This Month

This month, FDA CONSUMER presents its final article about the regulation of household products and toys. Beginning in March, this function will be assumed by the newly created Product Safety Commission. FDA's Bureau of Product Safety, whose protection activities have been prominently featured in past issues, will form the nucleus of this new regulatory agency. The history of the legislation that created the Product Safety Commission and the new law's highlights are summarized in "A New Era in Consumer Safety."

Our color story this month is about the laser—a beam of light that can work wonders. The laser holds great potential benefits, but if not used correctly can be very harmful to the eyes. We describe some things the laser can do for you, and precautions you should take.

Another story that emanates from the Bureau of Radiological Health this month is on the use of x rays to screen people for tuberculosis and other diseases. Last year, FDA in conjunction with professional groups advised against the use of x rays for mass screening programs. We describe the five reasons for this recommendation in "Mass Chest X Rays Are on the Way Out."

"Don't Let It Bug You" aptly describes our story about flu vaccines. If you've been in bed with the flu this year or in previous years, you ought to read this story. It won't help you get better any quicker, but it will tell you things you may not know about influenza, and what scientists are doing to try to bring it under control.

If you're a dog owner, you'll be interested in our story on dog foods—"Dishing Up the Dog Food." You'll learn what to look for on the labels of dog foods, and what FDA does to assure that dog foods are nutritious and safe.
Quotes

"The era of insularity is over for the FDA. We are not and we should not be shielded from the scrutiny of the consuming public, the regulated industries, the scientific community, or any other interest that has a right to pass judgment on our performance. The FDA is, I am proud to say, in the forefront of a sincere and vitally important effort to bring Government closer to the people it serves. We are seeking innovative ways of making the regulatory process more democratic, more open, and more creative. I am convinced that that is the only way we can carry out our mandate fairly and responsibly."

Charles C. Edwards, M.D., Commissioner of Food and Drugs, before the Food and Drug Law Institute, Washington, D.C., December 13, 1972.

"The fact that Congress simply has not considered or spoken on a particular issue certainly is no bar to the Food and Drug Administration exerting initiative and leadership in the public interest. Except where expressly prohibited, I believe FDA is obligated to develop whatever innovative and creative regulatory programs are reasonable and are most appropriate to achieve the fundamental objectives laid down by Congress. And in spite of the diversity of the Agency's new programs, I am not at all certain that FDA has yet begun to explore the full reaches of existing statutory authority."


Consumer Forum

In future issues the space on this page will be reserved for a new feature of FDA Consumer, a page we are calling CONSUMER FORUM. It gives you, the consumer, the opportunity to have your views published in FDA Consumer.

Letters of any length are acceptable, depending on content and interest, but letters of 150 words or less have a better chance of being published. Letters must be signed, but we will withhold the name upon request and for valid reason. We will, however, use initials if we don't use the name. We reserve the right to condense letters to a suitable length for publication.

Letters to CONSUMER FORUM can be on any topic of concern to FDA—foods, drugs, cosmetics, household chemicals, toys, vaccines, radiation, medical devices. But remember—if you have a complaint about a specific product, or you feel a product is hazardous, you should channel your comments to the FDA District office nearest you. You will get the quickest action on a consumer complaint by going directly to the District.

Send letters to CONSUMER FORUM, FDA Consumer, PA-25, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.
Section 705 [375] of the Food, Drug, and Cosmetic Act:

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

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.
Don't Let It Bug You

by Jim Buchan

The layman's flu is not always the same as the physician's flu. This and other misunderstandings about influenza, and the difficulty of controlling the virus of some types with vaccines because of periodic genetic changes in the virus, are some of the problems the Bureau of Biologies faces in research on and regulation of flu vaccines for consumer protection.

Your stomach's upset. Your head aches. A case of diarrhea keeps you in the general proximity of modern plumbing. You have the "flu." Right?

Wrong! You probably have one of a number of intestinal disorders, or one of a variety of common colds or respiratory diseases that are similar to flu and clinically often impossible to differentiate.

You've just read in the newspaper that the "flu" virus has been seen and photographed for the first time and that a new cure-all vaccine is about to emerge on the national and world scenes. You've conquered "flu," you reason.

Wrong again.

What these reports are describing is something called acute infectious gastroenteritis. But the news reports call it "flu" because it's a catch-all term that seems to fit any and all disorders of the stomach and respiratory system.

What, then, is influenza, or "flu"?
The dictionary says it's "an acute highly contagious infectious virus disease that is characterized by sudden onset, fever, prostration, severe aches and pains, and progressive inflammation of the respiratory mucous membrane, and is frequently complicated by secondary infections such as pneumonia."

"Flu" occurs in epidemic or pandemic forms. An "epidemic" is a local outbreak that infects a high percentage of the population in a particular region of a country or local area, while a "pandemic" is worldwide. Hence, the worldwide outbreaks of flu in 1957 and 1968, known to the public by "Asian" and "Hong Kong," were pandemics, while the outbreaks in isolated sections of the United States that occur every two or three years, are epidemics.

The Food and Drug Administration's Bureau of Biologies, where about 260 people are responsible for establishing and maintaining standards of quality and safety of all biological products including vaccines, has done extensive research into and regulation of flu vaccines.

The influenza virus was not positively identified until the 1930's, but influenza has been recognized for centuries. The actual discovery of the virus in 1933 was the culmination of more than a decade of research following the pandemic of 1918-19.

There are three types of flu virus, A, B, and C. Type A is the type associated with the worldwide pandemics, while type B is generally limited to epidemics within a country or region. Type C is associated with local outbreaks.

The current vaccine in use is formulated to protect against the most commonly known virus types A and B, since these are the two most likely to show genetic change. The type A virus present...
this year shows slight changes from the Hong Kong strain of 1968. If the changes appear to be significant, the vaccine now in use will be changed to incorporate the newly emerging virus. Changes in the vaccine are considered every year, with actual changes being made when new viruses appear which show both antigenic change and signs of spreading to produce epidemics.

The Center for Disease Control in Atlanta and the World Health Organization are constantly on the alert for the emergence of new flu strains in the world. Their findings are invaluable in determining the extent of disease being produced by the new flu strain and judging the effectiveness of new vaccines.

There is a real need for early warning of major virus changes in the world to allow time for specific vaccine production. There is sometimes a 6- to 8-month time lag to produce sufficient vaccine for general use and the selection of the strain that will be most effective.

Developing the Vaccine
The flu vaccine is produced in fertilized hens' eggs (chick embryo inside) inoculated with flu virus. The egg is inoculated and the embryo becomes infected along with the membrane surrounding it. The virus is then released in the fluids surrounding the embryo. The egg is then opened and the fluid removed. This infected fluid becomes the starting material for the vaccine. The virus is then killed.

It should be reemphasized that the virus in the vaccine is dead, and thus cannot produce flu. A dead virus cannot induce the disease.

Some people may develop fever and body aches after having received vaccine. These adverse reactions to influenza vaccines are generally believed to result from nonvirus proteins, mostly chick embryo products. It's one of the reasons people allergic to eggs, egg products, chickens, or chicken feathers should not take the vaccine.

We now have a more highly An important function in research into vaccines and other work concerning flu virus is the "manufacture" of supplies of the various types and strains of virus. The virus is usually reproduced in fertile eggs. At top left, eight-day-old eggs are candled for visual inspection through the shell to determine if the embryo is alive.

A vial of live virus is removed from a pool in cold storage, thawed, and (top right) is being pipetted into a flask of pH buffered solution by Ron Mayner, microbiologist.

A hole is made in the top of the egg and a quantity of the virus in solution is inoculated (bottom left) into the allantoic fluid surrounding the embryo. The hole is then sealed and the egg allowed to incubate for 48 hours.

After incubation, the egg is reopened (bottom right), the allantoic fluid containing the live virus is withdrawn, and after centrifugation to remove most of the particulate matter, is placed in ampules and stored at -70°C. The ampules in this batch constitute a pool for use when needed.
purified vaccine than a few years ago. The nonvirus proteins have been removed from the fluids by ultracentrifugation or other purification processes. The major advantage is that you now can give a higher dose of the antigen (which causes the protective antibodies) while reducing the possibility of reactions.

Who Should Get a Flu Shot?
One of the greatest misconceptions circulating about flu shots concerns who should get them. With mass inoculation programs the general rule for most communicable diseases, it's a natural public reaction to add flu to the list when visiting the family doctor.

The Public Health Service says that only people who are chronically ill or who are in the older segment of the population should use the vaccine. These are the target people. General immunization of children is considered unnecessary, except for those chronically ill.

There are situations, however, when some key segments of the community might be inoculated, but only when a truly major epidemic or pandemic is predicted. These might include essential service groups such as persons engaged in care of the sick, law enforcement, fire protection, transportation, and communication, or institutionalized people who are aged or debilitated.

The main reason the chronically ill and older citizens should get flu shots is the danger from pneumonia, which in these groups often evolves from a severe case of influenza.

The recommendations on who should or should not receive flu vaccine are based on statistically proven risk, not on a shortage of vaccine, as believed by some. Actually, each year unused vaccine is returned to the manufacturers.

A good vaccine offers about 80 percent protection. The degree of protection depends on the type of virus in the vaccine as compared to the flu strain that is currently circulating among the population.

The cyclic nature of the flu virus is a subject of much debate.

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Live flu virus is used by the Bureau of Biologies Division of Virology for several purposes. Virus is sent to manufacturers when needed in production of vaccines. Less frequently, strains of virus are sent to various research laboratories for experimental use. The Division regularly performs two kinds of tests with live viruses: The hemagglutination test is used to determine the titer, or potency, of specific virus pools. The hemagglutination inhibition test is used to check sera taken from individuals to determine if they have been infected with a particular virus strain, to identify unknown strains of virus, and to screen antisera for infectious antibodies in epidemiological work.

In the hemagglutination test, various dilutions of virus are made and tested and the thinnest dilution at which the virus is still present is called the “titer,” which becomes the measurement unit or standard for use of that virus. This is done by adding .5 cubic centimeter of the various dilutions to an equal amount of red blood cells from a chicken in wells of a tray. Agglutination forms a uniform haziness at the bottom of the well, indicating virus is present (left in photo). If no virus is present, the blood does not agglutinate and remains as a dot in the well (right in photo).
among scientists. Although major antigenic shifts tend to follow a cyclical pattern, it is not known whether flu viruses undergoing genetic changes will ever exactly "repeat" themselves. If such a recurring cycle could be determined, it might be possible to predict what viruses might appear next. This would allow vaccines to be prepared which might be available in advance of major antigenic changes. Such a prospect appears to be far in the future, however. To date, changes cannot be accurately predicted, and the struggle to update vaccines continues.

Who Makes Vaccines?
The Bureau of Biologies, as a regulatory body, keeps a tight rein on the production of such biologies as vaccines. Only about 250 plants are licensed to make biologies of any kind, with only six producing influenza virus vaccines.

Both the product and the manufacturer are licensed. Thus, a manufacturer with a license must get separate licenses for each product he makes.

Manufacturers' testing records are kept on each batch of vaccines, and total production records must be submitted to BoB along with samples taken at random. The manufacturer does the testing, but the Bureau of Biologies conducts random tests of its own. It provides extremely tight control over the production of biologies.

Over half of the staff at BoB is comprised of laboratory people. Its director, Dr. Harry M. Meyer, Jr., is a biologies researcher in his own right. So is his deputy, Dr. Ruth Kirschstein.

Among the group are internationally recognized experts. Dr. Meyer points out that by having key research people on his staff, the Bureau is in constant contact with the rest of the scientific field.

Where to Now?
For the future, the Bureau has geared its activities to improving present procedures, and preparing for the day when major

In the preparation of antiserum for use in the hemagglutination test, live virus is injected into the wing vein of a chicken (at left) by Bob Blackburn (left) and William Barthlow, biological laboratory technicians. After two weeks the blood is removed from the chicken and centrifuged. The serum is obtained, tested for sterility, frozen, and held for use.
breakthroughs may occur in our understanding and ability to control the devilish bug.

Dr. Meyer insists that existing regulations are enlightened and in keeping with the latest in biologics, but candidly admits that the present potency test is far from perfect and must be improved. He is delighted that the vaccine for flu has been greatly purified and improved in potency, but sees even greater progress in that direction in the future.

On a long-term basis, Dr. Meyer is keeping an eye on the promising research being conducted on new live vaccines for influenza. Although BoB is not in the business of actually developing new vaccines, Dr. Meyer wants the Bureau to be ready to keep pace with major research breakthroughs in this area. While it may be years before such breakthroughs will yield vaccines for routine use, BoB is preparing to implement its role as an arm of FDA so that the licensing and regulatory function can be carried out without delay for the safety and effectiveness of future products.

In the meantime, the Bureau of Biologies hopes the public becomes aware of the facts and fallacies associated with the term “flu.” You do NOT get flu every year. You cannot catch flu from taking a flu shot. You need not take a shot unless you are chronically ill or are in the older age group where respiratory ailments often produce complications such as pneumonia.

Yes, the flu vaccines are safe. No, there’s no general, lasting vaccine for flu. And by all means, please quit calling that stomachache “the flu.” In other words, don’t let it “bug” you.

J. W. Buchan is a free-lance writer.

Samples of manufacturers’ flu vaccine are subjected to extensive control tests in Bureau laboratories. In the general safety test, guinea pigs and mice are injected with massive doses of vaccine and observed for seven days. If no adverse reactions occur, the product meets the requirements for general safety. During the observation period, the animals are weighed and examined to determine if they are maintaining normal weight and in good health.

This electron micrograph (left) shows clumps of Type A flu viruses, Hong Kong strain, at a magnification of about 62,000 times.
This spring will mark the launching of a new Federal agency, the Consumer Product Safety Commission. The current functions of FDA's Bureau of Product Safety will be transferred to this new, independent agency. It will regulate an enormous range of products used by consumers each day. This is the story of what the new Commission is, and how it came about.

A New Era In Consumer Safety
by Malcolm W. Jensen and Thomas M. Folkes

The Consumer Product Safety Act, signed into law by President Nixon October 27, 1972, was the single most important consumer protection measure passed by the 92nd Congress. It represents a dramatic step forward in the Federal Government's efforts to protect the American public from unreasonable injuries associated with consumer products.

