972.)

THE PRESCRIBING PROBLEM

More than two years ago the Bureau of Drugs began to evaluate how well such measures as the package insert regulation and the advertising amendments had succeeded in closing the “communications gap.” We concluded that much still has to be accomplished.

We found that physicians rarely see the package inserts. The primary purpose of inserts has been to provide the basis for drug information disseminated by the drug companies. Physicians rely for their prescribing information on detailmen, advertising, medical journal articles, colleagues, medical meetings, and summarized labeling provided in such publications as the Physicians' Desk Reference (PDR).

We also found, through the Drug Efficacy Study conducted for FDA by the National Academy of Sciences/National Research Council, that 10 to 15 percent of the drug products for which New Drug Applications were approved between 1938 and 1962 on the basis of safety alone, lacked substantial evidence of effectiveness. Many of these ineffective drugs were among the most prescribed. FDA has taken steps to remove many of these products from the marketplace, and efforts in that direction are continuing. But the question lingers: How could so many questionable drugs remain on the market so long and be prescribed by physicians?

There is still other evidence that physicians need additional, objective information on which to base rational therapeutics. There is evidence that an adverse reaction or complication in drug therapy is found in about 10 percent of drug exposures, and that drug reactions are a major factor leading to hospitalization in about 5 percent of patients admitted to the medical services of general hospitals. It is estimated that 1.5 million hospital admissions each year are made.
necessary by diseases caused by drugs.

In addition, recent studies show that numerous physicians prescribe far too many drugs. The average hospitalized patient receives eight to ten drugs per admission. Some patients have been known to receive as many as 30 drugs in the hospital. In other cases, drugs have been used inappropriately. The story of chloramphenicol, for example, is well documented. Amphetamines and barbiturates are two classes of drugs which have been seriously overprescribed.

One study showed that in more than 40 percent of all drug exposures the result obtained was only fair or poor. Frequently the physician was unable to tell on observation of the patient whether the drug had accomplished any therapeutic effect.

Add to all this the facts that knowledge about drug interactions is still in its infancy, and that long-term studies on drugs used by patients for extended periods are infrequent, and it becomes obvious that a prescribing problem of major proportions exists in the United States. Physicians want to serve their patients well, but current drug information programs do not supply physicians with sufficient objective information on which to base rational prescribing habits. The need for the Federal Government to establish an effective and timely communications link with the medical profession to provide this information is clear.

If the physician had balanced information, honestly pointing out the limitations and actions of a drug, its beneficial and adverse effects, he would be better prepared to make rational therapeutic judgments. This type of information is not currently being provided in a form that makes rational therapeutics possible for many physicians.

FDA is in a unique position to provide American physicians with impartial prescribing information. The Bureau of Drugs is staffed by experienced physicians and other health-oriented professionals who are experts in drug therapy. Masses of scientific information flow into the Bureau of Drugs every day from practicing physicians, drug manufacturers, drug investigators, and consumers. FDA conducts numerous tests on drugs through the Bureau of Drugs' Office of Pharmaceutical Research and Testing and the National Center for Drug Analysis in St. Louis. In addition, some of the leading scientific and medical experts in the world serve on FDA advisory committees, meeting regularly to advise the Bureau on important issues.

FDA must make available to the medical profession and to the public its evaluation of all this information. The time has passed when FDA can be considered to be fulfilling its drug regulatory responsibilities merely by approving New Drug Applications or performing other evaluations, however important, without telling physicians and the public what it found. Our mission is to protect the American consumer from unsafe and ineffective drugs. Communicating with physicians is an important part of that mission.

The Drug Bulletin represents one attempt by the Bureau of Drugs to bridge the "communications gap" by providing physicians with balanced, accurate, nonpromotional, and timely information about drugs. The information is intended to be presented in a way that will serve the physician's needs as a prescriber, and the needs of his patients.

The Drug Bulletin is only one part of the Bureau of Drugs' communications program. The aim of the overall program is to deal with the "communications gap" from several vantage points. Like the rest of the program, the Drug Bulletin is still in its formative stages, and we are willing to make any necessary changes in the publication to assure its usefulness.

HISTORY OF THE BULLETIN

One of the earliest attempts to establish communications links with physicians came in September 1969, when FDA published a sample Drug Efficacy Study report on sulfonamides. The report contained "typical" NAS/NRC reports on individual drug products intended to help the practicing physician understand how the NAS/NRC study worked.

Current efforts to develop a timely and effective Drug Bulletin as part of this communications program date from April 1970. The subject of the initial bulletin, titled "Current Drug Information," was oral contraceptives. The Bulletin informed physicians that in FDA's judgment, "good therapeutics would indicate the use of the lowest effective dose of estrogen that is otherwise acceptable."
Less than two months later, in June 1970, the Agency published another issue of "Current Drug Information." It was timed to appear when FDA approved a new drug to deal with Parkinson's disease, L-Dopa. The Bulletin contained a summary of the package insert for this significant new product.

The present format of the Drug Bulletin was started in July 1971. In the introduction to that Bulletin, I said:

"The Bureau of Drugs of the Food and Drug Administration is probably the world's largest clearinghouse of drug information. One of our responsibilities is to make this important information available to practicing physicians.

"As one means of fulfilling this responsibility, we are initiating a regular series of drug bulletins which we hope will be helpful by providing accurate, objective, timely drug information to you for use in your medical practice.... Future issues of FDA Drug Bulletin will contain a greater proportion of information about matters of direct clinical import. We hope to use this means to inform you about significant new drugs prior to their marketing and also bring to your attention new information about drugs which are already in use."

The subjects covered in the initial Drug Bulletin were the NAS/NRC drug efficacy study, our policy on fixed combination prescription drugs, and oral hypoglycemic agents. The next Bulletin appeared in October. Subjects covered were methotrexate and its use in psoriasis, spectinomycin for acute gonorrhea, digoxin, isoniazid labeling changes, FDA approval of bone cements, fat labeling, and adverse reaction reporting.

In subsequent issues the Drug Bulletin dealt with such subjects as diethylstilbestrol, hexachlorophene and newborns, FDA's proposal to restrict use of hexachlorophene in drugs, soaps, and cosmetics, coronary vasodilator efficacy, the OTC Drug Review program, nitroglycerin packaging, and irrigating solutions.

More than 600,000 issues of each Drug Bulletin have been printed and sent by first-class mail. Recipients are: 320,699 physicians in the United States and possessions including military, 106,770 dentists, 12,698 osteopaths, 8,039 podiatrists, 8,590 hospital administrators, 23,344 medical students, 400 medical school deans, 7,467 third- and fourth-year dental students, 100,000 pharmacists, 9,669 pharmacy students, 87 pharmacy school deans, 55 dental school deans, and 2,973 others, including other Federal agencies, State and local health officials, and the press.

The diverse nature of the mailing lists indicates the importance we in the Bureau of Drugs place on communicating prescribing information not only to practicing physicians but to all other health professionals as well. Pharmacists in particular can use their professional status to help the Bureau communicate important drug information to consumers.

An example of how this can work is the nitroglycerin case. An FDA assay disclosed that nitroglycerin tablets decrease markedly in potency over a short period of time unless they are stored in tightly sealed glass or otherwise suitable bottles.

This information is of vital importance to physicians, who should know that unexplained patterns of therapeutic responses by patients may be caused by the manner in which the drug is packaged. FDA urged physicians to tell their patients about the need for proper packaging when prescribing the drug. But pharmacists also need to know about nitroglycerin packaging, because they are the ones who deal directly with the patients. We urged pharmacists also to remind patients to keep nitroglycerin in glass or other suitable containers at all times.

The effectiveness of the Drug Bulletin is now under review following six months of dissemination in its present format. As the Bureau of Drugs becomes more experienced in the field of medical communications, changes may be made so that the Bureau can fulfill its role more effectively by closing the "communications gap."

Henry Simmons, M.D., M.P.H., is director of the Bureau of Drugs.
A large part of the United States population wears eyeglasses—either prescription glasses to correct vision, or sunglasses. These people do essentially the same things during work, rest, and play as those who do not wear glasses, and are subject to the same accidental bumps and impacts. But they are also subject to the additional hazard of eye injury from shattering eyeglass lenses.

That’s why FDA has adopted new regulations to reduce the annual toll of eye injuries to eyeglass wearers by requiring that eyeglass and sunglass lenses manufactured after January 31 of this year be resistant to impacts.

The magnitude of the problem and the way to its solution became more evident in the past few years as eyeglasses were used in greater numbers to correct vision, and as sunglasses come into wider use. The Guild of Prescription Opticians of America says that numerous school-agers are accidentally injured each year by shattering lenses involving eyeglasses or sunglasses, and that significant numbers of Americans suffer eye injuries from eyeglass lenses broken in home accidents.

At the same time, the use of safety lenses has increased in certain industrial and other occupations where percentages of accidental bumps or impacts are high. The use in sunglasses of plastic lenses or laminated glass lenses has increased and has provided greater protection than ordinary glass lenses. And for some years now, the development and wider use of heat and chemical treatment to harden or temper prescription and other glass lenses to resist impacts have been intensifying because of the desire of eyeglass wearers to protect themselves.
physicians or optometrists to protect their patients, and parents to protect their children from accidents.

The new FDA regulations require that all prescription and nonprescription glasses or goggles manufactured after January 31 of this year, with specified exceptions, be equipped with lenses that are resistant to breaking upon impact, as determined by a standardized physical test.

The regulations apply only to lenses manufactured after January 31. Lenses in the pipeline before that date may still be sold after January 31.

Making prescription glasses impact-resistant and conducting individual tests on each lens will mean an overall increase to the consumer in the cost of a pair of glasses. Estimates are that the added cost will be $4 to $8 a pair. But this cost is expected to be offset somewhat by a reduction in accidental breakage of lenses. Nonprescription glasses with glass lenses will cost more too, but not nearly at the rate for prescription glasses because tests for impact resistance will be performed on samples only, and not on individual glasses.

The owner of glasses made before January 31 can have them treated for impact resistance by his optician or optometrist, but there can be some practical difficulties. Among them are the condition of the lenses, their thickness, and the fact that the optician or optometrist will be reluctant to assume liability for any damage that may be done to the lenses during treatment and the required testing afterward.

Under the FDA regulations, when old lenses in existing eyeglasses are replaced, impact-resistant types will be required, under the same set of conditions and exceptions as for new glasses.

The FDA rules, published in the Federal Register on February 2, contemplate that eyeglass and sunglass lenses made of glass can be made to meet the impact-resistance requirement through several means, such as heat or chemical treatment, or the use of thicker glass. Lenses not as likely to need additional treatment to meet the impact resistance requirements are plastic lenses and laminated lenses—those consisting of a sheet of plastic or other pliable transparent material sandwiched between two pieces of glass.

Contact lenses are not covered by the new regulations. Neither are the various forms of goggles and face masks such as those used in skiing and swimming. But toy sunglasses intended to be worn by children are required to be impact-resistant under the new rules.

The test for impact-resistance specifies the dropping of a steel ball ¾ inch in diameter and weighing 0.56 ounce from a height of 50 inches onto the geometric center of the lens, which rests on a prescribed surface to receive the impact. To pass the test, the lens must not fracture. Fracturing includes cracks or chips visible to the naked eye.

Every prescription lens used in eyeglasses, with certain exceptions, must be tested individually after it is finished (cut, ground, beveled, edged, polished, etc.) and before it is inserted into the frames. Nonprescription lenses of glass, plastic, or laminates must meet identical impact-resistance requirements but the test may be carried out at the factory on a “statistically significant sampling of lenses from each production batch,” instead of on each individual lens.

“Raised ledge” multifocal lenses will be tested similarly. For such lenses, the ball’s impact could chip off small bits of glass from the ledge on the side of the lens away from the eye. Such chipping would not indicate lack of safety of the lens, but would make the lens unmarketable. No such exception to individual testing is made for multifocal lenses without raised ledges, however. Consumers who do not know whether their prescription multifocal lenses are of the raised ledge type should check with their ophthalmologist, optometrist, or optician.

Also exempted from the regulations are lenses which the prescribing physician or optometrist believes cannot be made impact-resistant and still fulfill the visual requirements of the patient. Such exceptions might require grinding a lens to a thinness that would make subsequent treatment for impact-resistance impossible without affecting visual or corrective quality. Another exception might require the use of a special type of glass, such as “lent” glass, that cannot effectively be made impact-resistant. When such exceptional needs arise, the prescription must describe this need and the patient must be notified.

FDA’s new regulations also require certain record keeping by lens-making companies and dispensers of lenses. In the case of prescription lenses, the dispenser must keep prescription data and the name and address of the customer on file. Some record keeping is required for industrial safety glasses if they are of the prescription type, but here additional individual testing is not required by FDA, since such lenses must undergo more rigorous testing under American National Standards Institute specifications.
The Current Status of Food Regulation

by Virgil O. Wodicka, Ph.D.

There's "nothing to eat but food," said the poet, which is why FDA devotes so much attention to this critical regulatory responsibility. The Bureau of Foods handles a wide variety of programs and is responsible for assuring that the American food supply is safe and wholesome. Dr. Virgil O. Wodicka presides over FDA's regulatory efforts in the food area as director of the Bureau of Foods. In this interview with the editors of FDA PAPERS, Dr. Wodicka discusses some of the major issues in the Federal Government's efforts to regulate the food supply. Among the subjects he covers:

- Unavoidable defects in foods.
- Organic foods.
- Saccharin.
- Bureau of Foods priorities.
- Botulism and canned goods.
- Color additives.
- Fabricated foods.
- Steps for the consumer.
Q. Dr. Wodicka, is the American food supply safe at the present time?

A. It is safer than it has ever been before, and as safe as we know how to make it. Agricultural sanitary practices are probably better now than ever before. Pesticides, about which there has been a great deal of concern, are probably safer than the ones used by our grandparents. The whole trend of the times has been to increase safety rather than impair it.

Q. FDA recently stated its position on natural unavoidable defects in food that present no health hazard. What is FDA's position on "filth" in foods and what are the problems involved?

A. The issue of unavoidable defects in food for human use is difficult to discuss. Though these defects have been recognized since the limitation on mold in tomato pulp in 1911, the esthetics are troublesome to most of us.

But let's set some of the ground rules. First, we are talking about defects which present no health hazard. While this may seem obvious, it cannot be emphasized too strongly.

Second, we are talking about defects which are technologically unavoidable. The preparation, storage, and handling of food under insanitary conditions cannot and will not be condoned, regardless of the level found in the product.

Third, we are talking about defects that have been with us for a long time. Finally, we are talking about, for the most part, very minute amounts. With that as a background let me be candid about the kinds of defects involved.

Among other materials, parts of insects, larvae, and even waste material from animals may be found. Let me repeat, we are speaking about substances which may bother us esthetically, but which present no health hazards, and which under the best technology we have today, are simply and completely unavoidable.

Q. Dr. Wodicka, are you telling the American people that there may be pieces of insect in their food, and there is nothing you can do about it?

A. There is something we can do about it. First, we can vigorously enforce the law by inspecting food plants and warehouses to see that scrupulous attention is paid to quality control. We can see that every possible effort is made by industry to keep defects out of foods.

We can work with the scientific community and consumer groups to see that the latest methods of processing and the best plant designs are used by industry. We can see that guidelines are not thought of as engraved in stone, but intended only to represent the state of the art, and that such guidelines will continuously be reduced wherever possible.

However, I must say if your question is whether or not the Food and Drug Administration can keep every worm out of every apple on every tree, the answer is an unqualified no.

Q. Dr. Wodicka, is it dangerous for the American consumer to have these things in food?

A. No. The substances that truly concern us from a toxicological point of view are pesticide residues, heavy metals, and the like. As you will recall, one of our ground rules in the guidelines for unavoidable defects was that they present no health hazard.

