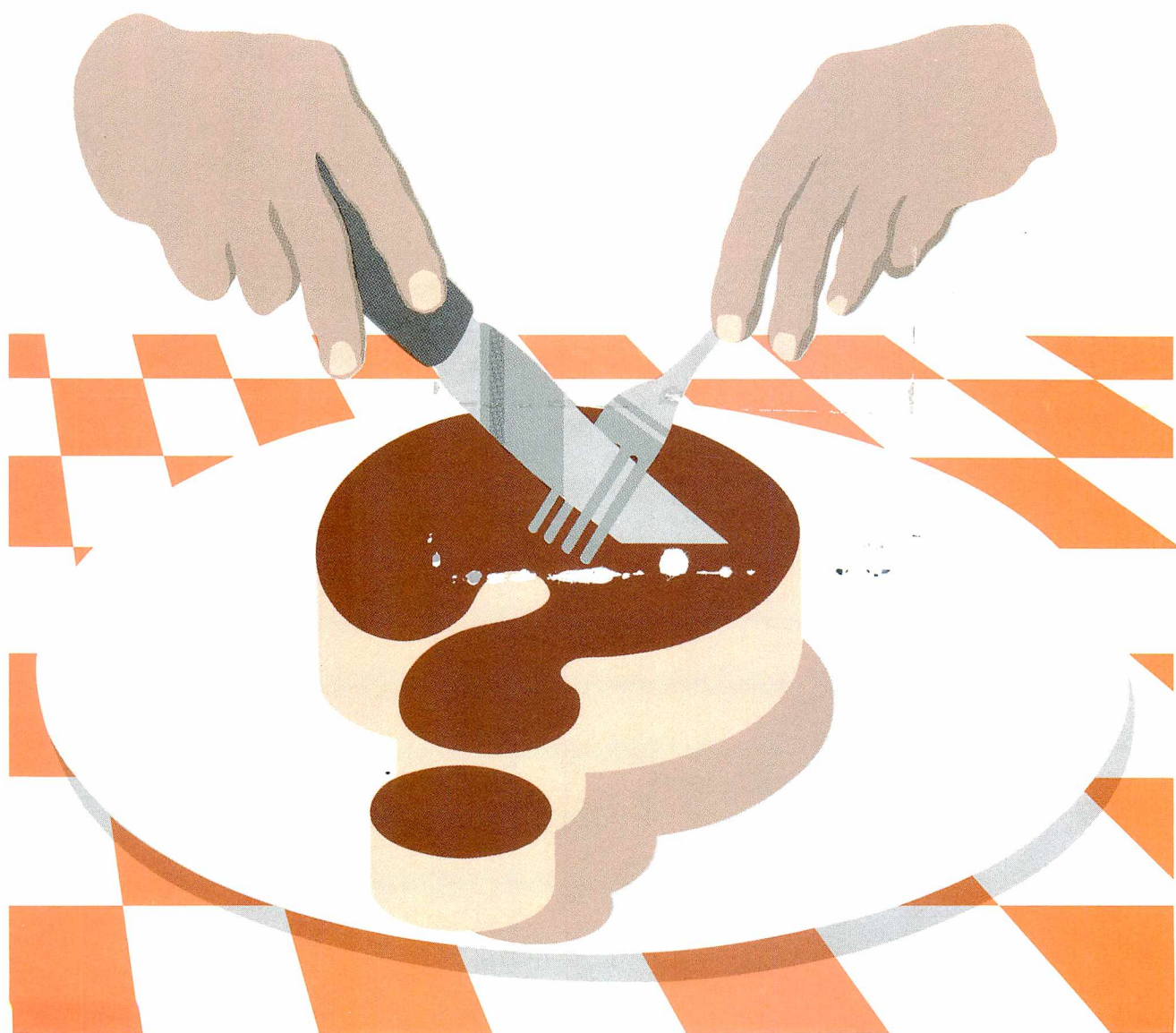


FDA **CONSUMER**

JULY-AUGUST 1975



Finding Out What ELSE You Eat

SEASON'S FINEST AT
MONEY-SAVING PRICES



This Month

“Can that boy eat!”

Most parents of teenage boys have said that, or something similar. Acne, adolescence, and an enormous appetite just seem to go together. And the enormous appetite part has nothing to do with girth; young men with cavernous stomachs come in all shapes, from pogo sticks to basketballs. Parents who are concerned that there is something unusual about a boy who eats as though he is housing a tapeworm might get some psychic—if not financial—consolation in knowing that the phenomenon is more universal than unique. So much so, in fact, that FDA uses the food intake of a teenage boy as the benchmark for its Total Diet Study.

This study is designed to find the kinds and amounts of pesticides, heavy metals, and industrial chemicals Americans swallow along with their food and drink. FDA employees go into supermarkets in all parts of the Nation, purchase the food that a teenager might eat over a two-week period, and send it to Kansas City where it is prepared for eating and then analyzed. If you're interested in *Finding Out What ELSE You Eat*, there's a report on the latest Total Diet Study in this issue.

Nutritionists probably would agree that most of us put too much emphasis on what we like to eat and too little on what we should eat. But because people do tend to eat what they like, taste tests are an important part of the work of FDA's test kitchen. New and novel foods are prepared and served to panels of volunteer tasters, thus making consumer acceptance an important consideration in the continuing effort to improve the nutritional quality of the foods we eat. It's all *A Matter of Taste*, which, not coincidentally, is the title of our article on the test kitchen.

People who discover a food or restaurant they particularly like often recommend it to friends. If the friends follow the recommendation and are displeased—taste is a highly personal matter—no harm has been done. But some people recommend, and then lend, prescription medicines to friends. That's a recommendation with considerable potential for harm. This month we've compiled a list of basic “do's” and “don'ts” on the use of prescription and nonprescription drugs. They're labeled, *Medicine: Handle With Care*.

Inside Front Cover Photo: *Americans get much of their food at the supermarket, so that's where FDA purchases the food for its Total Diet Study. An explanation of the study, and what it tells us about what we're eating, begins on page 8.*

FDA **C**ONSUMER

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

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

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

Cover Design: Zeb Rogerson

Quotes

I should like to emphasize that what we at FDA are trying to do, in simple terms, is to develop regulations which will assure that when a consumer walks into a store and buys a bottle of multivitamin tablets to provide nutritional 'insurance' for himself and his family, he will be getting a product which provides all of the vitamins that are truly useful for such purposes, in potencies that are likewise useful but not wasteful, and that the product will be informatively labeled, without false or misleading claims, and that it will not contain worthless ingredients which may falsely make it appear, to the uninformed layman, to be a superior product."

Stephen Hull McNamara, associate chief counsel for food, Food and Drug Administration, at the Stanford Day College for Nutrition and Health.

I suppose it is typical of human nature that the American consumer today wants not only more and safer food, but he wants it without paying proportionately more of his hard earned income for it.

"There are some who may think such demands unreasonable. Indeed, *some* of the demands are unreasonable. But the American consumer, in a democratic society, is a bit like the end result of crossing a tiger with a parrot—you may not like what the creature says, but when it talks, you had better listen!"

Alexander M. Schmidt, Commissioner of Food and Drugs, before the National Canners Association Spring Board Meeting.

Recently the President, in a much-publicized speech to the United States Chamber of Commerce, declared that vigorous action must be taken to eliminate the propensity in the Federal Government to promulgate new rules and regulations which raise costs and consumer prices at the same time. He also stated that where the objective is to achieve small or somewhat limited social benefits proposed regulations must either be revised to lower their costs or we must not

adopt them in the first place. In short, the speech was headlined as calling for 'Federal de-regulation.'

"It is most important, however, that this message be put in perspective by pointing out that the President specifically stated that he does not seek to eliminate all regulations. He indicated his appreciation that certain regulations may be costly, but are essential to preserve public health and public safety. We believe that most FDA regulations fall squarely into that category and the leadership of this Agency is determined that the outcome of FDA decision-making will stand up when subjected to hard-headed cost-benefit analysis on behalf of American consumers."

Howard R. Roberts, acting director, Bureau of Foods, Food and Drug Administration, at the Institute of Food Technologists Annual Meeting, Chicago.

A recent Lou Harris poll shows that the Food and Drug Administration is known to 86 percent of the public, a higher recognition than any other similar government organization.

"Of course, recognition is not nearly enough. Positive reaction is far more significant than is mere recognition, and in that area, Lou Harris found FDA at the top of the list of all government agencies, with a 61 percent positive mark. In fact, the FDA was the *only* Federal agency tested to be judged with favor by more than 50 percent of the questioned population."

Alexander M. Schmidt, Commissioner of Food and Drugs, before the Public Relations Society of America, Consumerism Conference.

Consumer Forum is an opportunity for the readers of FDA CONSUMER to express their views. Short, to-the-point letters are most acceptable for publication. Please address letters to Consumer Forum, FDA CONSUMER, HFI-20, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.



Medicine: Handle With Care

Shakespeare's advice about money —“neither a borrower, nor a lender be”—applies to prescription drugs as well. For more advice about handling medicines, not necessarily from the Bard, read on.

by Margaret Morrison

It's 3:00 a.m. You've awakened with a splitting headache. You grope your way into the bathroom without turning on the light (you *hope* to get back to sleep), reach for the bottle of aspirin that's always in the left corner of the medicine cabinet, gulp two tablets, and stumble back to bed.

You're going out of town for the weekend, you don't want to bother with that big bottle of capsules the doctor prescribed, so you pour half-a-dozen into a smaller container that another medicine had come in.

Some containers are too large for the medicine cabinet (like that douching formula, or the large bottle of rubbing alcohol), so you put them underneath the lavatory.

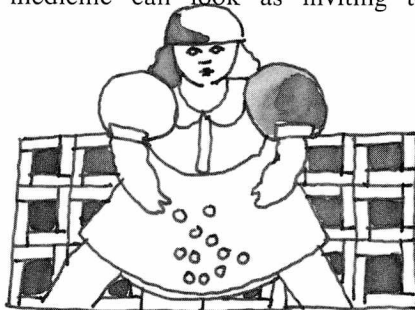
If you've ever done any of these things, you're guilty—along with millions of other American consumers—of mishandling medicines. And if you haven't suffered any unfortunate results from such mishandling, you're lucky.

Research and development of pharmaceutical products has resulted in a more abundant supply of medicines in the past few decades than ever before. We have medicines for the treatment of every type of health problem, from serious illnesses to minor symptoms. And how we handle them in our homes can be extremely important.

First, the matter of storing medicines. Some medicines have statements on their labels saying the product should be kept in a cool place, in which case you will probably refrigerate it. But most medicines are put in the medicine cabinet in the bathroom. In many homes, this is a small cabinet, only about a foot wide by two feet high by three inches deep. This is not normally enough space to hold all the medical products an average

family might use, and consequently there is a spillover to vanity tops, bathroom shelves, kitchen cabinets and shelves, dresser drawers, or—with large containers—the area underneath the bathroom lavatory. Such a scattering of products can lead to problems.

This is especially true if there are young children in the home. Toddlers like to crawl and climb and get into things. And a bottle of medicine can look as inviting to



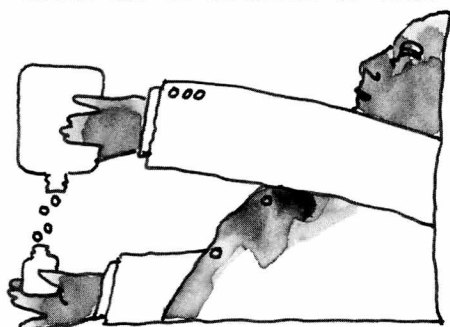
them as a bottle of soda pop, a box of bright-colored pills as interesting as colored candy. And what toddlers can get to, they put in their mouths. Every year thousands of young children suffer accidental poisoning in their homes, because adults were careless about keeping medicines out of reach or locked up. In a home where there are young children, all medicines—as well as any other chemicals used in the home—should be kept on a high shelf out of the children's reach, or in a locked cabinet.

But this precaution alone is not enough. It is important, also, to practice safety rules when using medicines around children. For example, if you carry medicines in your handbag, and leave the bag on a chair or bed or other place a child can reach, you are inviting trouble. Young children love to explore pocketbooks, and they'll go for a cold tablet as well as a compact, or take the lid off a bottle of

capsules as well as unscrew a lipstick.

Another reminder—if the phone or doorbell should ring when you're about to take (or have just taken) medicine, don't walk away and leave the medicine where a child can get it. It takes only a few seconds for a child to swallow medicine, and sometimes the consequences can be tragic.

To protect children from accidental use of medicines or other



products that could be harmful, FDA, under the Poison Prevention Packaging Act, requires that all such products be enclosed in safety packaging. This means containers are designed to be especially difficult for children to open or medicines are encased in an individually wrapped package. This can help prevent accidental poisonings—but only if you make sure the safety closure on a product is securely re-fastened after each use.

Accidents involving medicines are by no means limited to children. Careless adults also are susceptible.

For example, take the practice of using medicine in the middle of the night, in an unlighted room. Even though the aspirin bottle may “always” have been in the left corner of the medicine cabinet, that is no guarantee it will be there every time you want it. Someone else may have needed medicine and may have moved the aspirin bottle and put

in its place some medication for an entirely different symptom or condition. You could take the wrong medicine and end up with a serious reaction.

Another unwise practice is to take a prescription drug that was prescribed for someone else. The physician who prescribed medication for your friend or some other member of your family decided on the basis of a history, physical exam, or laboratory studies, to prescribe that particular medicine for that particular person.

Even though your symptoms may appear to you to be the same as the other person's, you may have a condition that is not the same—and which requires an entirely different medicine. Or you may have a health condition that makes the prescription inappropriate for you. Or you may be allergic to certain drugs—drugs the other person can take quite safely. In addition, the doctor will have no opportunity to tell you about necessary precautions or warn you of possible ill effects of the drug. When it comes to prescription medicines, “neither a borrower nor a lender be.”

A related bad practice is keeping leftover medicines around for long periods after the condition they were prescribed for is gone. While this may be appropriate for some drugs (for example, antihistamines or analgesics) that are used intermittently for symptomatic treatment, it is a bad idea for medications intended for a specific illness (for example, antibiotics). First of all, even though your symptoms seem to you to be the same as when you first were given the drug, they may not be and the drug may not be appropriate. Second, many drugs lose potency with the passage of time, especially when their original con-

tainers are opened or when they are put into new containers, and the drug may no longer be effective. Old medicines should be destroyed.

Changing the container a medicine came in also is a dangerous practice. You may forget in a few days that you changed the container. You may think you're taking one kind of medicine, when you're taking something entirely different. And just as bad, you may take the proper medicine but take it incor-



rectly—since the directions for using it will remain on the original container.

Physicians and consumers are increasingly recognizing the important role the informed patient plays in the safe and effective use of drugs. It has often been demonstrated, for example, that many patients do not take medications according to the prescribed directions, thus decreasing the likelihood that they will benefit from them. The communication between patient and physician is the responsibility of both persons and in many cases it needs improvement. As a patient you can help by not being timid about asking your doctor such questions as:

What is this supposed to do for me?

How long should I take it before checking with you again?

Are there any side effects I should watch for?

Is it all right to take this medicine along with other medicines I am taking?

When should I take this drug in relation to meals?

Are there any foods I should avoid?

Most doctors will welcome your interest and will be glad to answer your questions. And then it's up to you to follow his directions. For example, don't stop taking the medicine the moment you feel better. Take it as long as the doctor says you should—but no longer. And report any adverse reactions immediately.

In the case of nonprescription medicine, your responsibility is even greater. This is self-medica-

tion, and before you buy or use any nonprescription drug, you should learn all you can about it. What is it supposed to do? How long should you take it? What side effects could it cause? When should it *not* be taken? For example, some products will make you drowsy, so you should not use them if you plan to operate machinery or drive a car. Others should not be taken at the same time you're using certain other drugs. You will find

How Smart Are You About Medicines In Your Home?

Here's a checklist on your handling of medicines in the home and your personal practices in the use of medicines. The more "yes" answers you can check, the safer you and your home will be.

- | | Yes | No |
|--|--------------------------|--------------------------|
| 1. Do you keep medicines in a cabinet which is not accessible to children? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Do you make sure the safety closure is securely refastened after you use a medicine? | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Do you return medicines to their proper place as soon as you have used them? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Do you always check the label to be sure you're taking the medicine you intend to take? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Do you keep all medicines in their original containers? | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Do you refuse to take medicine prescribed for someone else or to lend your prescription medicine to another person? | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Do you learn all you can about the medicines you take—both prescription and nonprescription? | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Do you carefully follow directions on the labels? | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Do you throw out old medicines? | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Are you careful about using alcohol when taking medicines that make you sleepy? | <input type="checkbox"/> | <input type="checkbox"/> |



this information, and more, if you take the time to read the label on the medicine and ask your pharmacist any questions you have that the label doesn't answer.

It is amazing how many people forget that alcohol is a drug and does not mix well with some medicines. The sedative effect, in particular, of drugs may be increased by use of alcohol. In this regard, sleeping pills and antihistamines are two kinds of drugs to be especially careful about. Whenever you're using medicine, it's a good idea to ask your physician or pharmacist whether it could be dangerous in combination with alcoholic drinks.

Margaret Morrison is a member of the FDA publications staff.

Finding Out What ELSE You Eat

Through its Total Diet Survey, FDA keeps tabs on the kinds and amounts of residues of pesticides, heavy metals, and industrial chemicals Americans consume in their food and drink. To make sure there's no chance of underestimating the average person's intake, the study is based on the awesome appetite of a teenage boy.

by Harold Hopkins



What is dear to you and every day less near to you, causes you puzzlement and despair and pride and joy and, three times daily and often oftener, shovels in any and all victuals like a starving hippopotamus?

Your teenage son?

For the last ten years FDA has pitted the run of groceries available from the shelves, trays, and freezers of the neighborhood supermarket against the awesome appetite of the typical 15- to 20-year-old American male in a continuing study that holds significance for us all. This program involving all the foods we eat, domestic and imported, in all parts of the country is FDA's Total Diet Study, sometimes called the Market Basket Survey.

It is a system of collecting food in the marketplace, preparing it for eating, compositing or mixing it, and

analyzing it to find the kinds and quantities of residues of agricultural pesticides, heavy metals and, more recently, industrial chemicals called polychlorinated biphenyls (PCB's) that are actually consumed by Americans in their food and drink.

All this does not mean that FDA is using somebody's hulking, hungry heir as a human guinea pig. FDA is simply examining the total of food that such a youngster might eat over any given two weeks to provide him energy and add bone and sinew for his body's suddenly accelerated sprint to adulthood. The amounts and kinds of food collected are derived from the U.S. Department of Agriculture's food consumption survey, which is reevaluated periodically and is carried out on a regional basis to account for tastes, food availabilities, and economic conditions prevalent in major geo-



The Total Diet Study begins (top left) with the collection of a sample or "market basket" of 117 food items in grocery stores at any of 30 cities throughout the country.

At the Kansas City Field Office (bottom left), Paul A. Stark, physical science technician, unloads an incoming Total Diet Study sample for removal to the laboratory.



graphical areas of the country.

The digestive capacity of a teenage boy was settled on by FDA for its study because the dent he makes in the grocery bill, as every parent of one knows, is considerably larger than that made by the average person. Thus, FDA is using the biggest eater in the family as the norm in the knowledge that whatever amount of residues he is ingesting, most other people are ingesting considerably less. It's a way of padding the already comfortable safety margin between the maximum amounts of residues considered safe and the smaller amounts actually being eaten.

The foods analyzed in the Total Diet Study are composited, which simply means that they are mixed together, much as they would be when they reach the teenager's or anybody's stomach, but in this

case electric mixers and blenders do the job. Instead of mixing all the foods that might be eaten during a typical meal, however, FDA divides them into 12 general classes of food and mixes each class separately. In this way the Agency can estimate the population's intake of residues for each of the dozen classes and, when it finds a residue problem in a composite batch, can then take individual components from the same sample and assay them separately to pinpoint the specific food or foods of concern.

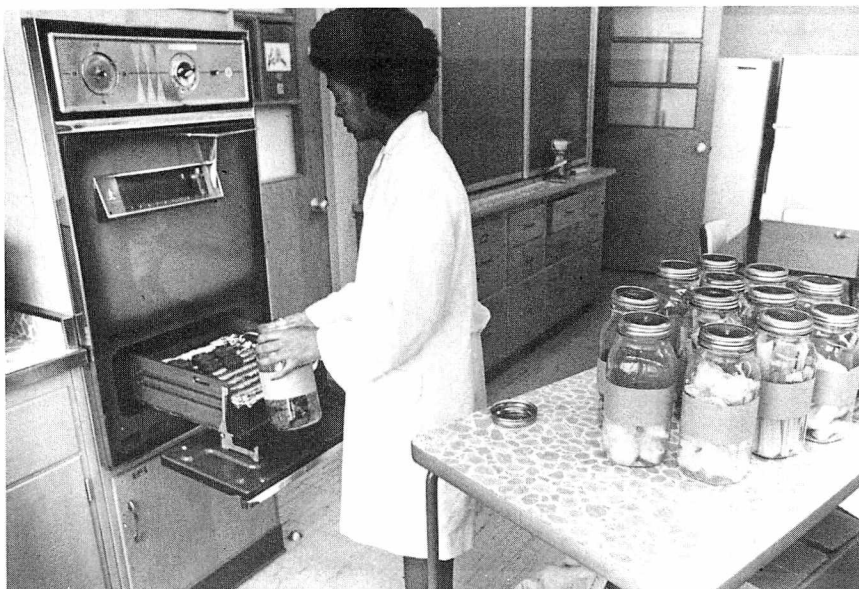
The Total Diet Study supplements FDA's routine and sometimes special surveillance of foods for regulatory purposes. These regulatory sampling programs cover food products or raw materials in interstate commerce as found in storage, in processing plants, in transit, as offered for import, and

In the laboratory preparation room, Stark (left) and Harold E. Watson, chemist, unpack shipping cartons and check to see if all items of the sample have arrived intact. Food items ready to eat are then composited or mixed into one of the dozen classes to which they belong, and cold stored. To each composite will be added the foods that have undergone further preparation.

as held for retail sale. Many of these products will undergo further processing at some later point, such as washing, trimming, mixing, and cooking, that may affect the amount of residues actually consumed. The results of analyses done as part of regulatory sampling programs or other special checks are measured against established tolerances or action guidelines for the specific con-



Foods not ready to eat are segregated by Watson (top left) to be sent to the Home Economics Department kitchens at St. Mary College, Lansing, Kansas, for preparation by dietitians before incorporation in sample composites.

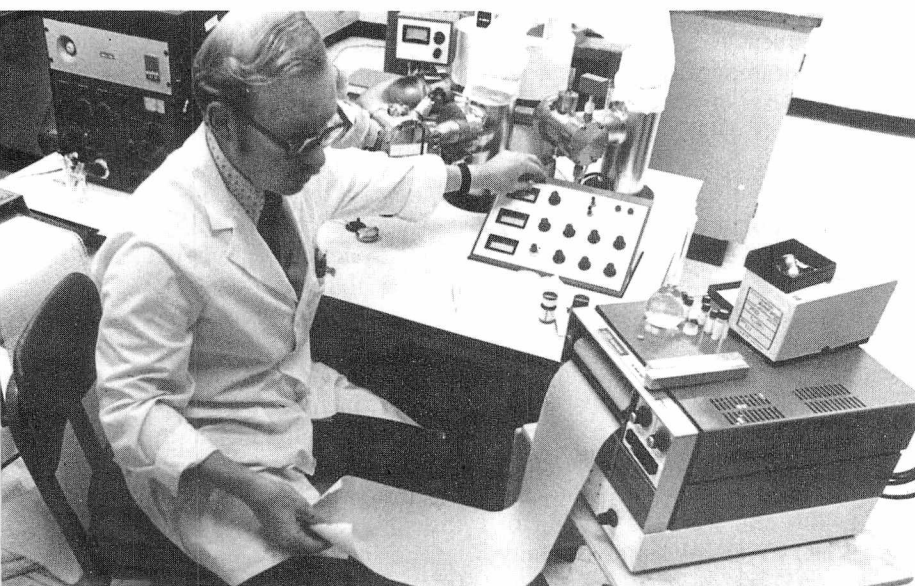


In St. Mary kitchens Esther Yemesgen broils hamburger (top right, this page) and assembles prepared foods in containers (bottom right, this page) for return to Kansas City District laboratories.