The Act established a Consumer Product Safety Commission which will operate independently. The new Commission will be responsible for regulating a wide variety of consumer products, including toys and thousands of household products not covered under previous laws. However, the term "consumer product" does not include motor vehicles, pesticides, aircraft, firearms, boats, or tobacco products. Regulation of these items is left to other agencies. The regulation of foods, human and veterinary medicines, cosmetics, medical devices, biologicals, and radiation remains with FDA.

The new law allows the public a wide degree of participation in assuring that products pose no unreasonable hazards. This article describes the history of product safety within the Federal Government and sketches some of the important provisions of the new law.

The History

Modern regulation by the Federal Government of consumer products is really still in its infancy. The FDA's basic, but limited, law which has protected the American public from hazardous household substances in the recent past has been the Federal Hazardous Substances Act of 1960. It requires all household containers of potentially dangerous substances to be labeled conspicuously, to warn consumers and to provide needed safety information.

An amendment to that law, the Child Protection Act of 1966, authorized the Government to ban household substances so hazardous that even warning labels are not adequate safeguards. The Child Protection and Toy Safety Act of 1969 further expanded that law to cover electrical, thermal, and mechanical hazards in toys and other articles intended for use by children.

These laws—plus several other related ones that affect product safety, such as the Poison Prevention Packaging Act of 1970—have been enforced by FDA's Bureau of Product Safety, and will be enforced by the new Commission.

The beginnings of the Bureau of Product Safety can be traced to the reorganization of the Public Health Service in 1968. Responsibilities for regulating the safety of household products and for investigating deaths and injuries associated with flammable fabrics were assigned to FDA.

After several internal reorganizations—which found product safety functions assigned in turn to the Bureau of Medicine, the Office of the Commissioner, and the Bureau of Foods—the Bureau of Product Safety was created in October 1970. Since then, the Bureau has grown to the point where it will form the nucleus for the new Consumer Product Safety Commission.

The New Law

The need for a new law to protect consumers from unsafe products stemmed from a determination by the Congress that an unreasonable number of injuries was occurring among American consumers. The Federal Hazardous Substances Act and other laws were deemed inadequate.

A new law was recommended by the congressionally appointed National Commission on Product Safety in 1970. The Commission's report provided the stimulus and model for the legislation that eventually was to be passed by Congress.

Hearings were held in both the House and the Senate in 1971 and 1972. The most publicized controversy was over the placement of the broader responsibilities for product safety protection. There were three proposals: to place them within a larger FDA, to take
FDA's functions and place them in an independent consumer safety agency, or to establish an independent Consumer Product Safety Commission while leaving the regulation of products such as foods and medicines within FDA. In October the Congress decided on the third course. The President signed the Act on October 27, 1972.

Congress was very specific in setting forth the purposes of the Act:
• To protect the public against injuries associated with consumer products.
• To assist consumers in evaluating the comparative safety of products.
• To develop uniform standards for consumer products.
• To minimize conflicting State and local regulations.
• To promote research and investigations into the causes and the prevention of product-related deaths, illnesses, and injuries.

To accomplish these goals, the Act provides for the establishment of an independent Consumer Product Safety Commission empowered to develop and enforce uniform safety standards and to ban hazardous products.

The Consumer Product Safety Commission

The Commission will have five Commissioners, appointed by the President, one of whom will be designated chairman. The terms of the first appointees will be staggered—each nominee will serve a term of three, four, five, six, or seven years. Subsequent appointees will serve seven years; none can be removed except for neglect of duty or malfeasance in office. No more than three of the members of the Commission may be of the same political party.

The Chairman will exercise all the executive and administrative functions of the Commission. He will appoint and supervise personnel, except those reporting directly to the other Commissioners, and will govern the use and expenditure of funds.

The Commissioners will be advised by a Product Safety Advisory Council. The Commissioners will name the 15 members. This group, selected for expertise in various areas of product safety, will be drawn from three sources: five members from Federal, State, and local governmental agencies; five members from industry, including at least one representative of small business; and five members who are community leaders or who represent consumer organizations.

This group will meet when called by the Commission, but must meet at least four times a year. All its proceedings will be public.

Other advisory groups will be the existing National Advisory Committee for the Flammable Fabrics Act and the Technical Advisory Committee for the Poison Prevention Packaging Act.

The Act authorizes the following operational funds for the first three years of the Commission:

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<th>Fiscal Year</th>
<th>Amount</th>
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<tr>
<td>1973 (beginning July 1, 1973)</td>
<td>$55 million</td>
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<tr>
<td>1974</td>
<td>$59 million</td>
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<td>1975</td>
<td>$64 million</td>
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These sums are the maximum basic amounts that may be made available; there is no provision stating that the full amount must be appropriated. Additional funds may be appropriated for planning and construction of research, development, and testing facilities.

Functions and Authority

The primary function of the Consumer Product Safety Commission is, of course, to protect the public from injuries associated with consumer products.

The basic source of information for Commission action will be an Injury Information Clearinghouse which will collect, investigate, analyze, and disseminate product-related injury data and information. This information will be used for continuing studies into deaths, injuries, diseases, other health impairments, and economic losses resulting from such accidents.

Other projects of the Commission include research and investigations into the safety and possible improvement of consumer products; developing product safety test methods and devices; and offering training in the product safety field, particularly in assisting other public and private organizations in the development of safety standards and test methods.

The Commission may require industry to maintain specific records, make reports, and provide needed information.

The Commission can conduct hearings and inquiries, and can require the attendance and testimony of witnesses and the provision of relevant evidence.

The Commission may make available to the public any of the results of any of its investigations, though it may not disclose trade secrets or other confidential information. It cannot be compelled to release information not normally available to the public under the Freedom of Information Act.

Those public disclosures which would readily identify a company, must be preceded by a notice to enable the company to comment before the release of the information. Notice is not required, however, when the disclosure involves an imminently hazardous product or a product not conforming to product safety standards.

The Commissioner is empowered to develop standards for products to eliminate or reduce the risk of injuries to consumers. If the Commission decides that no standard could significantly reduce a hazard, it can ban a product entirely.

The impetus for development of a safety standard may come from within the Commission, from a proposal by the Product Safety Advisory Council, from a private petition, or on the order of a district court.

When it has been determined that a standard is necessary, the Commission may either solicit offers from outside groups or may decide that a Federal or non-Federal standard already in existence will suffice. (continued)
If it is found that no standard already exists, the Commission must accept one or more of the qualified offers submitted. If after 30 days of requesting offers, no qualified one is received, or if the only offer is from the manufacturer, distributor, or retailer of the product, the Commission itself may proceed independently to set up such a standard.

Once the Commission has initiated development of a standard (the development period will normally be 150 days), it then has 210 days in which to publish a proposed standard or withdraw the notice. This period may be extended if necessary.

The publication of proposed standards and their effective dates will include a description of the hazards related to the products in question and give the following information:
- The degree and nature of the risk that the standard should eliminate or reduce.
- The type or number of consumer products subject to the standard.
- The need of the public for the products involved.
- The standard's probable effect on product utility, cost, and availability.
- Means of minimizing adverse effects on competition and manufacturing practices while protecting public health and safety.
- Data indicating that the standard is necessary to eliminate risk of injury; or, if the product is to be banned, that no feasible standard could adequately protect consumers from unreasonable risk of injury.

The completed standard has to be suitable for promulgation under the Act; be supported by test data; and provide suitable test methods for assuring that a product complies with the standard.

Once a rule, whether a standard or ban, is proposed, the Commission can hold hearings on it. Within 60 days, it must either publish or withdraw the proposal.

If published in final form, the rule will normally take effect 30 to 180 days later. Rules will ordinarily affect only products manufactured after the effective date.

Significant amendments to any previous rules can be made under these same procedures. A rule can be revoked by the Commission if it is found unnecessary.

Federal safety standards will supersede State and local standards and regulations unless the requirements are identical.

A State and local jurisdiction may apply for an exemption if a State standard is more stringent, is required by local needs, and does not unnecessarily burden interstate commerce.

Industry and the New Act

Each manufacturer of a product regulated under the law will have to issue a certificate to the distributor and retailer, guaranteeing its conformity to safety standards. This certificate will give the name of the manufacturer or private labeler, and the date and place of manufacture. The Commission may prescribe the tests the product must undergo.

The Commission may also require that labels contain the place and date the product was made, the name of the manufacturer, a certification that the product meets standards, and what those standards are. In addition, when the actual manufacturer's name does not appear on the label, the Commission can require that the label be coded so that the seller can identify the actual manufacturer to the purchaser.

The manufacturer of any consumer product that involves a design, material, or form of energy exchange which has not previously been used substantially in consumer products and about which little is known in terms of safety must notify the Commission of its proposed introduction and furnish it with a description. This is not, however, a requirement for premarketing clearance.

Every manufacturer, private labeler, or distributor of a consumer product must keep records as prescribed by the Commission. These records are open to inspection by the Commission. In addition, the Commission can inspect any site where consumer products are being manufactured, stored, or transported.

Every manufacturer, distributor, and retailer of a consumer product must immediately inform the Commission of any information that indicates the product may pose a substantial hazard. If, after hearings, the Commission determines that the product does indeed pose a hazard, it may require the manufacturer to release a notice to that effect to the public and to those known to have received the product.

The Commission may order the manufacturer, distributor, or retailer to bring a product into conformity with existing rule or to repair the defect. A second option for the company is to replace the product with an equivalent. A third option is to refund the purchase price to the purchaser, less a reasonable allowance for use.

The Commission may file an action in a U.S. district court against an imminently hazardous product or against anyone who manufactures, distributes, or sells it. The court in which the action is filed can declare the product imminently hazardous and order action to alleviate the risk.

An imported product may be denied entry into the United States if it fails to meet standards, is an imminent hazard, or is manufactured by a company failing to meet inspection and recordkeeping requirements.

If an imported product cannot be modified, or if its modification is not proceeding satisfactorily, it must be exported or, in certain cases, destroyed. Destruction is also permissible if the product is not exported within a reasonable time.

The Act does not apply to any consumer product manufactured solely for export from the United States unless it is to be sold at any U.S. installation outside the country.

The following acts are specifically prohibited under the law:
• Manufacturing or offering for sale any consumer product not in conformity with an applicable standard, or any product which has been banned.
• The importation into the United States of any such product.
• Failure or refusal to disclose records, make reports, or provide information as required.
• Failure to notify the Commission of a substantial product hazard; failure to comply with a subsequent Commission directive to give notice of this hazard; or failure to comply with a Commission order to repair, replace, or refund the purchase price of such a product.
• Failure or refusal to furnish a certificate guaranteeing the compliance of a product regulated under the Act.
• Knowing issuance of a false certificate.
• Failure or refusal to furnish records, make reports, or provide information as required.
• Failure or refusal to disclose records, make reports, or provide information as required.
• Failure or refusal to disclose records, make reports, or provide information as required.

Any person who knowingly commits a prohibited act is subject to a civil penalty of up to $2,000 for each violation. The maximum penalty cannot exceed $500,000 for any related series of violations.

Any civil penalty may be modified by the Commission after taking into consideration the size of the business, the person charged, and the gravity of the violation.

Any person who knowingly and willingly commits a prohibited act after receiving notice of noncompliance from the Commission can be fined up to $50,000 or be imprisoned for up to a year, or both. Any representative of a corporation can be subject to the same penalty.

Violation of prohibited acts may be restrained by order sought by the Commission and issued by the district courts. The courts may also restrain any person from distributing any product that does not comply with a consumer product safety rule. If any consumer product fails to conform to a rule (or other actions prohibited by the Act), it may be seized and condemned in an action in a U.S. district court.

**Participation of the Public**

Any interested person or organization may also bring an action in any district court to enforce a Commission order requiring public notice of a product hazard or requiring remedial action. Additionally, any person or organization adversely affected may seek judicial review of consumer product safety standards, orders removing or materially amending such rules, and banning orders.

Any person injured by a product in violation of a Commission rule or order may sue in any district court. Compliance with product safety rules does not relieve any person from liability. The failure of the Commission to take any action or begin a rulemaking proceeding on a consumer product will not be admissible as evidence in a product liability suit.

**Conclusions**

Several conclusions emerge from the legislative history and the language of the new law:

- A vigorous approach to the reduction of product-related injuries and deaths is to be taken.
- Unreasonable risk is to be determined on the basis of valid data.
- The economic impact of a consumer product safety standard being considered must be taken into account.
- The public is to be given full opportunity to play a major role in the development of standards.
- All segments to be affected by a standard are to be represented in the process of developing the standard.

Undoubtedly, the Consumer Product Safety Commission will continue activities already established by the Bureau of Product Safety and build further upon them. The basis for all Commission activities will be hard and valid data on product-related injuries and deaths. From these data will come analyses, and an effort to encourage action by the industrial and business community. If they fail to act or if their actions are not adequate or universally adhered to, the regulatory authority of the Commission will be brought into play.

Consumer education will supplement regulatory efforts.

The Commission will make every effort to establish a partnership with States to encourage them to establish State programs and to assume the responsibility for administration and enforcement of their related law or laws, consistent with the Federal program.

The Product Safety Commission faces an exciting and challenging future with a very real opportunity to provide maximum protection to the public with minimum disruption of the free market system.

**Malcolm W. Jensen** is director of FDA’s Bureau of Product Safety.

**Thomas M. Folkes** is executive assistant to the director of the Bureau of Product Safety.
Mass Chest X Rays Are On The Way Out

by Valorie Britain

Mobile chest x-ray units were used widely during the 1940's and 1950's to detect tuberculosis. Today, there are more effective ways. FDA is now urging elimination of mass x-ray screening of the general population. Here are the five reasons why FDA reached this decision.

Remember the days when local community chest fund drives used to allocate money for mass chest x-ray screening programs to detect tuberculosis? Remember the warning to have your annual, free TB x-ray check? Well, those days are gone forever. At least that's FDA's aim.

Modern diagnostic techniques, plus a decline in the incidence of tuberculosis, have made mass chest x-ray screening unnecessary among the general population.

In fact, the continued use of x rays for general tuberculosis screening is highly undesirable, because large numbers of people are being needlessly exposed to x rays.