Q. When we talk about these defects, does that include what is called extraneous matter such as dirt, rocks, and other non-food particles that may get into the food one way or the other?

A. Yes. These are also the consequences of exposure to the normal course of nature. Often these substances are introduced at the agricultural level, and many steps in factories and other processing plants are devoted exclusively to removing them.

However, these substances may get into food in factories operating under insanitary conditions. Again, it must be emphasized that such violations of the law will be severely treated.

Q. Does this mean FDA's position is that processed foods—foods that we can buy in the supermarket—are cleaner and more wholesome than organically grown foods?

A. No. Bear in mind that FDA imposes the same standards on everything in the marketplace which passes in interstate commerce. Avoiding commercial channels, and going to home gardening does not avoid the defect problem. So-called organic foods that are raised without pesticides may be subjected to even more pests.

Q. Does FDA have a formal position on the use of organic foods?

A. No. It's a free country, anybody can eat anything he wants to, whether or not it's clean, tasty, nutritious, or anything else. If organic foods are the things that strike his fancy, it is his opportunity to use them—unless they are...
contaminated to the point of being illegal or falsely represented under existing law and regulations.

Q. Does this mean that if a food is labeled as being “organic” that it has to be organically grown? Does FDA have a regulatory program on organic foods?

A. FDA does not have a regulatory program in this area because, although there is some loose commonality to the word “organic,” there is no unanimous agreement. Thus, the meaning of the term varies depending on who is using it.

FDA has traditionally avoided to the extent possible the imposition of any requirements on the food supply that it is not in a position to enforce, and there is no way to determine from the finished product whether it has been grown under the conditions specified by the common definitions of “organic” or “natural.”

Q. FDA has removed saccharin from the GRAS (Generally Recognized As Safe) list. Taken together with the cyclamate ban, this has caused some concern. Many people are wondering about risks that have recently been found with a variety of well-known chemicals. What’s the saccharin story? What is FDA doing about other chemicals?

A. When we talk about these chemicals, we are talking about everything we put in our mouths, from H₂O—or water—on, because they are all chemicals. And when we talk about the safety of these chemicals, we are talking about a negative concept, because safety consists of the absence of hazard, and we can never prove anything like this.

There is no such thing as testing for safety. You test for various specific hazards. If you don’t find them, you conclude that the product is safe.

On the other hand, if somebody thinks of a new hazard, tests for it, and finds it, then we have to change our minds on whether or not it is safe. This is bound to happen as time goes on and scientific knowledge increases.

In the specific case of saccharin, there have been some recent tests that were suggested by the committee of the National Academy of Sciences that reviewed the safety of saccharin a couple of years ago. These tests are in the process of being completed, but the first one to be finished has raised some questions about safety. We have referred it back to the committee. I would expect the committee would probably want to wait until other tests are in before reviewing the evidence and drawing some sort of conclusion. There is no telling what the conclusion will be.

Q. FDA has adopted certain regulatory action levels for residues of mercury and other toxic metals in tuna and swordfish which are based on the best judgments of scientists. However, reports seem to indicate that some of these metals may have been in tuna and swordfish and other large ocean fish for many years, possibly a hundred years or even thousands, and that the only way anybody can ever determine whether people were poisoned a hundred years ago would be to make a lifetime study, which is obviously impossible. Is FDA disposed to make any reasonably long-term studies of the effects of larger amounts of mercury in tuna and swordfish?

A. Obviously, we are not going to run lifetime studies of toxic materials in people. But whether these materials have been present in the food supply for decades or centuries or even millenia is really irrelevant.

The point is that the position on limits and control of foods must be based on our knowledge of consumption patterns and safe levels. The concept that has been incorporated pretty firmly into all our decisions in recent years has been that of a safety margin.

In other words, there are certain factors that are not tested for, because it is essentially impossible to test for them, and these are lumped into a safety factor. When we have data based on human exposure—which we happen to have in the case of mercury because of the 1950’s episode in Minamata, Japan—we try to establish a maximum permissible level at one tenth of the maximum no-effect level derived from human experience.

Where we have no human experience, we try to limit exposure to one one-hundredth of the highest level at which there is no injury to animals. In the case of mercury, the level was actually set at one-tenth of the lowest effect level—in other words, at 10 times the level we set in fish, there was injury to people in Japan.

You have to realize that most people don’t eat enough tuna or swordfish to get themselves into trouble, but it is possible to eat enough of these fish to invade the safety margin considerably. As a consequence, we have tried to control the food supply to avoid undue exposure of consumers to quantities that would border on toxic. We are trying to maintain a balance between the highest permitted exposure and the lowest level at which poisoning would show up.

We have this same kind of problem with many of the other hazards that have been attracting a lot of public attention. The aim is to build an open space

12 / March 1972 / FDA Papers
between the level of exposure and the level of injury, rather than to avoid injury that has occurred or might occur. We always seek to err on the side of caution.

Q. About a year ago all of us were reading about botulism in soup. What did FDA learn from this case and what has FDA done in the past year to see that similar situations are avoided?

A. I don't know that the FDA has necessarily learned anything from this botulism episode. Something went wrong; it was an abnormal situation, but this kind of thing is essentially unavoidable by any sort of regulatory approach or, for that matter, industrial approach.

People do make mistakes, and all you can do is try to design a system that will minimize them. But it won't eliminate them.

Q. Are there things that FDA can do to reduce the risk of this sort of thing?

A. Yes, and it is doing them. The industry has been strongly influenced by the crisis of public confidence created by this situation to the point where it too is moving forward actively to cooperate with FDA in setting up a more effective plan. We will publish any plan for consumer comment.

FDA is improving the effectiveness of its field operation to put the emphasis on inspection of quality control rather than production. This gives us more leverage in assuring that the processor himself is controlling the quality, including the safety. In this way we have some assurance that things are going to be under control on the days when the FDA inspector isn't present.

We have rejected the idea that inspectors should look at how a manufacturer runs its plant without regard to how good the controls are. All we can find under this inspection system is what a manufacturer does wrong habitually or what it does wrong on that day—and on a work sampling basis, we average one inspection every six years, which isn't much of a sample.

So in a general way, putting the emphasis on quality control will considerably improve the state of affairs in terms of reducing the chances that such incidents will happen. We are after more than assuring proper manufacturing sessions, we want a proper system that is on the job every day.

In the specific instance of canning, we are going beyond this, because there happens to be a specific provision of the law that was introduced to cope with this kind of problem.

The action proposed by the National Canners Association (NCA), with the concurrence of this Agency, would require canners to operate under a series of stringent good manufacturing practices or go out of business. The action would provide for the issuance of only a temporary permit to any processor who falls. Unless swift remedial steps are taken, the processor could be closed down.

If a processor does not employ good manufacturing practices at certain critical points, it is prima facie evidence of conditions that invoke the permit clause, and he could not operate without one. Obviously, if he is operating under poor conditions, even a temporary permit would be denied. This constitutes a persuasive argument for him to use good manufacturing practices in the first place.

Q. You have been with FDA for nearly two years. Are you pleased with the cooperation that you have received from industry in terms of voluntary compliance with FDA regulations?

A. Yes, I would say so. After all, industry's interest is the same as ours in keeping the consumer satisfied and healthy. If industry were not making some effort in this direction, nothing we could do would insure a safe food supply.

With a tremendous volume of food in interstate commerce daily, we cannot hope to check even a majority of shipments. The main reliance on safety and quality must be on the processor. Of course, if our audit discloses failure to perform, our authority under the law is substantial.

Q. The Bureau of Foods is the biggest FDA Bureau. The proposed budget for fiscal year 1973 as sent by the Office of Management and Budget to the Congress is $57 million. What is the scope of the Bureau of Foods? What activities does it get into and what do you propose to do with additional money that Congress might appropriate for the coming fiscal year?

A. The emphasis of the additional funds this year is going to be in the field operations. Most of the additional personnel will go to the District offices, where the emphasis of the program will fall. The Bureau is working with the Districts in planning the use of these resources, and much of the emphasis is going to be along lines I have indicated, such as training the additional inspectors in the techniques of industrial quality control. We hope to increase the frequency of inspections and to improve their effectiveness and efficiency to the point where the reliability of the food supply will be increased even beyond what it is now. In terms of scope, the food program obviously gives primary attention to food safety.

First on the list here is foodborne disease; botulism
being the most extreme example because it is so often fatal. But qualified assessments suggest that there are anywhere from 2 to 10 million cases a year of foodborne disease of all kinds now. Some new causes of disease are being identified. Whether they are in fact new causes or new identifications remains an open question, but in any event we are finding reasons for foodborne disease that we didn’t know about previously.

We are putting a considerable degree of our emphasis on ways to control these. They include the mycotoxins, such as aflatoxin, which we are finding more prevalent than we realized earlier. We are taking steps to cope with that.

The next hazard to public health associated with foods is malnutrition and we are working here to develop guidelines where the nutritive value might not otherwise be too clear. We also have a labeling program to communicate to consumers the nutritive value of food. This is about all we can do to permit the consumer to make informed choices of foods to avoid the problems of malnutrition.

The third hazard associated with food involves environmental contaminants, such as industrial chemicals, both of a metallic kind and of an organic nature such as the polychlorinated biphenyls (PCB’s). We are intensifying our program here to identify and characterize the hazards that may exist along these lines.

The fourth hazard I would list is that of naturally occurring toxins such as the goiter-promoting properties in vegetables of the cabbage family, and certain toxins that occur in certain seafoods or can occur naturally in leguminous vegetables. These toxins are destroyed by cooking, but if you eat raw lima beans, for example, you are taking chances. These are difficult to cope with—they are so varied in nature. The only defense against them is knowledge or rigid adherence to traditional practices.

The fifth hazard is pesticide residues. We have the responsibility for enforcing tolerances in this area even though the Environmental Protection Agency has responsibility for setting the tolerances.

Sixth, there is the matter of hazards associated with food additives. We are currently engaged in reviewing the safety of food additives to make sure there aren’t any known hazards associated with them, particularly some of those that have been in use for tens or hundreds of years but have never been formally tested despite extensive use all over the world.

This is pretty much our food safety program. We also have a program in the area of economics which involves such things as food standards and the Fair Packaging and Labeling Act, where the current emphasis is on nonfunctional slack fill. In that regard we have asked 11 States on a contract basis to investigate the space in packages of widely sold commodities that is not filled with product. This is the slack fill. Now that we know how much slack fill there is, our remaining task is to determine whether the space is functional or nonfunctional; in other words, whether or not it is possible for that space to be filled with the product when ordinary high speed commercial filling equipment is used. This cannot be categorically determined. It must be determined plant-by-plant and product-by-product to find out the conditions of operation and what might be done to use the space more effectively.

Q. What about color additives? Why have we been reading so much about them in the past two months?

A. Some work was done in Russia several years ago on the product Amaranth, which is known to us as Red No. 2, suggesting that it could impair reproduction in test animals. This attracted attention to the fact that few of the permitted color additives have been tested for effects on reproduction, even though they have been thoroughly tested for various other hazards. This is related to the point I mentioned earlier: when somebody thinks of a new hazard and tests it, he may raise problems. That’s what happened here.

As a consequence, we are requiring that all colors intended for ingestion be tested for reproductive effects before they can be permanently listed. The listing of the colors used in the past is still provisional until these tests have been completed.

Q. You mentioned the Fair Packaging and Labeling Act. The final part of the “cents-off” and other value representations regulations go into effect June 30. Could you explain the purpose of those regulations and how they will help the consumer make better judgments in purchases?

A. The idea of the “cents-off” campaign, of course, is to permit the consumer to buy a product at a lower than customary price. The difficulty is that the price marking is applied by the manufacturer while the price itself is determined by the retailer. So whether the retailer indeed does give the customer the benefit of a price reduction has remained a question in the past, and this is the reason for incorporation in the legislation of controls in this area. The purpose of the regulation therefore is to define conditions of operation so that the consumer can be reasonably assured that the discount offered is valid.

Q. Dr. Wodicka, what can consumers do individually to make sure that the foods they eat are nutritious and wholesome?

A. With respect to nutrition, the main thing to do is to stick to the eating
habits that have succeeded for our ancestors for many centuries, until we get to the point where nutritional labeling is available and consumers know the extent to which they can depart from these habits. As things now stand, when a new food comes on the market that has never been offered before, there is no good way the consumer can know its nutritive value or whether it reaches the expected average. This is the major reason, of course, for our program in guidelines and in labeling.

From the standpoint of being wholesome, the number one hazard, as I mentioned earlier, is microbiological. The main thing to do with perishables, such as fruits and vegetables, is to wash or peel. In the case of meat products, consumers should avoid contact of cooked food with raw and, most particularly, avoid handling cooked food right after handling raw food without washing their hands.

In the case of processed foods, I think the most important thing would be to stick to intact packages as much as possible and—most particularly—on canned food not to consume food from cans whose ends are bulged or in which there has been enough of a dent to cause a distortion of the seam.

If there is any doubt of the safety of foods or any reason to feel uneasy, consumers should consult with a recognized authority such as an FDA District.

Certainly if any action is indicated or if there is suspicion that something is definitely wrong that needs correction, we want to know about it.

Q. Dr. Wodicka, as a result of the cyclamate problem two years ago, FDA began a review of the substances on the list of substances that are Generally Recognized As Safe (GRAS). What is the current status of that review and where do you expect it to go from here?

A. The contract to determine by survey the uses of the GRAS substances and their levels of use is drawing to a close. The questionnaire returns are largely in. They are being tabulated and summarized now. The contract to conduct a literature survey on safety tests of these substances is also well along. We have the final reports on a number of substances, and others of course are continuing. We are in the late stages of awarding contracts for the preparation of a monograph for each of these substances based on results of the use surveys and the literature surveys.

We have several contracts under way to test a selected number of the materials for teratogenicity and mutagenicity, as much to test the methods as to test the substances. The novelty of these fields is such that the methods are not generally accepted or agreed to, and we need to make sure that the methods are okay before we draw any conclusions from the results.

Q. What kind of a hazard do PCB’s pose for the public and what is being done in this area?

A. The PCB’s are chlorinated organic compounds that have hazards similar in type and degree to those of some of the chlorinated pesticides, with which they tend to be confused in some analytical determinations. PCB’s can hardly be abolished because there is no satisfactory replacement for them, particularly their uses in electrical transformers and capacitors.

The only manufacturer of this class of compounds in this country has restricted their sale not only to essential uses but also—in isolated systems where the possibility for contact with foods is minimal—to situations where they will not be likely to get into the environment and eventually wind up in foods.

We were having problems because these materials were being used in inks, including those in no-carbon-required copy paper. When wastes from these papers are recycled into the manufacturer’s packaging for foods, the foods can become contaminated by transfer from the package.

In other instances, these materials were used as heat exchange media, and where such a heat exchanger was used in a food plant and a leak developed, the PCB could get into food or more particularly into animal feed—the area where most of our problems have arisen—and thence into food. The removal of the PCB’s from this type of application, we hope, has taken care of this problem.

A difficulty with PCB products is that their extreme durability is one of their advantages. They are very hard to break down chemically, and therefore function well in many of their uses. But because they don’t break down easily, they endure in the environment, too. So they tend to go into second and third generation appearances, and we have to be extremely vigilant to see that they don’t show up in unexpected places.

The occurrence so far has not been at levels that would cause acute poisoning. It has been such that if the consumption continued over an extended period, exposed persons might turn up with symptoms. But so far we believe we have been able to control the exposure to the point where extended exposure doesn’t happen.

