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Under the Federal Hazardous Substances Act

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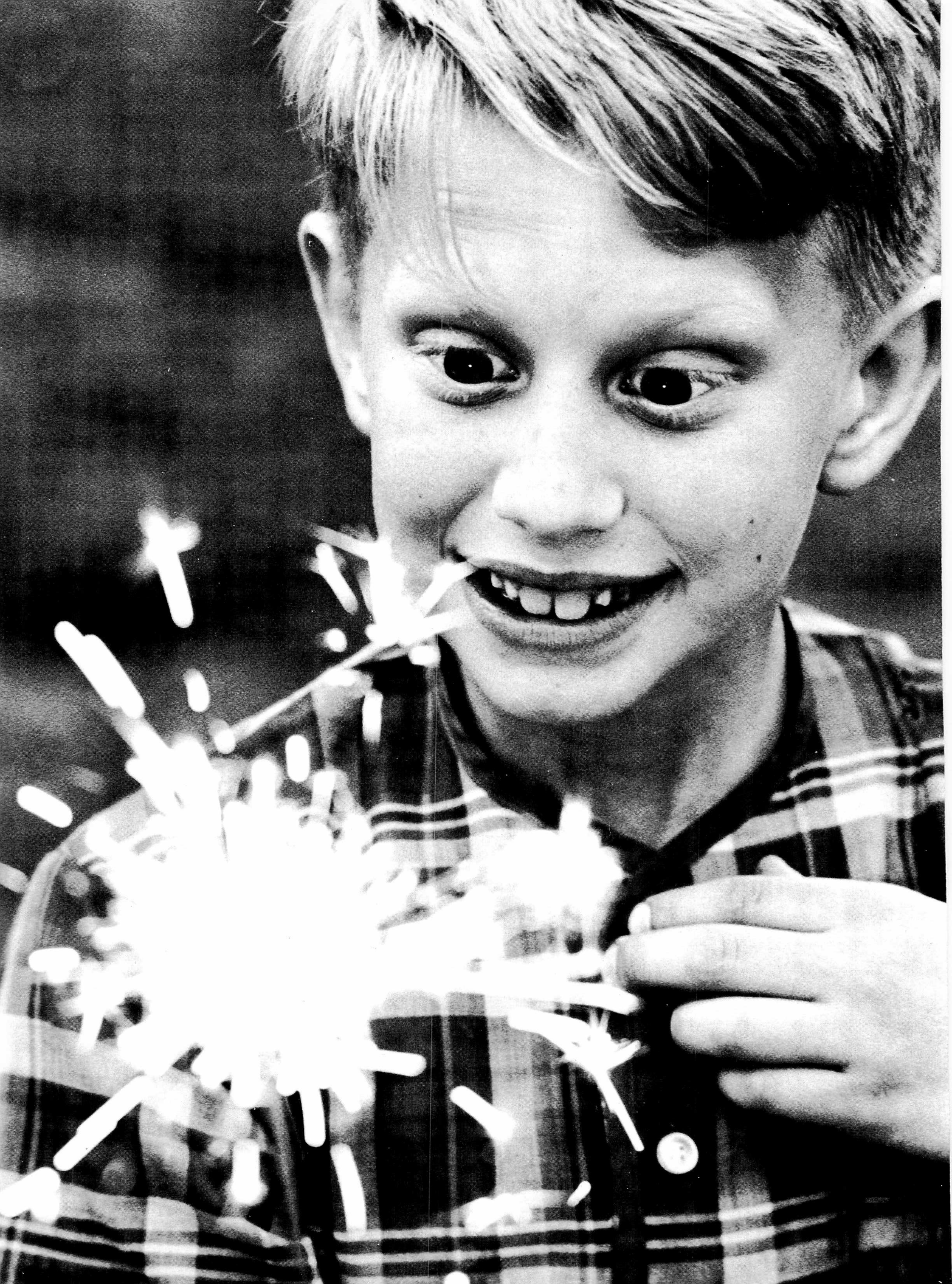
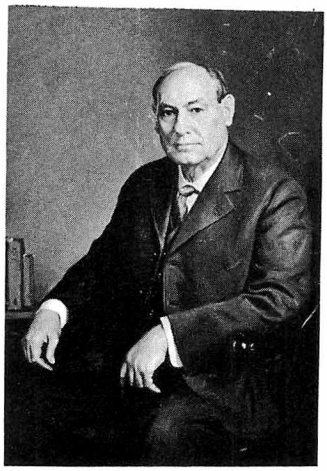
A new approach to drug control





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

Harvey W. Wiley
From his commencement address
"Life and the Coming Time"
Hanover College, 1867

O say, can you see . . One Nation, indivisible . . Three cheers for the red, white, and blue . . . . Yankee-Doodle went to town . . . You're a grand old flag . . . . FIREWORKS FOR SALE.

The 4th of July is coming. There will be parades, picnics, and fireworks. It should be a fun day—a day with a special meaning for all citizens of the United States of America. For years local and State governments have been trying to make it so.

This year the Federal Government officially joins the effort to protect children from injuries caused by dangerous fireworks. The Child Protection Act, passed by the 89th Congress, bans the sale of dangerous fireworks across the country (see page 17).

The law and regulations permit interstate sale of sparklers, fountains, and other relatively safe fireworks. Public displays . . . . . *Bombs bursting in air* . . . . . will continue. But local and State officials need be frustrated no longer; neighboring merchants and mail-order houses can no longer legally sell dangerous fireworks.

State and local officials, community leaders, and others interested in a happy, safe July 4th should know about the new law; and they should contact their nearest FDA District Office if they need help.

John W. Gardner
Secretary, U.S. Department of Health, Education, and Welfare

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FDA PAPERS
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Section 705 [375] of the Food, Drug, and Cosmetic Act.

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

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

National Drug Testing Center

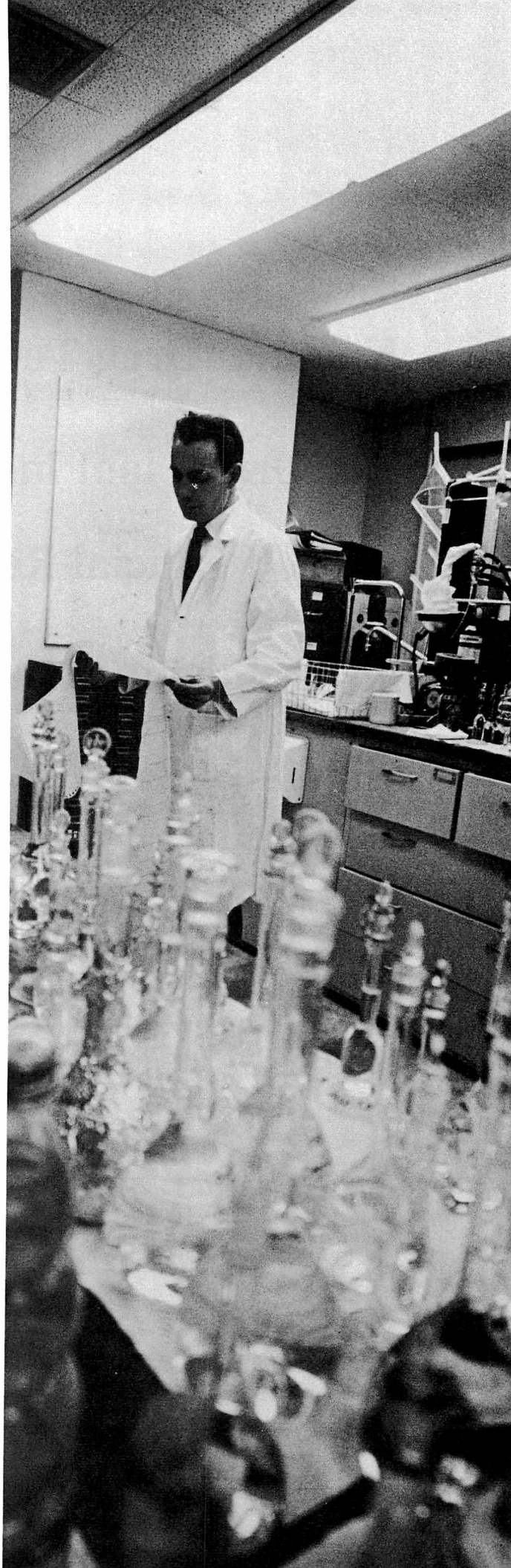
a new approach to drug control

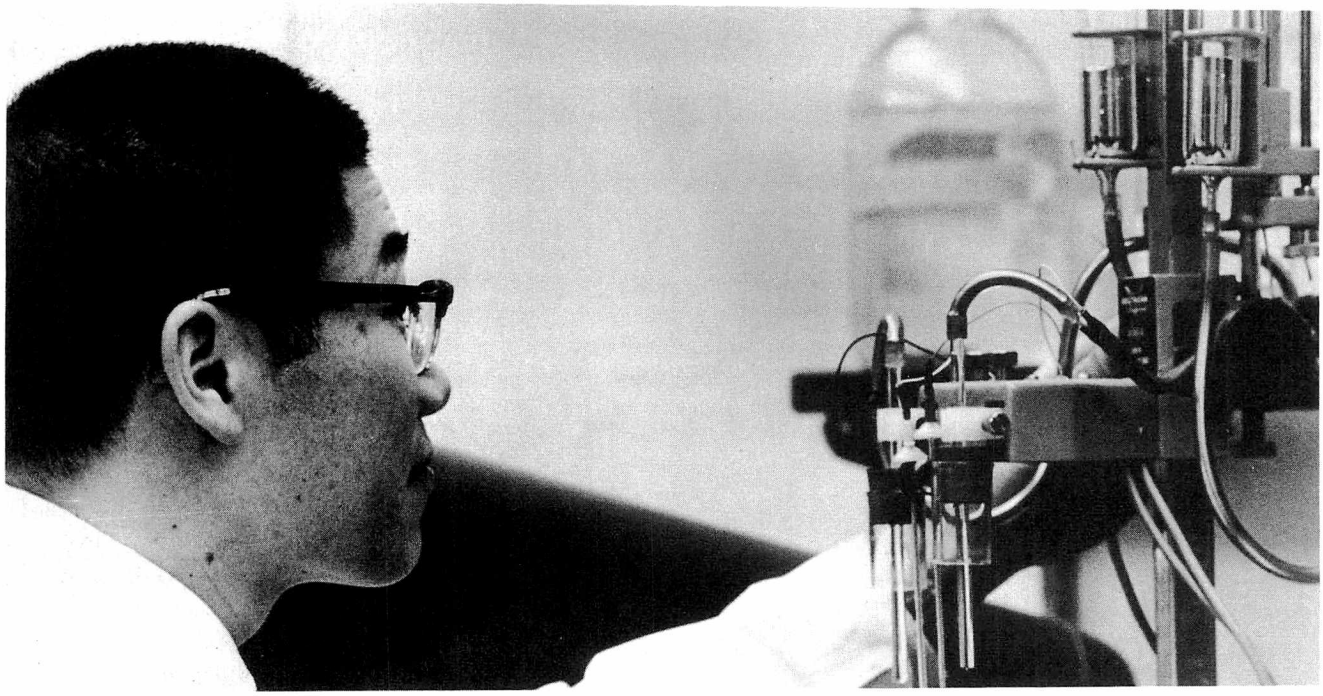
by Winton B. Rankin

The increasing incidence of recalls and other indicators have demonstrated the need for a new approach to control of drugs in the United States. The most important groups of drugs must be sampled and tested according to a plan that gives FDA a statistically reliable indication of the character of the drug supply of the Nation.

The need for revised control was shown dramatically in a survey of 20 therapeutically important groups of drugs conducted by FDA in the spring of 1966. More than 8 percent of the 4,700 lots covered in the survey were found to deviate significantly from their required potency. However, the nature of the survey does not make it possible to predict from these data the condition of the total drug supply.

Present calculations show that from 150,000 to 300,000 lots of drugs should be sampled and examined per year to keep abreast of the situation. Further, to determine that individual dosage units





Mass production and automated techniques may permit vastly increased drug sampling by FDA. Glassware with samples for the gas chromatograph covers the table (left).

Analyst (above) prepares polarograph for identification of drug sample. The machine analyzes a compound based on its ability to be oxidized or reduced at a dropping mercury electrode.

of important drugs meet the required standards—as well as composite samples representing several units—it may be necessary to conduct as many as a million individual analyses per year. When this figure is compared with the 37,000 drug assays conducted in FDA's field laboratories in the year ending June 30, 1966, it is apparent that new methods of analytical control must be developed.

Most of the drug analyses in FDA's 18 field laboratories are performed on a unit production basis. One sample is tested at a time. Even where a few samples of the same drug are handled simultaneously, as is now possible with some products, a tremendous amount of laboratory time is devoted just to assembly and dismantling of equipment as the analyst moves from one type of examination to another. It would be unwise to deal with the anticipated increase in drug samples by increasing the number of analysts, the amount of equipment, and the square feet of laboratory space devoted to unit production methods if better methods of handling the workload can be devised.

Two improvements deserve early exploration:

(1) Increased use of assembly line or mass production techniques.

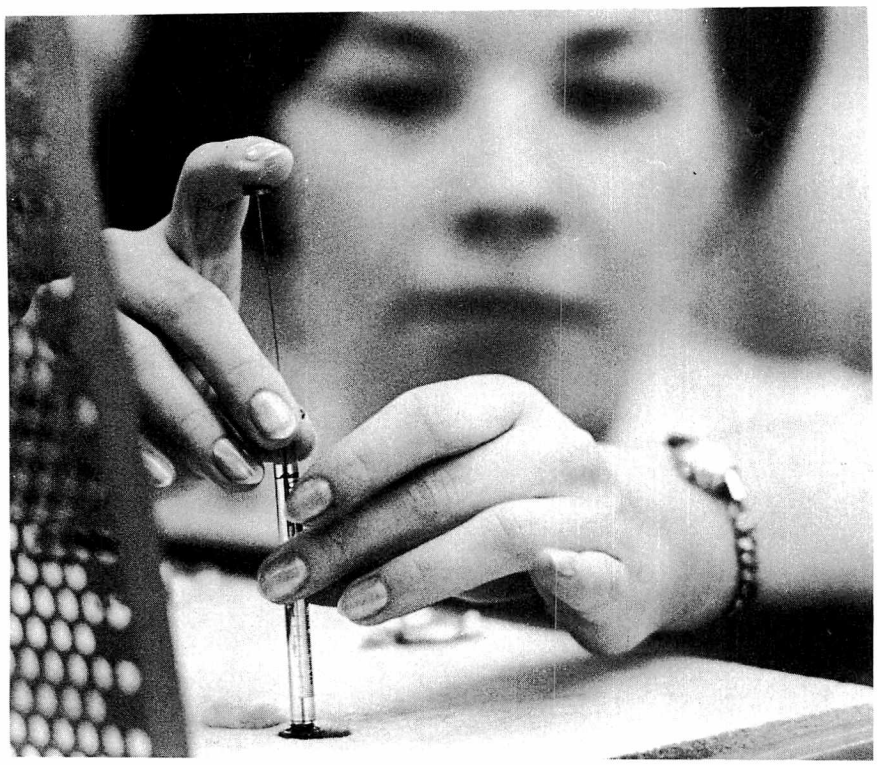
(2) Development and use of automated or semiautomated analytical procedures.

Both of these have been used to some extent in FDA laboratories. Mass production techniques have been employed with samples for pesticide, radioactivity, and certain vitamin examinations in the field laboratories. Semiautomatic analyses are currently performed in making certain tests on antibiotics, tests for sugar in blood samples (during potency tests on insulin), and in some color additive analyses. There is good reason to believe that the time required for a majority of the present routine control tests can be reduced materially.

FDA is making a pilot study in its St. Louis laboratory, to determine whether the need to expand its drug testing capability severalfold can best be met by establishing a National Drug Testing Center to handle most routine drug samples. Samples of anticoagulants and tranquilizers from the entire United States will be shipped to St. Louis for examination.

This pilot operation started on February 20, 1967, under the supervision of Dr. Daniel Banes, Project Officer, formerly Deputy Director of the Bureau of Science.

The laboratory is being rearranged to permit better use of existing equipment such as ultraviolet and infrared spectrophotometers and gas-liquid chromatographs. Additional advanced equipment (such as a spectrophotofluorometer, semiautomatic micro balances, and modules assembled in trains to permit automated analyses of such drugs as corticosteroids and barbiturates) will be tried as it can be obtained.



Analyst injects small amount of drug sample into gas chromatograph for confirmation of drug ingredients.

Extra technical and clerical help will be supplied to assist the professional analysts.

The Agency is seeking advice and assistance from others who have studied the automation of analytical work. In particular, through the Contact Section of the Pharmaceutical Manufacturers Association, it is seeking suggestions from those drug manufacturers who are using automated or semiautomated techniques in the production or control of finished drugs.

If the pilot study shows the expected improvements, additional groups of drugs will be directed to the St. Louis laboratory. Ultimately, the experiment could lead to the establishment of a National Drug Testing Center where large numbers of drugs can be examined at a fraction of today's cost, and where advanced research can be performed to improve procedures and equipment for drug analyses.

If the Center is established, the FDA field laboratories will retain their capability of examining drug samples. This is necessary to permit on-the-spot tests in emergency situations. Further, such laboratories probably will continue to make examinations that do not yet lend themselves to mass production techniques. These laboratories will also continue to handle products that are sampled in such small volume that use of the newer procedures offers no significant economies.

There were several reasons for selecting St. Louis as the site for the trial:

1. The city is centrally located and has good transportation facilities for delivery of shipments from various parts of the country.

2. The educational facilities in the area are excellent. FDA hopes to establish closer liaison with them to secure expert assistance in developing its program. The existence of these facilities will also make it easy for FDA employees to continue their training while on the job.

3. A high percentage of the professional personnel in the FDA laboratory there already have considerable training and expertise in drug work.

4. Certain administrative and district boundary changes which were desirable for other reasons at St. Louis make it possible to conduct the test there with minimum disruption of ongoing food and drug activities. (Food samples previously analyzed in St. Louis will be directed to other Districts.)

5. FDA is scheduled to get a new building to house the facility there. If a National Drug Testing Center is to be established, the building can be constructed to meet any special needs of the Center.

The St. Louis trial could have an impact beyond the drug area. It may be desirable to establish national testing centers for performing other types of control analyses which involve large numbers of samples.

This trial represents another step in FDA's continuing search for better methods of evaluating and stimulating improvement of the Nation's drug supply.

Deputy Commissioner Winton B. Rankin joined FDA in 1939.

drug plant inspections

what the FDA inspector looks for

by Philip Brodsky

One of the highly challenging and more responsible tasks performed by the Food and Drug Inspector is the drug establishment inspection. It aims at detecting actual or potential weaknesses in operations to assure that products comply with the laws so as to prevent misbranded or adulterated drugs from reaching the consumer.

Where possible, for the purpose of saving time at the plant, the inspector familiarizes himself with the firm's operations by carefully reviewing district files before the inspection.

Each inspector is furnished with credentials which bear his photograph and the seal of the Department. The inspection begins after the inspector identifies himself by showing these credentials and presenting a written notice of inspection to the owner, operator, or agent in charge.

Since the firms we inspect differ widely, no rigid guidelines are followed. The methods vary with conditions met, observations made, and attitude of responsible personnel. Whether the establishment does or does not handle prescription items does not materially affect the inspectional procedure since "Current Good Manufacturing Practice" applies equally to both prescription and nonprescription establishments in determining whether the processes, facilities, and controls conform to the regulations.

A preliminary inspection is often made to orient the inspector with

the plant layout. It may be brief or entirely eliminated depending on the inspector's familiarity with the firm's operations. He observes general production, analytical, and supervisory practices, and also notes signs indicating responsibility of key plant personnel. Apparent weak spots are noted for closer attention later.

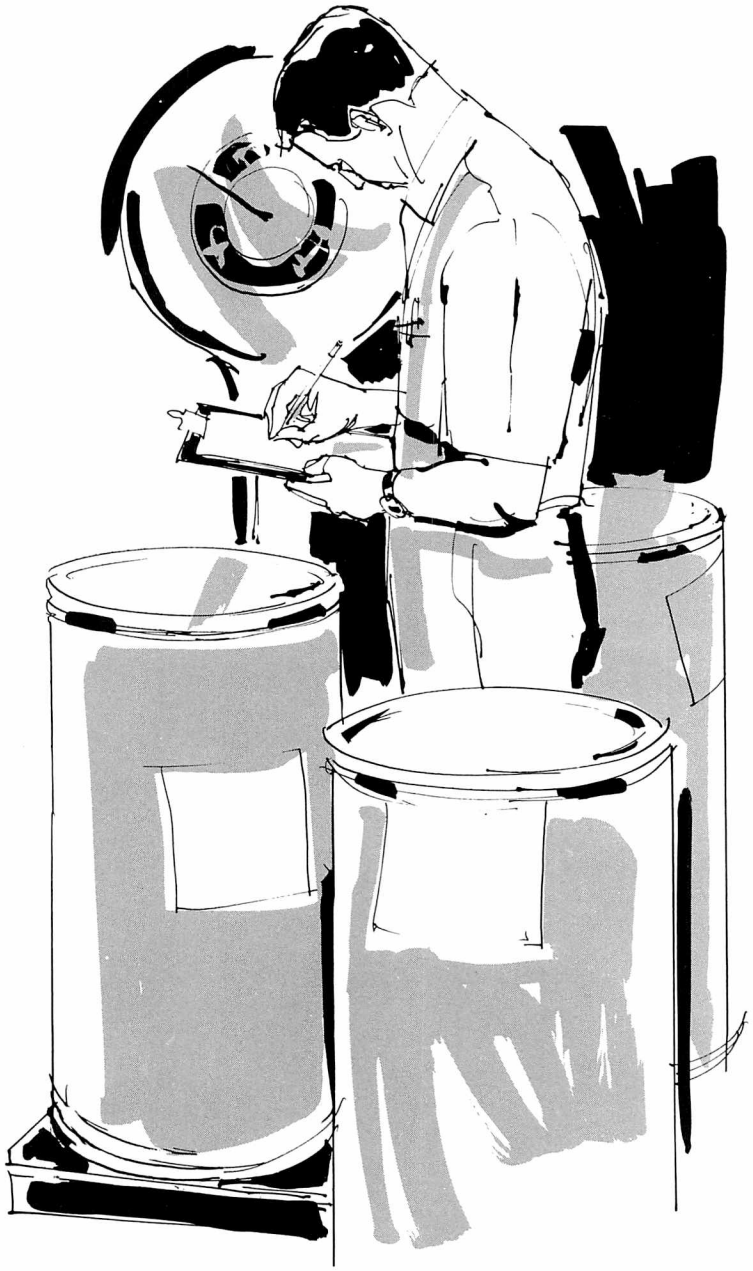
The comprehensive inspection may start at any of several areas in the plant in keeping with a plan developed from the preliminary inspection. Often, however, production is followed in a logical sequence, from receipt of components into the plant until the product is in a form ready for distribution.