TB detection is better accomplished today by the tuberculin skin test. This is a test in which a small amount of tuberculin is placed under the skin. If the skin becomes inflamed, then the person may now have TB or in the past have been infected and may require further examination.

The tuberculin test is safer than the chest x ray because it does not expose people to unnecessary radiation. Recognizing the increased safety of the tuberculin test, FDA's Bureau of Radiological Health, the American College of Radiology, and the American College of Chest Physicians prepared a joint statement in early 1972 recommending that mass chest x-ray surveys of the general population for TB and other cardiopulmonary disease be discontinued.

The first reason is that mass screening is not really an effective means of detecting TB. More than 95 percent of the people who develop active TB today are identified by means other than community x-ray screening programs. Most TB is discovered because a person has symptoms which lead him to seek medical advice.

This is true even for inner city areas and selected population subgroups where the incidence of TB is higher than in suburban and rural areas.

Mass screening programs detect active TB in fewer than 1/20th of 1 percent of persons x-rayed and, ironically, are least effective in the very areas they are particularly intended to serve—high TB incidence locations. This is because most people in such areas do not avail themselves of the chest x-ray service.

Surveys in various parts of the country have confirmed that mass x-ray screening is generally unproductive in detecting tuberculosis. A 1969 survey in Cleveland uncovered only 18 new active TB cases out of 93,159 persons x-rayed. And a Denver mass screening program between 1965 and 1970 found only 54 active cases among 276,498 chest x rays.

Some people have called for the continuation of chest x-ray screening on the basis of its value as an annual check for cardiopulmonary diseases other than TB, notably lung cancer and emphysema. This reasoning is not valid, however, since the x-ray examination has not been
What should consumers do about mass screening?

If you are healthy, do not decide on your own to have a chest x-ray as a precautionary measure. Have an x-ray examination only when recommended by a physician.

If you feel ill or are suspicious of some chest disorder, seek professional medical attention.

If you are directed by your employer, a health agency, or someone else to have a chest x-ray examination for TB, ask instead about the tuberculin skin test. Students, high TB incidence groups such as patients in mental hospitals and nursing homes, inmates of prisons and jails, and persons employed as food handlers, teachers, barbers, and hairdressers all may be asked to be tested for TB. In all these cases, consideration should be given to the skin test as an initial check. X-ray examinations should be restricted to positive reactors.

found rewarding in identifying these conditions.

A second reason for discontinuing mass screening is that TB is on the decline. The dynamics of tuberculosis have changed greatly in the United States in the last dozen years. The number of newly reported active cases of TB nationwide dropped from 57,535 in 1959 to approximately 35,217 in 1971.

In many sections of the country, the disease is virtually nonexistent today. Active TB cases are found mostly in individuals infected in the past, the disease having remained dormant over the years, rather than in persons who have newly acquired the disease, as well as in older age groups.

As a result of the decline in TB, the mass chest x-ray detection program produces a low yield of active, undiagnosed cases of TB. Such a yield no longer justifies the exposure of a large segment of the healthy population to radiation. Only those programs that result in significant case finding can be defended, such as an emergency survey program for a high incidence area or population group.

The third reason is that the tuberculin skin test provides a more accurate indication of the presence of TB than the x-ray film. If the tuberculin test indicates the presence of TB, then an x-ray can be used to determine whether the TB is active.

A fourth reason for discontinuing mass x-ray screening is the delivery of an unnecessary amount of radiation to a large segment of the population. The decreased incidence of TB has coincided with an increased concern about needlessly exposing persons to radiation. Since so few cases of active TB were found through the chest x-ray program and because the tuberculin test is more effective in detecting tuberculosis, and results in zero-radiation exposure, this was a situation where radiation exposure could be significantly reduced without jeopardizing medical care.

Why the increased concern about radiation exposure? While diagnostic x-ray procedures, including the chest x-ray, are among the most valuable tools of modern medicine, scientists today are concerned about the possible long-term effects on the body as a result of low-level doses. Their concern is about the cumulative effect of the numerous x-rays taken during a lifetime.

Since safe levels of radiation dose have not been established, prudence dictates that exposure to man-made radiation should be avoided except when it can be shown that the risk is justified by the expected benefit. Although the health risk from the small amounts of radiation received during a chest x-ray examination is exceedingly low, there is no reason to impose this minor hazard on the population without good cause.

The fifth reason is that the x-ray units often used for chest x-ray screening produce higher levels of x-ray exposure than other equipment. For the most part, photofluorographic machines, which use 2½- by 2½-inch films to record an x-ray image on a fluorescent screen, have been used in the x-ray vans, as well as in some health clinics.

Although more economical, these units may expose persons to up to 10 times more radiation than does the conventional or fixed x-ray unit, using a 14- by 17-inch film. In addition, the photofluorographic unit produces an x-ray film of inferior diagnostic quality when compared to the 14- by 17-inch film.

Because of these five reasons, the x-ray examination should not be used as a technique for screening the general population for TB and other cardiopulmonary diseases. Instead, TB x-ray screening programs should be aimed at specific groups with a high risk of contracting the disease, and even in these cases, the tuberculin skin test is the preferred technique for initial screening.

This is not to say that an individual should avoid having an x-ray examination when it is indicated. But the x-ray examination is a diagnostic tool that should be prescribed by a physician who has knowledge of the individual's case.

Valorie Britain is an information specialist in FDA's Bureau of Radiological Health.
LASER

The Powerful Little Light That Performs Like Magic

Because it is so powerful, the laser is potentially dangerous, and must be used with extreme care. This is what the laser is, what its potential is, and what cautions the public must take to protect itself from possible injury.

by Margaret Morrison

The year is 1983. You're shopping in your supermarket and come up to the checkout stand with a cart full of foods. Faster than you can say "six-pack," the label on every product in the cart is examined, recorded, the price rung up—and you're on your way in a fraction of the time it used to take.

Or it's 1978. You want to see a favorite movie from the 30's. So you walk into a music store, purchase a disc no larger than the average LP record, take it home and "play it back" on your TV screen—a full-length feature on one small disc.

Or it's now, 1973. You're getting settled in your seat on a Boeing 747 and you look out over the huge wings, each longer than the distance the Wright brothers first flew, and you know somebody—or something—had to precisely align those wings or you'd never get off the ground.

All of these things will happen—are happening—through the use of the laser, the amazing light that "came to light" such a few short years ago.

If you are like most Americans, you first heard about the laser beam sometime in the '60's. And you heard of it in terms of some new kind of magic invention that could work unheard-of marvels, much like the things you'd read in science fiction comics (Flash Gordon pulls out his ray gun and demolishes an entire planet with one pull of the trigger).

The laser is indeed a miracle maker. But in a much more practical, down-to-earth way than most people realize. In the few years since its power has been recognized, application of the laser has resulted in revolutionary contributions in the fields of medicine, science and industry, communications and education, and even in the home.

Remarkable as its uses are, the laser is actually nothing more than a device which produces and amplifies light. The word "laser" stands for Light Amplifica-
LASER

The need for radiation safety performance standards for laser products came about because of the wide variety of functions they are now performing.

One of the first uses of the laser principle was in medicine. The development of photoocoagulators which focus a laser beam through the pupil of the eye onto the retina made it possible to "fasten" or "mend a tear" in the retina, much more quickly and successfully than has been possible with conventional surgical tools.

In the operating room, the laser beam, focused into a small spot, serves as a surgical knife. And since it is of such high intensity, it can also sterilize or cauterize tissue as it cuts. This is important in surgical procedures on organs such as the liver and kidney, where loss of blood is a severe problem.

In the area of experimental research, lasers of varying intensities are being used to make precise lesions in portions of the brain or spinal cord without injury to surrounding brain tissues.

While information about use of the laser in the treatment of malignant disease is incomplete, experimental studies with animals have shown that the laser beam can destroy tissue, such as a tumor, when the involved tissue can be totally encompassed by a laser beam of sufficient density. Unfortunately, in some cases the impact of the laser beam may cause spreading of some viable malignant cells into adjacent healthy tissue.

Other promising medical applications of the laser are being investigated in the fields of dermatology, dentistry, genetic scanning, and medical teaching aids. But much of this work in medicine is still in the experimental stage, with a great deal of study yet to be done before conclusive results can be fully realized.

In industry, progress in the application of the laser has been much more rapid. With its intense energy, the laser already is performing a number of highly developed functions—doing things faster, and with greater precision, than was ever possible before.

The laser can slice through ultrahard metals, such as tungsten, in seconds. Heat-resistant metals can be manipulated with lasers, and this application is being used in our space program. The laser is used to drill completely smooth and precise holes, as small as a few millionths of an inch, in materials where the surrounding area must not be harmed by heat or vibration. Certain types of welding are far easier with a laser because the quick flash of heat binds materials together instantly in a solid mass; or it can perform the most delicate and minute electronic welding.

Because of its coherent light, the laser has many applications in the geodetic field, especially in surveying...
The yellow beam from a krypton-ion laser, at the top, is projected and split to travel to two calorimeters, allowing the most accurate measurement of laser energy yet achieved. A duplicate of this system is now in use in FDA laboratories. 

Photograph from the National Bureau of Standards.
An optical physicist at FDA's Bureau of Radiological Health (top) monitors the performance of a laser product in an effort to determine the magnitude of any possible hazards.

At the Shrine Burns Institute of the Medical Center, University of Cincinnati, CO₂ laser excision of a burn in a patient is followed by immediate graft replacement because of bloodless surgery of the laser.

One of the first and most important applications of the laser was in the treatment of eye disease. Here, Dr. H. Christian Zweng (lower photo), Stanford University and Palo Alto Medical Clinic, treats the eye of a patient using a laser photocoagulator. *Photograph courtesy of the Palo Alto Medical Clinic, Palo Alto, California.*
Lasers hold great potential for treatment of disease. At top, laser treatment of melanoma cancer of the leg.

At left, laser treatment of dental caries.

*Photographs from the Laser Laboratory, Medical Center, University of Cincinnati. Director, Leon Goldman, M.D.*
Lasers are being employed to measure long distances more accurately than ever before, as seen in a photograph (top) taken in the Southwest. A reflected beam from a mirror more than 5 miles away can be seen as a small dot on the horizon.

A common application of lasers today—a low powered helium-neon laser used in classroom instruction (below left).

Laser light is a convenient tool for the instructor, since it shows how light rays are reflected and refracted. In photograph (below right), two laser beams passing through lenses are refracted and show the focal point of the lens system where they cross. Experiments such as this formerly required a great deal more equipment and were much more time consuming and costly.
and measuring. The laser’s beam can be made to diverge as little as one-third of an inch per mile. Tunnels have been dug with amazing precision using laser alignment, for example, an 18-foot tunnel through 4 miles of rock, with an error of only 2 inches. The laying of cable or pipe over difficult terrain or under water can be facilitated beyond belief.

There are two areas in which the laser has been of special value to the military. Long distance measuring instruments—developed by use of the laser principle—make it possible to measure any line of sight on the ground, ground to air, or ship to shore, and this application is used by the military for missile tracking. Also the pilot of a bomber plane is able to designate a target by laser beam, and the bomb is then guided by the beam’s reflection from the target.

The laser has brought exciting possibilities to the field of photography, since a laser photograph termed a hologram gives a truly three-dimensional image. This no doubt will lead to innovative developments in the field of entertainment—motion pictures and TV—as well as education.

In the laboratory of the future, it is possible the laser will be used in spectroscopy (examining and determining the content and condition of substances by the colors they produce or absorb); the analysis of growing plants to determine the kinds of nutrients farmers should add in order to produce a better crop; the alignment and improvement of various scientific devices and research tools; and much more.

At present, one of the most common uses of the laser is that of a demonstration tool for teaching optics and wave mechanics. It is very effective in high school and college courses in physics and optics; and some students are experimenting with the construction of lasers in their home “laboratories.”

Wherever and however the laser is used, though, it can be an intensely powerful instrument. And since it is so powerful, it has—along with its usefulness—an obvious potential for misuse. With the growing use of lasers in the classroom and home, where there are numbers of people who might not understand the hazards, it is important that instructors, students, and parents be aware of the dangers, and of the precautions that can be taken to reduce the risks.

As might be expected, lasers used in classroom instruction are usually not as powerful as some in use in industry and research. However, even a small classroom-type laser can emit enough power to be unsafe for direct viewing. This means you should be extremely careful that the beam of light never strikes the eyeball—that you never look into the laser beam. Also, be sure the beam is directed in such a way that it will not strike a shiny surface, which can then reflect the beam into the eye. This should be guarded against even though the viewer may be seated in the rear of the classroom or auditorium.

Lasers are basically simple devices which can and are being constructed by high school students and other individuals interested in scientific devices. Some students have successfully constructed lasers in their basements. Working under these conditions, generally without supervision, can be safe only if fundamental safety precautions are followed strictly.

There are a number of simple steps and devices you should use to prevent the occurrence of an accidental contact between the eye and the beam of an unenclosed laser.

One such device is the beam shutter, a cover fitted over the aperture of the laser, which allows the operator to shut off the laser beam without turning off the laser. The shutter should be made of opaque, nonreflective material and should completely stop passage of the laser beam. As with all mechanical aids, however, the important thing is that the operator develop the habit of shuttering the beam at all times when it is not actually needed.

Another safety measure is the use of a suitable target for the beam, since it will travel out from the laser until it is absorbed or reflected. The target should be made of nonreflective light-absorbing material, such as black foam rubber, or black ink on blotter paper.

Since accidents can happen during the setup and alignment of a laser experiment, precautions must be taken to protect any observers by placing a shield between them and the laser and its associated equipment. One way of doing this, when working with low-power lasers, is to hang a black, dull-surfaced curtain or drape between the observers and the laser. Another easy way of accomplishing this is to use a large cardboard box with holes cut in the sides for setting up the demonstration and in the end for exit of the laser beam. Flaps can cover the openings when viewing of the experiment is not actually required.

Painting the experimental equipment with a flat, dull, black paint may be the single most important precaution you can take. Never use chrome or stainless steel, which can reflect the beam.

When purchasing a laser for classroom use, you should buy one with a key lock for the power
LASER

supply, if possible, or have such a lock installed. This will prevent its being used by someone not authorized to do so or not trained in safety precautions.

