NEW DIRECTIONS IN IMPORT COVERAGE

THE VETERINARIAN AND DRUG EXPERIENCES

Botulism

PROVING SAFETY OF FOOD ADDITIVES
The incidents in 1971 involving botulinum toxin in commercially processed foods, although regrettable, have brought to public attention once again how extremely potent is this foodborne poison and how a single instance of carelessness, accident, or error in canning and some other food preservation techniques can result in tragedy.

Because Americans depend more and more on foods that are commercially processed and ready to eat, it is fortunate that the food processing industries for many years have been well aware of the potential dangers of botulism and have developed safe methods of processing that when properly followed reduce the possibility of botulinum food poisoning from commercial products practically to zero.

But many householders still preserve some of their own foods and some of them fail to follow recommended canning and other preservation procedures that have been found to assure protection against botulism and other food poisoning or infections. Thus, most outbreaks of botulism are still caused by foods improperly preserved in the home.

Although neither FDA nor any Government organization can be responsible for how a householder preserves foods for his own use, this Agency believes that those who prepare or process foods—in industry and the home—should know more about botulism in general and the precautions that should be taken to avoid botulinum poisoning. The article in this issue (see page 16) is aimed toward that end.
One step being taken is the shift of emphasis in inspection from production to management of production, which is to say quality control. This is a way of apportioning the effort invested by FDA to supplement rather than duplicate the control being exercised by the industry. This is what we are terming Cooperative Quality Assurance. Where inspection shows the plant to have good quality control, that plant can be encouraged to come into the self-certification program, which substitutes paperwork for much of the physical and end-product inspection. Where deficiencies in quality control are identified, these can be given emphasis in further surveillance, with other factors diminished in emphasis.”

Virgil O. Wodicka, Ph.D., director, Bureau of Foods, for delivery to the National Association of Margarine Manufacturers, New Orleans, December 3, 1971.

On November 12, 1971, we published in the Federal Register a proposal of the National Canners Association for the issuance of a Statement of Policy. A series of specific requirements are proposed. These would facilitate the prompt application, when necessary, of the emergency permit provisions of Section 404 of the Federal Food, Drug, and Cosmetic Act. Commercially processed foods for human consumption would be covered. Under this far-reaching proposal, all food canners would be subject to registration with the Food and Drug Administration. The appendix attached to the National Canners Association’s proposed Statement of Policy actually sets forth detailed Current Good Manufacturing Practices for the canning of foods. We have allowed 60 days for comment on NCA’s proposal.”

Charles C. Edwards, M.D., Commissioner of Food and Drugs, for delivery to the 15th annual Joint Educational Conference, Food and Drug Law Institute-Food and Drug Administration, Washington, December 7, 1971.
New Directions in Import Coverage  New techniques and expansion in imports call for new methods to protect the consumer.

The Veterinarian and Drug Experience Reporting  Encouraging veterinarians to report on unusual or adverse effects of animal drugs.

Proving the Safety of Food Additives  The problems of conducting tests and assessing scientific data needed to assure safety of food additives.

Botulism  Some facts about how this deadly poison is produced in some preserved foods and how we can protect ourselves from it.

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New Directions In Import Coverage

by Richard Klug

Imported products have increased in dollar volume by 65 percent within the past ten years. They currently represent 12.5 percent of the $200 billion total spent by the American consumer on products whose processing or distribution or both are subject to regulation by the Food and Drug Administration.

Changes also have occurred in foreign trade and shipping. For example, imports formerly consisted in large part of raw materials that received further processing at a plant in the United States and subsequent inspection by FDA. Today imports consist more and more of ready-to-buy consumer products that receive no further processing. With some exceptions involving specific drugs, FDA does not inspect foreign firms as it does domestic ones and therefore the coverage or inspection of imports is restricted to the product itself.

Increased use of air freight and containerization has greatly increased the flow of imports through our entry ports. Containerization is the practice of shipping cargo in large, rugged, standardized size and shape boxes or vans from the exporting manufacturer's plant directly to the city of final destination in the importing country.

In January 1971 FDA's Office of the Executive Director of Regional Operations (EDRO) began developing a new program for coverage of imported products. EDRO directs and manages the operations of FDA's regional offices. These regional office operations are designed to obtain compliance with laws and regulations enforced by FDA through appropriate educational or enforcement activities. These include inspections and investigations, collection and analysis of samples, and the initiation of appropriate enforcement actions. Coverage of imported products is included in these operations.

The EDRO field import coverage strategy developed early in the calendar year 1971 drastically alters and in some cases abandons traditional operating procedures to cope with the increasing import traffic and changes in foreign commerce and shipping technology. The new direction consists of three major groups of activities: Administrative and procedural, state-side, and overseas. Two of the more important individual programs include the Ship-to-Ship method of imports coverage tested by New York District's International Section and the "Circuit Rider" program tested by Dallas District.

Administrative and Procedural Activities. The establishment of an import operations coordination office in EDRO is complete. This office will provide uniformity of import procedural operations, coverage, and enforcement; a central point for rapid dissemination of information; more efficient and proper use of resources; coordination of import activities with the Bureaus for program guidance; and management of the implementation and operation of the strategy.

The possible use of a new standardized reporting form (Report of Import Entry—RIE) is being considered. The new form, in addition to providing FDA with complete notification of entries of products it regulates, would replace four official forms, numerous unofficial forms, rubber stamps, and some other materials now in use; this form would save considerable time in the collection of import samples annually, would be a complete daily workload source, and would become a data resource document.

The possible development of a new FDA import data reporting system (data bank) is also under consideration for future use. This system, using the RIE, would identify FDA's total import workload as to commodity, problem, volume, country of origin, importer, and district. It would also be used to record accomplishment and enforcement data.

Stateside Activities. The use of mobile laboratories for import coverage is being and will continue to be tested. It is anticipated that mobile laboratories will greatly expand FDA's coverage. A weakness of the traditional program is the inability of laboratories to handle the number of analyses of import samples generated by the inspection staffs. The use of small, maneuverable, mobile laboratories, operated by inspectors and inspector technicians who have been trained to perform sanitation and economic examinations, may help to solve this problem. Through this approach the sanitation and economic samples collected annually can be examined right on the pier with no additional inspector manpower. In addition the analyst would be freed to use his talents more efficiently on complicated methods.

Ship-to-ship coverage of imports has been under study in a pilot test and preliminary results are promising. This involves actual field examination of more imported products instead of the mere review of entry documents to determine what lots are to be sampled.
Ship-to-Ship Coverage

by Frank Bruno

Although the idea of ship-to-ship coverage of imports is not new at FDA, it was never tested as a total concept until April 1971 when a pilot study was undertaken in a limited area of the port of New York. The objective was to determine if the scope of import coverage could be expanded to keep pace with the changing modes of cargo transportation without expanding the available manpower resources.

Under the traditional method, import commodities are covered by the preselection of consignments on the basis of review of U.S. Customs entry documents. This sometimes resulted in inspectional and analytical manpower being allocated to nonviolative products while unobserved, noncomplying consignments entered food channels through a "release without examination" action.

With the ship-to-ship method, the import inspector is placed at the point of discharge, a pier, airport, or container terminal, so he may inspect, examine, and/or sample cargo as it is discharged from its carrier. His determinations as to which import products require his attention for adulteration or misbranding are made from actual visual observations instead of review of documents that merely identify the importation and its ownership. Thus, a wider range of suspect imports come under his scrutiny for possible violations. This method requires the inspector to perform basic examinations in the field for all commodities suitable for field testing. It obviates the need for sampling of many commodities for laboratory examination and thereby frees the analysts to perform the more complicated analyses with their more sophisticated instrumentation. Stationing the inspector at the point of discharge where he can view the actual commodities places him in an advantageous position to detect cargo that has undergone physical damage or adulteration from polluted harbor water or spillage of toxic chemicals.

Aiding this new technique, modestly equipped mobile laboratories are used by the inspectors to increase their field examination capabilities and provide atmosphere and environment conducive to conclusive on-the-spot field examinations.

Ship-to-ship coverage is one way to keep in step with the modern trend toward rapid and uninterrupted movement of import cargo from origin to destination. The on-the-spot coverage it provides for many commodities is a boon to the importer, who demands the fastest possible delivery of his import shipment. Conclusive field analysis by the inspector expedites the clearance of those consignments that are in compliance and reduces the probability that the importer will have to pay needless demurrage charges.

The ship-to-ship pilot test by New York District has proved most gratifying. Coverage of imports increased over 200 percent as compared to the traditional method of operation. During the three-month test approximately 3,000 actions were completed as compared to the normal average of 900 actions.

The use of an import "Circuit Rider" program is now under study. It will extend our coverage to the remote ports not previously covered regularly. This program will also expand our information about these outlying entry ports. Regular but not prescheduled visits to these remote ports will permit FDA to improve local FDA/U.S. Customs relations, check products entering these ports, and advise Customs officials of current priorities and problems.

‘Circuit Rider’ Coverage

by Raymond V. Mlecko

Dallas District initiated the circuit rider imports coverage program in the Laredo District of the U.S. Bureau of Customs on August 9, 1971. Laredo District extends along a 390-mile stretch of the Texas-Mexico border and contains eight ports that process import entries that are subject to the laws enforced by the Food and Drug Administration. Each port specializes more or less in different commodities. For example, the port of Brownsville handles more than 2,800 entries of shrimp and fish products a year; the port of Hidalgo annually processes more than 6,200 entries of fresh fruits and vegetables; the port of Laredo is the main entry point for frozen strawberries.

During the week of August 9, FDA imports inspectors visited five of these ports. A specific FDA/Customs agreement was subsequently worked out at each port as to the method by which Dallas District will be notified of entries, types of entries from which Customs will take samples, and other elements. The agreements are specific for each port and the details will depend on such facts as the commodities entered and past relationships with Customs.

Based on our initial visit with Customs, these points became apparent:

• Most of the port directors and their staffs were pleased that FDA is now taking a more active role in regulating entries through their area.
• Customs officials at each port were aware that certain importers are making informal entries of foodstuffs and then consolidating the merchandise on the U.S. side for subsequent shipment. They stated that they require formal entries to be filed in these cases if they know that the merchandise is suspect.
• Laredo District has experienced a marked increase in food imports in recent years and a continuing increase is anticipated.

During the past seven weeks our circuit rider program has been operational, the immediate results have been gratifying. Some of these:

• At the port of Laredo, small informal entries of pottery (under $250 value) had entered the United States. However, Customs is now requiring that formal entries be filed for certain types of pottery shipments under $250 in value. Since Mexican pottery is relatively inexpensive, a large amount can be brought into the
A mobile laboratory (above left), equipped with basic analytical instruments for performing field examinations, arrives at a work site where a cargo vessel is ready to begin discharging imports. Inside the mobile laboratory (above right), the inspectors are performing a conclusive field examination for net weight of canned pineapple. Core material in canned pineapple is being checked (middle right) to determine if the amount present is within the established standard. A team of inspectors are performing an organoleptic examination of imported frozen shrimp (below right) after it has been made amenable to testing through a thawing process in the mobile laboratory. A shipment of cocoa beans is being sampled (below left) in preparation for an immediate examination in the mobile laboratory for an on-the-spot determination for compliance.
A search for suspect pieces intended to hold foods is being conducted in the contents of a case of pottery (above left) to carry out a field test that will disclose the presence of any amount of lead or cadmium. A reading is being taken (above right) after a qualitative chemical analysis was performed with a newly developed field test kit that indicates the presence of lead or cadmium in pottery. Although a labeling examination is being made (middle left) on a shipment of canned food, the inspector's primary concern is a search for abnormal tins which may indicate the need for a microbiological analysis in the District laboratory. An official sample is being collected (below left) for confirmation by the District laboratory of a defective seam condition detected in a shipment of canned goods.

country at a small cost. Our experience has shown that much of the inexpensive type of Mexican pottery may be highly adulterated with leachable lead in excess of the current guidelines. On September 28, 1971, Dallas District detained 1,422 toy earthenware pitchers because of excessive leachable lead content. The shipment was valued at $94 but Customs required the filing of a formal entry.

- At the port of Brownsville, Dallas District detained 96,816 pounds of frozen strawberries on September 27. This product was packed in 10- and 16-ounce packages, and the principal display panels did not bear a net weight statement as required by regulation under the Fair Packaging and Labeling Act. The sample on which this action was taken was collected by an FDA inspector while riding the "circuit."

- In recent weeks we have received numerous inquiries from importers about how to meet compliance requirements under law due to the increased coverage afforded by FDA's new circuit rider program. We believe this program will bring about a greater degree of voluntary compliance as importers realize that we are now checking more entries.

In general, we believe our circuit rider program is working well. We are receiving cooperation from Customs and brokers and there is no question that importers know that surveillance has increased. It is evident that FDA's periodic visits to the various ports are beneficial in alerting Customs to problem commodities that should be sampled in our absence. We believe our increased coverage will result in more detentions of noncomplying products, greater voluntary compliance, and most important, better consumer protection.

We intend to improve and update our coverage of containerized imported products. This technological and procedural innovation of handling cargo presents problems because inspection and sampling of merchandise in containers requires that the container be opened. However, FDA's obligation to the consumer must never be waived solely because of hardship to the importer. We intend to establish liaison with containerization centers and container users, maintain "inspection stations" at the centers, and pre-select commodities for coverage from our proposed RIE form to expand our coverage.

The development of cooperative agreements with industry groups will be encouraged. Formal, national agreements with strong industry groups which spell out the responsibilities of each party will promote voluntary compliance, reduce FDA coverage of the articles under agreement, and allow more FDA resources to be diverted to high priority import areas.

Saturation sampling of problem commodities will expand our coverage and should induce correction of specific problems by foreign shippers. A coordinated, national effort of this type would demonstrate that FDA's import policy is uniform; would open lines of communications with importers, trade groups, and foreign shippers and consulates, increasing the possibility of voluntary compliance; and would lead to invitations to FDA to inspect foreign establishments and thus greatly broaden our coverage.

**Overseas Activities.** FDA will seek to encourage expanding foreign consultative type inspections, where requests for inspection and consultative advice are received, especially in the area of foods where a specific problem exists, and where foreign funds are made available to underwrite costs. The possibilities of FDA consultative inspections of foreign food processing plants are often suggested during importer hearings after District detentions, at conferences with importer associations and trade groups regarding problems causing multiple detentions, in discussions with commercial attaches and foreign consular representatives after multiple detentions of products, and during visits from foreign government officials. These suggestions will be explored.