The evidence to date would suggest that general environmental contamination is not high enough to cause any great concern. The problem is with particular episodes in which there has been an accident and these materials have crept into the food supply in some fairly large scale situation. These are the things the processors and regulatory agencies are
now chasing and why we have recently had to re-
quire destruction of a rather considerable amount of food because of accidental contamination.

Q. What is FDA doing to prepare for the day when fabricated foods come on the market and may pose a health problem?

A. FDA is trying to prepare standards for certain of these materials, in part to give them an accepted nomenclature so that there is something to call them legally, and in part to establish nutritional properties that will cause them to be appropriate replacements for whatever part of the diet they happen to replace.

You have to keep in mind that food is a rather unusual commodity in that each of us has a relatively fixed calorie intake; if we eat a food material we haven’t eaten before, we eat it in place of other things. That being the case, it has to be nutritionally as satisfactory as what it replaces.

Therefore, even though the fabricated food may not be made to simulate any conventional food, it still replaces some conventional food or some other food, and therefore its nutritive properties need to be taken into account. Thus, our primary emphasis on new foods has been on nutrition, most particularly to see that they do not precipitate deficiencies of one kind or another.

Q. What is the future of food regulation?

A. The major thing that we are trying to do at the FDA is to anticipate problems instead of waiting for them to sneak up on us and cause crises. As a consequence, we are mounting programs to look for problems and trying to see that we get to them when they are small and controllable and can be handled with minimum input and excitement.

We are also trying to do our part to coordinate the endeavors not only of the regulatory agencies, which are working more closely together than they have done at times in the past, but also those of industry, consumer groups, and other elements.

We are all aimed in the same direction: to see that the whole is greater than the sum of its parts, to assure that we succeed jointly in controlling the hazards to man from the environment, from bad practices, from ignorance, from all sorts of causes, rather than arguing among ourselves as to whose fault the problem is or attacking each other for malfeasance. If we can succeed in integrating these efforts and see that they supplement instead of conflict with each other, we’ll all be better off, and the consumer will be the beneficiary.

Virgil O. Wodicka, Ph.D.
ATLANTA  Maurice Kinslow, acting regional food and drug director, Atlanta Field Office, and a staff of FDA resident inspectors based in Florida presented the program at Hazardous Substances Act-Product Safety Workshops held at Tallahassee and Fort Pierce. The workshops were conducted in cooperation with the Florida Division of Health to train county health officials, and were attended by approximately 70 local representatives of county health departments. The sessions appeared to be well received, and should be beneficial in carrying out a joint State-Federal consumer protection program.

A U.S. District Court at Oxford, Mississippi, has entered a summary judgment in favor of the Government, ordering the destruction of approximately $34,000 worth of Mornin’ Afta Hangover Remedy that had been seized on allegations it was a misbranded drug because of false and misleading claims for the treatment of hangovers and failure to name each active ingredient. The product had been distributed by Mornin’ Afta, Inc., Memphis, Tennessee.

BALTIMORE  Approximately 2,500 cans of various Bon Vivant soups, produced by Bon Vivant, Inc., Newark, New Jersey, were buried recently at the Prince Georges County, Maryland, Reclamation Center under the supervision of FDA and a representative of the U.S. marshal’s office. The lot was one of 13 seizures of Bon Vivant soups made by the District and was the only one of the total seizures on which the court signed a Default Decree of Condemnation providing for destruction. This represents the first destruction of the soups in Baltimore District under court order.

FDA started taking action against the soups last July 2 with a public warning when vichyssoise, a potato soup produced by the firm, was found to contain Clostridium botulinum, type A. One person died and another became seriously ill as a result of eating the soup. Total recalls followed immediately on all the firm’s production as a precautionary measure to protect the public health and safety.

BOSTON  Assistant U.S. Attorney James N. Gabriel has filed a four-count information at Boston against Cumberland Farms Dairy, Inc., Canton, Massachusetts, and Demetrios Haseotes, George Haseotes, and Francis N. Alger, general manager, assistant general manager and vice president, respectively, charging them with causing milk to be processed and packed in such a manner that it became adulterated. The information cited four separate instances from November 22, 1970, to January 22, 1971, in which Cumberland Farms is alleged to have had for sale certain quantities of milk with an odor similar to that of gasoline or kerosene. The filing of the information resulted from an extensive investigation conducted by the Boston Field Office.

F. W. Bryce, Inc., Gloucester, and Louis G. Ashby, president of F. W. Bryce, Inc., at Montreal, Canada, were each fined $1,000 in a court at Boston when they pleaded guilty to charges of substituting and marketing one species of fish for another of greater value.

BUFFALO  Through the cooperative efforts of Buffalo and other FDA Districts, various lots of the detergent concentrate Concern, totaling more than $80,000 in value, have been removed from channels of commerce. H. T. Developments, Inc., Buffalo, had marketed the product without testing, and subsequent testing by FDA showed it to be a toxic and irritant substance. It did not bear labeling required by law for such conditions. Although the manufacturer agreed to relabel all products in commerce, it was not able to do so because of bankruptcy. At this time, FDA has acted against all known lots of the product.

Voluntary destruction of violative products by their manufacturers or distributors should result in consumers receiving better products. Included in these destructions during December were 35,000 syringes containing a mastitis treatment denied certification: about 1,508,000 drug tablets in various retail containers and 10,130 single and multiple dose vials and ampuls destroyed because of age and questionable potency; about 30,400 diagnostic aids recalled and destroyed by the manufacturer because of contamination; and 32 lots involving 21 different drugs valued at about $5,000 destroyed by one firm because of lack of content uniformity, subpotency, or voluntary discontinuance of the products.

When Mercy Hospital and St. Joseph Hospital, Buffalo, join FDA’s National Electronic Injury Surveillance System (NEISS), FDA’s Buffalo District will have reached its full complement of seven hospitals. Both have agreed to participate but have not completed contract negotiations. Rochester General Hospital, Rochester, New York, began transmitting December 10 to become the fifth in the system. The other hospitals are Strong Memorial, Rochester; Emergency and Meyer Memorial, Buffalo; and Community General of Sullivan County, Monticello. During the week ending De-
CHICAGO In a followup to a recent recall of contaminated baby powder, Chicago District is investigating whether crude talc, an ingredient in many cosmetic products, contains objectionable soil micro-organisms. The contaminants found in the baby powder, which was manufactured by Avon Products, Inc, Morton Grove, Illinois, were identified as *Klebsiella pneumoniae*, type 66, and *Klebsiella*-like and *Clostridium tetani* organisms. The firm recalled and destroyed 7,200 containers of the powder, valued at $7,000. Although contaminants were found in only two manufacturing batches, the firm recalled all stocks, for they do not code this product.

Following recall and destruction of the powder, District inspectors visited the firm and found it had discontinued manufacturing the product. The company management explained that natural talc, the main component of the powder, cannot be made to conform with Avon’s microbiological standards.

CINCINNATI The District has issued a warning letter to an Ohio fireworks manufacturer and also plans to keep the firm under surveillance. The actions result from an investigation by the District following a report that the firm was manufacturing M-80 fireworks in violation of hazardous substances regulations. The investigation disclosed the firm’s attempt to produce M-80’s which would qualify as Class C fireworks. Its control procedures resulted in more explosive powder than was intended, which caused the M-80’s to be violative.

Cincinnati District has been selected to participate in a cooperative study of international scope to determine the relationship of methyl mercury to total mercury in tuna and swordfish. Others participating in the study are University of Rochester, New York; Bureau of Foods, National Canners Association; and laboratories in Japan, Sweden, and Canada.

DALLAS In response to a request, the District’s consumer specialist, Leona Allman, appeared at the President’s Committee on Health Education Regional Hearing at the Texas Medical Center, Houston. In her talk, Mrs. Allman stressed the need for education in nutrition and label reading if consumers are to use the nutritional labeling FDA will require in response to the mandate from the White House Conference on Food, Nutrition, and Health. Her presentation at the February 2 hearing was well received by the group and favorably commented on by Victor Weingarten, director of the committee.

Until a recently reported problem is resolved involving Texsun unsweetened orange juice, the Kroger Co., a chain of food stores, has asked all its stores in the Dallas regional area to remove the 6-ounce cans of orange juice from their shelves. During the first week in February, Dallas District received three consumer complaints about the juice, manufactured by Texsun Corp., Weslaco, Texas. The complainants had purchased the juice at three Kroger stores in the Dallas area, and upon opening the cans, found the orange juice to be brown in color.

District inspectors obtained samples of codes 10–11–30 (manufactured 11–30–71) and 0–12–9 (manufactured 12–9–71) from the three stores, and when examined, the can contents showed various shades of brown, and the liners of some cans were black. The situation was complicated because further examination from the same codes at the plant, Kroger’s warehouse, and another warehouse failed to show abnormal cans or products. The inspectors then went to the Texsun Corp., where a review of records showed nothing unusual. However, the firm was not manufacturing the orange juice during the inspection. The Texsun Corp. then sent a representative of the Continental Can Co. to the District office to check the sampled cans for possible defects, and also asked the Kroger firm to discontinue further shipment of the suspect lots.

DENVER As the result of joint efforts of the FDA Denver Field Office and the North Dakota State Laboratories Department, a U.S. marshal seized rodent-defiled wheat germ valued at $2,300 on the premises of the dealer, General Nutrition Mills, Inc., at Fargo, North Dakota.

Because the product was misbranded under FDA’s Fair Packaging and Labeling Act, Bakker’s Home Style Cookies were seized at Denver. The cookies, valued in excess of $2,000, were manufactured and shipped by Bakker’s Royal Dutch Cookies, Draper, Utah.

Cooperative efforts between FDA’s Los Angeles and Denver offices resulted in seizure at Great Falls, Montana, of approximately $400 worth of substandard frozen breaded shrimp. The product, containing less than 50 percent shrimp, was manufactured and shipped to Montana by Youngs Market Co., Los Angeles.

DETROIT Representatives of Detroit’s Lead Poison
Detection and Treatment Project met with District personnel to discuss mutual efforts to reduce lead poisonulings. They agreed to exchange information regarding products which may contribute to environmental exposure to lead.

The meeting was arranged after the Detroit City Health Department reported that a “lead belt” consisting of 375,000 dwelling units exists within the city. During January, representatives from the department visited 658 households in that area, and from among them, 44 children were found to have high blood levels of lead.

The District has nearly completed a program initiated in July 1971 to accomplish 100 percent annual inspectional coverage of medicated feed mills in Michigan and to commission about 20 inspectors and supervisors with the Michigan Department of Agriculture. The inspectors and supervisors completed two to three training inspections before attending a two-day workshop in December at Lansing. Each will complete two to three post-workshop inspections by April. Through this joint effort, more than half the medicated feed mills in the State of Michigan have been inspected.

Sawall Health Food Products, Detroit, met with District personnel recently to discuss labeling requirements after a U.S. marshal seized nine of the firm’s health food products and 850 promotional leaflets. The firm had re-packaged the products, which FDA alleged were misbranded due to false and misleading statements in the leaflets, incorrect nutritional claims, and noncompliance with the Fair Packaging and Labeling Act. At the conference with the FDA people, the firm reported that all its own literature would be destroyed and that all its labels would be redesigned to conform with regulations.

**KANSAS CITY** The Metropolitan Kansas City Conference of Food and Drug Officials held its quarterly meeting at FDA’s Kansas City Regional Office. The all-day session December 15 was devoted primarily to training and was attended by 35 enforcement officials from city, county, State, and other Federal agencies in the area.

Donald J. Rice, sanitarian with the Kansas City Health Department, was elected president for 1972 to succeed Armin Schannuth, sanitarian with the Independence City Health Department. Other officers elected were Perrin L. Fairleigh, compliance officer with the Compliance and Evaluation staff of the U.S. Department of Agriculture—first vice president; Leonard Powell, inspector in the Kansas Food and Drug Division of the State Board of Health at Topeka—second vice president; George L. Vinz, assistant to the director for Federal, State, and Industry Affairs, FDA’s Kansas City Office—reelected secretary.

**LOS ANGELES** Three District staff people recently used various media to talk to consumers about fraud, toy safety, and flammable fabrics. Fred Shalit, supervisory inspector, was one of three panelists on a consumer fraud forum at the Hollywood Jewish Community Center, where he discussed FDA’s Fair Packaging and Labeling Act and its impact on consumer protection. Other panelists were Herschel Elkins, deputy State attorney general and head of the California Consumer Fraud Unit, and Carol Sobel, consumer affairs reporter for the all-day news radio station KFWB in Los Angeles. Harry L. Baer, inspector, appeared on local channel 8 of the cable TV station at Long Beach, speaking on toy safety and FDA’s activities in relation to it. When interviewed locally on two segments of “Eye Witness News,” Elaine Roentgen, consumer specialist, also discussed toy safety. These news segments, seen nationwide on the ABC-TV network, originated on channel 7, KABC-TV, Los Angeles. Later, as a guest on channel 8, KFMB-TV, San Diego, Mrs. Roentgen discussed flammable fabrics as they relate to the holiday season.

Because the lot was undergoing progressive decomposition due to interaction of acid with the can lining, 2,900 cases of canned artichoke hearts under the label of Reese Finer Foods was seized at the firm’s premises in Los Angeles.

**MINNEAPOLIS** District personnel James A. Davis, supervisory inspector, and John D. Mahre, program analyst, attended a Pest Control Operators’ short course at the University of Minnesota in December. The course is offered annually by the university in cooperation with the State Department of Agriculture. It covers current procedures, pesticides, etc., employed in structural pest control, as well as the State and Federal regulations that apply to commercial pest control operators. Such operators doing business in Minnesota are required to attend the course as one prerequisite to obtaining a license for the following year. State law requires that each company be registered and licensed, and that each individual employee pass an examination to qualify as a master, journeyman, or apprentice pest control operator.

The FDA’ers found the course beneficial from the
standpoint of gaining a better insight into the activities and attitudes of the pest control operator industry in Minnesota and the upper Midwest.

In the last three months of 1971, as a result of FDA actions, U.S. marshals seized 107,000 pounds of foods, with a wholesale value of $43,000, in Minnesota and Wisconsin, the two States comprising Minneapolis District. Of the food seized, 63 percent was defiled by rodents and insects in the warehouses where stored. The District detained imports of 475,000 pounds of tomato paste because of in-transit damage, 2,574,000 pounds of cocoa beans because of mold and insect contamination, and 300,000 pounds of green mung beans because of contamination by endrin, an agricultural pesticide.

NEW ORLEANS A consent decree of permanent injunction has been signed and filed in the Western District of Louisiana at LaFayette prohibiting ABC Rendering of Louisiana, Inc., and Dmytro Gorczakowski, an employee of the firm, from violation of the FDC Act. The December 6 event concludes a lengthy effort by New Orleans District to halt the firm’s shipment of meat-scrap meal contaminated with Salmonella. Under the terms of the injunction, the firm may ship partially processed material to a qualified renderer provided the invoice specifies that the material contains Salmonella and, further, that the qualified renderer sterilize the material.

NEW YORK Albert L. Weber, organoleptic seafood specialist in the District’s Science Branch, has been involved in problems with tuna both in this and other countries.

In late December, Mr. Weber and Alfred C. King, District chemist, returned from Terminal Island, California, where Mr. Weber directed 17 scientists in the preparation of authentic packs of fresh and decomposed tuna fish to be used for training purposes and chemical analysis. Personnel participating in the workshop included 15 from FDA, two from Van Camp Co., two from National Marine Fisheries, two from Japan—representing the government and the industry, and one from the University of California—representing the State Bureau of Food and Drug and the National Canners Association.

Also in December, Mr. Weber was called upon to demonstrate the organoleptic method of testing tuna for decomposition to Dr. M. Bramao, commercial counselor with the Portuguese Embassy in Washington, who visited the District to discuss his interest in the analysis.