Also, when constructing or using homemade lasers, avoid possible electrical shock, and contain any possible explosions, by covering any exposed wiring or glass on the laser with a shield.

There should be a dry run of all experiments before they are presented to observers or to a schoolroom class. This helps the operator spot the possible hazards and eliminate them before any damage can be done.

The best safety rule is to know that a hazard may exist with any unenclosed laser and to combine this knowledge with common sense. Whenever an unenclosed low-power laser is used in the classroom, home, or laboratory, you'll be wise to follow these 20 rules:

Work Area Controls

1. Do not use the laser in areas where a chance passerby not aware of danger might be attracted to its operation.

2. Signs saying the laser is being operated and that it may be dangerous should be placed in conspicuous locations both inside and outside the work area and on doors giving access to the area.

3. Whenever possible, the doors should be locked to keep out nonessential onlookers during use of the laser.

4. The lighting in the area should be as bright as practicable, to constrict the pupils in the eyes of the observers.

5. Set up the experiment so the laser beam is not at normal eye level—place it below 3 feet or above 6½ feet.

6. Set up a target for the beam, made out of a black absorbing material. Also set up shields to prevent the direct beam, or strong reflections, from going beyond the area needed for the demonstration or experiment.

7. Double check to make sure no tool or other reflective material is left in the path of the beam.

8. To prevent shock, all exposed wiring and glass on the laser should be covered with a shield. All nonenergized parts of the equipment should be grounded.

9. The laser should be equipped with a key switch to lock the power supply.

10. An operable laser should never be left unattended.

Operating Controls

1. A detailed operating procedure for using the laser should be outlined beforehand.

2. Avoid looking directly into the laser beam at any time.

3. Do not aim the laser with the eye. Unexpected mirror-like reflection could cause eye damage.

4. Do not look at mirror-like reflections of the beam. This could also cause retinal burns.

5. Remove all rings and watches before changing or altering the setup. Shiny jewelry could cause damaging reflection.

6. Never depend on sunglasses to protect your eyes.

7. If laser safety goggles are used, be sure they are designed to be compatible with the laser being used. Never rely on safety goggles, however, as the primary protection for your eyes.

8. Report any after-image to a doctor, preferably an ophthalmologist who has had experience with retinal burns, since damage may have occurred.

9. Clear all personnel well away from the anticipated path of the beam.

10. Before operating the laser, warn all personnel and visitors of the potential hazard. Remind them of the possibility of irreparable damage to their eyes.

The laser, one of the most versatile tools of our time, is appearing in many diversified types and powers and already has affected our lives in many ways. And undoubtedly lasers will bring even more significant changes in the future, in applications not yet imagined. Their beams of light can be powerful. Some can pierce a small diamond precisely; others custom-cut a suit of clothes in seconds; “measure” a mountain; and beam straight to the moon, 240,000 miles away, and still return to earth to be measured.

But a beam of light that’s that strong can blind you. So never, never look into a laser beam. You might never look again—at anything else.

Margaret Morrison is a writer on FDA’s Consumer Education and Information Staff.
Dishing Up The Dog Food

FDA's suggestions on how to get a better diet for your dog through proper use of prepared foods.


Walk down the aisles of your supermarket, and you'll find many shelves of colorful packaged and canned foods devoted just to dogs.

Or turn on your TV set. Cuddly puppies tumble over each other to get to their morning tidbits. Full-grown dogs race across fields to gulp hungrily a full bowl of their own special food. And people brag about the brand they feed their dog.

Quite a different scene—isn't it?—from the days when Rover was fed whatever was left over from the table.

In the past decade, as consumers have become better informed about nutritional values, vitamins, minerals, and other supplements in their own diets, they have demanded the same high standards in foods for their pets.

This demand has created a vast industry which provides pet foods in unprecedented quantities—the largest percent of it for dogs, which now number an estimated 33 million in the United States.

The proliferation of canned and packaged foods for these pets has led to greater involvement by FDA in the field of pet food safety. The Fed-
eral Food, Drug, and Cosmetic Act, under which FDA operates, requires that animal foods be properly formulated and labeled, manufactured in clean plants, and free from poisonous or harmful substances or unapproved additives or drugs.

Generally, FDA is not involved in the regulation of nutritional values in commercially prepared pet foods. But FDA's responsibility for proper labeling necessitates a concern for food ingredients and nutritional claims.

What Should You Know About Dog Foods?

First, you should know how important the label is, and what you should expect from it. Naturally the label will give you the name and address of the manufacturer. In addition, it should include a statement of net content, a complete listing of ingredients, and a guaranteed analysis of the content. The latter is a listing of exact amounts of various nutrient substances, such as protein, fat, and vitamin and mineral additives.

For example, the list of ingredients may show simply “Meat by-products,” while the guaranteed analysis will show a specific amount of protein. The manufacturer guarantees that the product has these specified amounts of nutrient substances.

A small number of pet food firms are under U.S. Department of Agriculture inspection, and on their products you will see a USDA certification. This is a voluntary, continuous inspection program paid for by the manufacturer who requests the program.

A number of products now on the market are labeled as a “complete and balanced diet” for dogs. This term is generally based on the guidelines of the Subcommittee on Canine Nutrition of the National Research Council. The NRC Committee has published a booklet titled *Nutrient Requirements of Dogs*, which outlines the nutrients needed by dogs, such as protein, carbohydrate, fat, vitamin A, vitamin D, and a number of other vitamins and minerals. You may get this booklet by sending $1.50 to the National Academy of Sciences, National Research Council, 2101 Constitution Ave., N.W., Washington, D.C. 20418. Ask for Publication 989, *Nutrient Requirements of Dogs*.

When the manufacturer of a dog food uses the term “complete and balanced diet” on the label, this does not mean that the product can be used as the sole diet for every dog. It means the product provides the minimum diet to assure that the animal will maintain its body weight and size, with a normal amount of exercise. This is called a “maintenance diet.”

You may wish, however, to provide your dog with more than a maintenance diet, for a number of reasons. For instance, the protein needed for growth is greater than the amount needed for maintenance; pregnancy, having nursing puppies, or a situation of stress of some kind also can increase the need for protein.

Also, since there is such a wide variance in size, body structure, hair coat, and activity in dogs, naturally their nutritional requirements vary. A complete and balanced food for one dog may not be complete and balanced for another. Your veterinarian is your best source of information on nutritional needs of your particular animal.

FDA’s Bureau of Veterinary Medicine is working closely with the Pet Food Committee of American Feed Control Officials in an effort to assure that products labeled “complete and balanced diet” contain all the nutrients needed for proper maintenance. FDA has stressed the need to test experimental animals to determine more specifically whether these foods are complete and balanced according to the NRC guidelines. FDA will continue to monitor such foods and take corrective measures where claims are false or misleading.

In the past few years, there has been considerable controversy among pet food manufacturers—and questions in the minds of pet owners—about the relative merits of meat-plus other ingredients versus all meat products. At this time, there is no documented evidence that either type of food is superior to the other for maintaining proper nutrition. The important factor to remember is that, whether it is all meat or a combination of meat and other products, the diet must be a balanced one, with the protein, carbohydrate, fat, vitamins, and minerals that animals need; and it must not contain harmful substances.

Drugs in Pet Foods

The use of drugs in pet foods is a separate question from that of nutri-
ent additives. At present, only one drug is approved for use in commercial pet foods. It is diethylcarbamazine, a drug intended for use in the control of large roundworms in dogs. If added, it must be listed on the dog food label.

On occasion, other drugs which are being incorporated into pet foods illegally are brought to FDA's attention. In the past, for example, one particular dog food was labeled as containing methyltestosterone. This food was being sold with the claim that it should be fed to guard dogs, to increase aggressiveness. FDA initiated action which resulted in removal of the product from the market.

Your Part in Keeping Your Pet Well Fed

Wild animals, consuming other animals which they have killed and having access to a variety of foodstuffs, instinctively choose a diet which will as nearly as possible give them a balanced diet. Domesticated animals must depend for their nourishment on foods prepared by someone else—the pet food manufacturer and you.

Because of the great amount of nutrient research done in the past few years, by industry and government, commercial foods for dogs probably provide a safer and more complete diet than these pets have had in the past.

But commercial foods for pets vary in nutrient quality, as well as in various supplements. You should read the label on any food you buy for your dog; you should understand that each animal has its own requirements for a "complete and balanced diet"; and you should report to FDA any complaints you may have about false claims of manufacturers, illegal use of drugs, or other circumstances that could be considered hazardous to animal health.

Safeguarding Foods for Pets

FDA's responsibility for the safety of animal foods includes guarding against contamination of foods by bacteria such as Salmonella. Salmonella organisms occur in the intestinal tract of man, animals, birds, reptiles, and insects, and can cause widespread infection when transferred from one to another.

The symptoms of a Salmonella infection in humans usually are fever, stomach cramps, diarrhea, and sometimes vomiting. Pets suffer similar discomforts. FDA is working on a program to reduce Salmonella in animal- and fish-protein products, a major source of foods for pet cats and dogs.

From time to time, chemical contaminants are found in pet foods. When this happens, if it appears to be a one-time incident, it is studied as such. An investigation is made of the source of the contamination, the species of animal for which the food is intended, and all available data on toxicity in this species. FDA then takes appropriate action.

In the event a harmful substance in a food product appears to be a problem that could continue over a period of time, such as might occur because of natural or man-made contamination, FDA initiates a study to determine how the substance should be controlled.

In 1971, when there was a great deal of alarm about the mercury contamination of tuna and other fish, FDA became concerned that some of these foods might inadvertently be transferred to pet foods. FDA's Bureau of Veterinary Medicine relied on published reports of work done in Sweden, Japan, and in this country, which gave some indication of the levels of mercury which might be harmful to dogs and cats. Using this information, and results of work in progress within FDA, the Bureau was able to determine levels which would not be harmful to the pet even in extreme cases—such as those cases where pets consumed tuna or fish products as the sole diet.

At the same time, the Bureau sampled and analyzed a number of commercially prepared pet foods containing fish, including tuna. The results of these samplings indicated there was no alarmingly high mercury content in the products.

Following the initial survey of tuna for human consumption, FDA conducted a large-scale survey of the wholesale fish industry. It was able to use reports from this survey as an indicator of what might be expected in pet foods. With the exception of swordfish, there was no problem with any species of fish tested. None of the swordfish or high-mercury-level tuna was converted to pet food use.

Since fish meal also is incorporated into many foods, a check was made of the mercury content of this product. It also appeared safe for use in animal foods.

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News Highlights

New Regulations for Use of Methadone
In Drug-Addiction Treatment

Tightening of Federal regulations governing use and preventing misuse of methadone in the treatment of heroin addiction has been announced by three principal Government agencies, including FDA, concerned with drug abuse prevention.

Methadone is being increasingly used in the treatment of heroin addiction, both as a detoxification agent and in oral maintenance treatment.

Highlights of the new rules:
(1) Distribution of methadone will be limited to approved treatment-rehabilitation programs and to hospital or specially authorized community pharmacies in remote areas approved by FDA and the States. Pharmaceutical firms may supply methadone only to such facilities. This closed distribution system will help prevent diversion of methadone to illicit channels.

(2) Eligibility of patients for methadone maintenance will be limited. One condition will be a documented history of two or more years of drug dependency. Admission will be restricted for youths under 18 years. Patients may enter treatment only on a voluntary basis.

(3) Patients entering methadone maintenance will be required initially to receive medication in-clinic at least six days per week. Even after two years of treatment and demonstrated progress toward rehabilitation, patients will still be limited to a “take home” allowance (in child-proof containers) of a three-day supply at a maximum daily dosage of 100 milligrams. Random testing for narcotics and other drugs will be required.

(4) Methadone treatment programs will be required to provide counseling and other supportive services. The aim is to help patients return to a meaningful life.

The new methadone regulations were issued by FDA in conjunction with the White House Special Action Office for Drug Abuse Prevention and the Bureau of Narcotics and Dangerous Drugs of the Justice Department.

Filled Milk Act Unconstitutional;
FDA Recommends No Appeal

FDA has recommended to the Department of Justice that there be no appeal of a Federal Court decision which declared the Filled Milk Act unconstitutional.

The decision was handed down in a case brought by the manufacturers of Milnot, a filled milk product, against the Secretary of the Department of Health, Education, and Welfare.

Judge Robert D. Morgan of the Federal District Court for Southern Illinois agreed with the argument of Milnot’s producers that the law unjustly restricted the company’s operations. The company argued that its product was not substantially different from many other substitute milk products that are freely distributed in interstate and foreign commerce and not restricted by the Filled Milk Act.

A filled milk is a substitute milk product manufactured by adding a fat or oil other than milk fat to milk, cream, or skimmed milk. The Filled Milk Act prohibits interstate shipment of filled milk even if wholesome, nutritious, and honestly labeled.

It does not apply to other substitute milk and dairy products which do not use milk, cream, or skimmed milk as a component. Judge Morgan ruled that this is an irrational distinction which denies “due process” (fundamental fairness) to the manufacturer of Milnot, a canned filled milk product.

FDA believes that Judge Morgan’s decision is essentially correct, and the Agency will cease to apply the Filled Milk Act to Milnot or to other filled milk products. These products will, however, be subject to the requirements of the Federal Food, Drug, and Cosmetic Act, as well as the Fair Packaging and Labeling Act.

Consideration is being given to the adoption of a food standard for filled milk products and other substitute milk and dairy products. This standard would require fortification with appropriate nutrients.

The Filled Milk Act was enacted by Congress in 1923, at a time when food technology was in its infancy. It sought to protect consumers from fraudulent products by prohibiting the interstate and foreign shipment of filled milk products which looked like milk but were actually a combination of dairy and nondairy products.

Today many dairy substitutes, products of advanced modern food technology, are fabricated without any milk, cream, or skimmed milk, but often contain components derived from milk. They may lawfully be marketed because they are not banned by the Filled Milk Act.

Judge Morgan ruled that the appearance and continued existence on the market of other substitute milk and dairy products not banned by the Filled Milk Act was a significant new factor distinguishing the Milnot case from prior cases. In 1938 and again in 1944, the U. S. Supreme Court had upheld the constitutionality of the Filled Milk Act when Milnot’s producers appealed convictions for violating the Act.