FDA foreign consultative inspections offer advantages: Resolution of violations at the source can, through helpful recommendations, bring about rapid correction. A well planned consultative trip can reach a whole industry, country, or area and thereby broaden our coverage. Mutual exchange of information and cooperation with foreign government counterparts of FDA can be enhanced.

The Food and Drug Administration will also explore ways to increase the number of cooperative agreements with foreign governments so that the policing of products coming from those countries can be shared, thereby reducing the need for FDA surveillance of the products under agreement. All agreements will be formal, national in scope, and will set forth the responsibilities of each party.

Plans for implementation of the import coverage strategy are now under full momentum. As previously mentioned, the ship-to-ship and circuit rider methods are presently under pilot study. As the foregoing reports on these programs indicate, their initial results are quite encouraging. New York District has already determined that even a mobile laboratory that is not self-contained and that is equipped with only basic analytical equipment is proving useful in its import operations, especially in the ship-to-ship program. FDA has purchased its first three completely self-contained mobile units that can expand the number of analytical methods that can be performed in the field and thus can produce even better results. Delivery of these first units is expected by January 1, 1972.

Specific operating procedures for many of the programs in the strategy are being established. An initial conference for formal implementation of the strategy is planned for early January 1972.

As the world of imports changes, so must FDA's coverage, if it is to keep in step. We believe the new EDRO/field import coverage strategy is a change that will keep us abreast of new transportation technology and will afford the kind of protection concerning imported products that the American consumer has learned to expect in the domestic food and drug supply.
Two years ago, a practicing veterinarian observed signs of laminitis in horses he had treated with a corticosteroid product. The horses were being treated for either arthritis or tendonitis, and developed laminitis after treatment.

The practitioner notified the drug manufacturer, and talked to other veterinarians who had also observed signs of lameness and inflammation in horses treated with this product.

Since the drug had been marketed for several years, the manufacturer was required by law to make an annual report of drug experiences to the Bureau of Veterinary Medicine. Such reports as the veterinarian's are included in these company reports.

After receiving the drug firm's periodic report for the corticosteroid product, the Food and Drug Administration obtained additional information by interviewing many practicing veterinarians who had observed adverse effects among horses from use of this product. FDA also searched the literature on laminitis for any reference to this problem, but found none.

As part of the investigation, BVM asked the FDA District where the drug company was located to make an inspection of the company's complaint file on the product to check on other adverse reaction reports. The law requires that a manufacturer must establish and maintain a complaint file at his place of business.

As a result of the information provided by veterinary practitioners, the firm voluntarily revised the labeling, which was submitted to FDA and subsequently approved.

Demonstrating the application of a pesticide to kill cattle grubs is Walter L. Graves, D.V.M., chief of the Surveillance Branch of the Division of Veterinary Medical Review. In this method of application the solution is poured over a beef animal's back to kill insect larvae under the skin. The animals may be tied singly for treatment or driven through a chute, as shown, for faster handling.
Examining a horse for arthritis are H. Dwight Mercer, DVM, deputy director of the Division of Veterinary Research, with Silas L. McHenry, Ed.D., industry information officer.

The new labeling includes these precautions: "Corticosteroids have been used in the treatment of laminitis. (This product) is not recommended for this use. Cases of laminitis have been reported following the administration of (this product). Care is necessary when using any corticosteroid in the equine species." Because the reactions to this drug occurred at the higher dosage levels, the maximum recommended dosage in the labeling was reduced.

These changes improved the safety of the product usage—due to the alertness shown by practicing veterinarians and prompt follow-up by FDA.

When a New Animal Drug Application is approved, it often is not possible to foresee all the problems that might be encountered in the routine use of a product by different individuals under various conditions. It soon becomes apparent that reporting of experience by users is essential to bring about any necessary changes to increase the safety and efficacy of veterinary drugs.

The Food and Drug Administration considers it extremely important that veterinarians report to FDA any adverse drug reactions or unexpected responses associated with the clinical uses of a drug. A general rule might be that an unexpected response or an adverse reaction is one that requires a change in treatment from that which the clinician had originally planned.

A veterinarian may consider an unexpected response to treatment by a drug as an idiosyncrasy of an individual animal. However, it is important that he report all adverse reactions, whether or not they are determined to be attributable to the drug, since the individual case may be found to follow a pattern similar to that of other reported cases which are associated with the drug in question. In addition, investigations of individual cases may provide a clue to the cause of the reaction.

Recently an adverse reaction report was received by a firm that manufactures a drug used in killing lice and grubs (Hypoderma) on cattle. The rancher using this product reported an adverse reaction and death in all animals of one breed, but no significant adverse effect in another breed. A veterinarian’s diagnosis was drug toxicity due to breed hypersensitivity to the drug. The drug firm is being instructed by the Bureau to revise the labeling to include a warning that the product should not be used on this one breed.

This case indicates that a drug may be considered safe and effective for some species (or breeds within a species) of livestock, but not in others. It demonstrates the important function performed by
the Surveillance Branch in the Bureau of Veterinary Medicine's Division of Veterinary Medical Review. This Branch makes recommendations concerning these drugs, after it has taken the following action:

1. Review of the regular and special drug experience reports submitted by drug firms in accordance with the requirements in the Code of Federal Regulations.
2. Review of establishment inspection reports.
3. Review of complaints and reports by veterinary practitioners.
4. Review reports from veterinary colleges.

In addition to these reports, the Surveillance Branch monitors published literature for information concerning possible side effects of veterinary drugs.

Another source of information for the Branch is the "Veterinary Alert to Adverse Reaction" (Form 1932a), which is postcard size, franked, and self-addressed to the Bureau—to reduce the time required for making the reports. This card form alerts BVM to an unusual drug experience, but is not large enough for complete and comprehensive details. A letter-size form (1932) is presently used as a follow-up by FDA to obtain additional information. Later, this Form 1932 will be required for all drug manufacturers to submit with their periodic reports.

During the 12-month period ending in July, 46 alert cards were received from practitioners and 35 from contract colleges. These blank forms are distributed to practicing veterinarians by FDA District veterinarians, extension veterinarians, colleges of veterinary medicine, diagnostic laboratories, and State veterinary medical association secretaries. Three veterinary colleges are under contract to FDA to submit detailed reports of adverse reactions occurring in their clinics.

The Surveillance Branch is doing work that is valuable to the users of veterinary drugs. During the 1971 fiscal year, 1,629 drug experience reports were reviewed by the Branch. This included New Animal Drug Applications and Veterinary Antibiotic Drug Experience Reports. From these reports, 212 reactions involving a total of 95,000 poultry and 1,250 animals were noted. The Branch also reviewed 138 prescription drug advertisements in professional journals.

Approval for a drug may be withdrawn by the FDA if new information shows that:
1. The drug is unsafe.
2. Substantial evidence of effectiveness is lacking.
3. There is an untrue statement in the New Drug Application.
4. The required records have not been maintained or reports submitted.
5. Controls are inadequate.
6. Labeling is false and misleading.

A feed mill constitutes a commercial operation and falls within the purview of the Food, Drug, and Cosmetic Act. Under this statute, no medicated feed may be manufactured by a feed mill unless it is prior sanctioned or, as in the case of a new animal drug requiring prior clearance, the mill holds the requisite approval and the product is corrected labeled. Therefore, the feed mill is not permitted under the law to mix drugs with a feed in a formula not permitted under the law, even when such a formula is prescribed or requested by a veterinarian.

Some New Animal Drug Applications are being referred to the Surveillance Branch by the NAS/NRC (National Academy of Sciences/National Research Council) for review as possible "similar" drugs. More are expected in the future, since there were approximately 700 NADA's reviewed by NAS/NRC—and also some NADA's that were not reviewed. As a result of these reviews, the manufacturers of many more products will be required to submit Drug Experience Reports.

When a drug company prepares a Drug Experience Report, it is helpful to the Bureau if all pertinent data relative to the drug is included. Information on the quantity of drug administered and route of administration is essential. FDA would like to know the length of illness, treatment, and information about any possible adverse reaction to medication previously administered. The data should also include the breed, weight, age, and sex of the animal patient.

These reports are divided into three groups: (1) the periodic reports which must be submitted at intervals within six months during the first year and at yearly intervals thereafter; (2) the reports that must be submitted within 15 working
days of their receipt by the applicant; and (3) the reports that must be submitted immediately.

The kinds of reports that must be reported periodically are complete records and reports of clinical experiences, both published and unpublished, that are pertinent to the safety and effectiveness of the drug—or to the adequacy of the manufacturing procedures and controls. These experiences could be studies, investigations, or tests conducted by the applicant or reported to him. Also required in the periodic reports are copies of all mailing pieces and other labeling and—if it is a prescription drug—all advertising, including copies of the currently used package labeling that gives full information for the use of the drug. The copies of the currently used package labeling are required, whether or not this labeling is contained in the application. The quantity of the drug distributed must be reported in a manner that makes it easy to estimate the number of animals possibly affected.

The kinds of reports that must be made immediately (upon receipt by the applicant) are complete records and reports covering any incidence of drug or label mix-up or significant contamination, deterioration, or failure to meet specifications. Records and reports that must be sent to the Bureau within 15 working days of their receipt by the applicant cover unexpected reactions or unexpected incidents of severity of a reaction associated with the drug’s use—whether or not it is attributable to the drug and regardless of the length of time it has been marketed. Such reactions could be unexpected side effects, such as injury, toxicity, or sensitivity. This includes any unusual failure of the drug to exhibit its claimed pharmacological activity. The requirements for filing these special reports apply to all holders of New Animal Drug Applications.

The Surveillance Branch of the Bureau evaluates the safety and efficacy of marketed veterinary drugs, and animal (including poultry) feed. It also, when appropriate, recommends action to correct significant hazards or potential dangers that may result when directions, warning statements, and customary information on the label need revision.

The Branch conducts continuing surveillance and medical evaluation of clinical experience. It reviews establishment inspection reports and other findings that may indicate whether new drugs are being marketed in accord with commitments contained in New Drug Applications.

The Branch obtains and evaluates reports of adverse animal drug reactions, and reviews consumer and practicing veterinarians’ complaints and reports. It makes recommendations concerning withdrawal of approval of NADA’s.

FDA requests the cooperation of all veterinarians in reporting cases of unexpected effects from clinical use of drugs. With their help, we can continue to improve drug quality, safety, and truthful labeling. This will benefit the entire livestock industry, including veterinarians. The “alert” cards make it easy to do. Additional information may be obtained from the Surveillance Branch, Division of Veterinary Medical Review, Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.

VETERINARY ALERT TO ADVERSE REACTION

<table>
<thead>
<tr>
<th>VETERINARIAN’S NAME AND ADDRESS</th>
<th>DATE REPORTED</th>
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</thead>
<tbody>
<tr>
<td>OWNER’S NAME AND ADDRESS</td>
<td>MEDECINATION GIVEN BY</td>
</tr>
<tr>
<td></td>
<td>□ VETERINARIAN</td>
</tr>
<tr>
<td>NAME OF DRUG</td>
<td>□ OWNED</td>
</tr>
<tr>
<td>SPECIES</td>
<td>BREED</td>
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<td></td>
<td>AGE</td>
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<tr>
<td>TOTAL DAILY DOSE GIVEN</td>
<td>ROUTE OF ADMINISTRATION (Oral, IV, Topical, etc)</td>
</tr>
<tr>
<td>PRIMARY DIAGNOSIS</td>
<td>TYPE OF ADVERSE REACTION OR LACK OF EFFICACY</td>
</tr>
</tbody>
</table>

The Veterinary Alert card (FD Form 1932a) shown serves to call FDA’s attention to an adverse reaction observed by a practicing veterinarian.

Walter L. Graves, DVM, is chief of the Surveillance Branch of the Bureau of Veterinary Medicine’s Division of Veterinary Medical Review.

Silas L. McHenry, Ed.D., is industry information officer in the Bureau of Veterinary Medicine.
Proving the Safety of Food Additives
by Leo Friedman, Ph.D., and Alan T. Spiher, Jr., J.D.

"Safety" has already become a keyword for the 1970's. Safety in the streets, safety of our environment, safety of drugs, safety of automobiles, and safety of food additives are examples of the concerns of consumers and government officials alike. As with many words, understanding among interested persons is difficult, because the word "safety" means different things to different people. The assurance of safety through premarketing clearances further complicates communication, particularly with the consumer. We propose to examine the problems of proving safety under the premarketing clearance requirements for food additives as established by the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act.

The following is part of an address by Leo Friedman, while a university professor, at a 1969 symposium on the Evaluation of the Safety of Food Additives:

“We can all agree that tests on experimental animals cannot provide proof of the safety of a substance for the human species; for that matter, neither can experiments on human beings. The ultimate tests will be provided by experience in everyday use, and then only when we have much more sophisticated and effective surveillance of the health of the population so that we are capable of detecting more than the usual striking effects, and are better equipped to associate cause with effects far removed in time. But we know that studies in experimental animals are useful and essential.

“Safety evaluation at the present time is founded on the concept of the ‘maximum no-effect dose.’ The procedures are all designed to determine the largest daily intake over extended periods (including a lifetime) that will not produce the injurious effects characteristic of the substance when given in larger, that is, toxic amounts; and just as important, to exclude the possibility that these subtoxic amounts will produce some hitherto unsuspected reaction.

“Theoretically, if all the biochemical and physiological interactions of a substance and an organism, in every phase of its development, were known, one could determine with considerable confidence the level of exposure that would assure no probability of harm. Although ultimately the critical information is at the borderline between abnormal and normal function in the cell, for some time we must continue to rely on the relatively crude studies in experimental animals from which we extrapolate conclusions regarding people. We must be particularly alert for the unexpected and constantly review our experimental approaches and designs for holes that will permit deleterious effects to go undetected.”

The inherent difficulties in proving safety, therefore, require that toxicity studies of food additives be carefully designed and conducted. Any risk of undetected deleterious effects must be at an acceptably low level. Adequate margins of safety must be provided to protect against errors in the translation of effects from animals to man. The presence of a new substance in food must be consistent with a Federal regulation promulgated to prescribe the conditions under which the substance may be safely used, including the requirement that it may not be used at a level higher than reasonably necessary to accomplish the intended physical or other technical effect. For purposes of establishing the proper regulation, the Commissioner of Food and Drugs must have full and complete reports of studies properly designed to establish that the additive is safe for its intended use.