Dr. Bramao said he was interested in having several analysts from his country trained in the organoleptic detection methods shown, and that this could best be done by having Mr. Weber visit the Portuguese plants to train the personnel there. He said that he would make a request to this effect through channels.

On January 15, Mr. Weber, accompanied by District Bureau of Foods personnel Frank Allhands, Jr., and Caesar Roy, and Terry Musson, inspector from the San Juan District, returned from Japan, where they had been since January 9. The Japanese government had invited them to review the country’s problems with regard to mercury residues and decomposition in tunafish imported into the United States. The team visited testing laboratoires to assist in the development of a self-certification program for tuna. They also met with 25 people representing five groups: Chemistry, Agriculture and Forestry Administration; international trade and industry; Tuna Packers Association of Japan; Japan Canned Food Inspectors Association; and the Japan Canned Food Exporters Association.

The trip included a busy work schedule, including visits to district inspection’s offices and testing and chemical laboratories in Yokohama and Shimizu, a tuna cannery in Shizuoka, and the fish markets in Shimizu and Yaizu. On Wednesday night, January 12, Mr. Weber appeared with the group on Japan’s national television network, where he demonstrated the organoleptic examination of tuna for decomposition.

PHILADELPHIA Following imposition of a temporary restraining order against the American Tallow Corp., Corepolis, Pennsylvania, the firm has entered into a consent decree of preliminary injunction restraining it from shipping in interstate commerce any meat-scrap meal contaminated with Salmonella and from manufacturing operations not in conformity with practices that will assure uncontaminated animal food. The injunction action of December 27 followed a series of inspections and sample analysis during the spring and summer of 1971 revealing insanitary conditions and positive findings of Salmonella in meat-scrap meal shipped by the firm.

The D-N Laboratories, York, Pennsylvania, has instituted voluntary recall of all lots of contact lens wetting solution distributed by the firm in 1971 because the solution was found to be nonsterile. FDA’s factory inspection conducted last September revealed serious deviations from good manufacturing practices, and three follow-up samples showed gram positive bacteria.
SAN FRANCISCO The Modern Macaroni Co., Ltd., Honolulu, Hawaii, was fined $1,000 on each of two counts in an information which alleged interstate shipment of Oriental Noodle Products adulterated with rodent and insect filth. District Court Judge Nils Tavares, in the December 20 action at Honolulu, suspended payment of $500 on each count and placed the corporation on five years' probation. He said if the firm violated the Federal Food, Drug, and Cosmetic Act within the probation period, the remainder of the fine would be automatically imposed.

FDA detained an entry of 50 cartons of frog legs from Malaysia in December due to the presence of Salmonella. This was the initial shipment of frog legs into the port of San Francisco from that country.

SEATTLE During an FDA compliance inspection at a plant at Everett, Washington, the inspectors found decomposition in a 36,000-pound lot of frozen halibut. The lot had been received and frozen in Kodiak, Alaska, and was then shipped to Washington, where it was seized December 28.

FDA was granted a motion for summary judgment that ordered destruction of 8,631 cases of soft drinks and 166 one-gallon jugs of beverage syrups seized in January 1970 because of their cyclamate content. The motion was granted December 10.

Dave Flora, Bureau of Radiological Health representative, participated in and moderated the first Annual Region X Radiological Health Symposium in Portland, Oregon, during the week of December 6. The meeting was well attended by both State and Federal radiological health participants. Much information was exchanged regarding potential resources for support of State radiation control programs.
SUNLAMPS

Sunlamps are in wide use in the United States, but many people fail to recognize their potential danger, according to studies recently completed by the Bureau of Product Safety in the Food and Drug Administration.

Many children, teen-agers, and young and old adults use sunlamps the year around. Most devotees employ sunlamps to improve their appearance. Some bathers want to redden complexions into a ruddy outdoor appearance or develop glowing suntans even in midwinter. Many appearance-conscious persons feel that the contrast of a flashing white smile with a deep tan is extremely flattering.

However, sunlamp bathers should be aware that the ultraviolet radiation that tans and beautifies skin can also cause painful sunburns and possibly lasting eye damage. Basically, the Bureau has discovered, the problem of using sunlamps is one of "too much for too long." People do not realize that under some lamps one minute of ultraviolet radiation even at the specified distance between bather and lamp can be equivalent to one hour under the sun.

Case studies of sunlamp injuries show that although sunlamps and ultraviolet ray bulbs often come with instructions for proper use, many purchasers do not read the warning brochures. Others ignore what they do read. Many lose the accompanying notices entirely. Therefore the majority of users may not ever see a set of instructions or become otherwise aware of potential dangers in sunlamp use.

One typical case history is that of Henry, a teen-ager. Plagued with acne, he considers himself tougher than average. He screws an ultraviolet ray bulb purchased some time ago at the corner drug store into an ordinary floor lamp. As the bulb appears to have lost its intensity, Henry moves closer, sits a few minutes longer. Result: painful burns on his face and shoulders.

Another example: Mary, a secretary, takes time on a Saturday afternoon to lounge on a floor mat and read under a sunlamp. Because she thinks that protective goggles or sunglasses would leave white rings around her eyes and mar the facial tan she hopes to achieve, she ignores any eye protection whatsoever. As she reads, she loses track of time; perhaps she falls asleep. Result: painful burns on much of her body and damage to her eyes that may be lasting.

In other cases studied, because there are such differences in skin sensitivity, "safe" lengths of exposure time for persons with average skin may cause painful burning to those with more sensitivity. In some cases, users thought their lamps and bulbs gave off so little heat that more exposure time was needed. In almost all cases, protective devices such as timers and eye covers were either not provided or were not used.

Perhaps the major contributing factor to injury has been the careless use or failure to use eye protection. Because goggles or sunglasses can leave white rings around the eyes, many bathers left them off entirely. Some stared carelessly, directly into the light to achieve a well-tanned face. Ultraviolet rays admitted from the sides or below or above the lenses of sunglasses have caused painful eye burns even when such protection was worn. Eye injury occurred also when users read or watched TV. In these cases the injured tended to lose track of time and stayed too long under a lamp or they left off protecting glasses and goggles because these devices interfered with what they were trying to see.

Statistics produced through studies conducted by the Bureau of Product Safety Injury Study Units show that of the 70 injuries studied, 27 percent occurred to males and 73 percent to females. Over 50 percent of the injured were teen-agers between the ages of 12 and 19. The remaining victims ranged in age from 20 to 56, with the incidence of injuries 2½ times greater among females.

As might be expected, most of these burn injuries occurred in and around homes, specifically in bedrooms. However, a surprising 12 percent of injuries happened at YMCA's, YWCA's, or other health spas, despite the closer professional supervision that might be expected.
The Units, in seeking accident causes, found it difficult to relate exposure time and distance-of-lamp-to-user to the severity of burns. Directions by different manufacturers for exposure periods and measured distances varied considerably. However, it appears that the closer an individual was to the heat source and the longer he remained under the lamp, the more severe were his burns.

According to information compiled by the FDA Injury Study Units, most sunlamps are sold with no control devices or timers, especially those destined for home use, even though they are likely to be used by novices. It was found that sunlamps in health spas and sports clubs are usually installed with timers.

Even though the danger of eye damage from over-exposure is well known, only about 10 percent of the cases studied showed that eye protection equipment had been provided.

In about 60 percent of the cases studied, some instructions about the proper use of a sunlamp were available or were given to the individual user. These instructions were usually in the form of printed material accompanying the lamp or were stamped on the packing carton. In a few instances, instructions were given verbally. However, in some cases, exposure times and distances were not included—only operating instructions. Only eight of 70 sunlamps investigated were found to have permanently affixed warnings to serve as lasting safety reminders for succeeding users.

As previously noted, instructions were not read, were read but disregarded, or were long lost and forgotten. Thus, the Bureau's studies point out that a real need exists for a warning to accompany each sunlamp concerning that model's specific exposure times and distances for safe use. A warning notice should be attached permanently to each lamp so instructions can be easily and routinely read each time the lamp is used.

Here are suggestions for consumers from the Bureau of Product Safety for safe use of ultraviolet ray bulbs and sunlamps:

1. Upon purchase, read and observe all instructions carefully. If instructions are not permanently attached to the lamp, tape them to the lamp's base or stand so that they will not be lost and will be available to successive users.
2. Be precise in measuring exposure time and distance from the lamp. Use a tape measure. And use a timer with an alarm bell so that if one's attention wanders, one will be alerted immediately to over-exposure. Better still, purchase a sunlamp with a timing device to automatically turn off the lamp at the proper time.
3. Wear close-fitting eye protection.
4. Never stare directly at the lighted bulb.
5. Guard against mirrors that can reflect ultraviolet rays not only to the person using a sunlamp but also to persons nearby.
6. Never become so comfortable under a lamp that there is danger of becoming drowsy or falling asleep.
7. Remember, reading or similar activities under a sunlamp can be harmful to eyes.
8. Children should be carefully supervised under any form of ultraviolet light by responsible adults to guard against over-exposure and insure that eye protection is worn.
news highlights

Christmas Decorations Industry Urged To Correct Home Fire, Electric Hazards

FDA has urged manufacturers of Christmas decorations used in the home to correct potential fire and electric hazards in preparation for the 1972 Christmas season.

Officials of the Toy Manufacturers' Association and representatives of FDA's Bureau of Product Safety met to discuss identification of problem areas, consumer education programs, redesign of products, and the need for safety standards. Prior to the session in Washington, 60 representatives of 50 Christmas decoration manufacturers and importers convened in New York and agreed to meet with FDA to look into how they might develop a program to eliminate potential hazards.

Problem areas identified by an FDA injury study team included easily broken glass ornaments, exposed lighting circuits, and flammable decorations and trees, both synthetic and real, which may be classified as fire hazards. Although the Association does not represent the natural Christmas tree industry, it was agreed that a public education program is needed to alert the public to potential fire hazards from natural trees. Manufacturers of synthetic trees are developing safety standards as to flammability.

The Consumers' Insurance Information Bureau, a service sponsored by private companies to provide information to consumers, reported 50 fatalities from fires involving decorations during the 1970 Christmas season. Annual sale of Christmas decorations has been estimated at $1 billion.

Import Detentions Up 42% in FDA Move To Expand Checks for Violative Products

A 42 percent increase in detentions of imported products not meeting FDA requirements during the fiscal year 1971 has been announced. The number of shipments of imported products detained because they did not meet FDA requirements increased from 6,874 to 9,700. Inspections at dockside increased from 17,821 to 26,916.

The major reasons for detentions were mercury-contaminated tuna and swordfish, pesticide residues in cheese, and lead-leaching china and dinnerware. FDA's attention was directed to these specific areas after routine inspections began turning up increased shipments of contaminated fish, cheese, and leachable-lead-containing china entering the United States.

FDA is now stepping up its import surveillance program to keep pace with a 65 percent increase in the number of imports over the past 10 years. Changes in foreign trade and U.S. shipping operations such as containerization have brought about a pressing need for FDA to expand its inspection services, particularly at inland points. In earlier years imports consisted principally of bulk raw materials which received FDA attention at the user's plant, whereas recent trends are toward the importation of finished goods.

The new directions being taken by FDA drastically alter previous import inspection procedures. Features of the new import coverage strategy now being implemented include:

—Establishment of a central FDA import operations office which is coordinating import enforcement procedures among all FDA Districts.
—Use of mobile laboratories for on-the-spot analyses by inspectors and technicians on the piers and at other points of discharge.
—Ship-to-ship coverage where teams of inspectors make dock-side examinations on piers where cargo is being discharged.
—Circuit-rider coverage where inspections will be made at outgoing ports of entry only nominally covered in the past.
—Improved coverage of containerized products by establishment of liaison with containerization centers and companies, by maintenance of inspection stations at the centers, and by preselection of commodities for coverage.

Imported products regulated by FDA account for 12.5 percent of the $200 billion in goods purchased yearly by U.S. consumers. The Agency estimates that its overall import coverage will be increased 50 percent through implementation of the new strategy. This increase is projected on the basis of expanded operational efficiency instead of additional manpower.

FDA provides overseas inspections and technical advice to foreign exporters on a request basis and by cooperative agreement with foreign governments.

Revocation Proposed for Use of DEPC As Fermentation Inhibitor, Preservative

FDA has proposed to revoke the use of diethyl pyrocarbonate (DEPC) as a fermentation inhibitor and preservative. The proposal, published in the Federal Register, February 11, points out that recent studies have raised questions about the safety of diethyl pyrocarbonate.

Although there is no evidence that diethyl pyrocarbonate has caused any harm to humans, FDA is pro-
posing, as a precautionary measure, to remove it from use unless suitable data is presented to show the ingredient can continue to be used safely.

Recent concern about the safety of the additive arises from studies that show diethyl pyrocarbonate is, under some experimental conditions, capable of combining with other ingredients to form urethane, a known carcinogen. This possibility has not been shown at the levels of use permitted, or in any marketed product.

Diethyl pyrocarbonate was first approved by FDA as a fermentation inhibitor in still wines in March 1963 and in fermented malt beverages in March 1967. In August 1968, it was approved for use in noncarbonated soft drinks and in fruit-based beverages. As a preservative, it eliminates the need for pasteurization.

Iodide Information To Be Required On Table Salt Labels by Mid-1973

Final steps to require that the labels of consumer packages of salt specify whether the salt contains the nutrient iodide have been announced by FDA. The requirement will become effective in mid-1973.

Under the new FDA regulations, the label on a package of table salt containing iodide must carry the following statement: "This salt supplies iodide, a necessary nutrient."

Noniodized salt will carry labeling informing all consumers that it is not iodized, including those for whom noniodized salt might be recommended for medical reasons or those who prefer such salt. The noniodized product will carry the statement: "This salt does not supply iodide, a necessary nutrient."

In addition, salt, table salt, iodized salt, or iodized table salt to which anticaking agents have been added may carry a label statement describing the characteristics imparted by such agents as "free flowing."

The foregoing label statements to be required for iodized and noniodized salt may be omitted from individual serving packages of the product containing less than one-half ounce and packages containing more than 2½ pounds.

The regulation, published in the Federal Register on January 21, 1972, becomes effective in 18 months. It is a revision of an FDA proposal published in February 1971 based on recommendations made as a result of reports during the White House Conference on Food, Nutrition, and Health that iodized salt is effective for prevention of simple goiter caused by deficiency of iodine.

FDA Revises Requirements on 'Cents-off,' Other Food, Drug, Cosmetic Promotions

Revised regulations governing "cents-off," economy size, introductory offer, and other promotions for food, drugs, and cosmetics have been announced by the FDA.

The new FDA regulations, promulgated under the Fair Packaging and Labeling Act, require the sponsor of a "cents-off" promotion to print the amount of "cents-off" on the label of the product. The retailer must then stamp on the package the price to be paid by the consumer, and must post a placard or shelf marker with the product's regular price.

The regulations also require commodities labeled with economy size representations—such as "economy size," "bargain size," "budget pack," and "big value"—to be sold at a price at least 5 percent less than the lowest price per unit of weight, volume, or measure of all other sizes of the same product offered simultaneously.

Introductory-offer items must bear on their label the anticipated after-introductory-offer price; introductory offers can last no longer than six months and may be used only for products that are new, substantially changed, or being introduced for the first time in the marketing area.

Sponsors of promotions involving coupons not redeemable at the retail level are required to reimburse the consumers for the cost of redeeming their coupon by mail.

The "cents-off" regulation limits the number of promotions for any single size commodity in the same trade area within a 12-month period to no more than three such promotions, and requires a period of 30 days between promotions for any package size. The promotion may not be conducted in a trade area longer than six months during a 12-month period.