Specific products are selected for critical review. They will include drugs in various stages of processing and representative dosage forms and classes of the firm's line. Those selected are:

- Items known to be difficult to manufacture or assay.
- Formulations which are new or changed.
- Items about which complaints have been received.
- Products whose stability, disintegration time, potency, or sterility are questionable.
- Products requiring special packaging or labeling.
- IND's, New Drugs, or Antibiotics which we check against commitments made by the firm.

For example, we may choose time-release capsules, liquid multivitamin preparations, enteric-coated tablets, ophthalmic solutions for sterility and labeling, ophthalmic ointments for particles, or glandular preparations for bacteriological examination.

We give special attention to areas and practices where our experience has shown errors occur frequently. Some of these are:



Buildings, equipment, and personnel We observe the condition, layout of departments and buildings, and their suitability for the operations being performed to determine whether drug production is adversely affected. Equipment in all departments, including laboratory instruments and animals, is noted. We report on their operating and sanitary condition and adequacy to do the jobs intended. We observe construction and location of equipment for ease of inspection and cleaning, and for potential contamination or cross-contamination. Attention is given to:

- Ointment mills.
- Capacity of blenders and mixing tanks.
- Tablet compressors.
- Encapsulation equipment.
- Coating and polishing pans.
- Sterilization and sterility testing facilities.

In the laboratories, we make note of specialized instruments, animals, and apparatus.

We obtain information about the education, technical training, and experience of key production and control personnel.

Receiving, quarantine, and raw material storage Components requiring special storage or handling are of-

ten improperly controlled. Receiving personnel sometimes lack any formalized instructions and/or training to determine which components require special storage or handling to prevent deterioration, mixups, contamination, or cross-contamination. Identities and amounts of incoming components are often improperly checked or tested for cross-contamination. Cross-contaminated components go undetected and inventories become inaccurate and lose significance.

Identifying labels may be improperly affixed to containers and may lack essential information. Identification should include a serial number which, by reference to the receiving record, will identify the product, the supplier, his control number, and date of receipt. The serial number should follow the product through all its usages and this identification should be affixed to the container to insure its identity—never on a removable lid.

Quarantined, released, or rejected materials should be so specifically identified. Their status should not be determined by the locations in which they are stored. Sampling should be supervised and enforced by the control department according to established procedures. Access to storage areas should be limited to designated personnel only. Adding new stock to old or using common scoops for several ingredients is a dangerous practice.

Master formulas and batch records

We compare master formula records against corresponding batch records and finished product labeling. These records are checked for errors in transcription, clarity of reproduction, accuracy of calculations, and completeness of information as stated in the regulations. Special attention is given to whether separate masters are made for different batch sizes and whether calculations are made and checked by qualified individuals.

We compare actual against theoretical yields and explore unexplained discrepancies. We determine whether instructions for sampling are indicated, where, when, and how samples are obtained; what analyses or tests are run, and the methods used. We compare results against specifications listed in official compendia and by the firm. We seek explanations where products are released when results fall outside of specifications. We are interested in whether specifications are realistic.

We determine the batch sizes produced and check whether equipment is available to produce the size batches noted. We check whether firms have the laboratory animals and equipment needed to perform the tests and analyses indicated. We look for deviations from commitments when checking IND's, NDA's, and certified antibiotics.

We abstract identity numbers of active and inert components from

batch records and check them against receiving and laboratory records to insure proper components have been used. The receiving dates of components are determined, whether and when they were last assayed, and when they were used in compounding. The interval between their use in compounding and the last analysis may suggest a loss in drug content and indicate sampling of raw materials and finished products for further testing by our laboratories.

The master finishing records or packaging and labeling specifications are an essential part of the control records. This document may be part of the master formula record, or it may be a separate record. In any case, it should contain appropriate specifications for all labeling and packaging components. These include any special references to the containers, closures, seals, stoppers, cotton plugs, silica gel bags, labels, inserts, cartons, and the like. These specifications are usually developed, prepared, and approved, after usage tests in appropriate instances, by the joint efforts of the research, production, and control personnel.

Any changes in the established master documents will require complete review and special formal approval. These are also compared against the corresponding batch finishing records. The bulk yields released to finishing are checked against the bulk yields on the production records and also against the finished labeled yields on the finishing records. Any unexplained significant discrepancies are followed up. Finishing records are also examined for quantities of labels, inserts, and other packaging components issued for a run and compared to theoretical label yields. Investigation as to the disposition of excess, damaged, or rejected packaging components is made, if accounting is not satisfactory.

Manufacturing procedures and controls

We note methods employed and accuracy maintained during weighing, measuring, and mixing components into batches. We observe whether and when records of each operation are checked and how the identity of each ingredient in the batch is recorded. We check the accuracy of these records against the master formulas; we determine if adequate identification and segregation of batches is accomplished during various process steps. We compare average tablet weights against bulk tablet counts for significant deviations in yields.

We look for potential sources of contamination and cross-contamination. The coating and polishing operations can be a source of cross-contamination, especially in instances where active ingredients are a part of the coating. We are concerned with overcrowded manufacturing areas, especially where we find inadequate separation and identification of potent drugs (steroids, alkaloids, etc.) in various stages of processing. We pay particular attention to these conditions at repacking establishments.

These conditions are noted in storage areas, granulating and mixing departments, liquid-filling areas, drying ovens, tablet-compression areas, and tablet-coating rooms. We become especially concerned when we find inadequate dust control or cleaning of utensils and equipment where tableting and encapsulating machines are close together. These conditions become serious where we find nonpenicillin products being manufactured or processed on the same premises, or the same equipment as that used for penicillin products.

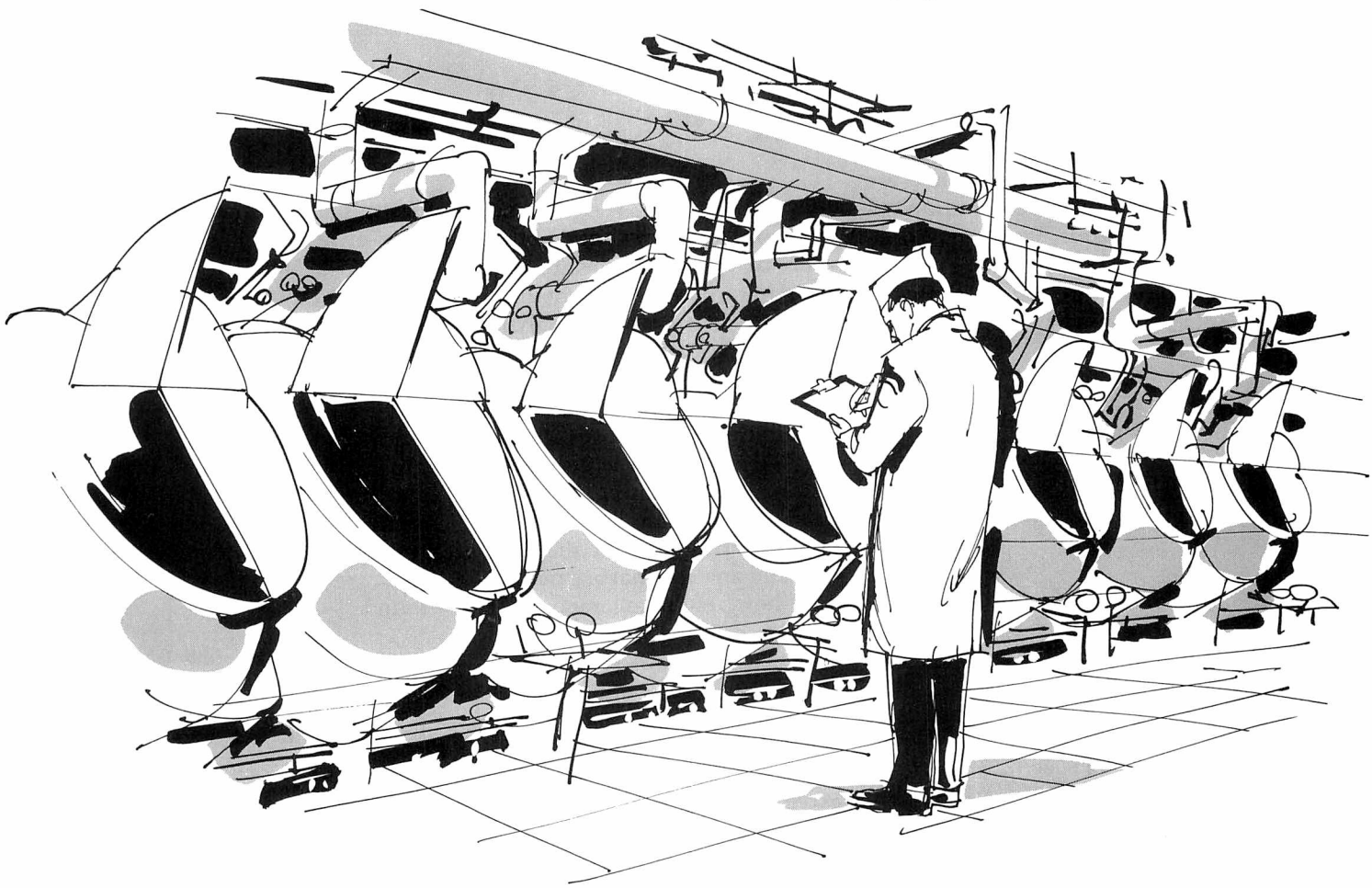
Sterile products We determine how product containers and closures are cleaned, sterilized, depyrogenized, and stored. We check deionizers, since they neither insure destruction nor guarantee removal of pyrogens or bacteria, and, if not reactivated frequently, may actually serve as a source for bacterial multiplication and pyrogen formation.

Proprietary remedies required to be sterile, such as ophthalmic solutions, are given special attention. Articles which purport to be sterile, such as adhesive bandage, purified cotton, adhesive tape, and the like, whether official or nonofficial products, are checked to determine if they are packaged in a manner that will assure their sterility.

Bulk glandular powders or solutions used as ingredients in the manufacture of drugs is another area which is checked closely. Recalls of many glandular substances have resulted, and may still be in progress, involving glandular substances and finished products containing them, because of *Salmonella* contamination.

We report if safeguards against mixups are employed when different solutions are being prepared at the same time. We describe the types of filters used for various purposes and the methods of testing, cleaning, sterilizing, and holding them until use. We list bacteriostats and the quantities used in various preparations. Close attention is given to sterile areas. We determine whether sterile air under positive pressure is provided, the provisions for cleaning, elimination of dust catchers, and of airborne contamination.

Special attention is given sterilization methods. We suggest that all sterility methods used by a firm be validated for each product before relying on the effectiveness of the



process. We have observed instances of sterility tests being performed on products containing bacteriostats where the bacteriostats were not diluted out sufficiently to support growth. These methods of operation obviously defeat their intended purposes.

Properly functioning autoclaves are an essential control in sterility. The autoclave should be provided with time-temperature recording thermometers installed in the exhaust line. We check autoclaves to make sure that drain lines are connected to the sewer in a manner to prevent back-siphoning. We recommend that firms keep time-temperature recordings and records to identify each separate sterilization load.

We note what controls are used to prevent mixups between sterile and nonsterile goods, containers, and equipment and how these are identified. We report the sampling procedures and sterility testing done on various products. We note precautions to prevent release of nonsterile or untested products.

Philip Brodsky is a Supervisory Inspector in the Cincinnati District. He joined FDA as an inspector in 1951 and has done mainly drug work, including recalls.

Laboratory controls We attempt through interviews and observations to determine the firm's attitude toward controls, whether the laboratory just makes analysis or actually has authority to exercise controls over production. We want to know what part it plays in the preparation and changes in formulas. We find out whether raw materials, intermediates, and finished products are sampled, when and how this is done, and the type of tests and analysis that are made. We note how results are reported and what records are kept.

We are interested in tolerances and specifications. These should be realistic. We often find specifications so limited that products are released even though the limits are exceeded. Others are so broad as to be meaningless. Responsibility and procedures for rejections or approvals are determined and disposition of rejected lots is followed up.

We find out whether reserve samples are retained from each batch, for how long, and how they are identified and stored. We also obtain information on stability studies. In plants where conditions are encountered which may cause contamination of other drugs by penicillin, we find out which nonpenicillin products are tested, what tests are run, and the test results found.

Printing, packaging, and labeling controls Errors occur most frequently during printing, packaging, and labeling operations.

We inspect the printing operations of the firms we visit. We suggest that contract printers be carefully inspected before contract-

ing their services.

We inquire into the checks made of label, insert, and carton copy before delivery to the printers and of printers' proofs before they are printed. We determine whether finished printed material in the firms' own print shops as well as those entering the plant from contract printers are inspected for accuracy of text, uniformity of identity marks if used, and mixups with other printed matter.

Where possible, we observe the care with which these inspections are made. We observe whether only labels of the same potency and quantity are printed on a single sheet. Gang printing is dangerous and should be avoided. Note is made during cutting operations whether adequate separation of partially cut sheets is maintained to avoid mixups. We also determine whether the print shop label counts are accurate. Numerous problems have resulted from reliance on printers' counts to label stock.

Finished labels and inserts should be carefully checked for count and identity, then sealed before being placed into label stock. We make detailed inquiries about the transfer of labels and labeling from label stock to label issue and from label issue to line supervisors. We note whether inventories of label stock are kept, if separate closed storage for each different label is provided, if stock labels are wrapped or sealed, and if after removal of labels from a package in stock whether both those removed and those remaining are resealed.

We determine who has access to label stock and label issue areas and observe whether plant policy is adhered to. We determine the mechanics of label issue, the checks made for accuracy of count and identity, and whether other than authorized personnel are able to requisition them. If labels are precoded before release to label issue, we observe how they are handled and accounted for. We have discovered label mixups where labels of similar size, format, and color scheme were being precoded on lines next to each other.

We report on the physical setup of labeling lines and tables, and how they are lighted, spaced, and identified.

We determine who supervises the finishing operations, and whether adequate checks are made to insure that correct products, label, inserts, and quantities have been furnished and have been released by control. We check finishing records for significant discrepancies between theoretical and actual yields, and check how the excess labeling, including that damaged in setting up machines or soaked off containers, is accounted for and disposed of.

The control codes on labels are checked against the batch and batch records for identity. The case or carton labels and codes are checked against the label and control code of the immediate container.

Checks are made to determine whether control and reserve samples have been taken after labeling has been completed, and whether representative samples of the finished labeled product have been adequately identified before release to warehousing or shipping.

Control codes We report the coding system employed by the firm, how it is interpreted, its relation to the batch number if they differ, and how each is used to determine the complete history of the original batch. We determine whether codes are listed on invoices or shipping records. We evaluate this information as it relates to efficiency in case of recall.

Warehousing and shipping The storage of unreleased labeled stocks in shipping areas while waiting release from control is often encountered. This practice results in the inadvertent distribution of unreleased goods. This applies also to returns. Warehousing facilities are examined for deteriorated, outdated, or otherwise unfit merchandise. The firm's policy concerning rotation of stocks and adherence to this policy is investigated.

Returned goods Inspection is made of returned goods to determine the products, quantities, and reasons for various returns. We determine what examinations are made of these products, who evaluates them, and the firm's policy in handling such merchandise. These stocks should be carefully controlled to prevent mixups with saleable stocks, errors in reworking or relabeling, and re-entrance into commercial channels through improper destruction or disposal.

Complaint files Complaint files are routinely requested to identify products that may be violative and require further investigation. We determine who evaluates complaints and what follow-up action is taken. Complete, specific, factual information on complaints is reported solely for evaluation by our Bureau of Medicine.

Distribution The firm's patterns and methods of distribution are checked as well as its distribution records. Invoices are copied to facilitate sampling of products. If distribution information is handled by electronic equipment, the mechanics of retrieving these data is explored to gain some insight into the effectiveness with which a recall can be instituted if necessary.

Special attention to distribution of IND products is made to assure that products are labeled properly and shipped only to qualified investigators as indicated in the regulations. New Drug products and certifiable antibiotic shipments are checked to insure that only those approved or certified have been shipped.

Discussion with management During the inspection and always at its conclusion, any objectionable conditions or practices noted are pointed out to responsible management. Suggestions and recommendations are also made at these times. During these discussions, or at the beginning of the inspection, the inspector inquires into the history of business, its legal status, annual value, and percent of interstate business. He asks whether raw materials are received from out-of-State sources, whether the firm is registered, and what other governmental agencies inspect the firm.

If, during the inspection, samples were collected and insanitary conditions were observed, a receipt for samples and a written notice of the observations made is given to responsible management.

The inspector generally does not review, evaluate, or comment on labels or labeling.

official reference standards for antibiotics

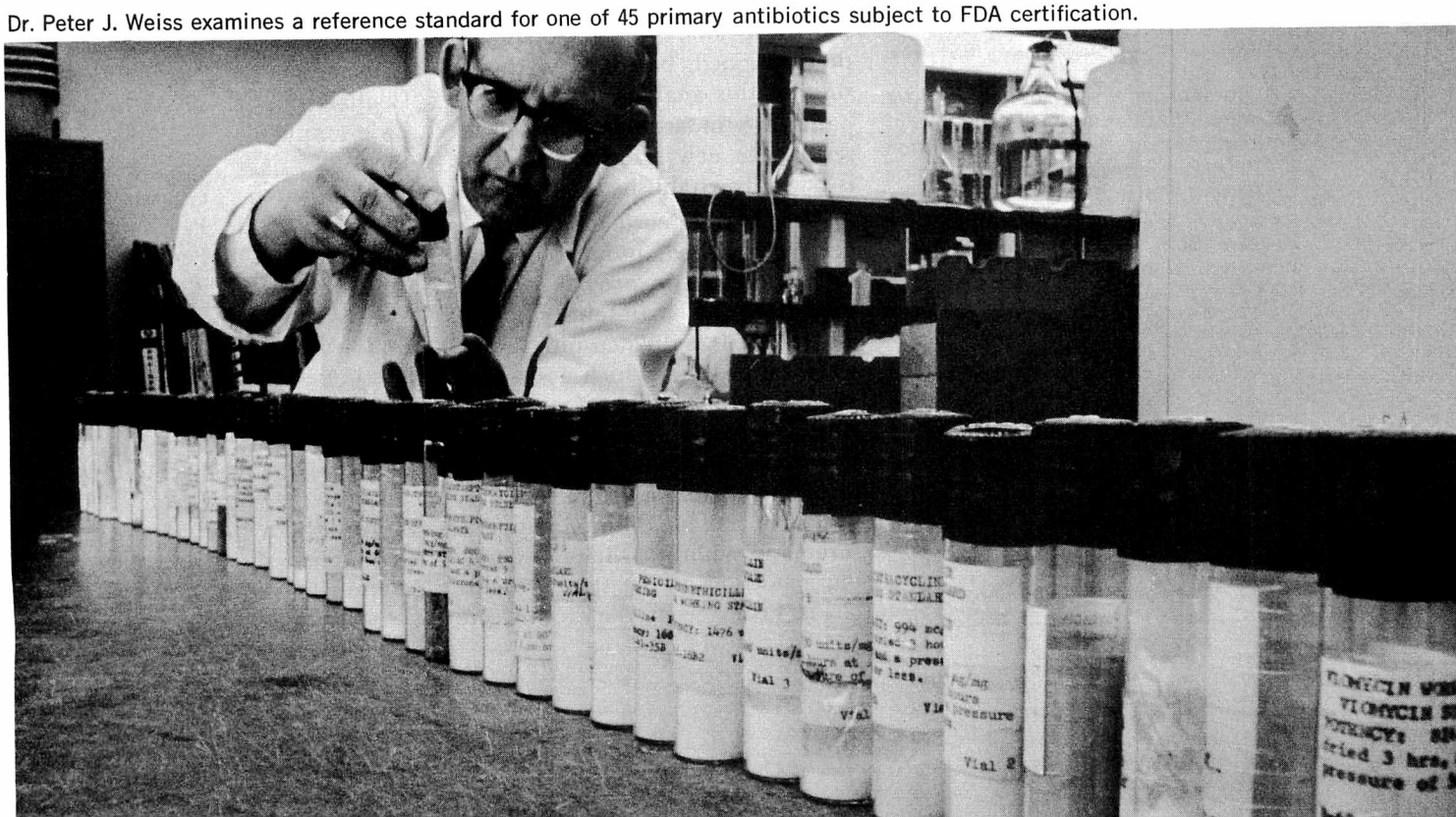
All antibiotics approved for human use and many for veterinary use must be certified by FDA before they can be sold in the United States. Representative samples of each batch produced must be submitted to FDA where they undergo laboratory analysis to determine if they meet the specifications of the *Antibiotic Regulations*. The most important single facet of this control is the antibiotic reference standard, since it is the "zero milestone" used to determine the potency of the commercial batch.

FDA maintains a reference standard for each of the 45 primary antibiotics subject to certification. Since many tons of commercial batches are produced yearly and the potency of each is related to the small quantity of reference standard maintained by FDA, the importance of the establishment and maintenance of these standards can be readily understood.

The potency of an antibiotic is not an absolute value which can be determined by chemical analysis, such as the sulfate or sodium content. The term is actually relative potency; i.e., relative to a reference standard, or, expressed another way, the commercial batch's killing effect on micro-organisms when compared to the reference standard. This is determined by microbiological assay. Therefore, the standard must be pure, homogeneous, and stable, and its assigned potency must be thoroughly established.

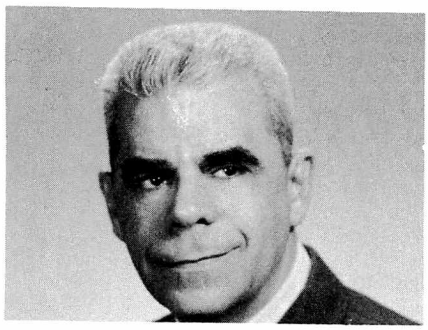
by A. Kirshbaum and P. J. Weiss

Dr. Peter J. Weiss examines a reference standard for one of 45 primary antibiotics subject to FDA certification.



When establishing a reference standard for a new antibiotic, FDA obtains a portion of a highly purified batch from each manufacturer intending to produce the antibiotic, together with all analytical data the manufacturers have available. Since, in the beginning, there is no reference standard to which the new antibiotic can be compared, a potency value must be assigned, based upon the theoretical maximum potency and the purity of the batch as determined by such tests as acid-base titration, chromatography, spectrophotometry, countercurrent extraction, phase solubility, melting point, elemental analysis, colorimetric reactions, and microbiological assay. After thorough analysis and study, a batch is selected as the reference standard, and a potency assigned to it.

When the potency is assigned, it must be clearly indicated whether it is on an anhydrous or "as is" basis. While we prefer to establish potencies on the anhydrous basis, hydrated salts or compounds that undergo physical changes on drying must have potencies assigned on an "as is" basis.



A. Kirshbaum, Assistant Director for Laboratory Evaluation in the Division of Antibiotics and Insulin Certification (DAIC), has been with FDA for 21 years; Dr. Peter J. Weiss, Chief of the Chemistry Branch, DAIC, has been with FDA for 20 years. Both have worked with antibiotics since joining FDA.