Evaluation of safety includes an estimation of the potential of the substance to cause injury and review and evaluation of sufficient data to warrant a conclusion that the conditions of proposed use will provide an intake so low in relation to the toxic dose that there is a practical certainty no harm can result. This information can usually be obtained only by studies in animals. The problems of designing animal experiments include uncertainty that the animals chosen are appropriate models from which to extrapolate the results to humans, and difficulty in detecting (with the limited number of animals that ordinarily can be used) any effects that would occur in a very low incidence.

Although the difficult scientific questions posed and the great practical significance of the results might be expected to have challenged competent toxicologists to apply their independent efforts to develop answers, in practice the industrialist has looked to the FDA for guidance. Recommendations on safety testing by FDA first appeared in 1943, succeeded by a more
comprehensive series of articles in 1949. These were revised in 1955 and again in 1959 under the title, "Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics." Many developments in toxicology have occurred since 1959 so that a revision today is timely. We have benefited from many advances in procedures and analytical techniques for metabolic studies; a greater availability of radioactive-tagged substances; and a clearer understanding of the microsomal enzymes and their role in metabolic conversion. An FDA advisory committee has recently emphasized the importance of including reproduction, teratogenesis, and mutagenesis data in safety evaluations. Carcinogenesis testing has been reviewed during the past few years by several national and international public committees.

Obviously, to keep the risks of undetected deleterious effects at a minimum, and to assure that the observed effects are not spurious, the safety evaluation studies must be properly designed and the results must be subject to adequate interpretation. Also essential is the maintenance of laboratory management and practice to prevent or minimize contamination of food, water, and equipment; to minimize the incidence of intercurrent disease; and to assure adequate records and the preservation of important experimental materials. Basic minimum requirements in the design of studies with test animals include observations on growth, food intake, clinical manifestations, hematology, blood chemistry, urinanalysis, gross pathology, and histopathology. Additional observations or tests should be included, either as a direct result of observations made during interim sacrifices of animals, or as a result of prior knowledge based on structural similarities of the additive to compounds studied previously or on earlier screening studies, either acute or subacute. Specific studies that may be required include the following:

1. Acute toxicity in several species of experimental animals with emphasis on providing a full and complete description of the effects observed, including observations at death.

2. Cumulative toxicity during a period of intermediate duration. This has been the traditional subacute toxicity test of 90 days. We now recommend that this study extend from time of weaning to sexual maturity, including reproduction according to protocols designed to produce valid data that will permit calculation of indices of reproductive performance, and including mutagenicity and teratogenicity. Such data should be derived from more than one species of animal, including at least one nonrodent species (as a practical matter, subacute reproduction tests should include a nonrodent species). Full and complete observations are to be reported, including gross and microscopic examination of tissues, either at death or at sacrifice.

3. Data on changes that may take place in the additive due to interactions of the additive with the food containing the additive during storage and preparation for consumption.

4. Data, from both short-term and long-term administration in several species of animals, on absorption, distribution, metabolic transformations, excretion, tissue distribution, and accumulation.

5. Establishment, by studies, that the metabolic pattern of the test animal chosen is closest to man so that similar responses to the test agent may be expected.

6. Initiation of chronic or long-term (lifetime in animals having short life spans) studies by administration of the test agent to the female prior to conception of the offspring to be used in the lifetime studies. In these studies, animals should undergo at least two cycles of reproduction according to protocols designed to give valid teratogenic and mutagenic data. The design should provide enough animals for interim sacrifice and study. We would urge that the chronic tests be combined with a three-generation reproduction test, and that the F1 generation be used for the lifetime study, so that the exposure starts at conception. More than one species should be used for carcinogenesis evaluation.

7. Whenever indicated, other specific tests; for example, teratogenic and mutagenic tests, and in the case of organo-phosphate and carbamate pesticides, cholinesterase inhibition and demyelination studies must be made. In the case of compounds containing nitrophenol groups in the molecule, cataractogenic studies may be required.

The changes in familiar protocols are not extensive. However, there are other areas of concern where suitable protocols have not progressed beyond the early stages of development and are not now ready for "routine" testing purposes. These include allergy, sensitization, photosensitization studies, and studies of food products made from new and unusual raw materials, food processed by new processing techniques, and foods derived from animals and plants modified by breeding and selection. Also under study are new approaches to the evaluation of experimental data with a view to a more rational estimation of potential hazard under various conditions of use. Progress on these problems may well result in the periodic announcement of new toxicological criteria. The creative input of industrial toxicologists or industry-supported academic research would be very useful to all in helping to resolve these problems.

Emphasis should be made also on the importance of
statistical evaluation procedures, including errors of the "second kind." Errors of the first kind are those uncertainties involved in a positive conclusion. Conclusions based on negative data that there is no adverse effect may contain errors of the second kind. These uncertainties tend to be generally overlooked and this leads to acceptance of sloppy work and questionable results as evidence demonstrating safety.

Obviously, the suggested requirements can be modified, depending on the known facts about a proposed new additive. Adjustments also may be possible on the basis of human data when such information is available. The extent and depth of the toxicological investigation of a substance to be added to food depends on the estimated daily intake, the findings during the investigation, and the nature of the substance itself. Where strong or alarming biological effects are observed, it may be necessary to proceed with additional animal studies before an acceptable daily intake of the additive can be set or, if the effect is carcinogenic, to prohibit use of it in food.

We have set forth the requirements we believe, in the current state of our knowledge, should be met for the proper evaluation of the safety of a new food additive. In the case of substances that have been in use many years, sometimes many generations, such as some of the materials on the GRAS List, it is difficult to reconcile a long history of apparently safe use with the need for additional study in experimental animals or, indeed, with adverse findings in experimental animals. The translation of animal data into conclusions about human safety is, under the present conditions, fraught with uncertainty. Nevertheless, the mere history of human use can tell us only that our present state of public health is in equilibrium with the exposures we are experiencing. Just as there is a great deal of uncertainty in judging that adverse findings in experimental animals will mean deleterious effects in human beings under similar conditions of exposure, so there is a great degree of uncertainty in concluding that the removal of traditional sources of exposure on the basis of adverse findings in animals will not result in an improvement in the current state of public health.

We must make our judgments at present on the basis of the best scientific data available. Whenever this information is obtained by human experimentation, it will have a much closer relevance to the human condition, but we must remember that mere experience is simply a reflection of an equilibrium situation.

As in the past, FDA toxicologists are ready to consult with petitioners over the data necessary for specific petitions.
In Bedford Village, New York, last June two persons ate commercially prepared canned soup unheated from the can; both became seriously ill, and one died. In Philadelphia in August three people became ill after eating home-canned green peppers and one died. At Bakersfield, California, in mid-September seven adults at a family meal tasted or ate chili sauce prepared from home-canned peppers and one died and six others became ill, one mildly, two seriously, and three critically.

In all instances the foods involved contained botulinum toxin, produced by the bacterium *Clostridium botulinum*, and the deadliest poison known to man. After the New York incident, the FDA, verifying the presence of botulinum toxin in the soup, produced by the Bon Vivant Company, Inc., of Newark, New Jersey, instigated a recall of all soup in that lot, and later, unsatisfied with the progress of the recall and with the manufacturing controls used by the company in canning soups and other foods, acted to remove all the company’s products from the market until questions concerning their safety could be resolved. In August the FDA announced that the Campbell Soup Company was recalling a lot of chicken vegetable soup produced in July in which the company had found *C. botulinum*. The soup was recalled before causing illness.

Botulism is a severe type of food poisoning caused by the ingestion of foods containing a potent neurotoxin formed during growth of *Clostridium botulinum*, a spore-forming bacterium for which oxygen is toxic. The incidence of the disease is low, but it has been the cause of considerable concern because of the extremely high mortality rate. The majority of the 10 to 20 outbreaks reported annually in the United States are associated with inadequately processed home-canned foods. Botulinum toxin is produced by the growth of the organism in the food material before it is consumed and thus the disease is an intoxication and not a foodborne infection.

The organism is widely distributed in nature and occurs in both cultivated and forest soils, bottom sediments of streams, lakes, and coastal waters, the intestinal tracts of fish and mammals, and the gills and viscera of crabs and other shellfish. Sausages, meat products, canned vegetables, and seafood products have been the most frequent vehicles for human botulism. Six antigenic types of toxin are produced by different members of the species and these form the basis of classification of the organism into types A through F. Types A, B, E, and F have been responsible for human cases; types C and D are associated with botulism in animals.

Although botulism has been known since ancient times, only in the last 200 years has there been sufficient knowledge to recognize it as a foodborne disease. It was first accurately described and made a reportable disease in southern Germany in the early nineteenth century after a study of more than 200 cases of poisoning from sausages. The term “botulism” (botulus, Latin-sausage) was first applied to this syndrome in 1870 and the causative agent was first isolated and described by Emile-P. Van Ermengem in 1896. He named the organism *Bacillus botulinus* (now *Clostridium botulinum*).

Until the causative agent was identified, botulism was thought to be associated exclusively with sausages or meat products, but shortly afterward one outbreak in Germany and another in California were traced to bean salads. However, the toxin produced by the strains isolated in both cases was immunologically distinct from that of Van Ermengem’s strain. These incidents were followed in the United States by a series of outbreaks that were traced to canned vegetables and fruits. Statistics for 1918 through 1922 show 83 outbreaks with 297 cases and 185 deaths. Since then the occurrence of botulinum toxin in commercially canned foods has been reduced by improved canning methods that resulted from research sponsored by the canning industry and public health authorities.

All of the outbreaks reported through 1922 were due to organisms producing one or the other of the two above types of toxin, later designated as types A and B. Both of the type C subtypes (C. Alpha and C. Beta) and type D were reported in 1922. Types C and D have caused heavy losses of chickens, ducks, aquatic wildfowl, cattle, horses, and mink, but there is little evidence that they have ever been responsible for human botulism, although there is no evidence to indicate man is not susceptible.

Type E was first identified as a toxigenic type in 1935. This strain, isolated from Russian sturgeon, was found to be identical to two other strains previously isolated in New York. One strain had been isolated from an outbreak in 1932 involving salmon caught and smoked in Labrador and the other from imported canned sprats responsible for an outbreak in 1934. Although one type E outbreak was due to commercially canned mushrooms in 1941, the majority of outbreaks in the United States have been associated with fish and seafood. Since 1960, outbreaks traced to fish
caught and commercially smoked in the Great Lakes area have been responsible for 21 cases and 9 deaths, but one outbreak responsible for two deaths in 1963 involved canned tunafish. This organism is an important public health hazard in areas where "Izushi," a dish made of fermented raw fish, rice, koji, and chopped vegetables, is a popular food. It has given rise to morbidity rates from type E botulism of about 50 percent with fatality rates of 20 percent to 100 percent.

Type F was first isolated in 1960 from an outbreak in Denmark in which a liver paste was the vehicle. The only other type F outbreak on record occurred in California in 1966 and was traced to contaminated deer jerky.

The disease, botulism, occurs throughout the world. Of the 659 outbreaks recorded in the United States from 1899 through 1969, 21.8 percent were due to type A, 5.6 percent to type B, 2.6 percent to type E, and 0.3 percent to type F. In 69.5 percent of the outbreaks the type was not determined. Outbreaks have been reported in 44 States, but five Western States account for over half of all reported outbreaks.

Of the 144 type A outbreaks, 92 percent were in States west of the Mississippi River, whereas 25 of 37 type B outbreaks, or 67 percent, occurred in Eastern States from 1899 through 1969. Type E outbreaks have been reported in 10 States. The geographic association of this type with Alaska and the Great Lakes area may be more apparent than real.

The regional distribution of outbreaks by toxin type is in keeping with the results of a spore survey of soil samples by K. F. Meyer and B. J. Dubovsky. These investigators found a predominance of type A in soil specimens from the West and of type B in soils of the Northeast and Central States. Other investigators have shown that type E is the predominant type in fish and sediments from the Great Lakes, in estuarine and coastal waters, and in sediments, fish, and shellfish from the Atlantic, Pacific, and Gulf coasts of North America.

In Europe, type B is the predominant type both in soils and in outbreaks. However, type E has accounted for 46 percent of the outbreaks in Japan, Canada, and Scandinavia in the Twentieth Century.

The types of foods involved in botulism vary according to food preservation and eating habits in different regions. Almost any type of food with a pH above 4.5 can support growth and toxin formation. Botulinum toxin has been found in a considerable variety of foods, such as canned corn, peppers, green beans, beets, asparagus, mushrooms, ripe olives, spinach, tunafish, chicken and chicken livers and liver pâté, and in luncheon meats, ham, sausage, stuffed eggplant, lobster, and smoked fish.

Foods that have been involved in outbreaks of botulism in the United States between 1899 and 1969, identified mainly on the basis of clinical symptoms instead of isolation and typing of the organism, include: vegetables—395 outbreaks of which 362 involved home-preserved foods; meat—44 outbreaks, 36 home-preserved; milk and milk products—7 outbreaks, 5 home-preserved; fish and seafood—48 outbreaks, 33 home-preserved; and fruit and pickles—35 outbreaks, of which 34 involved home-preserved foods. In many outbreaks the kind of food involved was not identified.

Most of the outbreaks have been traced to home-canned vegetables, fruits, fish, and meat products, with a smaller number involving commercially processed foods. Although many outbreaks were caused by commercially canned products during the 1920's and 1930's, home-canned string beans, corn, beans, spinach, and asparagus accounted for over half of the total number.

U.S. Department of Agriculture Home and Garden Bulletins on safe methods of preserving and handling foods in the home are for sale by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402: #8—Home Canning of Fruits and Vegetables, #40—Freezing Combination Main Dishes, and #174—Meat and Poultry—Care Tips for You, all 20 cents each; #106—Home Canning of Meat and Poultry and #70—Home Freezing of Poultry, 15 cents; #93—Freezing Meat and Fish, 25 cents; and #162—Keeping Foods Safe to Eat, 10 cents.

Botulism is usually associated with foods that have been given a preservation treatment, stored for some time, and consumed without appropriate heating. The growth of C. botulinum in foods frequently, but not always, produces a foul, rancid odor, that serves as a warning to the consumer. Signs of spoilage, however, have not prevented botulism because the degree of tolerance to disagreeable odors or off-flavors varies among individuals. Moreover, in foods that are smoked, heavily spiced, or fermented, the off-odor may be difficult to recognize.