The decision is in accord with a recommendation made in 1969 by the White House Conference on Food, Nutrition and Health that the Filled Milk Act be repealed.
FDA to Limit Strength of Some Vitamins Sold Over the Counter

FDA has acted to limit the strength of vitamins A and D products available for self-treatment without a prescription. The objective is to establish safe amounts of vitamins that can be effective as dietary supplements for use by consumers.

Based on current scientific knowledge, the Agency has proposed daily limits of 10,000 International Units (I.U.) for vitamin A and 400 I.U. for vitamin D. These figures are within the recommended daily dosages established by the Food and Nutrition Board, National Academy of Sciences—National Research Council, the recognized authority for determining vitamins and their nutritional requirements on humans.

The principal effect of the proposed regulations will be to have makers of multivitamins revise their formulas. Many multivitamin products are presently below the limits proposed for vitamins A and D. There are on the market, however, vitamin A products in dosages 10 times the recommended daily allowance (RDA) and vitamin D products 60 times the RDA.

High-dosage vitamin products prescribed by physicians for specific patients will be unaffected.

Both vitamins are recognized as necessary to good human nutrition. However, excess amounts can be dangerous to both adults and children.

Reports of misuse of large doses of both vitamins A and D have prompted medical groups and FDA to seek limitations on them. Widespread promotion of both vitamins has resulted in excessive use for conditions such as acne, night blindness, and arthritis. Neither vitamin A nor D is proven effective for these conditions in well-nourished people.

Excessive amounts of vitamin A taken over long periods can increase pressure within the human skull and may mimic a brain tumor. Large doses of this vitamin have also been shown to retard growth in children. Vitamin D has been known to retard mental and physical growth in children.

Pregnancy Test Kits Unreliable; FDA Requests Recall

At FDA’s request, a distributor and manufacturer of pregnancy test kits have begun nationwide recalls of their products.

Based on its evaluation of the test kits—Ova II and LPT Pregnancy Test—FDA believes the products to be inaccurate, unreliable, and prone to give false results. The Agency warns consumers not to rely on the results.

Distributed by Faraday Laboratories of Hillside, New Jersey, Ova II is sold in drugstores, without a prescription, for use by women at home and is advertised in newspapers and women’s magazines with the slogan “When you want to be the first to know.” FDA urges any woman who has recently used Ova II as a pregnancy test to see her physician immediately for accurate methods of detecting pregnancy.

LPT Pregnancy Test is for professional use only and is manufactured and distributed by La Mar Laboratories of Oceanside, New York.

Government Orders Restrictions On Sale of Small Turtles

The Department of Health, Education, and Welfare has ordered major restrictions on the importation, interstate transportation, and sale of small (less than four inches), live turtles, tortoises, and terrapins and their eggs.

The action follows investigations showing that the turtles, purchased mostly as pets, are a significant source of Salmonella, a bacterium which can cause abdominal pain, nausea, fever, and diarrhea, and may require hospitalization. An estimated 280,000 cases of salmonellosis in this country annually are attributable to turtles.

It is estimated that 15 million small turtles are sold in this country annually. Ninety percent sold as pets are domestically produced on commercial turtle farms or captured in the wild. The remaining 800,000 to 1,500,000 are imported.

The regulations were sponsored by the Health Services and Mental Health Administration (HSMHA) and the Food and Drug Administration (FDA), both agencies of the Department of Health, Education, and Welfare.

Under the regulations, importation of five turtles and their eggs will be limited to a combined maximum of six, except for bona fide scientific and educational purposes or for exhibitions. All importation above the maximum limit will require a permit from the director of the Center for Disease Control, Atlanta, Georgia.

For interstate commercial shipment and sale of live turtles or their eggs, a certificate declaring the turtles free of infectious bacteria will be required from a State health authority. If a certified lot is mingled with untested lots, all must be reinspected by a State health authority before further transport or sale is allowed.

FDA is empowered to seize and order the destruction of any turtles uncertified or otherwise found endangering the public health.
REGION I

Several charitable institutions in the jurisdictional area of the Boston Field Office recently received candy, ginger ale, and root beer that had been seized because FDA found they were either short weight or improperly labeled.

During an inspection of a food warehouse at Portsmouth, New Hampshire, an FDA inspector found two lots of candy kisses, one molasses and one peanut butter, which were short weight. The candy had been manufactured and shipped by Salem’s Old Fashioned Candy Co., Salem, Massachusetts. FDA had the two lots seized. Since the candy was not claimed, a default decree was entered which called for giving the seized goods to charity.

In Concord, New Hampshire, a U.S. marshal seized over 200 cases of 32-ounce bottles of ginger ale and root beer that had been shipped by the Canada Dry Corp., Waltham, Massachusetts, and was not labeled in compliance with the Fair Packaging and Labeling Act. Since these beverages were not claimed either, a default decree was entered, and all were donated to public charitable institutions within New Hampshire.

REGION II

Three manufacturers of matzo crackers in the New York District area got in trouble recently when they represented the crackers to have special dietary properties. The claims made, which FDA alleged were false and misleading, were that the matzos were “perfect for low sugar diets,” “diet thin,” and had “no sugar added.” The District instituted seizure when it found that the crackers had only slightly less caloric content than regular matzo crackers.

The District went into action following a recent report to the office from an area consumer. The woman reported she had the same allergic reaction to a drug, labeled to contain only acetaminophen, as she has when taking aspirin. FDA representatives collected the product from the woman, and analysis later showed it contained aspirin at a level of approximately 3 1/2 grains per tablet. In addition, spectroscopic examination showed it also contained salicylamide, caffeine, and the claimed acetaminophen. The drug was being repacked by a firm in Brooklyn.

Appropriate follow-up action is now underway by the District’s compliance branch.

Buffalo District representatives are keeping the Agway Stores in the area under surveillance to insure that they are putting correct warning labels on antifreeze containers. The action follows reports received earlier by the District that the stores were selling ethylene glycol antifreeze by filling unlabeled, customer-supplied containers. During the ensuing investigation, District inspectors contacted the firm’s office in Syracuse, New York, and were informed that some of the stores did not have adequate supplies of proper warning labels. The firm issued a “stop sale” order to all its stores without the proper labels until they could be supplied.

Entry was refused recently for a 132,000-pound lot of frozen northern pike fillets shipped from Canada. FDA’s refusal was based on a Buffalo District analysis finding that an import sample of the fish contained levels of mercury above FDA guidelines. The lot was valued at $48,840.

In line with FDA’s cooperative program with the Canadian government, the District contacted the Chief of Technical Services, Inspection Branch, Department of Environment, Ottawa, Canada. He expressed concern that the shipment had slipped through the Canadian department’s monitoring system, and assured the District that the fish would be disposed of under the supervision of the Canadian government.

REGION III

Prior to Christmas the Consumer Deputy Program was in full swing in the Philadelphia District area. Approximately 50 volunteers were participating, working diligently to get as many unsafe toys off the shelves as possible before many were introduced to unsuspecting children who might be injured from them.

The consumer deputies operate under a pilot program started in three FDA Districts—Chicago, Seattle, and Atlanta—in July 1972. They visit retail establishments in their areas looking for toys that have been banned by FDA. They have no legal authority and can only point out to the store manager that he is offering a banned toy for sale. If he refuses to remove the toy from his shelves, the deputy reports this to the FDA District office, and an inspector begins an investigation. The consumer deputy program represents a means by which local consumers can work with local businessmen to provide increased protection and safety by supplementing FDA’s inspection capabilities.

The program got a boost from the Philadelphia Model Cities Consumer Protection Program, a federally funded project which covers Philadelphia’s inner city. In addition to participating in the Consumer Deputy Program, the inner city group was conducting workshops, exhibits, and media programs to pass toy safety informa-
tion on to the individual consumers living in the model cities area—approximately 250,000 of them. The inner city group also held two training sessions for volunteers in the Consumer Deputy Program, one covered November 22 by WCAU-TV, Channel 10, Philadelphia.

The Pennsylvania League of Consumer Protection took part in the program in the District area.

Vilotti and Marinelli Baking Co., Inc., Philadelphia, has signed a consent decree of permanent injunction which directs the firm to cease manufacturing until it establishes controls and takes preventive measures to eliminate adulteration of its food products. The District's initial inspection of the firm's premises in October revealed heavy insect, bird, and rodent contamination of the plant and its products. After reviewing the inspectional findings and conferring with the presiding judge, the firm signed the decree.

To further improve coordination of joint consumer protection efforts in FDA's Baltimore District and in West Virginia, two State officials have been detailed to the District for two weeks. Terry Hall, director of the State's Agriculture Laboratory, will study FDA procedures in the District laboratory, and Donald James, assistant director of the State's Consumer Protection Division, will study inspectional procedures with the District Inspection Branch. These details will complement the assignment of Tom Price, Baltimore District program coordinator, to West Virginia for two weeks in August 1972 (see FDA Consumer, November 1972).

REGION IV

The Atlanta Field Office received an adverse reaction complaint recently from a consumer after she took thiamine hydrochloride (vitamin B1). Field Office representatives investigated and discovered mislabeled drugs. The consumer said she had taken the vitamin tablets as directed, then had noticed flushing and redness of her face and a "warm" feeling for about an hour, followed by chills. The complainant's tablets and follow-up samples were found to contain 100 mg of niacin per tablet and no thiamine hydrochloride. The tablets were repacked by Generix Drug Co., Hollywood, Florida. During the investigation FDA officials found that 85,000 thiamine hydrochloride tablets and 500,000 niacin tablets had been shipped at the same time from the same pharmaceutical company to the repacker. By mistake the repacker put niacin tablets in containers labeled thiamine hydrochloride. A recall was initiated.

Several groups within the Region, concerned about toy safety, nutritive labeling, and drugs, are forming consumer action committees. Among these are Georgia's YWCA's, Duke University Student Committee, Georgia Tech. Student group, and Beta Sigma Phi International Sorority (Delta Upsilon chapter). FDA consumer specialists in the Region are training group leaders to establish plans of action. The leaders will then take back to their respective committees the consumer information they have gathered.

REGION V

A recent Consumer Awareness Conference at Rockford, Illinois, reached over 300 people, and it seems likely to be repeated in the near future. The conference was sponsored jointly by FDA's Chicago District and the Harlem High School in Rockford.

Participants in the various sessions included William R. Clark, deputy regional food and drug director for FDA's Region V; Dr. Philip L. White, director, Department of Foods and Nutrition, American Medical Association; Marie A. Ekvall, consumer specialist, FDA; and local businessmen, bankers, insurance executives, and representatives from food stores in the Chicago area.

Consumer Specialist Marie A. Ekvall and Inspector Richard P. Spiller of the Chicago District conducted a series of workshops in the Chicago area for the Industrial Safety and Health Training Classes of the United Steelworkers of America. The men attending appeared to be vitally concerned about toy safety, food sanitation, nutrition, and food additives. They came out in inclement weather to hear what FDA had to say.

Cincinnati District initiated recent seizure of a two-ton lot of potato flakes in possession of Markin-Blanton Co., Ironton, Ohio. The lot was rodent-adulterated and had been stored under insanitary conditions. FDA inspectors found the adulterated potato flakes while conducting a sanitary inspection of the wholesale warehouse.

Detroit District inspectors accompanied three U.S. marshals for recent simultaneous seizures of lots of prescription veterinary drugs in the possession of three Michigan dealers. The drugs were being sold for use without the supervision of a licensed veterinarian and were therefore held to be misbranded under the Food, Drug, and Cosmetic Act.

The seizure actions followed up an investigation the District began after the Michigan Department of Agriculture reported finding antibiotic residues in milk.

Six fisheries in the Minneapolis District area have been permanently enjoined from shipping DDT-adulterated fish in interstate commerce, ending almost two years of legal seesawing in the courts. All are in Wisconsin, and include Goodman Fish Co., Kenosha; Ewig Bros. Fish Co., Inc., Port Washington; Strege & Rouar Fish Co., Racine; Ray's Fish Co., Racine; Robert Strege Co., Racine; and G and M Fisheries, Racine.

Early in 1971, FDA's Minneapolis District attempted to bring injunction proceedings against the fish dealers, found to be shipping fresh and smoked chubs containing DDT in amounts exceeding the 5 parts per million interim tolerance established for this pesticide by the Secretary of Health, Education, and Welfare.
After months of preliminary conferences between U.S. and defense attorneys, a hearing was held November 2, 1972, in Milwaukee, before U.S. District Judge Myron L. Gordon. On November 6, Judge Gordon ruled in favor of the Government, stating that the Secretary does have such authority, and there is a judicial obligation to enjoin the distribution of unsafe foods, even in the absence of a formally promulgated regulation. The judge then signed the order for permanent injunction against the six firms.

As a result, the National Commission for Strawberries (composed of representatives from government, strawberry-growing associations, packers, etc.) agreed to revoke the exportation licenses of growers who ship pesticide-adulterated strawberries to the United States. The Commission also indicated it will set up a pesticide laboratory in the strawberry-growing State of Michoacan to check berries intended for exportation to this country.

The Commission, as well as a number of government agencies, expressed a desire to send chemists to Dallas District for training in pesticide residue analysis and to continue the dialogue with FDA.

In the New Orleans District, Sars of Louisiana, Inc., a rendering plant at Baton Rouge, and its vice president, Felix Sapp, were sentenced in a Federal Court at New Orleans on charges of shipping Salmonella-contaminated meat-scrap meal in interstate commerce. The corporation had pleading guilty and was fined $5,000 on each of three counts; the sentence was suspended on one of the counts. Mr. Sapp, who had pleaded guilty to one count of the charge, was placed on two years' probation on condition that he not violate any local, State, or Federal laws.

REGION VII

The Kansas City Field Office is actively involved in enforcement of the permanent injunction handed down by the court in May 1972 against Diapulse Corp. of America forbidding sale of its Diapulse device. Not only is the firm enjoined but all persons involved in the distribution and promotion of the Diapulse unit. Diapulse is an electromagnetic generator similar to conventional medical diathermy, but differing in that its output is pulsed and it lacks the energy output of conventional medical diathermy.