The regulations governing frequency and duration of the savings representation promotions became effective January 29; the introductory offer, coupon, and economy size provisions of the regulations March 31; and the "cents-off" labeling rules on June 30. The new regulations were published in the Federal Register on December 30, 1971.

Roasting Bag Makers Agree to Provide Use, Safety Information to Consumer

Manufacturers of plastic oven roasting bags have agreed to provide additional package instructions to insure their safe use and to conduct an intensive public education effort to assure that consumers understand and abide by all safety instructions.

The agreement came at a meeting called by FDA on February 22 with major American companies, including Allied Chemical, Colgate-Palmolive, DuPont, General Foods, McCormick, The Drackett Co., Reynolds Metals, 3M Company, and Union Carbide. The companies either market roasting bags or make various kinds of plastics used in the products.

The meeting followed an intensive 10-day investigation by FDA and by industry after reports of 93 accidents involving oven bags. Twelve burn injuries were involved, one serious.
Information on the accidents and injuries was collected during February by the Burns Care Institute of the New York State Department of Health.

The FDA's National Electronic Injury Surveillance System (NEISS) has to date uncovered no similar accident reports beyond those provided by the Burns Care Institute. The NEISS system maintains a computerized accident reporting link with 60 hospital emergency rooms around the country.

In announcing the action, the FDA emphasized that information was insufficient to conclude that the bags present more of a kitchen hazard than cooking by more conventional means.

All information available to FDA at this point, however, supports a conclusion that the bags involve a new cooking practice requiring more detailed package instructions and better consumer understanding than now generally available.

On this basis FDA asked that labeling and education efforts be launched by industry as soon as possible.

The Agency also requested that all companies begin immediately to update and provide FDA full data on injury reports and consumer complaints received by them. Manufacturers have agreed.

Specific new labeling instructions agreed to by all manufacturers: (1) To protect against bursting and release of hot fats and juices, coat inside of the bag or the wrap with at least one tablespoonful of flour. If bag comes with seasoning or sauce mix do not use flour—follow package directions. (2) Use a pan large enough to contain the entire bag or the wrap and deep enough to hold all liquids that may be released during cooking. Pan should always be at least 1 1/2 to 2 inches deep. (3) Read carefully and follow other directions in package.

The labeling also would carry this warning: “For Oven Fires From Any Cause, Keep Oven Door Closed.”

FDA Looking Into New Assay Method For Detecting Drugs in Meat Tissues

FDA is investigating a new and significantly improved method for detecting residues of drugs in animal tissue.

Described as a radioimmunoassay method, the new method was reviewed for possible use in testing for diethylstilbestrol (DES) residues at a recent meeting involving representatives of FDA, the Canadian Food and Drug Directorate, and leading research groups.

Participants in the meeting concluded that the radioimmunoassay method shows promise of being a more sensitive and more rapid monitoring tool for regulatory use. Residue levels are measured in parts per trillion, approximately a 1,000-fold improvement over current methods which are sensitive to 2 parts per billion.

Scientists who reported results of their research at the February meeting were: Guy Abraham, M.D., Department of Obstetrics, University of California, Los Angeles; Harold D. Hafs, Ph.D., Animal Reproduction Laboratory, Michigan State University; Donald M. Hendricks, Ph.D., Department of Food Science & Biochemistry, Clemson University; William Hobson, Department of Dairy Science, College of Agriculture, Cornell University; Donald L. Loriaux, M.D., National Cancer Institute; and G. W. Niswender, Ph.D., Department of Physiology & Biophysics, Colorado State University.

FDA has asked the six scientists to submit a proposed plan to adopt this methodology for use in detection of DES.

FDA Issues Statement on Imipramine In Wake of Reported Birth Defects

In response to reported findings of birth defects linked to the drug Imipramine Hydrochloride by an Australian physician, the FDA on March 3 issued a general informational statement concerning this antidepressant drug, for which the major trade name is Tofranil by Ciba-Geigy, a Swiss based drug producer.

FDA approval for U.S. marketing was granted in 1959. FDA monitoring has been continuous since that time. As early as 1965, the FDA required label warnings about use in pregnant women and women of childbearing age. Current labeling notes:

“Safe use of imipramine during pregnancy and lactation has not been established; therefore, in administering the drug to pregnant patients, nursing mothers, or women of childbearing potential, the potential benefits must be weighed against the possible hazards. Animal reproduction studies have yielded inconclusive results . . . There have been clinical reports of congenital malformation associated with the use of this drug, but a causal relationship has not been confirmed.”

The McBride data from Australia had not been presented to FDA at the time of the statement. Before issuing the statement the Agency contacted Australian authorities, who said their evaluations up to that time indicated the data was inconclusive. As soon as the full data can be obtained, it will be promptly and fully evaluated to determine what if any further regulatory action is indicated by FDA.

“Almost all new drugs carry warnings about use in pregnancy. It has always been FDA’s judgment that drugs should be used during pregnancy only as necessary,” said Henry Simmons, M.D., director, FDA Bureau of Drugs.

“Imipramine is known to be effective in the treatment of depression. Due to deficiencies in present methodology, we cannot be sure of the safety of any of the known effective antidepressant drugs when used during pregnancy.

“Because of this, FDA has for at least seven years specifically recommended careful benefit-to-risk considerations by any physician using imipramine or any antidepressant drugs in women who are pregnant, or who may become pregnant,” said Dr. Simmons.
“But FDA recognizes that physicians may be faced upon occasion with severely depressed—even suicidal—pregnant patients in whom drug therapy is unavoidable.

“In such cases,” Dr. Simmons stated, “imipramine can be of major benefit and to the best of our knowledge is unlikely to have any more potential for risk than available alternative drugs.”

Percentage Statement To Be Required For Diluted Orange Juice Beverages

Diluted orange juice beverages must state the percentage of orange juice on the label under a new FDA regulation. The new rule, published in the March 11 Federal Register, establishes four categories of orange juice products and requires prominent labeling as follows:

- “Orange Juice Drink Blend Containing ___ Percent Orange Juice,” the blank being filled in in 5 percent increments. Range: Not less than 70 percent but less than 95 percent. (Blended products must contain juice from at least two orange producing geographical regions but with no less than 20 percent from each.)
- “Orange Juice Drink Containing ___ Percent Orange Juice,” the blank being filled in in 5 percent increments. Range: Not less than 35 percent but less than 70 percent.
- “Orange Drink Containing ___ Percent Orange Juice,” the blank being filled in in 5 percent increments. Range: Not less than 10 percent but less than 35 percent.
- “Orange Flavored Drink Containing ___ Percent Orange Juice,” the blank being filled in in 2 percent increments from 2 percent to 8 percent and the words “less than 2” if the beverages contain less than 2 percent but more than 0 percent orange juice.

New labeling regulations concerning certain orange flavored drinks containing no orange juice will be published later.

Concentrates and dry forms of the four categories are provided for except that the concentrate form is not permitted for “orange juice drink blend.”

Safe and suitable ingredients will be permitted with label declaration required. Certain orange components such as comminuted (ground up) oranges will be permitted in orange juice products in limited amounts.

A vitamin C level of 60 milligrams per 6 fluid ounces of finished beverage as consumed will be required.

In arriving at the new label regulations, FDA took into consideration the proposals made by the Florida Canners Association, the National Juice Products Association, and the FDA's own suggestions published for public comment in the Federal Register on September 9, 1971. The Agency also considered the large number of comments from consumers, consumer groups, industry, industry associations, and State and Federal public officials following the September action.

Unless objected to and a hearing requested, the new regulations will become effective 180 days after the March 11 publication in the Federal Register.

FDA Announces Plan to Prohibit Use Of Liquid-Form DES in Animal Feeds

FDA announced it is acting to eliminate the use of DES (diethylstilbestrol) in liquid form in animal feed. The action does not affect use of the growth promotion drug in dry form.

FDA's action, announced March 10, was prompted by field investigations which uncovered a liquid feed contamination problem. The contamination results from mixing liquid feed without DES in the same equipment as that used to produce feed with DES.

Because molasses, a viscous ingredient, is common in liquid feeds, the equipment is difficult to clean completely. This has resulted in unintentional but apparently unavoidable contamination of some feeds intended to be free of DES. These feeds are for use during the final seven days before slaughter to eliminate all DES residues from the animals.

FDA found at least one of two cases of DES residues reported in liver in episodes in Arizona to be caused by a cattle feeder who was using DES in liquid form. These violations as well as two previously reported are under continuing investigation by FDA.

FDA's current investigation of liquid feeds utilizes a newly developed and highly sensitive screening method which identifies trace amounts of DES in feed.

Using this new technique, FDA has to date found nonmedicated feed from 14 liquid feed manufacturers to contain low levels of DES. The Agency has caused a number of seizures of these feeds and has initiated further regulatory action against several of the manufacturers.

FDA published a notice of its intention to withdraw approval for DES in liquid form in the March 11 Federal Register. As required by law, manufacturers were given 30 days to ask for a hearing to show cause why such approvals should not be withdrawn.

Charles C. Edwards, M.D., Commissioner of Food and Drugs, stressed that the new restraints proposed are in accord with the Agency's commitment to keep the American meat supply free of DES.

The Commissioner concluded:

“The law does not allow DES residues in meat.” and added that if the FDA action, added to the mandatory certification and withdrawal programs instituted by the U.S. Department of Agriculture and FDA earlier this year, fails to adequately prevent DES residues, “then FDA is prepared to ban use of DES altogether in animal feeds.”
state actions

Virginia Department Actions  The Virginia Department of Agriculture and Commerce is considering the regulation of open-dating of infant formulas. The Board of Agriculture held a public hearing, and the decision as to whether regulations will issue was postponed.

The Department’s Hazardous Substances Section of the Division of Regulatory Services conducted recent surveys of Virginia retailers in search of toys banned by FDA. Several lots of the banned toys were found and removed from sale by the State inspectors.

As the result of a complaint from the Defense Supply Agency, the department’s Food Inspection Section, in cooperation with FDA’s Baltimore District, seized over $19,000 worth of insect-infested and rancid canned pecans. State seizures were placed on recalled lots as they were returned to the distributor in Richmond.

Commissioning  Nebraska becomes the fourth State in FDA’s Kansas City regional jurisdiction to have FDA-commissioned inspectors and supervisors. Bureau of Plant Industry officials in the State Department of Agriculture, at Lincoln, presented the commissions formally on January 10 to five Nebraska feed inspectors and two supervisors, although FDA had awarded them a month earlier. Those commissioned were Marvin L. Sitori, director of the Bureau of Plant Industry; Clarence E. McCurry, section head; and Inspectors Merle Breunsbach, William Houser, Thurl Resh, Rex Risinger, and Lloyd Vavrina.

The Nebraska Department will work with the FDA Kansas City Field Office in implementing the cooperative feed mill inspection program. The feed inspectors were given basic and comprehensive on-the-job training in FDA’s medicated feed inspection techniques.

Adulteration Warning  Food enforcement officials in the Missouri State Department of Public Health and Welfare and in the nearby States of Texas, Oklahoma, Kansas, and Arkansas, have given notice to sorghum syrup distributors in their areas that concerted action will be taken to prevent the adulteration and subsequent misbranding of their product for sale to the public.

The practice of adulterating sorghum syrup with substances such as blackstrap molasses, corn syrup, or sugar cane syrup, and then labeling the resultant product as sorghum, sorghum molasses, or similar designations, has become a perennial problem in these States. In Missouri alone, officials had embargoed more than a ton of misbranded products by mid-December.

Missouri officials have indicated that the misbranded products can be relabeled with an acceptable name such as table syrup, blended syrup, or sorghum-flavored syrup. However, they point out, failure to do so would result in a petition to the courts for an order of condemnation.

Ban in Effect  New York State’s Erie County Health Department is enforcing its ban on the sale of phosphate cleansing agents. The health department will take samples of detergents for phosphate assay on a routine basis and will monitor area hospitals for accident cases involving any supposedly phosphate-free products. Trace amounts of phosphates will be permitted, not to exceed 0.5 percent of such materials. The ban went into effect January 1.

Consumer Protection  A recent court decision in Pennsylvania was the first case reported under the Commonwealth’s Unfair Practices and Consumer Protection Law. Judge Theodore O. Rogers, sitting in a Commonwealth court at Har-

risburg, banned the sale of Hush-Tone hearing devices within the State. In a 37-page decision, he enjoined Hush-Tone Industries, Hush-Tone Eastern, Inc., and their salesmen, agents, and officers from the sale of, advertising of, or stating in any fashion that the devices will rehabilitate impaired hearing or will aid in speech discrimination. He further ruled that the devices are essentially worthless for any use or purpose claimed for them by the defendants.

Alfalfa Released  The California Department of Agriculture has released 1,600 bales of alfalfa hay from quarantine to be used as soil mulch. Department officials had quarantined the hay because it contained over-tolerance residues of toxaphene, a toxic agricultural insecticide.

Halts Fish Sale  The Florida Department of Agriculture and Consumer Services stopped the sale and shipment at Panama City, Florida, of over 100,000 pounds of a fish called skip-jack because it contained amounts of mercury in excess of FDA’s action guidelines. The fish was destined for Hawaii, where it is called ladyfish, to be ground and used in fishcakes.

Dr. George M. Rose, chief of the Food Grades and Standards Section of the department’s Division of Inspection, said the department was alerted to the problem by the Hawaii Health Department, which had sampled and found excessive mercury in previous shipments of skipjack.