Botulinum toxin causes paralysis by blocking motor nerve terminals at the myoneural junction. Paralysis progresses downward, usually starting with the eyes and face, to the throat, chest, and extremities. When the diaphragm and chest muscles become fully involved, respiration no longer is possible and death from asphyxia results.

Early signs are marked lassitude, weakness, and vertigo, usually followed by double-vision and progressive difficulty in speaking and swallowing. Difficulty in breathing, weakness of other muscles, abdominal distention, and constipation also are common symptoms. Type E, in addition, may cause severe nausea and vomiting in the early stages, and redness of the upper throat area and difficulty in urination later. The interval between the onset of symptoms and death in a series of cases analyzed in Japan varied from 8 to 28 hours, but in those who recovered, some symptoms such as thirst, weakness, throat pain, and abdominal swelling persisted for some time.

Although botulism can be diagnosed on clinical symptoms alone, differentiation from a variety of other diseases often is difficult. Initial mis-diagnosis as other
Clostridium botulinum is a large, flagellated, spore-forming bacillus. As noted, it is anaerobic, that is, will not grow in the presence of oxygen.

Since botulism is foodborne and results from ingestion of toxin formed in the food following growth of the organism, determination of the source of an outbreak is based on detection and identification of the toxin or cultivation of C. botulinum from the food involved. Currently the most widely used method for detecting toxin in suspect food is the injection of extracts of the food into passively immunized mice, and the first objective in an epidemiological investigation is usually the detection of toxin in the suspected food by such a test. Rapid identification of the toxin is important for proper treatment of the victims and for ascertaining the source so that the implicated food can be removed from further distribution as quickly as possible. This analysis is followed by culturing all suspect foods in an enrichment medium for the detection and isolation of the causative organism.

The details of these procedures will vary somewhat with the nature of the material to be examined. Products such as meat or fish are macerated with gel-phosphate buffer to extract toxin, whereas liquid portions of some products can be injected directly into mice. Suspect foods are cultured for the bacillus because, on occasion, the food is no longer toxic at the time the mouse test is performed. Human illness with symptoms of botulism and isolation of a toxic strain of C. botulinum from the food involved is considered a positive laboratory confirmation of the diagnosis even in the absence of positive toxicity tests on the food product itself.

There are many enrichment media used for the cultivation of the different types of C. botulinum. The most common of all contain reducing agents to maintain anaerobic conditions as well as buffering agents.

The usual incubation times and temperatures for maximum toxin production and growth of the various types range from 3 to 7 days, at 78°C to 96°F.

Elimination of nonspore-forming contaminants from enrichment cultures is performed in the laboratory by treatment with alcohol. Cultures are then streaked on plating media for the selection of typical colonies of C. botulinum. Plating media frequently employed are blood agar, liver veal egg agar, brain heart infusion agar, a variety of beef infusion agars, and modifications of special egg yolk media.

The majority of the known outbreaks of botulism have been traced to foods given inadequate or minimal processing such as in home canning, and smoking or pickling foods to be served with little or no cooking, or when they are held for periods of time under inadequate refrigeration. Government agencies continue to urge home processors to use processes which have proved to be safe, and the serving of home-preserved foods in public eating places is prohibited in some localities. However, the chief concern is with the safe processing of commercial products, which, if toxic, could affect large numbers of consumers in widely dispersed areas.

Fresh food, whether eaten raw or cooked, has not been implicated in an outbreak of botulism. Food preservation methods therefore must be designed to prevent the development of botulinum toxin unless the nature of the food itself is inhibitory to the growth of the organism. These are foods with a high acid, sugar, or salt content. Some of these are canned fruit juices, sauerkraut, many tomato products, heavily salted hams, jabs, and jellies. Adequate preservation methods must, in order of preference, either destroy all spores, prevent their germination and the outgrowth of vegetative cells, prevent the development of toxin, or provide conditions under which any toxin that might be formed will be inactivated.

The toxins of C. botulinum are heat sensitive and are therefore readily destroyed by normal cooking. Boiling for 10 minutes provides a reasonable margin of safety against all types.

The real safety problem in food preservation, however, is the destruction of spores in processed foods. If they are not destroyed, they may germinate, grow, and produce toxin under favorable conditions. Spores in themselves are not dangerous. Many are probably ingested by man under normal conditions, but indications are that they do not grow or produce toxin in the human intestinal tract.

Freezing will not destroy either toxin or spores, but will prevent the germination and outgrowth of spores which would lead to toxin production at higher temperatures. It is most important that nonsterile frozen products be kept frozen until cooked.

C. botulinum is an obligate anaerobe, and atmospheric oxygen has a toxic effect on its vegetative cells. Its growth in food, therefore, is related to the oxidation-reduction (O-R) potential of the food itself. Such potentials are established in many foods by oxygen-reducing systems present in the food such as sulfur-hydrogen molecular groups that bind up oxygen in meats; ascorbic acid or vitamin C, that binds up oxygen in many foods; and other micro-organisms that use up oxygen. No special conditions of incubation, therefore, are required for C. botulinum since frequently the food itself produces a sufficiently low oxygen-reduction potential to permit outgrowth.

The resistance of C. botulinum spores to chemical agents is quite high. For complete inhibition of spore germination and outgrowth, 5 to 10 percent common salt (sodium chloride) is required.

Canning procedures have been developed to destroy spores with a sufficient margin of safety to make the probability of any survivors extremely remote. Where there is a question about the safety of a product, cans should be discarded when they show even slightly bulging ends or any other evidence of spoilage such as souring, gas formation, discoloration, or leaks. All such...
Detecting and Confirming

C. BOTULINUM

Cans of food to be analyzed for *C. botulinum* are opened aseptically (left) after chilling to prevent release of the contents when the gaseous pressure that may be present in the can is released. Flame from ignited alcohol is used to sterilize both the top of the can and the can-opening device. If the food is liquid as shown here (bottom left), an aliquot is pipetted to a centrifuge tube and centrifugates are made to be analyzed for botulinum toxin. If the food product is solid or semisolid, extracts are prepared (bottom center) by homogenizing food in an equal portion with gel-phosphate buffer in a grinding process. A microbiologist examines an extract of the food (bottom right) which will be centrifuged to be tested in mice for toxicity without further processing.
Mice are injected (right) with the liquid portion of food extracts or cell-free subcultures to determine if toxin is present. If mice die within 72 hours it is presumptive evidence of the presence of botulinum toxin. For determination of type-specific toxin, further tests are performed in mice by passively immunizing groups of mice with antisera specific for *C. botulinum* types A, B, E, and F. If one group of mice receiving a specific antitoxin lives and the other mice die within 72 hours, the type of toxin in the food or culture has been determined.

In preparation of subcultures for analysis, a portion of the food is cultured (above left) in cooked meat or trypticase-peptone-glucose-yeast extract-trypsin (TPGYT) media. These cultures will be tested for toxicity after 5-7 days incubation. The subcultures or extracts are streaked on an agar medium and grown under anaerobic conditions (without oxygen). The atmosphere in the case-anaerobic jar (middle right) where the cultures will be incubated is being replaced by nitrogen gas. Nitrogen or hydrogen provides a satisfactory atmosphere for growth of *C. botulinum*. After incubation the subcultures are examined microscopically. This photo (right) shows typical cells and spores of *C. botulinum* at a magnification of about 4,500 times.
Rabbits are being used by FDA to produce antisera for cells and spores of *C. botulinum*. The antisera are used in a rapid screening method being developed for detecting *C. botulinum* based on fluorescent antibody techniques. Here (above left) a rabbit is being injected with an antigen. After an antiserum is produced in a rabbit, the animal is bled. The antiserum is separated from the other blood constituents and further prepared for use in the fluorescent antibody screening technique for cultures and food products. Some FDA microbiologists and laboratory technicians who work with suspect food samples and *C. botulinum* cultures daily are more subject to accidental exposure to botulinum toxin than the average person.

As a safety measure a microbiologist is being immunized (bottom left) with pentavalent botulinum toxoid in a Public Health Service clinic. The growth of *C. botulinum* in canned foods creates a gaseous pressure that usually, but not always, causes the can to swell, like these shown (bottom right). The contents of cans or jars that indicate the slightest evidence of swelling should not be eaten, nor tasted.
A microbiologist examines a sample (left) containing part of the contents of a jar of home-canned peppers that contained botulinum toxin and was responsible for the death of one person and the illness of two others. The sample was supplied to FDA for cooperative confirmatory testing for *C. botulinum*. The photos below show fluorescing vegetative cells of the four types of *C. botulinum* associated with human illness: at top left, Type A; top right, Type B; bottom left, Type E; bottom right, Type F.
These unusual photographs of cells and spores prepared by FDA were made through a scanning electron microscope at high magnifications and show (top left) a cell of *C. botulinum*, Type A, prior to sporulation, and (top right) another Type A cell during actual sporulation. At bottom are spores of Type B (left) and Type E (right).
cans should be suspected as potentially botulogenic and examined for toxicity and the presence of *C. botulinum*. Never under any circumstances should the contents of such products even be tasted, let alone eaten without thorough cooking.

The canning industry, using the information provided by research carried out in the 1920's and 1930's, has adopted a standardized process for treating low-acid foods so that the probability of *C. botulinum* spores surviving is very remote. The spores of *C. botulinum*, although quite resistant, are not the most heat-resistant known, and other more resistant sporeformers are frequently used in time-temperature studies. However, canning processes must be of such lethality that the likelihood of *C. botulinum* spores surviving is negligible. The concentration of spores in a food product is important because the greater the number of spores there are in the product, the greater the processing time and temperature required to insure their complete destruction. Therefore, the so-called 12 D standardized canning process was designed to reduce a bacterial load of a billion spores in each of a thousand cans to the level of one spore in a thousand cans.

These processes, which take into account among other things the consistency and chemical nature of the product and the size of the can, are now standardized to the point that only through recontamination after heating is it likely that a significant degree of spoilage or hazard from *C. botulinum* could occur. An additional safety factor is provided by proper sanitary control, as specified in FDA's Good Manufacturing Practice guidelines, which reduces the original bacterial load to be inactivated during the canning cycle.

The knowledge concerning the effects of chemicals, such as salt, nitrite, and organic acids, on the germination and outgrowth of *C. botulinum* spores has been utilized by the meat-curing industry to produce safe and acceptable products without subjecting them to the "12 D" canning process.

The preservation of food by drying, or smoking and drying, goes back beyond recorded history. Modern commercial drying processes are superior to the crude smoking-drying combinations of the past that were sometimes responsible for botulism. Freeze-dehydration and conventional air drying are commercially attractive because of increased shelf life, weight reduction, and packaging ease. Some type of pretreatment is usually required so that rapid freezing and dehydration can occur.

Vacuum packaging provides special hazards when foods with sufficient moisture content to allow bacterial growth are placed in an environment that will discourage growth of normal spoilage organisms on the surface, but will support the growth of anaerobes, such as *C. botulinum*. In vacuum-packaged foods, growth of aerobic or oxygen-using organisms is considerably curtailed, and the shelf life appears, therefore, to be extended because visible spoilage has not occurred.

This additional shelf life may be sufficient for anaerobes, such as *C. botulinum*, to grow and produce toxin. With vacuum-packaged foods, as with so many others, every attempt must be made to establish high levels of sanitation in the processing plant so that contamination levels with *C. botulinum* will be held to a minimum.

The radiation preservation of foods has been subjected to intensive study in recent years. Processes designed to pasteurize food by irradiation would have little or no effect upon the spores of *C. botulinum*, which are resistant to radiation damage. The extended shelf life obtained by low-dose irradiation might allow outgrowth and toxin production.

In any commercial operation for the preservation of foods, plant sanitation has an important bearing on the effectiveness of processing in the elimination of the hazard from *C. botulinum*. If the spores are present in the plant, they may gain access to the product through handling at any stage of the operation.

The ubiquity of *C. botulinum*, the resistance of its spores to physical and chemical agents, and the lethality of its toxin call for careful attention in the preparation of commercial food products. Thorough cleaning of all raw products in preparation for processing, scrupulous attention to sanitation in all phases of plant operation, and meticulous attention to processing conditions and the handling of the finished product are required. Although certain types of products have been more frequently incriminated than others, it is probable that almost any food may become contaminated. As new types of processing and packaging are contemplated, it is especially important that they be designed to eliminate the hazard presented by contamination with *C. botulinum*.
ATLANTA DISTRICT  James Shelton, product safety consultant in FDA's Region IV, took part in an orientation seminar on product safety held September 23 at Jacksonville by the Florida Department of Health and Rehabilitative Services. Mr. Shelton was a moderator for the seminar along with A. W. Morrison of the State health department. Sam Hart, deputy director of FDA's Bureau of Product Safety, provided comments and projections for the Federal approach to be followed in the area of consumer protection. The program was well received by the top staff people of the health department for whom the seminar was being held.

BALTIMORE DISTRICT  The second phase of the FDA-VDAC personnel exchange is underway; the first phase was earlier in 1971 (see FDA Papers, May 1971 issue).

FDA Supervisory Inspector H. Thompson Price, Jr., began a 60-day detail with the Virginia Department of Agriculture and Commerce on October 4. During this period, he will work under the direct supervision of A. Lee Turner, supervisor of VDAC's Food Regulatory Section. Mr. Price will receive indoctrination in every phase of the department's food inspection operations.

It is anticipated that this half of the exchange will be as beneficial as the first phase when VDAC detailed Howard R. Haynie to FDA's Baltimore District Office.

BOSTON DISTRICT  During July-September, over two million dollars worth of canned tuna imported from Japan was denied entry into the United States through the New England ports. FDA's examination of the tuna revealed either decomposition or mercury contamination in excess of the 0.5 parts per million guideline set by the Agency.

A U.S. District Court judge sitting at Boston signed an order of destruction September 20 that brought to a close an action that had been pending since early in 1970. On February 16 of that year a quantity of veterinary drugs was seized at Harilian Pharmaceuticals, Inc., Greenwich, Connecticut, on a complaint of forfeiture charging the goods were new animal drugs for which the firm did not have an approved New Animal Drug Application. The firm entered a claim to the drugs and filed a consent decree, but by September of this year it had not brought the goods into compliance and the recent court order was issued.