The greater part of the new standard is then set aside as the working standard and a smaller portion is reserved as the master standard. From then on, the continuity of the reference standard for that antibiotic is maintained in terms of this master standard. As time passes, the custodian notes when it appears that less than one year's supply is left. At this point, manufacturers are again asked to submit portions of a relatively pure, representative, homogeneous batch for consideration as a proposed standard. The data are reviewed, and one or more batches selected for further study. Since we now have a master standard with an assigned potency, it is necessary to establish the potency of the proposed standard in terms of the master standard. We therefore conduct a collaborative assay, sending portions of the master and proposed standards to each participant in the study with a protocol to be followed. When the participants have completed their assays and send results to us, they are subjected to statistical analysis. A potency is then assigned, based upon the results of this analysis. If all participants are in agreement with the result, the new reference standard is officially established.

After a reference standard has been established, it must be carefully protected to provide optimal conditions to maintain stability. Therefore, it is divided into several screw-capped jars which are sealed. We do not open the second jar until the first is depleted. The jars are stored in deep-freeze units to protect the antibiotic from light as well as to provide optimal temperatures and stability. Before removing a portion of the standard, the jar is taken from the deep-freeze and allowed to warm to room temperature prior to opening. Working and master standards are stored in different deep-freeze units as a safety measure, should there be a mechanical failure in one of the units.

FDA standards are periodically checked by assaying the working standard against the master standard or the International Standard (maintained by the World Health Organization) to make sure there is no loss of potency. If any loss occurs, steps are taken to establish a new standard.

FDA supplies antibiotic working standards to all laboratories using the certification services. The *United States Pharmacopeia* and the *National Formulary* supply standards for those primary antibiotics listed in these compendia. The standards have been established in terms of the official FDA standards and therefore serve as useful house standards.

The following are the antibiotics for which FDA maintains official reference standards:

Amphomycin
Amphotericin A
Amphotericin B
Ampicillin
Bacitracin
Candicidin
Carbomycin
Cephalothin
Chloramphenicol
Chlortetracycline
Cloxacillin
Colistimethate
Colistin
Cycloserine
Dactinomycin
Demethylchlortetracyclin
Dihydrostreptomycin
Erythromycin
Gentamicin
Gramicidin
Griseofulvin
Kanamycin
Lincomycin
Methacycline
Methicillin
Nafcillin
Neomycin
Novobiocin
Nystatin
Oleandomycin
Oxacillin
Oxytetracycline
Paromomycin
Penicillin G
Penicillin O
Penicillin V
D-Phenethicillin
L-Phenethicillin
Polymyxin B
Rolitetracycline
Streptomycin
Tetracycline
Triacetyloleandomycin
Vancomycin
Viomycin

child protection

under the Federal Hazardous Substances Act

by Dale C. Miller

The Child Protection Act of 1966 amended the Federal Hazardous Substances Labeling Act in several significant aspects. One of the most significant changes is reflected by the deletion of the word "labeling." The Hazardous Substances Act provides for consumer protection beyond that which can be realized through labeling.

The Federal Hazardous Substances Labeling Act was passed by Congress and signed by the President in 1960. That law was designed to help prevent accidental injuries by requiring cautionary labeling to alert householders to the potential dangers associated with articles commonly used and stored around the home. It also called for label information that would be useful in the event a curious child or an unwary adult was injured.

As FDA gained enforcement experience with this law, it became evident that several loopholes needed closing. This led to the President's recommending legislation to:

☐ bring all hazardous substances, regardless of their wrappings, under the safeguards of the Federal Hazardous Substances Labeling Act.

☐ ban from interstate commerce those household substances that are so hazardous that warning labels are not adequate safeguards.

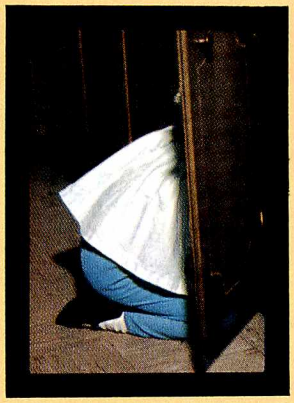
☐ ban the sale of toys and other children's articles containing hazardous substances, regardless of their packaging.

The 89th Congress did pass such a law, known as Child Protection Act of 1966. It was signed by President Johnson and became effective in November. FDA has published proposed regulations in the *Federal Register* to implement the amendment. Comments are being received and will be considered in formulating the final regulations.

The Federal Hazardous Substances Labeling Act was exactly what the name says—a labeling law. If a product's label carried the legally required warnings, it could be sold to anyone. There was no way of prohibiting it.

Early in 1962, a product known as "X-33" appeared on the market. It was sold as a waterproofing treatment for basement walls and other types of masonry. As then manufactured, it had a flash point (the lowest temperature at which the fumes or vapors from a substance will ignite) of 40° *below* zero, Fahrenheit. Before the FDA could remove the product from the market under existing legal procedures, at least three people had died and over 30 more were injured through flash explosions.

The first X-33 death involved a Minnesota housewife in May 1963.



Color, curiosity, and chemicals—that is a combination for household hazards to children. Colorful packages and other attractive objects of the adult world are irresistible to young children, a fact recognized by Congress in 1960 with passage of the Federal Hazardous Substances Labeling Act. The law requires a "KEEP OUT OF THE REACH OF CHILDREN" warning on the label of hazardous household products. Other label information is required for safe use.

She had painted her basement walls with X-33 and sat down to rest. The windows were open and no pilot lights were on, but an explosion and flash fire occurred nevertheless. Her husband on the floor above was severely burned and the roof of the attached garage was blown loose. The woman died two days later from burns over 95 percent of her body. An Iowa woman suffered fatal injuries from an explosion and flash fire in September 1963. The third fatality was a Georgia man who died of burns in June 1964.

As originally distributed, the product bore inadequate labeling. As a result of legal actions by the FDA, the firm revised the labeling to include the maximum warnings provided by the law. This included such statements as:

"DANGER—EXTREMELY FLAMMABLE,"
"VAPORS HIGHLY EXPLOSIVE,"
"HARMFUL OR FATAL IF SWALLOWED."

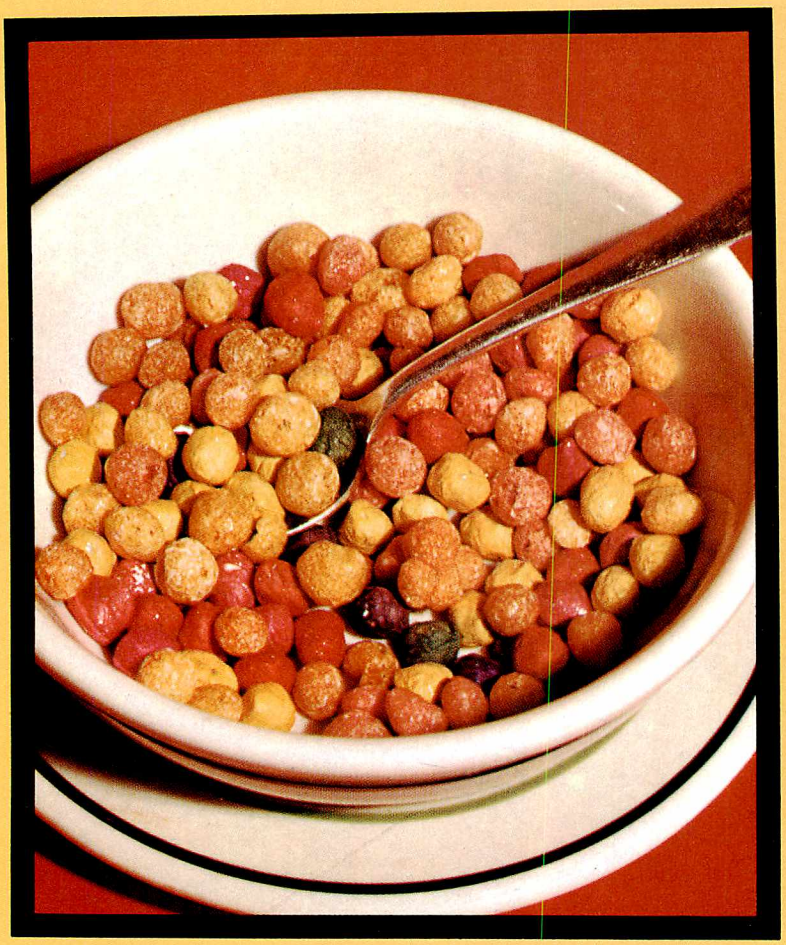
The label also included warnings to turn off all gas and electricity; not to use battery operated appliances; not to smoke.

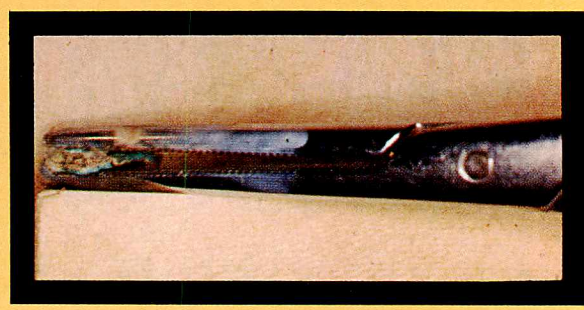
Even with such stringent labeling, accidents continued. Obviously such a product had no place on the market, yet FDA was able to remove it only by instituting a multiple-seizure campaign involving several hundred individual legal actions.

As revised, the law now gives the Secretary authority to ban such products from interstate commerce. He can do so for any hazardous substance intended or suitable for use in the household which by regulation he classifies a "banned hazardous substance." The ruling is based on a finding that regardless of labeling the hazard involved in the household is so great that the public health and safety can be adequately served only by keeping the substance out of the channels of interstate commerce.

Before an article can be placed in this category, the Secretary must publish his finding in the *Federal Register* where it is subject to comments and objections. Where the statutory requirements have been fulfilled, a public hearing may take place. The law also provides procedures for review by a U. S. Circuit Court of Appeals. If the delay caused by these procedures would involve an imminent hazard to the public health, the Secretary is authorized to suspend the article from the market immediately, pending completion of any hearings and judicial review.

Although X-33 is not currently being manufactured, an order proposing to place it and similar products in the "banned" category has been published with the proposed





regulations. If any such product ever again reaches the marketplace, FDA can take immediate corrective action.

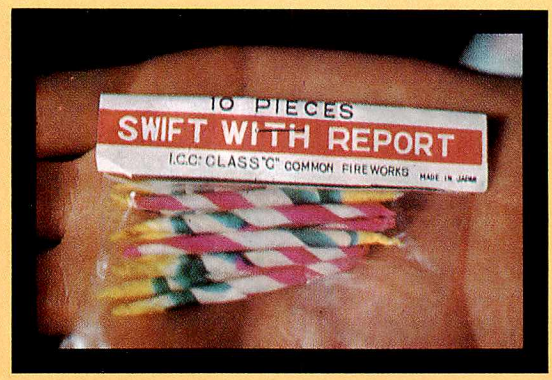
The new amendments are even more explicit with respect to toys and other children's articles. They ban outright "any toy or other article intended for use by children which is a hazardous substance or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted." The need for this was vividly illustrated 2 years ago.

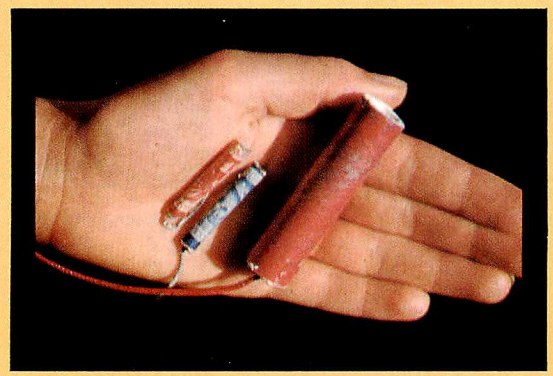
On May 28, 1965, the FDA warned parents and retail dealers across the country to be on the look-out for a dangerous type of imported fireworks known as "cracker balls" or "ball-type caps." These were small torpedo-like firecrackers that explode on impact. They looked like small colored candy balls and were almost indistinguishable from gumdrops and certain cereal products. They were frequently sold at candy counters. In addition to the explosion hazard, the balls contained an arsenic compound.

It was inevitable that children would mistake them for candy. FDA investigated over 30 cases where children suffered such injuries as loosened teeth, burns, and cuts of the gums, tongue, and cheeks. Once again an expensive multiple-seizure campaign was required to round up the estimated 60 million cracker balls on the market.

One importer-distributor elected to contest the seizure action on the grounds that the articles were not hazardous as charged, and that the injuries were innocuous. The judge in the case upheld the Government's position that the cracker balls were hazardous, but ruled against FDA's claim that adequate labeling could not be devised. As a result of the decision, the seized goods were released and distributed under revised cautionary labeling. Because of the amendments, FDA has been able to deny recent attempts to import additional lots of cracker balls.

Another early action by FDA under the new amendments was against certain dolls imported from Poland and England. The dolls ranged in height from 7 to 16 inches. The face was made of nitrocellulose, also known as "guncotton," and burned at the rate of approximately one inch in three seconds. The hair was also made of a cellulose type of material and burned at an even greater rate—over two inches in one second. Fortunately, there were no reports of injury. However, the FDA asked the firm to recall all outstanding stocks of the dolls, and denied entry of an additional 200,000. An-





Cracker balls (left), shown mixed with cereal, are banned under amended law. Sequence simulates mouth injuries. Flammable doll was also banned. Large firecrackers and other dangerous fireworks are banned, but "Class C" products under ICC regulations are legal for sale to the public.

other 100,000 dolls were seized.

The law does provide for children's articles which by reason of their functional purpose require the presence of the hazardous substance. These may be exempted from the "banned" category provided that they bear appropriate warnings and are intended for children old enough to read and heed the warnings.

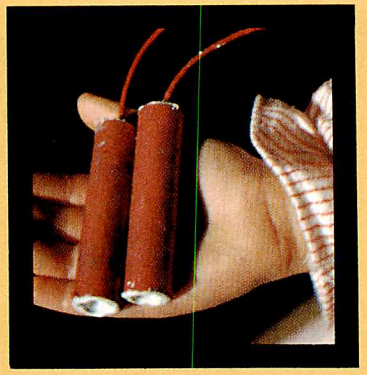
The proposed regulations, therefore, include exemptions for chemistry sets and for school supplies which may possess some degree of hazard, such as certain art materials, preserved biological specimens, and laboratory chemicals.

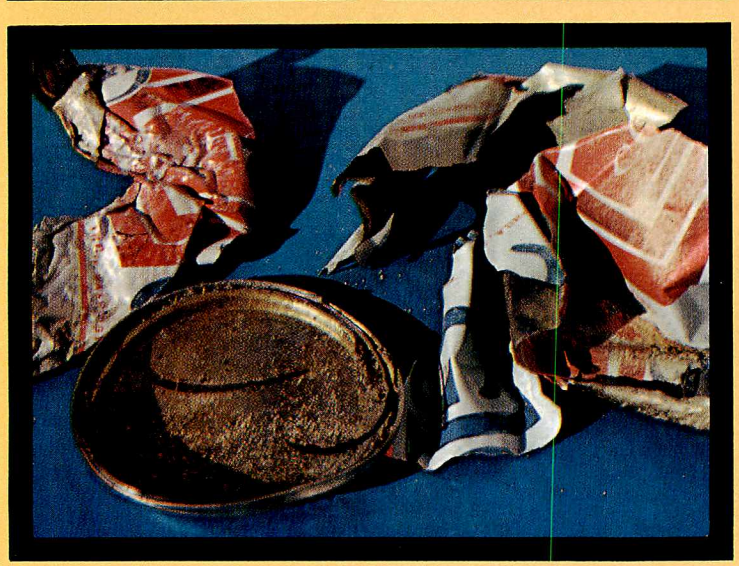
The final draft of the bill also deals specifically with fireworks. The law states that the Secretary shall exempt fireworks from the banned-toy classification "to the extent that he determines that they can be adequately labeled to protect the purchasers and users thereof." In considering this, FDA decided there was no reason for concluding that the ordinary "Class C Common Fireworks" were so hazardous that they should be banned. Based on this, the proposed regulations would exempt most of the fireworks that fall into the "Class C" category. This includes fountains, sparklers, torches, some skyrockets, and small firecrackers.

It does not include cherry bombs, salutes, and firecrackers more than one-and-one-half inches in length and one-quarter inch in diameter and containing more than 2 gr. of powder, nor does it include kits intended for producing explosive fireworks. Such kits, containing packets of chemicals, paper tubes, and pieces of fuse—all the materials necessary to produce explosive fireworks—are offered for sale by mail order. Although the kits do not contain actual explosive fireworks when shipped, they have no other possible use than to make them. Therefore these, and most other types of larger explosive fireworks, fall within the "banned hazardous substance" classification.

The proposed regulations do include an exemption which will permit the distribution of larger explosive fireworks for certain limited purposes. These are the fireworks used to protect crops from damage by birds and other wildlife. In use, the fuses of fireworks such as cherry bombs or M-80's are intertwined at various intervals into a slow-burning rope-fuse. When the smoldering rope reaches one of the fireworks, the fuse is ignited and the resulting explosion is intended to scare wildlife away.

Of course, it is possible that there will be diversion of such fireworks into illegal channels—that is, to the general public for fireworks purposes. This would be a clear violation of the law because the moment





Kits are advertised for home fabrication. When shipped, ingredients (far left, above) are not explosive. Danger of homemade firecrackers (left, above) is shown by grenade-like result of explosion in tin can (left). Stuffed toy duckling (above) is example of another banned product. Imported for Easter, the ducklings contained toxic pesticides and other chemicals. Jequirity bean jewelry is also banned. One bean, chewed and swallowed, would cause death.

there is any such diversion, the exemption becomes void. The fireworks become a banned hazardous substance, and the person or firm responsible for the diversion will be subject to possible criminal action.

There is also a substantial market for large fireworks such as rockets and aerial bombs intended for public display. As long as these types of fireworks are not sold for use in or around a household, they are not subject to this law. However, should they be encountered in retail channels, there would be no choice but to assume them to be "banned hazardous substances." As such, they would be subject to seizure and the individual responsible for introducing them or diverting them to the general public would be subject to possible criminal actions.

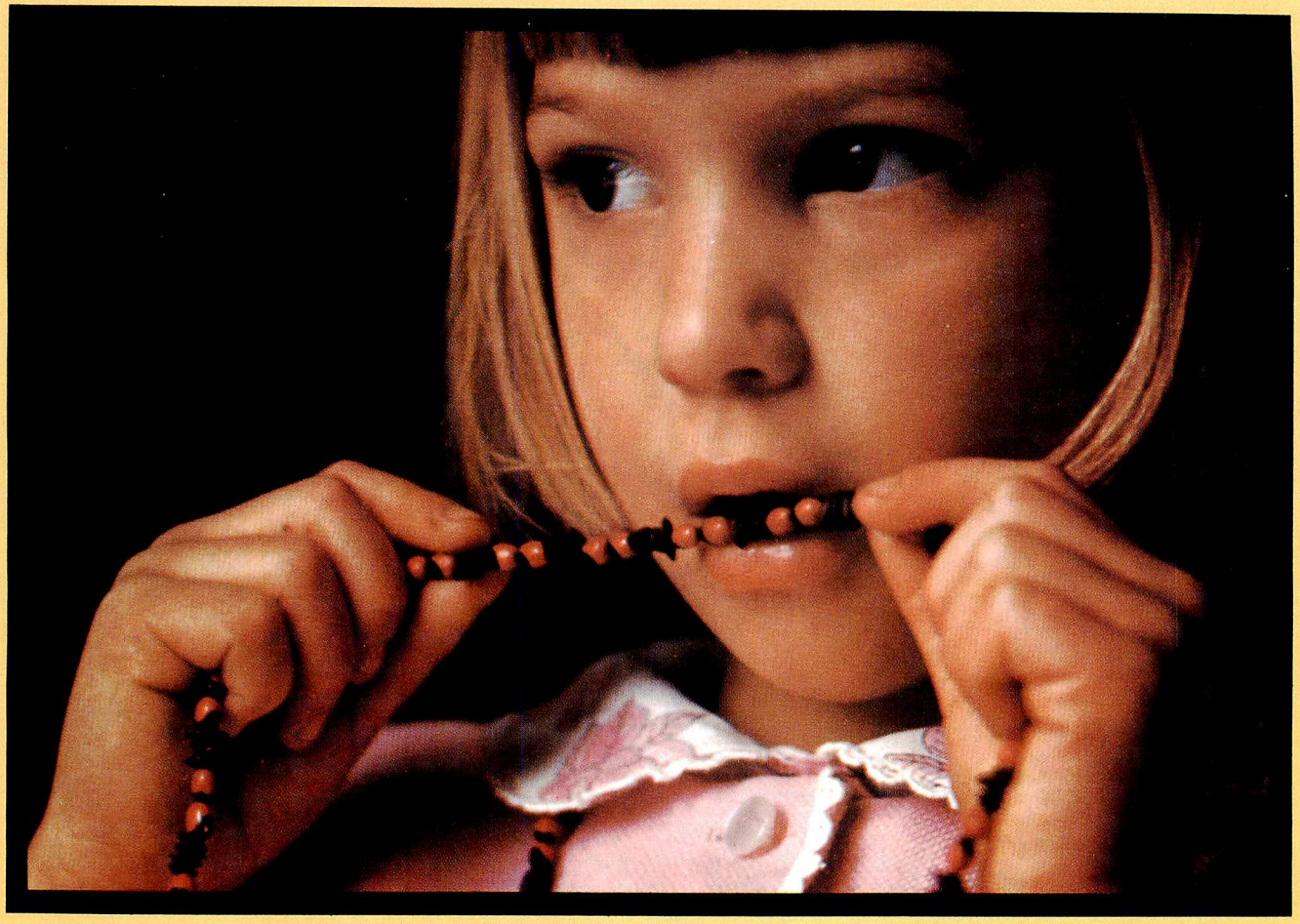
It is clear from the legislative history that various States and localities are free to ban or restrict the distribution and sale of any fireworks items that may be illegal under local or State laws.

Still another loophole in the original Act was plugged by the recent amendments. If products were not sold in a container or package, the Federal Government was powerless to require a warning on them and unpackaged hazardous substances escaped jurisdiction.

An example of the kind of problem this situation created was seen during recent Easter seasons. Stores throughout the country were selling imported toy ducklings that were potentially dangerous. These novelties were made from the stuffed skins of slaughtered ducklings and were found to contain high concentrations of benzene hexachloride, a poisonous insecticide which had been added as a preservative. Other such toys were contaminated by the *Salmonella* micro-organism and still others by arsenic compounds.

Other examples of unpackaged articles that escaped jurisdiction were objects made of the jequirity bean. These bright little red and black beans are pretty, but deadly. One bean, chewed and swallowed, can cause death in a matter of hours. Many gift shops and other stores sold necklaces, swizzle sticks, and other objects containing these beans.