Following the alert, the fish at Panama City was sampled and analyzed by the department’s Pesticide Residue Laboratory, and Doyle Golden, director of the laboratory, reported a preliminary finding of 0.55 parts per million of mercury.
seizures & postal service cases

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

A total of 79 actions to remove from the consumer market products charged to be violative were reported in December. These included

<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copra meal pellets/Honolulu,</td>
<td>Costa Dairy/Honolulu, Hawaii (D)</td>
<td>Contain aflatoxin which may render it injurious to health.</td>
</tr>
<tr>
<td>Hawai 11/30/71</td>
<td>Semo Grain Co./Morley, Mo. (S)</td>
<td>&quot; &quot;</td>
</tr>
<tr>
<td>Corn, white/Denton, Tex. 11/</td>
<td>United Dairymen’s Association/</td>
<td>&quot; &quot;</td>
</tr>
<tr>
<td>19/71</td>
<td>Ontario, Calif. (D)</td>
<td></td>
</tr>
<tr>
<td>Shreveport, La. 12/27/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cottonseed, whole/Ontario,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calif. 12/7/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Almonds, pieces, shelled, Virginia and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spanish peanuts, shelled/Milwaukee,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wis. 12/1/71</td>
<td></td>
</tr>
<tr>
<td>Artichoke hearts/Charlotte,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N.C. 11/10/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>canned, imported/Los Angeles,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calif. 12/5/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beef extract, liquid/South</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lebanon, Ohio 12/3/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Candy, assorted/Hazel Park,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mich. 11/6/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cheese/Clinon, Mo. 12/20/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chiles, green, frozen/El</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paso, Tex. 11/24/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corn, crunchy/Dallas, Tex. 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/5/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cornhusks, dried red chili</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pods/Denver, Colo. 11/10/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crabmeat/Little Rock, Ark. 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ginger root/Wilmington, Calif</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12/20/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grouper fillets, frozen/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Houston, Tex. 11/15/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Macaroni, semolina, medium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>shells, lasagna, thin/1000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>soccer, R.I. 11/15/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Margarine/Jacksonville, Fla.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12/27/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palm hearts/Miami, Fla. 11/5/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peanuts, shelled, Spanish/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chicago, III. 12/7/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Popcorn/Charlotte, N.C. 11/23/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minneaplis, Minn. 11/23/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigatoni/E. Hartford, Conn. 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salt, plain, country corn</td>
<td></td>
<td></td>
</tr>
<tr>
<td>flakes/Green Bay, Wis. 12/7/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sesame seed, hulled/Houston,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tex. 11/3/71</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FOOD / Poisonous and Deleterious Substances

- Contamination, Spoilage, Insanitary Handling

- Milwaukee Cold Storage Co./Milwaukee, Wis. (D)
- Fancy Foods of the Carolinas/Charlotte, N.C. (D)
- Reese Finer Foods/Los Angeles, Calif. (D)
- Fred Mushroom Canneries Co./South Lebanon, Ohio (D)
- Leader Candies, Inc./Brooklyn, N.Y. (M.S)
- Springs Cheese Co./Wesson Spring, S. Dak. (M.S)
- San Juanito Chile Products Co., Inc./San Miguel, N. Mex. (M.S)
- Crisp corn Co./Bellingham, Wash. (M.S)
- La Popular Mexican Foods/Denver, Colo. (D)
- Bayou Grab Co., Inc./Pascagoula, Miss. (P.S)
- Okimoto Toshio/Papakou, Hawaii (S)
- Tex-Mex Cold Storage, Inc./Houston, Tex. (D)
- Viva Macaroni Manufacturing Co., Inc./Lawrence, Mass. (M.S)
- Blue Plate Foods/New Orleans, La. (M.S)
- Shaw Foreign Trade Warehouse/Miami, Fla. (D)
- Gold Kist, Inc./Anadarko, Okla. (P.S)
- Manley, Inc./Tarkio, Mo. (P.S)
- Viva Macaroni Manufacturing Co., Inc./Lawrence, Mass. (M.S)
- Super Valu Stores, Inc./Green Bay, Wis. (D)
- Davis Warehouse Co./Houston, Tex. (D)

- Held under insanitary conditions; rodent contaminated.
- Decomposed while held for sale.
- "; metallic taste and blackened content.
- Decomposed and moldy.
- Rodent contaminated, human hairs, dirt.
- Prepared and packed under insanitary conditions.
- "; E. coli, staphylococci, and a high total bacteria count.
- Prepared and packed under insanitary conditions; short weight.
- Held under insanitary conditions; cornhusks were rodent contaminated.
- Filthy.
- Insect contaminated.
- Held under insanitary conditions; filth and odor of diesel fuel or similar hydrocarbon.
- Insect contaminated.
- ";
- Decomposed while held for sale.
- Held under insanitary conditions.
- Prepared and packed under insanitary conditions; insect contaminated.
- Held under insanitary conditions; rodent contaminated.
- Held under insanitary conditions; insect contaminated.
Contamination, Spoilage, Insanitary Handling (con’d)

<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soups, various, canned/ various places in Mass. and various dates 12/71</td>
<td>Bon Vivant Soups/Newark, N.J. (M,S)</td>
<td>Prepared under insanitary conditions; defective and abnormal cans:</td>
</tr>
<tr>
<td>Tucson, Ariz. 11/2/71</td>
<td>“ (M,S)</td>
<td>“</td>
</tr>
<tr>
<td>Westlake, Ohio 11/16/71</td>
<td>“ (M)</td>
<td>“</td>
</tr>
<tr>
<td>Amherst, Ohio 11/15/71</td>
<td>“ (M)</td>
<td>“</td>
</tr>
<tr>
<td>Rochester, N.Y. 11/1/71</td>
<td>“ (M)</td>
<td>“</td>
</tr>
<tr>
<td>Houston, Tex. 11/18/71</td>
<td>“ (M)</td>
<td>“</td>
</tr>
<tr>
<td>Fitchburg, Mass. 12/14/71</td>
<td>“ (M,S)</td>
<td>“</td>
</tr>
<tr>
<td>E. Longmeadow, Mass. 12/6/71</td>
<td>“</td>
<td>“</td>
</tr>
<tr>
<td>Natick, Mass. 12/9/71</td>
<td>“</td>
<td>“</td>
</tr>
<tr>
<td>Landover, Md. 11/9/71</td>
<td>“</td>
<td>“</td>
</tr>
<tr>
<td>and meat/Philadelphia, Pa. 11/8/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tuna, Breast O’Chicken/New Orleans, La. 12/23/71</td>
<td>Westgate California Foods, Inc./San Diego, Calif. (M,S)</td>
<td>“</td>
</tr>
<tr>
<td>Wheat germ, Hi Purity/Fargo, N. Dak. 11/19/71</td>
<td>General Nutrition Mills, Inc./Fargo, N. Dak. (D)</td>
<td>Held under insanitary conditions.</td>
</tr>
</tbody>
</table>

Economic and Labeling Violations

<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Candy-filled Christmas stockings/San Angelo, Tex. 11/8/71</td>
<td>Del-Tex, Inc./San Angelo, Tex. (D)</td>
<td>“</td>
</tr>
<tr>
<td>Cheese twists/Joplin, Mo. 12/29/71</td>
<td>T &amp; F Snacks, Inc./Wichita, Kans. (M,S)</td>
<td>Label (package) statement “Net Wt. 7 Oz.” is inaccurate.</td>
</tr>
<tr>
<td>Cookies, Bakker’s Royal Dutch/Denver, Colo. 12/14/71</td>
<td>Bakker’s Royal Dutch Cookies/Draper, Utah (M,S)</td>
<td>Not in conformity with the Fair Packaging and Labeling Act.</td>
</tr>
<tr>
<td>Campanello and Liguria brands/Chicago, Ill. 11/22/71</td>
<td>Western Food Corp./Chicago, Ill. (D)</td>
<td>Label fails to bear a statement that peaches fall below quality standard.</td>
</tr>
<tr>
<td>Peaches/Birmingham, Ala. 11/22/71</td>
<td>Jones Bros. Canning Co./Greer, S.C. (M,S)</td>
<td>Mislabeled; other substance was substituted for peanut oil.</td>
</tr>
<tr>
<td>Peanut oil/Scranton, Pa. 12/22/71</td>
<td>Hostess Products Corp./Brooklyn, N.Y. (M,S)</td>
<td>“</td>
</tr>
<tr>
<td>Pepper, black, Queen olives, onion stuffed olives/Gretna, La. 11/16-18/71</td>
<td>Zatarain’s Inc./Gretna, La. (D)</td>
<td>Below quality standard for canned peaches; fail to bear name of optional packing medium.</td>
</tr>
<tr>
<td>Preserves: peach, loganberry, gooseberry; concord grape jelly; plum butter; syrups: black and red raspberry fruit, wild blackberry, boysenberry/Seattle, Wash. 12/7/71</td>
<td>The Dickinson Co./Tigard, Ore. (M,S)</td>
<td>Label fails to bear a statement that peaches fall below quality standard.</td>
</tr>
<tr>
<td>Shrimp, frozen, breaded/Great Falls, Mont. 12/3/71</td>
<td>Young’s Market Co./Los Angeles, Calif. (M,S)</td>
<td>Misbranded; other substance was substituted for peanut oil.</td>
</tr>
<tr>
<td>Eskimo brand Diet Bar, Diet-Delux ice cream, Count Calorie: chocolate, vanilla, strawberry ice milk/Minneapolis, Minn. 12/15/71</td>
<td>Bridgeman Creameries, Div. of Land O’Lakes, Inc./Grand Forks, N. Dak. (M,S)</td>
<td>Lead leaching from plates.</td>
</tr>
<tr>
<td>Food Additives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamins—Dietary Food</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

30 / March 1972 / FDA Papers
PRODUCT, PLACE & DATE SEIZED | MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D) | CHARGES
--- | --- | ---
Wheat cereal/Glendale, Calif. 12/9/71 | ALL-O-WHEAT CEREAL MILLS/Ogden, Utah (M,S) | False and misleading label statement, “Parts of Wheat Kernel, Brandy-Proteins, Mineral Matter, Cellulose, Vitamin A and B,” suggesting that wheat bran contains nutritionally significant amounts of vitamin A and all of the B-group of vitamins, which is contrary to fact.

**DRUGS / Human Use**

Digoxin tablets 0.125 mg./Columbus, Ohio 11/23/71 | Philips Roxane Labs., Inc./Columbus, Ohio (M,D) | Below USP standard for strength.
“Menotab” conjugated estrogen S.C. tablets/St. Louis, Mo. 12/6/71 | Western Research Laboratories/Denver, Colo. (M,S) | ""

**Veterinary / Medicated Feed**

Compensator PR liquid feed supplement/Omaha, Nebr. 12/21/71 | Allied Chemical Corp./Omaha, Nebr. (M,S,D) | Contains diethylstilbestrol, a new animal drug without effective New Animal Drug Application.
Myconox medicated, Medi-Matic free choice poultry formula/Springfield, Mo. 11/1/71 | Naremco, Inc./Springfield, Mo. (D) | New animal drugs without effective approved New Animal Drug Application; false and misleading claims.

**COSMETICS**


**HAZARDOUS SUBSTANCES**

Concern laundry product/Bedford Heights, Ohio 11/17/71 | H. T. Developments Co., Inc./Buffalo, N.Y. (M,S) | ""; ""
Cleveland, Ohio 11/5/71 | ""; ""
Cleveland, Ohio 11/17/71 | ""; ""
South Milwaukee, Wis. 12/27/71 | ""; ""
Syracuse, N.Y. 12/8/71 | ""; ""
Syracuse, N.Y. 12/16/71 | ""; ""
Syracuse, N.Y. 11/3/71 | ""; ""
Buffalo, N.Y. 11/8/71 | ""; ""
Olean, N.Y. 12/29/71 | ""; ""
St. Louis, Mo. 12/13/71 | ""; ""
Washington, D.C. 11/30/71 | ""; ""
Landover, Md. 11/29/71 | ""; ""
Dolls, plastic/Metairie, La. 12/28/71 | Oriental Trading Co./Metairie, La. (D) | Banned hazardous substance; flammable.

**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 Assistant Postmaster General—Inspection Service.

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

December 3, 1971: False Representation Order issued against **Wonder Belt**, 1044 Northern Boulevard, Roslyn, New York. Advertising and sale by mail of a “Wonder Belt” represented as enabling wearers to reduce and melt away excess fat from any particular part of their anatomy.

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

December 30, 1971: **Ella Distributing Corp.**, 102-08 159th Road, Howard Beach, New York 11414. Solicitations of orders and sales through the mails of “Vigor-Vite,” a newly created “Youth-sex pill” that reportedly “doubles and even triples” the physio-sexual libido capacity in adult men and women.
NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

Swordfish, whole, at Oxnard, C. Dist. Calif. Charged 3-30-71: when caught in waters outside the territorial limits of the State of California the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (1)

Swordfish chunks, 2 seizure actions at National City, S. Dist. Calif. Charged 4-12-71: when caught in waters outside the territorial limits of the State of California, the article contained the added poisonous and deleterious substance mercury; 402(a)(1). Default decree ordered destruction. (2)

Tankage, dried, at Mason City, S. Dist. Ill. Charged 7-6-71: when shipped by Pene Talkow Co., Pittsburgh, Pa., the article contained the added poisonous and deleterious substance Salmonella micro-organisms; 402(a)(1). Consent decree authorized release to shipper for reconditioning. (3)

Grain, mixed, at Bonners Ferry, Dist. Idaho. Charged 1-6-70: when shipped by Lees Carney Co. of Portland, Ore., from Conrad, Mont., the article which had been involved in a grain elevator fire) contained insects, moldy grain, charred grain, nails, and rocks; 402(a)(3). Consent decree authorized release to Mill Mutuals of Minneapolis, Minn., for salvaging. (4)

Mustard seed, at New Orleans, E. Dist. La. Charged 4-2-71: while held by New Orleans Import Co., Inc., New Orleans, La., the article contained rodent filth and was held under insanitary conditions—402(a)(3), 402(a)(4); and when shipped by Montana Mustard Seed Co., Inc., Voss, N. Dak., the label of the article lacked the place of business of the manufacturer, packer, or distributor, lacked a statement of quantity of contents, and lacked the common or usual name of the food—403(1)(1), 403(e)(2), 403(f)(1). Default decree ordered destruction. (5)

Pecan pieces, at Boston, Dist. Mass. Charged 4-2-71: when shipped by Nut Tree Pecan Co., Beaconton, Ga., the article contained E. coli and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for salvaging. (6)

Pecan pieces, at Grand Rapids, W. Dist. Mich. Charged 4-29-71: when shipped by Dasher Pecan Co., Valdosta, Ga., the article contained E. coli and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for reconditioning. (7)

Potato flakes, at Houston, S. Dist. Tex. Charged on or about 4-16-71: while held by Houston Central Warehouse & Cold Storage, Houston, Tex., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (8)

Rice, at Mobile, S. Dist. Ala. Charged 4-20-71: while held for sale, the article contained an added deleterious substance, glass particles; the article contained moldy rice and was otherwise unfit for food because of glass particles; and the article had been held under insanitary conditions, since the article had been involved in a fire at the warehouse and was damaged by water and broken glass; 401(a)(1), 401(a)(3), 402(a)(4). Consent decree ordered destruction. (9)

Salmon, canned, at Beilingham, W. Dist. Wash. Charged 11-6-69: when shipped by Queen Fisheries, Inc., Clark's Slough, Alaska, the article had been prepared and packed under insanitary conditions; 402(a)(4). Consent decree authorized release to shipper for salvaging. (10)

Scallops, at Seattle, W. Dist. Wash. Charged 11-5-70: when shipped by the vessel Flamingo after being caught off the coast of Kodiak, Alaska, and while held for sale, the article, which had been frozen and packaged by New England Fish Co., Seattle, Wash., contained decomposed scallops; 402(a)(3). The article was claimed by Flamingo Fishing Corp., and the charge was denied. The parties served written interrogatories upon each other. Subsequently the case came on for trial by the court. The court found for the Government saying in part: “First of all let me say gentlemen that proof that the scallops were not fit for human consumption is immaterial. “Our statutes do not require such a finding, nor do I believe that the statute intended to do so. “The fact that the scallops before us emit offensive odors, that is the evidence before us, is sufficient; sufficient certainly, and the Government has the right, if not the duty to protect the consuming public from foul-smelling, decomposed food items. “The evidence to me is clear that of the Government’s sub-samples 20 through 29, out of 491 scallops [examined from one sampling], a total of 1:2 were classified as Class 2 decomposed and 36 classified as Class 3 decomposed. In other words, thirty percent of the scallops were decomposed to some extent. “Of the 378 [scallops examined from another sampling] sub-samples 1 through 11, 76 were classified as Class 2 decomposed and 12 scallops were classified as Class 3 decomposed. That figure constituted twenty-one percent of the scallops of those sub-samples. “Those classifications were determined by the organoleptic process by both Mr. LaRose and Mr. Thom, qualified experts in their field, I accept their analyses in the classification of the units involved. “I particularly accept the organoleptic approach in determining the decomposition status of the examined scallops; after listening to the testimony of Mr. Yokers an independent witness, a man well experienced and learned in the field of seafood and shellfish quality food control. “Doctor Liston [Director of the Fisheries Department at the University of Washington] and Mr. Yokers testified that the organoleptic test is the only accurate . . . test and is the test universally accepted and respected in the seafood industry. “I accept that testimony. Doctor Liston testified that the procedure followed by Mr. LaRose in carrying out the organoleptic analysis was properly carried out. * * * “The prayer of the Complaint is therefore granted. * * *” (11)

Soups of various kinds, canned, at Greensboro, M. Dist. N.C. Charged on or about 6-19-71: when shipped by Bon Vivant Soups, Inc., Newark, N.J., the articles, labeled in part “Cal Pre Brand Cream Chysposye Soup [or “Gazpacho.” “Onion Soup,” or other kind of soup] . . . California Preserves, Inc., New York City Distributors,” were unfit for food in that some of such foods had been found to be defective and abnormal, and in that the manufacturing procedures used 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 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). Consent decree ordered destruction. (12)

Soups of various kinds, canned, Bon Vivant, at Denver, Dist. Colo. Charged 8-17-71: when shipped, the articles were unfit for food in that some cans were defective and abnormal and in that the manufacturing procedures used 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 [by Bon Vivant Soups, Inc., Newark, N.J.] under 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). Consent decree authorized destruction. (13)

Tomatoes, canned, at Proctor, E. Dist. Okla. Charged 7-2-71: while held by Proctor Canning Co., Proctor, Okla., who had packed the article from raw tomatoes shipped from Texas, the article contained mold; 402(a)(3). Default decree ordered destruction. (14)

FOOD / Economic and Labeling Violations

Apricots, whole, unpeeled, canned, at Fargo, Dist. N. Dak. Charged 8-5-70: when shipped by Tillie Lewis Foods, Inc., Stockton, Calif., the article, labeled in part “Cal-top California Whole Unpeeled Apricots in Light Syrup . . . Packed for Modesto Canning Company, Modesto, California,” was in violation of the Fair Packaging and Labeling Act, since the quantity c’ contents declaration was not placed within the bottom 30 percent of the area of the principal display panel; the quantity of contents was expressed as “Net Weight 1 Lb. 15 Oz.,” rather than “Net Weight 29 Oz. (1 Lb. 13 Oz.)”; and the quantity of contents, appearing on the principal display panel with an area of more than 5 square inches, was in a type size less than 1/4 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(3)(C)(ii). Consent decree authorized release to the shipper for relabeling. (15)

Bac-Os soy-protein bits with bacon-like flavor, at Buffalo, W. Dist. N.Y.
Charged 8-25-66 and amended on or about 4-5-67: when shipped by General Mills, Inc., West Chicago, Ill., the article was an imitation of another food, bacon, and its label failed to bear in type of uniform size and prominence, the word "imitation," and immediately thereafter the name of the food imitated; 403(c).