BUFFALO DISTRICT  Import detentions recently have included several products from the Peoples Republic of China that failed to comply with FDA's Fair Packaging and Labeling Act requirements. These articles have been transshipped from Canada, where the producers have to a large extent taken steps to essentially comply with these regulations.

The District is concerned not only with such detentions but also with a recent problem that can vastly change its import coverage. Oceangoing vessels have been docking at Albany, New York, rather than at New York City. The boats apparently are making the trip up the Hudson to unload at this inland port to escape the longer delays. If this practice continues, it will bring about changes in Buffalo's import coverage.

Bon Vivant Soups occupied a considerable portion of the District's time into the month of October. Cooperative action between the New York State Division of Food Control Office, the local health departments, and Buffalo District brought Bon Vivant products distributed in upstate and western New York under control. County health departments cooperated in embargoing small lots of these products when found in distribution. These lots were then returned to wholesalers or were destroyed. New York State or Federal seizures were made at all distributors. The State seized 268 lots, of which about 160 were in the New York City area. Federal authorities seized 18,179 cans of the soup. Some voluntary destructions of smaller lots have been accomplished and many more are anticipated in a concerted effort to assure that these questionable products do not get back into the channels of commerce.

CINCINNATI DISTRICT  Homer R. Smith, District veterinarian, participated in the Farm Science Review at Columbus on September 21-23. He monitored an FDA exhibit on veterinary medicine and poison prevention that was part of the Review, which was sponsored by the Ohio State University and the Ohio Agricultural Research and Development Center.
DALLAS DISTRICT  During September, the Campbell Soup Co., Paris, Texas, voluntarily recalled chicken vegetable soup after one day's production was found to contain Clostridium botulinum toxin. In the subsequent follow-up investigation by Dallas District inspectors, one day's production of vegetarian vegetable soup found to contain abnormal cans was voluntarily recalled.

James Anderson, District chief inspector, and George Hintgen, chief of the city of Dallas Environmental Control Service, were interviewed September 21 on a local radio program. After a brief discussion concerning the type of work done by each agency, listeners telephoned the station to ask questions concerning food and drug matters—most of which were answered by Mr. Anderson.

KANSAS CITY DISTRICT  The Metropolitan Kansas City Conference of Food and Drug Officials held its fall meeting September 27 at the FDA District Building. Approximately 35 city, county, State, and Federal enforcement officials attended the day-long sessions at the District building.

Featured speakers and their topics included Regional Food and Drug Director Charles A. Armstrong—"Recent Developments in FDA"; Leon Hallberg, director of agri-business marketing, Vestal Labs, St. Louis, Missouri—"Training in the Marketplace"; and Randall Jesse, director of the Division of Public Affairs, Environmental Protection Agency, Region VI, Kansas City, Missouri—"EPA, What It Is and Does."

The morning sessions were devoted principally to open discussions by the group on a number of area problems, including communication, agency responsibilities, work sharing, recalls and responsibilities, Stop Sales, etc. Serving as a panel of experts to answer questions from the group were James A. Adamson, chief, FDA Special Programs Branch; Clarence Smythe, Kansas City, Kansas-Wyandotte County Health Department; Leonard L. Blanton, chief inspector, FDA Kansas City District; and Dr. William Raithel, Missouri Division of Health, Jefferson City, Missouri.

During the month of September, the District cited 11 producers of beef cattle (8), swine (1), chickens (1), and turkeys (1) intended for human consumption. The marketed animals and poultry contained illegal drug residues in tissues analyzed by the U.S. Department of Agriculture.

LOS ANGELES DISTRICT  A variety of products were either seized or destroyed through FDA action in the District during the month of September.

Protein powder labeled as an aid for weight reduction and as a source of amino acids was seized because of false and misleading claims for weight reduction and for special nutritional qualities. Made from bulk materials that had moved in interstate commerce, the lot of 95 cans had been packed for Arwin Co., Los Angeles, where seizure was made.

Because it was decomposed in part and had been packed under insanitary conditions, 4,681 cases of Bon Vivant canned soups was seized at five wholesale grocers. Although decomposition was found in samples, no botulinus was detected. Seizures covered the dealers' entire stocks of this manufacturer's product, and one dealer voluntarily destroyed his stock of the product.

A lot of 1,897 100-pound bags of brazil nuts was seized at a Los Angeles dealer because they contained insects and mold. Also seized because of heavy insect infestation was 704 boxes of cornhusks.

Violation of the Fair Packaging and Labeling Act with respect to quantity of contents statements resulted in seizure of five cosmetics and over-the-counter drugs in possession of a Los Angeles wholesaler. The products had been imported from England. Of the total, three were made by American firms in British plants and were the same as their American-made products except for violative labels.

A lot of 29,000 cases of candy mints and chewing gum containing cyclamates was voluntarily destroyed by a Los Angeles dealer. The lot had been manufactured by a San Francisco firm some time ago.

Elaine Roentgen, District consumer specialist, recently appeared on the Dinah Shore television show, discussing bacterial contamination of foods. Mrs. Roentgen represented Virginia Knauer on the NBC-TV program, "Agriculture USA," speaking on protection of the consumer.

MINNEAPOLIS DISTRICT  Severe difficulties seem to have plagued the food industries recently—at least it appears that way from the FDA point of view in the District area.

Because the product was found to contain Salmonella contamination, a manufacturer of macaroni and egg noodle products recalled and voluntarily destroyed more than 188,000 pounds of egg noodles with a wholesale value of $55,182. By replacing $17,000 worth of equipment, the firm's management hopes to correct the problem and has indicated that no further shipments will be made until laboratory analyses show all production to be free of Salmonella.

A corn-canning plant in Wisconsin operated for about four weeks packing this year's corn crop with defective can-seaming equipment, which resulted in extensive swelling of warehouse stock. Wisconsin Department of Agriculture authorities are cooperating and have embargoed 145,000 cases of the pack.

Added to this are bona fide complaints of illnesses from consumption of canned corn, canned peas, and the finding of a piece of rope in canned sauerkraut, as well as 15,000 large cans of asparagus found to be undergoing decomposition with the cans bursting in the warehouse.
NEW ORLEANS DISTRICT Universal Foods, Red Star Division, Belle Chase, Louisiana, is now experiencing difficulty in disposing of 150 tons of Salmonella-contaminated yeast accumulated under a recent recall. The Jefferson Parish Health Department estimated the disposal cost to the company at one hundred dollars per ton, due to possible environmental problems in this coastal area. The yeast is mostly in sealed two-pound cans.

The District detained over $309,392 worth of tuna during September because of excess mercury, decomposition, and lack of compliance with FDA standards. As a result of the west coast dock strike, a number of west coast importers were forced to use New Orleans as their port of entry, and canned tuna from Japan and Angola had arrived by the boatload.

Also detained during September were $776 worth of plastic toys with potential for accidental ingestion by children; $500 worth of decomposed olives; $31,500 worth of decomposed canned tomatoes; $5,063 worth of insect-infested sesame seeds; $17,400 worth of insect-infested mung beans; $69,200 worth of misbranded frozen shrimp; and $228 worth of illegal fireworks.

NEW YORK DISTRICT A problem that was brought to New York District’s attention recently now appears to be under control. As a follow-up to an anonymous complaint forwarded to this District by FDA’s Los Angeles District, New York District inspectors learned that Modern Maid Food Products, Jamaica, had produced 120,000 pounds of breading material contaminated with small pieces of rubber gasket that had been introduced into the grinding/sifting equipment. The problem had been discovered by a U.S. Department of Commerce fishery products inspector after 5,000 pounds of breading material had been used to bread fish at Icelandic Products, Camp Hill, Pennsylvania. The contaminated fish were placed under Commerce Department quarantine and the remaining 115,000 pounds of breading material was returned to Modern Maid, where it is currently being sold for pig feed.

In checking further, New York District found that the Los Angeles informant had learned of the problem from reading Commerce Department memos that were sent to their field inspectors alerting them to this situation.

The cooperative FDA/American Can Company booth at the New Jersey State Fair was one of the more popular booths there, it appeared. It was not unusual to see viewers crowded around the booth four and five rows deep. In the first four days, despite inclement weather, an estimated 15,000 to 20,000 visitors were attracted to the exhibit. FDA inspectors manning it reported that it was particularly gratifying to experience the interest and concern of the fairgoers, who commented on the abnormal cans exhibited and on food safety in general.

PHILADELPHIA DISTRICT District representatives participated in two workshops held in Philadelphia in September. On September 23 Loren Johnson, DRFDD; Francis J. Fiskett, food and drug officer; and Wardsworth Gray; along with Dale Miller and Richard Early of the Bureau of Product Safety, Washington, took part in a workshop on hazardous substances. The seminar, attended by approximately 150 industry representatives, was sponsored by the National Paint, Varnish and Lacquer Association.

On September 22-24, Region III and the FDA Training Institute cooperated in conducting a workshop for local and State health officials, entitled “Current Concepts in Food Protection.” This course was basically confined to regulatory aspects of food serving and handling, and was sponsored by the Philadelphia Department of Health. Attending this workshop were 63 sanitarians, representing the city and State departments of health, including those in New Jersey, Pennsylvania, and the Territory of Guam.

Drug officials from two foreign countries visited the District recently. Dr. T. N. Bhan and A. Chakravarti from India ended a four-week visit September 3. They had visited 13 different drug manufacturers with the District inspectors during their stay, observing and learning manufacturing procedures.

Drs. Peter Fischer, Max Sahli, and T. Witschi, a Swiss delegation, began their visit to the District on September 14. They visited two of this Nation’s major drug producers with District food and drug inspectors and observed the production of all types of dosage-form drugs. They were particularly interested in quality control systems, high-speed production, and inspectional techniques.

SAN FRANCISCO DISTRICT The largest seizure for economic violations in recent District history occurred September 13, when a U.S. marshal took into custody 33,000 pounds of cheese, charged to be totally lacking in any kind of labeling.

Because of subpotency, the District also ordered seizure September 22 of 7,400 vials of progesterone injection in oil. The product, seized in possession of a manufacturer in the San Francisco area, had been manufactured from raw materials received in interstate commerce.

The District’s seizure in September of four lots of Bon Vivant soups held by local distributors amounted to a total value of approximately $24,000. The products were alleged to have been processed under conditions whereby they may have become contaminated with filth or whereby they may have been rendered injurious to health.
The Fourth International Containerization Exposition and Technical Congress was held at the Oakland Coliseum from September 13 to 17. The District participated with headquarters personnel in preparing an FDA exhibit booth for the Exposition that was designed to portray the Agency's import inspections mission and to reflect changes in our procedures in recognition of containerization as a new concept in the handling of imported commodities. In preparation for the exhibit, San Francisco District personnel prepared a three-fold brochure entitled "Imports and FDA" portraying FDA's import obligation. This is the first handout of its kind ever designed solely to tell the FDA import inspections story.

SEATTLE DISTRICT  American Freezerships, Kodiak, Alaska, has ceased production for the present as a result of a joint FDA-Alaska State inspection. The firm, housed in a converted ferry boat, was found to be packing shrimp meat under insanitary conditions, which led to State seizure of more than 70,000 pounds of the product on September 29. Alaska State officials have indicated that future production will be prohibited until all violative conditions have been corrected. The shrimp meat never left the State, but it had been offered for introduction into interstate commerce.

U.S. District Court Judge William Beeks ruled in Seattle on September 15 that a Relaxacizor device shipped to Hollywood, California, in 1970 by a Seattle woman would not be returned to her. After the device arrived in California, FDA had sampled and seized it. The judge in ruling on the case said, "The device is inherently a very dangerous product, and there is no method by which its use may be rendered safe." He then ordered the Relaxacizor destroyed.
INJURIES ASSOCIATED WITH SNOWBLOWERS

Snowblowers can eliminate much of the drudgery of shoveling snowy walks and drives, but they can also have unexpected potentialities for serious injuries, according to the Bureau of Product Safety.

During the past several years, FDA's Injury Study Units in Boston and Denver have conducted 57 comprehensive investigations of snowblower accidents. These studies show that injuries from snowblowers can be severe. However, good power mower practices can be adapted for operating snowblowers for an effective, year-round safety program.

Snowblowers and power lawn mowers are similar in that both are machines with rotating parts. They eject semifluid material as they are steered along a path. Snowblowers differ in that a typical machine has a spiraling auger to cut into icy, hard-packed snow. This material is then ejected through a chute, which can clog, particularly after heavy, wet snowfalls. In 33 of 57 cases, according to John Locke, chief of the Injury Study Unit, wet snow was an environmental factor.

Studies show that householders are the most frequent owners and operators for both power lawn mowers and snowblowers. However, the mower operator has several factors contributing to his advantage. He can become proficient in handling the mower during frequent use in long summer months as he combats the rapid growth of well-tended lawns. He has time on his side, for he can wait until the grass is dry and the children are out of the yard. His clothing is light-weight and at a minimum. For body protection, he needs only sturdy work shoes and something to screen the sun's rays to avoid sunburn. His path is generally clear of obstacles to himself and his machine.

The situation changes drastically for the harried householder using a snowblower to clear driveway and walks of last night's heavy snowfall. Often he has a deadline for getting the job done. He has to clear the driveway quickly to get his car out, for he is due at the office. His children will be late for school. And his wife must make a meeting on time. He knows that he should clear sidewalks as promptly as possible to avoid injuries from falls to family members or passers-by with the resulting legal liabilities.

However, his work is often difficult, for he must work with slippery, uncertain footing from the snow itself and possibly ice beneath. He is bundled up in warm but cumbersome clothing, including mittens that hinder manipulation of handles and switches and can become caught in the machine's moving parts. His heavy scarf and cap can obscure his vision, as can the vapors of his frosty breath.

Because it snows only occasionally in many communities where snowblowers are used, the owner may be unfamiliar with his snowblower. He finds his cold machine difficult to start in the cold air. And once it's started, he is reluctant to turn off the machine for any reason. He isn't expert with the machine's controls.

When snow clogs the ejection chute, too frequently he has reached in with a gloved or mittened hand to clear away the snow, regardless of the whirling blades hidden by the hard-packed snow. Studies by the Boston Injury Study Unit show that 67 percent of the victims investigated were injured in this manner, and 95 percent of these suffered damage to the hands. (The accompanying chart shows the percentage of hand injuries in relationship to the total number of injuries investigated, as well as the preponderance of injuries occurring in discharge chutes.)