After ready-to-eat foods and those prepared at St. Mary are composited in each of the food classes in a sample, the composites are stored in a freezer (top, opposite page) until needed for various assays.

Mass spectrometer being operated (bottom, opposite page) by David L. Heikes, chemist, is used to identify pesticides and industrial chemicals in a food composite sample.





taminants involved, and if the residues exceed these tolerances or guidelines regulatory action is taken. These analyses are normally conducted in the appropriate laboratory in one of 18 FDA districts across the country.

The Total Diet Study, on the other hand, covers finished products that are ready to eat, either as marketed or as prepared by the Agency for typical meals, and thus reflects estimated actual intake of residues by the consumer. Analytical results are not measured against the tolerances and action guidelines used by FDA in enforcement, but against the daily intake levels of contaminants considered acceptable and not harmful to human health by the Food and Agriculture Organization (FAO) of the United Nations and by the World Health Organization (WHO) Expert Committee.

Total Diet Study analyses, as well as the necessary preparation of the foods, are carried out only at FDA's Kansas City Field Office, which has been specially equipped and staffed to use extremely sensitive analytical methods to find and measure residues of the pesticides and other contaminants involved at the lowest levels at which they can be practically detected in a regulatory laboratory. The residue levels found are in many cases lower than those measured in FDA's routine regulatory sampling programs.

The findings enable FDA to maintain a continuing year-by-year check on the residues being consumed, to compare them with the WHO-FAO Acceptable Daily Intakes, where available, and to compare them with those of the populations of some other countries which have similar programs. FDA also uses the findings to track trends in occurrences of pesticides, polychlorinated biphenyls, and heavy metals in certain classes of foods or in certain geographical areas over extended periods. Whenever Total Diet Study analyses do show residues higher than expected, the results, of course, are used to zero in on the source of the problem and

to take appropriate corrective action.

Analysis of the data for the annual Total Diet Study for fiscal 1973 recently was completed. This study was based on collection of "market baskets" that included 117 individual food items from each of 30 representative areas of the country. The market basket or sample, collected in each area during fiscal 1973 by one of FDA's 18 districts, consisted of these food classes:

Dairy products; meat, fish, and poultry; grain and cereal products; potatoes; leafy vegetables; legume vegetables; root vegetables; garden fruits such as tomatoes and cucumbers; fruits such as apples, grapes, and bananas; oils, fats, and shortening; sugar and adjuncts (such as syrups, jams, and jellies, candies, cake icings, and also including salt, pepper, and baking powder); and beverages, including drinking water.

The term "market basket" is an unofficial one used by FDA. It refers to the way the sample is collected on a retail shopping trip by FDA personnel in the particular area, much as the housewife in that area buys several days' supply of food for the family.

The FDA purchases differ somewhat in that they may be bought at several stores in the area. The 117 items purchased constitute the food for a complete diet of a teenage male for two weeks, but the average housewife might have trouble pushing the FDA cart. The FDA sample is actually about twice the amount a teenager might eat and at today's prices costs around \$200 at the checkout counter. The additional quantity provides spare food for possible further investigation and analysis if high amounts of residues are found.

Some of the excess is also used in other FDA programs to determine the levels of certain mineral nutrients consumers are getting in their diets and to detect and measure radionuclides in foods being eaten. The radionuclides check, carried out by FDA's Winchester Engineering and Analytical Center

in Massachusetts, is a way of monitoring foods for possible contamination from nuclear reactor sites or from nuclear testing, and from worldwide radioactive fallout. Such contamination might be present in either domestic or imported foods. Radionuclide levels currently being identified are of no toxicological significance.

When the food products for samples are collected they are immediately packed, preserved with dry ice where appropriate to prevent spoilage, and sent by air cargo to the Kansas City Field Office laboratories. The samples arrive at Kansas City all the year around and if a food in a sample is ready to eat it is also ready to assay. If not, it goes to the Home Economics Department of St. Mary College, Lansing, Kansas, where under a contract with FDA it is prepared as it would normally be eaten, and then sent to the FDA laboratory. Here all the foods are then measured directly into the composite for the appropriate food class.

In the laboratories the composites are analyzed for polychlorinated biphenyls, for organochlorine and organophosphorus pesticide residues, chlorophenoxy acids (herbicides), carbaryl, orthophenylphenol (both pesticides), and six metals—mercury, cadmium, arsenic, lead, selenium, and zinc.

The fiscal 1973 study found that DDT frequency and levels have declined "dramatically" from earlier years because of the ban on use of DDT, but DDE, a breakdown product (metabolite) of DDT, remains prevalent, especially in foods of animal origin. Daily intake of the total DDT family of pesticide chemicals has declined significantly. This trend was also observed in FDA's food surveillance program in fiscal 1973 (see DDT Residues in Food Decline, FDA CONSUMER, May 1975).

Residues of the insecticide diel-drin declined somewhat from the late 1960's and were 40 percent of the WHO-FAO Acceptable Daily Intake (ADI).

Daily intakes of the organophosphorus insecticides malathion and diazinon have increased about 50 percent over the 1965-70 average but still remain far below the ADI limits. Other compounds in the organochlorine and organophosphorus classes apparently underwent minor changes that were not considered unusual.

Polychlorinated biphenyls occurred only at "very low levels," primarily in the meat-fish-poultry composites (probably attributable to environmental contamination) and grain-cereal composites (attributable to contamination by recycled paper used in food packaging).

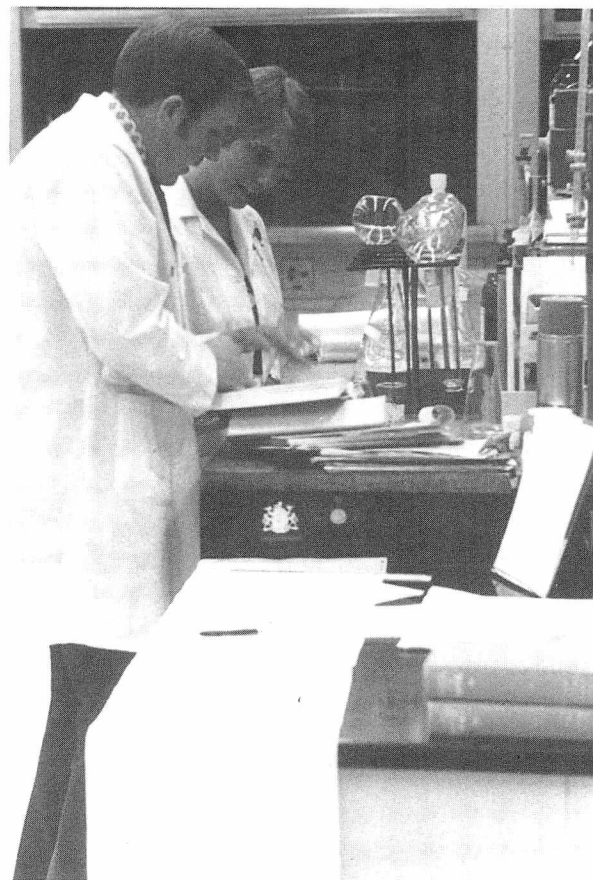
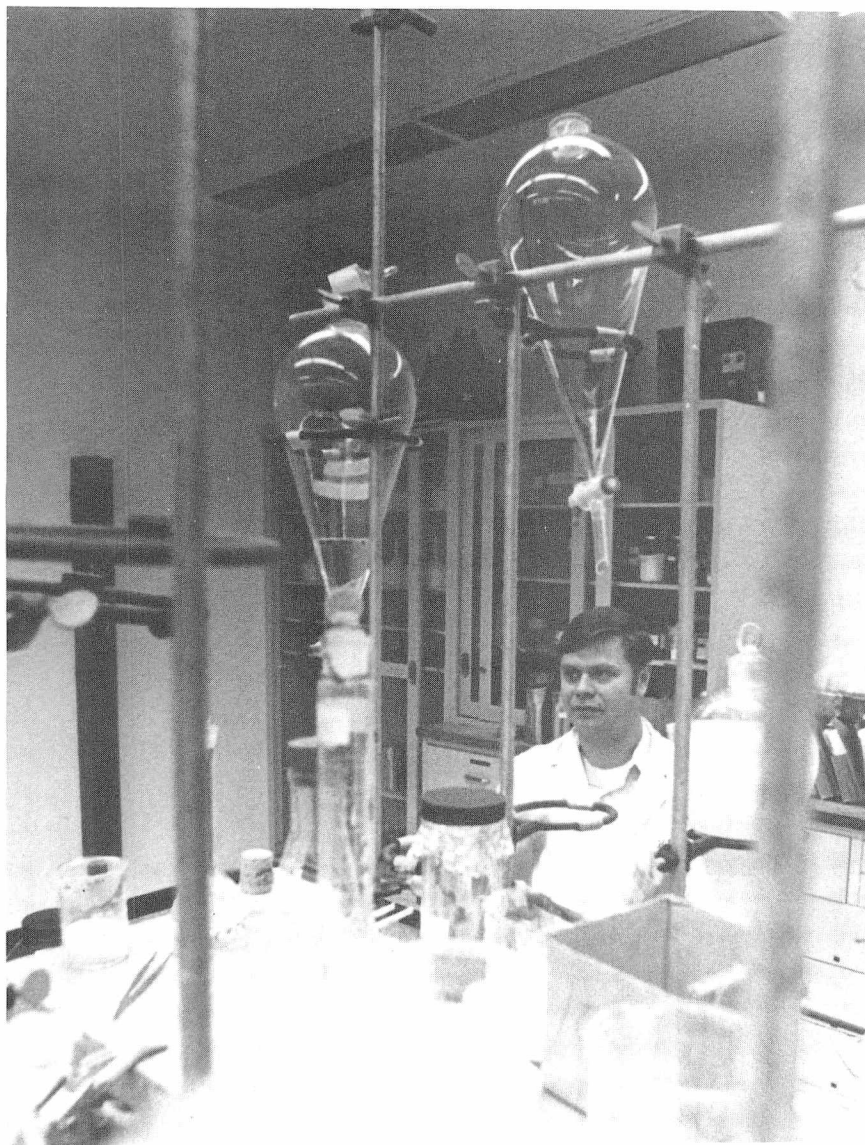
Incidence and daily intake of chlorophenoxy acids and orthophenylphenol were insignificant. Carbaryl occurred at moderate frequency but was far below the ADI. Pentachlorophenol (PCP) began to appear frequently in the sugars and adjuncts composite and has now been traced to an adhesive that was used in candy bar wrappers.

Mercury occurrence was found in the meat-fish-poultry composites and was traced to fish in the follow-up checks. The average intake of mercury was seven percent of the ADI, down a third from fiscal 1972.

Lead intake was calculated to be 14 percent of the ADI but it is possible actual intake was considerably higher because of limitations in the sensitivity of the method used to measure lead. Fruits and vegetables, both fresh and processed, were the major contributors to lead intake.

The intake of cadmium was about 80 percent of the ADI. Although it would not take much more cadmium from sources other than food for the tolerance level to be surpassed, FDA believes that food is the primary source of the population's intake of this metal. Other sources include cigarette smoking and occupational exposure. Cadmium probably enters the food supply primarily through uptake from the soil.

The amount of cadmium absorbed from food may be altered by the

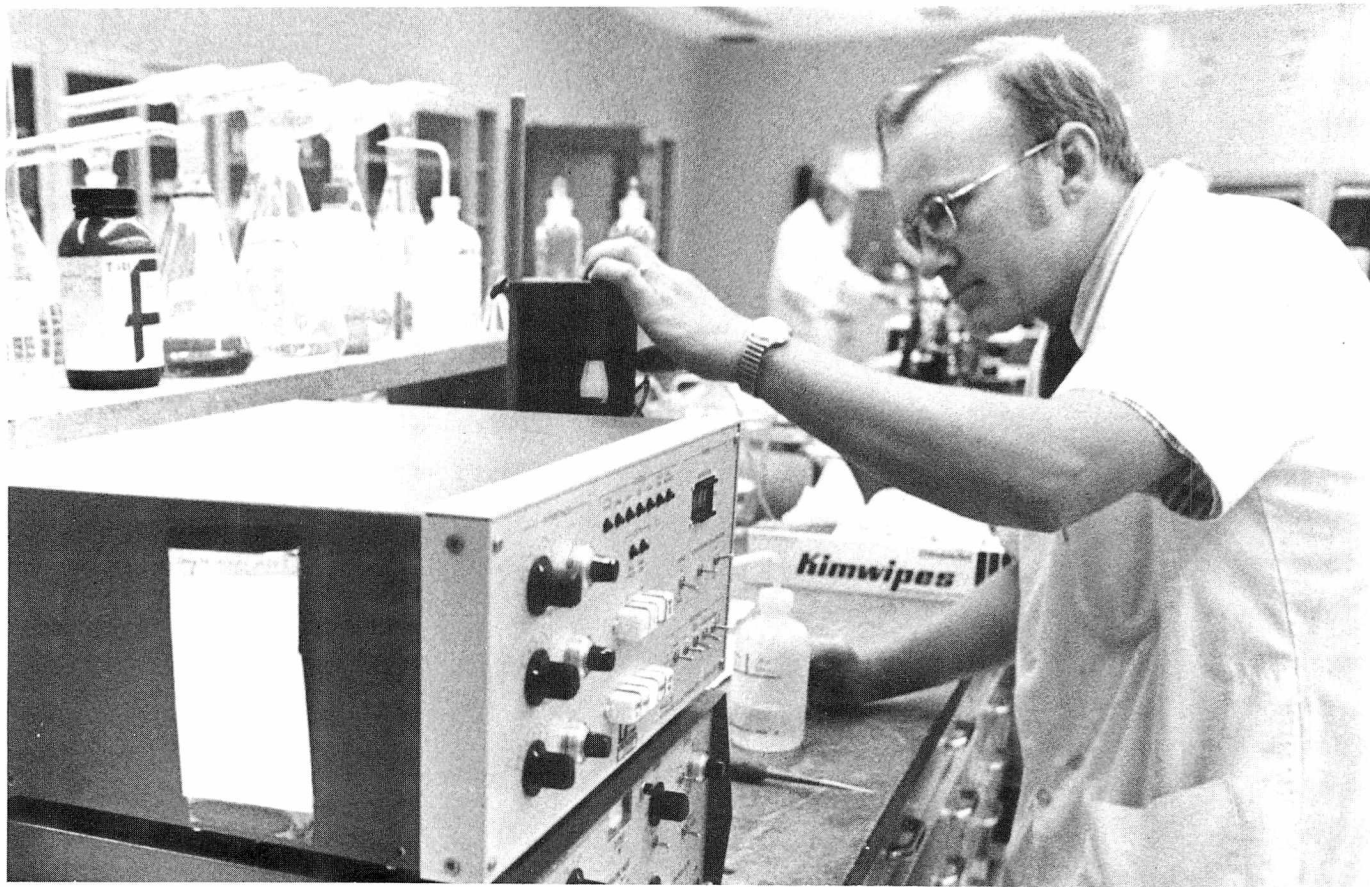


Duane Hughes, chemist, uses a separatory funnel (top left) in the first step to extract any pesticide residues from a food sample.

Hughes runs a Florisil column (bottom left) to further purify the extract, which may contain pesticide residues. The extract will then be subjected to analysis by gas-liquid chromatography to detect any pesticide present.

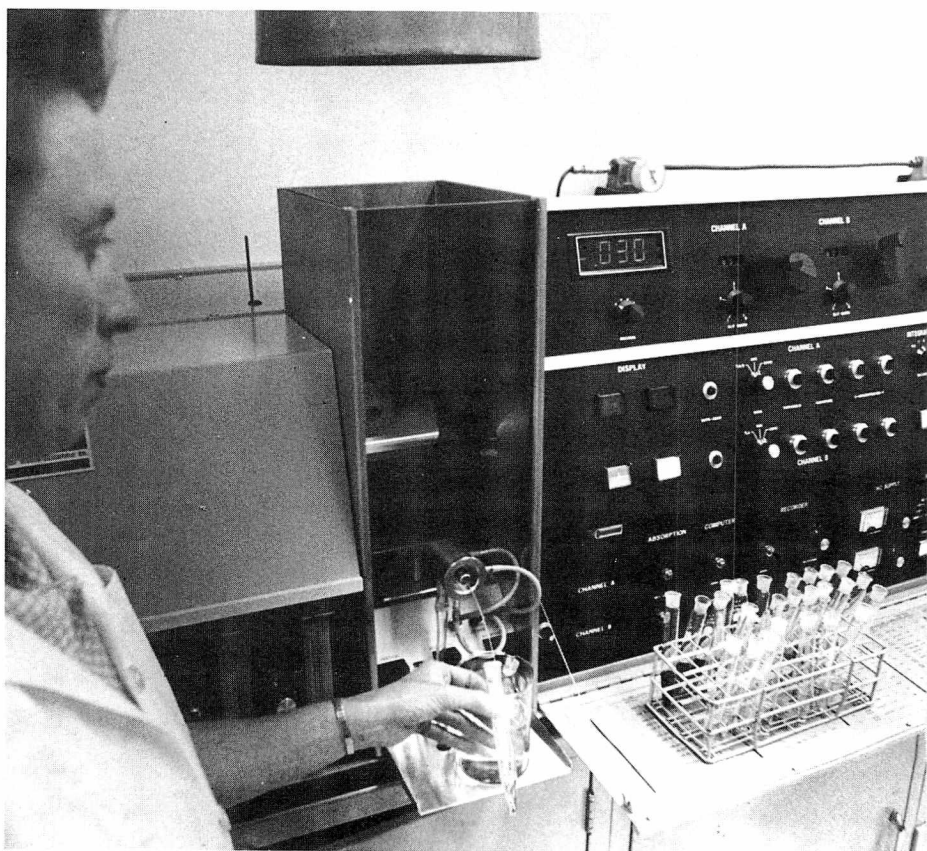


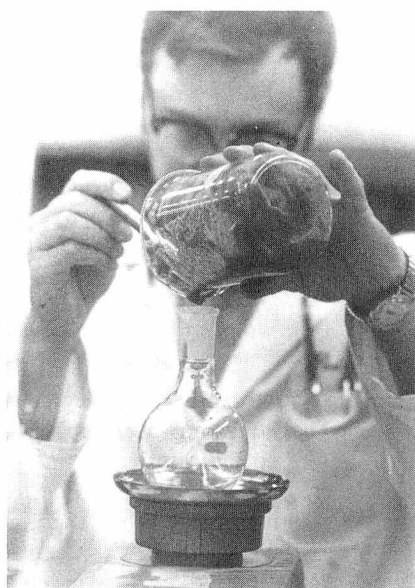
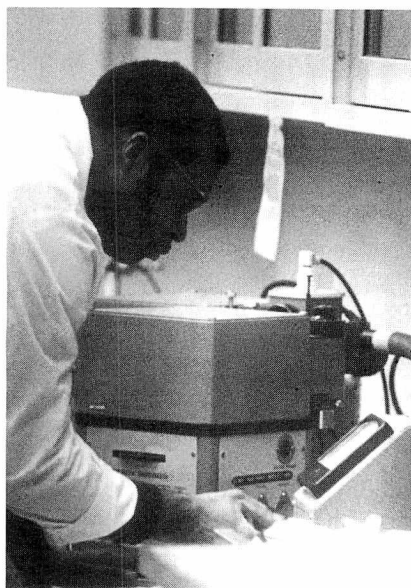
Discussing the results (top right) of a gas-liquid chromatogram (the sheet in the foreground) in an analysis for pesticides are David S. Podrebarac, chemist, and Pamela J. Fink, physical science technician.



Polarographic analysis for the detection and measurement of metal residues in a food composite sample (top) is conducted by Ronald W. Marts, chemist.

Atomic absorption analysis (bottom) to identify and measure lead in a food composite is performed by Barbara E. Young, chemist.





Spectrophotofluorometric analysis (left) for measuring selenium in a food sample is carried out by Charles E. Shumate, chemist.

A portion of a composite sample is weighed (right) for analysis for mercury by DuWayne Ready, chemist.

level of zinc present in the food. It has been postulated that the presence of zinc in food reduces the amount of cadmium absorbed by the body. Both often occur in the same natural soil deposits and thus may occur in the same food. The amount of zinc and cadmium in a food may be indicative of substantial to heavy concentrations of these metals in the soil where the food was grown. Changes in the typical ratios of these metals sometimes result from such practices as use on cropland of sewage sludge or certain chemical fertilizers containing cadmium.

For these reasons, zinc, an essential nutrient, is looked for in the Total Diet Study. Zinc intake from the diet in fiscal 1973 was found slightly over the U.S. Recommended Daily Allowance (U.S. RDA).

Arsenic intake, most frequent in the meat-fish-poultry composites, has declined substantially from the 1965-70 average. There is no WHO-FAO ADI established for arsenic. Fruit and vegetable composites have declined as a source of arsenic intake since the earlier Total Diet Studies, probably because of changes in use of pesticides containing arsenic.

Essentially all selenium in the diet comes from the meat-fish-poultry and grain-cereal composites, where it occurred at an average of

about 0.2 parts per million. WHO-FAO has not established an ADI for selenium.

The study pointed out that the foods included in the Total Diet Study do not reflect the more recent increases in consumption of prepared or convenience foods. The study said the need continues to improve analytical detection methods, particularly as concerns heavy metals. Some contaminants that may be present in food are not now detectable below certain levels. FDA is continually striving to lower the minimum detectable level of all contaminants so measurements of average intake by consumers can be as accurate as possible.

The Total Diet Study has undergone periodical change and refinement since its beginning. Some chemicals have been dropped from the study because they no longer are of health significance; others have been added because they have become recognized as a potential threat to health, or because analytical methods have been developed that can measure them at sufficiently low levels. Discovery of the hazard potential of polychlorinated biphenyls in the environment, of mercury in large fish, and of the contribution of other heavy metals to food contamination have caused these to be included in the study.

Samples are now collected from

more locations in the country than formerly so as to be more representative of the diet of the total population. Laboratory work has been moved from several FDA districts and centralized in the Kansas City District.

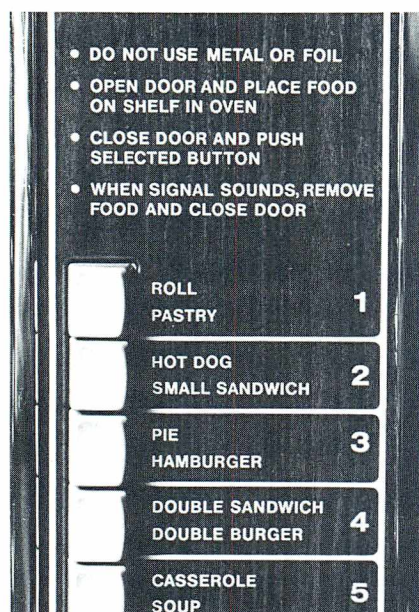
The food products in the samples will be changed when the Department of Agriculture publishes its revision reflecting changes in consumption habits since 1965. More study is in the works on heavy metals to pinpoint which foods cause the greatest problems and regulatory guidelines may ensue to reduce their hazard in the diet.

In fiscal year 1975 the number of adult market baskets was reduced from 30 to 20. The difference of 10 samples continues to be examined, but the foods collected are those constituting the diets of infants (6 months) and toddlers (2 years). FDA hopes to determine the amounts of residues this high risk group is eating by the institution of this new Total Diet Study. The infant-toddlers study for fiscal 1975 also included a check for certain mineral nutrients and for nitrates and nitrites, food preservatives which, if used in excess, may have the potential to cause harmful effects.

Harold Hopkins is editorial director of FDA CONSUMER.

Microwave Oven Labeling

by Valorie A. Britain



The new precautionary label will supplement instructions already carried on some microwave ovens, such as this operating information on an oven of the type often used in vending areas.