The article was claimed by the shipper. The Government served written interrogatories on the claimant. The claimant's objections to the interrogatories were overruled by the court, and when the claimant then failed to answer, the Government moved for a default decree for failure to answer. Thereafter, the claimant filed answer to the interrogatories. Thereafter, the Government moved for summary judgment. The court denied the Government's motion. The parties agreed that the article was beginning to show signs of decomposition, which meant that the article was adulterated within the meaning of 402(a)(3). Accordingly, a consent decree of condemnation was entered which ordered destruction of the article. (16)

Bananas, candy-coated, frozen, Cinderella, at Philadelphia, E. Dist. Pa. Charged 12-29-70: when shipped by Zendee's Frozen Food, Riverside, N.J., the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not placed within the bottom 30 percent of the area of the principal display panel in lines generally parallel to the base of the article as designed to be displayed; the quantity of contents declaration was not separated from other printed label information appearing to the left of the declaration; and the quantity of contents, appearing on the principal display panel with an area of more than 5 square inches, was in type size less than 1/4 inch high—15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i) (the shipper's label standard) and "Ingrdients: . . . banana, dark sweet chocolate" were false and misleading, since the coating of the article failed to conform to the standard of identity for sweet chocolate coating, in that the coating contained vegetable fats other than the specified "butter" and "vanilla F." Default decree authorized donation to charitable institution for use and not for resale. (17)

Beans, Lima, at Greely, Dist. Colo. Charged 12-8-70: when shipped by Mar-Bo Quality Foods, Inc., Fresno, Calif., the quantity of contents statement on the label of the article, labeled in part "Cacerole Brand California Large Lima Beans . . . Packaged for American Bean and Pea Growers, Inc., Denver, Colo." was not prominently placed thereon with such conspicuity as to render it likely to be read and understood, since the statement was printed in white ink on cursive characters, containing while beans—15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Default decree authorized donation to Outwest Bean, Inc., Denver, Colo., for relabeling. (18)

Bread, garlic, frozen, Lobello's, at North Little Rock, E. Dist. Ark. Charged 6-30-70: when shipped by Annette Lobello Co., Dallas, Tex., the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not separated from other printed label information; the quantity of contents, appearing on the principal display panel with an area larger than 25 square inches, was stated in a type size less than 1/4 inch high; and the label stated "8 Large Servings" and lacked a statement of the net quantity of each such serving; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Default decree authorized donation to charitable institution. (19) 

Candies, of various flavors, at Milwaukee, E. Dist. Wis. Charged 8-25-70: when shipped by Arlington Candy Co., Inc., Somerville, Mass., the articles, labeled in part "Old Fashioned Candies Wild Cherry [or other kind] . . . The Chocolate House Milwaukee, Wis.," were in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not placed within the bottom 30 percent of the area of the principal display panel; the quantity of contents was expressed as "Net Wt. 1 lb." instead of "Net Wt. 16 oz. (1 lb.);" and the quantity of contents, appearing on the principal display panel with an area of more than 25 square inches, was in a type size less than 1/4 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(ii), 1453(a)(3)(C)(i). Consent decree authorized release to Chocolate House, Inc., Milwaukee, Wis., for relabeling. (20)

Milk, nonfat, dried, Top Taste, at Hopkins, Dist. Minn. Charged 7-22-70: when shipped by Land O'Lakes Creameries, Inc., Instant & Specialty Products Div., Eau Claire, Wis., the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents was expressed as "Net Wt. 16 oz. (1 lb.);" and the net quantity of contents, appearing on the principal display panel with an area of more than 25 square inches, was in a type size less than 1/4 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(ii), 1453(a)(3)(C)(i). Consent decree authorized release to the shipper for relabeling. (21)

Peanuts, blanched, and peanuts, salted, at Salt Lake City, Dist. Utah. Charged 11-24-70: when shipped by Throby Foods, Inc., Salt Lake City, Utah which had repacked the articles from bulk, the articles were in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not placed within the bottom 30 percent of the area of the principal display panel; and the quantity of contents statement, appearing on the principal display panel with an area of more than 25 square inches, was in a type size less than 1/4 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Consent decree authorized release to dealer for relabeling. (22)

Pies, apple, cherry, peach, and pumpkin, frozen, at Green Bay, E. Dist. Wis. Charged 8-5-70: when shipped by Tony Down Foods Co., St. James, Minn., the articles, labeled in part "Fairy-rite Apple [or other kind] Pies. Some Frozen! Packed For Super Valu Stores, Inc., Hopkins, Minn." were in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not separated from the printed label information appearing to the left; the quantity of contents was expressed as "Net Wt. 1 lb. 6 oz." rather than "Net Wt. 22 Oz. (1 Lb. 6 Oz.);" and the quantity of contents, appearing on the principal display panel with an area of more than 25 square inches, was in a type size less than 1/4 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(ii), 1453(a)(3)(C)(i). Consent decree authorized release to shipper for relabeling. (23)

VITAMINS / DIETARY FOODS

Dr. Bronner's Calcium Food vitamin and mineral supplement and Vegetable-Amino Broth seasoning, at Portland, Dist. Ore. Charged 8-7-70: when shipped by Dr. E. H. Bronner & Associates, Escondido, Calif., the Calcium Food contained the food additive iodine which was non-conforming, since the recommended daily amounts provided were in excess of the daily level of 0.15 mg. of iodine permitted by regulation; the labeling of the Calcium Food contained false and misleading claims for use as a sugar replacement and of containing a U.S.P. recognized natural ground calcium; the label of the Calcium Food lacked the common or usual names for the ingredients that the label designated as "natural ground calcium—USP" and "vitamin B-12 yeast," and the label of the Calcium Food lacked required information concerning its dietary properties—402(a)(2)(C)(ii), 403(a)(4), 403(2), 403(3); and the label of the seasoning contained false and misleading claims concerning providing a significant amount of protein and being adjusted to contain a natural sodium potassium chloride balance; and the labeling of the seasoning lacked required information concerning its dietary properties—403(a)(4), 403(1). Default decree ordered destruction. (24)

Vitamin E capsules, at Denver, Dist. Colo. Charged 4-8-71 and amended 4-23-71: while held for sale, the article's accompanying labeling, reading in part "Health Rite Health Food Center . . . Vitamin E combats the Deadly Effect of Air Pollution . . . Lung disorders . . . hold back the ravages of emphysema," contained false and misleading claims for lung disorders related to air pollution, particularly emphysema; 502(a). Consent decree authorized release to BBL Laboratories, El Segundo, Calif., for relabeling. (25)

DRUGS / Human Use

Aldonnell beladonna and barbital combination capsules, at Fort Lauderdale, S. Dist. Fla. Charged 4-17-70: when shipped by Barrows Chemical Co., Inc., Inwood, N.Y., the strength of the article fell below its purported strength, since it contained 20 percent of its declared belladonna alkaloids; 501(c). Default decree ordered destruction. (26)


Cabisil (calcium, barium, sulfur, iodine, and lactocin combination) products, at Garden Grove, C. Dist. Calif. Charged 7-30-71: when shipped by Dr. Stuart Kabinck, Philadelphia, Pa., the accompanying mail-order form contained false and misleading claims for reducing cardiac distress, and the labeling of the article lacked the established name of each active ingredient, lacked adequate directions for use, and lacked adequate warning against unsafe use—502(a), 502(e)(1)(A)(ii), 502(f)(1), 502(f)(2). The labeling of some of the articles contained additional false and misleading claims as follows: Cabisil described and Concentrate Ointment 16-ounce and 4-ounce—sloughing or gangrenous tissues, Buergner's disease, diabetic gangrene, and chronic draining sinuses; Concentrate Liquid 3-ounce—sloughing or gangrenous tissues, Buergner's disease, diabetic gangrene, and chronic draining sinuses; Vaginal Suppositories—Vaginitis; Oral Tablets—minor stomach distress—502(a); and the Nose and Throat Powder, Oral Tablets, and Tooth Paste lacked an accurate statement of the quantity of contents—502(b)(2). Default decree ordered destruction. (28)

York," differed from the N. F. standard, since it contained approximately 80 percent of the minimum requirement for reserpine resinsamine group alkaloids; 501(b). Default decree ordered destruction. (29)

**DRUGS / Veterinary**

**Atro-Dote atropine methylknitrate injectable,** at Baton Rouge, E. Dist. La. Charged 3-29-71: while held by Hart-Delta, Inc., Baton Rouge, La., who manufactured the article from ingredients shipped in interstate commerce, the circumstances of the article's manufacture, processing, packing, and holding failed to conform to current good manufacturing practice; the article's strength differed from its purported 2 mg/cc strength; and its statement of strength was false and misleading, since the article contained approximately 147 percent that amount of atropine methylknitrate; 501(a)(2)(X), 501(c)(2), 502(a). Default decree ordered destruction. (30)

**Ferro-Lac medicated swine formula concentrate,** at Atkinson, S. Dist. III. Charged 5-18-66 and amended 10-31-67: when shipped by Naremco, Inc., Springfield, Mo., the article was a new drug without an effective approved New Drug Application—505(a); the article contained a nonconforming combination of additives (methyrosamine chloride, sodium phthalylsulfacetamide, and sodium propionate)—402(a)(2)(C); and the labeling contained false and misleading claims for infectious nonspecific diarrhea and bacterial enteritis in swine—502(a).

The shipper claimed the article and denied the charges. The parties served written interrogatories on each other. After a pretrial conference and the entry of a stipulation of uncontested facts, the Government moved for summary judgment on the new drug and food additive charges. Summary judgment was not sought on the 502(a) misbranding charge. The court granted the Government's motion for summary judgment. The claimant appealed. The Court of Appeals for the Seventh Circuit rendered the following opinion:

"The United States seized seven cartons of Ferro-Lac, alleging in a libel that the Ferro-Lac was unlawfully shipped by reason of (1) its being a new drug, (2) its containing unsafe food additives, and (3) its being misbranded. Claimant, Naremco, Inc., concedes that a finding in favor of the Government on any one of the three charges is sufficient to result in condemnation of the product.

"The district court, on motion for summary judgment, decided in favor of the government on both (1) and (2). Judge Morgan's opinion is reported, United States v. 7 Cartons, More or Less, Etc. (S.D. Ill., 1968), 293 F. Supp. 660. It is apparent that with respect to both (1) and (2) the critical question goes to the general recognition of the material among a described class of experts as meeting a specified standard. With respect to (1) the question is whether the material is so recognized as safe and effective for use under the conditions suggested in the label. With respect to (2) the question is whether the material is so recognized as having been adequately shown through scientific procedures to be safe under the conditions of the intended use. In neither respect need the government prove that the material is, in fact, unsafe.

"The affidavit in support of and opposition to the government's motion for summary judgment are adequately described in Judge Morgan's opinion. We adopt Judge Morgan's opinion with respect to (2), the unsafe food additive issue.

"Claimant suggests with respect to (1) that Judge Morgan was weighing the portions of the respective affiants. It is unnecessary to express an opinion with respect to (1) in view of our approval of his decision with respect to (2).

"The portion of the judgment of condemnation asserting that the seized article is a new drug is stricken as unnecessary and the judgment is in all other respects affirmed." (31)

**Formula 707 chlortetracycline hydrochloride feed additive,** at Salt Lake City, Dist. Utah. Charged 2-22-71: when shipped by John Ewing Co., La Salie, Colo., the article was a new animal drug without an effective approved New Animal Drug Application, and the drum label and accompanying pamphlet and booklet contained false and misleading claims that the article was effective as a conditioner for horses; that it contained the best balance of vitamins, minerals, and growth-promoting ingredients known today; that most American soils were badly depleted in important mineral elements and that nutritionally perfect grass and hay were practically impossible to find; that the article might be used for horses of all ages; that it was effective to promote the growth of a colt into a bigger more powerful animal that can run faster, work harder, and carry his rider with a little less effort; to keep horses in peak condition all the time; to quiet down nervous horses and enable them to win races; to promote better appetites, better coats, and more life; and to promote high hemoglobin level and build up horses' blood; 501(a)(5), 502(a). Consent decree authorized release to the shipper and Steve Regan from Salt Lake City, Dist. Utah, for relabeling. (32)

**Myconox medicated poultry concentrate and Ferro-Lac Improved medicated poultry concentrate,** 2 seizure actions at Center, E. Dist. Tex. Charged against Myconox on 5-23-66 and amended 12-7-66: the article contained the nonconforming combination of food additives methyrosamine chloride and sodium propionate—402(a)(2)(C); the labeling of the article contained false and misleading claims for control of mycosis in broilers and market turkeys—403(a); and the article was a new drug without an effective approved New Drug Application—505(a). Charged against Ferro-Lac on 5-27-66 and amended 12-7-66: when shipped by Naremco, Inc., Springfield, Mo., the article contained the nonconforming combination of food additives methyrosamine chloride and sodium propionate—402(a)(2)(C); the labeling of the article contained false and misleading claims for enteric infection associated with nonspecific disease in chickens and turkeys—502(a); and the article was a new drug without an effective approved New Drug Application—505(a).

The articles were claimed by the shipper who denied the charges. The two actions were consolidated for trial. The trial before court and jury resulted in verdicts in favor of the Government on at least a part of the issues in each case; and, thus, the charge of condemnation were entered against both products. The claimant appealed. Following the granting of an order for a new trial and the subsequent vacation of that order, the appeal was perfected. Upon appeal, the court found for the Government saying:

"The jury found that Myconox was misbranded, was a new drug, and was a food additive. As to Ferro-Lac the jury found in favor of the government only on the food additive charge, which alone is sufficient to support condemnation.