The same studies showed that human errors were the major factors in the cases investigated. Operators failed to take precautions in clearing discharge chutes. More than half of the victims had done the same thing several times previously and escaped injury. In almost half the cases, the operator was using the machine for the very first time or for the first time that season. Since more than half (65 percent) of the accidents studied in Boston and Denver occurred within the first hour of operation, fatigue was probably not an important contributing factor.

Also, work habits contributed further hazards. Records showed that injuries occurred when operators worked in front of machines or slipped on icy surfaces or both. As a result, a hand was struck by the impeller blades or auger. Other human factors were shown to be failure to disengage the blower's blades, failure to shut off the engine, and failure to wait for blades to stop rotating before attempting to clear the discharge chute.

The studies included two types of snowblower design:

The single-stage machine has a large auger in front, which cuts into snow and then ejects it through a discharge chute by means of an auger flange. This flange is usually located in the middle of the spiral-shaped auger, and snow is drawn into it as the auger rotates. For ejection of the snow efficiently, the auger must rotate rapidly.

A two-stage machine has, in addition to the
snow-cutting auger, a separate impeller at the base of the discharge chute. Although the auger of this type of machine turns more slowly, the impeller rotates at a high speed to eject the snow from the chute.

Some makes of snowblowers have a mechanism whereby the auger or impeller or both can be disengaged without shutting off the engine. Other machines have no such mechanism and the engine must be shut off to halt the rotation of the blades.

Most, if not all, of today's self-propelled models were shown to have either a gear shift, which can be moved to a neutral position, or a "dead man's" control, the release of which stops the machine's forward motion. With neither type, however, is the auger's or impeller's rotation stopped.

The most common type of chute guard was shown to be a piece of heavy-gauge wire in the shape of an "M." Another type of guard is flexible plastic in a paddle shape, which partially covers the chute opening and bends outward as snow is ejected. Major disadvantages of both types are that they may contribute to chute clogging, and the wire guard is easily removed.

Of the cases investigated, 65 percent of the machines involved had accompanying warnings, but these did not seem to be effective in preventing accidents. Such warnings included: "Stay clear of chute outlet when engine running," "Caution—stop engine before removing foreign objects from blower or rake," "Don't put hands or feet near auger when turning," and "Keep hands out of chute with motor running."

The Bureau of Product Safety makes several safety recommendations. The two most important recommendations for accident prevention would be changes in equipment design that would reduce the common tendency for chutes to clog or that would permit safe removal of clogged snow. To the extent possible, these changes should be so developed that they could be fitted to machines now in use as well.

Further recommendations include a "dead man's" control in a snowblower's handle that would not only stop the machine's forward motion but would also halt the rotation of impeller blades or auger.

The Bureau recommends that new operators be given thorough instructions and a short training session in proper snowblower use at time of purchase. Instructions should show specifically the hazardous aspects and practices as found in the Boston and Denver studies. The purchaser should be shown exactly how to clear a clogged discharge chute safely.

The Bureau's safety recommendations for snowblower operators include the following. (Many of these tips can be adapted to power lawn mowers.)

1. Disconnect the engine and wait until blades stop moving before trying to clear the discharge chute.
2. Don't try to hurry, especially when the work surface is wet or slippery. Melting ice provides slick, treacherous footing—a hazard often involved in snowblower accidents.
3. Don't leave a snowblower unattended for a moment. Stop the motor completely when you leave.
4. Don't work while wearing soft footwear. Wear sturdy work shoes and heavy, close-fitting slacks to protect feet, ankles, and legs.
5. At the beginning of each winter season, re-read manufacturer's instructions for the machine's safety and maintenance.
6. Know and practice using the machine's controls so in an emergency you'll do the right thing automatically. Be sure you know how to stop the motor in an instant.
7. Be sure that only competent, well-trained persons operate the machine.
8. If possible, clear the work area of stones, wire, toys, and other debris before the job is started. Watch for anything that could be forcibly ejected through the discharge chute.
9. Know where children and pets are while you work. Keep them at a safe distance. Remember, this is not a spectator sport!
Snowblower Accidents

67% of the injuries studied occurred during attempts to clear clogged ejection chutes and 95% of the accidents resulted in hand injuries.
Public Warned of Radiation Risk From Faulty Microwave Oven Model

FDA reported on October 1 that the RR-1 model of an Amana microwave oven has the potential of being operated with the door open, thus exposing users to dangerous levels of microwave radiation.

Four units of the RR-1 Amana Radarange manufactured by Amana Refrigeration, Inc., Amana, Iowa, have been found with defective safety interlock switches. Safety interlock switches are a safety feature designed to prevent operation of the units when the door is open. Exposure to microwave radiation from the open door could cause severe burns, eye cataracts, or other damaging effects.

FDA urged all owners of the RR-1 ovens to unplug the unit, call a local Amana service representative or the Amana Company, and refrain from using until serviced.

The company produced 5,400 of these models from September 1967 to October 1968. The model RR-1 oven is a portable unit which can be distinguished from later models by its two push buttons for oven operation. Later models have three push buttons.

FDA Proposes Child-Proof Packaging For Wintergreen Oil, Drugs of Abuse

The FDA has proposed to require "child-resistant" packaging for liniments and other liquid preparations containing more than 5 percent of methyl salicylate (oil of wintergreen) and for those drugs subject to controls under the Comprehensive Drug Abuse Prevention and Control Act of 1970. The proposal concerning products containing methyl salicylate was published in the Federal Register of September 29 and that concerning drugs of abuse in the Federal Register of October 15.

Charles C. Edwards, M.D., Commissioner of Food and Drugs, said injury reports to FDA's Bureau of Product Safety and other Government agencies show that 176 accidental ingestions of methyl salicylate by children under five years of age occurred in a 3-year period, 1968 through 1970. Of these, 33 children were hospitalized and eight died.

"This product is attractive to children because of its wintergreen odor," Dr. Edwards said. "As little as one teaspoon of methyl salicylate has been reported to be fatal."

The special packaging would be designed so that not more than 2 milliliters (less than half a teaspoon) will flow from the container when it is inverted and shaken or squeezed once. Also, the standard would require that 85 percent of a test group of 200 children (ages 42 to 51 months) be unable to open the container and that 80 percent fail after a demonstration of how to open it. Of a test group of 100 adults, 90 percent must be able to open and close the container.

The proposed regulations were reviewed by the Poison Prevention Packaging Act Technical Advisory Committee.

The proposal to require "child-resistant" packaging for drugs subject to controls under the Comprehensive Drug Abuse Prevention and Control Act of 1970 covers approximately 4,300 drugs listed under the Act. Controlled drugs are defined by the law as those that have been determined by the Attorney General to have a potential for abuse.

Dr. Edwards, in announcing the FDA move, said the proposed packaging regulations are designed especially to protect children under the age of five from accidental ingestion of narcotic, depressant, and stimulant drugs used in the home.

Reports to FDA's National Clearinghouse on Poison Control during 1970 concerning accidental ingestions by children under five show 945 ingestions and 108 hospitalizations from amphetamine-type products; 437 ingestions and 73 hospitalizations from barbiturate sedative products; and 10 ingestions and 5 hospitalizations from methadone, a drug used in the treatment of heroin addiction.

The proposed standards for closures on controlled drugs would require the same difficulty for opening as those for the oil of wintergreen products.

Industry Cooperation Urged in Study Of Materials Listed GRAS in Past

Manufacturers, formulators, and other users of food additives were urged by the FDA to cooperate in a survey to determine the levels of use of materials that have in the past been considered GRAS (Generally Recognized As Safe).

Charles C. Edwards, M.D., Commissioner of Food and Drugs, in announcing the survey October 19, said it is part of an overall review by FDA to determine what materials can qualify for listing as GRAS and what materials will be approved for food additive use only on the basis of individual review and regulation. The survey is being conducted for FDA by the National Academy of Sciences.

Questionnaires have been distributed to manufacturers, formulators, and other users of the substances through direct contact, various trade associations, and other methods. To provide the broadest possible basis
for making determinations about the toxicity of the substances, FDA is particularly anxious to reach small users and those who may not be affiliated with trade associations.

The specific substances about which FDA needs information are, in addition to those on the GRAS list, those sanctioned through FDA action, meat inspection action, or poultry products inspection action, prior to passage of the Food Additives Amendment of 1958.

Commissioner Edwards stressed that although obtaining and filling out the questionnaires is purely voluntary, it is important that all users of the substances have an opportunity to participate in the survey intended to help in reaching decisions about the toxicity data necessary to support continued safe use of such substances.

Anyone not yet contacted who wants to cooperate can obtain a questionnaire from the Subcommittee on GRAS Review, Food Protection Committee, National Academy of Sciences-National Research Council, 2101 Constitution Ave., N.W., Washington, D. C. 20037, attention Durwood Dodgen. If more convenient, Mr. Dodgen can be contacted by telephone at (202) 961-1537.

New FDA Policy Tightens Regulation Of Fixed Combo Prescription Drugs

FDA has made final a proposed Agency requirement that prescription drugs composed of more than one ingredient combined in fixed dosage form (a pill, capsule, teaspoonful) offer the patient a therapeutic advantage over any of the components administered separately.

The new policy, which became effective October 14, affects up to 40 percent of widely sold prescription drugs. Over-the-counter drugs—those sold without prescription—will be dealt with separately.

The new FDA policy on fixed combination prescription drugs:

(A) Two or more drugs may be combined in a single dose form when each contributes to the claimed effects. The dosage of each ingredient (amount, frequency, duration) must be safe and effective for a significant number of patients who require concurrent therapy with the drugs. Special cases of this general rule are where an ingredient is added to:

- enhance the safety or effectiveness of the principal ingredient; or
- minimize the potential for abuse of the principal ingredient.

(B) If a combination drug presently licensed is changed to meet new requirements based on a review for effectiveness by the National Academy of Sciences-National Research Council, then formulation, labeling, or dosage changes may be proposed and any resulting formulation may meet the basic requirement listed above.

(C) Any fixed combination drug for humans judged effective by FDA based on evaluation of the NAS-NRC reports meets the requirements of the policy.

FDA proposed the policy on fixed combination drugs on February 18, 1971. The Agency received more than 1,000 letters from physicians and comments from medical and pharmaceutical groups. Apparently the proposal was not completely clear.

The final statement has been simplified. The primary change is the removal of over-the-counter (OTC) drugs from the provisions of the proposed policy statement.

There was strong opposition to judging OTC drugs by the same criteria used for prescription drugs. FDA agrees that the differences in the two classes of drugs warrant separating the OTC drugs for separate consideration.

In addition the requirement that the combination drugs be useful for “most” patients for whom it would be prescribed has been changed to a “significant number,” as defined in the labeling for the drug.

Basically the policy proposed in February 1971 is unchanged. The revisions state the requirements more broadly with the intention that they will provide a useful guide to industry in considering introduction of future combination products.

The policy statement, published in the October 15 Federal Register, provides a clearer and more flexible amplification of FDA policy on prescription drugs in fixed combinations.

FDA Begins Inventory of All Drugs Currently Marketed for Human Use

FDA is initiating an inventory of all drugs marketed for human use in the United States. The Agency announced October 7. The drug industry will be asked to supply information voluntarily covering all prescription and nonprescription drugs, vitamins, and antibiotics.

“The objective,” said Charles C. Edwards, M.D., Commissioner of Food and Drugs, “is to obtain complete information on all finished dosage forms of drugs currently marketed for human use.” Much of this information is not now available to the Agency.

Legislation requiring mandatory registration of all drugs is being considered by the Congress. This legislation would require the industry to submit inventory information routinely starting December 31, 1972.

“In the interim,” said Dr. Edwards, “we believe that much can be gained by seeking voluntary industry cooperation in providing the much needed information.”

Between October 15 and November 1, 1971, report forms were to be sent out in preparation for the voluntary inventory. FDA officials scheduled a series of briefing sessions for industry in major cities between those dates to explain the purpose, scope, and details of the inventory.

The survey includes information on production, formulas, coding, and labeling all drugs for human use that are subject to the Food, Drug, and Cosmetic Act.
Frozen Dessert Change The Pennsylvania Department of Agriculture has announced that a public hearing has been set for taking testimony on a proposed change in the Pennsylvania Frozen Desserts Law. The change would allow greater use of locally produced dairy products.

Changing the regulation to include cheese whey, a byproduct of the manufacture of cottage cheese, could make the product more profitable to the local dairy industry.

The hearing has been scheduled for Wednesday, January 5, 1972, at 10 a.m., in Room 309, Department of Agriculture Building, Harrisburg.

Oregon to be Host State of Oregon representatives planned to be host for a Milk Sanitation Rating Officers Seminar to be held November 3-5 at the State Office Building in Portland. Milk sanitarians and inspectors for the States of Alaska, Washington, Idaho, and Oregon will attend the seminar set up by Region X of the Food and Drug Administration, Public Health Service.

Vergil Simmons, assistant administrator for milk and dairy products, Dairy and Consumer Services Division, Oregon Department of Agriculture, is in charge of the State's arrangements and will also be chairman of the first day's session. Kenneth E. Carl, administrator, Dairy and Consumer Services Division, will welcome those attending the seminar. William G. Kupp, Seattle, chief of the special programs branch, Region X, FDA, will open the sessions with a discussion of aims and purposes of the seminar.

Also participating in the program will be three top FDA people from the East: Harold Thompson, Washington, chief of the Milk Sanitation Branch, Division of Food Service and Milk Sanitation, Bureau of Foods; Milton Gates, Washington, assistant to the director of the Division of Regulation Guidance, Office of Compliance, Bureau of Foods; and Dr. John Messer of the laboratory development program of the FDA Research Laboratories, Bureau of Foods, Cincinnati, Ohio.

Also included on the program are to be the following Oregon men: Dr. Edward Press, State health officer, Oregon State Board of Health; Doug Pike, assistant director, Department of Local Health Services, Oregon State Board of Health; Floyd Bodyfelt, dairy extension specialist, Department of Food Technology, Oregon State University; and Al Tesdal, milk sanitarian, Oregon Department of Agriculture.

New City Program Henry Etchemendy, city manager, Carson City, Nevada, recently approved and announced the adoption of a program to motivate the enhancement of food service sanitation standards in Carson City restaurants. He said the program will be put into effect and managed by F. J. Picard, director, Environmental Health Services, Carson City Health Department.