There was no way of warning the buyer because such items were not sold in packaged form. The amended law requires the necessary warnings to appear on the article itself, or, if this is not possible, the warnings must be placed on a sticker or tag securely fastened to the article. The proposed regulations state that the tag or sticker must be attached securely enough to carry through distribution and merchandising until removed by



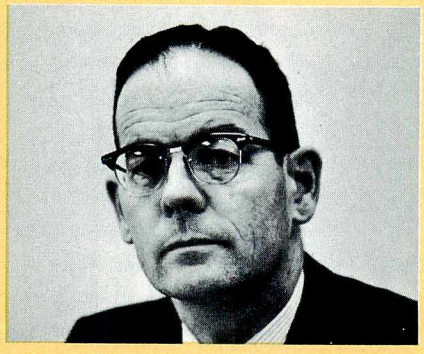
the ultimate purchaser or user.

The law places in the hands of the manufacturer, packer, or distributor, the responsibility for marketing a properly labeled and otherwise legal article. The FDA is always glad to assist a firm or group in achieving voluntary compliance. However, when enforcement becomes necessary because of distribution of seriously mislabeled or banned hazardous substances, the following actions are possible: Seizure, Injunction, and/or Prosecution.

A seizure is a civil action against a specific lot of goods and such actions may be terminated by forfeiting the goods, by contesting the action in court, or by petitioning the court for permission to bring the goods into compliance.

An injunction is also a civil action and is usually in the form of a court order to cease a certain specified prohibited act.

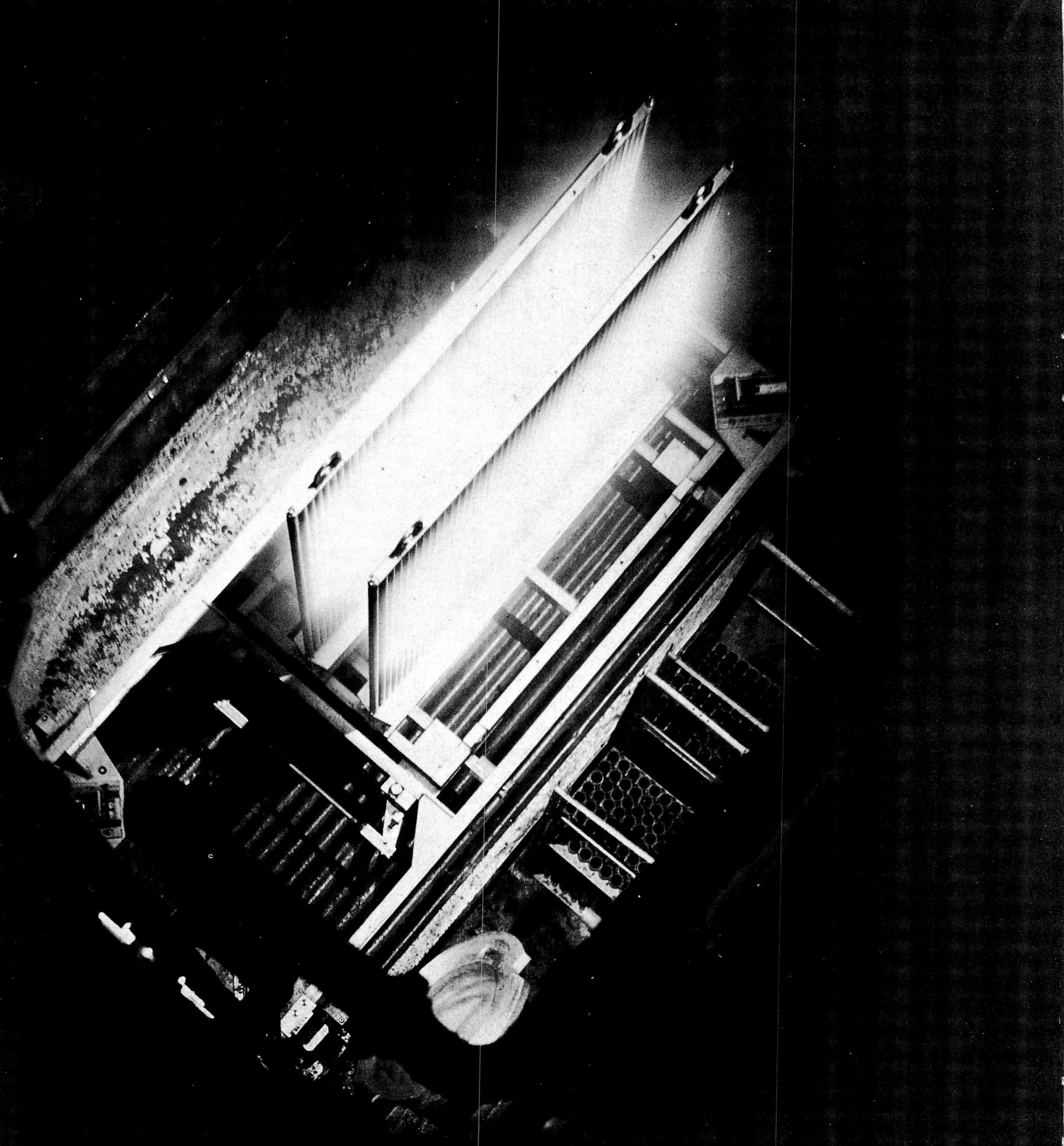
A prosecution is a criminal action and is brought against an individual or firm for violating one of the several prohibited acts. The prohibited acts include introduction or delivery for introduction into interstate commerce of any misbranded hazardous substance, or the doing of any act with respect to an article after shipment into interstate commerce which results in its becoming a misbranded or banned hazardous substance.



Dale C. Miller, Food and Drug Officer in the Office of the Associate Commissioner for Compliance, has worked in the hazardous substances field since 1960.

Upon being found guilty of violation of a prohibited act, a person may be fined up to $500 and imprisoned for up to 90 days, or both, on each count; but for offenses committed with intent to defraud or mislead, or for second and subsequent offenses, the penalty would be imprisonment for not more than one year or a fine of not more than $3,000, or both, for each count.

The passage of the "Child Protection Act," amending the FHSLA, has greatly strengthened the protection afforded to the consumer by the Hazardous Substances Act. No legislation will eliminate all injuries, but these new measures go well beyond the limitations of label cautions and will bring significant added protection to our families and homes.



radiation of food

by Robert S. Roe

. . . FDA food additive requirements

FDA has an interest and a responsibility in respect to radiation treatment of food. The Agency's interest is directed to the need for forward-looking research and better communication among those in the young field of food irradiation. FDA's responsibility pertains to enforcement of the Food Additives Amendment to assure the public that "no known hazard to health" should be introduced through such preservation methods.

The food additive regulations are established pursuant to the law enacted in 1958. The term "food additive" for the purposes of this law means any substance the intended use of which may result in its becoming a component, either directly or indirectly, of a food, or result in its otherwise affecting the characteristics of a food if such substance is not generally recognized as safe.

The amendment specifically includes "any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use." It is under this section of the law that the Food and Drug Administration has an interest and responsibility in the matter of radiation treatment of food.

Even prior to 1958, the Food and Drug Administration was aware of the interest in possible radiation applications to food. Our scientists had been consulted by Army and AEC scientists in regard to some of the investigations and research being carried out or contemplated by those agencies.

The obvious purpose of the Food Additives Amendment is to insure that food additives that become components of food, or that affect the characteristics of food, are safe under the conditions of use. The law admonishes that no regulation shall be granted unless a fair evaluation establishes that the proposed use will be safe; and the law contains a proviso that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal. . . ." It also provides that no regulation shall issue if "the proposed use of the additive would promote deception of the consumer in violation of this act, or would otherwise result in adulteration or in misbranding of food within the meaning of this act."

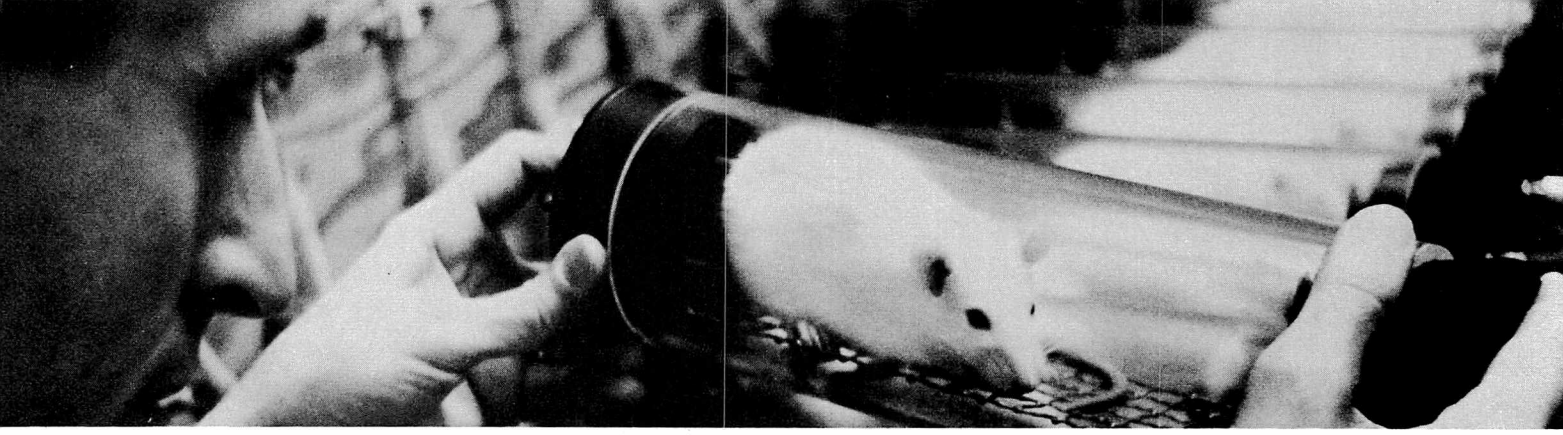
The data required to be submitted in support of a petition proposing a regulation must include full information concerning the identity of the additive, the conditions of proposed use, all relevant data bearing on the physical or other technical effect, and the quantity of such additive required to produce such effect. Also required are "full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations." For any food additive regulation, the supporting data need show what the technical effect of the additive is and must establish that the proposed use is safe.

This matter of establishing safety necessitates an evaluation of the possible toxicity of the food additive if it is a substance to be added to food, or the possible toxicity that may be brought about by the effect produced in a food. This appraisal usually calls for toxicology obtained through various appropriate feeding tests on laboratory animals. It may also require or include other types of scientific investigations, such as metabolism studies and biochemical procedures, including enzyme activity.

The types of tests and laboratory investigations that may be employed in the evaluation of a food additive are in many cases similar to those applied to evaluation of pesticide chemicals and drugs of various kinds. A booklet published by the Association of Food and Drug Officials of the United States in 1959 consists of a compendium of articles prepared by scientists of the Food and Drug Administration under the general topic "Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics." Publication 750 of the National Academy of Sciences—National Research Council entitled "Principles and Procedures for Evaluating the Safety of Food Additives" was prepared by the Food Protection Committee—Food and Nutrition Board in December 1959. These references have been widely used as guides in devising test protocols.

Ionizing radiation requires consideration as to just what investigations are essential to give basis for a sound appraisal of the safety of various proposed applications to food products. For instance, data are needed to show:

(1) Whether exposure to ionizing radiation causes



FDA scientists have suggested chronic feeding experiments with rats and dogs on low-dose irradiated foods.

induced radioactivity in the treated food. If so, this could not be adjudged as safe, because radioactivity is generally regarded as harmful and as carcinogenic. Data supporting the radiation applications to bacon, wheat, and potatoes showed that no detectable radioactivity above normal background was induced at the levels of the exposure involved. However, other products and other conditions of use need to be evaluated by appropriate tests.

(2) Whether ionizing radiation treatment produces toxic substances in the food exposed to the treatment. Here, the usual chronic long-term animal feeding studies have been considered necessary to enable evaluation.

(3) Whether proposed treatments adversely affect the nutritive values of exposed food. Effects on nutritive values, such as destruction of vitamins, are factors for consideration in evaluating safety or in determining whether the treatment is deceptive or results in any adulteration or misbranding.

(4) Whether the proposed treatments are effective for the intended purposes, and what doses are necessary to accomplish the purposes.

Throughout the report of a joint FAO/IAEA/WHO Expert Committee in April 1964—"The Technical Basis for Legislation on Irradiated Food" (World Health Organization Technical Report Series No. 316)—are suggested test procedures for evaluating various safety aspects. One chapter particularly is devoted to this subject: "4. Recommended Technical Procedures and Tests Required to Permit an Evaluation of the Safety for Consumption of Irradiated Food." Other aspects of safety considerations are mentioned in other chapters under such section headings as "Possibility of induced radiation resistance" (p. 34), "Considerations of nutritional value" (p. 7), "Assuring microbiological safety" (p. 30), "Packaging of irradiated food" (p. 9).

The FAO/IAEA/WHO report discusses the suitability of various animal species for test purposes, including reference to rats, mice, dogs, chickens, pigs, guinea pigs, and monkeys. The report states "Tests carried out in less than two species of laboratory animal are not acceptable . . . ."

This report also says that "Before any legislation is enacted to permit irradiation of food, there should be clear evidence that any disadvantages that might possibly arise from the use of the process are substantially outweighed by the expected advantages."

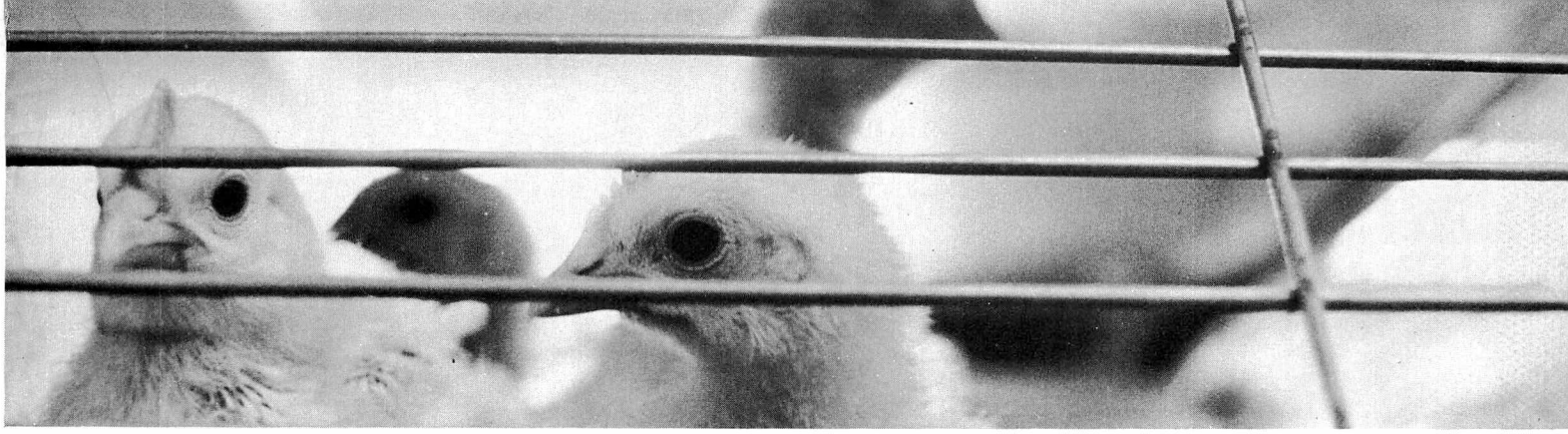
The Atomic Energy Commission has prepared extensive and detailed guides for conducting animal toxicity tests on low-dose irradiated foods—both long term (chronic) and short term (90-day). Its protocols utilize rats, dogs, and chickens.

The Food and Drug Administration scientists have suggested 2-year (chronic) feeding experiments with rats and dogs—essentially the same protocol as for other food additives. A third species—mice or chickens—may also be desirable and may provide additional supporting data. These tests need to be evaluated from the standpoint of general toxicity, pathogenicity, carcinogenicity, and effects on reproduction. Other tests, of course, frequently are necessary, such as effects on microbiological flora, production of induced radiation, etc.

Question has been raised as to how much safety data are needed on individual foods when data are available on other foods of the same general class. It has been suggested, for instance, that if long-term chronic feeding studies have been obtained on one irradiated fruit, such data may be used in evaluating safety with respect to another irradiated fruit, at least after short-term or 90-day feeding experiments indicate no abnormalities from the second irradiated fruit.

We, at one time, indicated that extrapolation of data in such circumstances might well be appropriate and serve satisfactorily as a basis of safety evaluation. However, we recently have had second thoughts in this matter. We are now very doubtful as to what guidelines may be reliable in enabling safe extrapolation of data from one product to another.

Reports on the apparent adverse effect of irradiation on sugar solutions and consideration of the variations in composition of different fruits as regards carbohydrates, acids, and other constituents now lead us to question the rationale of extrapolation of safety data. Maxie and Sommer, University of California, refer to the living nature of fruits, vegetables, and the pathogens which attack them, and point out that "Since irradiation induces stress in living cells and consider-



Toxicity tests on a third species, chickens or mice, may also be desirable and provide additional supporting data.

ing the great variability among various organisms in their tolerance to radiation, one would not expect all fruits and vegetables and the pathogens which attack them to respond similarly" (Radiation Preservation of Foods, Publication 1273, NAS-NRC, p. 39). Until more information is available that would give sound basis for extrapolation, we think that long-term tests will be necessary to enable sound safety appraisals of radiation treatment of specific products.

In the case of radiation treatment of foods, as well as in the appraisal of food additives generally and, for that matter, pesticide chemicals, we are hopeful that long-term chronic feeding studies can be replaced, at least in part, by other less time-consuming—and, it is hoped, more meaningful—means of evaluation. At present, however, we still find it necessary to rely heavily on these long-term feeding tests.

It is to be expected that with experience, and with acquisition of new information resulting from observations of the effects of radiation treatment, modifications in test procedures may from time to time be found feasible. It is also to be expected, however, that experience and observations from time to time will point to the need for some additional studies.

Reports suggesting the detection of mutagenic changes in bacteria from exposure to ionizing radiation, and reports of temporary inhibition of bacterial activity with likelihood of later resumption of viability, have suggested the need for possible additional or revised protocols for safety evaluations insofar as appraisal of microbiological facets are concerned.

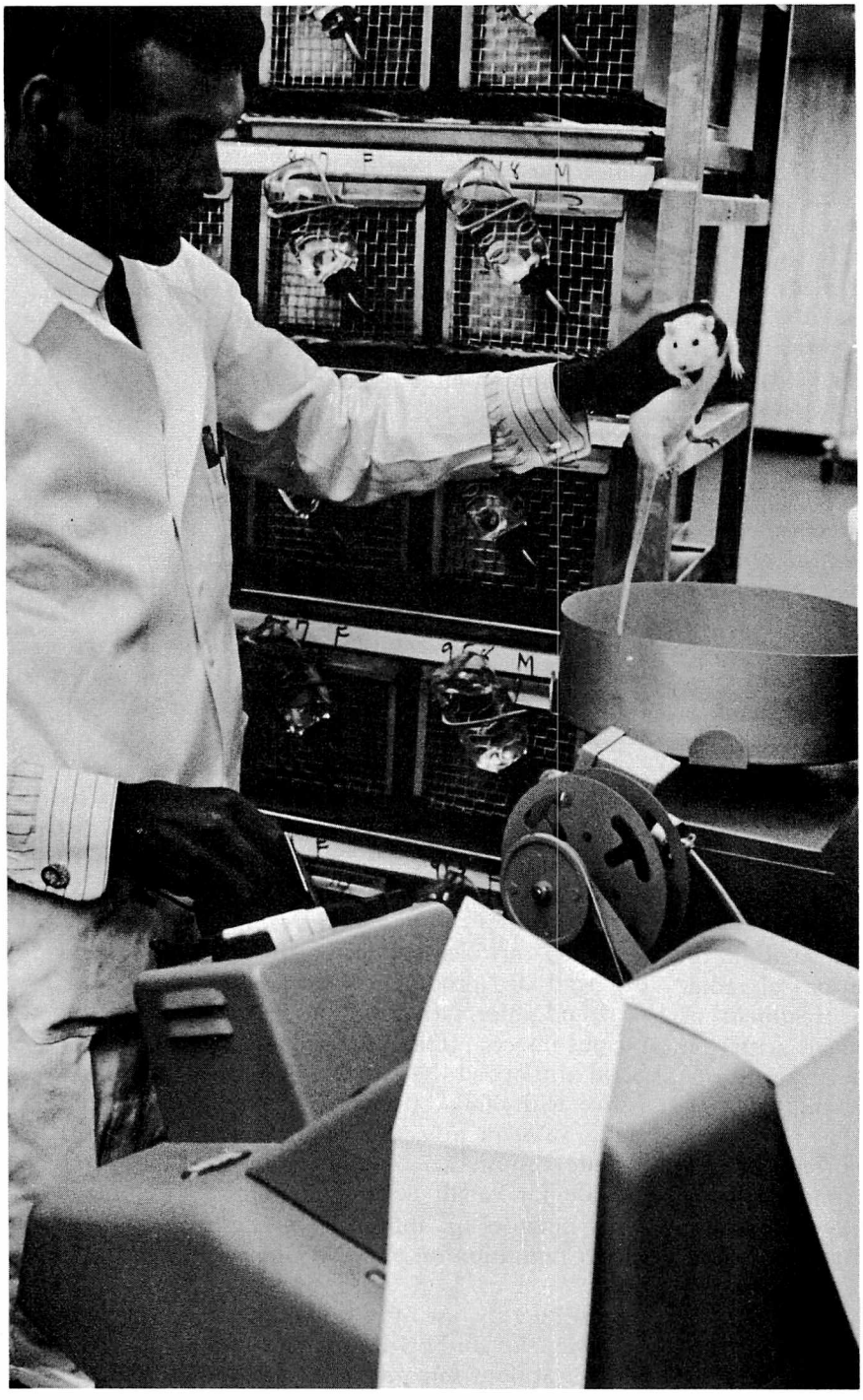
Several regulations have been promulgated in response to proposals for various applications of radiation in the inspection, packaging, or treatment of food. The first of these regulations deals with the application of radiation for purposes of inspection of food—for inspection of packaged food and for controlling food processing (Reg. 121.3001).

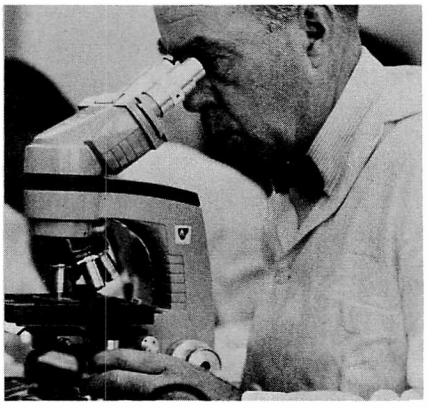
During 1962, a petition was submitted requesting a regulation for high-dose gamma radiation processing of canned bacon. This resulted in a regulation authorizing the cobalt 60 irradiation of canned bacon with the limitation of absorbed dose 4.5 to 5.6 megarads. The safety data submitted in support of this proposal included data showing that the authorized radiation did not result in any induced beta or gamma activity in the bacon. The data included four different studies by different investigators on feeding tests with two strains of mice and beagle dogs in which no indication of increased tumor production was detected. They included 2-year rat feeding studies and 2-year beagle feeding studies. The data also included bacteriological investigations demonstrating that a dose of 4.5 megarads provides safe radiation preservation for canned bacon even under conditions of gross contamination with *Clostridium botulinum*. The data also included results of studies on irradiated fat absorption, effects on nutritive values, and effect on unsaturated fatty acids.