The decision to require prominent display of instructions for proper use is aimed at assuring that the good safety record compiled by these "space-age" cooking devices remains unimpaired.

Microwave ovens—are they safe? That question was posed—and answered affirmatively—in an article in the May 1972 issue of the FDA magazine. Why, then, it might be asked, did FDA recently issue regulations requiring precautionary labeling on microwave ovens?

The 1972 article pointed out that over the previous two years, FDA had prompted microwave oven manufacturers to make numerous safety design changes, and that ovens meeting Federal standards were considered safe for home use. But even products that meet FDA standards can be hazardous if they aren't used or serviced properly. FDA's new regulations are aimed at reducing the possibility of injuries by requiring that microwave cooking ovens carry strategically placed labels reminding users and service personnel of certain safety precautions.

Permanently attached labels will be required on microwave ovens manufactured after October 3, 1975. The label addressed to the oven user will read: "Precautions for safe use to avoid possible exposure to excessive microwave energy. Do not attempt to operate this oven with: (a) object caught in door, (b) door that does not close properly, (c) damaged door, hinge, latch, or sealing surface." The label must be clearly visible during oven use.

The other label will advise that the oven should be serviced only by qualified personnel and that the service manual should be consulted for proper repair procedures.

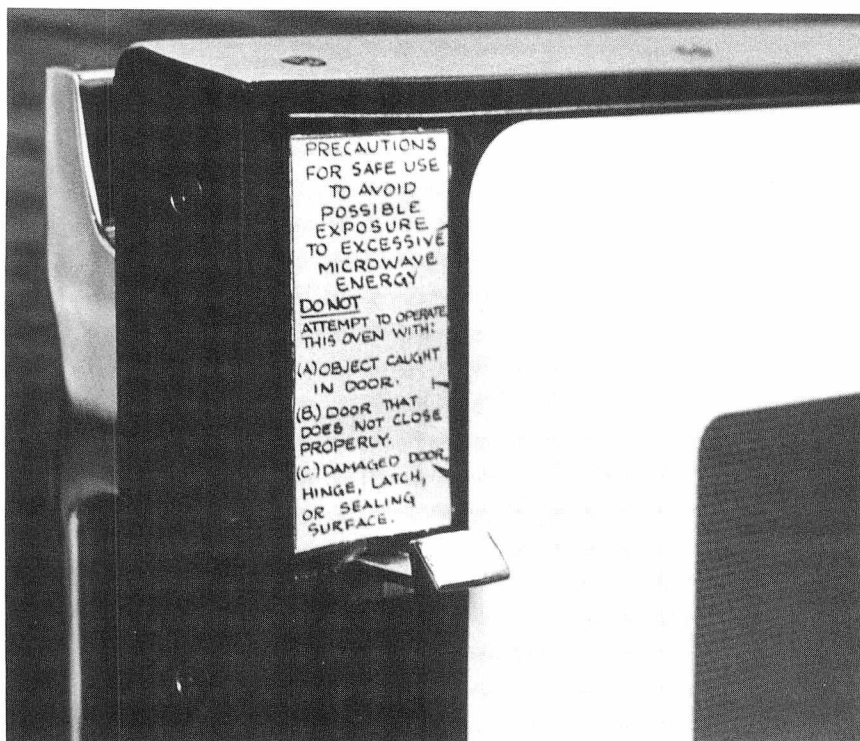
The consumer's need to know guided FDA's decision to require prominent display of commonsense

instructions for using what has been called the "space-age oven." Although such instructions and warnings have been included in the owner's manual for some time, these manuals often are put away, forgotten, lost, or, in the case of ovens in vending areas and apartments, not accessible to users. The new labels will make this information readily available to everyone who uses the oven.

In issuing the labeling requirements, which are an amendment to the Federal radiation safety performance standard for microwave ovens, FDA emphasized that the ovens have an excellent safety record. There have been no documented cases of injuries associated with ovens that conform to Federal specifications. But, as Commissioner of Food and Drugs Alexander M. Schmidt explained, "It is prudent to take suitable precautions against possible misuse or damaged equipment."

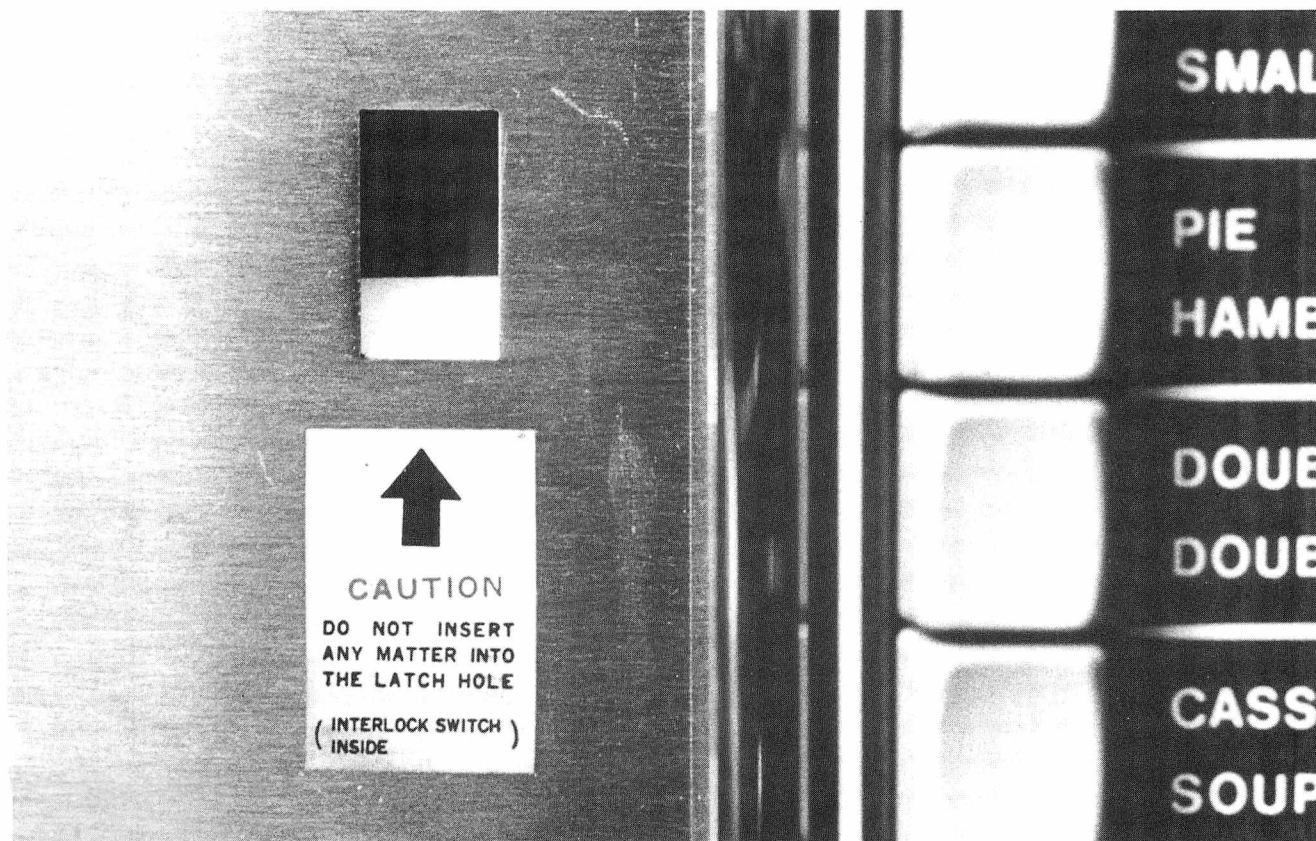
Precautions are especially important in using the microwave oven because of uncertainties about possible radiation effects. Under some circumstances, microwave radiation may cause heating deep in the body without an individual feeling any heat at the skin—where the body's temperature sensors are. Usually, these sensors serve as a clear warning to the user of gas or electric ovens to get away from the source of potential injury. This may not always be the case with the microwave oven.

Consumers Union petitioned FDA about two years ago to amend the Federal microwave oven standard to require warning labels and instructions and stricter tests for determining manufacturer compliance with the safety performance standard. The Agency rejected the request for additional tests, but agreed to consider the need for some precautionary labeling.



A mock-up of the label (left) that will have to be prominently displayed on microwave ovens manufactured after October 3, 1975. The label will have to appear on all ovens manufactured after this date except in cases where the manufacturer can demonstrate to FDA's satisfaction that construction features make it unnecessary.

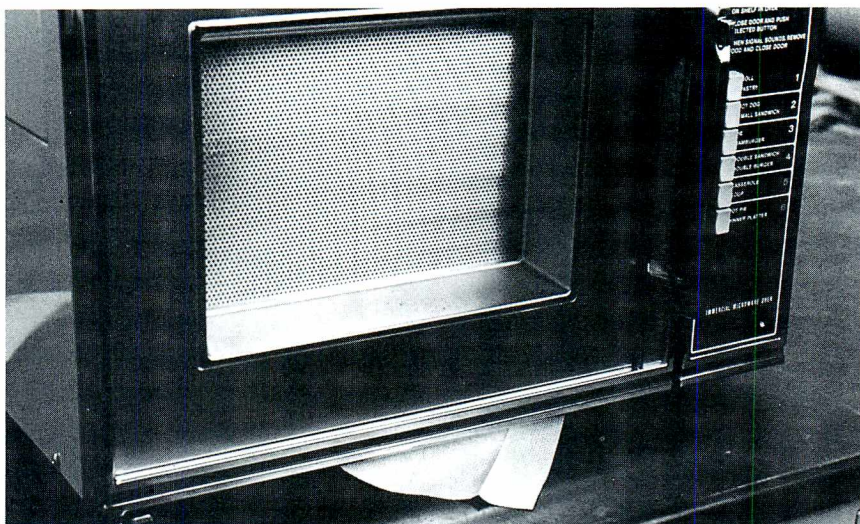
Users should never do anything that might interfere with the proper operation of the safety switches (below) that are required on all microwave ovens.



A basic rule: never operate a microwave oven when there is anything sticking through the door crack, as shown in this example (top).

Instruments (center) used by FDA technicians to check microwave ovens include a microwave survey meter and a radiation survey meter. Regulations require that a beaker of water be placed in each oven tested to assure that all units examined are checked under the same load conditions.

A microwave oven is checked for radiation leakage in an FDA laboratory.



Microwave ovens appear to be here to stay. It is estimated that well over a million are now in use and over 750,000 were sold in 1974—an increase of 70 percent over the previous year. Retail sales are expected to reach a million annually by the end of this year.

Microwave ovens use a tube called a magnetron to produce the microwaves—a form of electromagnetic energy—that cook the food. Microwaves cook by causing water molecules in the food to move, thereby producing a rise in temperature. In foods, the increase in temperature is rapid and makes it possible to cook quickly.

Metallic materials, such as oven walls and screens, largely reflect rather than absorb microwave energy. Glass and many nonmetallic wrapping materials allow microwaves to pass through them. As a result, the interior of the oven does not get hot during cooking, nor do cooking utensils.

FDA issued mandatory performance standards in 1970 for all home and commercial microwave ovens sold in this country. The standard, which became effective in October 1971, established a maximum limit for the amount of radiation that can escape or leak from the oven. This limit is 1 milliwatt per square centimeter at the time of purchase and no more than 5 milliwatts during the useful life of the oven. (A milliwatt is 1/1000 of a watt—a unit of electric power.) Although the standard allows for a minuscule amount of radiation to escape, the resulting human exposure is well below the lowest level known to cause biological effects.

The standard also requires every oven to have two door-safety interlocks that operate independently of each other and which turn off the oven automatically when the door is opened. The second interlock is a backup in case the first malfunction.

Questions Often Asked About Microwave Oven Safety

Is there any danger in eating food cooked by microwaves?

Food is cooked by heat in both microwave and conventional methods. The only differences are the sources of the heat and how it penetrates the food. Microwaves do not make food radioactive.

Can microwaves cause cataracts?

Laboratory studies have shown that prolonged exposure to *high levels* of microwave energy can produce eye damage, including cataracts, in test animals. These levels are many times greater than those associated with the use of microwave ovens, where the microwave radiation is contained within the oven cavity. There have been no documented cases of eye cataracts traced to microwave ovens in compliance with Federal specifications.

Can microwave ovens cause heart pacemakers to malfunction?

At one time, there was concern that proximity to an operating microwave oven caused interference with certain pacemakers. However, this problem has largely been resolved as a result of pacemaker redesign to shield against electromagnetic interference and Federal regulations limiting microwave emissions from these ovens.

tions. Recently, the standard was amended to require that the ovens include a system capable of electrically detecting a failure of either one or both interlocks and automatically rendering the oven inoperable until it is repaired.

FDA conducts sample testing of microwave ovens in homes, commercial establishments, dealer and distributor premises, factories, and in its own laboratories to assure that they comply with Federal requirements. It also evaluates manufacturers' radiation testing and quality control programs. When a problem is identified, FDA requires the manufacturer to correct all non-complying ovens at no cost to the consumer. Based on these checks, FDA believes that the microwave oven standard provides ample assurance against adverse effects on health and that ovens in compliance with the standard are safe. As with other electronic appliances, however, the microwave oven owner must take steps to assure proper operation of the equipment.

Here are some general hints for proper use and care of microwave ovens:

- Follow the owner's manual.
- Examine the oven for evidence of shipping damage.
- Never operate an oven if the door does not close firmly or is bent, warped, or otherwise damaged.
- Never insert objects through the door grill or around the door seal.
- Never tamper with the oven safety switches.
- Frequently clean oven cavity, door, and seals with water and mild detergent. Do not use abrasives.
- Have the oven serviced regularly.
- When using ovens manufactured before October 1971, stay at least an arm's length away from the door while the oven is operating.

Valorie Britain is a technical information specialist in FDA's Bureau of Radiological Health.

A Matter Of Taste

FDA's test kitchen is an all-electric marvel that rarely satisfies anyone's hunger. But volunteer tasters help the Agency determine consumer reaction to new foods, new ingredients, and new combinations of ingredients. The kitchen's agenda also includes cost and nutrition comparisons.

by Enoc P. Waters

The Food and Drug Administration has a kitchen with facilities, equipment, and a trained staff capable of turning out meals that would satisfy the appetite of the most fastidious gourmet or the greediest gourmand.

But, alas, it does neither.

For all its potential as a source of excellent meals and despite the culinary talents of its university-trained supervisor, a nutritionist, it is a test kitchen. If you enter it hungry, you are likely to emerge the same way.

Located in Washington, D.C., in an eight-story building covering an entire city block, two-thirds of which is devoted to laboratories, the test kitchen is itself a laboratory where foods are prepared for testing and tasting. This kitchen-laboratory is a basic resource for determining characteristics of new foods, food analogues, and novel foods. The work of the kitchen also contributes information for the drafting of food standards FDA establishes as part of its regulatory activities.

Many of the tests conducted in the kitchen involve taste, smell, or sight—more formally known as organoleptic tests. FDA employees often are pleased when invited to participate in these tests, but if

they accept in expectation of a delicious free meal they are disappointed. What they get is a few ounces of a liquid, or a bit of hamburger, not even enough to satisfy the hunger of a devout weight watcher on a stringent diet. It is enough, however, to help FDA determine consumer reaction to new foods, new ingredients, or new combinations of ingredients.

Organoleptic tests (meaning tests that involve the sense organs) are not unusual in the food industry. Tea is graded by expert tasters, who do their sipping under FDA supervision. Other FDA experts use their noses to determine the freshness of seafood, eggs, and other food products. A sensitive nose can make determinations regarding the freshness of some food products that can't always be made by other means.

In the FDA test kitchen, however, the tasters usually are not experts. The idea is to find out what the average consumer thinks of the foods being tested. One recent project involved a series of tests to determine whether pasteurized oysters would be acceptable to consumers. Pasteurization, if feasible, is to be desired because it could kill viruses that cause hepatitis. A number of cases of hepatitis have

been traced to oysters taken from waters that had not met the requirements of FDA's National Shellfish Sanitation Program.

The oyster tasters were divided into a control group and an experimental group, but the tasters did not know which group they were in or what kind of oysters they were getting. All the oysters were served cold and at a uniform temperature. The control group was given only freshly shucked, untreated oysters. The experimental group tasted oysters that had been pasteurized at various temperatures as well as freshly shucked oysters. It was found that pasteurized oysters generally were acceptable if they had not been heated beyond a certain temperature. Those pasteurized at higher temperatures were unacceptable.

Test results are still being analyzed and additional study is necessary before any conclusions can be drawn on whether oysters can be effectively pasteurized and remain acceptable to consumers.

Among the many new food products studied by the test kitchen are plant protein products, which are being used increasingly as meat extenders. For many consumers meat is the major source of protein, and meat consumes a large portion of



The test kitchen is equipped with a bevy of modern appliances as well as a pantry, an appendage often associated with a bygone era.

A number of test kitchen studies have focused on plant protein products (in beakers below) that are being formulated into meat analogues such as "ham" and "chicken" cubes or are being used as meat extenders.



the food dollar. Plant protein products can be added to ground beef for larger quantity, thus stretching the food dollar while maintaining high nutritional quality.

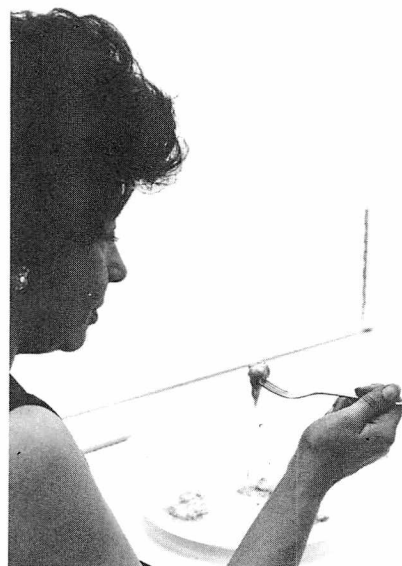
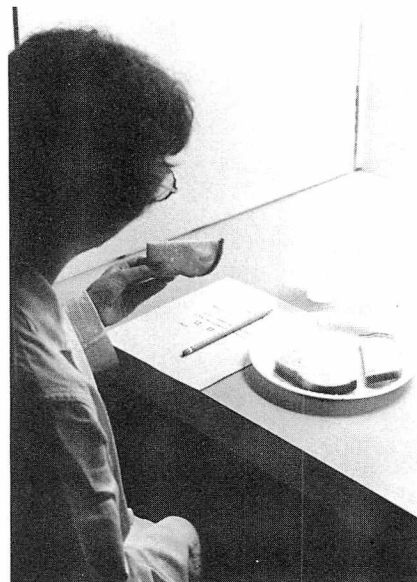
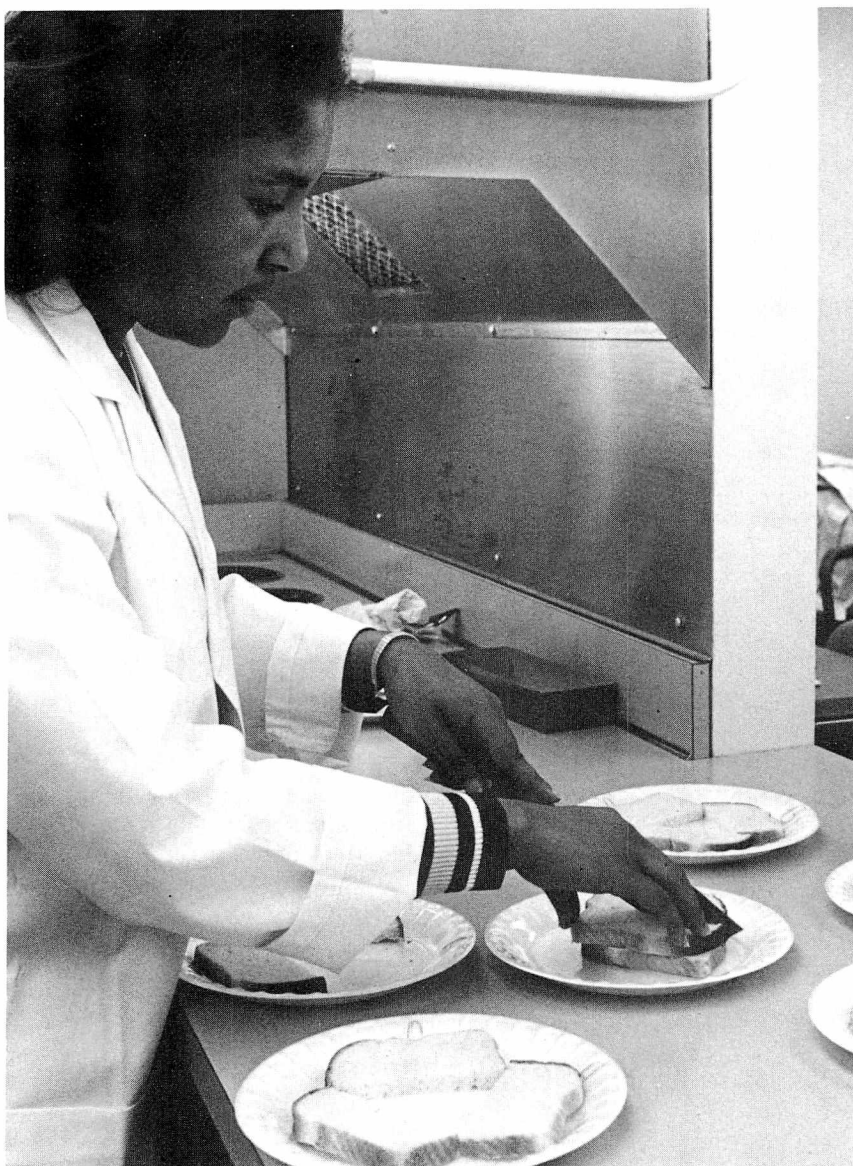
Taste panels were used to determine the proportion of plant protein products to meat that enjoyed greatest consumer acceptance. The tests showed that patties composed of 70 percent ground beef and 30 percent soybean granules were more acceptable than those that were only 50 percent beef.

The test also showed that all-beef patties shrink and brown more in cooking than do patties made of beef and soy.

Other typical projects of the kitchen have included a test to determine the weight loss in the cooking of various types of meat loaf, a taste test of macaroni products, and consumer acceptance tests of canned pears and stuffed green peppers. Such projects may have involved cost and nutrition comparisons as well as taste evaluations.

The kitchen where these tests are conducted is an all electric marvel with almost every aid and device that appliance manufacturers have developed. It has a range with eight burners of varying sizes, two household ovens, a microwave oven, a double sink in gleaming stainless steel, a dishwasher, a garbage disposal, a 15-foot refrigerator, and a 15-foot freezer.

There is 30 feet of counter space with cabinets above and below and upholstered stools with adjustable backs. At hand are all types of cooking and eating utensils includ-



ing electric chafing dishes, pressure cookers, scales, dishes, glassware, and silverware.

It has a well-stocked, well-lighted pantry, big enough to turn around in without knocking something over or bumping into something.

The air is continuously changed, purified by an electric vacuum system that withdraws odors and pumps in fresh regulated air. And what is a kitchen without a phone? It has one of those, too.

Along one wall is a 24-foot table equipped with fluorescent lights and dividers that can be opened to provide six private booths. When occupied, each of the six persons they accommodate is isolated from

his neighbor. This is where taste tests are conducted.

The lights at the taste panel table can be adjusted to a variety of colors. The importance of this feature was demonstrated recently when tests were being conducted on egg bread. To prevent tasters from being influenced by differences in the color of the egg bread, which has a yellow cast, and the other types of bread used in the tests, the lights were adjusted to make all the bread appear uniform in color. Color lighting is used in tests of foods if there is a possibility of identification being made on the basis of the color of the food rather than the taste.

The test kitchen is part of FDA's Division of Consumer Studies. Much of the division's work is aimed at determining consumer attitudes and knowledge about food. And when it comes to food, probably nothing is more unpredictable or more difficult to reduce to a science than taste preferences.

Nevertheless, taste and color are extremely important in the development and marketing of foods because they are the keys to consumer acceptance. Regardless of nutritional value or other factors, many people shun certain foods because they don't like their appearance or taste.