Following the announcement, Mr. Picard said, "This is only a logical follow-up to the newly introduced continuing education program initiated at the Sanitation Seminar held earlier this month. The restaurant operators' demonstrated enthusiasm toward achieving the highest sanitation standards in the State compelled the inception of a program such as that being introduced." Mr. Picard continued, "The program is a natural extension of the progressive attitude of the governing body of this community. This is only one of many activities that reflects the concern of this city's elected and appointed officials for the welfare of residents and visitors."

Beginning in January 1972, food service establishments will be grouped, for award eligibility purposes, into three categories. Those restaurants maintaining a competitively low, inspection-revealed violation rate over a period of six months will be eligible for the "Superior Sanitation Award." The award may be displayed in the establishment for the ensuing six-month period at which time it will be rewar ped or surrendered depending upon eligibility status at that time. When displayed, the certificate will be evidence of responsible management and employee effort to provide the safest, most wholesome food possible to the establishment's patrons.

Aid for Consumers Motivated not only by increasing consumer complaints but by the once frequently used term, "It just made me see red!" Jane Wyatt, consumer officer of the Oregon Department of Agriculture, has prepared a consumer pamphlet just to suit this mood of red. Its cover is a deep bright pink, seeming to reflect the mood of an irate consumer. Entitled, "Do You Have a Complaint . . . ?", the pamphlet tells a consumer how to protect herself.

Although "seeing red" has been supplanted by more modern terms for describing one's state of anger, there are times when this phrase conveys the most accurate picture of a consumer's feelings—when a purchase she has made turns out to be inferior to what it appeared to be in the store. This is particularly true of a food around which a menu has been planned and the consumer is forced to use it and make the best of it, or if it is a case of being short-weighted to the point that servings have to be reduced in size.

Mrs. Wyatt notes that one of the statutory functions of the Oregon State Department of Agriculture is to assure the consumers of the State a safe, wholesome food supply, properly packaged and labeled. She advises the consumer who has a problem with food articles to con-
tact the firm or individual involved to try to work out an adjustment, and to keep notes of all transactions and copies of receipts, letters, etc. Should the consumer fail with this approach, Mrs. Wyatt says, the next step she may want to take is a formal complaint. In the case of food products, the agency to contact is the Oregon Department of Agriculture.

To make it easy for the consumer to file this complaint, there is a consumer complaint report form on the back page of the new pamphlet.

Board of Health Survey The Alabama State Board of Health is conducting a survey to determine the adequacy of individual waste disposal facilities of all oyster processing plants. The work is being carried out by local health department sanitarians with special attention to disposal practices for human wastes. As of September 1, no plants had been certified for inclusion on the Interstate Shellfish Shippers list. One of the main purposes of this State survey is to document the need for a sewage treatment plant in Bayou La Batre.

Department Levies Penalties The New York State Department of Agriculture and Markets levied penalties against 177 firms and persons during August for alleged violations of the State Agriculture and Markets law. An additional 106 cases were referred to the Attorney General for disposition. A meat-packing firm in Jamaica was assessed the top penalty of a thousand dollars for cutting beef without State inspection.

Botulism Report Representatives of the Ohio Department of Health and A. J. Earney, Holmes County Health Commissioner, report that a Holmes County family recently had a narrow escape from disaster. Because the contents of two quart jars of home canned corn did not look nor smell right, the family fed the corn to their hogs. Ten pigs died. Other jars of the corn were discarded, resulting in the death of chickens, another pig, and a hog. The family called in a veterinarian who diagnosed the deaths as due to botulism. He sent some of the corn to the Ohio State Health Department, where botulism toxin type B was identified.

Cooperative Workshops The Iowa Department of Agriculture, Iowa Grain and Feed Association, and Iowa State University sponsored a series of Feed Mill Operations Workshops throughout the State the week of September 13. At least 300 feed mill operators and employees attended the evening sessions held at Des Moines, Williamsburg, Waterloo, and Storm Lake.

The program presented was designed primarily to assist and explain the responsibilities of those persons involved in the feed mill and delivery operations. Featured speakers included Dr. Robert A. Wilcox and Extension Specialist James L. Balding, of the Formula Feeds Division, Kansas State University, Manhattan, Kansas; and Dr. C. Phillip Baumel, research professor, Iowa State University, Ames, Iowa. The Kansas team of specialists has put on similar programs for feed mill operators and employees in that State for the past several years.

Consumer Complaints A consumer complaint to the Kansas City, Missouri, Health Department on September 9 concerning hamburger meat brought about immediate conviction of a local meat cutter and condemnation and destruction of 380 pounds of adulterated hamburger. Also detained by the City Health Department was approximately 30 pounds of "XXX Washing Powder," which was used as the adulterant and contained sodium sulfite.

Robert Smith, meat cutter at the Hen House Super Market charged with selling the adulterated meat, was found guilty in municipal court and sentenced to 30 days in jail. The sentence was suspended and the defendant was placed on probation for two years.

Dr. Edwin O. Wicks, city health director, said laboratory analysis revealed excessive amounts of sodium sulfite in the hamburger. This substance retards decomposition, masks the taste and odor of putrid meat, and gives the meat red color that falsely makes it appear to be fresh.

Pennsylvania Embargoes John Timo, a Pennsylvania State Department of Health inspector, embargoed and seized eight Relax N' Trim kits September 1 in possession of a Seward, Pennsylvania, dealer. The kits, sold as a reducing treatment, were deemed misbranded due to lack of mandatory labeling and because of inadequate directions for use. They had been shipped by Relax N' Trim, West Los Angeles, California. The State seizure was upheld by State court at a hearing held September 10, and the lot was ordered destroyed or relabeled to comply with State law.

During the week of September 20, Mr. Timo placed under State embargo a lot of crataegus digitalis strophanthus compound manufactured by the Zemmer Company, Oakmont, State charges were based on misbranding because of inadequate directions for use. The lot was voluntarily destroyed by the firm and the product dropped from its line.

California Restrains A fruit canning firm in Dinuba, California, and all of its officials were temporarily restrained recently by the State of California from further packing of fruit in its plant because of insanitary conditions. A hearing for a permanent injunction was held October 1, at which time the court temporarily enjoined the firm for a two-week period. This time was allotted to the firm to clean up and otherwise meet State requirements. At the end of the two-week period, or at a time when the firm felt it was ready, a joint inspection was to have been made by a California State food and drug inspector and an inspector from the U.S. Department of Agriculture. The inspectors were then to report to the State Attorney General for further decision by the court as to the permanency of the injunction.
SEIZURE ACTIONS charging violation of the Federal Food, Drug, and Cosmetic Act and the Federal Hazardous Substances Act are published when they are reported by the FDA District Office.

A total of 44 actions to remove from the consumer market products charged to be violative were reported in September. These included 28 seizures of foods: 3 involved charges concerning poisonous and deleterious substances, 18 involved charges concerning contamination, and 7 involved charges concerning economic and labeling violations. Other seizures included 1 of vitamins and dietary food, 2 of drugs, 1 of cosmetics, and 12 of hazardous substances.

<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catfish food/Guntersville, Ala. 8/19/71</td>
<td>Ralston Purina Co./Memphis, Tenn. (M,S)</td>
<td>Contains a polychlorinated biphenyl compound, which may render it injurious to health.</td>
</tr>
<tr>
<td>Montgomery, Ala. 8/19/71</td>
<td>Ralston Purina Co./St. Louis, Mo. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Trout chow/Lumber City, Ga. 8/24/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flour, all purpose, USDA Consumer Marketing Service/Chicago, Ill. 9/3/71</td>
<td>Shell Fish Imports/Miami, Fla. (S)</td>
<td>Held in rodent-infested railcar.</td>
</tr>
<tr>
<td>St. Cloud, Minn. 7/8/71</td>
<td>Bon Vivant Soups, Inc./Newark, N.J. (M,S)</td>
<td>Prepared under insanitary conditions; defective and abnormal cans.</td>
</tr>
<tr>
<td>Soups, Bon Vivant/Bristow, Okla. 9/2/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Bedford, Mass. 9/10/71</td>
<td>Bon Vivant Soups, Inc./Newark, N.J. (M,S)</td>
<td>Prepared under insanitary conditions; defective and abnormal cans.</td>
</tr>
<tr>
<td>Charlestown, Mass. 9/8/71</td>
<td>Bon Vivant Soups, Inc./Newark, N.J. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Amesbury, Mass. 9/8/71</td>
<td>Bon Vivant Soups, Inc./Newark, N.J. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Long Island City, N.Y. 9/13/71</td>
<td>Bon Vivant Soups, Inc./Newark, N.J. (M,S)</td>
<td></td>
</tr>
<tr>
<td>San Antonio, Tex. 9/3/71</td>
<td>Bon Vivant Soups, Inc./Newark, N.J. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Dundee, Ill. 9/7/71</td>
<td>Bon Vivant Soups, Inc./Newark, N.J. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Rolling Meadows, Ill. 9/7/71</td>
<td>Bon Vivant Soups, Inc./Newark, N.J. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Indianapolis, Ind. 9/10/71</td>
<td>Proctor Canning Co./Proctor, Okla. (D)</td>
<td>Partly decomposed.</td>
</tr>
<tr>
<td>“Bon Vivant” and “Ancora” brands/Lansdowne, Md. 9/7/71</td>
<td>Dottley’s Spice Mart, Inc./McGhee, Ark. (M,S)</td>
<td>Fails to bear an accurate statement of the quantity; ascorbic acid is not declared on label.</td>
</tr>
<tr>
<td>Tomatoes, canned/Proctor, Okla. 7/2/71</td>
<td>Holly World Foods, Inc./San Francisco, Calif. (S)</td>
<td>Not in conformity with the Fair Packaging and Labeling Act.</td>
</tr>
<tr>
<td>Cherries, canned/Tipton, Ind. 9/8/71</td>
<td>Imported from various countries. Mid-America Dairymen, Inc./Springfield, Mo. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Dot pork sausage seasoning/Houston, Tex. 8/3/71</td>
<td>Imported from the West Indies, Lou Scharf, Inc./New York, N.Y. (Distributor)</td>
<td></td>
</tr>
<tr>
<td>Fish balls, canned, gooseberries, canned, Hawaiian coconut snow, Maggi Swiss style dumplings, sweet pickled apricots/Salt Lake City, Utah 9/9/71</td>
<td>Mid-America Dairymen, Inc./Lebanon, Mo. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Lime juice, mangoes/Brooklyn, N.Y. 8/30/71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sour cream/Little Rock, Ark. 7/23/71</td>
<td>Procter Canning Co./Proctor, Okla. (D)</td>
<td></td>
</tr>
<tr>
<td>Strawberry yogurt, lemon yogurt/Houston, Tex. 7/19/71</td>
<td>Mid-America Dairymen, Inc./Lebanon, Mo. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Veron quince jam/Chicago, Ill. 8/5/71</td>
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<tr>
<td>Dwarfies Daily Dozen—Thirteen Vitamins w/Lemon Bioflavonoids Complex/St. Joseph, Mo. 9/2/71</td>
<td>Dwarfies Corp./St. Joseph, Mo. (D)</td>
<td>Vitamins—Dietary Food False and misleading labeling suggesting that lemon bioflavonoids are nutrients with special dietary properties; lacked required information concerning purported special dietary uses.</td>
</tr>
<tr>
<td>Arseno-Phos injection/Detroit, Mich. 7/22/71 “Gyben” vaginal suppositories/St. Louis, Mo. 7/14/71</td>
<td>Atlas Pharmaceutical Labs, Inc./Detroit, Mich. (M) Ingredients shipped from N.Y. Lee Way Motor Freight/St. Louis, Mo. (S)</td>
<td>DRUGS/Human Use Not in conformity with good manufacturing practice. Held in a truck in which a toxic chemical reportedly ruptured and spilled its content in transit.</td>
</tr>
<tr>
<td>Brylcreem/Detroit, Mich. 8/26/71</td>
<td>Beecham Products/Brentford, England (M)</td>
<td>COSMETIC Inconspicuous labeling.</td>
</tr>
<tr>
<td>Class B Fireworks/near Trenton, Mo. 6/30/71</td>
<td>Stand, approx. 3 miles N. of Trenton, Mo. (D)</td>
<td>HAZARDOUS SUBSTANCES Banned hazardous substances; lack consumer protection information required by the Fed. Hazardous Substances Act.</td>
</tr>
<tr>
<td>near Princeton, Mo. 6/30/71</td>
<td>Stand, nr. junct. 136 &amp; 65, Princeton, Mo. (D)</td>
<td></td>
</tr>
<tr>
<td>near Mercer, Mo. 6/30/71 (2 actions)</td>
<td>Stand, 4 miles S. of Mercer, Mo. (D)</td>
<td></td>
</tr>
<tr>
<td>near Tarkio, Mo. 7/16/71</td>
<td>Ted’s Tobacco &amp; Grocery, nr. Tarkio, Mo. (D)</td>
<td></td>
</tr>
<tr>
<td>near Wayland, Mo. 7/11/71</td>
<td>Kinkeade’s, 1 mile S. of Wayland, Mo. (D)</td>
<td></td>
</tr>
<tr>
<td>near Des Moines River Bridge, Clark County, Mo. 7/11/71</td>
<td>Tent, SE side of US 61/136, Clark County, Mo. (D)</td>
<td></td>
</tr>
<tr>
<td>Claud, Ala. 7/2/71</td>
<td>K &amp; R Grocery/Clau, Ala. (D)</td>
<td></td>
</tr>
<tr>
<td>Wetumpka, Ala. 8/2/71</td>
<td>Grantham’s Gulf Station/Wetumpka, Ala. (D)</td>
<td></td>
</tr>
<tr>
<td>near Jackson, Mo. 7/11/71</td>
<td>Kinder Fireworks/RFD #2, Jackson, Mo. (D)</td>
<td></td>
</tr>
<tr>
<td>Ice-O-Magic, storable refrigerant for portable ice chests/Glen Burnie, Md. 8/18/71</td>
<td>Chase Chemical Corp./Jacksonville, Fla., and Unipak, Inc./Indianapolis, Ind. (S)</td>
<td></td>
</tr>
<tr>
<td>Travel-ice refrigerant/New Orleans, La. 8/26/71</td>
<td>Linco Products Co./Costa Mesa, Calif. (M,S)</td>
<td></td>
</tr>
</tbody>
</table>

**U.S. POSTAL SERVICE**

actions taken in medical cases as authorized in the Mail Fraud Statute (18 U.S.C. 1341) and/or the False Representation Statute (39 U.S.C. 3005) as reported by the Assistant Postmaster General—Inspection Service.