Subsequently, the regulation (Reg. 121.3002) was amended to provide for use of cesium 137 as the radiation source, and subsequently also, in 1964, in response to additional petitions, a regulation issued to provide for high-dose electron beam radiation as the energy source in the preservation of canned bacon. This authorizes a beam of electrons at energy levels not to exceed 10,000,000 electron volts and provides for the limitation of 4.5 to 5.6 megarads absorbed dose (Reg. 121.3004).

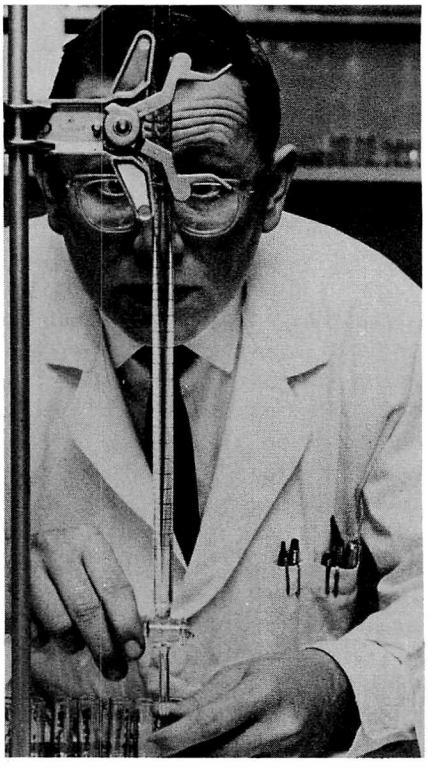
The data in support of the regulation on treatment of wheat for disinfestation (Reg. 121.3003) included feeding tests with rats and reproduction studies with rats and mice, using irradiated whole wheat or irradiated whole wheat cereal. They also included 2-year feeding studies on dogs, using irradiated wheat flour. The data included studies on the nutrient content of the irradiated products, blood and enzyme studies on rats, and information on the effect of radiation on various insects. The regulation as originally promulgated authorized the use of cobalt 60 as the radiation source with limit of absorbed dose 20,000 to 50,000 rads. Subsequently, this regulation was amended to include cesium 137 as the radiation source and to provide for cobalt 60 and cesium 137 treatment of white potatoes for inhibition of sprout development, with a limitation on absorbed dose of 5,000 to 15,000 rads.

Subsequently, use of low-dose electron beam irradiation was also authorized for the treatment of wheat and wheat flour for control of insect infestation. The





Establishing safety standards on food additives requires appropriate feeding tests on laboratory animals. Food and Drug Administration scientists examine animal tissues for evidence of toxic residues (above and below). A rat submits to being weighed (left).



authorized source consists of an electron accelerator producing a beam of electrons at energy levels not to exceed 5,000,000 electron volts striking the wheat directly or striking a target metal creating X-rays which irradiate the wheat. The same limitation of absorbed dose from 20,000 to 50,000 rads is maintained (Reg. 121.3007).

These regulations provide for certain label statements in order to assure safe use. In the case of the wheat, wheat flour, and potatoes, the label declarations called for are "Treated with ionizing radiation" on retail packages and "Treated with ionizing radiation—do not irradiate again" on wholesale packages and on invoices or bills of lading of bulk shipments. In the case of high-dose radiation exposures, the regulations require, for the purpose of informative labels, the declaration "Processed by ionizing radiation." However, in an order published January 7, 1967, alternative forms of declaration are proposed, such as "Processed with gamma radiation" instead of "Processed by ionizing radiation" and "Treated with electron radiation" instead of "Treated with ionizing radiation."

The precautionary label requirements in bulk are required because no data have as yet been presented which tell us what happens if the total dose is divided into increments. Certainly the data show deleterious effects to the wheat and potatoes exposed to single doses much in excess of the top level allowed. Thus, until data establish otherwise, we believe that food handlers should be warned not to irradiate again those foods which have already received the permitted treatment. Simple inspection will not indicate whether the product has been irradiated or not.

It should also be recognized that wheat irradiation imparts no lasting effect against insects. Although the treatment may kill the infestation existing at the time, this same lot of wheat can be reinfested from external sources. Since excessive treatments may impair the baking qualities of wheat and cause darkening of the potatoes, we believe the warning statements are essential. Whenever data are submitted showing that other conditions may be safely permitted, the regulations can be changed.

Several other proposals for regulations involving radiation treatments for various foods have been considered in connection with petitions that have been presented. These include proposals for irradiation of oranges and strawberries to inhibit spoilage and extend shipping times or shelf life. Included also are proposals for irradiation preservation of ham and for irradiation treatment of fishery products.

We have not been able to act favorably on these proposals pending further information concerning the investigations and experiments that have been made. We need further data to be sure that all of the safety factors have been adequately covered and that the treatments as proposed will accomplish the effects intended.

This peaceful application of atomic energy presents possibilities for significant advances in food processing. Applications in food preservation hold promise of improved products for the consumer and reduction of losses in foods through spoilage and insect devastation. However, the process obviously involves many complexities.

It is important that the greatest care be exercised, particularly at this stage of the development, to insure that any regulations issued are scientifically sound and will, in fact, provide for safe and effective uses. Mistakes in evaluations could be disastrous to successful development and consumer acceptance. The Food and Drug Administration will continue to proceed with care and, of course, continues to welcome the collaboration and cooperation of the scientific units of other agencies.

Robert S. Roe is Associate Director of the Bureau of Science. During the 42 years he has been with FDA, Mr. Roe has held positions ranging from chemist to Director of the former Bureau of Scientific Standards and Evaluation.

field reports

BALTIMORE DISTRICT The District co-sponsored a workshop for dispensing pharmacists on February 9, in Baltimore, Md. Other sponsors were the Maryland State Department of Health; Maryland Board of Pharmacy; School of Pharmacy, University of Maryland; Maryland Pharmaceutical Association; Baltimore Metropolitan Pharmacy Association; and Baltimore Drug Exchange. In spite of a snow storm, approximately 50 persons attended.

CINCINNATI DISTRICT The District helped sponsor three industry workshops in February. With the St. Louis District, the District jointly sponsored a sanitation workshop for warehousemen at Jackson, Tenn., on February 14. Another sanitation workshop was held at Knoxville, Tenn., on February 17. Other participants were the Tennessee Wholesale Grocers Association, Tennessee Retail Merchants Council, and Tennessee State Department of Agriculture. The Jackson workshop drew 101 participants, and Knoxville 110.

Approximately 75 persons attended a *Salmonella* workshop for the dry milk industry in Indianapolis, Ind., on February 21. Other participants were the Indiana and Kentucky State Health Departments and the Ohio Department of Agriculture.

DALLAS DISTRICT The pecan shelling industry in Oklahoma and Texas continues to be subjected to regulatory actions because of shipments of pecans contaminated with *E. coli*. D. McCrea & Sons, Yancey, Tex., were fined $4,000 on February 8-9. The firm and its two officials had pleaded guilty to an indictment charging shipments of contaminated pecan meats. The father and son were also sentenced to 30 days in jail, given 11-month suspended sentences, and placed on probation for 5 years. In November 1964, they pleaded guilty to an information charging similar shipments and were fined $1,000. Other seizures of contaminated pecans shipped by other companies have been requested by General Counsel.

DENVER DISTRICT Fermentation resulted in voluntary destruction recently of 240 cases of spiced apple rings belonging to Stone Hall Brokers, Denver, Colo.

Approximately 75,000 pounds of pinto beans were seized at Mimbres Valley Farmers Association, Deming, N. Mex., because they were held under insanitary conditions and were contaminated by rodent excreta.

DETROIT DISTRICT The Government's request for an injunction against Rand Development Corp., Cleveland Ohio, was granted by an Ohio judge on March 2. The injunction prevents the firm from distributing the vaccine in interstate commerce, and from possessing ingredients for the product received in interstate commerce.

The Rand Corp. recently developed an anti-cancer vaccine using an extract made from cancerous human tissues combined with rabbit gamma globulin. The vaccine supposedly stimulates the production of antibodies that fight cancerous growth.

A joint investigation of the manufacturers conducted by the National Institutes of Health and the FDA revealed that the firm did not comply with good manufacturing practice, and that the vaccine was being widely distributed to physicians throughout the United States without an effective NDA or IND. Collection of samples from interstate shipments showed that the article was not properly labeled and that some lots were nonsterile.

The firm failed to comply with the law and regulations with respect to complete records, labeling, and reserve samples of each batch.

KANSAS CITY DISTRICT A large shipment of assorted dietary supplements—approximately 522,460 tablets, 902 bottles, and 362 pounds of powdered material—and labeling and pamphlets were seized at Professional Foods, Cedar Rapids, Iowa, on February 2. The supplements were misbranded because the associated pamphlet entitled "This You Should Know" contained numerous health claims which were false and misleading, and several product labels had false and misleading statements. Total value of the seizure was $2,870.

KANSAS CITY BDAC A former prison official and his ex-wife were sentenced to jail terms in early March for smuggling drugs into the Kansas State Industrial Reformatory, Hutchinson, Kans. Marvin G. Miller, 49, Hutchinson, a correctional officer at the reformatory until his arrest, and his ex-wife, Frances R. Ellington, 46, South Hutchinson, were arrested on December 12. Miller had sold 11,000 amphetamines to a BDAC undercover agent for $200. Mrs. Ellington had been supplying the drugs to Miller. The arrests culminated a 3-month investigation of a suspected drug ring within the reformatory. Shortly after the couple was released

on $1,000 bonds, Mrs. Ellington was arrested for possession of a concealed weapon; she was later fined $25 and released. The two were sentenced to a year in prison on each of seven counts—three involving illegal sales of controlled drugs, three involving possession of controlled drugs, and one for failure to register as a distributor. The 3 years on the sales counts are to run consecutively; the other 4 years are to run concurrently with the 3 years.

LOS ANGELES DISTRICT Aflatoxin was found in two lots of brazil nuts sampled and examined at Los Angeles, and seizures were accomplished. The amount of toxin was as high as 19,000 parts per billion. Examination of these lots was part of an intensive program on aflatoxin following the discovery by Canadian officials that moldy brazil nuts may contain aflatoxin. The seizure covered 154 100-pound bags in one lot and 155 100-pound bags in the other.

LOS ANGELES BDAC A youth, Kent F. Hager, Santa Monica, Calif., was sentenced to 4 years in jail on January 9 for illegal sales of LSD. The judge suspended the sentence and placed the boy on probation for 4 years under the Federal Youth Corrections Act. The Act applies to offenders under 22 at the time of conviction, and allows for corrective and preventive guidance and training.

MINNEAPOLIS DISTRICT The District participated in the Sixth Biennial Governor's Conference on Aging on February 23 and 24. Skits on health frauds were presented, with staff chemists playing the roles of two types of fake practitioners, Dr. I. Q. Science, and Dr. I. M. A. Quack. A skit entitled "It's Up to You" dramatized how a consumer can report to the FDA. A workshop was also held entitled "Consumer Friend and Foe." Although the thermometer dipped to 20° below zero, there were over 600 people registered at the conference.

Due to misbranding, 30,640 pounds of Nutrena Egg Ration A Medicated were seized at Cargill Elevator, Hankinson, N.D., in early March. The product was misbranded because it contained less than the declared "Arsanilic acid 0.01%," and its labeling falsely represented the product as adequate and effective for increasing egg production and feed efficiency.

NEW ORLEANS DISTRICT Joint investigation by the District and the Division of Food and Drugs, Louisiana State Health Department, resulted in the voluntary destruction of 366 vials of Pancohemin for intramuscular injection. The drug contained cobalt gluconate. Under FDA's policy announcement in January 1967, such articles cannot be marketed except under an effective NDA. Bearing the distributor's label of Pan American Labs, Inc., New Orleans, La., the stock was manufactured in part by Maizel Labs, Chicago, Ill., and in part by a Philadelphia, Pa., laboratory.

NEW YORK DISTRICT A drug which failed to bear adequate directions for use was seized at Phoenix Pharmacal Co., Inc., N. Y., on February 28. More than 1,660 vials of Esplen, valued at approximately $8,520, were seized. The drug is a sterile aqueous solution of material derived from animal spleen intended for use in the treatment of arthritis and allergies.

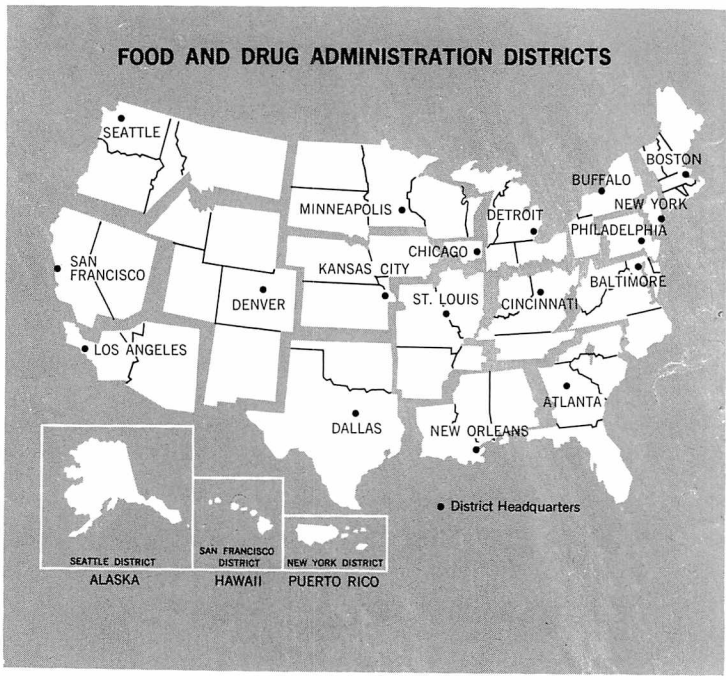
FDA had informed Phoenix on several occasions that Esplen was a new drug for which an approved New Drug Application or a notice of claimed investigational exemption was required. After the firm continued to ignore this advice and market the product, the seizure was made.

PHILADELPHIA DISTRICT Good manufacturing practice for medicated feed mixers was the topic of a workshop co-sponsored by the District on February 28 at Harrisburg, Pa. Other sponsors were the Pennsylvania Department of Agriculture, Pennsylvania Millers and Feed Dealers Association, and Pennsylvania State University. More than 100 medicated feed manufacturers in Pennsylvania attended. A similar workshop is scheduled for May 16 at Trenton, N. J.

ST. LOUIS DISTRICT A product used to clean and restore Dura Sealed surfaces and recondition and seal wood surfaces, was seized February 23 on misbranding charges. Twenty-three gallons of Dura Seal Renovator were seized at Flooring Supply Co., St. Louis, Mo. The product was manufactured by Pines International Chemical Co., Chicago, Ill. Packaged in a form suitable for home use, the product failed to bear precautionary and warning statements required by regulation.

SAN FRANCISCO DISTRICT A lot of king crabmeat finally met its doom in February. In May 1964, some 4,600 cases (60 pounds each) of frozen crabmeat were seized in Bellingham, Wash., after they were contaminated with ammonia from a broken refrigeration line aboard the freezer ship *MV Theresa Lee*. American Freezerships, Inc., filed claim to the merchandise, which was then released under bond for reconditioning to Sugarman Bros., San Francisco, Calif. After trying several methods of reconditioning, the firm decided to wash and can a portion of the crabmeat. This method removed the ammonia, but the crab decomposed. The firm then reconditioned the rest of the lot by washing and refreezing, which resulted in a satisfactory product. On February 10, 1967, about 4,980 cases (48 cans each) of the canned crabmeat were destroyed at the Brisbane, Calif., dump. All the crabmeat had been under FDA supervision until satisfactory reconditioning or destruction.

After a sample of egg albumen, used by DCA Food Industries, Oakland, Calif., was found contaminated with *Salmonella,* the firm voluntarily recalled all of the muffin mix made from it. *Salmonella* was found in the finished product, and 5,600 pounds of the mix were destroyed at a dump on February 15 and 17.



SEATTLE DISTRICT In response to a request from the Seattle-King County Civil Defense Office, a Seattle District Inspector, on February 9, witnessed the destruction of 14,985 vials of outdated procaine penicillin G. Destruction of the drug, valued at approximately $17,000, was carried out by crushing and covering at a local sanitary fill. The drug was also removed from disaster stocks which are purchased with both Federal and local funds.

FDA DISTRICT OFFICES

ATLANTA 60 Eighth Street, N.E.
Atlanta, Georgia 30309

BALTIMORE 900 Madison Avenue
Baltimore, Maryland 21201

BOSTON 585 Commercial Street
Boston, Massachusetts 02109

BUFFALO 599 Delaware Avenue
Buffalo, New York 14202

CHICAGO Main Post Office Bldg.
Rm. 1222/433 W. Van Buren Street
Chicago, Illinois 60607

CINCINNATI 1141 Central Parkway
Cincinnati, Ohio 45202

DALLAS 3032 Bryan Street
Dallas, Texas 75204

DENVER New Customhouse Bldg.
Rm. 5604/20th & California Streets
Denver, Colorado 80202

DETROIT 1560 E. Jefferson Avenue
Detroit, Michigan 48207

KANSAS CITY 1009 Cherry Street
Kansas City, Missouri 64106

LOS ANGELES 1521 W. Pico Boulevard
Los Angeles, California 90015

MINNEAPOLIS 240 Hennepin Avenue
Minneapolis, Minnesota 55401

NEW ORLEANS U.S. Customhouse Bldg.
Rm. 222/423 Canal Street
New Orleans, Louisiana 70130

NEW YORK 850 3rd Avenue (at 30th Street)
Rm. 700/Brooklyn, New York 11232

PHILADELPHIA U.S. Customhouse
Rm. 1204/2nd & Chestnut Streets
Philadelphia, Pennsylvania 19106

ST. LOUIS U.S. Courthouse & Customhouse
Bldg., Rm. 1002/1114 Market Street
St. Louis, Missouri 63101

SAN FRANCISCO Federal Office Bldg.,
Rm. 518/50 Fulton Street
San Francisco, California 94102

SEATTLE Federal Office Bldg.,
Rm. 501/909 First Avenue
Seattle, Washington 98104

FDA BUREAU OF DRUG ABUSE CONTROL FIELD OFFICES

ATLANTA 1831 Peachtree Road, N.E.
Atlanta, Georgia 30309

BALTIMORE 401 Water Street
Baltimore, Maryland 21202

BOSTON J. F. Kennedy Federal Bldg.
Rm. E-311/Boston, Massachusetts 02110

CHICAGO 205 West Wacker Drive
Engineering Building, Rm. 1700
Chicago, Illinois 60606

DALLAS 1114 Commerce Street
Rm. 723/Dallas, Texas 75202

DENVER 1814 California Street
Denver, Colorado 80202

KANSAS CITY U.S. Courthouse
Rm. 803/811 Grand Avenue
Kansas City, Missouri 64106

LOS ANGELES 714 West Olympic Blvd.
Rm. 1010/Los Angeles, California 90015

NEW YORK 346 Broadway, 12th Floor
New York, New York 10013

state actions

Tennessee Seizes Chickens The Tennessee Food and Drug Division seized 40,000 pounds of dressed, whole, frozen chickens recently because they were rancid. The lot was released for salvage under supervision of USDA Inspectors.

Ohio Holds School A hazardous substances school, sponsored by the Ohio State Department of Health on March 22 and 23, drew 40 State and local officials. Directed by the Division of Sanitation, the course familiarized the personnel with Federal and State hazardous substances laws and regulations.

New Jersey Monitors Damaged Additives An explosion and fire destroyed a Morningstar-Paisley Co. plant in Hawthorne, N.J., on March 3. Twelve persons died, and more than one million pounds of gums, starches, and stabilizers intended for use in foods were damaged. The New Jersey Bureau of Food and Drugs is monitoring all shipments of the damaged products to insure that they are used for nonfood products only. The Bureau has ordered all references to food or drug use removed from the products' labeling.

Wyoming Stops Feed Sales The Wyoming Department of Agriculture initiated a stop-sale against a lot of diethylstilbestrol and mixed feed at Cody Feed Co., Cody, Wyo., when an inspection revealed the firm had no NDA or Form 10.

Nebraska Issues Hunting Licenses Nebraska has declared open season on *Salmonella* and issued *Salmonella* hunting licenses.

During a *Salmonella* workshop program on March 31 at the University of Nebraska, the State Department of Agriculture passed out the licenses. They are nonexpiring, and carry no bag limit or weapons limitation.

Nebraska is making inspections and collecting random samples of dried milk, cottage cheese, meat scraps, and finished feeds as part of basic research on *Salmonella* contamination of animal-origin products.

Foods Salvaged The Indiana Division of Food and Drugs recently supervised the segregation and salvage of $960,000 worth of foods involved in two train wrecks and two fires.

Crushed cases of food shown mingled with twisted metal of railroad carrier.

New York Embargoes Thyroid Tablets The New York City Health Department embargoed 72,000 thyroid tablets contaminated with *Salmonella*. In mid-March the supplier advised Linden Medical Supply Co., New York, N.Y., that one lot of 1-grain tablets was contaminated, and suggested that the firm institute a sub-recall of the drug. After being notified of the recall, the city took action on April 3. Linden advised the city that it will recall the drug from its consignees.

Detail Men Stopped From Mislabeling Drugs Two detail men were prevented from mislabeling drugs in February and March by the California State Bureau of Food and Drug Inspections. Inspection of one drugstore disclosed stock bottles containing capsules or tablets which had been "washed" in solvent to remove imprinted identification. The detail man also furnished unlabeled containers of "washed" physicians' samples which were found under the prescription counter. He had exchanged the washed products for merchandise. In the second case, a druggist received misbranded bottles of tablets from a detail man friend in the Midwest.

In both cases the detail man had ceased to represent his company and was acting in his own behalf. They had removed the original label, including control numbers, from the drug samples and repacked a new drug or a certifiable antibiotic without a New Drug Application, without a license, without registration, and without controls. They had placed the drugs in used containers with little or no labeling and sold or bartered the drugs to druggists for personal gain.