"Predictably, the evidence as to the qualities of the constituent drugs had to be 'expert opinion.' A Food and Drug Administration veterinarian testified that he fed directed dosages of Ferro-Lac to certain chickens. At the end of this experiment the chickens were killed and certain parts were forwarded to an expert government chemist, who conducted tissue or chemical residue tests. Although these studies were limited to only one of the ingredients of Ferro-Lac, the chemist did find sulfuric acid, a breakdown product of the ingredient phthalylsulfacetamide, in tissues of chickens which had been fed Ferro-Lac at a dosage level of twenty pounds per ton. Consequently, the court could not say how the three chemicals would act in combination or whether they would be safe.

"On the food additive question testimony bearing on the general recognition for safety among experts came from Dr. Maurice Cover of the University of Delaware, Dr. Walter Gross of VPI, and Dr. Benjamin M. Pomery. Each testified that he kept abreast of veterinary pathology through professional meetings, colloquia, and constant review of the literature. In substance their testimony was that the particular combinations of chemicals at issue were not generally recognized as having been shown to be safe, since the available scientific literature was silent on the ingredients in Ferro-Lac and Myconox. Substantially identical testimony relevant to the new drug issue was elicited from both Drs. Cover and Pomery. In sum, these experts averred that Myconox was not generally recognized among qualified experts as safe and effective for its recommended use; that there was a total absence of published information on the subject.

"The thrust of claimant's argument is that the statutory definition of food additive in 21 U.S.C. §321(c) contains four elements: The substance must be (1) 'not generally recognized, among experts qualified by scientific training and experience,' (2) to evaluate its safety, (3) as having been adequately shown through scientific procedures to be safe under the conditions of its intended use. * * * *

A. Ferro-Lac—Food Additive

"Since no witness was asked a question which embodied each of the four statutory elements, appellant argues that the probative expert testimony of the government cannot amount to the required substantiality.

"The government's questions very clearly inquired into the safety of the product in the opinion of qualified experts. Thus, component number two of the statute is clearly implied.

B. Myconox—Food Additive

"Likewise, claimant asserts that elements 1 and 2 in the statutory definition are absent in the testimony of Dr. Cover: * * * *

"Attack on this question as reflecting only the personal view of Dr. Cover is unwarranted. The absence of scientific knowledge on the part of an expert and his colleagues is sufficient to show lack of general recognition of safety. United States v. Article of Drug etc. (N.D. Ga., 1968), 294 F.Supp. 1307, affirmed per curiam 415 F.2d 390 (decided July 25, 1969). As in (A) element number two may be implied.

C. Myconox—A New Drug

(28) Alleged discrepencies between the 'new drug' statutory definition and the questions posded to witnesses are once again the main complaint, and do not differ in kind from those discussed above. Here claimant also attacks the testimony of the government's expert witnesses because they were not qualified in areas required by the statute.

(33) The government's witnesses are all veterinarians specializing in

34 / March 1972 / FDA Papers
avian diseases. Even assuming that the witnesses are not qualified to judge the safety of the products, they are qualified to testify as to whether there is general recognition of the safety of the products.

D. Misbranding of Myconox

"[S] Misbranding of Myconox turns on whether mycosis refers to fungal infections in general or encompasses only digestive disorders. Conceding a conflict in the evidence, there was, at most, a question of fact for the jury.

"Counsel for the claimant has vigorously presented every reasonable possible basis for a reversal in this case. Nevertheless, we perceive no error and the judgment of the District Court must be Affirmed": 420 F.2d 1126 (1970).

Thereafter, the claimant's motion for a re hearing and claimant's petition for a writ of certiorari were denied. (33)

MEDICAL DEVICES

Relaxacisor electric muscle-stimulator, at Garden Grove, C. Dist. Calif. Charged 9-9-70: when shipped, the labeling of the article lacked adequate directions for safe use by laymen and lacked adequate warnings against unsafe use; 502(1)(c), 502(1)(c). Consent decree ordered destruction. (34)

Theramatic model AGO740 electronic instrument, at Indianapolis, S. Dist. Ind. Charged 8-25-70: when shipped by Dynapower Systems Corp., Los Angeles, Calif., the article's labeling lacked adequate directions for use, since adequate directions for the purposes for which the article was intended could not be written for use by laymen, and the article did not comply with Rx device exemption requirement, since adequate information could not be furnished under which practitioners could use the article safely; 502(1)(c). Default decree ordered destruction. (35)


Charged 8-16-62, 8-27-62, 9-21-62, 10-8-63, 7-13-67: the devices at Milwaukee, Boyceville, Eau Claire, Ladysmith, Marshfield, and Wisconsin Rapids, Wis., were shipped to those places from the Toftex Chiropractic Clinic, Cumberland, Wis., subsequent to their shipment to the clinic by the Electronic Instrument Co., Tiffin, Ohio; the devices at Cumberland, Wis., were shipped to the clinic by L. A. Nyberg, D.C., Wilmar, Minn., and Jennings I. Wilson, Minneapolis, Minn., the devices at Cambridge, Minn., and at Davenport, Des Moines, Indiana, and Keesauqua were shipped from the Toftex Chiropractic Clinic, Cumberland, Wis., and the device at Columbia Heights, Minn., was shipped by unknown shipper following its manufacture by the Toftex Chiropractic Clinic, Cumberland, Wis.; and the labeling of the devices lacked adequate directions for use for the purpose for which they were intended, namely, for the diagnosis of disease in man, since they were worthless for such purpose; 502(1)(c).

The Toftex Post-Graduate School of Chiropractors and the Foundation for the Advancement of Chiropractic Research, both of Cumberland, Wis., filed a joint claim and answer. Interrogatories were served by the Government and the claimants and subsequently answered, depositions were taken, and in the course of the proceedings the actions against the devices in the W. Dist. Wis., Dist. Minn., and S. Dist. of Iowa were transferred and consolidated for trial with the action in the E. Dist. of Wis. On 6-28-71, the claimants having consented to the entry of a decree without admitting or denying the allegations of the labels, the court entered a decree of condemnation and authorized the release of the devices to the claimants for salvage of the parts from the devices under the supervision of the Food and Drug Administration. (36)

HAZARDOUS SUBSTANCES

EPO panel and dry-wall adhesive, at St. Louis, E. Dist. Mo.

Charged 4-9-71: when shipped by Commercial Chemical Co., Cincinnati, Ohio, the article was extremely flammable, it lacked a number of required label statements, the signal word and statement of principal hazard were not located prominently in the main panel of the label, and the statement of hazard was not in capital letters; 2(p)(1)(C&F), 2(p)(2). Default decree ordered destruction. (37)


Charged on or about 5-14-71: while held for sale, the article was a banned hazardous substance and it was not exempted, since the packages of the article lacked the prescribed warnings; 2(q)(1)(A). Default decree ordered destruction. (38)

Porcelain Sparkle for porcelain, at Indianapolis, S. Dist. Ind.

Charged 5-14-71: when shipped by Wrap-On Co., Inc., Chicago, Ill., the article was an irritant, it contained approximately 42.5 percent hydrochloric acid, and it lacked a number of required conspicuous label statements—2(p)(1)(B&G), and the signal word "Warning" or "Caution" failed to appear on the main panel of the label—2(p)(2). Default decree ordered destruction. (39)

NOTICES OF JUDGMENT on Criminal Actions

FOOD


Charged 2-9-71: commuel mix, oatmeal cereal, hominy grits, and flour were held in a building accessible to rodents and, except for one lot of flour and the grits, were contaminated with rodent filth; 402(a)(3), 402(a)(4). Nolo contendere plea; fine. (40)


Charged 5-21-71: flour, beans, dried milk, rice, salt, and sugar were held under insanitary conditions in a building accessible to rodents and birds and were exposed to contamination by rodents and birds; 402(a)(4). Guilty plea; fines. (41)

D & L Slade Co. and Francis F. Brooks, president, Boston, Dist. Mass.

Charged 7-20-71: while held for sale, celery seed, basil leaves, cinnamon, black pepper, white pepper, and nutmeg were processed and packed into boxes that failed to bear a label containing an accurate statement of the quantity of contents, since when processed and packed in the boxes, the spices were short weight; 402(e)(2). Guilty plea by the corporation; fine. Guilty plea by the individual; probation. (42)

The Fink Co., a partnership, and Howard N. Fink, partner, Dallas, N. Dist. Tex.

Charged 6-11-71: tomato catsup mustards, and dates were held in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (43)

Chris Hoer & Son Co., East Peoria, S. Dist. Ill.

Charged on or about 6-28-71: rice, farina, oats, rolled wheat, lima beans, and kidney beans were held in a building accessible to rodents and, except for the lima beans, were contaminated with rodent or insect filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (44)


Charged 4-9-71: when shipped, apple-date bread and raisin brown bread contained rodent hair fragments and had been prepared and packed under insanitary conditions—402(a)(3), 402(a)(4); and sugar was held in a building accessible to rodents and exposed to contamination by rodents, resulting in such sugar being held under insanitary conditions—402(a)(4). Guilty pleas; fines plus costs. (45)

Rawi Distributing Co., Inc., Columbus, Dist. S.C.

Charged 5-12-71: rice and grits were held in a building accessible to rodents and birds, and the rice was contaminated with bird filth; 402(a)(3), 402(a)(4). Guilty plea; fine and probation. (46)


Charged 1-12-71 by grand jury: when shipped, unbleached dried meat scraps contained the added poisonous and deleterious substance Salmonella microorganisms and had been prepared and held under insanitary conditions; 402(a)(1), 402(a)(4). Guilty plea; fine. (47)

DRUG

Denver Veterinary Laboratories, Inc., Denver, Dist. Colo.

Charged 4-20-71 by grand jury: when shipped, vials of a drug, labeled in part "Rx Veterinary... Vitasec A, D & E 500 Emulsifiable Injection Manufactured for Rx Veterinary Products, Fresno, California," had been prepared and packed under insanitary conditions, the circumstances of the article's processing and packing lacked conformity to current good manufacturing practice, and the article's purity and quality were deficient, since it contained hairs, insect fragments, fibers, and other particulate matter; 501(a)(2)(A), 501(a)(2)(B), 501(c). Guilty plea; fine. (48)

NOTICE OF JUDGMENT on Injunction Action


Charged 7-12-66 and amended 6-15-67 in complaint for injunction: that the defendants were engaged in the business of designing, manufacturing, promoting, selling, and shipping in interstate commerce a device designated as Relaxacisor (one of the several models was also designated "Retone"); that the device was manufactured by Eastwood Industry Inc., Chicago, Ill., a wholly owned subsidiary of Relaxacisor Inc., and was distributed throughout the United States at the direction of Relaxacisor Inc. or Relaxacisor Sales Inc.; that the device provided electrical currents which caused intermittent contraction of the voluntary skeletal muscles beneath the skin area to which the pads of the device were applied; and that, in promoting the interstate sale and distribution of the device, the defendants used a number of items of labeling, which labeling contained false and misleading claims for reducing, figure improvement, pleasant exercise, etc., and which labeling contained purported testimonials by celebrities and others which were false and misleading in failing to reveal certain specified material facts, such as:

(a)

FDA Papers / March 1972 / 35
enjoin the defendants from enforcing the requirement of such regulations. Upon cross motions for summary judgment, the District Court found largely for the plaintiffs on the grounds that the statute did not sweep so broadly as to permit the Commissioner’s “everytime” interpretation, and accordingly declared null and void those sections of the regulations that required that the established name of a prescription drug must accompany each appearance of such drug’s proprietary name, and enjoined the defendants from enforcing such regulations. 226 F.Supp. 855 (1964).

The Government, and 26 of plaintiff-manufacturers who were not incorporated in the State of Delaware and who had been dismissed from the action for lack of proper venue, appealed. The Court of Appeals for the Third Circuit held that the District Court’s judgment for the plaintiff must be vacated, the injunction dissolved, and the action dismissed, because review of the regulations was unauthorized and there was no actual case or controversy, 352 F.2d. 286 (1965).

Upon appeal by the plaintiffs to the Supreme Court, the Supreme Court reversed the Circuit Court. The Supreme Court said, in part:

"The first question we consider is whether Congress by the Federal Food, Drug and Cosmetic Act intended to forbid pre-enforcement review of this sort of regulation promulgated by the Commissioner."

"* * * we are wholly unpersuaded that the statutory scheme in the food and drug area excludes this type of action. * * *

"Against this background [of the context of the entire legislative scheme] we think it quite apparent that the special-review procedures provided in § 701(t) [of Title 21 U.S.C.], applying to regulations embodying technical factual determinations, were simply intended to assure adequate judicial review of such agency decisions which it was thought did not manifest a congressional purpose to eliminate judicial review of other kinds of agency action."

"A further inquiry must, however, be made. The injunctive and declaratory judgment remedies are discretionary, and courts traditionally have been reluctant to apply them to administrative determinations unless these arise in the context of a controversy `ripe' for judicial resolution."

"Where the legal issue presented is fit for judicial resolution, and where a regulation requires an immediate and significant change in the plaintiffs’ conduct of their affairs with serious penalties attached to noncompliance, the courts under the Administrative Procedure Act and the Declaratory Judgment Act must be permitted, absent a statutory bar or some other unusual circumstance, neither of which appears here."

"Lastly, although the Government presses us to reach the merits of the challenge to the regulation in the event we find the District Court properly entertained this action, we believe the better practice is to remand the case to the Court of Appeals for the Third Circuit to review the District Court’s decision that the regulation was beyond the power of the Commissioner." 387 U.S. 136 (1966).

Thereafter, the Government revised its regulations (21 CFR 1.104(g)(1) and 21 CFR 1.105(b)(1)) so as to no longer require the use of the established name every time the proprietary name appeared, and pursuant to stipulation, the parties moved that the litigation be terminated, that the judgment be vacated, and that the cause be dismissed without prejudice as moot because of settlement of the matter by agreement. The Court of Appeals granted the joint motion of the parties. (50)

NOTICE OF JUDGMENT on Miscellaneous Action

Established names of prescription drugs and the prominent printing of such names, suit for declaratory judgment and injunction, Wilmington, Del. Charged 9-5-63 by Abbott Laboratories and 36 other pharmaceutical manufacturers, and Pharmaceutical Manufacturers Association, in suit for declaratory judgment and injunction against the New York Secretary Celebrbreze and FDA Commissioner Larrick: that the defendants have taken the position that the plaintiffs’ prescription drug labeling and advertising may not be distributed because such labeling and advertising do not contain the established name of the drug accompanying every appearance of the drug’s proprietary name; that the Commissioner’s regulations requiring the appearance of the established name in conjunction with each appearance of the proprietary name were inconsistent with and went beyond the requirements of the statute; that such regulations required plaintiff-manufacturers to review and reprint at substantial expense and without regard to advertising; that use of labeling and advertising which complied with the regulations would injure the plaintiff-manufacturers in their businesses; and that the plaintiffs prayed for a judgment declaring the regulations in question to be null and void, and to

NOTICE OF JUDGMENT are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act and section 13 of the Federal Hazardous Substances Act. Notices of Judgment report cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizures are civil actions taken against goods alleged to be in violation of the Act, and criminal and injunction proceedings are cases involving persons charged to be responsible for violations. The cases generally involve foods, drugs, cosmetics, or hazardous substances 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, Drug, and Environmental Health Division, Office of the General Counsel, DHEW. Published by direction of the Secretary of Health, Education, and Welfare.

Charles C. Edwards, M.D., Commissioner of Food and Drugs Washington, D.C. March 1, 1972.

36 / March 1972 / FDA Papers
It's the law. Withdraw D.E.S. 7 days before slaughter.

It's the law—there are no residues of DES (diethylstilbestrol) permitted in meat. New Federal regulations require cattle and sheep producers to withdraw feed containing DES 7 days prior to slaughter, and certify in writing that the 7-day withdrawal period has been observed.