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

September 2, 1971: False Representation Order issued against Thornwood Laboratories, 10 Burnside Ave., Congers, New York. Advertising and sale by mail of “Slenro Capsules” represented as enabling users to lose 10 pounds in one month.

September 9, 1971: False Representation Order issued against Bruce Roberts Co., 89 Worth St., New York, New York. Solicitations of orders and sales through the mails of “Viran” tablets represented as a sexual rejuvenator.

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

August 27, 1971: Easy Slim, Dept. 15-A26, Box 742, Encino, California. Firm advertised that the use of grapefruit juice, as prescribed in the diet plan, contributes to rapid weight loss by acting as a catalyst to help the body burn excess fat and body fluids.

September 13, 1971: Wonder Belt, 1044 Northern Blvd., Roslyn, New York. Advertising and sale by mail of a “Wonder Belt” represented as enabling wearers to reduce and melt away excess fat from any particular part of their anatomy.

September 17, 1971: Power Fashion Model Slims, 5th Floor, 3 West 30th St., New York, New York, and Power Fashion Model Slims, Inc. Advertising and sale through the mails of “Power Fashion Model Slim Capsules” guaranteed as enabling subscribers to lose 10 pounds in 10 days.

September 21, 1971: Neltor, Inc., and Grapefruit Diet Division, Fort Lauderdale, Florida. Firm advertised that newest Grapefruit “Super-C” diet enables subscribers to eat all they want while losing and retaining a substantial weight loss year after year.
NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Copra meal products, at Wilmington, C. Dist. Calif. Charged 5-21-70: when shipped from the Philippines, the article contained an added poisonous and deleterious substance, namely, aflatoxin; 402(a)(1). Consent decree ordered destruction. (2)

Cottonseed meal, at Draper, Dist. Utah. Charged 12-29-70: while held for sale, the article contained an added poisonous and deleterious substance, namely, aflatoxin; 402(a)(1). Default consent decree ordered destruction. (1)

Lettuce, Slim's, at Detroit, E. Dist. Mich. Charged 11-17-69: when shipped by Rala Singh Farms, Glendale, Ariz., the article contained the pesticide chemical toxaphene in excess of the prescribed tolerance; 402(a)(2)(A). Default decree ordered destruction. (3)

Peanuts, shelled, at Milwaukee, E. Dist. Wis. Charged 2-6-71: while held by Jack Lonk Co., Milwaukee, Wis., a portion of the article contained the added poisonous and deleterious substance, namely, aflatoxin; 402(a)(1). Consent decree ordered delivery to Baker Commodities, Inc., Los Angeles, Calif., for export to original foreign supplier. (1)

Swordfish, 2 seizure actions at Wilmington, C. Dist. Calif. Charged 2-16-71: when shipped by P. M. Foods, Inc., Phoenix, Ariz., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (10)

Flour, at Chicago, N. Dist. III. Charged 1-11-71: when shipped by North Pacific Canners & Packers, Inc., Portland, Ore., the article contained bacterial filth and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (19)

Donut mix, American Beauty, at Claremont, Dist. N.H. Charged 3-31-71: when caught in waters outside the territorial limits of the State of California, the article contained an added poisonous and deleterious substance, mercury; 402(a)(1). Default consent decree ordered destruction. (7)

FOOD/Contamination, Spoilage, Insanitary Handling

Beans, black, white, at South San Francisco, N. Dist. Calif. Charged 3-25-71: while held by Presco Food Products, Inc., South San Francisco, Calif., the article contained the poisonous and deleterious substance, Salmonella micro-organisms, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (3)

Swordfish, at Gloucester, Dist. Mass. Charged 2-19-71: when imported into the United States from Norway, the article contained an added poisonous and deleterious substance, mercury; 402(a)(1). Default decree ordered destruction. (3)

Swordfish, 2 seizure actions at Wilmington, C. Dist. Calif. Charged 3-30-71: while caught in waters outside the territorial limits of the State of California, the article contained an added poisonous and deleterious substance, mercury; 402(a)(1). Default consent decree ordered destruction. (7)


Yams, canned, at Blytheville, Dist. Ark. Charged 5-13-70: while held for sale, the article contained a decomposed substance; 402(a)(3). Default decree ordered destruction. (24)

Flour and sugar, at Franklin Park, N. Dist. Ill. Charged 2-17-71: when held by Central Grocers Cooperative, Inc., Franklin Park, Ill., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (14)

VITAMINS/SPECIAL DIETARY FOODS

Leen vitamin-mineral capsules, at Oakland, N. Dist. Calif. Charged 5-3-70: when held by Ray Drug Co., Inc., Oakland, Calif., who packed the article, the article's valuable constituents, vitamin B-12 and
calcium pantothenate had been in part omitted or abstracted, and the name "Leen" and the label statement "For Reducing Distress" was misleading in representing that the article had some unique prop-
erties which were not reflected in the label statement. A need in human nutrition for calcium pantothenate has not been estab-
lished, and the article contained false and misleading labeling. (40a). Consent decree ordered the destruction of the article and the return of certain advertising material and display boxes to the dealer. (29)

**FOOD ADDITIVES**

Castor bean meal, processed, Plainview, at Swink, Dist. Colo. Charged 11-37-70: when shipped by Plains Producers Co., Colo-
rado Springs, Colo., for pet food. Consent decree ordered destruction. (30)

**ANIMAL FEED**

All Ration rabbit pellets, Chick Grow mash, and 40% hogs concentrate, Diamond "S," at Colorado Springs, Dist. Colo. Charged 1-13-71: when held by Western Dairies, Inc., Colorado Springs, Colo., from ingredients shipped in interstate commerce, the Diamond "S" All Ration rabbit pellets was an animal feed which, unless repacked with adequate directions for approval of a New Animal Drug Application filed with respect to such animal feed was in effective and adequate directions for use. The labeling failed to establish that each of each of its active ingredients; and the labeling of the Diamond "S" Chick Grow mash which represented that such article contained 14% protein in that condition was false and misleading, since the article contained no protein in that condition. Consent decree ordered destruction. (31)

Super 700 animal feeds, Big A Crumbles, Hi-Energy Range Cube, and 3-ln-l Super Cube, at Hutchinson, Dist. Minn. Charged 1-13-71: when held for sale after manufacture by John Ewing Co., La Salle, Colo., from ingredients shipped in interstate commerce, the Super 700 animal feeds, Big A Crumbles, Hi-Energy Range Cube, and 3-ln-l Super Cube, lacked the name of each of its active ingredients; and the labeling of all of the articles lacked adequate directions for use—502(f)(2). Consent decree ordered destruction. (32)

**DRUGS/Human Use**

phia, Pa., the article was deficient in methyltestosterone (approx. 19 percent); 501(c). Default decree ordered destruction. (33)

**MEDICAL DEVICES**

Thermometric model A-60740 electronic instrument, at Rockford, N. Dist. III. Charged 7-28-70: when used in interstate commerce after manufacture by Dynapower Systems Corp., Los Angeles, Calif., the article failed to bear in its labeling adequate directions for use for the purposes intended, since such directions could not be written for use by laymen of the article for such purposes; and the article was not exempt as an aid device from the requirement of adequate directions, since adequate in-ormation for its use could not be furnished under which practitioners could use the article safely and for the purposes intended; 501(f)(1). Default decree ordered destruction. (41)

Zeigler facial exerciser, at Bethesda, W. Dist. Okla. Charged 9-28-66: when shipped by Zeigler Electronics, Inc., Gardena, Calif., the labeling of the article contained false and misleading repre-
sentations and suggestions that the article was adequate and effective as a treatment for fine lines, wrinkles, loose facial skin, and sagging facial contours about the eyes, cheeks, and chin line; to tighten skin; improve tone and texture, firmness and strength of muscles; improve circulation; build complexion; improve shape of facial contours of mouth, cheek, jaw, nose, eyebrow arch level, area between eye and eyebrow, and area over bridge of the nose; mitigate effects of aging on facial skin, and create more youthful facial contours; 502(e)(1)(A)(ii), 502(f)(2). Consent decree ordered destruction. (42)

Pursuant to stipulation by the Government and the claimant, Zeigler Electronics, Inc., the case was removed for trial to the Southern District of California, interrogatories were filed by the Government and were answered. Thereafter, the claimant having consented to entry of a decree of permanent injunction as to all of the articles and the court having adjudged that the article was misbranded, a decree was entered which provides, in effect, the condemnation of the article and for its re-inse to the Department of Health, Education, and Welfare for ex-
hibit purposes. In addition, the decree enjoined the claimant from in-
roducing and delivering for introduction into interstate commerce any article designated as "Zeigler Facial Exerciser" or any similar article which was accompanied by written, printed, or graphic matter which represented and suggested that the article was adequate and effective for the purposes and conditions described above. (43)

**PROPHYLACTICS**

Prophylactics, rubber, at Philadelphia, E. Dist. Pa. Charged 7-20-70: when held by Natex Corp. of America, Philadelphia, Pa., after repacking that by firm, the article’s quality was deficient and it failed to bear in its labeling adequate directions for use for its intended use for livestock and poultry; the article's labeling lacked adequate directions for use—502(f)(1); and the labeling of the article, Super 700, lacked adequate warnings against use—502(f)(2). Consent decree ordered destruction. (44)

Prophylactics, rubber, Peaches, at Milwaukee, E. Dist. Wis. Charged 4-19-71: when shipped by Dean Rubber Co., North Kansas City, Mo., the article’s quality was deficient, since the article contained hoses; 501(c). Default decree ordered destruction. (45)

**HAZARDOUS SUBSTANCES**

Detergent, at Brooklyn, E. Dist. N.Y. Charged 3-8-71: when shipped by Nutrex Corp., of America, Philadelphia, Pa., after repacking by that firm, the article’s quality was deficient and the labeling statement "Suds Detergent . . . Distributed by H. C. Bohack Company, Inc., Brook-
lyn, New York," was toxic, corrosive, and an irritant and lacked a warn-
3403(a), 3403(b). Consent decree authorized release to the claimant from in-

**NOTICES OF JUDGMENT on Criminal Actions**

Foods
**DRUGS**

Dow Corning Corp., and A. W. Rhodes, director of Medical Products Division, Hemlij, E. N., claims against Raymond Pollak, and the plaintiffs, director of Medical Products Division, Hemlij, E. N., in a Federal Food, Drug, and Cosmetic Act, Title 21, U.S.C., Sections 301, 302(a), 302(b), 302(c), 302(d) and 302(f)(2).

The defendants moved for a dismissal of the action. The court rendered the following ruling:

"The defendant is in a six-count indictment with violating the Federal Food, Drug, and Cosmetic Act, Title 21, U.S.C., Section 310-312, relating to shipments of a product designated as 'Dow Corning Medical Silicone Fluid 360.' The indictment states that the shipment was made from Michigan to Pennsylvania, Ohio, and the shipment was made for use and lacked adequate warnings against unsafe use—502(f)(1), 502(f)(2)."

The defendants filed a motion for a dismissal of the action. The court rendered the following ruling:

"The defendants moved in a sixteen count indictment with violating the Federal Food, Drug, and Cosmetic Act, Title 21, U.S.C., Sections 310-312, relating to shipments of a product designated as 'Dow Corning Medical Silicone Fluid 356.' The indictment states that the shipment was made from Michigan to Pennsylvania, Ohio, and the shipment was made for use and lacked adequate warnings against unsafe use—502(f)(1), 502(f)(2)."

The court ruled that the indictment was not sufficient to state a claim upon which relief could be granted.

**NOTICE OF JUDGMENT on Injunction Action**

**Better Foods Foundation Cooperative Association, a corporation, and John C. Hopkins & Co., a corporation, claimants, and John C. Hopkins & Co., a corporation, claimant, and John C. Hopkins & Co., a corporation, claimant.**

Charged 9:30-68 in complaint for injunction: that the defendants were engaged in manufacturing, processing, packaging, and holding flour, buckwheat and pancake mix, and carried on a business of manufacturing, processing, packaging, and holding flour, buckwheat and pancake mix, and engaged in interstate commerce, and that such foods contained insect and animal residues, and were adulterated with such residues, to the damage of the claimants. The court granted the defendants' motion to dismiss the complaint.

"Therefore, for the above-mentioned reasons, the motion to dismiss the indictment is denied. An appropriate order may be submitted."
A new organization has been formed to make it easier for the consumer to learn what the Federal Government knows about family economics, safety and health, medicines, food and nourishment, clothing and fabrics, appliances, automobiles, housing, landscaping, gardening, pest control, and a number of other subjects in which today's consumer has a stake.

The Consumer Product Information Coordinating Center has compiled a list of 192 publications published by 15 Federal Government agencies that contain many kinds of information useful to the householder. These publications may be purchased at moderate cost. Many are free.

For a free copy of the Consumer Product Information Index of Selected Federal Publications on How to Buy, Use, and Take Care of Consumer Products, send your request to: Consumer Product Information, Washington, D.C. 20407. Bulk supplies of the index will be made available free to organizations for distribution to their members.
COMMITTEE OFFICERS NAMED Bradley Allyn McMain, practicing community pharmacist, Houston, Texas, and a member of the Texas Pharmaceutical Association's Board of Directors, has been named Chairman of the Local Hospitality Committee for the 119th American Pharmaceutical Association annual meeting to be held April 22-28, 1972, at Houston.

The announcement made by APhA President Lloyd M. Parks also included notice of the appointment of William J. Edwards, a practicing community pharmacist, Galveston, as secretary of the Local Hospitality Committee.

The APhA meeting will be held in what has been described as "the world's largest and most unique entertainment complex"—the Astrodome. Supplemental hotels for meetings and sleeping rooms will include the nearby Shamrock Hilton and new Houston Marriott Motor Hotel.

FDA POSTER AVAILABLE An employee-motivational poster, "Did You Really Wash Your Hands," is now available to food industry management for use in promoting sanitation programs. The poster complements FDA's taped color-slide show, "Clean Hands" (FDA PAPERS, March 1971). The use of this poster will remind employees to keep their hands clean and encourage them to produce clean, safe food products.