Washington Embargoes Wheat Approximately two million pounds of bulk wheat stored at Odessa Union Warehouse Co., Reiner Station, Odessa, were involved in a cement storage bin explosion, and were placed under state embargo by Inspector Charles Logan. Because of extensive commingling of cement particles with the grain, reconditioning efforts have been unsuccessful and negotiations are currently under way between the owner's insurance company and Inspector Logan to determine final disposition.

seizures and Post Office 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 60 seizure actions to remove adulterated, misbranded, and unsafe products from the consumer market were reported in February. These included 38 seizures of foods: 4 because of poisonous and deleterious substances, 23 because of contamination, and 11 because of economic violations. Other seizures included 8 of drugs, 4 of medicated feeds, 2 of medical devices, 2 of color additives, and 6 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
	FOOD / Poisonous and Deleterious Substances	
Beans, dry, Garbanzo/New Orleans, La. 1/27/67	L. H. Hayward & Co./New Orleans, La. (D)	Contains DDT in excess of established tolerance for pesticide chemicals on dried Garbanzo beans; held under insanitary conditions.
Brazil Nuts/Los Angeles, Calif. 2/7/67	Imported from Brazil by L.A. Nut House Co.	Contains poisonous aflatoxin.
Cheese, grated Parmesan, and cheese, grated Romano/Los Angeles, Calif. 1/31/67	Arthur Schuman, Inc./New York, N.Y. (S)	Contains hexachloride, a nonpermitted additive.
Eggs, frozen/Jersey City, N.J. 1/31/67	Billy Tolbert Egg Co./Oneonta, Ala. (S)	Contains Salmonella micro-organisms.
	Contamination, Spoilage, Insanitary Handling	
Beans, misc./San Juan, P.R. 1/12/67	Quintana Hnos., Inc./San Juan, P.R. (D)	Held under insanitary conditions; rodent contaminated.
Pinto/Harlingen, Tex. 1/16/67	M & M Sales & Co./Harlingen, Tex. (D)	"
Pinto/Somerset, Ky. 1/17/67	Economy Wholesale, Inc./Somerset, Ky. (D)	"
Soya/Los Angeles, Calif. 12/13/66	Japan Food Corp./Los Angeles, Calif. (D)	
Cauliflower in Brine/Stamford, N.Y. 1/12/67	Stamford Packing Co./Stamford, N.Y. (M,S)	Prepared and packed under insanitary conditions.
Eggs, frozen/Chicago, Ill. 12/21/66	Nulaid Egg Co./San Leandro, Calif. (S)	Decomposed.
Flour, enriched/West Point, Ga. 1/6/67	West Point Wholesale Grocery Co./West Point, Ga. (D)	Held under insanitary conditions; insect contaminated.
enriched/Marshall, Mo. 1/16/67	Shryack-Wright Grocery/Marshall, Mo. (D)	"
Potato/Los Angeles, Calif. 1/31/67	King of Spuds, Inc./Jerome, Idaho (M,S)	Prepared and packed under insanitary conditions.
Peaches, canned/Clearfield, Utah 1/24/67	California Packing/Sacramento, Calif. (P,S)	"
Peanuts/Berkeley, Calif. 1/23/67	Ellis L. Ganey Peanut Co./Abilene, Tex. (P,S)	"
granul./Aubrey, Tex. 1/17/67	Choice Products Co./Aubrey, Tex. (D)	Held under insanitary conditions; rodent contaminated.
shelled/Berkeley, Mo. 1/16/67	St. Louis Terminal Whse. Co./Berkeley, Mo. (D)	"
Peas, green, whole/Harlingen, Tex. 2/1/67	Sharboneau Brokerage Co./Harlingen, Tex. (D)	"
canned Crowder/East Point, Ga. 1/6/67	King Pharr Canning Operat./Cullman, Ala. (S)	Insect contaminated.
Pecan Meats/Cleveland, Ohio 1/25/67	B. S. Tanner Pecan Co./Mobile, Ala. (P,S)	Prepared and packed under insanitary conditions; E. coli.
Popcorn/Pulaski, Tenn. 2/2/67	M. Cohen & Sons, Inc./Pulaski, Tenn. (D)	Held under insanitary conditions; insect contaminated.
Rice, Navy Beans/Bridgeport, Conn. 1/30/67	Henry Bresky & Sons/Bridgeport, Conn. (D)	Held under insanitary conditions; rodent contaminated.
Shrimp, frozen/Hattiesburg, Miss. 1/12/67	New Orleans Shrimp Co./New Orleans, La. (P,S)	Decomposed.
breaded/Indianapolis, Ind. 1/23/67	Henderson's Portion Pak/Coral Gables, Fla. (S)	Staphylococci, high bacteria count.
breaded/New Orleans, La. 1/26/67	Henderson's Portion Pak/Coral Gables, Fla. (S)	"
breaded/Waterloo, Iowa 1/23/67	Singleton Packing Corp./Tampa, Fla. (S)	"
Strawberries, frozen/Maumee, Ohio 2/6/67	Kelley, Farquhar & Co./Salem, Oreg. (P,S)	Decomposed.
	Economic Violations	
Apricots, canned/Lincoln, Nebr. 2/3/67	USP Corp./San Jose, Calif. (M,S)	Below standard of fill of container for canned apricots.
Broccoli, frozen/Kansas City, Kans. 12/21/66	Stokely-Van Camp, Inc./Mount Vernon, Wash. (S)	Chopped and sliced pieces have been substituted for broccoli heads as depicted on label.
Dips, Barb-B-Q, Martini, Sour Cream, Blue Cheese/Cincinnati, Ohio 1/30/67	Food Specialties of Kentucky/Louisville, Ky. (M,S)	Inaccurate quantity of content statement.
Fruit Cocktail, canned/Syosset, N.Y. 11/29/66	Tillie Lewis Foods/Modesto, Calif. (S)	Not in conformity with standard of identity set for canned fruit cocktail.

seizure actions

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
	Economic Violations (Cont'd)	
Lollipops/Philadelphia, Pa. 2/2/67	Mumsey Candy Co./Camden, N.J. (M,S)	Inaccurate quantity of content statement.
Mushrooms, canned/Canandaigua, N. Y. 1/23/67	United Canning Corp./East Palestine, Ohio (S)	Short weight.
Oysters, canned/Houston, Tex. 2/7/67	Aughinbaugh Canning Co./Biloxi, Miss. (S)	Below standard of fill of container for canned oysters.
Peaches, canned/Church Point, La. 1/31/67	Carolina Products Co./Inman, S.C. (P,S)	Below quality standard for canned peaches.
Sorghum Syrup/Chattanooga, Tenn. 2/1/67	Rayford Farmer/Section, Ala. (M,S)	Corn syrup has been substituted for sorghum syrup.
Knoxville, Tenn. 12/30/66	Rayford Farmer/Section, Ala. (M,S)	"
Shrimp, canned/Richmond, Calif. 2/2/67	Safeway Stores, Inc./Seattle, Wash. (S)	Broken pieces have been substituted for whole shrimp as depicted on label.
	Color Additives	
Plums, pickled/Los Angeles, Calif. 1/10/67	Imported from Japan.	Contains artificial food dye not declared on label.
Spice Mac O Pep/Louisville, Ky. 2/9/67	McClancy Spice Co./Beaumont, Tex. (M,S)	"
	DRUGS / Human Use	
Alergimist Solution A and B/Covina, Calif. 12/24/66	Brunson Corp./Miami, Fla. (M,S)	New drug not approved for safety and effectiveness.
Antigen RCFA/Old Westbury, N.Y. 1/23/67	Rand Development Corp./Cleveland, Ohio (M,S)	Not in conformity with good manufacturing practice.
Atropine Sulfate Injection/Orlando, Fla. 12/28/66	Gooddeal Supply Co./Orlando, Fla. (D)	Inadequate directions for use; no "Caution" statement.
Embryo Serum Skin Rejuvenator/Hato Rey, P.R. 12/29/66	Glamour Corp., Inc./Hato Rey, P.R. (D)	New drug not approved for safety and effectiveness.
Fitical Tablets, Fitinol Tablets, Cebrina Tablets/Miami, Fla. 2/2/67	Nysco Laboratories, Inc./Long Island City, N.Y. (M,S)	"
Lironvit 12 Injection and Eritrogen Injection/Hato Rey, P.R. 11/2/66	Terrier Laboratories, Inc./Hato Rey, P.R. (D)	Below labeled strength.
Nasprin Pain Reliever Tablets/East Point, Ga. 1/6/67	Rexall Drug Co./St. Louis, Mo. (M,S)	Below National Formulary quality standard.
Red Head Cold Remedy/Royal Oak, Mich. 1/24/67	Michigan First Aid, Inc./Royal Oak, Mich. (D)	No adequate directions or warnings on repack labels.
	Medicated Feed	
Co-op Chick Pre-Starter/Eagle Grove, Iowa 1/27/67	Boone Valley Cooperative Processing Assn./ Eagle Grove, Iowa (D)	Below labeled strength; deficient in amprolium; not from certified batch.
Kem-Pen-10 Feed Concentrate/Cairo, Ga. 1/26/67	Mixon Milling Co. of Cairo, Inc./Cairo, Ga. (D)	Not in conformity with good manufacturing practice.
Premium Calf Milk Replacer/Springfield, Mo. 12/14/66	Mutual Products Co./Minneapolis, Minn. (M,S)	False and misleading claims to prevent bacterial enteritis.
Sweet Pig Formula/Downsville, Wis. 1/26/67	Land O'Lakes Creameries, Inc./Minneapolis, Minn. (M,S)	Below labeled strength; contains antibiotics not in compliance with regulations; not from certified batch.
	MEDICAL DEVICES	
Ionic Air Kleener/Newark, N.J. 1/31/67	Ionic Air Kleen, Inc./Montoursville, Pa. (M,S)	False and misleading claims to relieve asthma, hay fever, mental depression, reduce possibility of lung cancer in cigarette smokers.
Muscle Stimulator, Ultraviolet Lamp, Ultra-Sound Device/Philadelphia, Pa. 11/14/66	R. A. Fischer & Co./Glendale, Calif. (M,S)	Inadequate directions for use.
	HAZARDOUS SUBSTANCES	
Magic Rocks/Omaha, Nebr. 1/13/67	Hassenfeld Bros., Inc./Pawtucket, R.I. (M,S)	Lacks consumer protection information required by the Fed. Hazardous Substances Act.
Denver, Colo. 1/20/67	Magic Rocks/Los Angeles, Calif. (M,S)	"
Oklahoma City, Okla. 1/19/67	Magic Rocks/Los Angeles, Calif. (M,S)	"
Thornburg, Va. 1/26/67	Enco, Inc./Cleveland, Ohio (M,S)	"
Paint Remover/Royal Oak, Mich. 1/30/67	Helperize, Inc./Chagrin Falls, Ohio (M,S)	"
Pistol Tie Bar, Pistol Key Chain, Blank Cartridges/Atlantic City, N.J. 2/6/67	Silvercraft Co., Inc., Boston, Mass. (S)	"

POST OFFICE DEPARTMENT

actions taken in medical cases under provisions of the Postal Fraud Statutes as reported by the Chief Postal Inspector.

Complaints Docketed Under 39 U.S.C. 4005 (Fraud)

March 14, 1967: **G. R. Sullinger,** Box 286, Arlington, Wash., and **G. R. Sullinger,** Box 297, Darrington, Wash.
Using the mails to advertise and obtain remittances for a product called "Marvel," represented as an inexpensive invention that causes immediate, lasting sexual strength for sexually weak men of any age.

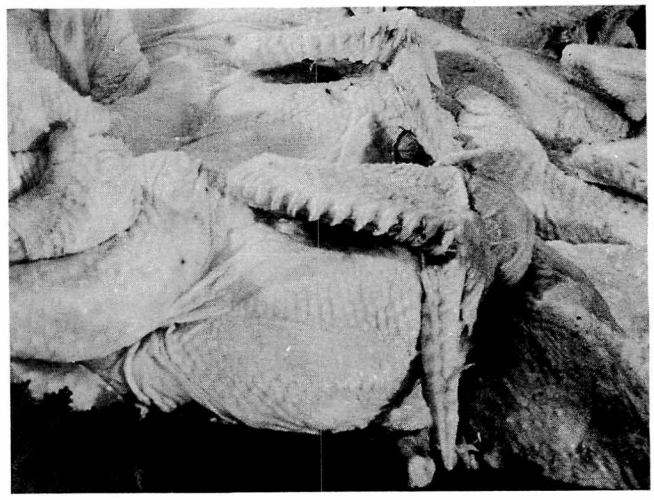
March 16, 1967: **Smythe-Farrington Corp.,** 250 West 57th Street, New York, N.Y.
Solicitation of orders and sale through the mails of a vitamin-mineral preparation under claims for immediate stimulation and "pick-you-up."

Fraud Orders Issued by Judical Officer Under 39 U.S.C. 4005 (Fraud)

March 17, 1967: Fraud Order No. 67-20, against **Sam Bruce,** P.O. Box 322, Rolling Fork, Miss.
Solicitation of orders and sale through the mails of a cancer cure and "sugar cure." Analysis of the clear liquid furnished by Bruce indicated it was nothing but water. However, one sample had the odor of sewage and the source of his water supply was dubious at best.

Arrests, Indictments, or Convictions Occurring Under 18 U.S.C. 1341 (Fraud)

Dr. Howard H. Beard, Ph.D., owner of **Beard Biochemical Labs,** 5220 Locke, Fort Worth, Tex., was indicted by a Federal grand jury at Lubbock, Tex., on March 13, 1967, and charged with nine counts of mail fraud relating to rendering fake and medically worthless cancer reports on urine samples. These were received through the mails. Dr. Beard, who holds a Ph.D. in biochemistry, claimed to have perfected the "Anthrone Test" which purportedly detects cancer in its early stages. Postal Inspectors investigating Dr. Beard's activities satisfied themselves the reports were wilfully falsified.

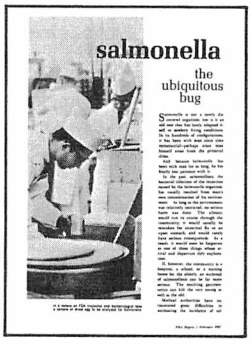


FDA evaluates the use of antibiotics in poultry and cattle to prevent unsafe residues in consumer products (above).

An inspector checks the condition of a sample of iceberg lettuce (left).

REPRINTS
REPRINTS
REPRINTS


Ecologic effects of antibiotics


salmonella
the ubiquitous bug

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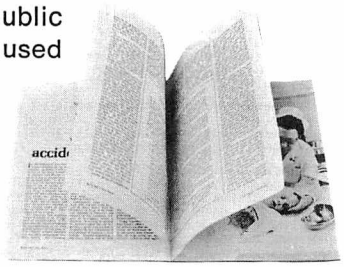

notices of judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

Drink mix, Champion Whip Brand, at Newark, Dist. Del.
Charged 8-18-66: when shipped by Farmer's Cooperative Creamery Co., Ogilvie, Minn., the article labeled in part "Baker's Champion Whip Brand Chocolate Flavor Drink Mix. . . . General Foods Corporation Institutional Food Service Div. . . White Plains, New York" contained the added poisonous and deleterious substance Salmonella micro-organisms; 402(a)(1). Consent decree ordered destruction. **(1)**

Yeast, dry, brewer's, at Orangeburg, S. Dist. N.Y.
Charged on or about 3-24-66: when shipped by Yeast Products, Inc., Paterson, N.J., the article contained the added poisonous and deleterious substance Salmonella micro-organisms; 402(a)(1). Default decree ordered destruction. **(2)**

FOOD / Contamination, Spoilage, Insanitary Handling

Cheese, cheddar, at Booneville, N. Dist. Miss.
Charged 7-20-66: when shipped by Ardmore Creamery, Inc., Ardmore, Tenn., the article labeled in part "Kraft Foods Fact 1 41" had been prepared from filthy milk; (402(a)(3). Consent decree authorized release to J. E. Beasley for denaturing for use as animal feed. **(3)**

Codfish portions, breaded, Fresh Lock, at Atlanta, N. Dist. Ga.
Charged on or about 6-11-66: when shipped by Gorton's of Gloucester, Inc., Gloucester, Mass., the article contained staphylococci and bacterial filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. **(4)**

Corn husks, at Los Angeles, C. Dist. Calif.
Charged 10-4-66: when shipped by Texas Broom Factory, San Antonio, Tex., the article contained insect filth; 402(a)(3). Default decree ordered destruction. **(5)**

Eggs, frozen, at Dallas, N. Dist. Tex.
Charged 12-20-66: when shipped by Southland Farms, Inc., Jacksonville, Fla., the article contained decomposed eggs; 402(a)(3). Default decree ordered destruction. **(6)**

Flour, at Bronx, S. Dist. N.Y.
Charged 12-29-66: while held for sale, the article contained insect filth; 402(a)(3). Default decree ordered destruction. **(7)**

Flour, at Spruce Pine, W. Dist. N.C.
Charged 11-10-66: while held by Spruce Pine Wholesale Co., Spruce Pine, N.C., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. **(8)**

Flour and **cornmeal mix,** at Lancaster, Dist. S.C.
Charged on or about 8-29-66: while held by Plyler Wholesale Co., Lancaster, S.C., the articles contained insect filth, and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. **(9)**

Noodles, rice and grits, at Chester, Dist. S.C.
Charged on or about 9-1-66: while held by Thomas & Howard Co., Inc., Chester, S.C., the articles contained insect filth, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. **(10)**

Onions, pickled, and **olives, stuffed,** at Lindsay, S. Dist. Calif.
Charged 11-30-65: while held by V. R. Smith Olive Co., Inc., Lindsay, Calif., the articles contained insect filth, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to V. R. Smith Olive Co., Inc., for salvaging. **(11)**

Pecan pieces, Fiesta Brand, at Los Angeles, S. Dist. Calif.
Charged 2-24-66: when shipped by D. McCrea & Son, Inc., Yancey, Tex., the article contained E. coli, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for reconditioning. **(12)**

Perch fillets, frozen, Taste O'Sea, at Gloucester, Dist. Mass.
Charged 7-11-66: when shipped by O'Donnell-Usen Fisheries Corp., Portland, Maine, the article contained parasitic copepods; 402(a)(3). Default decree ordered destruction or donation to public/charitable institution for use as animal feed. **(13)**

Pies, turkey, Manor House, at Kansas City, Dist. Kans.
Charged 5-13-66: when shipped by Ocoma Foods Co., Humboldt, Tenn., the article labeled "Manor House . . . Turkey Pie . . . Packed for Safeway Stores Inc." contained staphylococci and bacterial filth; 402(a)(3). Default decree ordered destruction. **(14)**

Pizza crusts, at Jacksonville, M. Dist. Fla.
Charged 5-3-66: while held by Original Crispy Pizza Crust Co. of Jacksonville, the article, manufactured in part from flour shipped in interstate commerce, contained insect filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. **(15)**

Poppyseed, at New York, S. Dist. N.Y.
Charged 10-10-66: while held by Port Warehouse, Inc., New York, N.Y., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Joseph A. Zaloom & Co., Inc., New York, N.Y., for salvaging. **(16)**

Rice, at Charleston, Dist. S.C.
Charged on or about 11-8-66: while held by Robert Kahn Wholesale Grocers, Inc., Charleston, S.C., the article contained insect and rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. **(17)**

Shrimp, breaded, frozen, at Des Moines, S. Dist. Iowa.
Charged 11-4-66: when shipped by Booth Fisheries Corp., Brownsville, Tex., the article contained E. coli, coagulase positive staphylococci, and other bacterial filth, and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. **(18)**

Shrimp, frozen, at Somerville, Dist. Mass.
Charged 4-11-66: when shipped by American Export Isbrandtsen Lines, Inc., Boston, Mass., the article labeled "Red Shrimp . . . Packed by Crustaceos de Andalucia Cadiz Spain" contained decomposed shrimp; 402(a)(3). Consent decree authorized release to Slade Gorton & Co., Inc., Boston, Mass., for export to original supplier. **(19)**

Spaghetti, canned, at Cambridge, Dist. Mass.
Charged 4-13-66: while held for sale, the article contained a decomposed substance; 402(a)(3). Default decree ordered destruction or donation to public/charitable institution for use as animal feed. **(20)**

Tomatoes, canned, Lulu Brand, at Norfolk, E. Dist. Va.
Charged on or about 8-5-66: when shipped by W. T. Onley Canning Co., Inc., Snow Hill, Md., the label lacked the place of business of the distributor; and, while held for sale, the article contained a decomposed substance; 403(e)(1), 402(a)(3). Default decree ordered destruction. **(21)**

DRUGS / Human Use

Acecoline acetylcholine chloride ampuls, at Marion, N. Dist. Ohio.
Charged 12-15-64: while held by American French Drug Co., Marion, Ohio, the dealer's accompanying labeling contained false and misleading therapeutic claims; 502(a). Default decree ordered destruction. **(22)**

Aceto-Cort hydrocortisone combination tablets, at Beecher, N. Dist. Ill.
Charged 6-16-66: when shipped by Mallard, Inc., Detroit, Mich., the article's strength was deficient (approx. 48 percent); 501(c). Default decree ordered destruction. **(23)**

Alergimist intranasal solutions A and B, 7 seizure actions at Fort Washington and Philadelphia, E. Dist. Pa., Atlanta, N. Dist. Ga., Washington, Dist. Columbia, Dallas, N. Dist. Tex., and Wilmington, E. Dist. N.C.
Charged between 6-22-65 and 11-9-65: when shipped by Brunson Corp., Miami Springs, Fla., the articles were new drugs without effective New Drug Applications; 505(a). Default decree ordered destruction. **(24)**

at Wichita Falls, N. Dist. Tex.
Charged 6-7-66: when shipped by Brunson Corp., Miami Springs, Fla., the articles were new drugs without effective New Drug Applications; 505(a). Default decree ordered destruction. **(25)**

at Dallas, N. Dist. Tex.
Charged 5-4-66: when shipped by Brunson Corp., Miami Springs, Fla., the articles were new drugs without effective New Drug Applications; 505(a). Default decree ordered destruction. **(26)**

Alfa-Lite alfalfa-extract tablets, at Forest, S. Dist. Miss.
Charged 6-28-62: while held by Pasco Products, Inc., Forest, Miss., the labeling of the article contained false and misleading therapeutic claims for arthritis and rheumatism; 502(a). Upon the Government's subsequent motion for summary judgment, the court said in part:

"The only question is as to whether or not Alfa-Lite will do what its manufacturer claims for it. All of the scientific men say that the Alfa-Lite pill is worthless. The lawyer who sells it and several of his lay customers who have taken these pills say that these pills will cure, or help in the relief of arthritis sufferers. Neither the lawyer nor his customers can qualify under universal rules of evidence as expert witnesses on this subjest. Even a doctor of medicine would not be competent to so testify merely from his personal experience.

"Rule 56 required the defendant to come forward now with his proof, or with a showing which would excuse it under the rules, and show that there is a genuine issue as to the value of this medicine as a cure or as beneficial to a sufferer of arthritis. The defendant's response to the motion in this case does not repel the thrust of the motion with any substantial competent evidence to disentitle the movant to judgment. The defendant's jury arguments in his affidavit contain many interesting contentions, but fail to meet the test indicated. The motion for summary judgment will be sustained and a judgment accordingly may be presented."