FDA investigators are visiting all known consignees or users of the devices, and affording them the opportunity to voluntarily dispose of them. If the devices are not destroyed voluntarily or released to the FDA for disposition, seizure is recommended.

Over 125 practitioners in Iowa, Kansas, Nebraska, and Missouri are involved. To date, approximately 35 units have been voluntarily destroyed or surrendered, and Federal seizure action has been initiated against approximately 50 additional devices. Kansas State health officials are assisting in this activity.

Over 4,000 Diapulse devices have been distributed throughout the United States and in several foreign countries. Purchasers include hospitals, clinics, medical doctors, chiropractors, and other practitioners, who have paid $2,400 to $3,000 for each machine.

REGION VIII

Mike Kuchta, consumer safety officer with the Denver Field Office, found recently that a large bakery in Den-
ver was producing bread packaged 5 percent short of labeled weight. When contacted, the bakery voluntarily destroyed 2,650 pounds of the bread on hand. It also destroyed raw material contaminated with water that had condensed on the equipment.

REGION IX

In the San Francisco District, F. G. Wool Packing Co., San Jose, California, consented to an injunction November 1 prohibiting shipment of its 1971 pack of canned fruit cocktail into interstate commerce. FDA had found that the product contained mold from canning machinery and had been packed under insanitary conditions. The firm was further enjoined from shipping any contaminated products, or products packed under insanitary conditions, into interstate commerce at any time in the future.

Lassen Foods, Inc., Paradise, California, and Wayne W. Schlothauer, president, and Conrad L. Craft, manager, were each fined $500 October 31 by Judge Philip C. Wilkens, U.S. District Court, Sacramento. The two individuals were also placed on a year's unsupervised probation. All had pleaded guilty earlier to an FDA charge of holding wheat-germ meal under insanitary conditions in a home environment, and food purchasing pointers relating to packaging and labeling, among other things.

The second and third workshops dealt with the use of OTC and Rx, drugs, cosmetics, and medical devices; and selection and care of fabrics, flammable fabrics, and toy safety.

Also in Arizona, Mrs. Roentgen addressed three classes in contemporary nutrition concepts at the State University in Tempe. As an indication of the tremendous interest in nutrition that currently prevails on college campuses, 90 students were registered in each of these classes. Only a small percentage are nutrition majors, and the students represent a variety of age levels.

REGION X

The Seattle Field Office is helping conduct a six-month consumer education workshop on the Indian reservations in Washington, Oregon, and Idaho. The workshop is aimed at community action program aides, health "outreach" workers, coordinators, counselors, and other "help-oriented" people working with Indian families.

The first workshop was presented November 16 in Lapwai, Idaho, for representatives from the Nez Perce and Coeur d'Alene tribes. Program topics included use of ads in shopping, health frauds, aerosol sniffing, purchase of nonprescription drugs, purchase of meat and convenience foods, door-to-door sales, and credit. Representatives of the FDA, the Federal Trade Commission, the Idaho State Attorney General's office, and the Cooperative Extension Service participated in the presentations.
State Actions

Home-Processed Food Regs
When food is processed in a domestic kitchen for sale to the public, says the Oregon Department of Agriculture, persons allowed in the kitchen at the time of processing, preparation, packaging, or handling of the commercial foods will be limited to the licensee and those working on the product, directly under supervision of the licensee.

This is one of the requirements in the regulations now covering processing of commercial foods in domestic kitchens. The regulations further require:

- That all domestic kitchen doors or openings to other rooms or structures be kept closed and no other domestic activities of any kind be carried on in the kitchen while the commercial food is being processed, prepared, packaged, or handled.

- That no pets be allowed at any time in the structure or building in which the domestic kitchen is located.

- That there be separate storage space for ingredients, the finished products, containers, and labels for the commercial foods.

- That household cleaning materials, other chemicals, toxic substances, or medical supplies not be stored in the domestic kitchen.

- That all domestic kitchen doors or openings to other rooms or structures be kept closed and no other domestic activities of any kind be carried on in the kitchen while the commercial food is being processed, prepared, packaged, or handled.

The regulations require that the regulations now in effect require that unpackaged meat products such as sausage and bologna sold in bulk to retail stores must be identified to the consumer by a wallboard or chart, or a card for each item in the display case. Prepackaged meat items with two or more ingredients also must be labeled to identify these ingredients.

New Food-Labeling Law
Hot dogs, sausage, sandwich meat, bologna, scrapple, and other popular staples manufactured from meat products for sale to consumers, must have their ingredients clearly labeled, according to a food-labeling law now in effect in Pennsylvania, and enforced by the State’s department of agriculture.

The regulations stem from the State’s Meat and Poultry Hygiene law of 1968. Although the meat industry has had a good record of voluntary compliance with labeling requirements, violations have occurred when retail outlets buy manufactured meat products in bulk and repackage the meat for sale in smaller quantities.

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Training Session
The Bureau of Consumer Affairs and Marketing Services of the Pennsylvania Department of Agriculture held a two-day training session at Harrisburg recently for its consumer coordinators representing all seven regions in the department. The purpose of the event was to instruct the coordinators in forming consumer councils throughout the State and educating council members.

Consumer councils will be composed of citizens, representatives of consumer organizations, and other qualified persons interested in the consumer protection aspects of food production, food processing, and food marketing. The council members will be responsible for informing the public about consumer protection laws and existing consumer programs. They will be direct lines to the department for registering consumer complaints in matters of high prices, deceptive advertising and labeling, and inferior quality of food commodities.

Contaminated Nuts
State Inspector Lawrence Burns of the Food Inspection Division of the Michigan Department of Agriculture recently supervised the destruction of approximately nine tons of contaminated nuts. The department had cooperated with FDA’s Detroit District, in mid-November, by seizing all lots of nuts in possession of the Rocky Peanut Co., Detroit, after an FDA inspector observed a general rodent problem at the firm.
Seizures and Postal Service Cases

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

A total of 43 actions to remove from the consumer market products charged to be violative was reported in October. These included 20 seizures of foods: 2 involved charges concerning poisonous and deleterious substances, 12 involved charges concerning contamination, and 6 involved charges concerning economic and labeling violations. Other seizures included 1 of vitamins and dietary food, 1 of drugs, 17 of medical devices, and 4 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>Alfalfa hay, baled/Chino, Calif. 10/11/72</td>
<td>Arie Breedyk Dairy/Chino, Calif. (D)</td>
<td>FOOD/Poisonous and Deleterious Substances, Contains a pesticide chemical, toxaphene, in excess of established tolerance of 1 ppm.</td>
</tr>
<tr>
<td>Seed corn, treated/Louisville, Ky. 10/11/72</td>
<td>Caudill Seed and Warehouse Co./Louisville, Ky. (D)</td>
<td></td>
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<tr>
<td>Actif-8, flour salt/Henderson, N.C. 10/25/72</td>
<td>Sanford Milling Co./Henderson, N.C. (D)</td>
<td>Contamination, Spoilage, Insanitary Handling, Held under insanitary conditions.</td>
</tr>
<tr>
<td>Beans, green, canned, “Lake Region,” “Spring Valley”/Arlington, Minn. 10/26/72</td>
<td>Indianhead Food Products, Inc./Bloomer, Wis. (M,S)</td>
<td></td>
</tr>
<tr>
<td>garbanzo/Modesto, Calif. 10/17/72</td>
<td>Ed J. Lyng Co., Inc./Modesto, Calif. (D)</td>
<td></td>
</tr>
<tr>
<td>Great northern, navy/Toledo, Ohio 10/18/72</td>
<td>The Bartley Co./Toledo, Ohio (D)</td>
<td></td>
</tr>
<tr>
<td>mung/San Francisco, Calif. 10/12/72</td>
<td>South End Warehouse/San Francisco, Calif. (D)</td>
<td></td>
</tr>
<tr>
<td>pinto, ML brand, Ma Hat Ma Texas patna rice/Fresno, Calif. 10/4/72</td>
<td>Hobbs-Parson Co./Fresno, Calif. (D)</td>
<td></td>
</tr>
<tr>
<td>Chili peppers, dried, brazil nuts/El Paso, Tex. 10/17/72</td>
<td>Brown’s Refrigerated Warehouse, Inc./El Paso, Tex. (D)</td>
<td>Contamination, Spoilage, Insanitary Handling, Held under insanitary conditions; rodent contaminated.</td>
</tr>
<tr>
<td>Coffee beans, green/San Francisco, Calif. 10/21/72</td>
<td>Thompson Bros., Inc./San Francisco, Calif. (D)</td>
<td></td>
</tr>
<tr>
<td>Popcorn/Charlotte, N.C. 10/3/72</td>
<td>John Purvis Co./Charlotte, N.C. (D)</td>
<td></td>
</tr>
<tr>
<td>Rice, brown/Penns Creek, Pa. 10/26/72</td>
<td>Arrowhead Mills, Inc./Hereford, Tex. (M,S)</td>
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<tr>
<td>Shrimp meat/San Francisco, Calif. 10/26/72</td>
<td>Bianco Fisheries, Inc./Port Orford, Ore. (P,S)</td>
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<tr>
<td>Wheat germ, hulled sunflower seeds, hulled sunflower chips/Spokane, Wash. 10/2/72</td>
<td>Pilgrim Fine Foods, Inc./Spokane, Wash. (D)</td>
<td></td>
</tr>
<tr>
<td>Coffee mix, Luzianne Instant/New Orleans, La. 10/6/72</td>
<td>Luzianne Coffee Co., Inc./New Orleans, La. (D)</td>
<td>Economic and Labeling Violations, Chicory and malto-dextrin was substituted in part for coffee; label fails to bear the common or usual name of article.</td>
</tr>
<tr>
<td>Molasses kisses, peanut butter kisses/Portsmouth, N.H. 10/17/72</td>
<td>Salem’s Old Fashioned Candy Co./Salem, Mass. (M,S)</td>
<td></td>
</tr>
<tr>
<td>Olives, Durkee Spanish/Denver, Colo. 10/12/72</td>
<td>SCM Corp./Cleveland, Ohio (M); SCM Glidden-Durkee/Brooklyn, N.Y. (S)</td>
<td></td>
</tr>
<tr>
<td>Pelures De Truffes, Truffes Brossees/ Denver, Colo. 10/12/72</td>
<td>Liberty Import Corp./Carlstadt, N.J. (S)</td>
<td></td>
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<tr>
<td>Pepper, black, ground/Jackson, Miss. 10/12/72</td>
<td>Unknown (M)</td>
<td></td>
</tr>
<tr>
<td>Tortillas/Seattle, Wash. 10/19/72</td>
<td>Macgowan Coffee Co./Jackson, Miss. (D)</td>
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<td></td>
<td>Ashley’s Inc./El Paso, Tex. (M,S)</td>
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<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>PENTA-VIRON tablets/San Francisco, Calif. 10/2/72</td>
<td>Leo Linden Laboratories, Inc./Los Angeles, Calif. (M,S)</td>
<td>Deficient in vitamin B-1 (thiamine); false and misleading label statements representing article to be necessary and useful as a daily dietary supplement; not in conformity with the Fair Packaging and Labeling Act.</td>
</tr>
<tr>
<td>Diapulse/Medford, Oreg. 10/17/72</td>
<td>Diapulse Corp. of America/New Hyde Park, N.Y. (M,S)</td>
<td>Inadequate directions for safe use by laymen.</td>
</tr>
<tr>
<td>Diapulse/Portland, Oreg. 10/3/72</td>
<td>Diapulse Corp. of America/New Hyde Park, N.Y. (M,S)</td>
<td>Inadequate directions for safe use by laymen.</td>
</tr>
<tr>
<td>Diapulse/Charlotte, N.C. 10/15/72</td>
<td>Diapulse Corp. of America/New Hyde Park, N.Y. (M,S)</td>
<td>Inadequate directions for safe use by laymen.</td>
</tr>
<tr>
<td>Diapulse/Franklin, Pa. 10/24/72</td>
<td>Diapulse Corp. of America/New Hyde Park, N.Y. (M,S)</td>
<td>Inadequate directions for safe use by laymen.</td>
</tr>
<tr>
<td>Diapulse/Quakertown, Pa. 10/16/72</td>
<td>Diapulse Corp. of America/New Hyde Park, N.Y. (M,S)</td>
<td>Inadequate directions for safe use by laymen.</td>
</tr>
<tr>
<td>Diapulse/Columbus, Ohio 10/3/72</td>
<td>Diapulse Corp. of America/New Hyde Park, N.Y. (M,S)</td>
<td>Inadequate directions for safe use by laymen.</td>
</tr>
<tr>
<td>Diapulse/Louisville, Ky. 10/5/72</td>
<td>Diapulse Corp. of America/New Hyde Park, N.Y. (M,S)</td>
<td>Inadequate directions for safe use by laymen.</td>
</tr>
<tr>
<td>Diapulse/Louisville, Ky. 10/5/72</td>
<td>Diapulse Corp. of America/New Hyde Park, N.Y. (M,S)</td>
<td>Inadequate directions for safe use by laymen.</td>
</tr>
<tr>
<td>Diapulse/Selma, Ala. 10/12/72</td>
<td>Diapulse Corp. of America/New Hyde Park, N.Y. (M,S)</td>
<td>Inadequate directions for safe use by laymen.</td>
</tr>
<tr>
<td>Diapulse/Lake City, Fla. 10/11/72</td>
<td>Diapulse Corp. of America/New Hyde Park, N.Y. (M,S)</td>
<td>Inadequate directions for safe use by laymen.</td>
</tr>
<tr>
<td>Diapulse/Sacramento, Calif. 10/2/72</td>
<td>Diapulse Corp. of America/New Hyde Park, N.Y. (M,S)</td>
<td>Inadequate directions for safe use by laymen.</td>
</tr>
<tr>
<td>Diapulse/Hope, Ark. 10/6/72</td>
<td>Remington Rand Div., Sperry Rand Corp. (M), Diapulse Corp. of America/New Hyde Park, N.Y. (M)</td>
<td>Inadequate directions for safe use by laymen.</td>
</tr>
<tr>
<td>Diapulse/Palm Springs, Calif. 10/1/72</td>
<td>Remington Rand Div., Sperry Rand Corp. (M), Diapulse Corp. of America/New Hyde Park, N.Y. (M)</td>
<td>Inadequate directions for safe use by laymen.</td>
</tr>
<tr>
<td>Climalene detergent booster/Fort Wayne, Ind. 10/17/72</td>
<td>Climalene Co./Canton, Ohio (M,S)</td>
<td>Toxic, corrosive, and an irritant; no adequate warnings.</td>
</tr>
<tr>
<td>Re-Silvering polish/Pittsburgh, Pa. 10/26/72</td>
<td>Ag Bond International, Inc./Batavia, N.Y. (M,S)</td>
<td>Banned hazardous substance containing soluble cyanide salts.</td>
</tr>
<tr>
<td>Silver Replate/Cincinnati, Ohio 10/18/72</td>
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<td>&quot; &quot;</td>
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</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**

August 30, 1972: False Representation Order issued against Health Activators and Arnold King Distributors, 7008 S. W. 4th Street, Miami, Florida, and Personal Professional Products, P.O. Box 493, Miami, Florida. Advertising and sale by mail of "P.E.P.P.,” represented to be effective as a sex stimulant, wrinkle remover, and bust developer.