The unpredictability of taste pref-

Opposite Page:

Samples for a taste panel on egg bread are prepared by test kitchen supervisor Dorothy Stringfellow.

Bread and water is Spartan fare, but it's all in the interest of science.

Would pasteurized oysters be acceptable to consumers? The reactions of a volunteer taster will help FDA find out.

Right:

Lights at the taste panel table can be adjusted to make all products look the same color in instances where color differences might influence the taster's judgment, such as in this test (above) on egg bread.

Alice Fusillo (standing, left background), acting director of FDA's Division of Consumer Studies, discusses some of the division's projects involving new food products with a group of college students. Student groups often visit the test kitchen as part of a briefing on the work of the Consumer Studies Division. Test kitchen supervisor Dorothy Stringfellow is at right.



erences has been demonstrated many times. Some years ago, for instance, food scientists experimenting with fish flour worked long and hard in their laboratories to eliminate its fishy taste. They believed that if it could be made tasteless, the flour could be used to nutritionally enrich the foods of people with varying taste preferences living in Africa, Asia, and Latin America.

After finally achieving this objective, the scientists conducted extensive taste tests on all three continents. They tested three versions of fish flour—one with a strong fishy taste, another with a slight fishy taste, and the tasteless one they had labored so hard to de-

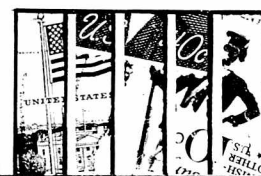
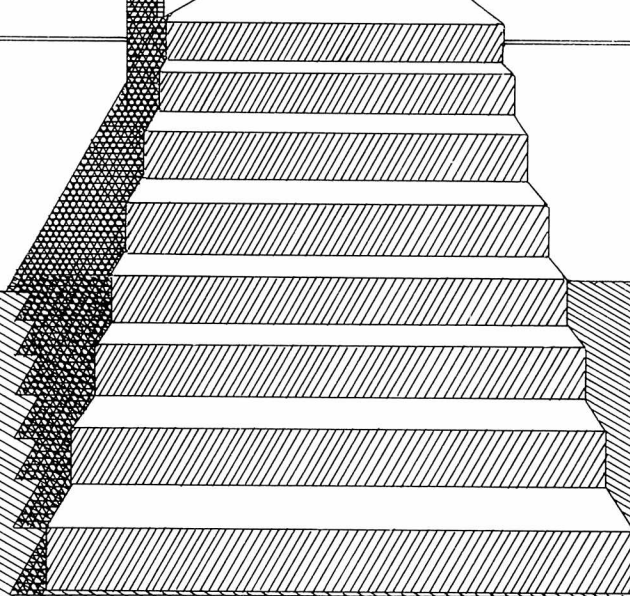
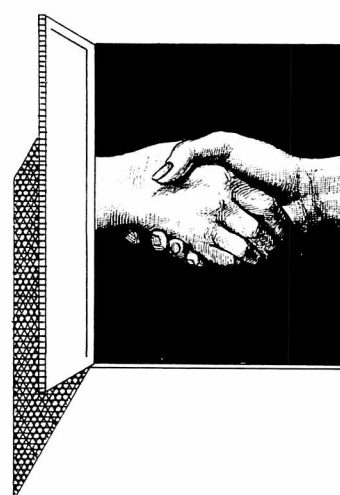
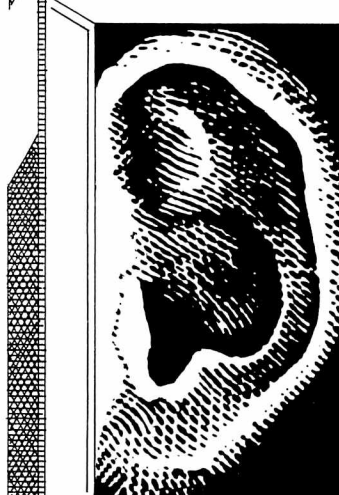
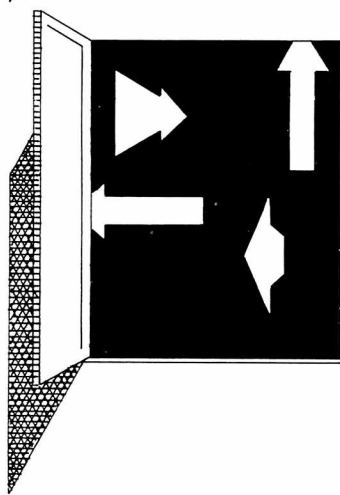
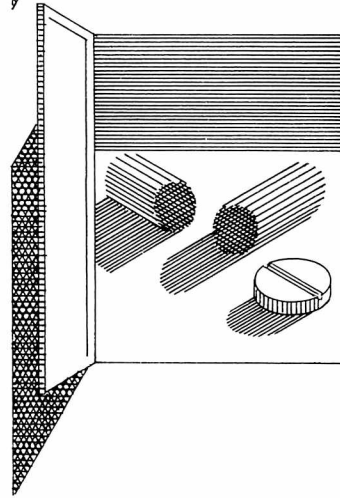
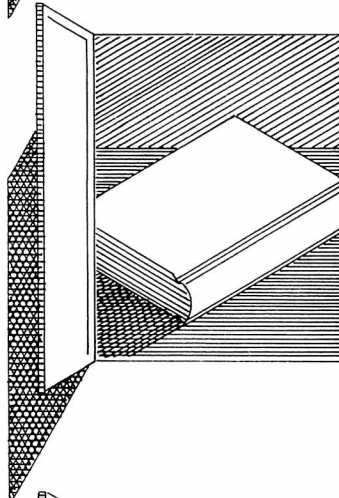
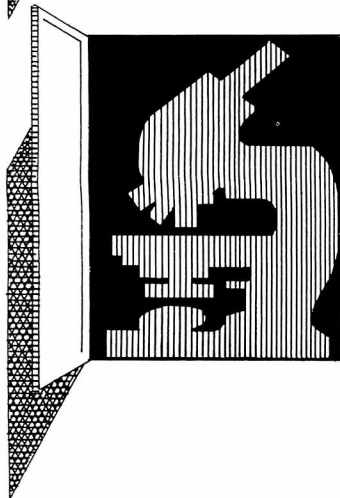
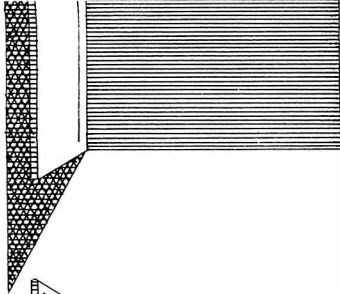
velop. To their surprise, the flour with the slight fishy taste was preferred.

Taste can have dramatic psychological impact. In an experiment reported in the press several years ago, people with colds were given two types of pills—some pleasant tasting, others bitter. Neither contained any drugs. Though the colds of both groups were unaffected, those who had taken the bitter pills reported they felt better.

Taste tests that measure the psychological impact of bitter pills or the acceptability of fishy flour or beef patties laced with soy may be done on a relatively grand scale, but the basic technique is familiar to

just about everyone who has ever stirred a pot. The average cook, whether preparing food for a family or for the public in a restaurant, hotel, or catering service kitchen, samples the stew. The difference is that FDA's tests are not dependent upon the taste buds of one individual. By using a larger number of subjects and by controlling non-taste factors that might influence the results, FDA seeks to make its tests as scientific as possible and thus a more accurate indicator of what the consuming public desires.

Enoc Waters is a public information specialist with FDA's Office of Public Affairs.



Putting FDA's Procedural House In Order

The massive task of sorting, assembling, and clarifying hundreds of rules governing the way FDA does business has been completed. The resulting Procedural Regulations will make it easier for members of FDA's various publics—consumers, industry, professionals—to make their voices heard in Agency decisions.

by Emil Corwin

For the past two years, the Food and Drug Administration has been engaged in sorting, assembling, and clarifying hundreds of regulations governing the way it does business. These regulations had been spread through many documents and manuals. Now that the task is completed—the revised regulations were published in the *Federal Register* on May 27, 1975—what does it mean to the world outside FDA?

For one thing, it means it will be a lot easier for any member of FDA's publics—consumer, industry, professional—to make his voice heard in Agency decisions. Anyone—individually or with group support—can petition FDA to issue, amend, or revoke a regulation or order, or to take or not to take any other form of administrative action.

In the past, there was no clear and consistent published procedure for petitioning FDA. The result at times was confusion and uncertainty on the part of the petitioner, as well as on the part of FDA personnel who received various requests and have been without consistent guidance on how to handle them. Under the detailed new procedures, appropriate form letters are available and petitioners and others who use these form letters are advised where and to whom to send them.

Even the formality of filing a petition may be avoided if anyone wishes merely to make a request or suggestion. Simply stating the suggested action in an informal letter to FDA is all that is necessary. Petitions generally are reserved for those specific matters where, perhaps after informal discussion and correspondence, a member of the public decides that a formal proceeding should be initiated to resolve a particular matter.

This procedural change is typical of revisions made in a number of regulations designed to encourage greater public access to FDA and broader participation in its decision-making process. As Commissioner of Food and Drugs Alexander M. Schmidt has said:

"FDA has made its rules easier to find, easier to read, and easier to understand so that more people can make use of them to submit comments, ideas, data and information. We welcome assistance from anyone in developing our policies and regulations. We will try to ensure that every question raised is dealt with fairly and honestly."

How important is this kind of public comment in the actual development of Agency policy and regulations? The question may be answered by considering these recent experiences:

- A letter from a concerned parent led to the drafting of a proposal designed to protect children from being harmed by potentially hazardous products sent through the mail as promotional samples.

- A consumer petition to require cans of fruit or vegetables to be labeled with the drained weight of the contents instead of the net weight is expected to be published as a proposal that would apply to many kinds of fruits and vegetables.

- A detailed study of hearing aids conducted by the Retired Professional Action Group was an important factor in establishing a task force within the Department of Health, Education, and Welfare to examine the subject. Following publication of the task force report, which was aimed at remedying problems of misrepresentation, mis-evaluation, and misfitting of hearing aids, FDA received 5,000 letters on the report. FDA, independently of the HEW task force, is developing labeling regulations for hearing aids, to include directions for use, care of the device, statements of performance, and a patient instruction brochure.

- A petition by consumer advocates led to an FDA ban on the sale of small pet turtles. The turtles are carriers of *Salmonella* bacteria which can cause acute gastrointestinal infections that can be particularly severe in children.

In addition to simplifying the mechanism for entering petitions, the new regulations suggest other

ways in which interested persons may more fully participate in Agency activities. Thus, the regulations tell any citizen how to:

- Ask FDA to reconsider a decision or any part of it.

- Attend and participate in the discussion of an open public FDA meeting or conference without giving advance notice to the Agency or making an advance request for time to make a presentation.

- Learn in advance about future meetings through FDA's publicly posted weekly calendar of open meetings and conferences. The same calendar lists meetings of the previous week, about which anyone can request full details.

- Contest any FDA action in the courts if he believes the Agency has acted improperly. (The petitioner who seeks judicial review, however, must first have exhausted remedies before the Agency.)

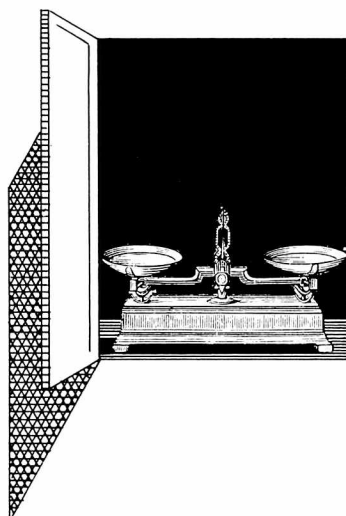
Beyond explicit rules such as these, the Procedural Regulations also offer a number of "helpful hints" and definitions for those unfamiliar with FDA requirements.

For example, persons or organizations who send comments on a proposed regulation are advised that a single comment, relying on sound data and information will be given far greater weight than a large number of form letters which simply support or oppose a proposal with opinion rather than facts.

All FDA decisions are contestable in court and the Agency must act on the basis of scientific facts it can defend. Therefore, it is the quality and persuasiveness of public comments to the FDA that count, not their number or length.

The new regulations make clear the differences among formal trial-type hearings, boards of inquiry, advisory committee hearings, public hearings before the Commissioner, and regulatory hearings before FDA. All of these are designed to assure full scientific and public input without encumbering decision-making with procedures that simply prolong rather than illuminate the problem.

Because "paper work" is an in-



evitable concomitant of most FDA activities, the new regulations spell out for the guidance of those inside and outside FDA the differences between the Agency's four major types of documents: regulations, guidelines, recommendations, and agreements.

Like most rules, the Procedural Regulations define the limits governing as well as the new opportunities for participation in FDA's decision-making processes. For example, there are limits in the new regulations for the time allowed for public comment on any new regulation (including these new Procedural Practices and Regulations) and for reconsideration of FDA decisions.

Another limitation concerns the practice of trade associations and other organizations which file law suits on behalf of their members to determine the legality of FDA action. If the decision in such a case goes against the petitioner and members of the group continue to litigate the matter in separate judicial proceedings, as has happened in the past, this litigation then becomes duplicative and a waste of public resources. For this reason the new regulations require that a determination in any suit involving a trade association or similar organization binds all of its members.

Updating FDA regulations does not end with the Procedural Regulations. New Enforcement Regulations will be issued soon. The Enforcement Regulations will cover such mechanisms as citation hearings, recalls, regulatory letters, and

the Agency's use of publicity in matters under litigation.

In spelling out in detail how the public can do business with FDA, the new Procedural Regulations at the same time simplify and systematize procedures for the Agency itself. Many internal procedures and practices developed over the years on an ad hoc basis to meet immediate needs, were inconsistent, incomplete, and out of date. The Procedural Regulations update and codify the Agency's internal administrative practices.

As a result, FDA employees now have consistent rules on matters dealing with their personal conduct and with conflicts of interest; participation with outside organizations in setting standards (such as labeling, manufacturing practices, etc.); and rules for attending meetings (no Agency representative, for example, may participate in any meeting which is closed on the basis of sex, race, or religion.)

The overall effect of the Procedural Regulations is, as Commissioner Schmidt put it recently, to open the FDA operation to all "who want to see not only what we are doing, but why we are doing it, how we are doing it, and, most importantly, the scientific basis on which we take action."

"I am very anxious that everyone know exactly why we are doing what we are doing," Dr. Schmidt said.

The regulations that were published May 27 were intended as a final order with an effective date of July 28, 1975. But on July 30 the U.S. District Court in the District of Columbia granted an injunction against the regulations on the grounds that they should have been issued as a proposal before being made final. As a result, FDA is reissuing the regulations as a proposal for public comment. An effective date will be set after FDA has received and reviewed the comments.

Emil Corwin is a public information specialist with FDA's Office of Public Affairs.

News Highlights

Patient Labeling Proposed for IUD's

FDA has proposed new labeling for all intrauterine device (IUD) contraceptives. Included in the proposal is labeling intended for physicians as well as a separate brochure for patients. The new labeling will include information on effectiveness rates, precautions, and adverse reactions. If the proposed regulations are made final, IUD's will be the third prescription product required by FDA to include patient labeling. (Previously required to carry patient labeling are oral contraceptives [the pill] and aerosolized asthma drugs.)

IUD's, which are implanted in the uterus to prevent pregnancy, are used by an estimated four million women in this country. Although they are highly effective contraceptives, complications such as excess bleeding, perforation of the uterus, and septic abortion have been reported.

The patient labeling is designed to assure that women who use the IUD have been fully informed of the advantages and disadvantages of the device, and that they are aware of alternative means of contraception. Physicians are to make the labeling available to the patient and to obtain patient consent prior to IUD insertion.

The proposed physician labeling will include details on patient examination prior to insertion, insertion technique, removal, and adverse reactions. Also included on the labeling will be results from clinical trials listing rates of pregnancy, expulsion, continuation, and removal experience.

IUD's have been in wide use since the early 1960's. Although pregnancy rates differ slightly among the various brands, the general effective rate of IUD's in preventing pregnancy is estimated at 95 percent.

Comments on FDA's proposal, which was published in the July 1 *Federal Register*, may be submitted to the Hearing Clerk, Food and Drug Administration, Parklawn Building, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20852 until August 29.

FDA States Position on Food Regulations

FDA has reiterated its position on various legislative proposals affecting food regulatory authorities.

In testifying before congressional committees, the Agency has made the following points:

- **Food Surveillance**—FDA's ability to determine the manner in which food is processed is hampered because FDA inspectors are not entitled to inspect

records showing source of materials, quality controls, or formulation of products. The Agency supports new legislation to require that such records be kept and made available for inspection.

FDA also supports provisions for administrative detention of food as an adjunct to seizure authority, FDA subpoena authority to require witnesses to testify in regulatory investigations, and mandatory FDA notification of industry recalls.

- **Food Labeling**—FDA supports the need for fully informative food labeling but objects to a proposed mandatory feasibility study on listing spices and flavors. FDA's objections are based on the fact that spices and flavors are already being reviewed under the Agency's GRAS (Generally Recognized As Safe) substances program, and because the Agency sees no economic or health benefit from such a study.

FDA opposes legislative exemptions from ingredient labeling regulations. The exemption of related ingredients, for example, could be interpreted by a cereal manufacturer to permit the listing of the single term "grains" without explicitly declaring the individual generic names of the grains.

Concerning percentage ingredient labeling, FDA feels that it already has general authority to require such labeling. FDA regulations now require percentage labeling of characterizing ingredients in seafood cocktails and other products. FDA believes it should continue as at present to have discretionary authority to decide where and when such information will be useful to consumers, rather than to have such authority imposed through legislative mandate on a wide range of food products.

FDA supports the "sell date" and nutrition labeling concepts, and feels it already has authority to issue regulations to deal adequately with both matters.

- **Criminal Liability**—FDA strongly objects to the proposal that only when a person "knowingly or willfully" violates the Food, Drug, and Cosmetic Act, will criminal penalties be applicable. FDA believes that any violation of the Act, regardless of a person's knowledge or intent, should be subject to criminal sanctions. This concept was reaffirmed on June 9, 1975, by the U.S. Supreme Court.

FDA to Distribute X-ray Shields

FDA is planning to distribute male gonad shields to medical facilities of the Public Health Service, Indian

Health Service, and Coast Guard as part of its campaign to promote the use of testicular shielding during x-ray examinations of the abdominal-pelvic area. It is hoped that use of gonad shields in Federal medical facilities will stimulate more widespread adoption of this means of patient protection.

Initial distribution of the shields and related informational material is planned for the fall of 1975. In a related effort to promote this concept, FDA's Bureau of Radiological Health has developed a proposed guideline recommending the use of gonad shielding.

Cosmetic Injury Survey Results Released

FDA has released the results of a three-month study of adverse reactions among a nationwide sample of 36,000 cosmetic users. The study, a cooperative effort by the FDA and the American Academy of Dermatology, is the first attempt involving a government agency to obtain cosmetic-related injury statistics from such a large group of consumers.

The study, begun in September 1974, involved 10,000 households. All adverse reactions reported by the participants were evaluated by dermatologists. Some 703 consumer-perceived cosmetic reactions were reported, of which 589 (84 percent) were confirmed by dermatologists as product-caused. This finding suggests that consumers have the ability to determine correctly, in most cases if a reaction is related to cosmetic product usage.

Of the 589 confirmed cases, the vast majority, 86 percent, were considered mild; 11 percent moderate; 2 percent severe; and the remaining 1 percent could not be classified because of insufficient data.

For purposes of the study, a mild adverse reaction is defined as a minor irritation not requiring medication or a physician's attention; a moderate reaction is one which persists for a prolonged period and could cause loss of time from normal activities; and a severe reaction is painful and severe enough to require a physician's evaluation and would result in a loss of time from normal activities.

When adverse reactions are related to the number of products used in each category, the ten products showing the highest rate of reported and verified cosmetic reactions were: depilatories (chemical hair removers); deodorant/antiperspirants; moisturizers/lotions; bubble bath and oil; hairspray/lacquer; mascara and eye cream; hair color/dye lightener; facial skin cream/cleaner; and nail polish.

In announcing the study, Commissioner of Food and Drugs Alexander M. Schmidt, M.D., said:

"This study is an essential first step in measuring the total population experience and developing a reasonable and adequate program to assure consumer safety in the use of cosmetic products."

The study, conducted by Westat, Inc., Rockville, Maryland, and entitled "Consumer Perceptions of Ad-

verse Reactions from Cosmetics," was done under a \$250,000 contract.

Copies of the study report, containing the findings and a description of methodology, may be obtained for \$5.25 from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22151. Also available from NTIS are data from the study on magnetic tapes.

Cut Sought in Dental X-ray Exposure

FDA has launched a wide-scale effort to encourage State health agencies to participate in a program to reduce unnecessary exposure to radiation in dental x rays.

Called DENT, for Dental Exposure Normalization Technique, the joint Federal-State program is designed to help State radiological health officials identify dental x-ray machines that show exposures above an acceptable range and correct these situations through consultation with practitioners.

Under the DENT system an x-ray exposure card for each dental x-ray unit is mailed by the State health agency to the dentist. The dentist is instructed to expose the card using his x-ray unit, record certain machine information, and mail it back to the health agency. From the exposed card the agency is able to determine machine output and to compare it to an acceptable exposure range established by a panel of dentists.

Dental facilities with units that register exposures above the acceptable range are then visited by a radiological health surveyor. The surveyor identifies causes of the excessive exposure—for example, shortcomings in equipment, technique, or film processing—and suggests way to reduce it.

Results of DENT pilot projects in Idaho, South Dakota, and the District of Columbia indicate that the system is effective in reducing exposure. In South Dakota, for example, almost 40 percent of the 327 units initially checked exceeded the acceptable exposure range. Following office visits by a radiological health surveyor, the average exposure per film for the units that exceeded the acceptable levels was reduced by more than half. Similar results were obtained in Idaho and the District of Columbia.

Participation in DENT is being promoted by FDA's Bureau of Radiological Health through its regional representatives. Once an agency has decided to adopt DENT, FDA will assist in planning and will provide the DENT Instruction Manual, x-ray exposure cards, exposure card readout services, survey equipment on loan, DENT survey forms, automatic data processing services, and training. The participating health agency will administer and operate the program, provide surveyors, maintain a current list of dental x-ray machines, assemble exposure cards, and publish a report on program results.

Regional Reports

REGION II

Investigations by FDA's **New York District** resulted in Federal Government seizure of all spice products stored at Gardner Brooklyn Warehouse because the products were defiled by rodent excreta and urine and because the warehouse was infested by rodents. About 2.2 million pounds of spices valued at \$1.2 million wholesale was involved. It took a U.S. deputy marshal and four FDA investigators three days to effect seizure and compile an inventory.

An FDA investigator on a routine inspection of a warehouse in New York City uncovered a large lot of spoiled anchovies valued at \$10,000. Spoilage was obvious because cans were swelled and in some cases had burst from a buildup of gas as a result of inadequate processing when canned. The owners authorized destruction by incineration, which was witnessed by FDA personnel.

An investigator from FDA's **Westchester Resident Post** accompanied a deputy U.S. marshal to Becker Brothers Warehouse, Bronx, New York, to seize 12,000 pounds of rodent-defiled unshelled walnuts that the investigator had noted on a previous inspection.

Several shipments of imported fresh shallots, totaling 550 cases valued at \$5,500, were detained by FDA's **Buffalo District** because they were adulterated with mold, nematodes, and aphids. The shallots, vegetables prized by some chefs as the ultimate in seasoning, were being shipped by New House Onions, Ltd., Ontario, Canada, to California.

The Federal Government seized 456,000 cans of tomatoes imported from Argentina at a warehouse in Little Ferry, New Jersey, after field examination by the **Newark District** found about 25 percent of the cans to be swelled. The FDA laboratory determined the swelling was caused by hydrogen gas produced by the reaction of the acid in the product with the lining of the can, rendering the product unfit for food.

Acting on a complaint that labels for "Slim-ette" brand Imitation Maple Flavored Pancake Syrup contained confusing information, the Newark District found the label on the front of the bottle stated "no

sugar, artificially sweetened" while the label on the back stated, "Caution to diabetics. This product contains sugar." An investigation of the manufacturer, Chelton House Products, Pennsauken, New Jersey, revealed the firm had inadvertently used some old labels on the back. The firm recalled the lot when advised of the problem.

REGION III

The Government seized 22 bags of chick peas from the Jacob Kaufman Co. warehouse in Philadelphia after the **Philadelphia District** found them contaminated by pigeon excreta.

As a result of inspection by the Philadelphia District, the Penn Central Transportation Co. has spent \$5,100 to upgrade and improve the management of Philadelphia's 30th Street Station watering point facilities. The improvements will assure the purity of the water used for drinking and other purposes on 131 train cars serviced daily in the area.

Three lots of kidney beans, chick peas, and horsebeans totaling 6,020 pounds were seized in the possession of American International Specialties of Wilmington, Delaware, following inspection of the firm by the Philadelphia District. All three lots were contaminated with filth as a result of being stored under insanitary conditions.

Beaver Valley Baking Co., New Brighton, Pennsylvania, and Rudolph J. Fabyanic, a partner in the firm, entered pleas of nolo contendere before Judge Barron P. McCune, U.S. District Court, Western District of Pennsylvania, Pittsburgh, to charges of operating an insect-infested bakery. The firm was fined \$250 and Fabyanic \$150. FDA Philadelphia District inspectors had found bakery products contaminated with insect fragments and raw materials and finished products held under insanitary conditions.

Maintaining an insect-infested bakery also led to fines totaling \$1,500 paid by Stangl Bakeries, Inc., Ambridge, Pennsylvania, and Sarah Jane Stangl, president, and John D. Corbin, vice president. Magistrate Robert C. Mitchell, U.S. District Court, Western District of Pennsylvania, Pittsburgh, fined the individuals \$250 each and the firm \$1,000 after Philadelphia District

inspectors found that bakery products were processed and held in insanitary condition.

For the next five years Better Foods Foundation—a Pennsylvania company—cannot mill flour or any similar product at its Reid, Maryland, mill, and company president John C. Eshelman cannot be employed or participate in the milling business, regardless of ownership, at any location. These stipulations are part of a sentence handed down by Judge C. Stanley Blair, U.S. District Court for the District of Maryland. The company and Eshelman admitted violating a Consent Decree of Injunction that prohibited interstate shipment of flour, buckwheat, pancake mix, and cornmeal prepared at the company's Reid mill. Inspectors from FDA's **Baltimore District** had found evidence of insect infestation in grain handling equipment, around the flour milling equipment, on new bags for the finished product or on burlap bags used for bran. Despite repeated warnings by FDA, the company and its president failed to correct these insanitary conditions.

Ira J. Somerset, shellfish consultant for the Baltimore District, and Daniel Hunt, associate director, Shellfish Sanitation Branch, Bureau of Foods, just back from an inspection tour of oyster-growing areas and processing plants in the Republic of Korea, report that the quality of the Korean product is extremely high. The inspection was made as part of an international agreement between Korea and the U.S. permitting the exportation of frozen oysters to this country. Under this agreement Korea will comply with the provisions of FDA's National Shellfish Sanitation Program including annual program appraisals.

While in Korea, Somerset and Hunt gave talks on water well sanitation and operation, prevention of cross connections in the water system, basic plant sanitation, and waste treatment.

REGION IV

FDA's **Atlanta District** detained a package of silver-colored tablets labeled as "Memory Tablets" because of false and misleading claims, after being alerted to the mailed package by the U.S. Customs Service. The tablets, offered for import by Masiah Zaman, Bombay, India, were offered as a guaranteed brain-energy tonic and "the only remedy to be taken internally that cures brain weakness, dull memory, and mental fatigue." The tablets were also claimed in labeling to be "a sovereign brain intelligence tonic for students, schooling children, barristers, pleaders, masters, artists, and for all types of brain-workers."

Lee Brothers Wholesale Grocery Co., Inc., Lester Lee, Jr., president, and Joe F. Gaines, warehouse manager, all of Elberton, Georgia, were found guilty

of storing food intended for interstate commerce in an insect-infested warehouse where it became contaminated. The prosecution was the result of two inspections by FDA's **Atlanta District**. U.S. District Court Judge William A. Bottle, Athens, fined each defendant \$300 and placed all on a three-years' probation contingent on correction of all deficiencies within 90 days.

FDA **Nashville District** Investigator Tura L. King was on hand to verify voluntary destruction of 1,690 cases of crecky greens valued at approximately \$15,000 by the Monticello Canning Co. at its Crossville, Tennessee plant. The greens had been recalled due to contamination with cocklebur.

The destruction by International Drug, Inc., Smyrna, Tennessee, of drugs valued at \$30,000, was witnessed by FDA **Nashville District** Investigator Gloria J. Dunnavan in Nashville. Three truck loads of the drugs were buried under terms of a consent decree signed by the firm and issued by Judge Frank Gray, Jr., in U.S. District Court for the Middle District of Nashville, Tennessee. Inspections by the Nashville District had found gross deviations from good manufacturing practices and the presence of foreign substances in the drugs and variations in potency. Over 300 lots of drug products by the same manufacturer have been released by FDA for distribution under the same consent decree.

Two shipments of "Mont-Kar Slimming Soap," a product from Spain alleged to make the user's fat and flab disappear, were detained at the port of Miami by FDA's **Orlando District**. According to the label, the soap contained select marine algae specially treated to penetrate the skin and exert a powerful slimming action by dissolving substances which cause obesity. FDA informed the importer that such therapeutic claims would make the soap a drug requiring FDA approval.

REGION V

The Government seized nonprescription drugs valued at nearly \$20,000 at Indiana Botanic Gardens, Hammond, Indiana, when FDA's **Detroit District** found the firm was disregarding FDA's Current Good Manufacturing Practice Regulations for the manufacture of drugs. Some drug items were seized at this firm in 1974. When recent followup inspections revealed failure to correct the violative conditions, virtually all of the drug materials in the company's possession were seized.

The **Detroit District** reports that the ADM Milling Co., doing business as Fuhrer-Ford Co. in Mt. Vernon, Indiana, pleaded guilty in Federal court, Indianapolis, to five counts of operating an insect-infested flour mill.

The company was fined \$2,500. After pleading nolo contendere to one count of operating an insect-infested mill, H. D. Hale, president, and Jeffrey W. Banister, manager, were fined \$500 each.

REGION VI

A shipment of raw sesame seed weighing 1,052,800 pounds and valued at \$310,000 was detained in Dallas, Texas, by FDA's **Dallas District**. The seed, a product of Ethiopia, was contaminated by insect excreta.

FDA's **New Orleans District** referred Freitag's Bakers, New Orleans, Louisiana, operating on an intrastate basis, to the Louisiana State Health and Human Resources Administration for followup after an FDA inspection revealed massive rodent infestation and defilement of products on hand. State and city sanitarians made a series of inspections which resulted in an order to show cause why the firm's permit to operate should not be revoked. The firm promised to make immediate corrections and was permitted to continue operations, since it had stated its intention to go out of business as of December 1975.

REGION IX

Wing Sing Chong Co., San Francisco, California, and the firm's treasurer, Steve Siu, were fined a total of \$3,500 after FDA's **San Francisco District** charged that rice and bean thread in the company's warehouse was contaminated by rodents. The firm pleaded guilty to three counts and was fined \$1,000 for each and Siu pleaded nolo contendere to two counts and was fined \$500 by Magistrate David Urdan, U.S. District Court, Northern District of California.

Crystal Cream and Butter Co., Sacramento, California, entered into a consent decree of permanent injunction in U.S. District Court, Eastern District of California, prohibiting it from interstate shipment of powdered milk containing penicillin residues. Analysis by the San Francisco District of samples of powdered milk manufactured by this firm showed them to contain such residues. The court granted the injunction sought by FDA against the company.

REGION X

Alcoholic beverages valued at \$265,000 that had been submerged in floodwaters at Nome, Alaska, while stored in the basements of six taverns, were seized by the Federal Government after investigation by the **Seattle District**. FDA acted upon the Alaska State government's request on the basis that the products had been shipped in interstate commerce. State government officials had encountered legal difficulties in getting the products removed from consumer channels.

When FDA Region X Food and Drug Director James W. Swanson ordered a doughnut for breakfast in an Anchorage, Alaska restaurant, he found more than the hole missing. There were no doughnuts available. This temporary shortage was one result of Government seizure of approximately 225,000 pounds of bagged flour at the North Star Bonded Warehouse in Anchorage. An inspection by FDA's Seattle District had disclosed that the facility was rodent infested and that food stored there was rodent defiled.

The flour shortage was alleviated after the company filed claim, produced bond, and signed a consent decree of condemnation in the U.S. District Court, Anchorage, agreeing to bring the products into compliance with FDA requirements. FDA inspectors released those bags found uncontaminated and the company destroyed, under FDA supervision, those found defiled by rodents. Under the court order the company was also required to bring the establishment into an acceptable state of sanitation.

Two test panels set up by FDA's Bureau of Foods in its Washington, D.C. headquarters, recently evaluated a sample of sugar by smelling it and members of the panels described the samples variously as "sour, musty, fishy, and/or similar to urine, fertilizer, dirty socks, and animal feed." This eventually led to Government seizure in the Seattle District of 26,700 pounds of granulated sugar manufactured by the Amalgamated Sugar Co., Ogden, Utah, on the charge that the sugar was unfit for food by reason of having an objectionable odor. The cause was not determined.

Terminal 20, Seattle's busiest major food terminal, has a new, clean look. As a result of action initiated by the Seattle District, the port of Seattle has spent \$39,000 to correct insanitary conditions at the Terminal. In addition, the Port of Seattle has adopted a comprehensive sanitation program which will be extended to its other marine facilities and has authorized the hiring of a permanent sanitation consultant.

The corrective action came about after two Seattle District inspections within a month found two adulterated lots of sesame seeds being held at Terminal 20 in rodent-, bird-, and insect-infested buildings.

At the initial hearing on FDA's request for a motion for a preliminary injunction to halt storage of food at the Terminal, Judge Donald S. Voorhees, U.S. District Court, Seattle, ordered a 25-day continuance to determine what action the port was taking on its own. When the hearing resumed, the Government reported that an FDA inspection two days earlier had shown insanitary conditions and two additional lots of adulterated sesame seeds. After a tour of facilities at Terminal 20, Judge Voorhees denied the motion, saying he was not willing to grant an injunction as broad as that proposed unless FDA could prove the port had ways of assuring a pest-free warehouse.

Seizures and Postal Service Cases

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

A total of 31 actions to remove from the consumer market products charged to be violative was reported in May. These included 25 seizures of foods: 1 involved charges concerning poisonous and deleterious substances, 23 involved charges concerning contamina-

tion, and 1 involved charges concerning economic and labeling violations. Other seizures included 1 of food additives, 1 of vitamins and dietary food, and 4 of drugs.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD/Poisonous and Deleterious Substances		
Radishes/Seattle, Wash. 2/19/75	Muranaka Farms, Inc./Northridge, Calif. (M, S); Mike Yurosek & Son/Newhall, Calif. (S)	Contain Dacthal, a pesticide chemical, for which no tolerance has been prescribed.
Contamination, Spoilage, Insanitary Handling		
Alcoholic beverages/Nome, Alaska 4/1/75	Board of Trade Bar/Nome, Alaska (D)	Held under insanitary conditions.
Nome, Alaska 4/1/75	Nome Liquor Store/Nome, Alaska (D)	"
Alfalfa juice concentrate, red clover tops, goldenrod herb, chamomile flowers, haw- thorne berries, Harbor City, Calif. 4/8/75	Hathaway Allied Products, Harbor City, Calif. (D)	Held under insanitary conditions (goldenrod herb, chamomile flowers, hawthorne berries); insect contaminated (red clover tops, alfalfa juice concentrate, chamomile flowers, hawthorne berries).
Beans, kidney; horsebeans/Wilmington, Del. 4/1/75	American International Specialities, Inc./ Wilmington, Del. (D)	Held under insanitary conditions; rodent contaminated (horsebeans).
pinto, popcorn, scratch grain/Paintsville, Ky. 2/21/75	Williams Wholesale Grocery Co./Paintsville, Ky. (D)	"; "
Candy pacifiers/Chatanooga, Tenn. 4/15/75	Ravico S.A./Brussels, Belgium (M); The Paul Spitz Co., Inc./Bronx, N.Y. (S)	Unfit for food due to choking and aspiration hazards to those likely to use.
Virginia Beach, Va. 4/11/75	Imported from Belgium.	"
Fargo, N. Dak. 4/7/75	The Paul Spitz Co., Inc./Bronx, N.Y. (M, S)	"
Sacramento, Calif. 4/11/75, 5/5/75	Pico-Plastics/Brussels, Belgium (M)	"
Boston, Mass. 5/15/75	"	"
Corn, white/Phoenix, Ariz. 4/11/75	Azteca Bakery & Tortilla Shop, Inc./Phoenix, Ariz. (D)	Held under insanitary conditions; rodent contaminated.
Dog food/Vineland, N.J. 3/25/75	Vineland Grocery Co./Vineland, N.J. (D)	"; "
Drink, orange-flavored/Cheektowaga, N.Y. 1/10/75	Esmond Dairy/Sandusky, Ohio (S)	Contains mold.
Flour/New Prague, Minn. 4/24/75	Returned from Waterville, Maine.	Held under insanitary conditions; rodent gnawed.
Beattyville, Ky. 3/11/75	Beattyville Wholesale Grocery Co./Beattyville, Ky. (D)	"; rodent contaminated.
Flour, potato/Garland, Tex. 4/7/75	Southern Maid Donut Co./Garland, Tex. (D)	"; insect contaminated.
Macaroni/Miami, Fla. 1/27/75	Buitoni Foods Corp. Warehouse/Miami, Fla. (D)	"; "
Peanuts/Charleston, S.C. 4/9/75	J.S. Weeks & Co./Charleston, S.C. (D)	"; rodent contaminated.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Contamination, Spoilage, Insanitary Handling (cont'd)		
Rice/Newark, N.J. 3/20/75	Galdo Sons, Inc./Newark, N.J. (D)	Held under insanitary conditions.
Carlstadt, N.J. 3/18/75	Pioneer Food Stores Cooperative, Inc./Carlstadt, N.J. (D)	contaminated. "; insect and rodent
Sesame seed, hulled/Seattle, Wash. 4/11/75	Old Liquor Locker/Seattle, Wash. (D)	contaminated. "; bird and rodent
Walnuts, black, shelled/Nashville, Tenn. 4/16/75	Block Bros., Inc./Nashville, Tenn. (M)	Prepared, packed, and held under insanitary conditions.
Wheat, bulk/Topeka, Kans. 4/7/75	Stratton Equity Corp./Stratton, Colo. (S)	Unfit for food.
Economic and Labeling Violations		
Tomatoes, canned/Hopkins, Minn. 3/25/75	M & R Sales Corp./Oak Park, Ill. (S)	Contains excess tomato peel.
FOOD ADDITIVE		
Bird food, wild/Landover, Md. 3/11/75	Barzen of Minneapolis, Inc./Minneapolis, Minn. (S)	Contains malathion, a nonconforming food additive.
VITAMINS—DIETARY FOOD		
Vitamins plus iron/Patrick Air Force Base, Fla. 3/17/75	American Vitamin Corp./Los Angeles, Calif. (M)	Net quantity of contents does not contain letters and numerals in a type size which has been established by regulation.
DRUGS/Human Use		
Amygdalin (Laetrile)/Birmingham, Ala. 2/7/75	Mr. E.C. Overton/Birmingham, Ala. (D)	New drug without an effective approved New Drug Application.
yellow tablets/Paynesville, Minn. 2/7/75	John A. Richardson, M.D./Albany, Calif. (M)	"
Atropine Sulfate, Pilocarpine Hydrochloride solution/Quincy, Mass. 4/11/75	Muro Pharmacal Laboratories, Inc./Quincy, Mass. (M)	Failed U.S.P. requirements for strength and/or quality; manufactured under circumstances not in conformity with current good manufacturing practice.
Pancreatin powder, Kanulase cores, Kanulase tablets/Lincoln, Nebr. 4/9/75	Inolex Corp./Park Forest So., Ill. (M)	Consists in whole or in part of E. coli and streptococci ; quality and purity are substandard in that the U.S.P. test for Salmonella was positive (pancreatin powder). Kanulase cores and tablets were prepared, packed, and held under insanitary conditions.

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

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

- March 19, 1975: **Treatment**, P.O. Box 221, Lovelock, Nevada 89419. Advertising and sale by mail of a hair growing treatment.
- March 26, 1975: **Van Owen Enterprises**, 13440 Ventura Blvd., Sherman Oaks, California 91423. Advertising and sale by mail of Damiana Super Blend represented to be effective for increasing sexual desire and potency.
- March 28, 1975: **Lady Hamilton Health Products**, Box 384, Canoga Park, California 91303. Advertising and sale by mail of Fat Off Formula represented to be effective for weight loss.
- March 28, 1975: **Lady Hamilton Health Products**, Box 384, Canoga Park, California 91303. Advertising and sale by mail of Ginseng Creme represented to be effective for skin maladies.
- March 28, 1975: **Robert S. Ford**, B.S. d/b/a **Magnolia Laboratory**, 701 Beach Blvd. and/or Box 1306, Pasagoula, Mississippi 39567. Advertising and sale through the mails of a fresh food diet to relieve arthritis.

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

- March 24, 1975: Against **E-Plus Diet**, 18588 Ventura Blvd., Tarzana, California 91356. Advertising and sale by mail of a multi-vitamin tablet represented to be effective for weight loss.
- March 24, 1975: Against **Nutri-Diet**, 22028 Ventura Blvd., Woodland Hills, California 91364. Advertising and sale by mail of multi-vitamin tablets represented to be effective for weight loss.
- March 27, 1975: Against **Multi-Marketing**, 4676 Mirasol, Calabasas, California 91302. Advertising and sale by mail of an RNA/DNA product represented to be effective for cellular rejuvenation.
- March 28, 1975: Against **Beauti-Breast of Paris**, P.O. Box 3725, Beverly Hills, California 90212. Advertising and sale by mail of a product represented to be effective for enlargement and firming of the female bust.

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Pike filets, frozen, and perch filets, frozen, at Milwaukee, E. Dist. Wis.

Charged 1-31-75: when shipped by Hugh J. Meeter & Associates, Grand Rapids, Mich., after being imported from the Netherlands, the articles contained the poisonous and deleterious substance mercury; 402(a)(1). Consent decree authorized release to Hugh J. Meeter & Associates, Grand Rapids, Mich., for export to original foreign supplier. (F.D.C. No. 60193; S. No. 64-648 H et al.; N.J. No. 1)

Seeds, Bio Snacky, and seed sprouting apparatus kits, 2 seizure actions, at Brooklyn, E. Dist. N.Y., and Tulsa, N. Dist. Okla.

Charged on or about 11-21-73 and 12-7-73: when the Brooklyn lot of Bio Snacky cress seeds and "soya" (mung) seeds, and Bio Snacky kits containing plastic seed-sprouter dishes with wheat, cress, mustard, and "soya" (mung) seeds, were shipped by Gebr. Scholl & Co., Laufenburg, Switzerland, and when the Tulsa lot of Bio Snacky kits containing the plastic dishes with mung, cress, and mustard seeds, as above and kits containing stacking glass, seed-sprouter dishes with mustard, cress, "soya" (mung), and wheat seeds, were shipped by Miracle Exclusives, Inc., New York, N.Y., the article contained the added poisonous and deleterious substance *Bacillus cereus*—402(a)(1); the seed packet labels and the accompanying booklets entitled "Biosnacky Recipe Book," contained false and misleading claims such as the following: that the articles will grow good health, and will supply one with health and well-being; that the wheat seed supplied in the Bio Snacky kits would provide a significant amount of wheat germ; that the wheat germ so supplied has life-giving and vital substances; that such wheat germ was an essential nutritional supplement; that such wheat germ contained the anti-sterility and fertility vitamin E, and vitamin F, which was of particular value for a healthy and beautiful skin; that wheat germ was nature's tonic; that a daily intake of freshly-grown wheat germ was essential where there are nutritional deficiencies; that the wheat germ grown with Bio Snacky was one of the most valuable nutritional aids produced by nature; that wheat germ was required for continuous growth; that the daily intake of wheat germ from Bio Snacky, would provide the energy and freshness of youth; that the amount of wheat germ grown through the use of Bio Snacky supplied a significant amount of vitamins; that soya was supplied by the Bio Snacky kits; that such soya had valuable nutritional substances, including the highest quality amino acids; that the highest quality amino acids were cystine, lysine, tryptophane, leucine, and tyrosine; that soya sprouts had a high fatty acid content which is highly unsaturated and is required for the healthy metabolism of fatty substances and the prevention of cholesterol build-up in the blood vessels; that the soya sprouts contained starchless types of sugar which can be used without restriction by diabetics and obese persons; that soya was nutritionally superior to meat and milk and equal to egg yolk because of its high lecithin content; that soya had the highest mineral content of any food; that soya sprouts had an extremely high content of essential vitamins; that the ingestion of enzymes was necessary for digestion; that plants which germinate first in the springtime were vitamin rich; that soya sprouts in a salad give health; that the Bio Snacky kit would provide all the nutritional substances which your family needs for health and vitality and with it you can grow good health; and that the Bio Snacky kit was the modern way to safeguard your family's health—403(a); the various packets of seeds, lacked a quantity of contents statement—403(e)(2); that seed packets labeled "Soya" lacked the food's common or usual name, mung beans—403(i)(1); the kit carton labels lacked the common or usual name of the kit ingredients—403(i)(2); and some lots of cress seeds and mung seeds at Brooklyn which were not part of kits, were in violation of the Fair Packaging and Labeling Act, since the quantity of contents statements on the seed packages lacked the term "net weight"; the quantity of contents statement on the cress seed packages was not adequately separated; the quantity of contents statement on the envelopes (each of which contained 5 packets of seeds) was in a type size less than 3/16 inch high when the principal display panel area was more than 25 square inches; and the quantity of contents declaration on the mung seeds was not within the bottom 30 percent of the principal display area—15 U.S.C. 1453(a)(3)(A)(i), 1453(a)(2), 1453(a)(3)(C)(i). Miracle Exclusives, Inc., New York, N.Y. claimed the articles. Subsequently, upon motion of the claimant, the Tulsa, Okla. action was removed to the Eastern District of New York and consolidated with the other action. The claimant moved for release of the seed-sprouter dishes as not being an article of food as defined by statute; and the Government opposed the motion contending that the seed-sprouting dishes were part of the article subject to seizure and could not be released until an adjudication of the case. Ultimately, a consent decree condemned the articles, authorized their release to the claimant for bringing into compliance with the law by removal and destruction of all seeds, seed packets, and booklets. (F.D.C. Nos. 59550/1; S. No. 72-522 G et al.; 36-238 G et al.; N.J. No. 2)

FOOD/Contamination, Spoilage, Insanitary Handling

Apricot halves, dried at Portland, Dist. Ore.

Charged on or about 9-18-74: while held for sale, the article contained insects, animal hairs, and other debris; 402(a)(3). Default decree authorized donation to municipal zoo

for animal feed. (F.D.C. No. 59945; S. Nos. 19-036/7 H; N.J. No. 3)

Beverage, bottled, orange-flavored, noncarbonated, at Cheektowaga, W. Dist. N.Y.

Charged 1-9-75: while held for sale, the article contained mold masses; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60156; S. No. 106-125 H; N.J. No. 4)

Breeding mix, at Old Monroe, E. Dist. Mo.

Charged 12-19-74: while held by Sun Ring Foods, Div. of Tamara Foods, Inc., Old Monroe, Mo., the article was rodent-gnawed and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60119; S. No. 79-653 H et al.; N.J. No. 5)

Buttermilk solids, at St. Louis, E. Dist. Mo.