The decision of the district court was affirmed per curiam by the Fifth Circuit Court of Appeals, 338 F 2d 699 (1964). **(27)**

Amidotal tablets, Special Aminopyrine Formula, at Norristown, E. Dist. Pa.
Charged 6-16-64: when shipped by Cowley Pharmaceuticals, Inc., Auburn, Mass., and while held for sale after being labeled with an additional label by Devon Pharmacal Co., Ambler, Pa., the labeling of the article lacked adequate directions and information for intended uses; the article was dangerous to health when used as directed in its labeling, and the article was a new drug without an effective New Drug Application; 505(a), 502(f)(1), 502(j). Default decree ordered destruction. **(28)**

Amphetamine tablets and **capsules,** at Rock Island, S. Dist. Ill.
Charged 12-2-64: while held by Donald G. Serres, the labeling of the articles failed to bear adequate directions for use and the articles were not exempt therefrom; 502(f)(1). Default decree ordered the articles retained by U. S. Marshal for exhibit purposes. **(29)**

Ashley Springs mineral water, at Lafayette, W. Dist. La.
Charged 7-8-65: when shipped by Ashley Mineral Springs, Crossett, Ark., and while held by Paul Edwin Dronet, the accompanying leaflets furnished by the shipper and the cards prepared by the dealer contained false and misleading therapeutic claims; 502(a). Default decree ordered destruction. **(30)**

Atropine sulfate ophthalmic solution, at San Jose, N. Dist. Calif.
Charged 6-20-66: while held for sale, the article was short in volume (approx. 18 percent); 502(b)(2). Default decree ordered destruction. **(31)**

Cutracin extract cucurbitaceae, at Garden City, E. Dist. N.Y.
Charged 3-30-64: when shipped by Orange Crystal Div., Plant Industries, Inc., Plant City, Fla., the article was a new drug without an effective New Drug Application; 505(a). Consent decree ordered destruction. **(32)**

Desoxyephedrine hydrochloride tablets and **dextro-amphetamine sulfate tablets,** 2 seizure actions at East Ridge, E. Dist. Tenn.
Charged 4-28-66 and 5-2-66: while held by Calhoun Pharmacy, East Ridge, Tenn., the labeling lacked adequate directions for use and was not exempt therefrom, since the articles were not being dispensed upon prescription; 502(f)(1). Default decree ordered destruction. **(33)**

Dextro-amphetamine sulfate tablets, and other amphetamine tablets and capsules, at Rockford, N. Dist. Ill.
Charged 8-6-64: while held by Richard C. Trank, the labeling of the articles lacked adequate directions for use and the articles were not exempt therefrom; 502(f)(1). Default decree authorized delivery to FDA. **(34)**

Meprobamate tablets, U.S.P., at Baltimore, Dist. Md.
Charged 5-27-66: when shipped by Riverton Labs., Inc., Newark, N.J., the article was a new drug without an effective New Drug Application, and conditions of its manufacture, processing, packing, and holding lacked conformity with current good manufacturing practice; 505(a), 501(a)(2)(B). Default decree ordered destruction. **(35)**

Meprobamate tablets, U.S.P., at Battle Creek, W. Dist. Mich.
Charged 5-23-66: when shipped by Riverton Labs., Inc., Newark, N.J., the article was a new drug without an effective New Drug Application, and the article had been manufactured, processed, packed, and held under conditions lacking good manufacturing practice; 505(a), 501(a)(2)(B). Default decree ordered destruction. **(36)**

Meprobamate tablets, U.S.P., at Philadelphia, E. Dist. Pa.
Charged 5-17-66: when shipped by Riverton Labs., Inc., Newark, N.J., the article was a new drug without an effective New Drug Application, and the circumstances of its processing, packing, and holding lacked conformity to current good manufacturing practice; 505(a), 502(a)(2)(B). Default decree ordered destruction. **(37)**

Papavtral L-A pentaerythritol tetranitrate capsules, at Stamford, Dist. Conn.
Charged 2-15-66: when shipped by Kenwood Labs., Inc., New Rochelle, N.Y., the article was a new drug without an effective New Drug Application; 505(a). Default decree ordered destruction. **(38)**

Pollenets tablets, at Tenafly, Dist. N.J.
Charged on or about 4-25-66: while held, after being packed and labeled in part by Chem-Aid, Inc., Hackensack, N.J., the article labeled in part, "Pollenets . . . immunization from allergic disorders . . . Bradley Laboratories, Inc., Hackensack, N.J.," had labeling which contained false and misleading therapeutic claims, and which lacked adequate directions for use; 502(a), 502(f)(1). Default decree ordered destruction. **(39)**

Quinidine sulfate tablets, U.S.P., at Gardena, S. Dist. Calif.
Charged 5-24-66: while held by S. O. Barnes & Son, Inc., Gardena, Calif., who packed and labeled the article from bulk, the quality of the article was deficient, since a mixture of quinidine sulfate tablets, niacinamide tablets, and niacin tablets had been substituted for the article; 501(b), 501(d)(2). Default decree ordered destruction. **(40)**

Quinidine sulfate tablets, U.S.P., at Gardena, S. Dist. Calif.
Charged 6-6-66: while held for sale, the quality of the article was deficient and the labeling was false and misleading, since niacin and niacinamide tablets had been substituted in part for quinidine sulfate tablets; 501(b), 502(a), 501(d)(2). Default decree ordered destruction. **(41)**

Quinidine sulfate tablets, U.S.P., at Long Beach, S. Dist. Calif.
Charged 6-8-66: while held for sale, the article's quality was deficient, and label statements "Quinidine Sulfate U.S.P." were false and misleading, since niacin tablets had been substituted in part for the article; 501(b), 502(a), 501(d)(2). Default decree ordered destruction. **(42)**

Quinine sulfate, N.F., at Memphis, W. Dist. Tenn.
Charged 3-16-65: when shipped by Wesley Laboratories, Inc., and by Stanley Blackman Laboratories, Inc. (Div. of Wesley Laboratories, Inc.), South Hackensack, N.J., the purity of the article was deficient and the claim of National Formulary conformity was false and misleading, since the article contained metal fragments, wood chips, and hairs; 501(b), 502(a), 501(a). Consent decree authorized release to Stanley Blackman Laboratories, Inc., for reconditioning. **(43)**

Quinine sulfate, N.F., at South Hackensack, Dist. N.J.
Charged 4-7-65: while held for sale, the article lacked purity and its labeling was false and misleading as to claim of National Formulary conformity, since the article contained extraneous material, including wood splinters, and metal and insect fragments; 501(b), 502(a), 501(a). Consent decree authorized release to Stanley Blackman Laboratories, Inc., for reconditioning. **(44)**

Quinine sulfate capsules, N.F., at Gardena, S. Dist. Calif.
Charged 6-20-66: while held for sale, the quality of the article was deficient, and the labeling false and misleading, since capsules containing calcium, phosphate, and starch had been substituted in part for the article; 501(b), 502(a), 501(d)(2). Default decree ordered destruction. **(45)**

Silicote dimethicone liquid skin spray, at Washington, Dist. Columbia.
Charged 5-2-66: when shipped by Arnar-Stone Labs., Mount Prospect, Ill., the article was a new drug without an effective New Drug Application; 505(a). Default decree ordered destruction. **(46)**

Spanish Fortify wheat germ oil capsules, at Belton, W. Dist. Mo.
Charged 5-16-66: while held by Belton Dietary Foods Clinic, Belton, Mo., who packed and labeled the article, its labeling contained false and misleading claims for sex rejuvenation and stimulation; and its labeling lacked adequate direction for use for such purposes; 502(a), 502(f)(1). Default decree ordered destruction. **(47)**

MEDICAL DEVICES

Beautiator electrical manicurist device, at Phoenix, Dist. Ariz.
Charged 3-16-66: when shipped by Abar Manufacturing Co., Cleveland, Ohio, the accompanying booklet contained false and misleading therapeutic claims; 502(a). Default decree ordered destruction. **(48)**

Contour chair, heating and vibrating, at Seattle, W. Dist. Wash.
Charged 5-26-64: while held by Finch's Contour Chairs, Seattle, Wash., the accompanying leaflets, folders, and reprints prepared by the dealer, contained false and misleading therapeutic representations; 502(a). Consent decree authorized release to Loran W. Finch, t/a both Loran W. Finch Co. and Finch's Contour Chairs, for relabeling. **(49)**

Hi-Dro Whirlpool bath aerator, at Dearborn, E. Dist. Mich.
Charged 3-15-65: when shipped by Hi-Dro Whirlpool Bath Co., St. Louis, Mo., and while held by Hi-Dro Whirlpool Co., Dearborn, Mich., the accompanying booklets of the shipper and the accompanying business reply cards, posters, and newspaper reprints prepared by the dealer, contained false and misleading therapeutic representations; 502(a). Consent decree authorized release to Brian G. Fry, Bellevue, Mich., for relabeling. **(50)**

Kirby sanitronic VII vacuum cleaner, at Fresno, S. Dist. Calif.
Charged 4-26-65: while held by Kirby Co., Fresno, Calif., the labeling lacked adequate directions for the therapeutic uses for which the device was offered by Martin Claspill, dealer representative; 502(f)(1). Default decree authorized release to FDA. **(51)**

Spine-Ease spine-stretching device, at Ogden, Dist. Utah.
Charged 5-6-66: when shipped by Bert Lowry, Los Angeles, Calif., the labeling lacked adequate directions for use and was not exempted therefrom as a prescription device, since it lacked required compliance therefor; 502(f)(1). Default decree authorized release to FDA. **(52)**

Teething ring, water filled, at Baltimore, Dist. Md.
Charged 9-30-65: when shipped by Nippy Manufacturing Co., Inc., Jamaica, N.Y., the article contained mold; 501(a)(1). Default decree ordered destruction. **(53)**

Teething ring, water filled, at Baltimore, Dist. Md.
Charged 1-11-66: when shipped by Crib Mates, Div. of Formulette Co., Inc., Long Island City, N.Y., the purity and quality of the article was deficient and the label false and misleading as to sterility, since the water contained viable micro-organisms; 501(c), 502(a). Default decree ordered destruction.. **(54)**

Teething ring, water filled, at East Hanover, Dist. N.J.
Charged 1-27-66: when shipped by Crib Mates, Div. of Formulette Co., Inc., Long Island City, N.Y., the purity and quality of the article was deficient and the label false and misleading as to sterility, since the article contained water with viable micro-organisms; 501(c), 502(a). Default decree ordered destruction. **(55)**

Vacuum cleaner, at Sacramento and Yuba City, N. Dist. Calif.
Charged 4-6-65: while held by Motherlode Enterprises, Sacramento, Calif., the labeling lacked adequate directions for use for the therapeutic purposes for which the device was offered by Robert Ayers and Richard Story, dealer sales representatives; 502(f)(1). Consent decree authorized release to dealer for relabeling. **(56)**

PROPHYLACTICS

Rubber prophylactics, Derbies, at Dallas, N. Dist. Tex.
Charged 6-11-65: when shipped by National Hygienic Products Corp., Akron, Ohio, the quality of the article was deficient and the labeling false and misleading, since the article contained holes (approx. 1.5 percent); 501(c), 502(a). Default decree ordered destruction. **(57)**

Rubber prophylactics, Peacocks, at St. Paul, Dist. Minn.
Charged 9-24-65: when shipped by Dean Rubber Manufacturing Co., North Kansas City, Mo., the quality of the article was deficient, since it contained holes (approx. 1.6 percent); 501(c). Default decree ordered destruction. **(58)**

Rubber prophylactics, Prime With SK-70, at Baltimore, Dist. Md.
Charged 8-2-65: when shipped by The Akwell Corp., Akron, Ohio, the quality of the article was deficient, since it contained holes (approx. 0.8 percent); 501(c). Default decree ordered a number turned over to Chief Sales Co., Baltimore, Md., for testing and research only, and the remainder destroyed. **(59)**

Rubber prophylactics, Romeos, at San Francisco, N. Dist. Calif.
Charged 10-7-65: when shipped by National Hygienic Products Corp., Akron, Ohio, the article was deficient, since it contained holes (the bulk lot approx. 1.5 percent and the packaged lot approx. 4 percent); 501(c). Default decree ordered destruction. **(60)**

Rubber prophylactics, Royal Marquis and **Tops,** at Chicago, N. Dist. Ill.
Charged 12-16-65: when shipped by M & M Rubber Co., Kansas City, Mo., the articles were deficient and the labeling false and misleading, since they contained holes (approx. 0.9 percent); 501(c), 502(a). Default decree ordered destruction. **(61)**

HAZARDOUS SUBSTANCES

Airflam lighter fluid and **Airflam cigarette lighter,** at Chicago, N. Dist. Ill.
Charged 1-28-66: when shipped by Murphy-Reier, Inc., Barrington, Ill., to Van Nuys, Calif., and while held after return to Chicago, Ill., the articles were or contained a flammable toxic substance presenting special hazards due to methyl alcohol content (99.5 percent), and the container labels and accompanying literature lacked required conspicuous label statements; 2(p)(1)(F,G,I&J), 2(n)(1)(B,E,F,G,I&J), 2(n)(2)(A,B,E,F,G,I&J), 3(b). Default decree ordered destruction. **(62)**

Antifreeze, glycol type and **methanol type,** 2 seizure actions at Sedalia and Columbia, W. Dist. Mo.
Charged 11-27-64: while held by Midwest Auto Stores, Sedalia and Columbia, Mo., the articles were toxic substances presenting special hazards due to ethylene glycol content (approx. 54 percent or more) and methyl alcohol content (approx. 92 percent), and their containers lacked required conspicuous label statements; and the articles had been packed by the dealer into re-used food bottles; glycol type, 2(p)(1)(A,F,G&J), 3(b), 4(f); methanol type type 2(p)(1), (A,B,E,F,G,I&J), 3(b), 4(f). **(63)**

Cracker Ball ball-type explosive caps, 5 seizure actions at San Antonio, W. Dist. Tex., Spartanburg and Dillon, W. Dist. S.C., Albuquerque, Dist. N. Mex., Sioux Falls, Dist. S. Dak., and Shreveport, W. Dist. La.
Charged between 2-1-65 and 6-15-65: when shipped by Sanyu Co., Ltd., Shizuoka, Japan, S. Mantsuna & Co., Ltd., Yokohama, Japan, Onda Enterprises, Ltd., Tokyo, Japan, Nan Sing Hand Fireworks, from Taiwan and unknown shippers in Japan and Taiwan, the articles were extremely flammable solid substances that generated pressure through explosion when subjected to friction or to percussion, and their containers lacked required conspicuous label statements; 2(p)(1)(A,C,E,F,I&J). Default decree in W. Dist. S.C., and consent decree in W. Dist. Tex., ordered destruction. Consent decrees in Dist. N. Mex., Dist. S. Dak., and W. Dist. La., authorized release to Liddell Fireworks Co., Shreveport, La., F & S Co., Inc., Albuquerque, N. Mex., and Rich Brothers Co., Sioux Falls, S. Dak., for export. In addition, in the cases of the claimants, Liddell Fireworks Co., F & S Co., Inc., and Rich Brothers Co., it was ordered that such claimants be enjoined from introducing into interstate commerce any hazardous substance called by the name "Cracker Balls," or "Ball-type caps," or by any other name, which are irregularly shaped spheres of paper (or similar substances) which contain an explosive material that generates pressure and explodes when subjected to percussion or friction, and which is extremely flammable, unless the immediate container is conspicuously labeled with certain specified consumer protection information. **(64).**

Dry cleaning fluid, at Kansas City, W. Dist. Mo.
Charged 6-27-63: when shipped by Western Oh-Zo-Dry Co., Tonganoxie, Kans., the article labeled in part, "Famous Parkview Special French Dry Cleaner . . . Made Especially for Parkview Drugs, Kansas City," was a flammable and toxic substance presenting special hazards due to its petroleum distillate (Stoddard solvent) content, and its containers lacked required conspicuous label statements; 2(p)(1)(B,C,E,G&J). Consent decree authorized release to Parkview Drugs, Inc., Kansas City, Mo., for relabeling. **(65)**

Peace Bird toy, 2 seizure actions, at Denver, Dist. Colo.
Charged 10-23-63 and 12-2-63: when shipped by United Trading Co., Yokohama, Japan, the article contained a highly flammable substance, diethyl ether, and it lacked required conspicuous label statements; 2(p)(1)(A,B,C,E,F,I&J). Consent decree authorized release to Western Novelty Co., Denver Colo., for relabeling. **(66)**

Peace Bird toy, at Richfield, Dist. Utah.
Charged 12-9-63: when shipped by Western Novelty Co., Denver, Colo., the article contained a highly flammable substance, diethyl ether, and it lacked required conspicuous label statements; 2(p)(1)(A,B,C,E,F,I&J). Default decree ordered destruction. **(67)**

Peace Bird toy, at Omaha, Dist. Nebr.
Charged on or about 5-7-64: when shipped by Frank P. Dow Co., Inc., Seattle, Wash., the article contained a highly flammable substance, diethyl ether, and it lacked required conspicuous label statements; 2(p)(1)(A,B,C,E,F,I&J). Consent decree authorized release to Oriental Trading Co., Omaha, Nebr., for relabeling. **(68)**

Turpentine, at Cincinnati, S. Dist. Ohio.
Charged 1-7-63: while held by Amsco Solvents & Chemicals Co. (subsidiary of Central Solvents & Chemical Corp.), Cincinnati, Ohio, the article repacked from bulk by the dealer was a toxic substance presenting a special hazard and its containers lacked required conspicuous label statements; 2(p)(1)(C,E,F&G). Consent decree authorized release to dealer for relabeling. Thereafter, Government moved for forfeiture of dealer's bond due to relabeling without Government supervision. Dealer made direct payment to the Government for the amount of the bond and forfeiture motion was dismissed. **(69)**

NOTICES OF JUDGMENT on Criminal Cases

FOOD

Economy Stores, Inc., Norfolk, E. Dist. Va.
Charged 7-8-66: pancake mix, flour, and cornmeal, were held in a building accessible to rodents, and contaminated with rodent filth; 402(a)(3), 402(a)(4). Nolo contendere plea; fine. **(70)**

Koehler Food Co., Inc., Indianapolis, S. Dist. Ind.
Charged 9-7-66: flour, cocoa mix, waffle mix, muffin mix, and sweet dough mix, were held in a building accessible to rodents and insects, and contaminated with insect and rodent filth; 402(a)(3), 402(a)(4). Nolo contendere plea; fine, plus costs. **(71)**

Port Stockton Food Distributors, Inc., and **Joseph L. Tackel,** president, Stockton, N. Dist. Calif.
Charged 9-26-66: green split peas were held in a building accessible to rodents and contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Guilty plea by individual; probation. **(72)**

Sherwood Candy Co., partnership, and **Albert J. Plunkett,** partner, Atlanta, N. Dist. Ga.
Charged 11-10-66: shelled peanuts and bulk corn syrup were held in a building accessible to rodents and insects and contaminated with rodent and insect filth; 402(a)(3), 402(a)(4). Nolo contendere pleas; fines. **(73)**

D. C. Renner Wholesale, and **Hazel R. Richards,** partner, at Cleveland, E. Dist. Tenn.
Charged 10-11-66: cheese pizza mix, bran cereal, sausage pizza mix, popcorn, and egg noodles, were held in a building accessible to insects and contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty pleas; fine. **(74)**

C. W. Traeger Wholesale Grocer, and **Olivia S. Traeger** and **C. Winston Traeger, Jr.,** partners, Seguin, W. Dist. Tex.
Charged 7-6-66: flour was held in a building accessible to rodents and insects, and was contaminated with rodent and insect filth; 402(a)(3), 402(a)(4). Guilty plea by partnership; fine. Guilty pleas by partners; fines **suspended. (75)**

DRUGS

Heather Ann Alford, Los Angeles, S. Dist. Calif.
Charged 10-20-65: while held for sale, amphetamine sulfate tablets were dispensed in unlabeled paper bags without a prescription; 502(b)(1&2), 502(e)(1), 502(f)(1&2), 503(b)(1), 503(b)(4). Guilty plea; fine and probation. **(76)**

Harold S. Blume, t/a Blume Pharmacy, and **Wayne A. Andrews,** pharmacist, South Bend, N. Dist. Ind.
Charged 9-15-66: penicillin tablets and Equanil tablets were dispensed as unauthorized refills; 503(b)(1). Guilty plea by Blume; fine, plus costs. Guilty plea by Andrews; fine. **(77)**

Jimmy Lee Buckner, truck driver, Madison County, W. Dist. N.C.
Charged 11-3-65: capsules of dextro-amphetamine sulfate and amobarbital were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment suspended, fine and probation. **(78)**

Cargill, Inc., t/a Nutrena Mills Div. of Cargill, Inc., East St. Louis, E. Dist. Ill.
Charged 9-27-65: when shipped, the strength of Nutrena Medicated Pre-Shoat-38 concentrate and Nutrena Medicated Pig-16 pellets differed from that claimed; the labeling of the articles was false and misleading as to chlortetracycline and penicillin content and as to adequacy and effectiveness as a treatment for various swine diseases; and the articles contained some of the above antibiotics but were not exempt from batches certification, since when mixed as directed the finished swine feed prepared therefrom would be deficient; 501(c), 502(a), 502(1). Guilty plea; fine and costs. **(79)**

Robert T. Conner, director of a New Jersey pharmaceutical laboratory, Dist. Columbia.
Charged 11-8-65: when shipped, the labeling of Dornwal (amphenidone) tablets lacked adequate warnings, since it lacked warnings as to duration of administration, and lacked precautions regarding possible adverse and toxic reactions of agranulocytosis associated with the use of Dornwal therapy in humans; 502(f)(2). Guilty plea; probation. **(80)**

Garden Laboratories, Inc., West New York, Dist. N.J.
Charged 9-16-63: when shipped, the labeling of three amphetamine-type drugs and of sodium pentobarbital capsules lacked adequate directions for use and were not exempt therefrom as prescription drugs, since they were shipped to a dealer not regularly and lawfully dealing in prescription drugs; and the articles were dispensed without a prescription; 502(f)(1), 503(b)(1). Guilty plea; fine. **(81)**

Wilbur Graham Fisher, M.D., Columbus, S. Dist. Ohio.
Charged 4-25-66: dextro-methamphetamine hydrochloride tablets were dispensed without a prescription; 503(b)(1). Guilty plea; probation and fine. **(82)**

James Leo Lanham, at Pine Hill, E. Dist. Ky.
Charged 5-31-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment. **(83)**

Goff P. Lilly, M.D., Charleston, S. Dist. W. Va.
Charged 4-5-66: methamphetamine-combination capsules were dispensed without a prescription; 503(b)(1). Nolo contendre plea; probation and fine. **(84)**

David S. Macklin, pharmacist, Lombard, N. Dist. Ill.
Charged 5-12-66: Preludin tablets were dispensed without a prescription, and Dexedrine tablets and Prednisone tablets were dispensed as unauthorized refills; 503(b)(1). Nolo contendere plea; fine, plus costs. **(85)**

Wm. S. Merrell Co. and **Richardson-Merrell, Inc.,** of Cincinnati, Ohio, and **William M. King, Evert F. Van Maanen,** and **Harold W. Werner,** toxicology and research officials of **Wm. S. Merrell Co.,** at Washington, Dist. Columbia.
Charged 12-21-63 by grand jury: in connection with a New Drug Application for MER/29 (Triparanol) and amendments thereto, false material statements and entries were wilfully made and material facts were wilfully concealed, in the submission of various communications with FDA in Washington, D.C., concerning animal studies using the drug that showed corneal opacities, deaths of experimental animals, serious abnormal blood changes, gonadal and ovarian abnormalities, and other adverse information; 18 U.S.C. 1001. Nolo contendere pleas by corporations; fines. Nolo contendere pleas by individuals; probation. **(86)**

Jimmy W. Mitchell, Lily, E. Dist. Ky.
Charged 5-31-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment. **(87)**

Pharmadent Co., and **Erwin J. Franke, Jr.,** partner, Lake Jackson, S. Dist. Tex.
Charged 9-19-66 by grand jury: when shipped, prednisolone desensitizing solution was a new drug without an effective New Drug Application; 505(a). Not guilty pleas. After trial by court and jury, verdict of guilty; partnership and individual were fined. **(88)**

Albert H. Pollack, pharmacist, Chicago, N. Dist. Ill.
Charged 6-9-66: when shipped, the labeling of some dextro-amphetamine sulfate capsules lacked adequate directions for use and were dispensed without a prescription; and while held for sale, some dextro-amphetamine sulfate capsules and phenylbutazone tablets were dispensed without a prescription; 502(f)(1), 503(b)(1). Guilty plea; fine, plus costs and probation. **(89)**

Francis A. Riley, t/a Greenwood Pharmacy, and **Anna L. Woulfe,** pharmacist, Warwick, Dist. R.I.
Charged 12-6-65: Miltown tablets were dispensed as unauthorized refills; 503(b)(1). Guilty pleas; fines. **(90)**

Bennett A. Robin, M.D., of Silver Spring, Md., at Washington, Dist. Columbia.
Charged 10-3-63 by grand jury: in connection with New Drug Applications for Entoquel with neomycin syrup, Rynadyne, Naquival (also known as CMR-807), Linodil (WIN 9154), and Tigan Hydrochloride, false material statements and entries about clinical tests of such drugs were used and filed with FDA in Washington, D.C., and in such statements and entries, the defendant wilfully and falsely caused to be represented that clinical tests had been made by him, when he had not made such tests; 18 U.S.C. 1001. Nolo contendere plea; imprisonment suspended, fine, and probation. **(91)**

Success Chemical Co., Inc., Brooklyn, E. Dist. N.Y.
Charged 10-3-63: when shipped, hydrocortisone tablets (Count I) and quinidine sulfate tablets (Count IV) differed from U.S.P. Standards; the strength of ergotamine with caffeine tablets (Count II) differed from that claimed for the article; and the label of ergotamine tartrate tablets (Count III) was false and misleading as to content; 501(b), 501(c), 502(a).
After an initial plea of not guilty, the defendant moved for election of counts, and for a bill of particulars. The particulars sought related to the mechanical details of all three shipments and the dates when the Government tested the drugs; they related, separately for each shipment, also to the precise chemical data.
The court found that the requested particulars concerning the shipment of each drug had no evident relevancy, were not said to be a matter of uncertainty, and, if supplied, would not apparently assist in defining the issue or facilitating the defense. Since the challenged shipments were alleged to have been made 4 years before, it was found that information as to when the Government tested drugs should be furnished. Precise chemical data including a range of quantities (although not necessarily a particular test amount) which would indicate what the Government meant to show and to claim was violative of the law were also to be furnished.
The court found that an election between adulteration and misbranding counts was not required, and said that to compel an election would create a theoretical risk that some unanticipated development of facts might make necessary a resort to the word that the election had taken out of the case.
Thereafter, the defendant pleaded nolo contendere to Counts II and III and was fined. Upon motion of the Government, Counts I and IV were dismissed. **(92)**

Antonio Trevino, Brownsville, S. Dist. Tex.
Charged 9-16-66 by grand jury: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment suspended, fine, and probation. **(93)**

Universal Nutritions, Inc., Supro-Zyme, Inc., and **Emanuel Fred,** president of both corporations, at New York, S. Dist. N.Y.
Charged 9-6-60: when shipped, Supro-Zyme Improved tablets and Improved Formula Neo-Hemo Plus Sorbitol tablets had labeling which was false and misleading and which lacked adequate directions for use; 502(a), 502(f)(1). Guilty pleas by corporations; fines. Guilty plea by individual; imprisonment suspended and probation. **(94)**

Veva Enterprises Health Food Store, a partnership, and **Barbara J. Hill,** partner, Denver, Dist. Colo.
Charged 3-14-66: tablets labeled "Enzymatic Digestant prepared for Veva Enterprises" were offered for sale and sold as a drug for use in the treatment of various conditions for which the article's labeling lacked adequate directions for use; 502(f)(1). Guilty pleas; probations. **(95)**

Wallace Laboratories, Div. of Carter-Wallace, Inc., Cranbury, Dist. N.J.
Charged 8-5-65: when Pree MT meprobamate-combination tablets were shipped, advertisements for the article lacked information relating to side effects and contraindications; 502(n). Nolo contendere plea; fine. **(96)**

Wallace & Tiernan, Inc., of Belleville, N.J., and **Charles E. Hough,** medical director, at Washington, Dist. Columbia.
Charged 8-24-64 by grand jury: in connection with a Supplemental New Drug Application for Dornwal (amphenidone) tablets, material facts were wilfully concealed and false material statements were wilfully made in the submission of various communications with FDA in Washington, D.C., showing no serious adverse and toxic side effects attributable to Dornwal, when the defendants knew of a number of reports associating agranulocytosis with the administration of Dornwal; 18 U.S.C. 1001. After dismissal of indictment on the ground that the special grand jury had been illegally constituted because it had been called by the presiding judge of the district court instead of the chief judge (234 F. Supp. 780), the case was appealed and the Court of Appeals reversed the lower court (349 F. 2d 222). Thereafter, nolo contendere plea by corporation; fine. Nolo contendere plea by individual; probation. **(97)**

James Sam Williams and **David Smith,** truck drivers, Chillicothe and Columbus, S. Dist. Ohio.
Charged on or about 9-12-66: capsules of dextro-amphetamine sulfate with amobarbital were delivered for introduction into interstate commerce, which capsules were in unlabeled bottles and were dispensed without a prescription; 502(b)(1&2), 502(e)(1)(A)(i), 502(f)(1), 503(b)(1)(B). Guilty pleas by both defendants. The case transferred to Greensboro, M. Dist. N.C. Williams; imprisonment, probation. Smith; imprisonment suspended, probation. **(98)**

INJUNCTION ACTIONS

Ernst T. Krebs, Sr., M.D., t/a Krebs Laboratories, San Francisco, N. Dist. Calif.
Charged 5-3-65 in a complaint for injunction: that the defendant was engaged in the business of manufacturing, processing, packing, labeling, promoting, selling, and distributing in interstate commerce, Laetrile, a new drug for which no approval of an application filed pursuant to law was effective; and that the defendant owned and operated an establishment at San Francisco, Calif., which was engaged in the manufacture, preparation, propagation, compounding, and processing of drugs;
That Laetrile was a new drug in that the composition of it was such that it was not generally recognized, among qualified experts, as safe and effective for use as labeled, i.e., for the prevention, treatment, and cure of cancer of all kinds, for raising hemoglobin index and red count, and for relieving pain due to malignancy; and
That the defendant shipped in interstate commerce, Laetrile, without having an effective New Drug Application and failed to register with the Secretary of Health, Education, and Welfare, his name, place of business, and his drug processing establishment; 505(a), 510.

Thereafter, a temporary restraining order and a consent decree of permanent injunction were entered and the defendant was enjoined from doing the violative acts complained of.
Charged 1-7-66 in an information: the failure to register a drug processing establishment owned and operated between 1-9-64 and 12-23-64; 510. Guilty plea; probation.
Charged 6-16-66 as a violation of probation: the indirect shipment of Laetrile in interstate commerce from Los Angeles, Calif., for delivery to Lebanon, Oreg. Guilty plea; fine. **(99)**

Laurinburg Oil Co., t/a Maxton Oil & Fertilizer Co., McNair Evans, president, and **John D. Medlin,** vice president, Maxton, E. Dist. N.C.
Charged 5-9-63 in complaint for injunction: that the defendants operated a cottonseed oil plant at Maxton, N.C., and were preparing and distributing in interstate commerce, cottonseed oil prepared under insanitary conditions at that plant, that quantities of adulterated cottonseed oil on hand constituted a menace to interstate commerce, that the refining process was such that the oil soluble portions of insect, bird, and rodent filth remained in the cottonseed oil, and that the defendants were well aware that their activities were violative; 402(a)(4).
A preliminary injunction was entered which enjoined the interstate shipment of any cottonseed oil, cottonseed, and any similar article of human food, thereafter prepared or held at the Maxton plant until FDA inspected; which similarly enjoined any such shipment of any cottonseed oil, etc., thereafter held at the Laurinburg storage facilities for use at the Maxton plant unless and until such storage facilities were renovated; and which similarly enjoined violative shipment of cottonseed oil, etc., except that then on hand at the Maxton facility. After FDA inspection, the latter exception was deleted, the preliminary injunction was ordered made permanent, costs ordered against the defendants, and the action ordered dismissed. **(100)**

Notices of Judgment are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act and section 13 of the Federal Hazardous Substances Labeling Act. Notices of Judgment report cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizure proceedings are civil actions taken against **goods** alleged to be in violation, and criminal and injunction proceedings are against **firms** or **individuals** charged to be responsible for violations. The cases generally involve foods, drugs, devices, cosmetics, or hazardous substances which were alleged to be adulterated or misbranded or otherwise violative of the law when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce.
Published by direction of the Secretary of Health, Education, and Welfare.

JAMES L. GODDARD, *Commissioner of Food and Drugs.*
WASHINGTON, D.C., *May 1, 1967*

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FDA Fact Sheet

May 1967

NUTRITION NONSENSE - AND SENSE

American consumers enjoy a food supply that is unsurpassed in quantity, in variety, and in nutritional value. Americans, generally, have to go out of their way to avoid being well fed. Diet deficiency diseases are now almost unknown, and overweight instead of underweight has become one of our major health problems.

Yet, in this well-fed and, in many ways, well-informed country, a great deal of nonsense about food exists. Self-styled nutrition "experts" spread false ideas to undermine public confidence in the nutritional values of common foods. Their books and lectures are often designed to sell the "special" products they represent. James L. Goddard, M.D., Commissioner of the Food and Drug Administration, states it this way: "The woods are still as full of the same quacks and charlatans today as they were yesterday. They are still there, ready to prey upon the unsuspecting or frightened person who will fall for a short-cut to health."

The Dangerous Thirteen

Nutrition quacks and food faddists often make the following false claims:

CLAIM	FACT
1. You are what you eat.	In one sense, yes. You are also what heredity and environment have contributed. Health quacks often use this statement as an introduction to their twisted ideas about nutrition.
2. Our soil has lost its vitamins and minerals; our food crops have little nutritional value.	This is just not so. If plants will grow at all, they will have the vitamins and minerals that you need.
3. Chemical fertilizers are poisoning our soil.	Chemical fertilizers are not poisoning our soil. Modern fertilizers are needed to produce enough food for our increasing population.

CLAIM	FACT
4. Natural, organic fertilizers are not only safer than chemical fertilizers, but produce healthier crops.	Many American are being deluded into believing this falsehood. Organic fertilizers cannot be absorbed as such by plants. They must be broken down by bacteria in the soil until they finally become the same chemicals--nitrate and ammonium compounds--that are supplied directly and more quickly by modern chemical fertilizers.
5. Pesticides are poisoning our Nation.	When pesticides on food crops leave a residue, FDA makes sure the amount will be safe for consumers. The amount allowed, if any, is set at the lowest level that will accomplish the desired purpose, even though a larger amount might still be safe.
6. Modern processing removes most of the vitamins and minerals in foods; we are starving in the midst of plenty.	Dr. Goddard has often stated his views on this subject: "There are some food faddists and quacks who would have you believe the wildest stories about the depletion of our soil, the loss of food values because of modern processing techniques, and a lot of other nonsense. Frankly, it is time we faced the facts about our American diet. Our soil is naturally rich and the envy of every Nation. Our ability to grow, pack, ship, and sell food is a modern marvel because the natural value of the food is not lost in the process. In fact, the reverse is true: foods can get better in the process."
7. Aluminum cooking utensils are dangerous to health.	This falsehood has been peddled for many years. Aluminum is the third most abundant element in the earth's crust, and it occurs naturally in many foods. Cooking in aluminum utensils is harmless.
8. Cooking with Teflon-coated utensils is dangerous.	Careful testing of this commercial product has proved that no danger can come either from normal kitchen use or from overheating the utensil.

CLAIM	FACT
9. Modern preservatives are no more than dangerous embalming fluids.	Dangerous food preservatives were a major concern of the Food and Drug Administration when it began operations on January 1, 1907. Today's scientific knowledge, working through good laws to protect consumers, assures the safety and the wholesomeness of every component of our food supply.
10. If you have an ache or pain, or are just feeling tired, you are probably suffering from a subclinical deficiency.	"Subclinical deficiency" just means that there is nothing wrong with you that can be detected. Self-styled nutrition experts have used this term for years to persuade you to buy their books--and their vitamin and mineral products.
11. You have to eat special foods if you want to correct overweight or underweight.	If "special" foods mean any not available in a modern grocery store, the statement is not true. Your physician should prescribe any special diet you may need. Personal experimenting and fad diets can be highly dangerous to your health.
12. Synthetic vitamins are dead and ineffective; vitamins from natural sources are much more beneficial.	Vitamins are specific chemical compounds, and the human body does not care where they come from. The source makes no difference.
13. Everyone should take vitamins, just to be sure.	Dr. Goddard's reply to this statement is important to every American: "Very few of us regularly eat the same foods as our neighbors eat. There is some variation that makes our diet different from everyone else's. But we have enough variety so that the American consumer--whatever his age and whatever his financial condition--has an excellent chance of taking in the recommended daily requirements of vitamins and minerals through the foods he eats, <u>without</u> resorting to any of the dietary, multi-vitamin , or mineral supplements. This is not true for everyone. Some patients under doctor's care or in institutional situations need the food supplements. Some infants and small children with unstable digestive

systems may need food supplements, again on the advice of a physician. If your doctor feels you should alter your diet, he will tell you. Put your trust in him, rather than in a get-rich-quick food faker."

What Can You Do?

What can you do to protect yourself and your family from nutritional quackery?

Don't buy a product or alter your eating habits on impulse or from fear. Take enough time to ask yourself the following questions:

Does the promoter belittle normal foods? This is the first sign of nutritional quackery.

Does the product, or the person, promise or imply a quick correction for a condition you think you may have?

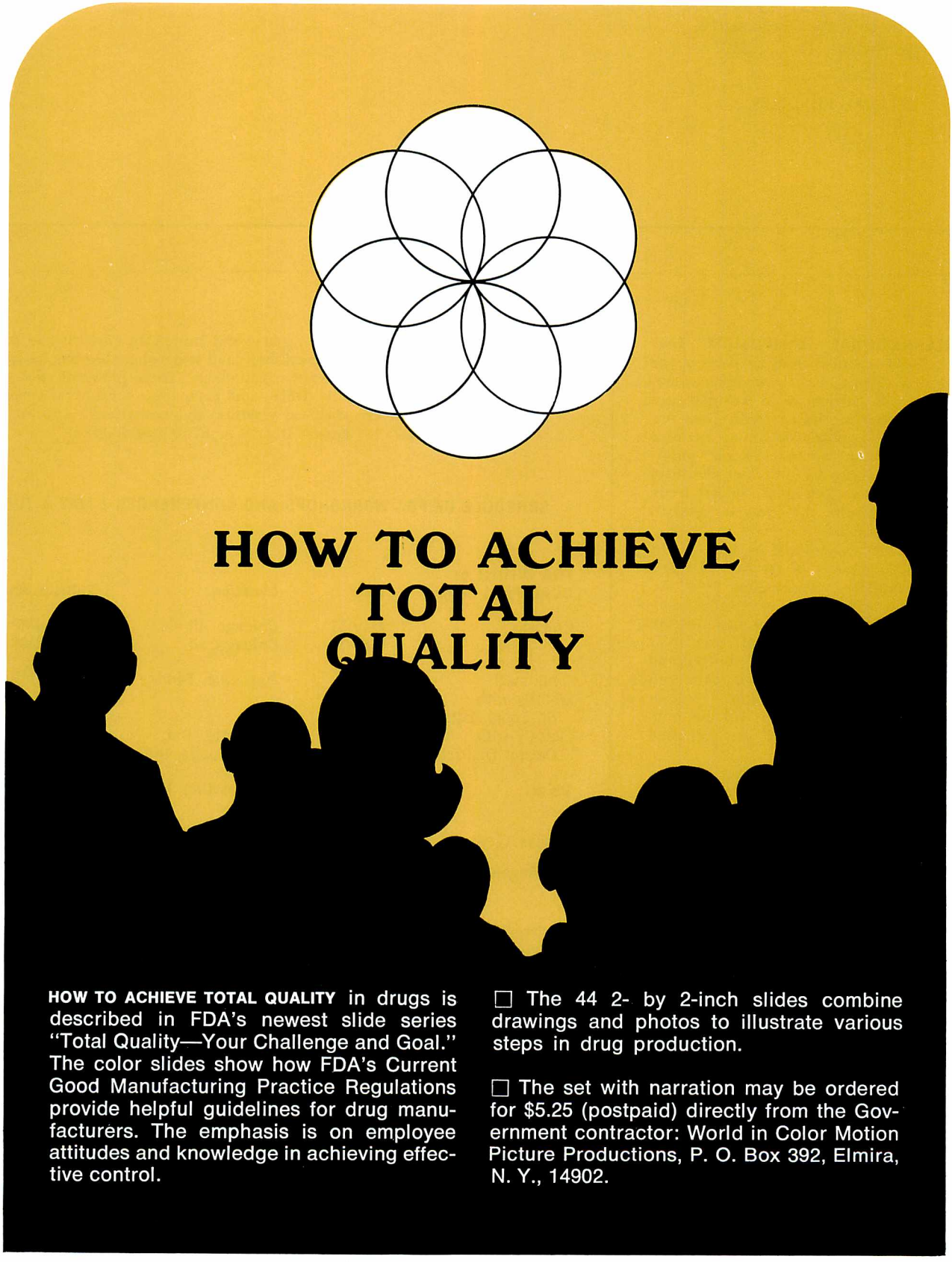
Is the product sold in homes by people who tell you they are interested only in helping suffering humanity? We call these people "Doorbell Doctors." They will agree with any ailments you may say you have, and they have a product to treat your condition. They are not doctors--they are not experts on nutrition--they are salesmen.

When you see a testimonial, remember that legitimate practitioners do not use them. Testimonials are commonly bought and sold; some are sincere--and worthless, due to the individual's nutritional and medical ignorance.

Ask known, competent authorities for all information concerning your health. You will receive honest, dependable facts.

Dr. Goddard states further:

"When the art of healing is twisted into the art of stealing, then I can assure you that the full power of the Food and Drug Administration and the United States Department of Justice will be exercised."



HOW TO ACHIEVE TOTAL QUALITY in drugs is described in FDA's newest slide series "Total Quality—Your Challenge and Goal." The color slides show how FDA's Current Good Manufacturing Practice Regulations provide helpful guidelines for drug manufacturers. The emphasis is on employee attitudes and knowledge in achieving effective control.

☐ The 44 2- by 2-inch slides combine drawings and photos to illustrate various steps in drug production.

☐ The set with narration may be ordered for $5.25 (postpaid) directly from the Government contractor: World in Color Motion Picture Productions, P. O. Box 392, Elmira, N. Y., 14902.

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OFFICIAL BUSINESS

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Announcements

INTERNATIONAL SYMPOSIUM Fifty eminent scientists from all parts of the United States, and some other countries, will participate in a 3-day symposium on medicated feeds, June 5-7, 1967. Their objectives are to examine the scientific aspects and the public health significance of the veterinary medical uses of drugs in animal feeds, and to identify the areas of research that are needed.

The symposium will be held in the main auditorium of the State Department Building, Washington, D. C. Attendance will be open to research scientists, public health personnel, officials from State and Federal regulatory agencies, reresentatives of the feed and drug industries, livestock producers and other interested persons. Proceedings of the symposium will be published and distributed to registered persons.

At FDA's request, the National Research Council—National Academy of Sciences is conducting the symposium. There is no charge for registration of FDA personnel. Programs and registration forms can be obtained from Dr. Silas McHenry, Division of Industry Education, Bureau of Education and Voluntary Compliance, 200 C Street, S. W., Washington, D. C., 20204 (or telephone 962-4545).

CORRECTION: In the March issue of *FDA PAPERS,* on page 23, under "Obligations of Investigators," the statement was made "The investigator must keep careful records of his study and retain them for at least two years after completion." The regulations, however, state that the investigator shall maintain his records for a period of two years following the date the New Drug Application is approved for the drug, or, if no application is to be filed or is approved, until two years after the investigation is discontinued and the Food and Drug Administration is so notified. In many cases this may be several years after a given investigator has completed his study.

FDA INDUSTRY WORKSHOPS During May and June, FDA Districts and BDAC Field Offices will conduct a series of workshops and regional conferences on specific compliance problems of major health significance. These problems deal with drugs (good manufacturing practice (GMP) and drug abuse control) and foods (microbiological contamination, chemical residues, and sanitation). Anyone desiring to attend should contact the nearest District or BDAC Field Office.

SCHEDULE OF FDA WORKSHOPS AND CONFERENCES / MAY & JUNE 1967

FDA District or BDAC Field Office	Date	Location	Subject Area
Chicago	May 11	Chicago, Ill.	Drugs–GMP
	May 12	Chicago, Ill.	Drugs–GMP
Cincinnati (Jointly with St. Louis District)	May 17	Nashville, Tenn.	Drugs–GMP
(Jointly with Detroit District)	May 9	Lafayette, Ind.	Food Warehousing
	May 11	Indianapolis, Ind.	Food Warehousing
Dallas	May 4	Brownsville, Tex.	Breaded Shrimp Processors
Kansas City	May 4	Kansas City, Mo.	Food Warehousing
Los Angeles	May 6	Los Angeles, Calif.	Breaded Shrimp Processors
Minneapolis	May 10	Minneapolis, Minn.	Drugs–GMP
Philadelphia	May 16	Trenton, N.J.	Medicated Feeds
St. Louis	May 22-23	St. Louis, Mo.	Drugs–GMP
Seattle	May	Anchorage, Alas.	Seafoods with NCA & Alaska King Crab Mktg. Board
Baltimore	May 1-2	Corvallis, Oreg.	GMP and DACA
	June 7	Richmond, Va.	Sanitation & Standards in Canning
Chicago	June	Chicago, Ill.	Sanitation in Food Warehousing
New Orleans	June	Clanton, Ala.	Medicated Feed
San Francisco	June	Sacramento, Calif.	Medicated Feed
	June	Lake Tahoe area	Salmonella—Dairy Products