August 30, 1972: False Representation Order issued against Health Activators and Arnold King Distributors, 7008 S. W. 4th Street,
False Representation Orders Issued by Judicial Officer Under 39 U.S.C. 3005 (cont.)

Miami, Florida, and Personal Professional Products, P.O. Box 493, Miami, Florida. Advertising and sale by mail of a product called “Instant Erecto Cream,” represented to be an effective sex stimulant for men.

August 30, 1972: False Representation Order issued against Health Activators and Arnold King Distributors, 7008 S. W. 4th Street, Miami, Florida, and Personal Professional Products, P.O. Box 493, Miami, Florida. Advertising and sale by mail of a product called “La Fem Climax Cream,” represented to be effective as a sex stimulant for women.

August 30, 1972: False Representation Order issued against Stature House, P.O. Box 146, Brampton, Ontario, Canada, and P.O. Box 550, Mississauga, Ontario, Canada. Advertising and sale by mail of a course which will allegedly effect a significant increase in height.

September 5, 1972: False Representation Order issued against Hair Growth Bureau, P.O. Box 146, or 158 Kennedy Road, South, Brampton, Ontario, Canada. Advertising and sale by mail of a course which will allegedly reverse a balding condition and restore hair to balding areas of the head.

September 6, 1972: False Representation Order issued against Fun House, P.O. Box 239, Gary, Indiana. Advertising and sale by mail of a product called “Mexican Spanish Fly in Liquid Form,” represented to be effective as a sex stimulant.

September 7, 1972: False Representation Order issued against Information Resources Co., P.O. Box 173, Encinitas, California 92024. Advertising and sale by mail of “U.S. Women’s Ski Team Diet,” which promised a weight loss of 20 pounds in two weeks.

September 7, 1972: False Representation Order issued against J. Carlton’s and Inchaway Wrap, 176 Madison Avenue, New York, New York 10016. Advertising and sale by mail of “Inchaway Wrap,” represented as enabling users to lose three inches off their waistlines in just one hour without having to diet or exercise.

September 14, 1972: False Representation Order issued against Ann Jones, 324 S. First Street, Alhambra, California 91802. Advertising and sale by mail of “Spanish Fly Love Pills,” represented to be an effective aphrodisiac or sexual stimulant.

September 20, 1972: False Representation Order issued against Obadiah, 324 S. First Street, Alhambra, California 91802. Advertising and sale by mail of “Sex Stimulant,” represented to be an effective aphrodisiac or sex stimulant.

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

August 25, 1972: Dyna Power, Ltd., Dyno-Power, and P.O. Box 239, Gary, Indiana 46401. Advertising and sale by mail of “Dynamite” and “Prolong Tablets,” represented to be effective as sex stimulants.

August 29, 1972: Citrus Publishers, P.O. Box 47, Northridge, California 91324. Advertising and sale by mail of a diet plan which promises a weight loss of 10 pounds in 10 days.

August 29, 1972: Gwendolyn, 152 West 42nd Street, Suite 536, New York, New York 10036. Advertising and sale by mail of “French Love Powder,” represented to be an effective aphrodisiac or sexual stimulant.

August 30, 1972: Hernandez, 324 S. First Street, Alhambra, California 91802. Advertising and sale by mail of “Pseudo Spanish Fly Chewing Gum,” represented to be an effective aphrodisiac or sexual stimulant.

August 31, 1972: Nina of Germany, 152 West 42nd Street, Suite 536, New York, New York 10036. Advertising and sale by mail of “Super Nature Tablets” or “Spark Pills,” represented to be an effective aphrodisiac or sexual stimulant.

August 31, 1972: Thornton and Thornton Lab., 152 West 42nd Street, Suite 536, New York, New York 10036. Advertising and sale by mail of “Mad Dog Weed,” represented to be an effective aphrodisiac or sexual stimulant.

September 1, 1972: Products of Ann Lee, 9864 Bird Road, Miami, Florida 33165. Advertising and sale by mail of a product called “Up and Atom,” represented to improve sexual ability of men.

September 1, 1972: Products of Ann Lee, 9864 Bird Road, Miami, Florida 33165. Advertising and sale by mail of a product called “Dynamic Kaps,” represented to be effective as a sex stimulant and to restore good health.

September 5, 1972: United Distributors, 152 West 42nd Street, Suite 536, New York, New York 10036. Advertising and sale by mail of “Frenchie’s Spanish Fly Chewing Gum,” represented to be an effective aphrodisiac or sexual stimulant.

September 6, 1972: Harco Distributors, Inc., Elmhurst, New York, New York 11373. Advertising and sale by mail of “Slimming Caps,” guaranteed as enabling subscribers to lose 10 pounds in 10 days.

September 6, 1972: United Distributors, 6915, 6919, and 6921 S. Vernon Avenue, Chicago, Illinois 60637. Advertising and sale by mail of products called “Spanish Fly,” “Knockout Drops,” “Spanish Fly Chewing Gum,” and “Spanish Fly Candy,” represented to be effective as sex stimulants.

September 20, 1972: Brentwood Research, 1800 N. Highland Avenue, Los Angeles, California 90052. Advertising and sale by mail of “Report 43,” alleged to be a weight reduction tonic.

September 22, 1972: Lockwood Distributors and P.O. Box 798, Miami, Florida. Advertising and sale by mail of a product called “Instant Erecto Cream,” represented to be an effective sex stimulant for men.

September 22, 1972: Lockwood Distributors and P.O. Box 798, Miami, Florida. Advertising and sale by mail of a product called “P.E.P.,” represented to be effective as a sex stimulant, wrinkle remover, and bust developer.

September 22, 1972: Lockwood Distributors and P.O. Box 798, Miami, Florida. Advertising and sale by mail of a product called “La Fem Climax Cream,” represented to be effective as a sex stimulant for women.
NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

Cottonseed meal, at Albuquerque, Dist. N. Mex. Charged 3-2-72: while held for sale, the article contained the added poisonous and deleterious substance aflatoxin; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 57580; S. Nos. 32-323; N.J. No. 1)

Meat and bone meal, at Lake Charles, W. Dist. La. Charged 3-6-72: when shipped by Barvin Packing Co., Houston, Tex., the article, which was in burlap bags that had been poison-treated, the rice seed, contained the pesticide chemical aldin, and its use and intended use were not in conformity with a regulation or exemption therefrom; the article had been prepared, packed, and held under insanitary conditions; the label statement on the bags of “seed rice” was false and misleading in representation of the business of the manufacturer, packer, or distributor; and the label lacked the common or usual name of the rice and had been prepared for sale; 402(a)(3), 403(d)(1). Default decree ordered destruction. (F.D.C. No. 57583; S. No. 53-202 F; N.J. No. 2)

FOOD / Contamination, Spoilage, Insanitary Handling

Almonds, at Chicago, N. Dist. III. Charged 3-16-72: while held by American Bakers Co., St. Louis, Mo., the article contained rodent filth and was held under insanitary conditions; 402(a)(3). Default decree authorized delivery to a Government commission for use as a wildlife fodder. (F.D.C. No. 57586; S. No. 42-630 F; N.J. No. 4)

Caraway seeds, at St. Louis, E. Dist. Mo. Charged 2-6-72: while held by American Bakers Co., St. Louis, Mo., the article was held under insanitary conditions; 402(a)(3); 402(a)(6). Default decree authorized delivery to a Government commission for use as a wildlife fodder. (F.D.C. No. 57577; S. No. 53-108 F; N.J. No. 5)

Cookies, at Round Lake, Dist. Minn. Charged 1-12-72: while shipped by American Wafer Co., Joplin, Mo., the article, labeled in part “Sather’s Cream Rye Crisp,” and by Sather Cookie Co., Round Lake, Minn., “contained rodent filth and had been prepared, packed, and held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 57575; S. No. 64-958 E; N.J. No. 6)

Fruit cocktail, canned, 2 seizure actions at Montgomery, M. Dist. Ala., and Greenville, Dist. S.C. Charged 1-27-72, and on or about 2-2-72: when shipped by Institutional Warehouses, Inc., East Stockton, Calif., the article, labeled in part “Asst Fruit Cocktail,” and by the Montgomery Canning Co., San Francisco, Calif., “Asst Fruit Cocktail,” contained mold from unclean machinery and had been prepared under insanitary conditions; 402(a)(3), 403(d)(2). Default decree ordered destruction. (F.D.C. No. 57579; S. Nos. 52-959 E; N.J. No. 7)

Mushroom chips, canned, 2 seizure actions at Kansas City, Dist. Kan., and Tamoka, M. Dist. Nebr. Charged 2-17-72 and 3-9-72: while held for sale, the articles were undergoing progressive decomposition; 402(a)(3). Default decree ordered destruction. (F.D.C. Nos. 57571/2; S. Nos. 65-160 E & 1-200/1 E; N.J. No. 10)

Peas, dried, lima beans, dried, Great Northern beans, dried, and marrow beans, dried, 4 seizure actions at Marcellus, N. Dist. N.Y. Charged 3-29-72: while held by Allen V. Smith, Inc., Marcellus, N.Y., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for reconditioning. (F.D.C. Nos. 57574/5; 78-425/6 E et al; N.J. No. 11)

Pecans, shelled, at Mansura, W. Dist. La. Charged 1-7-72 when shipped by Keasbey’s Baking Co., Memphis, Tenn., the article, labeled in part “Byron Nut Company,” was distinctly different from other macaroni and noodle products; the statements “Net Wt. 1 lb.” instead of “Net Wt. 16 oz. (1 lb.),” and the area of more than 25 square inches, was in a type size less than 3/16 inch high—15 U.S.C. 1453(a)(1), 1453(a)(3)(c)(i). Default decree ordered destruction. (F.D.C. Nos. 57437 & 57465; S. Nos. 53-445/7 E et al & 54-444 E; N.J. No. 18)

Peanuts, black, lima beans, dried, and peas, dried, at Carrollton, N. Dist. Tex. Charged 3-16-72: while held by Adams & Storage, Kansas City, Mo., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 57576; S. Nos. 31-804/8 F; N.J. No. 14)

Potato, at Kansas City, W. Dist. Mo. Charged 3-5-72: while held by Adams & Storage, Kansas City, Mo., the article contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 57576; S. Nos. 31-804/8 F; N.J. No. 14)

Peaches, diced, dehydrated, Idahoan Ready Diced, at Forest Park, N. Dist. Ga. Charged 1-17-72: when shipped by Idaho Fresh Pak, Inc., Lewisville, Idaho, the article contained insects and insect larvae; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 57577; S. No. 3-701 E; N.J. No. 16)

Rice and plate beans, at Fresno, E. Dist. Calif. Charged 2-15-72: while held by Maritio Quality Foods, Inc., Fresno, Calif., who had repacked some of the rice into 1-lb. bags from 100-lb. bulk bags, the 1-lb. bags of rice were held under insanitary conditions; 402(a)(3). A 1-lb. bag of rice was destroyed. (F.D.C. No. 57578; S. Nos. 31-906/7 F; N.J. No. 17)

Soup, at Glens Falls, N. Dist. N.Y. Charged 9-8-71 and 9-15-71: when shipped by Bon Vivant Soups, Inc., Newark, N.J., the articles were unfit for food in that some cans of these foods had been found to contain residues and impurities; 402(a)(3), 402(a)(4). Consent decree authorized release to a Government commission for use as a wildlife fodder. (F.D.C. Nos. 57437 & 57465; S. Nos. 53-445/7 E et al & 54-444 E; N.J. No. 18)

Soups of various kinds, canned, Bon Vivant and Ancora, 2 seizure actions at Kansas City, Dist. Mo., and Dallas, N. Dist. Tex. Charged 2-11-72: while held by American Soup Mfg. Co., Minneapolis, Minn., the article contained insects and insect fragments; 403(e)(1), 403(i)(l). Default decree ordered destruction. (F.D.C. No. 57437 & 57465; S. Nos. 53-445/7 E et al & 54-444 E; N.J. No. 18)

Tuna, canned, at New Orleans, E. Dist. La. Charged 2-25-72: while held for sale, the article was undergoing chemical decomposition; 403(e)(1). Default decree ordered destruction. (F.D.C. No. 57583; S. Nos. 53-443/4 F; N.J. No. 20)

Vegetable noodles, wheat and soya noodles, vegetable shell macaroni, vegetable elbow macaroni, vegetable spaghetti, and whole wheat macaroni, at North Bergen, Dist. N.J. Charged 2-9-72: when shipped by Florence Macaroni Manufacturing Co., Los Angeles, Calif., the article, labeled in part “Whole Wheat Cut Macaroni,” contained insects and insect fragments; 403(e)(1), 403(i)(l). Default decree ordered destruction. (F.D.C. No. 57437 & 57465; S. Nos. 53-445/7 E et al & 54-444 E; N.J. No. 18)

Vegetable noodles, wheat and soya noodles, vegetable shell macaroni, vegetable whole wheat macaroni, at North Bergen, Dist. N.J. Charged 2-9-72: when shipped by Florence Macaroni Manufacturing Co., Los Angeles, Calif., the article, labeled in part “Whole Wheat Cut Macaroni,” contained insects and insect fragments; 403(e)(1), 403(i)(l). Default decree ordered destruction. (F.D.C. No. 57437 & 57465; S. Nos. 53-445/7 E et al & 54-444 E; N.J. No. 18)
Cookies, at San Lorenzo, N. Dist. Calif.