Charged 9-3-74: while held by Universal Flavors of Missouri, Inc., St. Louis, Mo., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59942; S. No. 79-146 H; N.J. No. 6)

Candy, at North Kansas City, W. Dist. Mo.

Charged 1-6-75: while held by Roberts Sales Co., Inc., North Kansas City, Mo., the article had been held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60113; S. No. 074-383 H; N.J. No. 7)

Catsup, at Forest Park, N. Dist. Ga.

Charged 12-3-74: when shipped by Naas Foods, Inc., Portland, Ind., the article, labeled in part "Tomato Catsup . . . Red Gate Distributor: Cobis Products Co. Inc. . . . Atlanta, Ga.," contained decomposed tomato material; 402(a)(3). Consent decree authorized release to shipper for salvaging. (F.D.C. No. 60073; S. Nos. 116-843/4 H; N.J. No. 8)

Channa, roasted, lentils, and tapioca, at Chicago, N. Dist. Ill.

Charged 2-4-74: while held by India Gifts & Foods, Chicago, Ill., the articles contained rodent and/or insect filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59647; S. No. 24-993 G et al.; N.J. No. 9)

Cheeses, brie and camembert, at East Boston, Dist. Mass.

Charged 2-5-75: while held for sale, the article contained decomposed cheese; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60199; S. Nos. 108-355/8 H; N.J. No. 10)

Coconut, toasted, at Findlay, N. Dist. Ohio.

Charged 10-16-74: while held by Hainen's Candy Co., Findlay, Ohio, the article contained insects and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60026; S. No. 94-625 H; N.J. No. 11)

Coffee beans, at Chicago, N. Dist. Ill.

Charged 11-20-74: while held for sale, the article was held under insanitary conditions in bags contaminated with insect and rodent filth; 402(a)(4). Consent decree authorized release to Illinois Central Gulf Railroad Co., Chicago, Ill., for salvaging. (F.D.C. No. 60067; S. No. 97-517 H; N.J. No. 12)

Flour, at Indianapolis, S. Dist. Ind.

Charged 12-25-74: while held by AAA Warehouse Co., Indianapolis, Ind., some lots of the article contained rodent filth and all lots were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60079; S. No. 82-536 H et al.; N.J. No. 13)

Flour, at Indianapolis, S. Dist. Ind.

Charged 1-6-75: while held by Regen Baking Co., Indianapolis, Ind., the article had been held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60158; E. Nos. 82-292/4 H; N.J. No. 14)

Flour, at Seattle, W. Dist. Wash.

Charged 8-19-74: while held by Oscar Lucks Co., Seattle, Wash., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59888; S. No. 20-401 H; N.J. No. 15)

Mushrooms, canned, at Stockton, E. Dist. Calif.

Charged 5-23-74: while held for sale, the article contained decomposed mushrooms and was held in swollen and leaking cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59782; S. No. 26-039 H; N.J. No. 16)

Oats, rolled, quick cooking, at Vineland, Dist. N.J.

Charged on or about 10-23-74: while held by Safeway Freezer Storage, Inc., Vineland, N.J., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the State of New Jersey for salvaging. (F.D.C. No. 59874; S. No. 55-587 H; N.J. No. 17)

Oysters, smoked, canned, at Oakland, N. Dist. Calif.

Charged 6-25-74: while held for sale, the article contained decomposed oysters and was held in swollen cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59821; S. No. 92-511 G; N.J. No. 18)

Peanuts, shelled, at Brookfield, E. Dist. Wis.

Charged 3-13-75: while held by A. L. Schutzman Co., Inc., Brookfield, Wis., the article contained insects and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60282; S. No. 64-659 H; N.J. No. 19)

Peanuts, shelled, at Hopkins, Dist. Minn.

Charged on or about 10-9-74: while held by Johnson Nut Co., Inc., Hopkins, Minn., the article contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to United Packaging Co., Hopkins, Minn., for salvaging. (F.D.C. No. 59985; S. No. 63-852 H; N.J. No. 20)

Peanuts, shelled, at Leesburg, M. Dist. Ga.

Charged 9-19-74: when returned from Everett, Mass., to LeeCo Farm Center, Inc., Leesburg, Ga., the article contained insect filth; 402(a)(3). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59977; S. No. 115-780 H; N.J. No. 21)

Raisins, at Omaha, Dist. Nebr.

Charged 10-11-74: while held by Millard Warehouse, Omaha, Nebr., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60017; S. No. 78-106 H; N.J. No. 22)

Rice, at South San Francisco, N. Dist. Calif.

Charged 7-31-74: while held by Oriental Trading Co., South San Francisco, Calif., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59877; S. Nos. 27-681/3 H; N.J. No. 23)

Sesame seed, at Detroit, E. Dist. Mich.

Charged on or about 12-12-74: when shipped by Louis Furth, Inc., Brooklyn, N.Y., the article contained insects, and sesame seeds treated with a pink dye and intended solely for use as seed had been substituted in part for sesame seed which did not bear a pink dye and which were intended for food use; 402(a)(3), 402(b)(2). Default decree ordered destruction. (F.D.C. No. 60053; S. No. 85-137 H; N.J. No. 24)

Sugar, at Dallas, N. Dist. Tex.

Charged on or about 1-7-75: while held by Goodman Produce Co., Inc., Dallas, Tex., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60091; S. No. 4-425 H; N.J. No. 25)

Sugar, at Tunica, N. Dist. Miss.

Charged 12-13-74: while held by Whittington Wholesale Co., Tunica, Miss., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60111; S. No. 60-840 H; N.J. No. 26)

Sugar, powdered, at Pensacola, N. Dist. Fla.

Charged 1-14-75: while held by Saunders Food Distributors, Inc., Pensacola, Fla., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60150; S. No. 40-613 H; N.J. No. 27)

Various food stocks, at Atkins, E. Dist. Ark.

Charged 12-9-74: while held by Cheek Wholesale Grocer Co., Inc., Atkins, Ark., seven lots of foods contained rodent filth, and the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 60123; S. No. 54-861 H; N.J. No. 28)

Various food stocks, at Toledo, N. Dist. Ohio

Charged 5-30-74: while held by Great Lakes Terminal Warehouse Co., Toledo, Ohio, six lots of foods contained rodent filth, and the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). A number of lots of foods were claimed by their owners and consent decrees authorized the release of such foods for salvaging, or, in one instance, for personal use and not for resale. Upon motion by the Government, food owned by the State was released for salvaging. Default decrees ordered the remaining articles destroyed. (F.D.C. No. 59795; S. No. 92-930 H; N.J. No. 29)

Wheat, at Minneapolis, Dist. Minn.

Charged 3-6-75: when shipped by Cargill, Inc., Minot, N. Dak., the article contained insect-damaged wheat kernels; 402(a)(3). Consent decree authorized release to shipper for salvaging. (F.D.C. No. 60260; S. No. 63-990 H; N.J. No. 30)

Wheat germ, at Oakland, N. Dist. Calif.

Charged 10-22-74: while held by Peavey Co., Coast Dakota Flour & Baking Supply Div., Oakland, Calif., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60036; S. No. 26-962 H; N.J. No. 31)

FOOD/Economic and Labeling Violations

Beer, Gablinger's, at Suffern, S. Dist. N.Y.

Charged 12-7-67: when shipped by Rheingold Breweries, Inc., Orange, N.J., the article's label statements "Doesn't Fill You Up," "No Carbohydrates," "No Available Carbohydrates," "No Fat," and "Protein 0.25%" were false and misleading in suggesting and implying that the article was calorie-free or low in calories, and that, in the setting in which such statements were presented, the articles were of significant value for use for reducing and for weight control; and the article purported and was represented as a food for special dietary use and it lacked required information for such use; 403(a), 403(j).

The article was claimed by the shipper who denied the charges. The claimant affirmatively alleged that the label statements were truthful and not misleading, that the article was lower in calories than most other beers, that it was free of available carbohydrates, that the U.S. Treasury Department regulations prohibited any reference to the calorie content of any malt beverage, including beer; that the article contained approximately 99 calories per 12-ounce container and no available carbohydrates, when the majority of beers contained approximately 150 to 165 calories and significant amount of available carbohydrates; that seizure and condemnation of the article would be arbitrary, capricious, and unconstitutional because such seizure and condemnation was sought, in part, because the article's label lacked a statement of caloric content, although such statement would be contrary to such U.S. Treasury Department regulations, and that the article's label had been approved by the U.S. Treasury Department.

Subsequently, at the request of the claimant and with the consent of the plaintiff, the article was moved to claimant's White Plains, N.Y., warehouse. Proposals were made by plaintiff for a new form of label as a basis for settlement. A new form of label was approved and was put into use in essentially the approved form. Ultimately, the claimant wished to destroy the article because it was a potential threat to health, seriously interfered with the warehouse operations, and had become unfit for consumption due to the passage of time. Accordingly, the claimant moved for destruction of substantially all of the article. Accordingly, the goods were destroyed and the action terminated. (F.D.C. No. 54949; S. Nos. 41-390/1 C; N.J. No. 32)

FOOD ADDITIVE

Macaroni products, at Ann Arbor, E. Dist. Mich.

Charged 12-11-74: while held for sale after manufacture by Greenfield Noodle & Specialty Co., Detroit, Mich., who manufactured the articles using whole wheat flour shipped in interstate commerce, the articles, labeled in part "Greenfield's Real Egg Noodles ["Whole Wheat"] Detroit, Michigan," and "Eden Foods Ann Arbor, Mich. . . . Contains No Egg Whole Wheat," contained the nonconforming food additive diazinon; and the articles failed to conform to the definition and standard for noodles (which they purported to be), since the articles contained less than 5.5 percent by weight of the solids of egg or egg yolk, and contained whole wheat flour; 402(a)(2)(C), 403(g)(1). Default decree ordered destruction. (F.D.C. No. 60110; S. Nos. 84-534/6 H; N.J. No. 33)

VITAMINS/SPECIAL DIETARY FOODS

Nuclomin trace mineral tablets with multivitamins, at St. Louis, E. Dist. Mo.

Charged 9-21-71: while held by E.W. Heun Co., t/a Miller Laboratories, Inc., and Norwood Laboratories, Inc., who manufactured the article using vitamin B12 which had been shipped in interstate commerce, the article's label statements "Each two tablets contains: . . . Choline (as Bitartate) [sic] 50.5 mg.* Inositol 50.0 mg. * . . . p-Aminobenzoic Acid 10.0 mg. * . . . Other Factors Natural to Yeast Extract . . . Potassium 20.0 mg. * . . . Magnesium 20.0 mg.* In association with Calcium Succinate 50 mg." and "A concentrated source of . . . other nutritional factors, plus the micronutrients associated with the amino acids and polypeptides as found in a special yeast extract," falsely and misleadingly represented and suggested that the article was of special dietary value by reason of the presence therein of those ingredients; 403(a). In addition, the article was erroneously alleged to be deficient in its labeled vitamin B12 content. However, such allegations were abandoned at the time that the Government moved, prior to trial, to amend the charges and to elaborate upon the above charge involving false and misleading special dietary claims. Hunt Investment, Inc., t/a Miller Laboratories, Inc., St. Louis, Mo., claimed the article and denied the charges. The Government served written interrogatories on the claimant. The case came on for trial by the court. In finding for the Government, the court said:

"The controverted issue is whether the label of the article represents and suggests that Nuclomin is of special dietary value because of the ingredients named thereon, and if so, whether such representations and suggestions are contrary to fact and therefore false or misleading within the meaning of Section 343(a), 21 U.S.C.

"The label on the bottles in which the tablets are packed contains the following statements:

**AMINO ACID COMPLEXED TRACE MINERAL
WITH MULTI-VITAMINS**

A concentrated source of vitamins, minerals and other nutritional factors, plus the micronutrients associated with the amino acids and polypeptides as found in a special yeast extract.

DOSAGE

Adults, orally as a dietary supplement, two tablets per day.

Each two tablets contain[s]	MDR	
VITAMINS		
Vitamin A	5000 Units	125%
Vitamin D	1000 Units	250%
Vitamin E	5 Units	*
Vitamin B1	2.5 mg.	250%
Vitamin B2 (Riboflavin)	5.0 mg.	400%
Vitamin B6	1.5 mg.	*
Niacinamide	25.0 mg.	250%
Panthenothenic Acid (as Cal. Pan)	25.0 mg.	*
Choline (as Bitartate)	50.0 mg.	*
Inositol	50.0 mg.	**
Vitamin C	50.0 mg.	166%
Vitamin B-12	1.0 meg.	*
p-Aminobenzoic Acid	10.0 mg.	**

[Other Factors Natural to Yeast Extract]

MINERALS		
Copper	1.0 mg.	*
Iodine	0.075 mg.	75%
Manganese	2.0 mg.	*
Iron	10.0 mg.	100%
Potassium	20.0 mg.	*
Zinc	2.0 mg.	*
Magnesium	20.0 mg.	*

In associate with:
Calcium Succinate 50 mg.

MDR: Minimum Daily Requirement.

*Need in human nutrition, established
Requirement not determined.

**Need in human nutrition not established.

"Admittedly, Nuclomin is a food for special dietary use. As set forth on its label, the product contains in nutritionally significant amounts, vitamins A, B, B₁, B₂, C and D, and Niacinamide, as well as iron and iodine. Additionally, other ingredients such as Choline, Inositol, Para-Aminobenzoic Acid, Potassium, Magnesium and Calcium Succinate, each of which, as noted supra, is listed on the label, are contained in the product.

"The Government does not dispute the truth of the statements contained in the label respecting the amounts of each ingredient supplied by each two tablets as well as the need therefor for human nutrition as established. Rather, plaintiff urges, and we agree, that the very listing of such ingredients on the label of Nuclomin constitutes a representation and suggestion that all such ingredients are of special dietary value, and that this is particularly true where, as here, the label also lists other ingredients that are commonly known to be of nutritional value. We are also of the opinion that the statement on the label that the product contains 'other nutritional factors, plus the micronutrients associated with the amino acids and polypeptides as found in a special yeast extract,' true though such statement may be, is a representation and suggestion that the presence of these ingredients makes the product by reason thereof one of special dietary value. In our judgment, the very intent and purpose of listing numerous ingredients on the label is to make it appear to a prospective purchaser that the product is of more value as a dietary supplement than one which does not contain all such ingredients.

"We next turn to the decisive question of whether the representations we have found are false or misleading in any particular (the criterion of the statute, Section 343(a), 21 U.S.C.). With respect to the mineral potassium, the evidence which we credit discloses that the body requires 2000 to 4000 mgs of potassium daily, although no minimum daily requirement has been established. According to the label, the amount of potassium supplied by two tablets of the product is only 20 mg. This amount is so infinitesimal that the presence of the potassium in Nuclomin would not make it of any value as a supplement to the diet.

"So, too, the amount of 'other nutritional factors' (fats, proteins and carbohydrates) and amino acids and polypeptides is so small (approximately 600 mgs at most) in relation to even the probable minimum amount required, that they do not add in any real sense to the nutritional value of Nuclomin as a dietary supplement. And the fact that the label truthfully states either that there is no established minimum daily requirement for choline, inositol and p-Aminobenzoic acid or that the need therefor in human nutrition has not been established does not authorize the implied representation, without basis in fact, that the presence of these ingredients, particularly in the quantities listed, makes the product of special dietary value. In our opinion, these ingredients are either of no nutritional value per se or the quantities are so minute as not to enhance the nutritional value of the tablets.

"Claimant contends, and the Government concedes, that Nuclomin does have value as a dietary supplement because of the presence therein in significant quantities of certain established nutrients, including vitamins A, B, B₁, B₂ and iron. However, the other questioned ingredients would not have been listed on the label (or included in the product) except for the purpose of attempting to persuade a purchaser that the product is of more value as a dietary supplement by reason thereof than a product which does not contain some or all of these inconsequential ingredients.

"As we have noted, supra, an article of food is misleading if the label is false or misleading in any particular. Hence, any single false or misleading representation on the label misbrands the article within the meaning of the statute. Plaintiff having established by a preponderance of the credible evidence that the labeling is false or misleading, it is entitled to a decree condemning the seized articles."

The claimant appealed. After the claimant filed its brief, the Government sought and obtained permission to file an enlarged brief, which included, in its appendix, 47 notices of judgment involving misbranded dietary supplements, and a memorandum by the FDA Chief Council concern health food labeling that had been incompletely quoted in the claimant's brief. In addition, the National Health Federation, Monrovia, Calif., sought and obtained permission to file a brief, as *amicus curiae*, urging that the District Court be reversed. In affirming the judgment of the District Court, the Court of Appeals said:

"This is an appeal from an *in rem* proceeding brought under the Federal Food, Drug, and Cosmetic Act against a special dietary product 'Nuclomin' claiming it is misbranded in violation of Section 403(a) of the Act, 21 U.S.C. §343(a). Hunt Investment, Inc., owner of Nuclomin, intervened. Jurisdiction rests under 21 U.S.C. §334. The district court upheld the government seizure and condemnation on the basis that several ingredients listed on the label were 'either of no nutritional value per se or the quantities are so minute as not to enhance the nutritional value of the tablets.' The district court, the Honorable John K. Regan presiding, found that such label was false and misleading in that it could persuade a purchaser that the product possessed greater nutritional value than it actually did.

"The basic issues on appeal include (1) whether the Food and Drug Administration (FDA) possessed the authority to prohibit the sale of a product that lists, as required by the regulations, completely safe ingredients that may be unnecessary or insignificant; (2) whether sufficient proof was presented to establish that the questioned ingredients were not needed or were included in inadequate amounts, and (3) whether the product label was in fact misleading. We affirm the trial court's ruling.

THE FDA'S AUTHORITY

"The government does not challenge the factual accuracy of the Nuclomin label: rather it claims that the label is misleading to the public because some of the ingredients are either not needed in human nutrition or are included in such insignificant amounts as to be valueless. Specifically, the government attacks the vitamin constituents choline, inositol and p-aminobenzoic acid, the mineral elements potassium, magnesium and calcium succinate, and the amino acids found in the yeast extract. It is undisputed that these ingredients are consumed daily by the public and are completely safe.

"Most of claimant's arguments relate to Section 403(j), 21 U.S.C. §343(j), relating to

the misbranding of special dietary articles. This, however, overlooks the direct authority of the government to bring a condemnation suit for violation of Section 403(a) pertaining to misbranding because of the use of a misleading label. * * *

SUFFICIENCY OF PROOF

"The testimony of the government's witnesses, Dr. Thomas D. Luckey (a professor of biochemistry at the Missouri School of Medicine and chairman of the graduate nutrition program), and Dr. Harold L. Rosenthal (a professor of physiological chemistry at Washington University Dental School who has done considerable research in the field of nutrition, primarily the metabolism of Vitamin B-12 and amino acids) and the appellant's witness, Dr. Edward Doisy, Jr., (a nutritionist, biochemist, and nonpracticing physician) was admittedly conflicting. Nevertheless, there was substantial evidence for the trier of fact to believe that the disputed ingredients in Nuclomin were either not needed in the human diet or that the amount of the ingredient was so small that it would have no value. * * *

WHETHER MISLEADING

"The claimant urges that the FDA has failed to prove that any of Nuclomin's customers were actually misled by the product label, relying on *United States v. 119 Cases . . . 'New Dextra Brand Fortified Cane Sugar'*, 231 F. Supp. 551 (S.D. Fla. 1963), aff'd 334 F.2d 238 (5 Cir. 1964). This case simply held that the government failed to carry its burden of proof through its nutritional experts that the label used was misleading. Other courts have held that although admissible on the issue of whether a label is false or misleading, the fact that no purchasers have actually been misled is not a defense under the Act. * * *

"In several contexts the claimant has portrayed Nuclomin as a safe or harmless product and, on the basis of its other nutrit[iti]onally accepted ingredients, a beneficial dietary supplement. The safety of a product, however, cannot be a basis for substantiating the legality of a seized article. Numerous authorities have held that it is immaterial to a question of misbranding whether the condemned article is inherently dangerous or harmful or whether it may in some way be beneficial. * * *

"We accept the well[-]reasoned opinion of the district court. The Nuclomin label defines itself as a dietary supplement and lists the challenged ingredients among known nutritional vitamins and minerals. As the district court found, this ambiguity could represent by indirection that these elements contributed some additional benefit when in fact they do not." (F.D.C. No. 57337; S. No. 45-587 D; N.J. No. 34)

DRUGS/Human Use

AquaLens lens blanks, lens rods, and methyl methacrylate component, at Dallas, N. Dist. Tex.

Charged 8-22-72: while held by Morgan Optics, Inc., Dallas, Tex., who was manufacturing the lens blanks and lens rods using hydroxyethyl methacrylate which had been shipped in interstate commerce, the name "AquaLens" and statements in the accompanying press release, advertisement, and card were false and misleading in representing the article as a "Hydrophilic" plastic lens possessing the characteristics of a soft lens in reducing surface tension between the lens and the tear layer of the eye; and the labeling of the article (which was represented as a drug by virtue of statements that AquaLens was created by changing the molecular structure of methyl methacrylate so that it was hydrophilic) failed to bear adequate directions for use and was not exempted therefrom since the article lacked an effective approved New Drug Application; 502(a), 502(f)(1). Consent decree ordered destruction. (F.D.C. No. 58163; S. No. 83-022 F; N.J. No. 35)

Bethanechol chloride tablets, U.S.P., at Brainerd, Dist. Minn.

Charged 2-3-75: while held for sale, the article contained insect excreta and wood splinters; 501(a)(1). Default decree ordered destruction. (F.D.C. No. 60195; S. No. 64-242 H; N.J. No. 36)

Cyanocobalamin and thiamine HCl injectable, at Hatillo, Dist. P.R.

Charged 9-8-71: while held for sale, the article's strength fell below its purported strength since the article contained less than 50 percent of the declared cyanocobalamin; 501(c). Default decree ordered destruction. (F.D.C. No. 57435; S. No. 32-942 E; N.J. No. 37)

Immune serum globulin (human), U.S.P., staphylococcus vaccine, and pregnancy test kits, at Canton, N. Dist. Ohio.

Charged on or about 8-19-74: while held by McKesson & Robbins Drug Co., Canton, Ohio, the articles (whose labeling directed storage at 2 degrees to 8 degrees Centigrade) were held under circumstances that failed to conform to current good manufacturing practice, since they were stored at temperatures above 8 degrees Centigrade; 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 59883; S. Nos. 95-915/7 H; N.J. No. 38)

Progesterone injection, N.F., 2 seizure actions, at Cherry Hill, Dist. N.J., and Dallas, N. Dist. Tex.

Charged 11-16-72 and 12-15-72: when shipped (Dallas lot of the article) and while held (Cherry Hill lot of the article) by Elkins-Sinn, Inc., Cherry Hill, N.J., who had manufactured the article using the raw ingredient progesterone which had been shipped in interstate commerce, the article's strength differed from the N.F. standard, since it contained approximately 86 percent of the labeled amount of progesterone; 501(b). The article was claimed by the manufacturer who denied the charges, and litigated the actions. Upon consent of the parties, the court ordered the Dallas actions transferred to New Jersey and consolidated with the Cherry Hill action. The claimant contended that the article's strength met National Formulary standards, and that the National Formulary method of analyses, as constructed, was difficult and often unreliable because of the nature of the test and the reagent used in performing the test. The claimant also contended that the Cherry Hill lot was not held for sale after shipment in interstate commerce. Ultimately, the claimant agreed that the seized articles of drug be destroyed; and the court so ordered, with the provisions that claimant's consent not be deemed as any admission, that the court's orders of destruction and dismissal not be used in any other proceedings and that, upon the confirmed destruction of the article, the actions be dismissed with prejudice. (F.D.C. Nos. 58490, 58501; S. Nos. 54-994 F, 54-994 F; N.J. No. 39)

MEDICAL DEVICES

Diapulse electromagnetic energy generator, at Otterbein, N. Dist. Ind.

Charged 12-20-72: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the accompanying treatment chart and leaflets (including leaflets entitled "Pulsed Short Wave in Sinus and Allied Conditions in Childhood," "Peripheral Blood Flow Measurements During Application of Pulsed High Frequency Currents," "Pulsed Short Wave in the Treatment of Bursitis with Calcification," and "Management of Rheumatic Diseases in General Practice") contained false and misleading claims for infections, fractures, smooth muscle spasm, bursitis, arthritis low back pain, headaches, and blood flow to peripheral areas; and the labeling lacked adequate directions for use for the article's intended purposes and neither adequate information for lay use nor adequate information for use by licensed practitioners could be written; 502(a), 502(f)(1).

The article was claimed by the partners who had possession of the article, who denied the charges, and who alleged that the article was exempt from the need for information for use by licensed practitioners, since such information was currently known to such practitioner. Upon motion of the claimants, a stay of the proceeding was granted upon the provision that the claimants, regularly file status reports of the related litigation pending in the Eastern District of New York and the Second Circuit Court of Appeals. The Government subsequently alleged that the claimants were using the article (which had been seized, but left at the claimant's office) to treat patients during the pendency of the action and the Government requested an ex parte order directing the U.S. Marshal to remove the article from the claimants' office. The Government also subsequently moved to vacate the stay on the grounds that the related litigation in the Eastern District of New York had been resolved in favor of the Government. The Government also served written interrogatories on the claimants. The court granted the Government's motions saying:

"This cause is before the court on plaintiff's motion to vacate the ex parte order to stay the proceedings entered by this court on April 5, 1973 and on plaintiff's request for an ex parte order directing the United States Marshal to remove the 'Diapulse Device' from claimants' office. Both the motion to vacate and the request for an order directing removal of the device will be granted. * * *

"The question presented by the motion to vacate the April 5, 1973 order is whether it is necessary to continue to stay the proceedings. Claimants, Donald L. McKinney, M.D. and Thomas J. Stolz, M.D. in support of their motion to stay the proceedings, cited **United States v. Diapulse Corp. of America**, No. 68 C 391 in the United States District Court for the Eastern District of New York where a motion for modification of judgment was pending at that time. However, that motion was denied on February 16, 1973. Claimants had also cited an appeal then pending in the U.S. Court of Appeals for the Second Circuit, entitled **United States v. Diapulse**, in support of their motion to stay. On October 24, 1973, that Court affirmed the District Court. Both of these rulings were adverse to the position argued by the claimants in this case. Although the attorney for the Diapulse Corporation of America has indicated that he intends further action in both cases, a continued stay of the instant action is not warranted. Plaintiff's contentions have been heard and accepted in several district courts and have been argued before the U.S. Court of Appeals for the Second Circuit on several occasions and its arguments have been found meritorious on each occasion. Any further stay of these proceedings to await some planned action by the attorney for 'Diapulse' will only result in a needless prolonging of the instant litigation.

"The second question presented is whether the Government has a right to remove the 'Diapulse Device' from claimants' offices, since it has reason to believe that such device is being used during the pendency of this litigation. It cannot be disputed that the device is currently in the custody or constructive possession of the United States Marshal. . . . It is clear in the instant action that the United States Marshal was authorized to seize the 'Diapulse Device' when the Warrant of Seizure and Monition was issued. At that time the Marshal could have taken actual possession of the device but chose instead to 'store' it at claimants' office. Under provisions in 21 U.S.C. § 334, the United States is authorized to seize misbranded devices without proof of justification for seizure. . . . The United States, therefore, has the power to take actual possession of misbranded devices without proving any justification for seizure. When the marshal seized the 'Diapulse Device' in this action, he took custody of it constructively. Nothing bars him from converting the constructive possession to actual possession. No reason exists to prevent him from removing the device from the office of claimants to another place of storage. . . . In the instant action, the fact that the device is used by a licensed physician will not except it from seizure and condemnation. Commercial use of an alleged misbranded device, even by a licensed physician, must yield to the right of the Government to condemn such devices if transported in interstate commerce. * * *

"Whether the device is being used or not is not controlling since the device is in the custody of the marshal who can convert his constructive possession to actual possession if it becomes convenient for him to do so. In any case it was held in **United States v. Diapulse**, No. 73 C 157, United States District Court for the Northern District of Illinois, that in view of the prior litigation involving this device, the court would not release the device for use **pendente lite**. For all of the above reasons, claimants have no basis to contend that the Government has no right to remove the device from their office. The device is in the custody of the United States Marshal and may be removed and stored elsewhere."

When the claimant failed to answer the Government's written interrogatories, the Government moved for a decree of condemnation based on such failure. However, such motion was denied because the claimant subsequently filed answers; the claimant also served written interrogatories on the Government. The Government thereafter moved for summary judgment on the grounds that there was no genuine issue of material fact and that, as a matter of law, the article was violative as alleged. Ultimately, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 58600; S. No. 38-786 F; N.J. No. 40)

Diapulse electromagnetic energy generators, 2 seizure actions, at Central Point, Dist. Oreg., and Baton Rouge, M. Dist. La.

Charged 12-19-72 and 12-17-74: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' accompanying

labeling (treatment chart and/or leaflet) contained false and misleading claims for normal bone and tissue healing, sinusitis, bursitis, rheumatoid arthritis, and blood flow to peripheral areas; and the labeling lacked adequate directions for lay use and adequate information for use by licensed practitioners could not be prepared; 502(a), 502(f)(1). The possessor of the device at Central Point, Oreg., claimed the article. The Government served written interrogatories on the claimant. Thereafter, the claimant consented to a decree of condemnation authorizing release of the device for salvaging. In the Baton Rouge, La., action, a default decree ordered destruction. (F.D.C. Nos. 58596, 60099; S. Nos. 79-907 F, 54-502 H; N.J. No. 41)

Specific Adjusting Machine for spinal adjustments, at Morehead City, E. Dist. N.C.

Charged on or about 10-17-74: when shipped by Arden D. Zimmerman, D.C., San Jose, Calif., the accompanying lease agreement contained false and misleading claims for adjusting the axis or atlas of the spine; the article's labeling lacked adequate directions for lay use for the article's intended purposes and adequate information for use by licensed practitioners could not be prepared; and the article's labeling lacked adequate warnings against unsafe use; 502(a), 502(f)(1), 502(f)(2). Default decree ordered destruction. (F.D.C. No. 59981; S. No. 116-383 H; N.J. No. 42)

COSMETICS/BEAUTY PRODUCTS

Devra Harris Exquisite Nails methyl methacrylate monomer fingernail lengthener kits, at Hialeah, S. Dist. Fla.

Charged 9-24-74: when shipped by House of Barri, Inc., N.Y., N.Y., the article contained the poisonous and deleterious substance methyl methacrylate monomer, which might render the article injurious when used as directed or as ordinarily used; 601(a). Default decree ordered destruction. (F.D.C. No. 59956; S. No. 38-689 H; N.J. No. 43)

Hair brushes of boar bristle and nylon, at Carle Place, E. Dist. N.Y.

Charged 12-19-74: when shipped by Toho Beauty & Co., Ltd., Tokyo, Japan, the article, labeled in part "Rembrandt . . . For The Professional Hair Stylist . . . Rembrandt Products a Division of Select Beauty Brands Inc. . . . Carle Place, N.Y.," contained nits; 601(b). Default decree ordered destruction. (F.D.C. No. 60117; S. No. 43-327 H et al.; N.J. No. 44)

Long Nails methyl methacrylate monomer nail lengthener kits, at St. Louis, E. Dist. Mo.

Charged 9-5-74: when shipped by C.E.B. Products, Inc. (formerly Dark Eyes Co., Inc.), Chicago, Ill., the article contained the poisonous and deleterious substance methyl methacrylate monomer which might render the article injurious when used as directed or as ordinarily used; 601(a). Default decree ordered destruction. (F.D.C. No. 59958; S. No. 79-589 H; N.J. No. 45)

NOTICES OF JUDGMENT on Criminal Actions

FOOD

Ace Baking Co., Inc., and Leo Feldman, president, and **Arthur Feldman**, treasurer, Boston, Dist. Mass.

Charged 1-11-74: shelled walnuts and raisins were held in a building accessible to rodents and insects and were contaminated with insect filth; 402(a)(3), 402(a)(4). The defendants moved to suppress evidence obtained by FDA inspections of the defendants' premises; the defendants claimed that the inspections were violative, warrantless searches and that the samples collected by FDA were similarly violative seizures. The Government contended that consent to the inspection and collection of samples had been freely and voluntarily given, and that neither search warrant nor consent was required where an inspection is conducted pursuant to statutory authority. After a hearing, the court denied the defendants' motion. Guilty plea by corporation; fine. Nolo contendere pleas by individuals; sentences of imprisonment suspended; fines; and probations with special conditions for compliance with FDA regulations. (F.D.C. No. 59304; S. Nos. 13-731 F, 14-169 F; N.J. No. 46)

Arrow Salvage Co., Inc., and Charles G. Parisi, president, Detroit, E. Dist. Mich.

Charged 8-27-73: while held for sale, cornmeal, flour, and cornmeal mix were held in a building accessible to rodents and insects and were contaminated, except for the flour, with insect and/or rodent filth; 402(a)(3), 402(a)(4). Not guilty pleas were entered. The case came on for trial by jury. The defendants stipulated all elements of the case except that the articles were "held for sale." After trial on that issue, the jury returned a verdict of **not guilty**. (F.D.C. No. 59303; S. No. 40-601 G et al.; N.J. No. 47)

Cheney Bros. Food Products, and **Dean Starr**, secretary-treasurer, and **J. Walton Cheney**, assistant treasurer, Union City, N. Dist. Calif.

Charged on or about 5-23-74: rice, flour, and a prepared mix were held in a building accessible to rodents and the rice and flour were contaminated with rodent filth; 402(a)(3), 402(a)(4). The individual defendants moved for a bill of particulars with respect to their responsibility concerning the alleged violations. The defendants also moved for discovery and inspection of FDA inspectional items, various reports, and other items of Government evidence. The Government filed a motion for reciprocal discovery. After the Government had answered the individual defendants' bill of particulars, J. Walton Cheney moved to dismiss the information as to himself on the grounds that Dean Starr admitted that Dean Starr was in charge of the physical operation of the warehouse, including its sanitation program. The court granted the defendants' motion for discovery but denied the motion to dismiss the information as to J. Walton Cheney. The case came on for trial by the court. At the conclusion of the trial, the court found the corporation and Dean Starr guilty, and fined them. J. Walton Cheney was **acquitted**. (F.D.C. No. 59404; S. No. 75-065 F et al.; N.J. No. 48)

Cumberland Dairy Farms, Inc., Canton, Dist. Mass.

Charged 1-3-72: milk and skim milk were processed and packed into half gallon size, polyethylene, returnable-type bottles so as to result in the articles being prepared and packed under insanitary conditions, and in the articles being unfit for food by reason of the presence of an odor similar to gasoline or kerosene, and (in one of the four counts) by reason of the presence of droplets of a liquid similar to a petroleum product; 402(a)(3), 402(a)(4). Guilty plea; fine. (F.D.C. No. 57373; S. No. 16-412 D et al.; N.J. No. 49)

Domasco Bakers Supply Co., **Homer E. Wharton**, vice president, and **Frank G. Federico**, plant

superintendent, Oakland, N. Dist. Calif.

Charged 6-5-74: donut flour was held in a building accessible to rodents and insects and was contaminated with rodent filth; 402(a)(3), 402(a)(4). The defendants pleaded not guilty and filed a motion to dismiss the action based on the contention that delay between the claimed violations (January-February 1973) and the filing of the Information (June 5, 1974) had materially prejudiced the defendants in the defense of their suit, since the plant where the alleged violations took place was no longer accessible to the defendants and since material evidence had been destroyed. After a hearing, the court denied the defendants' motion. Thereafter, the corporation changed its plea to guilty and was fined; and the individuals changed their pleas to nolo contendere and were fined. (F.D.C. No. 59699; S. No. 92-113 G; N.J. No. 50)

Monsour's, Inc., and Joseph C. Monsour, president, and **Peter T. Monsour**, secretary-treasurer, Pittsburg, Dist. Kans.

Charged 2-8-74 by grand jury: flour (count 1), cracker crumbs (counts 2 and 5), enriched flour (count 3), breakfast cereal (count 4), and cracker meal (count 6) were held in a building accessible to rodents, were exposed to contamination by rodents, and the flour (count 1) and breakfast cereal (count 4) were contaminated with rodent filth; 402(a)(3), 402(a)(4). The defendants pleaded not guilty and moved to suppress the Government's inspectional evidence on the grounds that, although the defendants had submitted to the FDA inspections they had not consented to the inspections. The defendants also sought to have the case tried in magistrate's court without a jury. The Government opposed. The court found as follows:

"Before the Magistrate is the question of whether or not the Government may, by refusing to consent, pursuant to Rule 23, Federal Rules of Criminal Procedure, to the trial of this case without a jury, prevent this case from being tried in Magistrate's court.

"The three defendants are jointly charged in each of six counts by Indictment charging six distinct and separate violations of 21 U.S.C. §331(k), i.e., permitting food to be held under [i]nsanitary conditions whereby it may have become contaminated with filth.

"The maximum penalty for a first violation of Section 331 is fixed by Section 333(a) of Title 21, United States Code, at not more than one year or a fine of not more than \$1,000.00, or both. This is a minor offense (18 U.S.C. §3401(f)) triable before a Magistrate if, in the words of Rule 2(c) of the Rules of Procedure for the Trial of Minor Offenses Before United States Magistrates, '... the defendant signs a written consent to be tried before the Magistrate.'

"The three defendants in this case have all expressed their desire, in open court, that this case be tried in Magistrate's court, and have indicated their desire to sign a written consent, pursuant to Rule 2(c) waiving trial before a Judge of the District Court and a jury. The Government, pursuant to Rule 23(a), FRCrP, refuses to consent to the defendants' waiver of a jury trial. This has the practical effect of forcing the defendants to a jury trial before the District Court. * * *

"Since the question of whether or not the consent of the Government is required in order to enable a defendant to waive a jury trial is not 'specifically covered' by the Magistrate's Rules, the Federal Rules of Criminal Procedure apply.

"Accordingly, the Magistrate finds that this is a minor offense case, 'required to be tried by jury' and that unless and until the Government consents to the defendants' waiver thereof, pursuant to Rule 23(a), FRCrP, it must be tried in the United States District Court before a jury."

The case came on for trial by jury in the U.S. District Court. Prior to trial, the court denied the defendants' motion to suppress. After trial the jury rendered verdicts as to both the corporation and the individuals of **not guilty**. (F.D.C. No. 59412; S. No. 41-152 F et al.; N.J. No. 51)

New Colonial Bakery, Inc., Nicholas Maisto, president, **Hamlet Maisto**, vice president, and **Peter Casarico**, secretary-treasurer, Trenton, Dist. N.J.

Charged 7-31-74: when shipped, bread and rolls had been prepared and packed under insanitary conditions; and flour was exposed to contamination by rodents and insects and was held under insanitary conditions; 402(a)(4). Guilty plea by corporation; fine. Guilty pleas by individuals; fines, suspended imprisonments, and probations. (F.D.C. No. 59484; S. No. 63-503 F et al.; N.J. No. 52)

Pacific Macaroni Co., Peter F. Vagnino, plant manager, and **George M. Horey**, plant superintendent, Los Angeles, C. Dist. Calif.

Charged 5-20-74: when shipped, spaghetti (count 2), labeled in part "American Beauty Spaghetti... American Beauty Macaroni Co.," had been prepared, packed, and held under insanitary conditions; and whole egg solids (count 1) had been held under insanitary conditions in a building accessible to rodents and insects, and had been exposed to contamination by rodents and insects; 402(a)(3), 402(a)(4). Nolo contendere pleas by individuals to count 1; fine and probation. Guilty plea by the corporation to counts 1 and 2; fine. (F.D.C. No. 59489; S. Nos. 45-830 F, 47-064 F; N.J. No. 53)

Paramount Bakery—Italian Bread, Inc., and Frank J. Pomic, president, Newark, Dist. N.J.

Charged 7-31-74: flour was held under insanitary conditions and was exposed to insect and rodent contamination; 402(a)(4). Nolo contendere pleas; fines. (F.D.C. No. 58896; S. No. 63-483 G; N.J. No. 54)

NOTICES OF JUDGMENT on Injunction Actions

Cross Brothers Meat Packers, Inc., and Samuel Cross, chairman of the board, and **Anthony Pugliese**, plant engineer, Philadelphia, E. Dist. Pa.

Charged 4-30-73 in complaint for injunction: that the defendants were engaged in operating a rendering plant at Philadelphia, Pa., manufacturing, processing, packing, holding, and distributing in interstate commerce, meat and bone meal (tankage) for use in animal feeds, which meat and bone meal contained the added poisonous and deleterious substance *Salmonella* microorganisms, and had been prepared, packed, and held under insanitary conditions; that FDA inspections had disclosed the existence of insanitary conditions and that the defendants had been warned of their plant's insanitary conditions; 402(a)(3), 402(a)(4). A consent decree of preliminary injunction was entered that enjoined the complained of violations, and enjoined the interstate shipment of any such meal until a number of specified conditions were met to assure that such meal was not contaminated with *Salmonella*; although the decree permitted for a limited period of time, the shipment of the firm's meat and bone meal to a de-

contamination facility for treatment and processing to destroy *Salmonella* microorganisms. Thereafter, the time for the defendants to comply with the terms of the preliminary injunction was extended several times in order for the defendants to make substantial alterations and changes in their plant, equipment, and procedures. Subsequently, the defendants moved to dissolve the consent decree of preliminary injunction because the firm had made extensive alterations to its plant and facility, had extensively revamped its procedures, and had complied with all of the requirements of that decree. The Government did not oppose the defendants' motion, and the consent decree of preliminary injunction was dissolved. (Inj. No. 631; S. No. 66-063 F et al.; N.J. No. 55)

Ravarino and Freschi, Inc., t/a Red Cross Macaroni Co., and Richard A. Zajac, registered agent, **William H. Kleveno**, a production manager, and **Alex Dobowski**, plant engineer, Chicago, N. Dist. Ill.

Charged 8-8-73 in complaint for injunction: that the defendants were engaged at their Chicago plant in preparing, labeling, and holding for sale, various macaroni products, in shipping such products in interstate commerce, and in holding for sale such products after shipment of some of their components in interstate commerce; which macaroni products bore or contained the nonconforming food additive Strobane (a pesticide chemical); and which macaroni products were manufactured, prepared, packed, and held under insanitary conditions, whereby they may have been rendered injurious to health; that, despite statements that the firm had stopped using a residual-type pesticide containing the pesticide Strobane early in 1973, had stopped using any residual-type pesticide in the spring of 1973, and had thoroughly washed and scrubbed the firm's walk-in dryers, FDA analyses of swabs subsequently taken from inside various dryers showed Strobane contamination of approximately 33 to 110 mcg per square foot and FDA analyses of some macaroni products showed as much as approximately 0.22 ppm of Strobane; and that the defendants were well aware of the violations; 402(a)(2)(C), 402(a)(4). A temporary restraining order was issued enjoining the complained of violations, which order was subsequently continued in effect upon consent of the parties. Thereafter, a temporary action level of 0.5 ppm for residues of Strobane was set by the Environmental Protection Agency. The temporary action level was subsequently rescinded and the defendants ceased the manufacture of macaroni products at the Chicago plant and began to dismantle their manufacturing equipment. The Government alleged that the defendants' machinery and devices (especially the wooden components thereof) were a possible and likely source of contamination of pasta products, and that further use of such machinery and devices was likely to result in contamination of such pasta products, and that the defendants should be enjoined from shipping or otherwise disposing of such machinery and devices without adequate safeguards. The court enjoined such disposition of the firm's manufacturing and processing machinery, including all dryers, drying rooms, and components, except under FDA supervision, providing that under no circumstances should any wooden components be used in the construction or reconstruction of any machinery, device, dryer, or drying room for the production of pasta products. Ultimately, upon defendants' assurances to the court of continued FDA supervision of the dismantling of equipment, the assurance that the wooden portions of the equipment would not be used for the manufacture of pasta, and assurance of the firm's cooperation for the three months until the firm vacated the Chicago plant building, the court dismissed the action without prejudice as far as the Government was concerned. (Inj. No. 654; S. No. 4-279 G et al.; N.J. No. 56)

Richlyn Laboratories, Inc., et al., Philadelphia, E. Dist. Pa.

Petitioned 11-2-72: that the court's order dismissing with prejudice the consent decree of preliminary injunction against Richlyn Laboratories, Inc., et al. (see N.J. No. 100 of Dec. '67/Jan. '68 FDA Papers) be vacated, that the case be reopened, and that the preliminary injunction be reinstated. Also petitioned for was an order to show cause why certain defendants in the injunction action should not be held in contempt based on three shipments of *Rauwolfia Serpentina* and one shipment of *Estrad-Gens*. Although the court ordered that its order dismissing the injunction action be amended by substituting the words "without prejudice" in place of the words "with prejudice," the court otherwise **denied** the Government's petitions, saying:

"On November 2, 1972, the present motion was filed. In support of the motion, the government urges that it was unaware of the status call, of the defendant's letter indicating the case was settled, and of the dismissal, until March 1972, when the Food and Drug Administration (FDA) 'discovered' the dismissal and recommended to the United States Attorney in Philadelphia that he move to reinstate the injunction. Appended to the government's brief are affidavits indicating that recent inspections of the defendant's plant have uncovered literally scores of deviations from the FDA's 'Current Good Manufacturing Practices,' which are published in the Code of Federal Regulations.

"The government asks us to draw upon our reservoir of equitable power, codified in rule 60(b)(6), to grant relief, where justice so requires, from the operation of a judgment. For the reasons that follow, we decline the invitation to exercise that power and deny the government's motion. Because the parties exhaustively briefed all issues raised by the motion, we will give only a succinct discussion of the several reasons for our decision, rather than review all the arguments expounded in the briefs.

"The government's delay in moving for finalization of the injunction resulted in the lawsuit's becoming stale long, long ago. The drugs and specific violations forming the basis of the complaint are no longer involved in the affidavits submitted to us, which relate to more recent violations. The government's current contempt petition is based on three shipments of *Rauwolfia Serpentina* in May and June of 1970 and one shipment of *Estrad-Gens* in January of 1971. These matters were not involved when the action was filed in 1964; indeed, neither of these drugs was involved in the original complaint, which referred to many other drugs. Thus, the facts alleged in the 1964 complaint and forming the basis for the consent injunction bear no relation to the facts existing eight years later when the motion to reinstate the injunction was filed. This state of affairs supports our conclusion that any further action by the government against the defendants can most appropriately be pursued in the context of a fresh lawsuit. In addition, we have serious reservations about the propriety and even the constitutionality of permitting the continuation for so long of a preliminary injunction so broad

that it might give rise to strict liability, i.e., liability without scienter, in criminal contempt.

"The government's delay of twenty months in moving to reopen the case after entry of a 23(b) order also militates against reopening. Surely one touchstone of our judicial system is the principle of the finality of its judgments. * * *

"The government's failure to comply with our status call order would of itself justify dismissal, even if we had not believed the case settled. We find that the United States Attorney's office did receive our three-page status call list. Furthermore, notice appeared in The Legal Intelligencer. Thus, although the dismissal under rule 23(b) was technically inappropriate . . . , under the circumstances, equity requires that it be allowed to stand. Indeed, the Court's power to dismiss a case in the circumstances presented here flows from several additional sources.

"First, we have inherent power to dismiss a case on our own motion for want of prosecution. See *Torino v. Texaco, Inc.*, 376 F. 2d 268 (3d Cir. 1967). Second, rule 41(a) authorizes dismissal on the defendant's motion for failure to prosecute or to comply with any order of court. Third, local rule 23(a) allows dismissal of an action in which no papers are docketed for two years—in this case, only the dismissal order interrupted a period of over two years without a docket entry. Want of prosecution is particularly burdensome to a defendant who remains under the force of a preliminary injunction.

"Furthermore, the suitability of rule 60(b) relief in this case is questionable. A maximum of one year is allowed for a motion based on rule 60(b)(1): 'mistake, inadvertence, surprise, or excusable neglect.' And 60(b)(6), 'any other reason justifying relief,' under which the motion must be brought 'within a reasonable time,' may not be used as a catchall to avoid the one-year limitation where 60(b)(1) applies. *Gambocz v. Elmer*, 438 F.2d 915 (3d Cir. 1971). Nor do we feel that the motion here was made within a reasonable time after discovery of the dismissal. As noted in the text, the government still delayed over seven months after we advised an FDA representative to file a motion. * * *

"Finally, and most importantly, it is patently obvious that no prejudice whatever will be suffered by the government as a result of our refusal to reopen the case. We fail to see the logic in the government's desire to exhume a stale injunction whose issuance resulted from facts that have long since changed. Indeed, even were we to reinstate the injunction, we would have doubts concerning the constitutionality of using contempt sanctions for unintentional failure to comply with a decree so broad as simply to recite a statutory standard. Recognizing that the dismissal could not possibly prejudice the government's right to proceed against more recent violations of law, the defendants have offered to agree to the modification of the dismissal to make it specifically 'without prejudice.' We will modify the order accordingly." (Inj. No. 488; S. No. 33-139 E et al.; N.J. No. 57)

NOTICES OF JUDGMENT on Miscellaneous Actions

Iodinated casein products, and new drug status thereof, suit for declaratory judgment and injunction, Kansas City, W. Dist. Mo., and suit for judicial review, U.S. Court of Appeals 8th Circuit.

Petitioned 5-3-72 in petition for judicial review by Agri-Tech, Inc., Kansas City, Mo., against H.E.W. Secretary Elliott L. Richardson: that the Agri-Tech, Inc., petitioned the court for review of the order of the H.E.W. Secretary withdrawing approval of two New Animal Drug Applications covering certain iodinated protein products. Subsequently, the petitioner moved for a stay of such order of the H.E.W. Secretary. The petitioner alleged that, at that time, the Food and Drug Administration was pursuing a course of action which promised to put the petitioners out of business before the court could act to review the issues before it, such actions including: a) institution of a seizure action of iodinated casein products at Florence, Ala., b) causing California State authorities to withdraw permission to sell and distribute iodinated casein products, and c) harassment and interference with purchasers and customers located elsewhere in the United States; that petitioner had for many years distributed and sold "iodinated casein" products; that petitioner's products had become so well established that they were no longer "new drugs"; that official procurements and authoritative compendia confirmed that such products were "not new animal drugs"; and that, despite such circumstances, FDA had not granted petitioner a hearing. The court granted a stay to the petitioner. Thereafter, the cause was submitted to a panel of judges of the 8th Circuit Court of Appeals. In denying Agri-Tech's petition to review, the court said:

"The statutory history and regulatory scheme are discussed and considered in *Weinberger v. Hynson, etc.*, . . . hereinafter referred to as *Hynson*). Therefore, another full recitation of the applicable statutes and regulations is unnecessary. We will, however, discuss the pertinent provisions of the legislation in our consideration of the issues which petitioner continues to urge upon us.

"By way of background, petitioner has for approximately 25 years distributed and sold in interstate commerce products for animal feeding purposes containing 'iodinated casein,' also known as Protamone. For some years subsequent to 1945, animal applications of 'iodinated casein' were the subject of new animal drug applications, specifically, NADAs Nos. 5-633V and 5-987V, respectively. The applications had been approved by the United States Food and Drug Administration.

"In 1962, Congress amended the Food, Drug and Cosmetic Act to expand jurisdiction of the Commissioner of the Food and Drug Administration to allow review of 'new drugs' for substantial evidence of both safety and effectiveness. . . .

"To effect the provisions of the 1962 amendment, particularly 21 U.S.C. §355(e), the FDA by notice in 31 Fed. Reg. 9426 on July 9, 1966, announced that the National Academy of Sciences-National Research Council (NAS-NRC) had agreed to assist the FDA in its review of claims of effectiveness for drugs that had been approved from 1938 until October, 1962. All holders of NDAs were directed to submit data to NAS-NRC in order to facilitate or determine whether there was ground for invoking § 505(e) of the Act, and to provide each holder of an approved new-drug application an opportunity to present for the consideration of NAS-NRC the best data available to support the claims.

"Petitioner responded to the notice by submitting data for each 'iodinated casein' product on a 'Drug Efficacy Study-Form Letter A.' . . .

"In support of these claims [for improvement in production etc., of various food animals] petitioner submitted with these Forms A various citations to and reprints of studies allegedly evidencing the claims of effectiveness. The NRC then reviewed these data, and revealed its detailed reasoning on Forms B-1, which appear as a part of the official record filed in the office of the clerk of this court, but not in the Appendix. Apparently, petitioner never received the Forms B-1, but only the Forms B-2, which contain only the NRC's ultimate findings, and the FDA Notice of Hearing, . . . which summarized these findings. * * *

"Following this NRC evaluation of the data submitted by petitioner, the Commissioner published on October 8, 1970, at 35 Fed. Reg. 15859 his findings based upon the NRC evaluation. They were:

"1. Iodinated casein is effective for increasing daily gain in growing ducks and increasing milk production in dairy cows.

2. Information provided does not contain substantial evidence of effectiveness of iodinated casein for improving fertility in bulls; increasing milk production in goats, beef cows, and sheep; in improving fertility in boars, goats, and sheep; and for improving rate of gain in dairy cattle, sheep and goats.

3. Iodinated casein is not effective for improving growth and feathering in turkeys and chickens; increasing milk flow in nursing sows; or improving egg production and eggshell texture in chickens."

"As to the uses found effective, the NRC and FDA found the label should qualify the claims by informing the user as follows:

"1. The claim for increased milk production in dairy cows should be qualified as follows: (a) Effective for limited periods of time, (b) effectiveness is limited to the declining phase of lactation, (c) administration must be accompanied with increased feed intake, and (d) may increase heat sensitivity of the animal.

2. The claim for improving growth and feathering in growing ducks should state "increases daily gain"."

"This order gave petitioner six months in which to alter its labeling to conform to these findings or submit additional evidence of efficacy. **Petitioner did neither.** Instead, its technical counsel wrote the FDA on March 22 and April 13, 1971, requesting the Forms B-1 of the NRC studies.

"Upon expiration of the six months, the Commissioner entered a Notice in the **Federal Register**, 36 Fed. Reg. 17367 (Aug. 28, 1971) proposing to withdraw petitioner's NADAs for iodinated casein pursuant to §512 of the Act, 21 U.S.C. §360b(e), on the grounds that there is a lack of substantial evidence of its effectiveness for its labeled purposes. . . .

"Subsequently, petitioner filed an Appearance and Request for Hearing, **but did not file** the requisite 'well-organized and full-factual analysis of the clinical and other investigational data they [were] prepared to' present at the demanded hearing.

"Instead, petitioner's request for a hearing and a subsequent letter declared it sought to prove at that hearing (1) that Protamone is generally recognized as effective, is therefore not a new animal drug, and thus is exempt from the statute; (2) that pre-1962 letters from the FDA certify Protamone is not a new drug; (3) that the FDA order withdrawing such pre-1962 letter opinions is invalid and [/] or inapplicable; (4) that the withdrawal procedure is defective because (a) there was no 'new information' before the Commissioner to warrant activation of the withdrawal procedure, (b) the failure to reveal fully the NRC's findings (i.e., the B-1 forms) violates due process; (c) the NRC study itself found Protamone effective for some uses; and (d) there were no NRC reports on petitioner's other thyro-protein products, Mom Sow Milking Tablets and Stimulac Pellets.

"Thus, petitioner offered to reveal at the hearing no clinical evidence, but rather demanded an evidentiary hearing on the foregoing questions of law and demanded access to the B-1 forms of the NRC before such a hearing. Consequently, on March 4, 1972, the Commissioner published the order **sub judice**, 37 Fed. Reg. 4730, denying a hearing on the proposed withdrawal and withdrawing approval of petitioner's NADAs for 'iodinated casein' products * * * .

"From the outset of this controversy, petitioner has adamantly insisted that the data and material it submitted to the NRC for review on Forms A, above referred to, were sufficient to constitute compliance with the statutory requirements essential to prevent withdrawal of a new animal drug application. . . .

"But the undeniable fact is that at no time did petitioner adhere to the mandate of the statutes and the regulations promulgated by the Commissioner by filing a well-organized factual analysis of the clinical and other data that it was prepared to prove in support of its opposition to the withdrawal of its drugs. Petitioner endeavored to justify its non-compliance by postulating that the burden of proof rested upon the Commissioner to prove at an adversarial hearing the deficiencies in the data and material submitted in support of its drug-efficacy study forms 'A.' That is to say, petitioner argues that before it was required to submit any additional scientific data, it was entitled to a hearing at which the Commissioner was required to prove why the material submitted by petitioner did not constitute substantial evidence of the efficacy of its products. And, it also argued that it was entitled to a copy of the NRC B-1 reports and the names of the members of the panel constituting the reviewing board. But there is no caselaw to support petitioner's position. To the contrary, it has been held that in enacting the 1962 statute, Congress placed the burden of proving efficacy upon the manufacturer of the product. . . .

"Furthermore, the Supreme Court, contrary to petitioner's contention, held that the regulatory scheme does afford an applicant due process: 'There can be no question that to prevail at a hearing an applicant must furnish evidence stemming from "adequate and well-controlled investigations." We cannot impute to Congress the design of requiring, nor does due process demand, a hearing when it appears conclusively from the applicant's "pleadings" that it cannot succeed. * * * . *Hynson*, . . . (Emphasis supplied.)

"Although petitioner also argues that it is entitled to a hearing before the Commissioner on the question of whether or not its product constitutes a new animal drug within the meaning of the Act, we regard the *Hynson* case as dispositive of that issue. In *Hynson*, the Court held that if there is not 'substantial evidence' of the drug's effectiveness, it cannot be considered generally recognized as effective. *Hynson* clearly holds that the initial determination whether a drug is a new animal drug is within the

jurisdiction of the Commissioner and he may summarily deny a hearing on the issue whether a drug is 'generally recognized' and therefore exempt from the withdrawal provisions if he finds there is no 'substantial evidence' raising an issue of fact. . . .

"In summary, we hold that petitioner failed to comply with the regulatory provisions for the withdrawal of approval of its NADAs and thus, it failed to fully exhaust its administrative remedies. We do not find any authority in this area of the law to sustain petitioner's contention that it was entitled as a matter of right to a hearing on the record that it filed for review by the NRC.

"We further hold that there is no substance in petitioner's claim that the Commissioner lacked authority to withdraw its NADAs as to those products which had been found effective. The drug applications in question covered all of the products and, under the clear terms of the statute, when the petitioner failed to follow the prescribed procedures, the Commissioner was fully authorized to withdraw the approval of the NADAs in their entirety."

The petitioner petitioned the Court of Appeals for a rehearing and for a continuation of the stay of the order of the H.E.W. Secretary. The petition for a stay was opposed. Thereafter, the Court of Appeals denied the continuation of the stay and denied the petition for rehearing.

Charged 7-12-72 in complaint for declaratory judgment and injunction by Agri-Tech, Inc., Kansas City, Mo., against H.E.W. Secretary Elliot L. Richardson, and FDA Commissioner Charles C. Edwards: that for many years and prior to October 9, 1962, plaintiff had distributed and sold in interstate commerce various products for animal feeding purposes containing so-called "iodinated casein" for various uses for animals such as dairy cattle, ducks, chickens, turkeys, swine, sheep, and goats; that certain animal applications of iodinated casein were initially the subject of New Drug Applications; that, as time went by and wide usage of such products continued in the field and throughout the United States, the function and purposes of such products became so well established that they were no longer regarded as "new drugs"; that FDA had confirmed the "non-new drug" status of such products on various occasions, including three specified communications from FDA officials addressed to the plaintiff; that authoritative compendia had confirmed such status; that plaintiff's iodinated casein products were commercially used or sold as of October 9, 1962, and were thereby protected by "grandfather rights"; that, alternatively and separately, the iodinated casein products were, and had been for many years, "old drugs"; that, despite the above, the defendants had purported to order withdrawal of the iodinated casein products (a circumstance concerning which plaintiff had petitioned the U.S. Court of Appeals for the 8th Circuit for a review) with immediate and irreparable damage to plaintiff's business activities; and that plaintiff sought that their iodinated protein products be declared not "new drugs" and the FDA order of no legal effect, and sought that the defendants be enjoined from interfering with the interstate sale and distribution of the plaintiff's products.

The defendants moved to dismiss on the ground that the District Court lacked jurisdiction, because the plaintiff's request for a hearing was pending before the 8th Circuit, which thereby had exclusive jurisdiction over the matter. The plaintiff moved that the action be stayed pending adjudication of the matter presented to the Court of Appeals for the 8th Circuit, and the defendants did not oppose such motion. After the Court of Appeals had rendered its opinion in the 8th Circuit action, this action was dismissed with prejudice, as being moot. (Misc. Nos. 190, 195; N.J. No. 58)

Mastitis multiple ingredient antibiotic drugs, and decision as to hearing on regulations revoking certification thereof, Washington, Dist. Columbia.

Charged 4-25-72 in complaint for stay of FDA order and for mandamus, by Pharm-House, Taftville, Conn., Animal Health Co. of Minnesota, So. St. Paul, Minn. and eleven other manufacturers and distributors of intramammary infusion products for treating inflammation within the mammary glands of milk-producing cows, against FDA Commissioner Charles C. Edwards, Associate FDA Commissioner Sam D. Fine, and the Food and Drug Administration: that the defendants published an order revoking certain food additive regulations and antibiotic certification provisions providing for intramammary infusion products for mastitis; that the plaintiffs filed timely objections to the order, with a request for a hearing and a motion for a stay of the order; that the defendants had neither granted nor denied the plaintiffs' request for a hearing, but had denied the plaintiffs' motion for a stay; that since the defendants' order was in effect, certain of the plaintiffs' products were barred from interstate commerce and such bar continued throughout whatever time period the defendants might take to determine the plaintiffs' right to a hearing; and that defendants owed it to the plaintiffs to rule upon their request for a hearing quickly, and, if for a time the defendants were unable to rule as to a hearing, then due process required that the order be stayed until such a ruling was made. The plaintiffs moved for an early hearing on the merits. The defendants moved to dismiss, or in the alternative for summary judgment of dismissal, on the grounds: (1) that the request for a hearing had been denied thereby making moot much of plaintiffs' action, (2) that insofar as the plaintiffs' complaint sought a stay, mandamus would not lie, (3) the court lacked jurisdiction to enter a stay, and (4) the complaint did not allege sufficient grounds for a stay. Subsequently, the parties stipulated that the Agency action requested by plaintiffs had been granted, and that, therefore, the case was moot. Accordingly, the action was dismissed. (Misc. No. 189; N.J. No. 59)

Methadone Maintenance Center's Investigational New Drug Exemption, the termination thereof, Chicago, N. Dist. Ill.

Charged 4-12-72 in complaint for injunction by Gerald McCabe, sponsor of Methadone Maintenance Center, Chicago, Ill., against the Department of Health, Education & Welfare and FDA Bureau of Drugs Director Henry E. Simmons: that the Methadone Maintenance Center was treating nearly 500 patients who had been previously addicted to heroin and were being treated by the use of the investigational new drug Methadone; that on April 12, 1972, without notice, warning, or hearing, plaintiff was informed that his exemption was terminated; that Federal regulations required notice to a sponsor of any irregularities in his program, invited his correction or explanation, provided for a conference with the Bureau of Medicine and provided for an informal hearing on the question of whether the exemption should be terminated; that Federal regulations also provided that, where an imminent hazard to public health was found, the exemption might be terminated forthwith, but the sponsor should be informed that the exemption

was subject to reinstatement on the basis of additional submissions that would eliminate any hazards, and the sponsor was to be afforded an informal hearing on the reinstatement of the exemption; that the plaintiff had not been granted an informal hearing or informed of his rights by the defendants and they had not stated the basis for a forthwith termination; and that plaintiff's patients and the plaintiff would suffer irreparable injury unless the defendants were enjoined from enforcing their order.

The court granted the plaintiff a temporary restraining order. Thereafter, FDA rescinded its previous order and issued a new order terminating the plaintiff's exemption, on the grounds that the investigation presented an imminent hazard to the public health, reciting in detail the grounds for the action, and advising of the opportunity of an informal hearing. The Government also moved to dismiss the action and to deny the plaintiff's motion for a preliminary injunction. The court continued the temporary restraining order for several additional days so as to include time for plaintiff's hearing and the findings of FDA thereon. After the hearing, FDA advised the plaintiff that he had 30 days to conform his methadone maintenance program substantially to a recently published regulation governing methadone maintenance programs, that within 60 days his program was to be free of major deficiencies, and his program was to adhere in all respects to the model protocol within 90 days. Thereupon, upon motion of the plaintiff with agreement of the defendants, the action was dismissed and the plaintiff's bond was ordered released.

Charged 9-22-72 and amended 10-4-72, in complaint for injunction by Gerald E. McCabe against H.E.W. Secretary Elliot L. Richardson, FDA Commissioner Charles C. Edwards, and FDA Bureau of Drugs Director Henry E. Simmons: that on September 18, 1972, without a hearing, plaintiff received an FDA notice terminating his methadone exemption. The court issued a temporary restraining order pending the holding of a hearing by FDA. Pursuant to regulations, an informal conference was held by FDA with the plaintiff. Thereafter, FDA ordered the plaintiff's investigational New Drug application terminated. The plaintiff filed another motion for a temporary restraining order and an amended complaint for injunction charging that the plaintiff had been denied due process of law by the so-called hearing that he had been given. The Government moved to dismiss. After the court heard the Government's motion to dismiss and the plaintiff's motion for a temporary restraining order, the court ruled in favor of the Government, saying:

"This is an action for review of a decision by the Food and Drug Administration. The case was dismissed by Judge McLaren and was subsequently transferred to this Court. Plaintiff has now filed a motion to vacate the order of dismissal and requests leave to file a second amended complaint.

"Plaintiff has operated a Methadone Maintenance Center under an Investigational New Drug Exemption granted by the Food and Drug Administration pursuant to Section 355(i) of Title 21, United States Code. This exemption was terminated on September 30, 1972, after an informal hearing as required by 21 C.F.R., Section 130.3 and as ordered by Judge McLaren. Plaintiff now alleges that he was not given a due process hearing. The sole question before this Court is whether the order of dismissal should be vacated. Dismissal was based on lack of jurisdiction owing to plaintiff's failure to exhaust his administrative remedies. That decision was based upon the principle first announced in *Turkel v. Food and Drug Administration*, . . . and later adopted by another Judge of this District in *Rutherford v. American Medical Association*, . . . As stated by Judge Decker of this Court at page 5 of the unreported decision in *Rutherford*:

Even if the FDA were to act arbitrarily, unfairly, or on the basis of a mistake of law, resort to a United States District Court is not permitted. The entire regular course of appeal from FDA action must first be employed. In this case, since direct appeal from a holding that a §355(i) (Investigational New Drug Exemption) application is insufficient cannot be taken, Krebiozen's sponsors would have to file a §355(b) application. If that were denied, then the sponsors could appeal FDA action under both §355(i) and §355(b) in the appropriate Court of Appeals. §355(h). . . .

"We concur in that result as reached by the *Turkel* Court, by Judge Decker in *Rutherford*, and by Judge McLaren in this case."

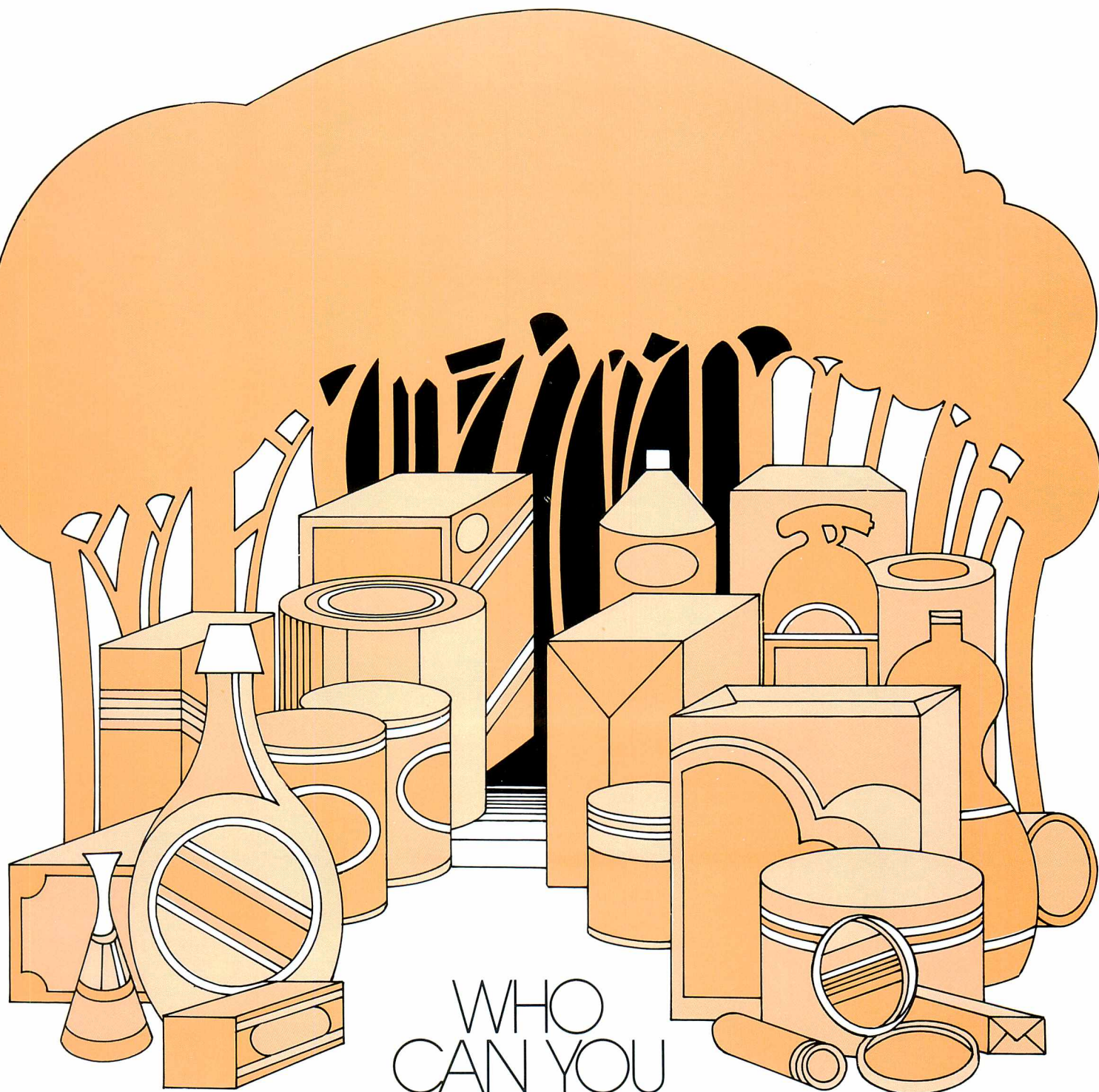
Subsequent motions by the plaintiff for a preliminary injunction for reconsideration, for leave to file a second amended complaint, and for vacating of the dismissal of the action were denied by the court. (Misc. No. 187; N.J. No. 60)

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

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

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Alexander M. Schmidt, M.D., *Commissioner of Food and Drugs*
Washington D.C., July 1, 1975



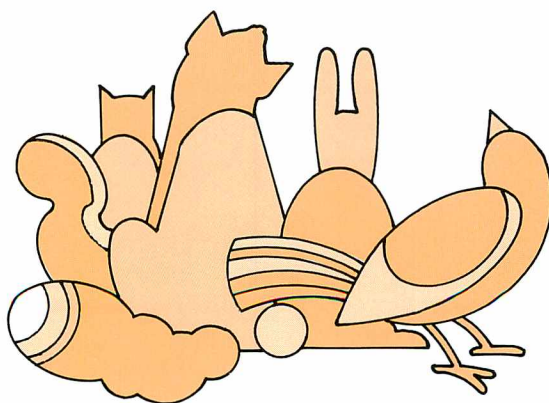
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