Peach halves, canned, Greer, at Little Rock, E. Dist. Ark.

Charged 1-26-72: when shipped by Bakkers Royal Dutch Cookies (Hawk whole wheat macaroni) was in a type size less than 3/16 inch high—square inches of all articles (except the wheat and soya noodles and the quantity of contents declaration was not within the bottom 30 percent of the principal display panel area; since the quantity of contents statement, appearing on the principal display panel area of more than 25 square inches, was in a size type less than 3/16 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(I), 1453(b). Consent decree authorized donation to a charitable institution. (F.D.C. No. 57766; S. No. 17-538 E; N.J. No. 22)


Charged 1-27-72: when shipped by D. DeFranco & Sons, t/a New England Tomato Co., Los Angeles, Calif., the articles were in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not separated from other printed labeling appearing above the declaration, and since the quantity of contents statement, appearing on the principal display panel area of more than 25 square inches, was in a size type less than 3/16 inch high. (F.D.C. No. 57780; S. No. 83-274/80 E; N.J. No. 21)

Charged 1-29-72: when held for sale by Allied Chemical Corp., Omaha, Nebr., the article, the article contained diethylstilbestrol, a new animal drug for which there was no approval of a New Animal Drug Application in effect with respect to the use and intended use of the drug. 402(a)(2)(D). Consent decree authorized release to Hub City Feed & Seed Co., Aberdeen, S. Dak., for reconditioning. Thereafter, pursuant to stipulation, the article was destroyed. (F.D.C. No. 57772; S. No. 92-925 E; N.J. No. 30)

Animal feed concentrate liquid, at Greenleaf, Dist. Kans.

Charged 2-9-72: while held for sale, the article contained diethylstilbestrol which was a new drug approved New Animal Drug Application in effect with respect to use and intended use; 402(a)(2)(D). Default decree authorized destruction. (F.D.C. No. 57779; S. No. 83-487 E; N.J. No. 33)


Charged 2-24-72: when returned to Kay Dee Feed Co., Sioux City, Iowa, who had manufactured the article, the article contained diethylstilbestrol, a new animal drug for which there was no approval of a New Animal Drug Application in effect with respect to the use and intended use of the drug. 402(a)(2)(D). Consent decree authorized release to the manufacturer for salvaging. (F.D.C. No. 57838; S. No. 41-667 F; N.J. No. 38)

Feed supplement liquid, Compensator PR, at Rock Port, W. Dist. Mo.

Charged 1-14-72: when shipped by Allied Chemical Corp., Omaha, Nebr., the article contained diethylstilbestrol, a new drug without an effective approved New Animal Drug Application for use in the article. 402(a)(2)(D). Default decree authorized destruction. (F.D.C. No. 57737; S. No. 92-892 E; N.J. No. 33)

Feed supplement liquid, Compensator PR, at Stamford, Dist. Nebr.

Charged 1-7-72: when shipped for sale after manufacture by Allied Chemical Corp., Omaha, Nebr., from ingredients shipped in interstate commerce, the article contained diethylstilbestrol, a new animal drug without an effective approved New Animal Drug Application for use in the article; 402(a)(2)(D). Default decree ordered destruction. (F.D.C. No. 57781; S. No. 97-891 E; N.J. No. 33)

Medicated liquid animal feed, at Loveland, Dist. Colo.

Charged 3-10-72: when shipped by Prescription Premix, Minatara, Nebr., the article, labeled in part "Puregro Company P-M-S Feed Initiator . . . Oxytetracycline . . . Neomycin . . . Distributed By Puregro Company Denver, Colo.,' contained the drugs Oxytetracycline and neomycin which in combination with each other in the animal feed were new drugs for which there was no effective approved New Animal Drug Application for use in the article; 402(a)(2)(D). Default decree ordered destruction. (F.D.C. No. 57861; S. No. 33-960 F; N.J. No. 35)

DRUGS / Human Use


Charged 3-15-72: while held by Kapco, Inc., Kalamazoo, Mich. (who manufactured the article, the article contained "Fellows Med. Mfg. Co. Inc. Oak Park, Mich. . . . Anaheim, Calif.," using caffeine and acetaminophen shipped in interstate commerce), the listing on the label of ascorbic acid as an active ingredient falsely and misleadingly represented and suggested that the ascorbic acid was of value leadingly represented and suggested that the ascorbic acid was of value for the article's intended purpose for temporary relief of headache, since it was a new drug without an effective approved New Drug Application; 201(a), 502(a), 505(a). Consent decree authorized release to Hub City Drug Application in effect with respect to the article's intended purpose for temporary relief of headache, since it was a new drug without an effective approved New Drug Application; 201(a), 502(a), 505(a). Consent decree ordered destruction. (F.D.C. No. 57846; S. No. 46-364 E; N.J. No. 37)


Charged 2-19-71: when shipped by McFarland Laboratories, Inc., California, Ill., the circumstances of the article's manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; and the article's strength differed from the U.S.P. standard; 501(a)(2)(B), 501(b). Default decree ordered destruction. (F.D.C. No. 57846; S. No. 46-364 E; N.J. No. 37)

Sodium iodide and foreign protein injection, at St. Louis, E. Dist. Mo.

Charged 3-15-72: when the article, labeled in part "PROZIDE . . . Sodium Iodide . . . Purified Beef Protein (lodinated) . . . Manufactured for Fleming & Co. St. Louis, Mo.,' was shipped by Maizel Labora
tories, Inc., Chicago, Ill., the circumstances of the article's manufacture, processing, packing, and holding failed to conform with current good manufacturing practice; and the article was a new drug without an effective approved New Drug Application; 501(a)(2)(B), 501(b). Default decree ordered destruction. (F.D.C. No. 57871; S. No. 43-357 F; N.J. No. 38)

Vaginette hydroquinone and boric acid combination tablets, at New York, S. Dist. N.Y.

Charged 2-2-72: when shipped by Aloe Products, Inc., Houston, Tex., the article contained "Aceto-para-amino-phenol . . . caffeine . . . Ascorbic Acid (Vitamin C) . . . Calcium Glutamate . . . Analgesic . . . Capsules Fellows Testagar Div. of Fellows Med. Mfg. Co. Inc. Oak Park, Mich.," using acetaminophen and ascorbic acid shipped in interstate commerce, the article fell below the standard of quality for the article's intended purpose for temporary relief of headache, since it was a new drug without an effective approved New Drug Application; 201(a), 502(a), 505(a). Consent decree authorized release to Hub City Drug Application in effect with respect to the article's intended purpose for temporary relief of headache, since it was a new drug without an effective approved New Drug Application; 201(a), 502(a), 505(a). Consent decree ordered destruction. (F.D.C. No. 57794; S. No. 7-3-205 E; N.J. No. 27)


Charged 11-10-71: when shipped by Aron Streit, Inc., New York, N.Y., the article contained "No Spices, No Shortening Added' were false and misleading in representing and suggesting that the article was a substitute for a substitute for articles restricted by such statements; 15 U.S.C. 152(a). Default decree authorized donation to a publiccharitable institution. (F.D.C. No. 57578; S. No. 6-839 E; N.J. No. 29)

ANIMAL FEED

Aloe vera juice, Alvera, and aloe vera gel, Alvera, at Compton, C. Dist. Calif.

Charged 2-18-71: when shipped by Aloe Products, Inc., Houston, Tex., the article contained "No Sulfur, No Sugar, No Spices, No Shortening Added' were false and misleading in representing and suggesting that the article was of significant value in weight control diets as a whole carbohydrates; 403(a). Default decree authorized donation to a publiccharitable institution. (F.D.C. No. 56993; S. No. 66-724/72 E; N.J. No. 29)


Charged 1-27-72: while held for sale, the article contained the new drug diethylstilbestrol, and was a new Animal Drug Application in effect with respect to the use and intended use of the drug. 402(a)(2)(D). Consent decree authorized release to Hub City Feed & Seed Co., Aberdeen, S. Dak., for reconditioning. Thereafter, pursuant to stipulation, the article was destroyed. (F.D.C. No. 57772; S. No. 92-925 E; N.J. No. 30)
Diapulse electromagnetic energy generators, 3 seizure actions at Natchez, S. Dist. Miss.

Dipyrone injections for cattle, at Muleshoe, N. Dist. Tex.

Concern detergent liquid, 5 seizure actions at Melrose Park and Chicago, N. Dist. Ill.

Hairbrushes, at Bladensburg, Dist. Md.

Jumping Frogs fireworks, at Fort Worth, N. Dist. Tex.

**NOTICES OF JUDGMENT on Criminal Actions**

**FOOD**


Charged 2-5-72: flour was held in a building accessible to rodents and was contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea; fine and probation. (F.D.C. No. 57726; S. No. 2-116-1 E; N.J. No. 55)

Continental Nut Co., Gerald W. Stiefvater, president, and Frank M. Pangburn, plant manager, Fort Wayne, Ind.

Charged 2-14-72: when shipped, cut walnut pieces contained insect filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty pleas by corporation and individuals. (F.D.C. No. 57725; S. No. 6-570 E; N.J. No. 54)


Charged 6-21-72: peanut butter, labeled in part “HONEY Chunky Style PEANUT BUTTER” was prepared from peanuts which were contaminated with rodent urine and were packed in a bag bearing a label advertising the peanut butter containing rodent filth and being prepared under insanitary conditions—402(a)(3), 402(a)(4). Guilty plea by corporation and individuals. (F.D.C. No. 57724; S. No. 3-47 F; N.J. No. 53)


Charged 10-30-71: self-rising flour, corn flakes, wheat flakes, and all-purpose flour were held in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea; fine plus costs, and probation. (F.D.C. No. 57323; S. No. 1-904 E; N.J. No. 56)

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

Charged 3-3-72: popcorn was held in a building accessible to insects and was contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty pleas; fines. (F.D.C. No. 57730; S. No. 27-742 E; N.J. No. 57)


Charged 5-15-72: when shipped, cookies contained rodent and/or insect filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea; fine plus costs, and probation. (F.D.C. No. 57831; S. No. 52-959 F et al; N.J. No. 58)

**HAZARDOUS SUBSTANCES**

Cherry bombs and Super Cherry N-Bombs firecrackers, at Jackson, E. Dist. Miss.

Charged 1-7-71: while held by Kindred Supply Co., Jackson, Mo., the articles were banned hazardous substances intended to produce audible effects by a charge of more than 2 grains of pyrotechnic composition—19(l)(B). Default decree ordered destruction. (H.S.L. No. 1150; S. No. 7-839 E; N.J. No. 46)

Concern hazardous liquid, 5 seizure actions at Melrose Park and Chicago, N. Dist. Ill.

Charged 9-29-72 and 10-21-71: when shipped, it was a flammable substance which contained over 80 percent methanol and over 15 percent acetone and which presented a special hazard, and its label lacked a number of required conspicuous label statements—2(2)(1), 15, 402(a)(3), 402(a)(4). Guilty pleas by corporation and individuals. (F.D.C. No. 57725; S. No. 31-301 D et al; N.J. No. 53)


Charged 5-15-72: when shipped, it was a flammable substance which contained over 80 percent methanol and over 15 percent acetone and which presented a special hazard, and its label lacked a number of required conspicuous label statements—2(2)(1), 15, 402(a)(3), 402(a)(4). Guilty plea; fine plus costs, and probation. (F.D.C. No. 57323; S. No. 1-904 E; N.J. No. 56)

Charles Murry, Denham Springs, E. Dist. La.

Charged 2-18-72: cherry bombs, silver salutes, and block bust' firecrackers were intended to produce audible effects by a charge of more than 2 grains of pyrotechnic composition—2(2)(l)(B). Default decree ordered destruction. (H.S.L. No. 1145; S. No. 8-809 E; N.J. No. 48)


Charged 2-17-71: while held by Cope Plastics Industries, Inc., Godfrey, Ill., who had packed the article into 2-oz. bottles from the bulk article shipped in interstate commerce, the article was a flammable substance which contained over 80 percent methanol and over 15 percent acetone and which presented a special hazard, and its label lacked a number of required conspicuous label statements—2(2)(1), 15, 402(a)(3), 402(a)(4). Guilty plea; fine plus costs, and probation. (H.S.L. No. 1141; S. No. 25-116 E; N.J. No. 48)

Jumping Frogs fireworks, at Fort Worth, N. Dist. Tex.

Charged 8-21-71: while held by Atlas Enterprises, Inc., Fort Worth, Tex., the articles were banned hazardous substances intended to produce a visible effect by a charge of more than 2 grains of pyrotechnic composition—2(2)(l)(B). Default decree ordered destruction. (H.S.L. No. 1146; S. No. 9-562 E; N.J. No. 50)
It takes more than safety packaging.

In 1970, Congress enacted the Poison Prevention Packaging Act to require safety packaging for household products that could be injurious to children. The Food and Drug Administration's Bureau of Product Safety is enforcing this law.

But safety packaging will work only if you, the consumer, let it.

Don't forget to store potentially hazardous substances out of children's reach. A locked cabinet or high shelf is appropriate.

Keep close watch on young children.

And when safety packaging is available, get it and use it. Preventing accidental poisonings is your responsibility as well as ours.
SUBSCRIPTION ORDER FORM

ENTER MY SUBSCRIPTION TO FDA CONSUMER @ $6.50. Add $1.75 for foreign mailing. No additional postage is required for mailing within the United States, its possessions, Canada, Mexico, and all Central and South American countries except Argentina, Brazil, British Honduras, French Guiana, Guyana, and Surinam. For shipment to all other foreign countries include additional postage as quoted.

Send Subscription to:

NAME - FIRST. LAST

COMPANY NAME OR ADDITIONAL ADDRESS LINE

STREET ADDRESS

CITY

STATE

ZIP CODE

□ Remittance Enclosed (Make checks payable to Superintendent of Documents)

□ Charge to my Deposit Account

No

MAIL ORDER FORM TO: