

MARCH 1971

FDA PAPERS

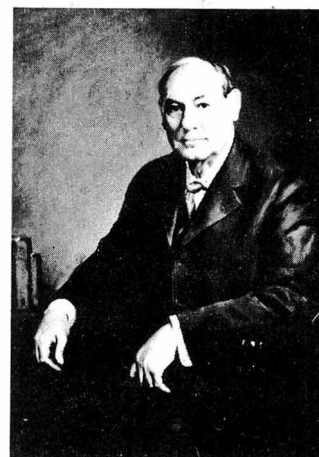
**CONSUMER EDUCATION
AND INFORMATION**

**ADVERSE REACTION
SURVEILLANCE**

**The Poison Prevention
Packaging Act**

**THE LAB SCIENTIST
AND IDIP**





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

Harvey W. Wiley, 1844-1930

Father of the Federal Food and Drugs Act of 1906

From his commencement address
"Life and the Coming Time"
Hanover College, 1867

The real tragedy about the deaths of and injuries to children from accidental poisoning (see page 14) is that most of them didn't have to happen. A child's curiosity is one of the best assurances we have that mankind will prevail and it's doubly saddening to realize that some children who possessed this trait in the greatest degree paid an undeserved penalty—simply because Nature didn't make them mature enough early enough to negotiate the treacherous terrain of our man-made chemical environment. As adults, we have been remiss in not moving sooner to take some of the relatively simple actions needed.

Now the Congress has taken a major step to remedy this intolerable situation by authorizing FDA to require, through safety packaging, that containers for toxic substances be made difficult for little fingers to open. This will not cure the basic trouble—that of adult carelessness in leaving toxic substances where the young and curious can reach them; for this problem, there is probably no complete and lasting solution.

Nevertheless, we at FDA believe the new law will be one of the most effective pieces of health legislation ever enacted. Frankly, once the law has been fully implemented, we expect those melancholy child poisoning statistics to plummet.

quotes

"In the past decade, health care has seen a phenomenal increase in the development and use of medical devices. Heart valves, intensive care monitoring equipment, and plastic implants are examples of devices that have saved or prolonged thousands of lives. While it is clear that most devices serve very useful purposes, it is also becoming evident that some devices are potential hazards and can cause injury or death if not properly designed and manufactured. Although the magnitude of these hazards is very difficult to determine, most experts agree that the problem is becoming serious enough to warrant Government attention. It is our goal to develop, in cooperation with industry and the medical profession, the scientific methods and procedures that will result in the protection of the consumer while at the same time encouraging innovative development of medical devices."

Charles C. Edwards, M.D., Commissioner of Food and Drugs, to the American Association for the Advancement of Science, Chicago, Illinois, December 30, 1970.

"We have recently been encouraged to hear that we shall probably be given the facilities at what has been the Pine Bluff Arsenal in Arkansas to create the National Center for Toxicological Research. The main emphasis of this facility will be in the strengthening of the science of toxicology, particularly in the area of chronic low-dose studies. We hope to arrive at firmer and more definitive criteria for safety, particularly for foods, but in view of the fact that the facility will be a national center, also for other environmental hazards. The Environmental Protection Agency is also being funded for work in this facility. No doubt other Government Departments will also have needs along these lines. As soon as these facilities can be converted and made available for this type of study, we shall be starting on the studies of food additives, on pesticides, and on other environmental chemicals that come to us by way of our food supply."

Virgil O. Wodicka, Ph.D., Director, Bureau of Foods, at the USDA/ARS National Agricultural Outlook Conference, Washington, D.C., February 23, 1971.

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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.

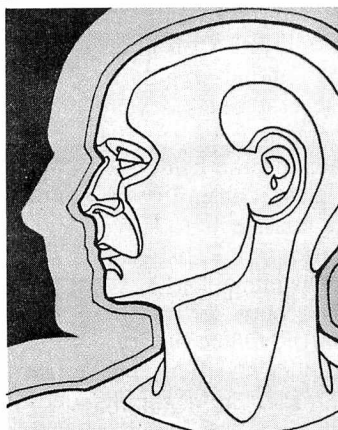
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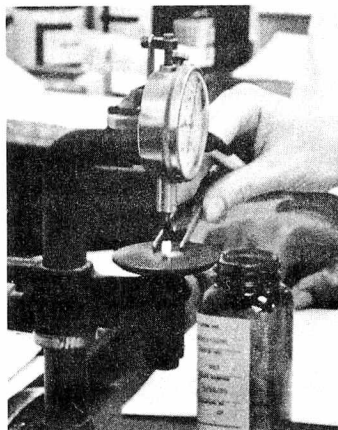
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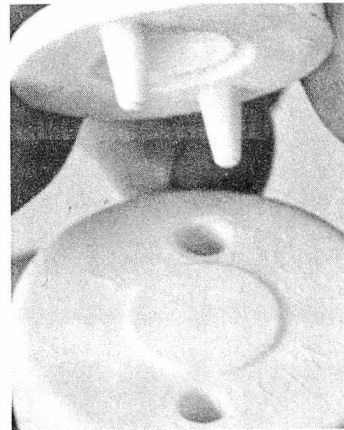
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CONSUMER EDUCATION AND INFORMATION

by Mervyn Silverman, M.D.

During the past decade the Food and Drug Administration has conducted a consumer education and information program based on the "rights of consumers." FDA's consumer education program is based on the premise that an informed consumer is better prepared to protect himself, and FDA has been responding to this need to inform the consumer.

In today's complex environment, there is an even more urgent need not only to inform consumers about FDA programs and policies, but also to counsel consumers so they can protect themselves in the marketplace and at home. It is equally important to measure the needs and expectations of the consumer.

This need is being increasingly met through programs conducted by FDA's Office of Consumer Affairs. With the support of a small but dedicated staff in Washington and 20 Consumer Specialists in 17 FDA District Offices, the Agency provides an educational program reaching all parts of the Nation at the grassroots level.

Although the Food and Drug Administration has been in the field of consumer protection since its inception in 1907 and maintained a constant vigil in behalf of the consumer, it was in 1952 that it began to actively seek the counsel of citizens when it first employed Consumer Specialists. They gather regularly in Washington several times a year to maintain contacts between the headquarters staff and the field, and to obtain the latest consumer information. Their mission is to serve as a communications link between the FDA and consumers, either as individuals or as groups.

In Washington the Office of Consumer Affairs replies to thousands of consumer inquiries in a timely and informative manner. Flowing

into FDA's headquarters in Rockville, Maryland, are an average of a hundred letters a day from consumers, plus numerous telephone calls inquiring about all kinds of problems involving food, drugs, medical devices, cosmetics, and environmental situations.

These 2,000-3,000 letters received monthly are not a one-way street. They provide viewpoints and information of great value to FDA. This data, combined with the input received from Consumer Specialists in the field, gives essential information from which FDA can base its education and information programs. At the same time the input provides consumers with an effective voice inside FDA because of the product intelligence provided by tens of thousands of concerned consumers.

To strengthen the input into FDA's Office of Consumer Affairs, a continuing liaison is maintained with Virginia Knauer, Special Assistant to the President and Director of the Office of Consumer Affairs, and Patricia Hitt, Assistant Secretary for Community and Field Services, and Barbara Burns, Deputy Assistant Secretary for Consumer Services, both in the Department of Health, Education, and Welfare; the Federal Trade Commission; the Department of Agriculture; and other interested Federal agencies and consumer organizations.

In establishing an FDA field corps of Consumer Specialists, our aim was to provide on-the-spot information and assistance to individual inquiries from consumers and to meet with organizations and groups seeking educational information at the local level. The specialists now provide a direct channel of communication for consumers so that a flood of opinions and questions reaches FDA every day. They provide an invaluable source of knowledge about how FDA's programs are working in the field. Further, this evaluation helps FDA learn what other problems concern consumers. All of this information helps to provide guidance to FDA

so that it can provide future constructive responses to the consumers who buy and use products manufactured and distributed under regulations for which FDA is responsible.

Consumer Specialists also work closely with many organized public groups. Many belong to professional organizations such as the American Home Economics Association, the American Dietetic Association, and the American Public Health Association. They meet with local community leaders in education and health, and work with them to provide additional information for transmittal to large numbers of consumers in the form of pamphlets, brochures, news releases, special statements, announcements, exhibits, etc. Community participation in educational projects sponsored by FDA and its District Consumer Specialists often involves large numbers of consumers. This was the case when a one-day conference on the subject of "Drugs and Our Society" attracted over 20,000 people. They also work with other government agencies in their districts who have collateral interests, such as the Administration on Aging of the Department of Health, Education, and Welfare, and the Department of Agriculture's Co-operative Extension Service.

To achieve mass communication, the Consumer Specialists have been especially effective in working with the news media. Large amounts of time and space have been provided by radio, television, and newspapers. The Consumer Specialists reach millions of Americans with messages of importance concerning their health and welfare. Most recently, during the month of March, programs were developed from Washington headquarters and the field for television, radio, and the printed media involving "Poison Prevention." In an average month the consumer program may provide as many as 100 radio spot announcements and interviews, over 50 television appearances, and 20 news releases on some meaningful subject for the consumer. Often ex-

hibits are set up in locations where large numbers of consumers congregate to provide information that may range from fair packaging and labeling to health frauds.

One of the most important functions of the Consumer Specialists is to help "educate the educators"—the leaders in local government and the educational system. The specialists are on a virtually continuous circuit of conferences and workshops with health departments, boards of education, public health nutritionists, dietitians, nurses, and women's clubs. Many other groups bring the Consumer Specialists into contact with leaders in the professions who, in turn, are responsible for influencing the education of the consumer constituency in their respective professional fields. In an average month over 130 speeches are given by the specialists on such topics as "Your Health Protection and FDA," "Food Additives," "Flammable Fabrics," "Poison Prevention," and "Our Health Needs and Nutrition."

In addition to public speaking before the "educators" the specialists also give talks to various consumer groups. The volume of input may be gauged in a single month's activities. During this period, they reached an audience of 27,600.

The average consumer who may not have had direct access to some of the Consumer Specialists' more formal presentations still has access to FDA's educational activities through the use of the Consumer Phone. In the cities where FDA has them, one needs only to dial a number made public by the news media to receive instant access to current information on subjects of interest to consumers—ranging from mercury in tunafish to the use of artificial sweeteners. Prior to September 1970, there were Consumer Phones in six cities: Chicago, Los Angeles, Dallas, New York, Minneapolis, and New Orleans. Over a one-year period, 108,676 calls were made by consumers who could listen to recorded messages on topics of interest, such as the proper storage of drugs in the home and the safe use

of potentially dangerous household cleaners. Because of the success of this program, FDA has established Consumer Phones in 12 other cities.

Today the Consumer Specialists provide the vital link between the complex activities of the Food and Drug Administration and more than 200 million American consumers.

But what of future consumer education? In the near future we hope to strengthen FDA's national program with consumer educational materials that will encompass more public communication of the Drug Evaluation Study Implementation program, and FDA's responsibility for informing youth of the rationale for proper use of drugs under the Agency's jurisdiction. We also hope to develop a program to communicate FDA's function of assuring the safety of the American food supply through surveillance, testing, and inspection. Another phase of activity could involve education about FDA's voluntary nutritional guidelines that would stimulate consumer awareness and understanding of nutritional labeling.

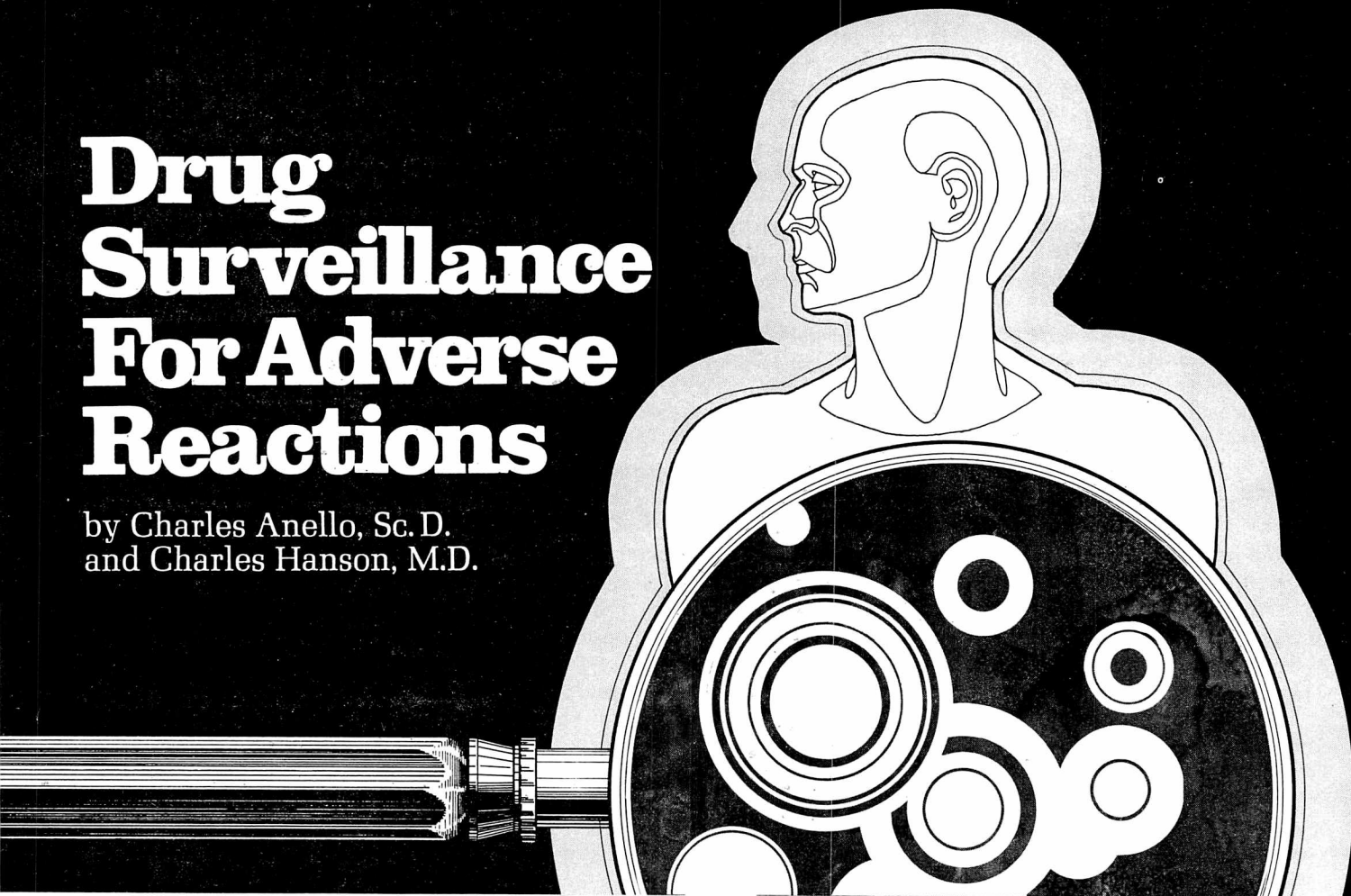
Despite the fact that we are in an era of dynamic consumerism, it is unlikely that any regulatory program mounted by the Government for consumers in the marketplace can provide 100 percent protection. Therefore, the Food and Drug Administration feels that it should provide enough information so that the consumer can make a wise decision while shopping, and also acquire enough knowledge to properly use a product after it is purchased.



Mervyn Silverman, M.D., director, Office of Consumer Affairs, since September 1970, joined FDA in July 1969 as special assistant to the commissioner. He previously served as a commissioned officer in the PHS.

Drug Surveillance For Adverse Reactions

by Charles Anello, Sc. D.
and Charles Hanson, M.D.



The chemical and biological functions of the human body are specifically adapted to maintain each individual in a state of homeostasis or biological equilibrium. Disease occurs when this balance is upset by some internal or external force. The physician treating diseases may administer drugs to try to restore the equilibrium. If the appropriate medication exists, it must be given at the right time by a suitable route, and in a proper amount and dosage form to obtain the desired response.

Even with properly administered drugs, biological variation being what it is, particular sets of conditions existing in some individuals may produce untoward events, that is, unfavorable responses not intended by the prescribing physician, at least not to the degree they occurred.

These untoward events may occur relatively often with administration of the drug, as a rash following treatment with penicillin, or with relative infrequency, as blood dyscrasia after administration of chlor-

amphenicol. Even though the risk of untoward events can be anticipated, their occurrence in a particular treatment situation is usually unpredictable and sometimes is threatening to health or life.

The FDA has the responsibility of keeping a constant vigil to uncover adverse drug effects, to estimate the degree of risk, and to take remedial regulatory action where indicated. Our objective here is to review the kinds of adverse reaction data currently available to the FDA, to describe some additional kinds of adverse reaction data needed by the Agency to safeguard the public health, and to summarize some of the major problems that must be resolved to obtain such additional data.

Manufacturers' Reports. Reports of adverse experience with drugs for human use are required as part of a New Drug Application under Section 130.4, of the New Drug Regulations, and as a part of a supplemental new drug application under Section 130.9. For the pur-

poses of the New Drug Regulations the term "adverse experience" refers to "any adverse experience associated with the use of the drug, whether or not considered drug-related," and includes "any side effect, injury, toxicity, or sensitivity reaction, or significant failure of expected pharmacological action."

The information, except for investigational study Phase I and II reports (early pharmacological and clinical studies of a drug) and literature reports, should be reported on Standard Form FD-1639, Drug Experience Report, or, alternatively, in an approved computer-generated report. The identical information elements are required in either case; these elements include the date sent to FDA and designation as initial or follow-up report, and the patient's initials, identification number, sex, height, weight, date of birth, racial origin, the date of reaction onset, source of report and source's address, description of the suspected reaction, reaction outcome, listing of all drugs in order of suspicion to-

gether with dosage form, total daily dose, route of administration, duration of therapy and dates of administration, reason for use of the drug, substantiating laboratory studies, potentially noxious or environmental factors, existing or prior disorders, past drug reaction or allergic history, and reproductive history.

The time requirements for reporting depend on the content of the reports. The general requirements, if the drug is intended for administration to man, are that routine reports shall be submitted at intervals of three months during the first year that begins with the date of approval of the application; at intervals of six months during the second year; and at yearly intervals thereafter. The regulations require, however, within 15 days of receipt by the applicant, complete records or reports of information concerning any *unexpected* side effect, injury, toxicity, or sensitivity reaction or any *unexpected incidence* or severity of such conditions associated with clinical uses, studies, investigations, or tests, whether or not determined to be attributable to the drug. For the purposes of this regulation, "unexpected" refers to conditions or developments not previously submitted as part of the New Drug Application or not encountered during clinical trials of the drug, or conditions or developments occurring at a rate higher than shown by information submitted as part of the New Drug Application.

Spontaneous, Voluntary Reporting. Besides the reports from the manufacturer required by regulation, there exist several other sources of adverse drug effect information which depend on the spontaneous, voluntary, direct reporting of untoward events believed to be drug-related. These sources generally include clinical investigators, practicing physicians, other medical workers, participants in paid hospital-reporting programs and patients themselves. These additional "spontaneous voluntary reporting" sources serve as an alerting system for those untoward events in which the effect can be easily related to the drug

responsible. Usually such untoward events are acute and quickly follow administration of the drug, anaphylaxis to penicillin, for example. A simplified reporting form is being developed that will be convenient to use and will encourage reporting of adverse drug experiences.

Major deficiencies exist in the voluntary reporting programs, whether hospital-based or based on individual physicians. These include:

1. Reports are likely to identify only those events already familiar;
2. Diagnosis of drug reactions may be mistaken and misleading;
3. Reports do not establish the *incidence* of untoward events;
4. Delayed effects tend to remain unattributed to the drug; such effects include, for example, potentially serious hazards, such as phocomelia as related to thalidomide, or aplastic anemia as related to chloramphenicol.

The British use of voluntary reporting systems seems more advanced than our own. W. H. W. Inman, reporting at the International Conference on Adverse Reaction Reporting Systems in October 1970, noted that the basic elements of the British approach include: (a) a computer based printout, (b) motivation of the physicians to report suspected untoward events, (c) a highly qualified team of medical investigators to validate the report, (d) a good system of drug utilization data, and (e) a feedback procedure to the practicing physicians and other professionals to encourage the medical community to participate in the national drug monitoring programs.

But this system, like its American counterparts, is subject to bias and a substantial degree of underreporting of untoward events, since many events that occur can go unrecognized. Particularly likely to be overlooked are those subtle drug-related events that occur in an outpatient environment and those for which the time between drug administration and effect is long. For assurance that we have comprehensive surveillance, spontaneous reporting must be supplemented by intensive sur-

veillance programs and controlled clinical trials.

Existing Intensive Surveillance Systems. Hershel Jick, at the recent International Conference on Adverse Reactions, defined the term "intensive drug surveillance" as a study in which a defined population is continuously monitored to determine:

1. the frequency with which certain events are associated with drug administration;
2. whether a causal relationship between the drugs and event is likely; and
3. whether there are subpopulations at greater risk, namely, more susceptible to reaction to the drug than is the general population.

The essential criteria for an intensive surveillance program, so defined, is that: (a) the target population is clearly defined; and (b) standardized and routine procedures exist for the collection of information on patient characteristics, drugs administered or discontinued, and changes in the patient's condition (events).

Intensive hospital monitoring has already revealed that the incidence of adverse reactions is higher than suspected from voluntary reporting studies. Depending upon the institution and the investigational methods and the definitions used, the incidence of adverse reactions in patients during hospitalization has been reported in a range of values including 13.6 percent, and 30.9 percent (some of which were judged nontrivial).

The Food and Drug Administration, the National Institutes of Health (National Institute of General Medical Sciences), and others over the past few years have sponsored programs designed to improve the Nation's monitoring and drug surveillance capabilities. These programs have included both outpatient and inpatient populations. The requirements for the outpatient system are somewhat more complex and this system will take longer to perfect. Both of these types of intensive surveillance programs bear resemblance to the model suggested by

D. J. Finney in a proposal for an "International Drug Safeguard Plan," published in 1964. This model calls for the collection of drug use and medical history data on a total population of patients without regard to whether a particular medical condition is believed to be a consequence of a drug. The medical history data used for drug monitoring should also include identification of the therapeutic indication for starting the drug and the reasons for stopping a particular treatment regimen. These two facts appear to be helpful for the proper interpretation of the untoward effects of drugs. Finally, in this proposed model, information is compiled and analyzed by a central computer, which determines incidence rates or suspicious correlations.

Three monitoring programs that have been developed over the past few years represent prototypes of potentially expandable intensive surveillance programs. The in-hospital intensive programs primarily cover patients in selected hospital medical wards. In the Tufts University program, pertinent information is recorded by nurse monitors, while in the University of Florida program pharmacists record the data. The outpatient program developed at Kaiser-Permanente in California has employed on-line entry of pharmacy records of prescriptions filled, optical scanning of forms containing physician diagnoses obtained during outpatient visits, and other modes of putting in data as directly recorded in patient care activities.

These programs differ substantially in "intensity" of monitoring, reliability of the information obtained, duration over which surveillance is possible, and capability for searching the computer records for unsuspected drug reactions. Even taken together, and not denying their merit, these programs fall far short of filling the total national needs for surveillance. W. H. W. Inman, in his report mentioned earlier, has pointed out that the majority of serious or fatal drug reactions are rare, with an incidence

ranging from perhaps 1 in each 1,000 to 1 in each 1,000,000 courses of treatment. The existing intensive surveillance systems do not have adequate numbers of patients under treatment to demonstrate reactions of such incidence.

General Problems in Design. The fundamental issues related to design of drug surveillance arise with the selection of an appropriate population to be monitored, the selection of drugs that because of their extensive use or relative recent entry into the physicians armamentarium require intensive or special monitoring, and the selection of those variates which need to be observed and screened to avoid serious consequences to the drug-consuming public.

To date little attention has been given to the characteristics which would make a population appropriate for a national drug surveillance program. Size and proximity to quality medical institutions have been viewed as essential characteristics, but these are not sufficient in identifying a target population. Most individuals take medication at some point in their lifetimes, and the specific drugs taken and duration of consumption vary greatly.

Hospital populations are convenient for surveillance because they can be intensively monitored and their medical records are readily accessible. In the hospital situation, however, the administration of drugs is carefully controlled and the choice of drugs is not representative of the pattern of drug administration in an outpatient environment. A comprehensive drug surveillance program must ensure that most sectors of the drug-consuming population are represented. The population under surveillance should include those subjected to less than the highest level of medical care. Attention should be given to the effects of drugs on the outcome of pregnancy.

Since it may not be economically feasible to monitor all drugs over an extended period of time, some selection of drugs may be necessary. It is clear that those drugs which will be used by patients for an extended

period of time, those which are taken just prior to or during pregnancy, and those which are given to a large segment of the population must be kept under surveillance. The recent studies with oral hypoglycemic agents have shown that many years may elapse before one can establish the existence of trends or identify possible adverse effects attributed to a specific drug. There should also be a procedure for terminating specific surveillance once confidence in a drug's safety has been established. This, however, is difficult to identify.

Considerable thought must be given to the particular biological effects that must be monitored as a minimum. A list of such effects could be almost unlimited. It includes mortality, selected morbidity, signs, diagnoses, symptoms, and laboratory findings. Not only must a decision be made concerning which variables are to be observed, but a decision also is needed on the timing of an observation. In the past, potentially drug-related events were recorded as part of the standard medical practice and little attention was given to drug surveillance objectives. The recent trend suggests that future programs, inpatient or outpatient, will provide for more intensive monitoring specifically designed to detect untoward events that may be shown to be related to drug intake. The outpatient situation, more complex than the inpatient situation, will require considerable thought and study. This is particularly true because, unlike hospital situations, the health status of an outpatient cannot always be ascertained. The most that can be expected of a drug surveillance program is that it provide sufficiently intense screening to detect significant morbidity and mortality which would not be detectable through other programs, such as spontaneous and voluntary reporting.

Several important issues need to be considered, assuming agreement can be reached on the population to be brought under surveillance, the variates that should be observed as a minimum, and the drugs that

must be included in the monitoring programs. The major issues include: (a) quality of the data, (b) size of population, (c) estimate of attributable risk, (d) use of retrospective and prospective studies, and (e) role of sampling.

First, as with all of science, the quality of information used to make inferential statements about a population must be defined and its credibility established; otherwise, there can be no confidence in the findings or conclusions. To this general scientific requirement, however, we must add that findings relating drugs to adverse effects can have important medical, legal, and economic consequences. Therefore, the usefulness of a comprehensive surveillance program will depend to a large extent on the reliability and the defensibility of the data and the subsequent findings. Every effort must be made to eliminate known or potential sources of bias and unsubstantiated subjective inferences. Intensive surveillance programs augmented by special clinical or animal studies should produce a data base acceptable to the medical profession, the academic community, and the drug-consuming public.

Another issue concerns the size of the population needed to provide an adequate basis for inference. Those trained in biometry know that this depends on the size of the population at risk, the expected frequency of an adverse effect, and significance attaching to a possible error. Intensive hospital monitoring programs have not covered large populations with diverse drug exposures. They have for the most part been restricted to medical wards. Clearly, any expansion in existing programs must include a greater variety of drug exposures. The outpatient environment, like the program at Kaiser-Permanente, offers an opportunity to keep large populations under surveillance (specifically, subscribing members of a prepaid medical program). But "under surveillance" is not the same as "exposed to drugs," and it is the size of the population exposed to the drug that must be considered when one is

attempting to specify surveillance programs.

An important objective for any comprehensive drug surveillance program, in addition to identifying whether a specific untoward effect may be related to the administration of a particular drug, concerns the need to estimate the magnitude of the excess risk attributable to that drug. The attributed risk can be expressed in a variety of ways (for example, a relative risk or an excess risk measured from a suitable control group). In addition, a surveillance system should be capable of providing estimates of the benefit that can be attributed to the drug. An estimation of risk without an estimation of benefit is an insufficient basis for making regulatory decisions on marketed drugs.

Recent evidence of drug effects has been generated by both retrospective studies (thromboembolism and oral contraceptives) and prospective controlled studies (the recently reported University Group Diabetes Program). Once a surveillance program has alerted us to the potential hazard of a drug, confirmational investigation must be initiated. Of course the reverse could also possibly occur: the finding could first be generated by controlled experiments, and confirmational evidence might be obtained through the intensive monitoring or other surveillance programs. This cross-checking of findings is necessary to assure the scientific objectivity of research in this difficult area.

Finally, we should consider anew the role of survey sampling in support of a national drug surveillance

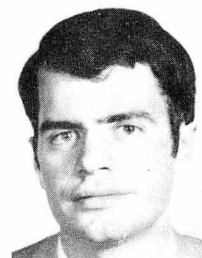
system. Good information on drug utilization appears to be essential if the magnitude of any drug-related benefit or hazard is to be viewed in proper perspective. Interpretation of drug usage data is complicated because some patients do not take drugs as prescribed, and tend to ingest many drugs based on their own evaluation of the therapeutic effect. A complete monitoring program will take into account the totality of drugs and devices and view them in the light of actual levels of consumption.

Those making efforts to deal with adverse reaction hazards should recognize that some such hazards will inevitably persist. They will persist even though the appropriate medication has been administered at the right time by a suitable route, in a proper amount and dosage form, because of the intrinsic variability of biological response to potent drugs. But adverse reactions can be minimized by foreknowledge of the risks. This knowledge, if it cannot always be established prior to approval of the drug for marketing, can be derived from post-marketing drug experience data. Such data is presently provided to the FDA in the form of spontaneous, voluntary reports, either transmitted by the manufacturer or submitted directly and voluntarily to the Agency from the observer of the reaction. These isolated reports in themselves do not constitute an adequate method of surveillance; intensive surveillance programs and controlled clinical trials are also required. Our objective is a comprehensive drug monitoring program to safeguard the public health.

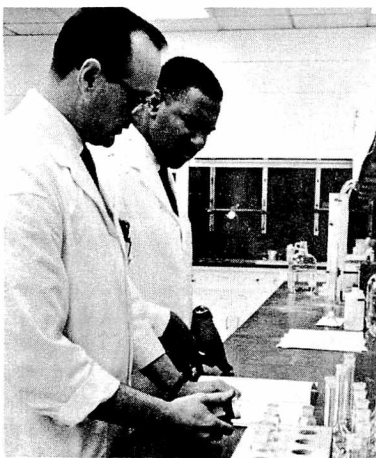


Charles Anello, Sc.D. (left), director of the Division of Statistics, Office of the Assistant Director for Scientific Coordination, Bureau of Drugs, joined FDA in April 1969.

Charles Hanson, M.D., medical officer, Division of Biometry and Epidemiology, Office of Scientific Coordination, Bureau of Drugs, joined FDA in October 1969.



A company chemist (left) reads the methodology before beginning an analysis as the FDA chemist looks on.



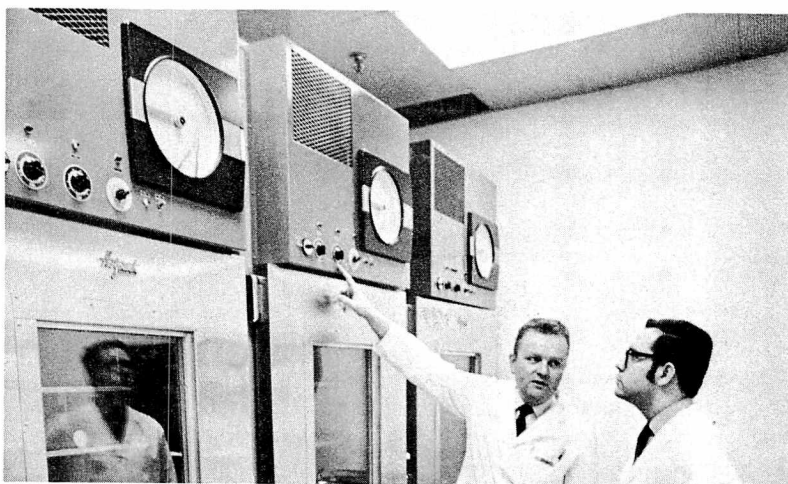
A technician (right) examines a drug tablet for conformance to the firm's weight specifications as an FDA chemist observes the procedure.



An FDA microbiologist (right) reviews the company's product specifications with a plant microbiologist.



A plant microbiologist (left) shows an FDA microbiologist the company's incubator controls.



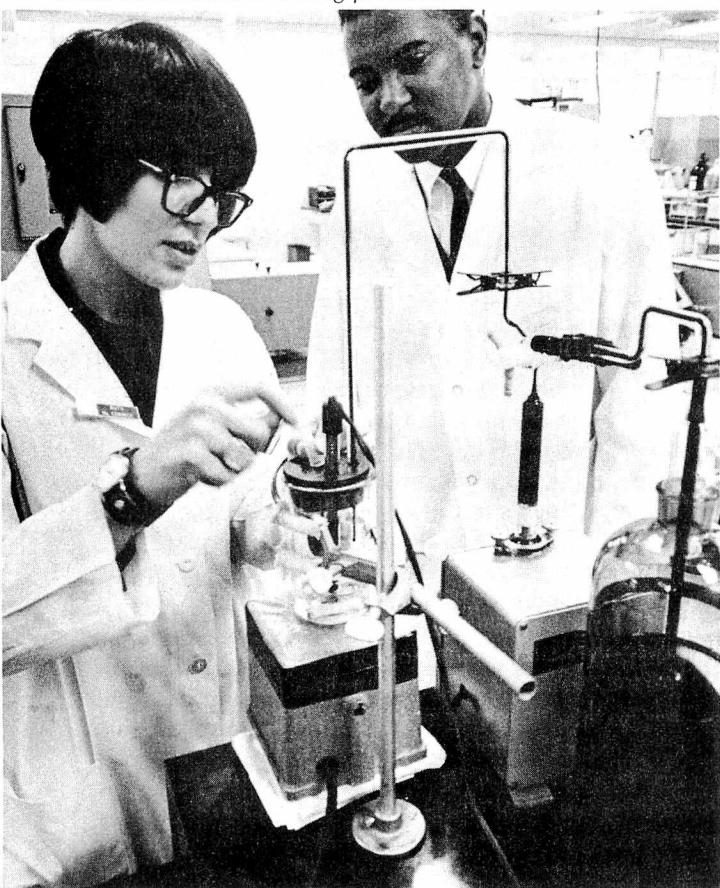
THE LABORATORY SCIENTIST AND IDIP

by Matthew H. Lewis
and Anthony Duran

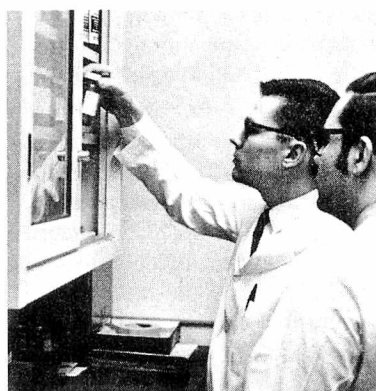
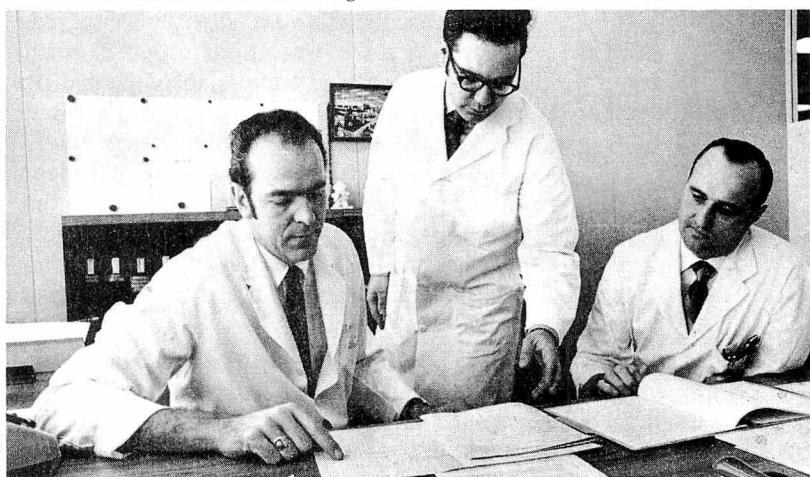
One of FDA's most ambitious field activities is the Intensified Drug Inspection Program, popularly called the IDIP. This program had its beginnings with the 1962 Kefauver-Harris Drug Amendments to the Federal Food, Drug, and Cosmetic Act. The goal of the IDIP is to ensure that manufacturers produce quality drug products through adherence to the Current Good Manufacturing Practices regulations published in the U.S. Code of Federal Regulations, Title 21, Part 133. The IDIP is intended to achieve compliance, when possible, through a cooperative effort by the FDA and the drug industry.

The new concept of intensified inspections was initiated in fiscal 1969. Unlike the more limited establishment inspections normally conducted in FDA operations, the Intensified Drug Inspection may last several months. Another significant difference is that the inspection is made by a *team* of FDA experts. This team consists of one or more inspectors (one of whom is the team leader), a chemist experienced in drug chemistry, and, when the firm deals with sterile products, a microbiologist. For the chemist and the microbiologist to be fully effective members of the team, they participate with the inspectors in the pre-IDIP meeting between

An FDA chemist (right) observes the procedure as a firm's chemist performs a Karl Fischer test for determining moisture content in a drug product.



A drug plant analyst (left) discusses his worksheet on a completed analysis with his quality assurance supervisor (right), while the FDA microbiologist (center) monitors the discussion.



Storage conditions of the drug company's reference standard chemicals are checked by FDA microbiologist (right) and a plant quality assurance representative.

the firm's management and FDA personnel. They accompany the inspectors on the early stages of the inspection that takes them into all areas of the plant. This is the first time in recent history in which laboratory scientific personnel have been actively involved in drug plant inspections.

It is the objective of the IDIP to improve the quality of drugs manufactured or distributed in this country. This objective is to be achieved through a twofold approach: (1) To work with drug manufacturers in a joint effort to improve manufacturing practices to assure drug quality and (2), when that fails, to take legal steps to discontinue the distribution of those drugs that are not produced in a manner and under conditions that assure quality. Fortunately the first part of this approach has generally been effective. In the great majority of inspections, drug manufacturers have cooperated with, and in fact welcomed the IDIP team.

The selection of a manufacturer for intensified inspection is determined from a careful review of these three factors: (1) history of violations and unsatisfactory conditions noted during past inspections; (2) unusual processes; and (3) significance of drugs produced.

The effectiveness of this new inspectional program has been due in large part to the saturation coverage the inspected firm receives. Until the inspection is terminated or temporarily suspended, the IDIP team is in the plant daily. Every department, every process, every procedure is observed and evaluated, not by one

expert but by several. The inspectors, the chemist, and the microbiologist all bring their respective experience and expertise to bear on the firm's total operation. Each IDIP team member has the opportunity to find procedural weaknesses or potential hazards that his background enables him to recognize.

In the New York District the Intensified Drug Inspection is conducted in four phases. The entire scientific team of inspectors, chemist, and microbiologist is normally involved in all four phases.

First Phase. The first phase of the IDIP is the pre-inspection conference. The management of the firm is invited to the District office to meet with the members of the IDIP team. At this meeting the purposes and organization of the inspection are explained, and the firm has an opportunity to ask questions. Usually the manufacturer is asked to designate a responsible staff member as management liaison with the IDIP team.

Second Phase. Orientation of the IDIP team comprises the second phase of the inspection. The team studies the administrative and functional structure of the firm, observes the manufacturing operations, and becomes familiar with the plant layout and the flow of records and materials. This phase, sometimes referred to as a "tour," may require several days to two weeks, depending on the size and the complexity of the firm.

Third Phase. The third phase constitutes the comprehensive inspection of the firm. Each department is studied thoroughly. Actual operations such as tableting,

coating, packaging, and labeling are carefully observed. Conditions under which the operations are performed are critically viewed. Since the team is accompanied by a member of management, any existing or potential problems are brought to his attention immediately. On-the-spot conferences are held with the department heads. In addition, a weekly meeting is held with the company's top management at which a written report of the week's observations is presented by the team leader. This report is discussed with a view to initiating corrective measures.

Fourth Phase. The final phase of the IDIP is the preparation of a written report by the members of the IDIP team. This comprehensive report describes the firm and its operations in detail and summarizes all that has occurred during the inspection. Critical observations are discussed, conferences with management are described, and the responsiveness of management in terms of corrective actions is described. The final report is then submitted.

During the actual inspection, the chemist is most concerned with the activities of the quality control laboratory and the adequacy of testing of raw material, in-line product, and final dosage forms. The concern of the microbiologist is focused on microbiological testing and on the structure of "sterile" areas and the performance of sterile operations.

Aside from their areas of primary attention, laboratory-oriented team members have on numerous occasions pointed out dangerous practices in other areas of operation. One chemist, for example, noticed that prior to filling, bottles were rinsed with a solvent but not adequately drained and dried. The solvent in this case was methyl alcohol, and the person responsible for the operation was unaware that this solvent is a highly poisonous substance. On another occasion a dangerously combustible organic solvent was found stored in open bottles next to an infrared lamp. Again the responsible party did not realize the potential explosive hazard. Another FDA chemist, because of his laboratory experience with methylcellulose was able to determine why a plant using methylcellulose in product formulation, was getting low assay results. The company did not realize that this substance prevented complete extraction of the active ingredient, in this case, barbiturates.

Chemist's Responsibility. The chemist spends most of his time in the quality control department of the drug firm. At the very least, this department will consist of a laboratory that analyzes raw materials, intermediate products, and finished dosage forms. More often today this department is called "Quality Assurance" and has considerably expanded duties. For example, stability studies may be handled by a unit in this department. Containers may be tested for suitability by the quality assurance department, and methods development for new products may also be undertaken. Appropriately, the quality assurance department is responsible for making certain that no

substandard product leaves the plant. To discharge that responsibility fully, this department must have considerable independence, authority, and a wholesome budget. All of these factors can create situations that may exasperate other departments in the firm; for example, "rush" shipments of dosage forms may be detained awaiting completion of analysis. The independence and power of this department are essential if it is to resist the natural pressures put on it. These qualities are observed and evaluated by the IDIP chemist just as carefully as are the firm's analytical methods.

Most firms understand that their quality control department serves as their first checkpoint as well as their last line of defense. Since the FDA cannot sample each batch of drugs produced in the country, these quality control departments more often serve as the consumer's last line of defense. For this reason these departments are given a considerable amount of careful and critical attention during an IDI.

The importance of the quality control department can be related to drug recalls initiated by a firm at the request of FDA or the firm. Our experience so far indicates that the majority of these recalls would not have been necessary had the deficiency been detected by the quality control department.

The most common deficiencies found in quality control departments reflect the use of inadequate or inappropriate methods, the inadequacy of or complete lack of specifications for product or raw material, and poor record-keeping procedures. Examples of some of the worst conditions observed:

1. A nonspecific analytical method was used that was affected by one of the excipients, giving apparent high potency results for the active ingredient. On the basis of the analysis, the production department reworked the tablets and diluted the active ingredient. The resulting product, of course, was subpotent.

2. Reference standards (chemicals certified for identity and purity) were stored improperly and as a result deteriorated with time. The firm, unaware of this instability, used the standards for chemical analysis. Some of the subsequently marketed products were found to be substandard by the FDA.

3. Average weight and weight variation tests were being performed by a high school graduate who could not handle simple arithmetic. These weight figures were used to determine the running weight for manufacturing and to release products for sale.

4. A consulting laboratory was employed for quality control testing. The laboratory performed an inadequate number of tests to determine the strength, purity, and identity of the active ingredient. The consulting laboratory would inform the firm only that the product had "Passed" without specifying what tests were performed or supplying any raw analytical data. The firm, on the other hand, had no written product specifications. (NOTE: The operations of commercial laboratories

that do work for drug firms under investigation are included for inspection under the IDIP.)

5. A part-time chemist was hired who worked during regular hours for another firm. He brought standard solutions from his regular job to use on his part-time job without bringing or developing the necessary standardization data. When a problem arose concerning a product, the firm could not review and adequately explain its analysis because this data was lacking.

6. A product was manufactured which, available records on file indicated, passed the disintegration test at the time of manufacture. The IDI team discovered, however, that the same product, after standing four days, no longer passed this test. No studies had been done by the firm of the effects of aging on this product.

7. A consulting laboratory employed on a part-time basis a high school student who was performing chemical assays without adequate supervision. On one occasion this employee ran a sample in duplicate and obtained results of 80 percent and 120 percent. The average of the results was reported as 100 percent.

8. One firm, in sampling its raw materials for assay, did not use a trier, but instead sampled only from the top of the drum. This firm also neglected to mix the drum's contents before sampling. The sampling personnel apparently failed to realize the dangerous implications of assaying a nonuniform sample.

Microbiologist's Responsibility. The microbiologist member of the IDIP team must examine the construction of sterile areas in drug plants to determine if they are adequate for the job.

Among the many factors a microbiologist must consider in evaluating a sterile area are location of major sources of air pollution, air currents, area of the sterile facility, number of people working in the area, types of products handled in the area, amount of traffic in and out of the area, and number and size of openings into the sterile area. The last factor is important because most sterile areas are operated under positive pressure.

A person entering a sterile environment can contaminate through the normal shedding of bacteria from his skin and by carelessness. This carelessness may result from an incomplete understanding of the precautions necessary to preserve the sterile condition. The shedding of bacteria is controlled by the use of sterile, lint-free garments, gloves, hoods, and overshoes. Carelessness, however, is much more difficult to control. At one drug firm an IDI microbiologist observed a maintenance man

entering the sterile area only partially gowned and carrying nonsterile tools. Two minutes later a technician entered the same sterile area without changing his non-sterile uniform. Further, examination of the dressing rooms, where sterile gowns are donned prior to entering the sterile area, revealed that there was no soap in the dispensers.

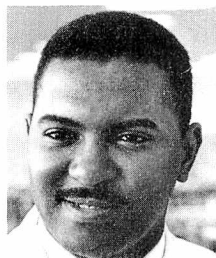
At another firm a laboratory worker was observed with a pencil placed between his cap and head. He removed the pencil periodically to mark objects under the sterile filling hoods. This, of course, subjected the room to bacterial contamination from the man's hair and scalp.

Firms have been observed to have sterile areas that ranged from a semienclosed space of only 30 square feet to a completely enclosed area of over 6,000 square feet. One plant used only a home air-conditioning unit to filter the air entering the sterile area. In another, it was discovered that the ceiling of the sterile room opened into a manufacturing room where tableting and other processing was going on. This firm was re-packing sterile penicillin powder. Thus, in addition to producing a penicillin product that was not sterile, the plant was allowing other drugs to be subjected to cross-contamination by this potent antibiotic.

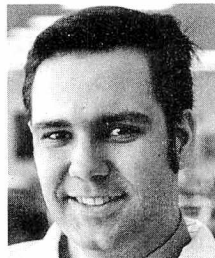
One drug plant was especially careful in its sterile operation. Air was filtered through a prefilter, a precipitron, past ultraviolet radiation, and then through a bank of Cambridge filters into the sterile area. Some manufacturers operated their entire sterile area under a laminar flow air system.

Examples of poor chemical and microbiological laboratory practices are mentioned because of their extremes. Most firms are found to have well-planned and well-executed quality control programs, substantial sterile rooms, and excellent sterile room technique.

Firms that effectively monitored themselves and those found to be lax in their procedures generally responded well to the IDIP and agreed that the intensified inspection had been beneficial. In any event, the laboratory scientists of the FDA found an essential role in the Intensified Drug Inspection Program and have used it to teach and to learn. An exchange between FDA and industry has been established with, in most cases, a substantial degree of trust on both sides. The laboratory scientists by this exchange have had a large share in this joint effort by Government and industry to insure consumer protection.



Matthew H. Lewis, recently transferred to Boston District as a supervisory chemist from New York District, joined FDA in 1964.



Anthony Duran, microbiologist, New York District, joined FDA in 1966.

THE POISON PREVENTION PACKAGING ACT

by James J. Corrigan

Among the important bills signed into law by the President during the closing days of the 91st Congress was the Poison Prevention Packaging Act of 1970 (P.L. 91-601), which will be administered by FDA. The basic concept of the legislation is to protect children from accidentally ingesting toxic substances by requiring safety closures and other safety packaging.

In 1967, the last year for which complete figures are available, the National Center for Health Statistics of the Public Health Service reported that 325 children died from accidental poisoning. Over 116,000 accidental ingestions of drugs and other toxic materials were reported to the poison control centers in 1969. Children under five years of age accounted for 76,155 of these accidents and 3,844 hospitalizations occurred within this group. Although drugs account for approximately 50 percent of the reported accidental ingestions, many other common household chemicals are associated with these tragedies. For example, reports of 782 ingestions of petroleum distillate furniture polish were received by FDA in 1968.

FDA has already acted under the Federal Hazardous Substances Act against certain liquid drain cleaners containing more than 10 percent sodium or potassium hydroxide by publishing a proposal to require child-resistant packaging. Products failing to comply would be classified as banned hazardous substances.

Dramatic testimony before the Senate Commerce Committee's Consumer Subcommittee in 1969 described the pain and suffering that resulted when a curious child gained access to a packaged dishwashing detergent. The 18-month-old boy underwent a tracheotomy to permit breathing and a tube was inserted in his stomach so that he could receive nourishment. The possibility

of averting such incidents through the use of safety closures was highlighted in testimony by a pediatrician in the Army Medical Corps. Treated cases of accidental poisonings were down from 251 to 175 at the Madigan General Military Hospital serving approximately 100,000 persons in the Tacoma, Washington, area the first year (1967) that safety containers were used by the hospital pharmacy and to 108 the succeeding year.

Enactment of the Poison Prevention Packaging Act is the culmination of a legislative effort that began in 1966 with the introduction of the Child Safety Act (H.R. 13886, 89th Congress), which would have made the use of safety closures mandatory. This legislation, which was not enacted, was the impetus for FDA's convening the Conference on Prevention of Accidental Ingestion of Salicylate Products by Children in 1966 in an effort to stimulate voluntary methods on the part of industry to reduce the incidence of poisonings. The Conference, including representatives of the medical community and industry, resulted in the limitation of children's aspirin ($1\frac{1}{4}$ grain) to 36 per bottle, ordinarily less than a lethal dose. A subcommittee on safety closures was also formed and has since been developing methods for evaluating safety closures.

The subcommittee filed its report with the Commissioner of Food and Drugs on December 7, 1970, specifying closure testing methodology. The standards proposed by the subcommittee call for packages that will resist the efforts of 65 percent of children between 42 and 52 months and 50 percent of such children after a demonstration of how to open the container. The standard recommended was the result of testing only three closures. With the increased efforts stimulated by the

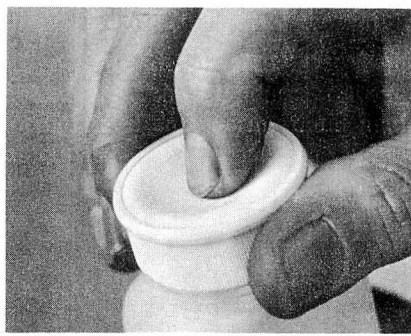
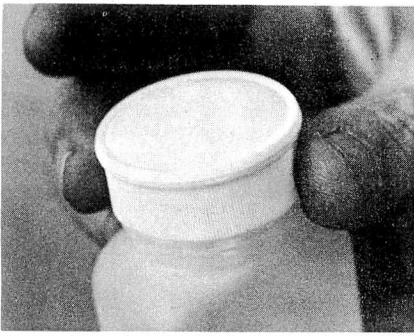
legislation, these recommended standards would be expected to be raised as new test data becomes available. Containers should also be capable of being opened by 90 percent of adults 45 years old and younger.

However, in view of the evidence of the accidental ingestions occurring yearly and the failure of previous efforts to produce widespread use of safety closures, the Congress determined that legislation was needed to foster the use of child-resistant packaging.

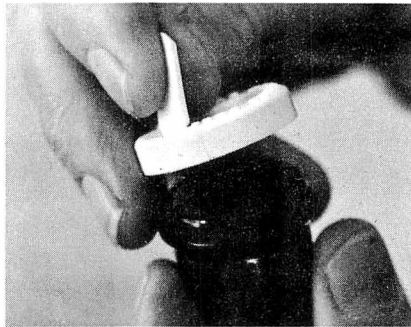
The legislation is aimed specifically at protecting children under five years of age—an age group particularly vulnerable because of their inability to read, their natural curiosity, and the "Pica phenomenon," namely the tendency among young children to eat nonfood items.

Coverage of the Act extends beyond that of the Federal Hazardous Substances Act and includes all hazardous substances, economic poisons, foods, drugs, cosmetics, and household fuels in portable containers in the regulated category of "household substances." The limitation to products intended for household use in the FHSA is abandoned so that coverage in the Poison Prevention Packaging Act is extended to items customarily stored around the household even when such products may not be destined for use around the household. Thus, boat maintenance items, model airplane fuels, and products of this ilk are clearly within the jurisdiction of the Act.

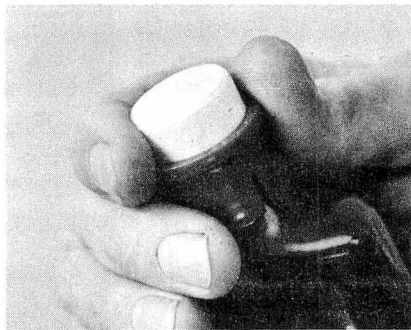
The bill authorizes the Secretary of Health, Education, and Welfare to establish special packaging standards for virtually all household substances after consultation with a technical advisory committee, upon a finding that the degree or nature of the hazard to children, in the availability of a substance to them



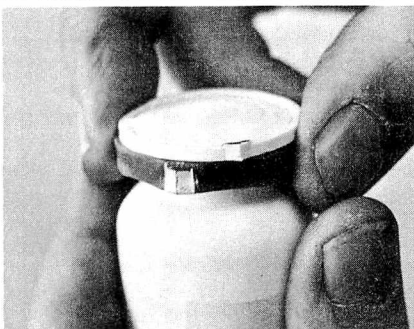
Among safety closures under development is this one with a convex, flexible top (left) which defies attempts to open until depressed firmly in the center while simultaneously unscrewing the cap (right).



This safety closure has a hinged plastic tab firmly recessed flush with the top and almost unnoticeable (left). The end of the tab must be pried upward to loosen it and the cover may then be removed by pulling on the tab (right).



This two-piece safety closure (left) has a plastic free-turning outer protective ring that must be pulled down with moderate force so that the common screw cap may be grasped for turning (right).



In opening this safety closure the keyed markings on the bottle cap and its outer ring (left) must be lined up to allow the outer ring to be depressed, thus releasing the inner cap for opening (right).

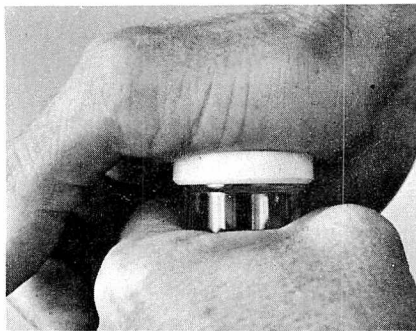
because of its packaging, is such that special packaging is required to protect children from access to quantities that could cause serious personal injury or illness. He must also find that the proposed standard is technically feasible, practicable, and appropriate. By "feasible" it is meant that the technical expertise exists to produce such packaging, and therefore the Secretary is under no obligation to promulgate standards that can be easily met. Thus, this proviso does not mean that the standard must be gauged to the lowest level of technological skill

available or even the average level packaging technology. Adaptability to modern methods of mass production is the criterion for fulfilling the requirement that the standard be "practicable." In finding that a standard is "appropriate," the Secretary should determine that the packaging will not be detrimental to the integrity of the substance.

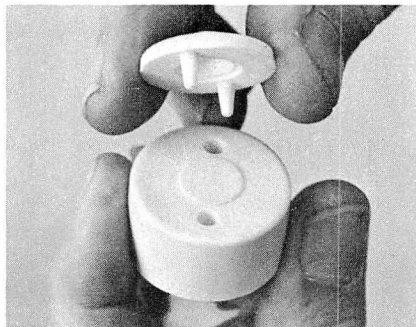
The Act also directs the Secretary to give consideration to the reasonableness of the standard, relevant medical and engineering data, manufacturing practices, and the nature and use of the substance. Although

no formal finding is required with regard to these guidelines, they are included to insure that evidence on these factors cannot be excluded in issuing packaging standards. Publication of all the findings of the Secretary, the reasons therefor, and citation of applicable provisions of the law are required in promulgating a standard.

Special packaging standards need not be restricted to safety closures and may require packages of such design or construction as to make it difficult for a youngster to obtain a toxic amount of a substance in a



This firmly locked safety closure (left) defies opening unless moderately heavy pressure is applied from the top, as with the heel of the hand, and it is turned simultaneously (right).



This safety closure (left) employs the free-turning outer ring, which must be pulled down with one hand while the top is removed with the other.

This closure consists of a detachable "key" part containing prongs that must be inserted into the corresponding holes in the bottle cap to open (right).



Strip packaging provides individual wrapping of each dosage unit, and individual opening. Although a normal small child may be able to open them, he must do so one at a time. Young children must work slowly and are likely to lose patience before they obtain a quantity sufficient to be dangerously toxic.

Young children, especially those under five, find that opening a well-designed safety closure is frustrating work. Some toddlers, even when shown how to do it, do not have the strength in their tiny fingers to employ the moderate force necessary to open most of the enclosures.

reasonable period. The requirement that the packages be difficult for children under five years of age to obtain a toxic amount from within a reasonable time does not necessarily mean that all such children will be unable to open or otherwise obtain a toxic amount. Of course, the packaging standard cannot be such that normal adults are unable to use the product. Special packaging can also include packaging which limits the amount children will be able to ingest, such as strip packaging or bottle caps that permit only a few drops at a time. The Secretary

may also prohibit packaging that is unnecessarily attractive to children in a regulation establishing special packaging for a substance.

To insure that innovation is not stifled the law specifically prohibits the Secretary from prescribing specific designs, package quantity, content, or labeling. This provision is to make it clear that container performance standards are intended to be established under the Act.

One of the major controversies that had arisen over this legislation, if not the only controversy, related to the exemption permitted for the

benefit of the elderly and handicapped. It was pointed out during the congressional deliberations on the legislation that debilitated or handicapped persons might be unable to cope with the special packaging because of wrist infirmities or other lack of dexterity. The Senate, recognizing this contingency, provided that one size of a product could be marketed in noncomplying packages for this purpose if such packages bore a label stating that the noncomplying packages are intended for households without young children.



Some squeeze toys have easily removable squeakers which children may pull out and put in their mouths.

by Carol Young

Carol Young is a staff writer in the Bureau of Product Safety.

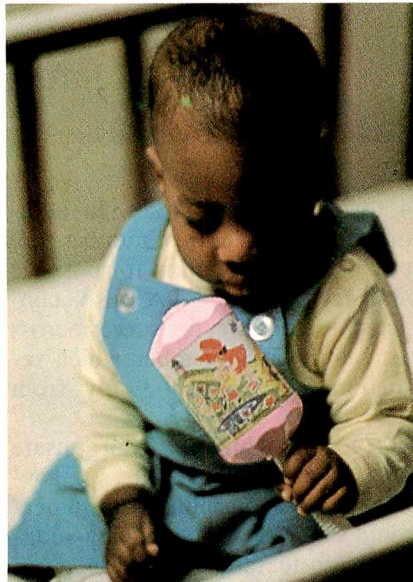
Gifts of toys are tokens of love. It is important that they be chosen with care. It is tragic when a toy, meant to bring happiness, seriously injures a child.

Protecting children from unsafe toys is one of the responsibilities of FDA's Bureau of Product Safety. The Child Protection and Toy Safety Act of 1969—which became effective in January 1970—empowers the Food and Drug Administration to remove and keep from the market toys and other children's products with electrical, mechanical, and thermal hazards.

How big is the hazardous toy problem? How many children are injured? Toy-associated injuries accounted for less than 5 percent of over 120,000 reported injuries in and around the home compiled for a year's period from FDA's injury surveillance system. This system includes reports from 130 hospitals in 31 States.

Bicycles were involved in the majority of the toy-associated injury cases. Other vehicle-type toys, such as roller skates, sleds, and tricycles were linked with most of the rest of these injuries. Dolls, homemaker items such as toy stoves and irons, stuffed animals, chemistry sets, and molding equipment accounted for

Noise-making rattles of flimsy plastic can be broken easily to expose wire prongs which can puncture skin or jab eyes.



Playing Safe In Toyland

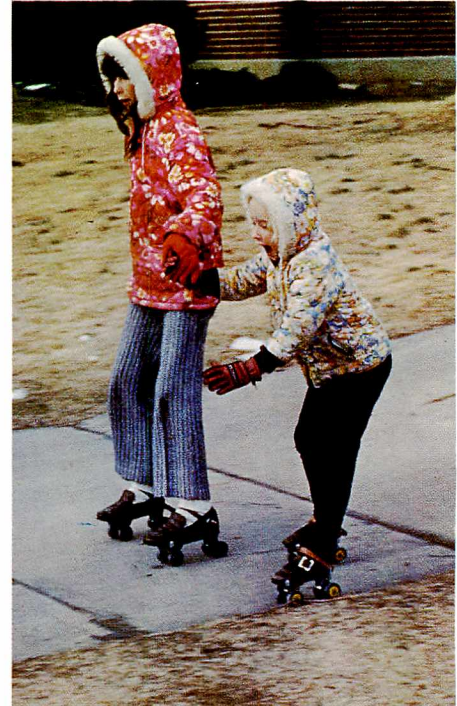


Riding in wagons is fun, but children should be cautioned not to ride in streets.

Finding a place softer than the sidewalk to fall to is a good idea when skating. Parents should take time to give their children a few basic "tips" such as this to help them avoid painful injuries.



Staying up on skates is a challenge to many girls and boys. Parents should caution their children against skating in the street and unnecessary roughness, such as pushing.



less than 1 percent of the reported cases.

Almost half of the total reported injuries to persons involved live animals, personal use items, and environmental factors. Next in number were injuries associated with buildings and their fixtures and furnishings.

No law can protect a child completely from all dangers. Complete surveillance of the toy market is impractical due to its size. There are approximately 1,200 toy manufacturers in the country producing an estimated \$2.5 to \$3 billion in toys each year and there are approximately 83,000 entries of imported toys each year.

With limited money and manpower resources diverted from other product safety programs to toy safety activities, FDA has obtained voluntary modifications or removal of

24 toys from the market. In addition, about twice this number are now under investigation for possible voluntary action. FDA also conducted a retail level toy survey across the country in December which resulted in the banning of 39 toys from sale.

Protecting children from unsafe toys is a parental as well as a governmental responsibility. Consumers should exercise sound buying judgment. Consideration should be given to the age and size of the child, his ability, and the area in which he plays with his toys. The ages of other children in the family also should be considered. A toy that is safe for one child may be dangerous in the hands of an unsupervised and less skillful younger brother or sister.

Toy buyers in the family should reject those with obvious hazards—sharp points; rough or unfinished

surfaces; small, detachable parts that may be swallowed; brittle plastic or glass that breaks easily and leaves sharp edges that may cut; poorly constructed toys with sharp spikes or pins that are exposed when the toy is pulled apart by a curious child; toys with triggers, gears, or other parts activated by a spring or motor that may pinch fingers or catch hair.

Toys that feature exposed flame in use or are made of combustible materials should be avoided. Chemistry sets, rocket kits, and similar toys should be bought only for children old enough to handle them wisely. The minimum age recommended by the manufacturers of such toys should be heeded.

Since wires can wear through, electric toys such as trains and "home appliances" for little girls should be checked periodically. Such toys should not be purchased for the

Sledding is a favorite winter sport for many girls and boys. Parents should caution children against the risks involved in this activity.

Tricycles, like wagons, should not be ridden in the streets.



Bicycle riders should be taught commonsense rules for riding. A bicycle should be adequately equipped and the right size for the child to handle properly.

very young. A child should be shown how to insert a plug safely into an electrical outlet and how to unplug the cord.

Special care must be taken with toys that have trailing loops and cords. A child should be taught never to put these loops or cords around him in such a way that they may trip or choke him. Toy arrows should be tipped with some soft substance that cannot be removed. Care must be taken with suction tips. They can come off and expose dangerously sharp ends.

Care also must be taken with balloons—they can choke a child if accidentally taken into the windpipe. Whistles and toy instruments should not have parts (mouthpieces, for example) that can be easily detached. Children should be taught to sit or stand still when playing toy musical instruments. A push or fall can cause

serious mouth or throat injury.

A large number of bicycle injuries result from misuse and could be prevented if parents took the time to teach their children some of the commonsense rules for riding. Bicycle riders should be taught to obey all appropriate traffic regulations, lights, stop signs, and one-way streets; to slow down at intersections, look both ways, and proceed with caution; to give pedestrians the right-of-way; to ride single and single file; to “play it straight” in traffic and leave stunt riding and racing for open areas free of traffic; and to never hitch a ride on other vehicles.

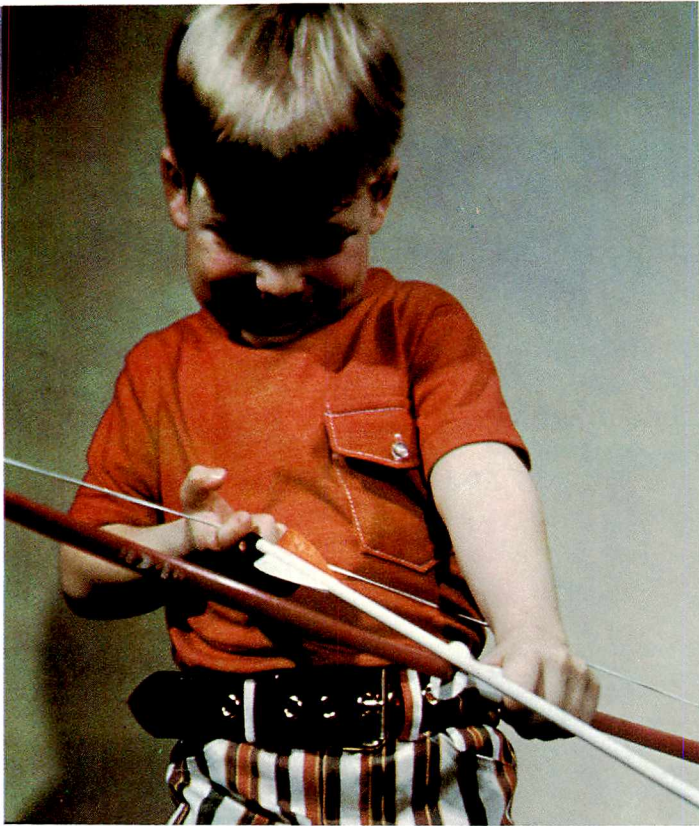
In a special study conducted on bicycle injuries, “horseplay” and colliding with obstructions were the two leading factors found to contribute to accidental injuries among the group studied.

Parents should make certain that

a bicycle is the right size for the child to handle properly and that it's equipped with headlight and reflector, if it's to be ridden after dark. It also should have a bell or horn, chain guard, brakes, pump, and mirror. And it should be kept in good condition.

FDA currently is developing safety standards for electrical, mechanical, and thermal toys and will insure compliance by monitoring factories and retail outlets where toys are sold. The Agency also is working with manufacturers to correct possible structural or design hazards reported by consumers.

With these activities, and with consumers exercising sound judgment in making their selections, and giving proper instruction to children to use toys and games as they were intended to be used, toys can be the source of enjoyment instead of tears.



Toy arrows (upper left) should be tipped with some soft substance that cannot be removed. The child's age should determine whether or not he plays with this kind of toy.

Teddy bears (upper right) and other stuffed animals are dear companions to small girls and boys. Make certain that eyes, which may be pulled off, do not have sharp barbs.

Dolls (lower left) are a part of every little girl's growing-up years. Dolls with hair and hair ribbons should be checked to determine if there are sharp pins holding the hair and ribbons and if they can be removed easily.

THE POISON PREVENTION PACKAGING ACT *cont'd. from p. 16*

The Committee on Interstate and Foreign Commerce of the House of Representatives also sought to accommodate households without children from one to five years of age; it was estimated that 75 percent of the households in this country have no children in this age category. The House, therefore, reported legislation that would require special packaging to be available only in one popular size, thereby making special packaging the exception rather than the rule.

The Senate-House Conference Committee resolved the matter in favor of the Senate version, and both the Senate and House later agreed to this version. The law thus permits only one size to be used for noncomplying packages for the benefit of the handicapped, provided the product is available in at least one other size utilizing the special packaging and provided the nonstandard packages conspicuously bear the legend, "This package for households without young children." Other suitable language can be designated by the Secretary for packages too small to accommodate this label.

In authorizing the one size for noncomplying packages the Senate Commerce Committee report emphasized that it expects manufacturers to make every effort to assure adequate distribution and advertising of special packaging so the public will become familiar with it and said manufacturers are also expected to insure that the one size of conventional packages will be directed only to those for whom it is intended. In pursuance of this concept the Senate Committee does not expect the manufacturers to exact a premium price for the special packaging. Testimony indicated that the cost of special closures would be approximately one-half cent per container at the manufacturer's level. If a manufacturer (or packer) fails to make special packaging available in a popular size, the Secretary may require marketing exclusively in special packaging after giving the manufacturer a chance to comply

and if, after an opportunity for a hearing, he determines that the exclusive use of safe packaging is necessary.

Prescription drugs for which a standard is in force are treated a little differently. Noncomplying containers will be available only on order of the prescribing practitioner or by request of the purchaser. The legislative record again reveals the expectation by the Congress that pharmacists as professionals will demonstrate the operation of the closure and will encourage the use of safe packaging.

Regulations for the establishment of standards may be issued pursuant to informal rulemaking procedures unless the Secretary elects the formal procedures of the Federal Food, Drug, and Cosmetic Act. If the informal route is followed, adversely affected parties may within 60 days appeal to an appropriate court of appeals for judicial review. If the petitioner shows that additional evidence is material and that there was no opportunity to adduce such evidence, the court may order additional evidence to be taken by the Secretary. The Secretary may, on the basis of the additional evidence, amend, modify, or set aside the standard. The court may void the standard if it is not supported by substantial evidence, and appeal to the Supreme Court is provided in the legislation.

Establishment of a technical advisory committee of up to 18 members by the Secretary is mandatory under the Act and consultation with the committee prior to making findings and in establishing standards is required. The committee shall include representatives of the Department of Health, Education, and Welfare; the Department of Commerce; manufacturers of products subject to the Act; scientists with expertise in this area and licensed medical practitioners; consumers; and manufacturers of packages and closures. The legislative history suggests that the Department of Commerce representatives should be from the National Bureau of Standards and that the chairman of the committee should be one of the nonindustry members.

The legislation provides for accomplishing enforcement by amending the misbranding sections of the Federal Insecticide, Fungicide and Rodenticide Act; the Federal Food, Drug, and Cosmetic Act; and the Federal Hazardous Substances Act.

The law also includes a preemption provision prohibiting States from adopting special packaging requirements for substances subject to a Federal standard unless the State standards are identical, including any exemptions.

The Act became effective upon enactment (December 30, 1970), but regulations issued under it shall not be effective sooner than 180 days after an order is made final, but in no event shall the final order specify an effective date later than one year from that date. This provision is included to permit inventories of packaging and containers to be exhausted. A "grandfather" clause provides that the standard will not be effective against any substance already packaged prior to the effective date or the Standard. The Secretary may, for good cause, stipulate an effective date prior to 180 days if he determines this to be in the public interest and publishes his reasons for the determination.

FDA's Bureau of Product Safety is developing plans for implementing this new responsibility. The Bureau will be the focal point for this program as well as those associated with hazardous substances, children's toys and other articles, burn injury investigations associated with fabrics, and injuries associated with consumer products of an electrical, mechanical, or thermal nature.



James J. Corrigan, legislative analyst with the Office of Legislative Services, joined FDA in 1964.

field reports

BALTIMORE DISTRICT On a charge brought by the FDA, a U.S. marshal in December seized \$900 worth of Dextrocell No. 2 Tablets and accompanying labeling while the drug was being held for sale by a dealer, Jones & Vaughan, Inc., Richmond. The firm had re-packed and labeled the drug after shipment in interstate commerce. FDA charged the article was a new drug without an approved New Drug Application and was misbranded while held for sale because the labeling carried false and misleading claims for effectiveness, based on the products thyroid components, in treating a variety of clinical conditions.

Also in December, FDA caused seizure of 133 cans of Misty Dog Food while it was held for distribution at Washington, where the product had been shipped by the manufacturer, Quaker City Packing Co., Allentown, Pennsylvania. FDA charged the food was not safe for use because it contained the new animal drug, methyltestosterone, and no New Animal Drug Application has been approved by the Agency for the use and intended use of animal feed containing this drug. FDA charged that false and misleading statements in the product's labeling represented the feed as adequate to enhance aggressive characteristics and bolster these traits in shy dogs and in guard and watch dogs.

BOSTON DISTRICT A small lot of aminophylline solution manufactured by Leplar Laboratories, Inc., Brookline, Massachusetts, was seized there after District analysis disclosed that the active ingredient was present at 109 percent of the declared potency. During an inspection at the manufacturer's plant, FDA inspectors had found that the drug was being produced entirely from memory, with neither master formulas nor batch records in use. They found that the product also failed to comply with Current Good Manufacturing Practice regulations in that individual units did not bear identifying lot or control numbers, and that directions for use were inadequate.

A consumer complaint about decomposed frozen sole fillets led to two recalls in December—one by a local supermarket chain, Star Market Co., Cambridge, Massachusetts, and the other by the distributor, Topco Associates, Skokie, Illinois. Both firms agreed to recall outstanding stocks of "Top Frost Sole Fillets" in 1-pound packages after FDA notified them that sample analyses showed more than 40 percent decomposition. An estimated 900 cases were placed under recall,

representing the remainder of a 928-case lot originally imported from Canada in August.

BUFFALO DISTRICT Charged with operating a food storage establishment under insanitary conditions, the firm of William Griffith & Sons, Utica, New York, and its operator, William Griffith, were fined \$1,000 in Federal Court at Syracuse on December 14 following a guilty plea to two of the five counts of an information filed by FDA earlier in the year. When Judge Edmund Port imposed the fine, he remarked that he believed a fine was necessary to impress not only the defendants, but other persons, with the necessity of operating within the law.

A flour mill/warehouse in Buffalo has diverted about 62,000 pounds of insect-infested flour and cake mixes to animal feed and destroyed about 53,000 pounds of similar products because of rodent contamination. The insect and rodent contamination was discovered during a cooperative inspection by District inspectors and a State inspector. The unfit food materials were valued at approximately \$10,000.

CHICAGO DISTRICT When the District opened its new resident station in Rockford, Illinois, it represented the culmination of an agreement proposed by the Illinois Bureau of Environmental Health's Divisions of Milk Control and of Food and Drugs, and the Chicago District's inspection branch. Under the agreement the State milk control and food and drug inspectors will assume inspectional responsibility for all food commodity processors, including complaint followup in the nine-county Rockford travel area, regardless of interstate status of the products. FDA's resident food and drug inspector, Delbert Porter, will give inspectional coverage to all drug, device, and hazardous substances obligations regardless of their interstate status.

Facilities for the resident post, housed in the State Regional Office Building, are provided by the State at no cost to FDA.

CINCINNATI DISTRICT When the District notified the Frank Tea & Spice Co., Cincinnati, that *Salmonella* organisms had been found in ground black pepper that it produced, the firm impounded 12,000 pounds of the material in its plant and initiated a voluntary recall of the pepper from the market. The recall lot consisted of 49,000 pounds and was packed under several labels.

The contamination appears to have resulted from a lot of contaminated pepper corns, and the firm is working on a method for sterilizing these goods.

DALLAS DISTRICT FDA has terminated its prosecution case against McCraw Candies, Inc., Farmersville, Texas, and its secretary-treasurer, Ben Cohen. The Government charged the defendants had held a lot of peanuts under insanitary conditions under which they became rodent contaminated and had shipped into interstate commerce candy contaminated with insect and rodent filth. Judge Wayne Justice, in the Eastern District of Texas, sentenced Mr. Cohen to one year in jail; however, he later reduced this sentence to one year's probation. The corporation was placed on two years' probation and fined \$3,000, of which \$2,000 was suspended for two years.

DETROIT DISTRICT Alan L. Hoeting, deputy regional food and drug director in Detroit, is representing the District on the Federal Trade Commission's Consumer Protection Committee, which was formally established December 9. The committee, composed of all Federal and State regulatory agencies concerned with consumer protection, will exchange information nationwide and serve as a one-stop consumer complaint service. Frank Kelly, attorney general for the State of Michigan, is chairman.

KANSAS CITY DISTRICT George L. Vinz, assistant to the District director, will serve as secretary on the slate of officers elected for 1971 for the Metropolitan Kansas City Conference of Food and Drug Officials. Others named to serve are Armin W. Schannuth, sanitarian, Independence, Missouri, City Health Department—president; Don Rice, sanitarian, Kansas City, Missouri, Health Department—first vice president; and Perrin L. Fairleigh, compliance officer, Compliance and Evaluation Staff, U.S. Department of Agriculture, Kansas City—second vice president.

Finis was recorded in December to part of the aftermath of an accident which had occurred in early July 1970 on a Nebraska dairy farm, when a mislabeled fly spray containing dieldrin was used on the dairy herd. Persistent residues of the pesticide were found in milk as late as December, resulting in the destruction and burying of 50 animals during the week of December 13.

Kansas City District officials, along with State food and drug officials from Nebraska, Kansas, and Missouri had taken prompt action when they found, following the accident, that milk from the contaminated herd was used with other producers' milk in the manufacture of cheese. Through their cooperative effort, 31,000 pounds of natural cheese and almost a half-million pounds of processed cheese were recalled and are being held pending destruction. Approximately 2,000 pounds of contaminated whey cream for use in the manufacture

of ice cream mixes was destroyed earlier under the supervision of Kansas dairy officials.

LOS ANGELES DISTRICT FDA ordered a recent seizure at San Pedro, California, of 8,000 pounds of frozen kingfish found to contain DDT. The fish, in possession of a wholesale fish dealer, had been caught off the southern California coast, outside the U.S. continental limits, and was therefore subject to Federal jurisdiction. This particular lot was found by District inspectors during a surveillance sampling of the fish products to determine if high pesticide residues were present. Sampling of the kingfish showed an amount of DDT and related chemicals about four times the action level of 5 parts per million.

MINNEAPOLIS DISTRICT Because a wholesale grocer in St. Paul continued to hold for sale products sweetened with cyclamate after the FDA deadline banning the sale of such products, a U.S. marshal seized 268 cases of various canned cyclamate-sweetened fruits and cranberry juice in possession of the firm. As a result of this action ordered by FDA, plus a notice of hearing regarding lots of rice, prunes, and pancake mix that the firm had permitted to become badly insect infested, the respondent stated at the hearing that the firm will go out of business by June 30.

NEW ORLEANS DISTRICT Nevis Cook, District director, David Bryant, District workshop coordinator, and Charles Price, FDA resident inspector at Fort Smith, Arkansas, conducted a canners and freezers workshop in December at Fayetteville, Arkansas. The workshop was sponsored by the Ozark Canners and Freezers Association.

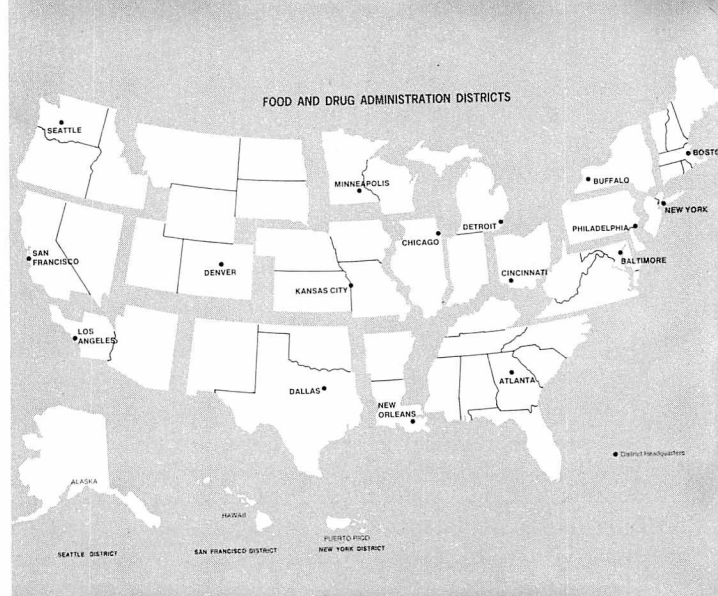
A variety of articles offered for import were detained by the District in December. Among them were misbranded biscuits, canned sardines, drugs, and artichoke hearts, with a total value of over \$6,000; adulterated black pepper and frozen shrimp—total value, over \$13,000; and insect-damaged green coffee, valued at \$96,000.

NEW YORK DISTRICT A recent cooperative effort involving the New York District and the New Jersey Department of Health typifies the kind of joint enforcement activity that has become routine in New Jersey. District inspectors assigned to the Newark office had inspected a local bakery and found gross rodent and insect infestation. When officials from the Newark office contacted the State Health Department at the conclusion of the inspection, they learned that a State inspector had inspected the bakery several weeks earlier and had also found it operating under filthy conditions. The State had issued a 30-day "clean up or close up" letter as a followup to the earlier inspection. To facilitate further action, FDA delivered by courier to Frank Timko,

chief, Bureau of Food and Drugs, NJDH, photographs and written inspectional observations describing current conditions at the firm. Based on this evidence, Mr. Timko immediately issued a closure order, which was served jointly by a State and an FDA inspector. At the same time, the State embargoed the entire stock of food in the bakery as well as a trailer truckload of baked goods about to be shipped. This material was subsequently destroyed because of rodent and insect defilement. The State Department of Health notified the States of Pennsylvania and New York, both of which license the Newark bakery, that the firm had been ordered closed because of filthy conditions. FDA then ordered seizure of a large lot of the firm's fruitcake awaiting sale at Salem, Virginia, after the Agency found the lot adulterated with rodent and insect filth.

PHILADELPHIA DISTRICT Lemmon Pharmacal Co., Sellersville, Pennsylvania, has voluntarily destroyed 4 million tablets and 700,000 capsules of Obestat, which the firm recalled following several FDA-ordered seizures (see FDA PAPERS, December 1970/January 1971). Obestat is a thyroid-central nervous system drug found by FDA to be unsafe and ineffective in the treatment of obesity for which it was indicated in its claims. The recalled lot, valued at \$125,000, was destroyed by trenching and burning. Approximately 9,168,000 Obestat tablets for which the firm has entered claim are being held under attachment by the U.S. marshal following seizure.

SAN FRANCISCO DISTRICT Meredith Fish Co., Sacramento, California, and the firm's president, Joseph Lloyd Turnacliiff, Sr., were fined a total of \$245 on February 23 at Sacramento for introducing into interstate commerce shrimp meats which contained coagu-



lase positive staphylococci and which had been prepared and packed under insanitary conditions. FDA had filed the information against the defendants on December 15, with arraignment on December 30.

SEATTLE DISTRICT James Shoemake, detailed from the Special Programs Branch, HEW Region V, to Seattle District as a regional milk and food consultant, was in Idaho when radioactive dust accidentally escaped during an underground nuclear test shot in Nevada on December 18. The Southwest Regional Radiological Laboratory requested that Mr. Shoemake immediately activate Idaho's standby milk radiological network. Following the activation, raw milk samples were submitted to the laboratory over a seven-day period beginning December 27 and pasteurized milk samples during the weeks of December 21 and 28. Rain and snow samples were also collected in the State. Tentative laboratory reports indicate one raw milk sample had a level of 30 pico curies Iodine 131, which laboratory officials indicate is not considered significant from a health standpoint.

FDA DISTRICT OFFICES

ATLANTA 60 Eighth St., N.E.
Atlanta, Ga. 30309

BALTIMORE 900 Madison Ave.
Baltimore, Md. 21201

BOSTON 585 Commercial St.
Boston, Mass. 02109

BUFFALO 599 Delaware Ave.
Buffalo, N.Y. 14202

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

CINCINNATI 1141 Central Pkwy.
Cincinnati, Ohio 45202

DALLAS 3032 Bryan St.
Dallas, Tex. 75204

DENVER New Customhouse Bldg.
Rm. 5604/20th & California Sts.
Denver, Colo. 80202

DETROIT 1560 E. Jefferson Ave.
Detroit, Mich. 48207

KANSAS CITY 1009 Cherry St.
Kansas City, Mo. 64106

LOS ANGELES 1521 W. Pico Blvd.
Los Angeles, Calif. 90015

MINNEAPOLIS 240 Hennepin Ave.
Minneapolis, Minn. 55401

NEW ORLEANS U.S. Customhouse
Rm. 222/423 Canal St.
New Orleans, La. 70130

NEW YORK 850 3rd Ave. (at 30th St.)
Rm. 700/Brooklyn, N.Y. 11232

PHILADELPHIA U.S. Customhouse
Rm. 1204/2nd & Chestnut Sts.
Philadelphia, Pa. 19106

SAN FRANCISCO Federal Office Bldg.
Rm. 518/50 Fulton St.
San Francisco, Calif. 94102

SEATTLE Federal Office Bldg.
Rm. 5003/909 First Ave.
Seattle, Wash. 98104

HEW REGIONAL OFFICES I-X

BOSTON J. F. Kennedy Federal Bldg.
Boston, Mass. 02203

NEW YORK 26 Federal Plaza
New York, N.Y. 10007

PHILADELPHIA 401 North Broad St.
Philadelphia, Pa. 19108

ATLANTA 50 7th St., N.E.
Rm. 404/Atlanta, Ga. 30323

CHICAGO New Post Office Bldg.
433 W. Van Buren St./Chicago, Ill. 60607

DALLAS 1114 Commerce St.
Rm. 911/Dallas, Tex. 75202

KANSAS CITY 601 E. 12th St.
Kansas City, Mo. 64106

DENVER Federal Office Bldg.
19th & Stout Sts./Denver, Colo. 80202

SAN FRANCISCO Federal Office Bldg.
Rm. 416/50 Fulton St.
San Francisco, Calif. 94102

SEATTLE Arcade Bldg. Mezzanine
1319 2nd Ave., Seattle, Wash. 98101

product safety report

PRODUCT SAFETY STUDIES

The Division of Consumer Product Safety of FDA's Bureau of Product Safety operates a hospital reporting system to determine the number, type, and severity of injuries treated in hospitals throughout the country. The system includes reported information from hospital emergency room records in 136 hospitals located in 33 States. The information is being used to identify types of products that—because of improper design, assembly, construction, labeling, or consumer use—are associated with injuries.

One of the more serious injury problems is related to large areas of glass, such as are used in sliding glass doors and storm doors. Because of deceptive lighting and age or behavior patterns of individuals, an increasing number of people, especially children, are reported as walking or running through glass panels, resulting in serious and sometimes fatal injuries.

Available data indicates that over 250,000 persons are injured each year in the United States from door glass of all types. Based on past trends, up to 100,000 persons can be expected to receive injuries from accidental impact with sliding glass doors during the coming year. Most victims think the doors are open and try to go through them, often while in a hurry. Children frequently are the victims.

Although sliding glass doors opening onto patios are involved in a large number of these accidental injuries, storm doors and other structural doors with glass panels—as well as glass enclosures for bathtubs and showers—are also involved.

Between July 1, 1969, and June 30, 1970, the Division received reports of approximately 121,000 injuries involving products of all types. Of this number, 570 involved doors containing glass; 165 of this 570 specified that the injury involved glass storm doors and 14 specified involvement of tub or shower enclosures.

A review of the 570 reports reveals that the percentage of persons injured varies by age and sex. Of the cases, 12 percent involved children four years old and under and 38 percent involved the 5-14 years age group. Over 75 percent involved persons 24 years old and under. Table 1 indicates the number of injuries received according to age and sex.

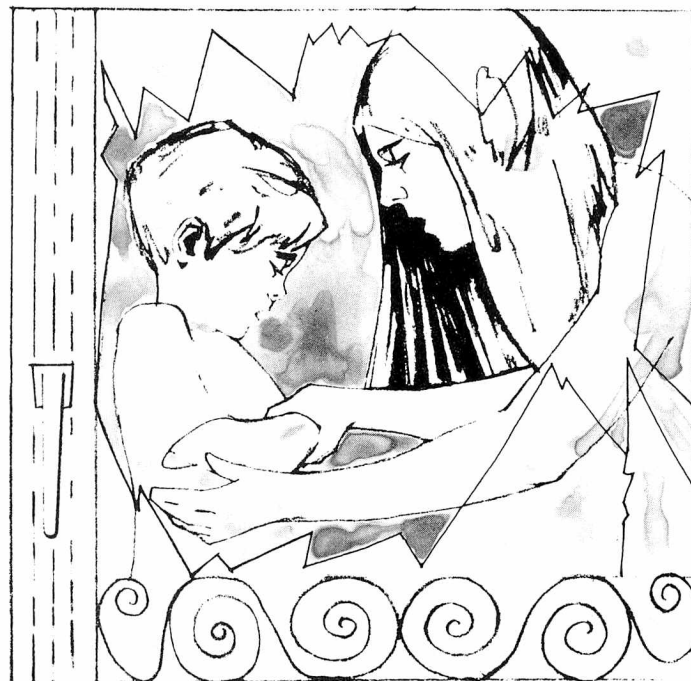


Table 1: Age and Sex of Victim

Age	Sex		Total
	Male	Female	
TOTAL	331	239	570
Under 5	45	25	70
5-14	123	97	220
15-24	86	54	140
25-44	56	41	97
45-64	13	16	29
65 and older	5	5	10
Unknown	3	1	4

Data collected concerning the day of the week of the injury is not significantly revealing. Accidents due to glass in doors and panels occur at much the same frequency each day of the week. Injuries, however, appear to occur more frequently during warm months than cold months.

Table 2 shows the disposition of injuries throughout the day. Of the accidents, 4-6 percent occurred during late afternoon and early evening hours.

Table 2: Time of Day of Injury

	Number	Percent
TOTAL	570	100
Midnight-8:59 a.m.	40	7
9:00-11:59 a.m.	46	8
Noon- 2:59 p.m.	62	11
3:00 - 5:59 p.m.	113	20
6:00 - 8:59 p.m.	149	26
9:00 -11:59 p.m.	54	9
Unknown	106	19

Data collected during this period—July 1969 through June 1970—did not reveal any fatalities due to injuries received from broken glass doors or glass panels. Table 3 shows patient disposition as a result of injuries.

Table 3: Patient Disposition

	Number	Percent
TOTAL	570	100
Hospitalized	15	2
Treated & Referred to M.D. or Outpatient Department	231	41
Treated & Released	317	56
Other or Unknown	7	1

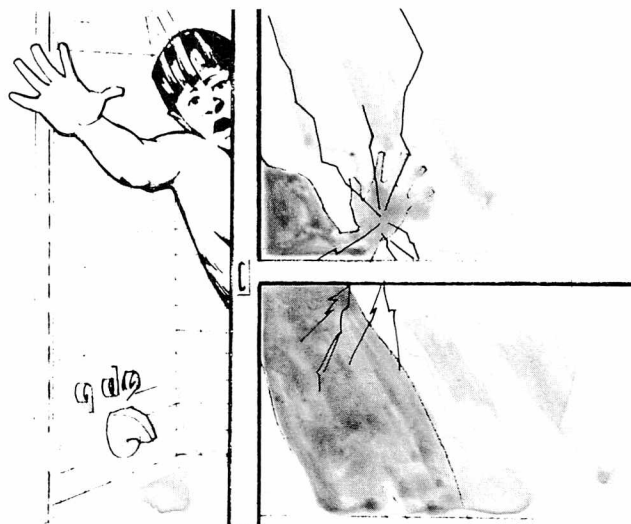


Table 4 shows the number of injuries by body part. Slightly over 60 percent of the injuries reported involved hands and wrists (34.8 percent) and lower arms and elbows (26.2 percent).

Table 4: Most Frequently Mentioned Injuries*

	Number
Hand/Wrist	210
Lower Arm/Elbow	158
Finger	75
Lower Leg/Knee	50
Upper Arm/Shoulder	40
Face	37
Head/Skull	33

*More than one body part may be involved per case.



Summary

- Based on past trends, it is estimated that about 100,000 persons will receive injuries from impact with sliding glass doors during the coming year.
- Data from the hospital reporting system shows that 50 percent of those injured are under 15; over 75 percent are under 25.
- Data collected indicates more injuries occur during warm weather months. Of all the reported injuries of this type, nearly half occurred in late afternoon or early evening hours.
- Over 60 percent of these injuries were to hands, wrists, lower arms, and elbows.

Safety Suggestions

- Encourage the adoption of State and local laws and ordinances requiring safety glazing in new construction.
- Install and replace with safety glass in your own home.
- Do not allow running or "horseplay" in areas near glass doors and panels.
- Watch where you are going.
- Identify glass doors and panels with decals or colored tape that is easily visible at eye level.
- Arrange furniture to protect glass doors and panels.
- Install safety bars or grills.
- Use rubber mats or safety strips in tubs and showers.

news highlights

Health-Related Items Industry Invited To Apply for Labeler Code Designations

Manufacturers and repackagers of health-related items have been invited by FDA to apply for labeler code designations under the National Health Related Items Code System (NHRIC).

Applications should be sent to the FDA's Center for Drug Information (BD-124), 5600 Fishers Lane, Rockville, Maryland 20852.

Items affected include bandages, surgical dressings, syringes, needles, intravenous administration sets, wheelchairs, and any other products used in the care of patients. Drugs are covered under the National Drug Code System (NDC). This system is now being expanded to include distributors as well as the manufacturers and repackagers of pharmaceutical products.

Both the NHRIC and NDC systems will make it possible for manufacturers, distributors, retailers, hospitals, and insurance companies to process their transactions related to these articles on computers. This automated processing is expected to promote efficiency and economy throughout the entire health industry.

Both systems were designed by FDA with the assistance and cooperation of drug and health-related item manufacturing and distribution industries.

Approximately 50 pharmaceutical firms have placed national drug code numbers on their product labels. Another 250 firms are preparing to take similar action. These 300 firms represent more than 95 percent of the dollar volume of the prescription drug market.

Exemptions Lifted for 19 Radioisotopes, FDA Proposes to Require Filing of NDA's

New Drug Applications would be required for 19 radioactive isotopes used for a wide variety of diagnostic and body function studies under a proposal by FDA in the January 27 issue of the *Federal Register*. Several of these radioisotopes also are used to treat various forms of cancer.

Interested persons were given 30 days from the publication date to file written comments.

The isotopes are produced by nuclear reactors. FDA officials said these products have been used largely in research and have been exempted from the Agency's regulations as long as they meet the Atomic Energy Commission's requirements for such research.

More extensive use of the 19 isotopes in recent years caused the FDA, in cooperation with the AEC and the Division of Biologics Standards of the National Institutes of Health, to review the exemption.

The three Agencies concluded that the exemption should be lifted for the 19 products and that they should be labeled for uses for which safety and effectiveness can be demonstrated by New Drug Applications or through licensing by the DBS in the case of biologics.

Manufacturers or distributors of the 19 isotopes have been given 90 days within which to submit New Drug Applications containing evidence that the drugs are safe and effective. The applications must be approved by FDA to permit continued shipment of the drugs in interstate commerce.

An alternative procedure is to file a detailed plan to test one or more of the isotopes on humans, in accordance with the FDA's investigational drug requirements.

If the drug is a biologic, the investigational plan or an application for a license should be submitted to the Division of Biologics Standards, National Institutes of Health, Building 29, 9000 Rockville Pike, Bethesda, Maryland 20014.

Mercury in Frozen Fish Blocks Found Well Below FDA's Guideline of 0.5 ppm

FDA and the Department of Commerce's National Oceanic and Atmospheric Administration announced that tests on frozen fish blocks (compressed fish) have shown mercury levels well below the FDA guideline of 0.5 parts per million. Frozen fish blocks are a source for several popular convenience fishery products such as fish sticks, fish portions, fish cakes, and fish for frozen dinners. The announcement was made February 1.

FDA and NOAA are conducting a cooperative program to determine the level of mercury in fish and fishery products.

In more than 80 different fish blocks sampled by NOAA's National Marine Fisheries Service, the average level of mercury was 0.06 ppm. The highest was 0.16 ppm and this was found in only one sample. The samples were selected from seven U.S. processors and originally came from four countries that export large quantities of fish blocks to the United States.

Frozen fish blocks are made only from the edible portion of several species of fish, primarily from the North Atlantic, such as cod, haddock, flatfish (flounder, sole, etc.), and pollock. Some 270 million pounds are utilized in this country each year. Of this amount, approximately 98 percent is imported from nations such as Canada, Iceland, Norway, Poland, Denmark, and Greenland.

Test results from Canada corroborate the FDA and NOAA findings, the Agencies said.

Tuna on Shelves Within FDA's Limits For Mercury, Violative Percentage Low

FDA announced completion on February 5 of a massive program of testing tuna for mercury and reported that stocks of the fish presently marketed in the United States are within the Agency's 0.5 parts per million guideline for mercury content. FDA said tuna exceeding this guideline, estimated at between 3 and 4 percent of the country's domestic and imported supply, had been withheld from sale or removed from the market.

The testing program, carried out since mid-December by FDA and the tuna industry, involved examination covering approximately 3 million cases of imported and over 5 million cases of domestically packed tuna. During the program FDA conducted the testing of imported tuna, while the industry, supervised by FDA and coordinated by the National Cannery Association, examined domestic stock.

FDA said 3.6 percent of 4,000 imported can codes examined exceeded the 0.5 ppm guideline and is under recall by the importer or distributor of record. Malaysian Big Eye Tuna, representing only a minor share of the total imported pack, accounted for one-third of the violative codes exported to this country, the Agency said.

As of February 1, 1971, the domestic sampling program, conducted by industry and audited by FDA, involved analysis of some 1,000 master lots comprising 269 million cans from 12,000 codes. A total of 39 of the master lots representing 378 codes (180,400 cases), or 3.6 percent of the canned tuna tested, were found to exceed the guideline. This tuna either has been recalled or withheld from sale. A master lot is one made up of fish of the same species taken from a common catch point by a single boat.

Commissioner of Food and Drugs Charles C. Edwards, M.D., expressed gratification that final statistics showed the problem of mercury in tuna to be less serious than had been feared initially. Original samples, he noted, had been taken from the most suspicious lots of tuna. Only when these fragmentary results became part of the total data did they take on proper perspective.

In announcing results of the tuna surveillance program, FDA said it has now turned its major laboratory resources to completing the program of testing swordfish for mercury. This program was first announced by Dr. Edwards December 23. Approximately 87 percent of 297 swordfish samples analyzed to date exceed the mercury guideline. The sampling program as of February 1 was about half completed. Total samples to be tested are 667. The swordfish industry is being called upon to withhold all uncleared shipments voluntarily. Where voluntary compliance is not effective, FDA is using its seizure authority.

FDA also announced today that it had begun a survey of 19 other fish species to monitor for possible mercury content. The program, initiated January 29, will cover fresh, frozen, processed, and canned fish of

commercial significance in this country. This will supplement work also in progress at the National Oceanic and Atmospheric Administration of the Department of Commerce. The species selected will be collected at wholesale warehouses throughout the United States. Samples of 40-year-old frozen fish are also being tested by the Agency to try to determine any possible historical trend in mercury contamination.

Dr. Edwards said he was confident that the 0.5 ppm mercury guideline, recently reevaluated and reaffirmed by a Department of Health, Education, and Welfare task force, offered a broad margin of safety and is adequate to protect consumers. He said he is optimistic that the Agency through its testing and surveillance can assure consumers a safe supply of fish products.

FDA, in Efficiency Move, Reorganizes Its Bureau of Veterinary Medicine

The Bureau of Veterinary Medicine has been reorganized as part of the continuing program to streamline and improve the efficiency of the Food and Drug Administration.

"The reorganization will create two new Divisions—the Division of Compliance and the Division of Nutritional Sciences—to absorb increased workloads and new responsibilities which have grown out of earlier FDA structural changes," according to Commissioner of Food and Drugs Charles C. Edwards, M.D. The reorganization took place in November 1970.

Dr. C. D. Van Houweling, Director of the Bureau of Veterinary Medicine, announced the appointment of two Bureau staff members to be acting directors of the new Divisions. James O. Gesling, assistant director for regulatory and administrative management, will be acting director of the new Division of Compliance. Dr. Richard P. Lehmann, now assistant to the director for statistical and program analysis, will be acting director of the Division of Nutritional Sciences.

Dr. Van Houweling said the Division of Nutritional Sciences will review all New Animal Drug Applications (NADA's) and Investigational New Animal Drug Applications (INADA's) for drugs used in medicated feeds. He said the new Division of Nutritional Sciences will allow the existing Division of New Animal Drugs to concentrate on and give faster action to the applications for disease control and therapeutic uses of animal drugs. The Division of Nutritional Sciences also will be responsible for the computerized information storage and retrieval systems and provide statistical service to the entire Bureau.

The Bureau of Foods will continue to evaluate, for the Bureau of Veterinary Medicine, the safety of food derived from animals and to review data to assure that no unauthorized residues will be present in the edible products of animals fed medicated feeds.

The new Division of Compliance will assume the regulatory compliance responsibilities of the Bureau

of Veterinary Medicine. The Division will also be responsible for the administrative management and document handling duties for the entire Bureau.

The Bureau's present three Divisions, Veterinary Medical Review, New Animal Drugs, and Veterinary Medical Research, will remain intact. A new Industry Information Branch in the Division of Veterinary Medical Review will handle the voluntary compliance activities of the Bureau.

FDA Warns Consumers It's Illegal To Sell Secondhand Relaxacizors

The sale of secondhand Relaxacizors is illegal, FDA has warned.

The warning was issued in January after reports that owners of the electrical devices were attempting to dispose of them by offering them for sale in newspaper classified advertisements.

The devices provide electrical shocks to the body through contact pads. They were declared dangerous to health in a California court ruling last April against Relaxacizor, Inc., the distributor. In his decision, Judge William P. Gray said the devices could cause miscarriages and could aggravate many preexisting medical conditions, including hernia, ulcers, varicose veins, and epilepsy.

More than 400,000 units have been sold for exercising and reducing. After Judge Gray's decision, many concerned owners wrote to the distributor requesting a refund. In seeking to allay their fears, the firm said it had filed an appeal and was confident the ruling would be reversed. The appeal was dismissed last November 25, by agreement between the firm and the Government, thus ending the case.

FDA has supplied posters to all post offices warning against use of the devices. In its warning to both sellers and prospective purchasers of the devices, the FDA said such sales are in violation of the Food, Drug, and Cosmetic Act and the devices are subject to seizure. The Agency recommended that owners of the devices either destroy them or render them inoperable to avoid any possibility of harm to unsuspecting users.

Proposal Would Allow Fixed Combo Doses Only if Advantageous Over Separates

FDA has published a proposed agency policy that would result in improved patient care through insuring that drugs composed of more than one ingredient combined in fixed dosage form (a pill, capsule, teaspoonful) are used only when they offer the patient a therapeutic advantage over any one or more of the components administered separately.

The proposed new policy, published in the *Federal Register* on February 18, affects up to 40 percent of the most widely sold prescription drugs and most over-the-counter drugs—those sold without prescription.

In announcing a formal declaration of proposed policy, Commissioner of Food and Drugs Charles C. Edwards, M.D., said, "FDA fully recognizes that some combinations have a legitimate place in medical practice."

He continued: "Our purpose is to insure that fixed combination drugs not only are safe and effective but are formulated so they can be used rationally and in dosages matching concurrent therapy needs of the patient."

As a result of FDA's Drug Efficacy Study and Implementation program (DESI), the Agency has taken a number of actions to make clear its attitude toward combination drugs. Some combinations already have been declared ineffective on the basis of DESI.

The statement in the *Federal Register* stems directly from the FDA experience with DESI to date. In addition to formalizing currently effective policy, the proposal is expected to provide useful guidance to industry in considering the introduction of future combination products.

The policy proposal sets several criteria for new drugs coming to the marketplace as combinations and for old combination drugs remaining on the market. FDA would approve combinations where there is proof that each active ingredient contributes to the effects claimed for the fixed combinations.

Each added ingredient would have to enhance:

- effectiveness of the drug by increasing potency or prolonging its effects; or
- safety of the drug by decreasing or reducing severity of adverse effects; or
- prevention of possible misuse or abuse.

When two or more drug components are given, instead of one, the advantages of the combinations would have to apply for schedules and durations of use recommended.

"FDA has found combination drugs present a unique problem," said Dr. Edwards. "They sometime have advantages for the patient of convenience, economy, and better adherence to medication-taking schedules."

But they frequently have disadvantages which include:

- lack of flexibility for physicians to adjust dosage of each component to patients' needs;
- possible exposure of patients to unnecessary drugs when one ingredient would be effective alone;
- increased possibility of adverse reactions without increased effectiveness.

Since 1966 the National Academy of Sciences—National Research Council has reevaluated for the FDA the claims of effectiveness for all drugs marketed between 1938 and 1962. The Academy found limitations in medical practice of many fixed combination drugs. The DESI program, including the FDA position on combination products, stems largely from the NAS/NRC evaluation program.

Interested persons were given opportunity to comment within 30 days after publication of the proposal in the *Federal Register*.

state actions

Pesticide Controls Tightened The State of Wisconsin Department of Agriculture has adopted more stringent regulations on the registration, sale, and use of pesticide chemicals. In addition to tightening departmental control over the distribution, application, and disposal of pesticides in general, the regulations establish "Prohibited Use" and "Restricted Use" pesticide classifications. Prohibited use pesticides include DDT, DDD, and endrin. Only the State Pesticide Review Board may authorize permits for research, experimental, or emergency use of DDT and DDD. Restricted use pesticides may be registered, sold, and used only for specified purpose, or for research, experimental use, or emergency use by special permit. They include aldrin, benzene hexachloride, dieldrin, heptachlor, lindane, and alkyl mercury compounds.

Oregon Department Objects Oregon's Department of Agriculture and the Dairy Relations Advisory Committee to the department have entered their objections to a Food and Drug Administration proposal to establish four classes of creamed cottage cheese. At a meeting held November 19, department and committee officials studied the proposed standards, which provide for four milk fat content levels for the cheese and would require the milk fat content to appear on the label. The four levels are .5 percent fat, 1 percent fat, 2 percent fat, and 4 percent fat. The latter is the only standard now used by the FDA.

In entering their objections, both department and committee have urged that, instead of the four classes, the FDA adopt the standardized low fat creamed cottage cheese proposed by the Milk Industry Foundation and the States of Ohio and New York. Oregon is one of some 40 States endorsing this proposal.

Kenneth Carl, chief of the depart-

ment's Dairy and Consumer Services Division, said the MIF proposal would allow not more than two percent butterfat and 82.5 percent moisture in the low fat creamed cottage cheese. The standard for creamed cottage cheese is not less than 4 percent butterfat and not more than 80 percent moisture. Oregon now has a low fat partially creamed cottage cheese that allows not more than 2 percent butterfat. Mr. Carl said most States have such a product and feel it is a standard that the public understands and one to which it is accustomed.

Plastic Milk Containers If consumers continue to complain, and if enough conclusive information is developed by a State university project, the returnable opaque plastic milk container may be eliminated. In speaking to dairy sanitarians attending the annual Oregon Department of Agriculture's Dairy Sanitation Staff Conference December 1-4, Kenneth Carl, chief of the department's Dairy and Consumer Services Division, said the division had up to that time received 23 consumer complaints about the multiple-use container. Of these, 13 were because of the odor in the container or the taste of the milk. He said it appeared that the mechanical devices used to detect foreign odors in the containers were not doing an adequate job. The department has received reports of children becoming ill after drinking milk that had been in this type of container and of a foreign odor being detected when it was checked. Mr. Carl told the inspectors that if they receive complaints of illness from use of milk in such containers, they should advise persons involved to immediately notify their local health officer and to see a physician.

Whether the container should be eliminated is based also on information being developed by Oregon

State University, which is now running a project to determine the amount of foreign materials absorbed by the plastic from which the containers are made. Reporting on the project, Floyd Bodyfelt, extension dairy processing specialist at the university, told the sanitarians it appeared that the plastic was like a sponge in absorbing some materials. He said the analyses made by chromatography indicated some containers had absorbed 15 to 20 chemical compounds and one had as many as 55 peaks, which was indicative of that many different chemical compounds.

Herbicide Use Restricted In concurrence with the action announced by the U.S. Department of Agriculture's Pesticide Regulation Division, John M. Stackhouse, director of the Ohio Department of Agriculture, on December 10 issued an order restricting the use of the herbicide 2,4,5-T. The restriction covers use around lakes, homes, recreation areas, and food crops.

Training for New Post Prior to establishing a new laboratory in Santa Fe, the State of New Mexico's Department of Health and Social Services sent the chemist who will be in charge of the laboratory to FDA's Dallas District for further lab training. He spent the week of December 13 at the District.

Training Program To improve its consumer program, the Alabama State Department of Agriculture and Industries has joined with FDA's Atlanta District in setting up a training program at the District in which six State inspectors will participate. Part of the training will be joint inspections with FDA personnel. Three of the inspectors have successfully completed the course. The others are scheduled to do so within this fiscal year.

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 51 actions to remove from the consumer market products charged to be violative were reported in December. These included 30 of foods: 9 involved charges concerning poisonous and deleterious substances, 17 involved charges concerning contamination, and 8 involved charges concerning economic and labeling violations. Other seizures included 2 of food additives—dietary food, 9 of drugs (including 3 of veterinary and medicated feed), and 6 of medical devices.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD / Poisonous and Deleterious Substances		
Eggs, whole, frozen/Weedsport, N.Y. 11/20/70	J. Fleishman & Co., Inc./Boston, Mass. (P, S)	Contain Salmonella micro-organisms.
Feta cheese/Watertown, Mass. 12/10/70	Standard Importing Co., Inc./New York, N.Y. (S)	Contains benzene hexachloride, an unsafe food additive.
Dover, N.H. 12/11/70	Columbo & Sons Creamery Association, Inc./ Andover, Mass. (S) Imported from Yugoslavia.	"
Kingfish, frozen/Wilmington, Calif. 12/7/70	Fiesta Del Mar Frozen Foods/Wilmington, Calif. (D)	Contains DDE, DDT, and TDE, pesticide chemicals not in conformity with regulations.
Lettuce/Utica, N.Y. 11/19/70	Rala Singh Farms/Toltec, Ariz. (S)	Contains 1.5 ppm parathion, a pesticide not in conformity with regulations.
Buffalo, N.Y. 11/25/70	"	Contains 1.8 ppm parathion.
Syracuse, N.Y. 12/1/70	"	Contains 2.0 ppm parathion.
Pecorino romano cheese/Jersey City, N.J. 11/23/70	Imported from Italy by N. Dorman & Co./ New York, N.Y. (S)	Contains high pesticide residue.
Shrimp patties, frozen/Mandan, N. Dak. 11/18/70	Appert's, Inc./St. Cloud, Minn. (M), Moore's Seafood Products, Inc./Fort Atkinson, Wis. (S)	Contain Salmonella micro-organisms.
Contamination, Spoilage, Insanitary Handling		
Almonds, in shell/Fairhope, Ala. 12/3/70	Schermer Pecan Co./Fairhope, Ala. (D)	Held under insanitary conditions; rodent contaminated.
Banana peppers/Omaha, Nebr. 11/12/70	Chicago Pickle Co./Redgranite, Wis. (M,S)	Prepared and packed under insanitary conditions; insect and rodent contaminated.
Cashew nuts, shelled/Detroit, Mich. 11/4-5/70	Imported from India by Hollander Trading Corp./New York, N.Y. (S)	Insect contaminated.
Curd cheese/Atlanta, Ga. 11/2/70	Avalon Cheese Co./Leitchfield, Ky. (M,S)	Prepared and packed under insanitary conditions; insect contaminated.
Flour, baker's patent/ Cedar Lake, Mich. 11/30/70	Cedar Lake Foods/Cedar Lake, Mich. (D)	Held under insanitary conditions; rodent contaminated.
Kidney beans, dried/Las Vegas, Nev. 10/22/70	Madonna Italian Foods/Las Vegas, Nev. (D)	Held under insanitary conditions.
Nuts, mixed, canned/Denver, Colo. 12/3/70	Johnson Nut Co./Hopkins, Minn. (M,S)	Prepared and packed under insanitary conditions; insect contaminated; label vignette depicts pecan nuts, but article contains no pecan nuts.
Johnson's Home Treat/Boise, Idaho 11/18/70	"	Prepared and packed under insanitary conditions.
Peanuts, No. 1 Spanish, shelled/Charlotte, N.C. 12/8/70	Burke County Peanut Co./Waynesboro, Ga. (M,S)	Unidentified, live larvae contaminated.
Popping corn/Commerce, Calif. 12/2/70	Dart Warehouse Corp./Commerce, Calif. (D)	Insect contaminated while held for sale.
Rice, Texas patna/Sacramento, Calif. 11/13/70	North American Foods Distributors/ Sacramento, Calif. (D)	"

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
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Contamination, Spoilage, Insanitary Handling (cont'd)

Sausage links, pork/Oklahoma City, Okla. 11/25/70	United Refrigeration Services, Inc./ Oklahoma City, Okla. (D)	Decomposed and rancid.
Scallops, frozen/Seattle, Wash. 11/12/70	New England Fish Co./Vessel "Flamingo" from Alaskan waters (S)	Contain decomposed scallops.
Sesame seed, hulled/Detroit, Mich. 11/19/70	Brown Bun Baking Co./Detroit, Mich. (D)	Held under insanitary conditions; rodent and insect contaminated.
Shrimp meat, frozen/Seattle, Wash. 11/13/70	Winchester Bay Seafood Co./Winchester Bay, Oreg. (M,S)	Prepared and packed under insanitary conditions; staphy- lococci.
Snacktime walnuts/Boise, Idaho 11/18/70	Johnson Nut Co./Hopkins, Minn. (M,S)	Prepared and packed under insanitary conditions; moldy and insect damaged.
Whiting/Gloucester and Boston, Mass. 12/11/70	J. C. Murray/Brooklyn, N.Y. (S) (Imported from Argentina)	Decomposed.

Economic and Labeling Violations

Cherries, canned/Minneapolis, Minn. 10/22/70	Jebavy-Sorenson Orchard Co./Manistee, Mich. (P,S)	Not in conformity with the Fair Packaging and Labeling Act.
Diet Dr. Pepper/Mobile, Ala. 12/4/70	Pepsi Cola-Dr. Pepper Bottling Co./Mobile, Ala. (D)	Fails to bear common or usual name of each ingredient; "invert sugar" not declared.
Feta cheese/New York, N.Y. 10/23/70	William Faehndrich, Inc./New York, N.Y. (D)	Short weight; active fermentation.
Lima beans/Greeley, Colo. 12/15/70	Mar-Bo Quality Foods, Inc./Fresno, Calif. (P,S)	Not in conformity with the Fair Packaging and Labeling Act.
Ma Cohen's Home Made Pickled Schmaltz Herring, Ma Cohen's Imported Party Snack in Wine Sauce/Pittsburgh, Pa. 11/25/70	City Smoked Fish Co.(label)/Detroit, Mich. (M)	"
"Old Fashion Candies" Wild Cherry, Sea Coast Mints, Honey Horehound, Butterscotch, Fruit Mix, Spice Mix, Anise/Milwaukee, Wis. 9/8/70	Arlington Candy Co., Inc./Somerville, Mass. (M,S)	"
Peanuts, Virginia, blanched, and Spanish, salted/Salt Lake City, Utah 11/30/70	Thrifty Foods, Inc./Salt Lake City, Utah (D)	"
Senf Gurken pickles/St. Louis, Mo. 12/3/70	Atkins Pickle Co./Atkins, Ark. (M,S)	"

Food Additive—Dietary Food

Castor bean meal/Swink, Colo. 11/24/70	Plains Cooperative Oil Mills, Inc./Plainview, Tex. (M,S)	An unsafe food additive intended for use in fattening cattle.
Tiger's Milk nutrition booster/Tulsa, Okla. 10/16/70	Plus Products/Los Angeles, Calif. (M,S)	False and misleading labeling concerning biotin and pantothenic acid; no minimum daily requirement.

DRUGS / Human Use

Conjugated estrogens tablets/Baltimore, Md. 12/10/70	DuMont Pharmacal Co., Inc./Philadelphia, Pa. (M,S)	Below labeled potency; 80–83.9 percent of labeled strength.
Dextrocell #2 tablets/Richmond, Va. 12/2/70	Jones & Vaughan, Inc./Richmond, Va. (D)	New drug not approved for safety and efficacy; false and misleading claims for a variety of clinical conditions because of its thyroid components.
Methyl salicylate USP, triethylene glycol/ Jacksonville, Fla. 9/1/70	U.S. Filtronic/Jacksonville, Fla. (D)	False and misleading claims.
Obestat Ty-Med tablets/Auburn, N.Y. 11/6/70	Lemmon Pharmacal Co./Sellersville, Pa. (M,S)	New drug not approved for safety and efficacy.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
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DRUGS/Human Use (cont'd)

Theracort/Hazel Park, Mich. 12/2/70	C & M Pharmacal, Inc./Hazel Park, Mich. (M)	Not processed in conformity with good manufacturing practice.
Vita-Jec A, D, E/Fresno, Calif. 11/23/70	Denver Veterinary Laboratories, Inc./ Denver, Colo. (M,S)	" ; contains particulate matter; labeling implies vitamin E content makes it effective for the prevention and treatment of avitaminosis.

Veterinary—Medicated Feed

Diethylcarbamazine syrup/Savannah, Ga. 10/28/70	Babineaux's Pharmacy/Metairie, La. (M,S)	New animal drug not approved for safety and efficacy.
Muscle Radiol (M-R)/Oceanside, N.Y. 10/26/70	Radiol Chemicals, Ltd./Stepfield Witham Essex, England (M,S)	"
Rabbit feed pellets, chick grow mash, 40% hog concentrate/Colorado Springs, Colo. 11/24/70	Simpson & Co./Colorado Springs, Colo. (D)	Rabbit pellets, a new animal drug not approved for safety and efficacy, contains chlortetracycline, unsafe for use and not declared on label; chick grow mash contains bacitracin, undeclared, and represents to contain procaine penicillin, which is false and misleading; 40% hog concentrate contains undeclared bacitracin and penicillin.

MEDICAL DEVICES

Airox air purifier, Airox water purifier/ Dallas, Tex. 10/22/70	Pollution Control Industries, Inc./Stamford, Conn. (M,S)	False and misleading labeling.
Life Breather-Resuscitator/Gardena, Calif. 11/2/70	General Medical Devices, Inc./Gardena, Calif. (S) Return shipment from Doylestown, Pa.	False and misleading claims to be effective for resuscitation and as a life-saving device in emergency due to asphyxiation from drowning.
Oxygen device/Jacksonville, Fla. 6/5/70	Life Aid Products/Toronto, Ont., Canada (M,S)	False and misleading claims to provide 15-20 minutes of medical oxygen for emergency first-aid; inadequate directions for lay use under the conditions recommended; inadequate warnings against unsafe methods and duration of application which may be dangerous to health.
Port O ₂ Matic/Elk Grove Village, Ill. 12/8/70	Erie Manufacturing Co./Milwaukee, Wis. (M,S)	Claims to be effective for emergency treatment of body injury, electrical injury, exhaustion, and noxious gas inhalation; ineffective for suggested uses and dangerous to health.
Relaxacizor/Redondo Beach, Calif. 10/21/70 Santa Barbara, Calif. 9/17/70	Eastwood Industries/Chicago, Ill. (M)	Inadequate directions for safe use by laymen; labeling fails to bear warnings against unsafe methods and duration of application which may be dangerous to health.
Theramatic device/Indianapolis, Ind. 9/16/70	Dynapower Systems Corp./Los Angeles, Calif. (M,S)	Inadequate directions for safe use by laymen.

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

False Representation Order Issued by Judicial Officer Under 39 U.S.C. 4005

December 29, 1970: False Representation Order issued against Post Shop, P.O. Box 45438, Chicago, Ill. 60645. Advertising and sale

by mail of a product called "New Super Formula Sex Pep Pill," represented to be an effective aphrodisiac.

notices of judgment

NOTICES OF JUDGMENT on Seizure Actions FOOD / Poisonous and Deleterious Substances

Chubs, eviscerated, frozen, at Chicago, N. Dist. Ill.

Charged 12-30-69: while held for sale, the article contained the non-conforming food additives, DDT, DDE, DDD, and dieldrin; 402(a)(2)(C). Default decree ordered destruction. (1)

Eggs, frozen, at Grantsville, Dist. Md.

Charged 5-22-70: when shipped by Roof Garden Egg Co., Meyersdale, Pa., the article contained the added poisonous and deleterious substance, *Salmonella* micro-organisms; 402(a)(1). Default decree ordered destruction. (2)

Eggs, frozen, at Meyersdale and Somerset, W. Dist. Pa.

Charged 6-19-70: when shipped by Roof Garden Egg Co., from Grantsville, Md., the article contained the added poisonous and deleterious substance *Salmonella* micro-organisms; 402(a)(1). Default decree ordered destruction. (3)

FOOD / Contamination, Spoilage, Insanitary Handling

Cornhusks, at Phoenix, Dist. Ariz.

Charged 6-1-70: when shipped by George Walcher, Weimar, Tex., the article contained insect filth and moldy cornhusks; 402(a)(3). Default decree ordered destruction. (4)

Cornmeal, yellow, at Oblong, E. Dist. Ill.

Charged 4-27-70: when shipped by Mont Eagle Mills, Inc., Oblong, Ill., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (5)

Eggs, frozen, at Louisville, W. Dist. Ky.

Charged 8-11-70: when shipped by Illini Egg Products, Inc., Olney, Ill., the article contained decomposed eggs and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (6)

Flour, rye, at Seattle, W. Dist. Wash.

Charged 6-1-70: while in transit and while held in a railroad car, the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to Union Pacific R.R. Co., Seattle, Wash., for salvaging. (7)

Milk, nonfat, dried, at Salem, W. Dist. Va.

Charged 6-18-70: when shipped by Newman Grove Cooperative Creamery Co., Newman Grove, Neb., the article, labeled in part "Valley Lee Brand . . . Pasteurized Nonfat Dry Milk Mid-West Producers Creameries, Inc., South Bend, Ind. Distributor," had been prepared and packed under insanitary conditions; 402(a)(4). Default decree ordered destruction. (8)

Onion rings, breaded, frozen, at Wilmington, E. Dist. N.C.

Charged 12-24-69: when shipped by Southern Frozen Foods, Inc., Montezuma, Ga., the article, labeled in part "Gold King Raw Breaded Onion Rings . . . Packed by Gold King Frozen Foods, Inc., Thunderbolt, Ga.," contained *E. coli*, and bacterial filth, and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (9)

Orange and grapefruit sections, canned, at Norwood, Dist. Mass.

Charged 6-17-70: when shipped by Florida Citrus Cannery Corp., Plant City, Fla., the article, labeled in part "Food Club Pure Florida Grapefruit & Orange Sections . . . Distributed by Topco Associates, Inc., Skokie, Illinois," had been packed and held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (10)

Pecan pieces, at Louisville, W. Dist. Ky.

Charged 5-8-70: when shipped by Sunny South Pecan Co., Statesboro, Ga., the article contained *E. coli*; 402(a)(3). Default decree ordered destruction. (11)

Rice, at Phoenix, Dist. Ariz.

Charged 6-12-70: while held by Arctic Storage Co., Phoenix, Ariz., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (12)

Shrimp, breaded, Trade Winds, at Florence, Dist. S.C.

Charged 5-15-69: when shipped by Trade Winds Co., Thunderbolt, Ga., the article contained coagulase positive staphylococcus and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (13)

Walnut meats, at Seattle, W. Dist. Wash.

Charged 6-1-70: when shipped by Willamette Valley Walnuts, McMinnville, Oreg., the article contained *E. coli*; 402(a)(3). Consent decree ordered destruction. (14)

Whiskey, Seven Crown, at Relay, Dist. Md.

Charged 5-19-70: when shipped by Seagram Overseas Sales Co., New York, N.Y., the article had been held under insanitary conditions, since it had been inadvertently dropped overboard into the harbor waters at Hoboken, N.J.; 402(a)(4). Consent decree authorized release to Joseph E. Seagram & Sons, Inc., New York, N.Y., for reconditioning. (15)

FOOD / Economic and Labeling Violations

Beans, peas, and lentils, dried, at Greeley, Dist. Colo.

Charged 6-17-70: when beans, peas, and lentils, labeled in part "Cas-serole Brand California Baby Lima Beans [or "Split Peas," or "Great Northern Beans," or "California Large Lima Beans," or "California Blackeye Beans," or "Lentils" or "Whole Peas," or "Split Peas"] . . . American Bean & Pea Growers, Inc., Spokane, Wash.," were shipped by Marbo Quality Foods, Inc., Fresno, Calif., Inland Empire Pea Growers Association, Spokane, Wash., and Big Horn Cooperative Marketing Association, Basin, Wyo., and when beans, labeled in part "High Protein . . . Outwest Brand Idaho Red Beans Distributed by Outwest Bean, Inc., Denver, Colo.," were shipped by Bean Growers Warehouse Association,

Idaho, the articles were in violation of the Fair Packaging and Labeling Act, in that the quantity of contents declaration was not in the lower 30 percent of the principal display panel, in that for all lots except the 4-lb. bags of Great Northern Beans the quantity of contents was expressed as "Net Wt. 1 Lb." or "Net Wt. 2 Lbs." instead of "Net Wt. 16 Oz. (1 Lb.)" and "Net Wt. 32 Oz. (2 Lbs.)," and the principal display panels of the packages had an area between 25 and 100 square inches and the statements of the net quantity of contents stated on the panel contained letters and numerals in a type size less than 3/16 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(A), 1453(a)(3)(C)(i). Consent decree authorized release to Outwest Bean, Inc., Denver, Colo., for relabeling. (16)

Candies, orange, grape, and coffee flavored, Stix Pak, at San Francisco, N. Dist. Calif.

Charged 6-2-70: when shipped by Jolly Rancher, Inc., Wheatridge, Colo., the articles were in violation of the Fair Packaging and Labeling Act, in that the principal display panel of the label lacked a declaration of the net quantity of contents; 15 U.S.C. 1453(a)(2). Default decree ordered destruction. (17)

Corn, cream-style, canned, Good Pak, at Salt Lake City, Dist. Utah.

Charged 5-20-70: when shipped by Big Horn Canning Co., Cowley, Wyo., the article was in violation of the Fair Packaging and Labeling Act, in that the net quantity of contents declaration was not separated from other printed label information appearing above or below the declaration, in that the net quantity of contents statement was expressed as "Net Weight 1 Pound" rather than "Net Wt. 16 Oz. (1 Lb.)," in that the principal display panel had an area of between 5 and 25 square inches and the net quantity of contents was stated in a type size less than 1/8 inch high, and in that the label did not state the net quantity of each of the servings of label statement "Servings 4"; 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(3)(C)(i), 1453(a)(4). Default decree authorized donation to public institution. (18)

Herring fillets in sour cream, and herring cuts, spiced, Lasco, at Phoenix, Dist. Ariz.

Charged 5-1-70: when shipped by Los Angeles Smoking & Curing Co., Los Angeles, Calif., the articles were in violation of the Fair Packaging and Labeling Act in that the declaration of net quantity of contents was not in the bottom 30 percent of the principal display panel, and in that the principal display panel had an area between 5 and 25 square inches and the net quantity of contents was stated in a type size less than 1/8 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Consent decree authorized release to the shipper for relabeling. (19)

Peas, canned, Stokely Van Camp, at Pauline, Dist. Kans.

Charged 6-18-70: when shipped by Kumer-Empson Co. (Stokely Van Camp, Inc.), Brighton, Colo., the article was in violation of the Fair Packaging and Labeling Act, in that the declaration of the net quantity of contents was not in the bottom 30 percent of principal display panel, in that the net quantity of contents was expressed as "Net Weight 1 Lb. 1 Oz." instead of "Net Wt. 17 Oz. (1 lb. 1 oz.)," and in that the principal display panel had an area between 5 and 25 square inches and the net quantity of contents was stated in a type size less than 1/8 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(4). Consent decree authorized release to shipper for relabeling. (20)

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

Charged 8-5-70: when shipped from Malaysia, the article, labeled in part "Nugget Brand Sliced Pineapple . . . Distributed by Nugget Distributors, Inc., Stockton, Calif.," fell below the standard of quality for canned pineapple because more than 7 1/2 percent of the more than 27 units in the cans were excessively trimmed; 403(h)(1). Default decree ordered donation to a charitable organization. (21)

Salad dressing, Flav-O-Rite, at Liberty, W. Dist. Mo.

Charged 6-10-70: when shipped by Guy's Foods, Inc., Tulsa, Okla., the article lacked conformity to the standard of identity, since it was deficient in vegetable oil; 403(g)(1). Consent decree authorized release to shipper for compliance operations. (22)

VITAMINS / DIETARY FOODS

Iodine dietary supplement tablets, at Grand Rapids, W. Dist. Mich.

Charged 10-12-70: while held by Muir Drug Labs, Inc., Grand Rapids, Mich., who manufactured the article from kelp shipped in interstate commerce, the valuable constituent, iodine, had been in part omitted or abstracted from the article, and the label lacked required information concerning the minimum daily requirement for iodine supplied by the article; 402(b)(1), 403(j). Default decree ordered destruction. (23)

FOOD ADDITIVES

Flour, at Kansas City, W. Dist. Mo.

Charged 8-4-70: when shipped by Wheat Products Co., Inc., Colorado Springs, Colo., the article, labeled in part "New Improved W.M.C. Baking Specialty Wolf Unbleached Hard Wheat Flour and Soya Flour," contained the nonconforming food additives, nitrites and nitrates; 402(a)(2)(C). Default decree ordered destruction. (24)

ANIMAL FEED

Cattle feed, medicated, Hi-Energy Range Cubes, at LaSalle, Dist. Colo.

Charged 5-28-70 and amended 6-3-70: while held by John Ewing Co., LaSalle, Colo., who manufactured the article from a premix which contained neomycin sulfate and had been shipped in interstate commerce, the article was an animal feed containing a new animal drug, and no approval of an application filed with respect to such animal feed was in effect; and the labeling contained false and misleading claims concerning the efficacy of the article in the prevention of scours in calves by feeding to the mother cow; 501(a)(6), 502(a). Consent decree authorized release to the dealer for compliance operations. (25)

Pig feed, medicated, at Horse Cave, W. Dist. Ky.

Charged 8-27-70: when shipped by Cooperative Mills, Inc., Cincinnati,

Ohio, the article, labeled in part "SS Pig Starter Medicated . . . Southern States Cooperative Inc., Cooperative Mills Div. General Office Baltimore, Maryland," was deficient in arsenic acid (approx. 90 percent), and its labeling with respect to its arsenic acid content was false and misleading; 501(c), 502(a). Consent decree ordered destruction. (26)

DRUGS / Human Use

Amphetamine-barbiturate-vitamin combination capsules, at Mansfield, N. Dist. Ohio.

Charged 5-27-70: when shipped by Plymouth Labs., Inc., Plymouth, Mich., the strength of the article, labeled in part "Amvidex Timecaps . . . Distributed by The Caldwell & Bloor Company, Mansfield, Ohio," differed from that which it purported to possess, and the label declaration of potency was false and misleading, since the article contained only 73.3 percent of the declared amount of dextro-amphetamine sulfate and 79.1 percent of the declared amount of amobarbital; 501(c), 502(a). Default decree ordered destruction. (27)

Bacitracin ointment, U.S.P., at Atlanta, N. Dist. Ga.

Charged 5-26-70: when shipped by Abbott Laboratories, North Chicago, Ill., the article's strength differed from U.S.P. standard, since the article was understrength in bacitracin (approx. 24 percent); 501(b). Default decree ordered destruction. (28)

Calcium chloride injection, N.F., at Detroit, E. Dist. Mich.

Charged 2-13-70: while held for sale after manufacture locally by Atlas Pharmaceutical Labs., Inc., Detroit, Mich., from ingredients shipped in interstate commerce, the labeling lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information; and the article was not packaged as prescribed by the National Formulary, since it was packaged in multiple dose containers; 502(f)(1), 502(g). Default decree ordered destruction. (29)

Calstron calcium-gluconate strontium-bromide combination injection, at Mableton, N. Dist. Ga.

Charged 6-30-70: when shipped by Farnsworth Laboratories, Inc., Chicago Heights, Ill., the article was a new drug without an effective approved New Drug Application, and the labeling contained false and misleading claims for various types of dermatological conditions; 505(a), 502(a). Default decree ordered destruction. (30)

Cold Sore IVO camphor thymol combination cream, at Minneapolis, Dist. Minn.

Charged 6-25-70: when shipped by Walter S. Wanacke, t/a Ivo Co., Milwaukee, Wis., the labels of both lots of the articles lacked a quantity of contents statement, and some labels of one lot of the article lacked the established name of each active ingredient; 502(b)(2), 502(e)(1)(A)(ii). Default decree ordered destruction. (31)

Formula 1275 KI and lobelia combination elixir, at Keokuk, S. Dist. Iowa.

Charged 5-14-70: when shipped by Ulmer Pharmacal Co., Minneapolis, Minn., the labeling lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information; 502(f)(1). Default decree ordered destruction. (32)

Iodinated casein tablets, at Louisville, W. Dist. Ky.

Charged 9-11-69: when shipped by Beth Corp., Miami, Fla., the article was a new drug without an effective approved New Drug Application; 505(a). Consent decree ordered destruction. (33)

Lipo-K lipotropic factor combination injectable, Ossonate Plus mucopolysaccharide extract combination injectable, at Philadelphia, E. Dist. Pa.

Charged 10-24-69: when shipped by Marcen Laboratories, Inc., New Rochelle, N.Y., the articles were new drugs without effective approved New Drug Applications; 505(a). Default decree ordered destruction. (34)

Lubricating jelly, sterile, at Augusta, S. Dist. Ga.

Charged 4-7-70: when shipped by Badger Laboratories, Inc., Jackson, Wis., the article's quality and purity were deficient and its labeling was false and misleading, since the article was not sterile; 501(c), 502(a). Default decree ordered destruction. (35)

Pentaerythritol tetranitrate tablets and reserpine tablets, U.S.P., at Chicago, N. Dist. Ill.

Charged 4-17-69: while held by G & G Drug Co., Chicago, Ill., who was repackaging the articles, their labeling failed to bear adequate directions for use and the articles were not exempt from such requirements; 502(f)(1). Consent decree authorized release to the dealer for compliance operations. (36)

Thyroidig T-13 tablets and T-32 tablets (thyroid-digitalis combinations), Thyroidig anterior pituitary tablets (thyroid, digitalis, and anterior pituitary combination), and thyroid 5 gr. tablets, at Houston, S. Dist. Tex.

Charged on or about 5-28-68: when shipped by Western Research Labs., Inc., Denver, Colo., the labeling of the Thyroidig T-13 tablets and Thyroidig anterior pituitary tablets contained false and misleading claims that thyroid-digitalis combinations were of value in the treatment of individuals requiring the thyroid effect and that thyroid safely accelerated cellular metabolic processes increasing the metabolic rate; the labeling of the Thyroidig T-32 tablets contained false and misleading claims that thyroid safely accelerated cellular metabolic processes, increasing the basal metabolic rate, that Western Research Labs., Inc., had overcome many of the thyroid disadvantages, and that Western Research Labs.' thyroid-digitalis preparations were safe and effective adjuncts in the treatment of obesity; the labeling of the thyroid 5 gr. tablets contained false and misleading claims that such tablets accelerated cellular metabolic processes, were safe and effective as an adjunct to the dietary treatment of obesity, and were safe and effective in the treatment of menstrual disorders, infertility, threatened abortion, and skin diseases; the labeling of the thyroid 5 gr. tablets failed to reveal the material facts that such tablets were not safe and effective in treatment of obesity, menstrual disorders, infertility, threatened abortion, and certain skin diseases except where such conditions were associated with hypothyroidism, and that the overwhelming number of persons suffering from such conditions are not afflicted with hypothyroidism; the labeling of all the articles lacked adequate directions for use and did not comply with the Rx drug exemption requirement for disclosure of information; all articles were dangerous to health when used in the dosage and with the frequency and duration suggested in their labeling; and all articles were new drugs without effective approved New Drug Applications; 502(a), 502(f)(1), 502(j), 505(a). Consent decree ordered destruction. (37)

MEDICAL DEVICES

Dynatone electronic facial stimulator, at Minneapolis, Dist. Minn.

Charged 9-27-67 and amended 6-28-68: when shipped by Dynatone, Inc.,

Wichita, Kans., and while held by Powers Dry Goods Co., Minneapolis, Minn., the accompanying labeling contained false and misleading claims for firming and toning key age-revealing areas of the face and neck, firming underlying areas strengthening sagging muscles electronically exercising hidden face and neck muscles, firming delicate facial muscles thereby preventing or eliminating double chins, crow's feet, and other facial contour problems, and making the user look years younger; the article's label lacked the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; the article's labeling lacked adequate directions for use, since a number of packages did not bear or contain directions for use; and the article's labeling lacked adequate warnings against unsafe use; 502(a), 502(b)(1)(2), 502(f)(1), and 502(f)(2).

The article was claimed by Dynatone Electronic Corp., New York, N.Y., who denied that the article was misbranded as alleged in the complaint. Thereafter the Government served interrogatories upon the claimant and moved to amend the complaint to include misbranding charges in addition to the original 502(a) charge. The claimant objected to the interrogatories and resisted the motion to amend the complaint. The court overruled the claimant's objections to the interrogatories, except where, on the authority of *United States v. Article of Drugs*, 43 F.R.D. 181(D. Del. 1967), the court sustained the claimant's objections to a number of interrogatories which depended upon the identification of certain exhibits as being copies of brochures seized in the action. The court also concluded that the Government was entitled to amend its complaint pursuant to Rule 15(a), saying:

"The United States failed to amend its complaint within the time allowed as a matter of right. Rule 15(a) provides as to amendments on motion that 'leave shall be freely given when justice so requires.' The claimant objects under Rule 7(b)(1) contending that the moving papers lack the necessary particularity. In fact the moving papers do fail to set forth any reasons for requesting the amendment. However, each proposed paragraph in the amendment alleges the violation of a precise statutory provision of the Federal Food, Drug, and Cosmetic Act and the interests of justice and the lack of showing of any significant prejudice to the claimant militates in favor of permitting the amendment. The new paragraphs of the amendment speak for themselves in alleging violations of statutory provisions. The grounds for seeking leave to amend are implicit in the amendment and it is obvious from a quick perusal that the United States believes that the device Dynatone infringes additional statutory provisions beyond those alleged in the original complaint. Trial date is some months off and claimant has adequate time to prepare his defense without prejudice."

The case came in for trial by the court. Two expert medical witnesses testified for the Government in a test involving use of the device; and "Before and after" color photos were received in evidence. To the court and according to the testimony of those experts, there was no distinguishable or observable difference or improvement in facial difference in any of the subjects. The court said:

"More forceful and convincing however than the above experiment was the medical testimony concerning the effect of aging on the skin and the results not obtained by muscle contraction. One of the aforementioned experts and two other medical experts called by the Government, one a specialist in physical medicine and rehabilitation, the other a dermatologist, testified in summary that facial and neck muscle exercise or contraction would have no effect on wrinkling of the skin, or if anything would promote or increase it. The testimony was to the effect that exercise does nothing for wrinkled skin overlying a muscle. Electrical stimulation, while causing a muscle contraction, will not cause muscle growth, i.e., hypertrophy, though it might slow down but will not stop muscle atrophy. Voluntary exercise can cause increase in muscle size, and to that extent would or might stretch the overlying skin and thus reduce wrinkles therein to some extent. No such result can be obtained however by artificial electrical muscle contraction. The testimony was clear that the use of the device would not be effective to help or reduce crow's feet, double chins, or jowls. These conditions relate to the elasticity of the skin itself and have no relation to muscle tone or the loss thereof nor to weakness or atrophy of facial muscles. Wrinkling is in large part caused by the skin's failure to resume its normal state after a bending or folding caused by muscle contraction. Increased exercise of underlying facial muscles if it affects the wrinkling process at all, probably makes the wrinkles worse. This evidence was very convincing to the court and the court finds it to be true."

On the basis of the evidence received at the trial, a study of the parties' memoranda, and in all of the files, records, and proceedings of the action, the court found that the article was in violation of 502(a), condemned the article and authorized delivery of the article to FDA for destruction or use only for exhibition purposes. (38)

Oxygen mask, Respirax, at Los Angeles, C. Dist. Calif.

Charged 9-5-69: when shipped by Respirax International, Guadalajara, Mexico, the labeling contained the false and misleading claim that the article contained a 10-minute supply of life-sustaining oxygen for vital emergency first aid; the labeling lacked adequate directions for use for heart attack, drowning, stroke, asthma, shock and smoke inhalation, and such directions could not be written for safe use by the untrained laity; and the labeling lacked adequate warnings against use; 502(a), 502(f)(1), 502(f)(2). Consent decree authorized release to the Respirax Corp., Los Angeles, Calif., for export to the original foreign supplier, and perpetually enjoined the Respirax Corp., and its agents, servants, employees, and attorneys, and all persons in active concert or participation with them from introducing into interstate commerce the Respirax device consisting of a mask and oxygen container purportedly containing 38 liters of oxygen. (39)

Respirator, at Nashville, M. Dist. Tenn.

Charged 7-24-69: when shipped by Crown Products Co., Cleveland, Ohio, the article, labeled in part "For every breathing difficulty . . . Res-Q-Aire Emergency Respirator . . . A product of Machsa Incorporated Distributed exclusively by Crown Products Co. . . A Division of the Chilcote Company," bore the name Res-Q-Aire and statements on the carton label and attached card which were false and misleading as to the adequacy and effectiveness of the article as a means of resuscitation; the labeling lacked adequate directions for use, and such could not be written, since the article was neither effective nor safe for its intended purpose; the labeling lacked warnings against use involving obstructions, aspirated objects and dentures, and involving infants or children where the volume of air would be excessive; and the article was dangerous to health when used as directed by its labeling; 502(a), 502(f)(1), 502(f)(2), 502(j). Default decree ordered destruction. (40)

Theramic model A-6DT40 electronic instrument, at Daytona Beach, M. Dist. Fla.

Charged 5-27-70: when shipped by unknown shipper, the article's labeling contained false and misleading claims for infections, otitis media, fractures, bone and tissue healing, smooth muscle spasm, bursitis, arthritis, low back pain, headaches—parietal and occipital, urinary tract infections, ulcers—decubital, prostatitis, and sinusitis; its labeling lacked adequate directions for such uses and adequate directions could not be written, since the article was worthless for such uses; and the article was dangerous to health when used in the dosage and with the frequency and duration recommended in its labeling, since it was ineffective for the treatment of the serious disease conditions for which it was recommended and by reason of its ineffectiveness, it was unsafe for such use; 502(a), 502(f)(1), 502(j). Default decree ordered destruction. (41)

COSMETICS / BEAUTY PRODUCTS

Hair brushes, at Buffalo, W. Dist. N.Y.

Charged 5-18-70: when shipped by unknown shipper from outside the United States, the article, labeled in part "Vienna [or "Vienco"] Made in France," contained nits; 601(b). Default decree ordered destruction. (42)

HAZARDOUS SUBSTANCES

Cherry bombs, at Hanna Junction, Dist. Wyo.

Charged 6-30-70: while held at a fireworks stand, Hanna Junction, Wyo., the articles were banned hazardous substances, since they were packed in a form suitable for use in the household and were intended to produce audible effects by a charge of more than 2 grains of pyrotechnic composition; 2(q)(1)(B). Default decree ordered destruction. (43)

Lime-Elim rust and lime eliminator, at St. Paul, Dist. Minn.

Charged 6-10-70: when shipped by Winn-Sol Products, Inc., Oshkosh, Wis., the article was an irritant substance containing approximately 15 percent phosphoric acid, and it lacked a number of the required conspicuous label statements; 2(p)(1)(B,D,E,G,J). Default decree ordered destruction. (44)

NOTICES OF JUDGMENT on Criminal Actions

FOOD

Atlanta Textile Corp., and Isahag Aprahamian, president, at Brooklyn, E. Dist. N.Y.

Charged 3-18-70: when received from Brazil and delivered for pay in Brooklyn, N.Y., black pepper contained mold—402(a)(3); and when shipped from New York to Illinois, black pepper contained mold—402(a)(3). Guilty plea by corporation; fine. Nolo contendere plea by individual; fine. (45)

City Sales Co. of Mobile, Inc., and John P. Finlayson, president, Mobile, S. Dist. Ala.

Charged 4-7-70 by grand jury: 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). Nolo contendere pleas; fines. (46)

Hollar & Greene Produce Co., a partnership, and Lige C. Hollar and Dale L. Greene, partners, Boone, M. Dist. N.C.

Charged 4-9-70: when shipped, cabbage contained quantities of toxaphene and parathion in excess of the tolerances; 402(a)(2)(B). Guilty plea by partnership; fine. Guilty pleas by individuals; fines and probation. (47)

Zatarain's, Inc., and Chloe R. Anderson, president, at Gretna, E. Dist. La.

Charged by grand jury 3-26-70: when shipped, Fish-Fri corn flour, Chick-Fri seasoned corn flour, and Zatarain's Crab Boil seasoning contained insect filth and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Nolo contendere plea by corporation; fine. Nolo contendere plea by individual; probation. (48)

HAZARDOUS SUBSTANCE

Richard Chalaire, t/a Plaquemines Parish Bar, and Murray D. Latapie, bartender, Braithwaite, E. Dist. La.

Charged by grand jury 10-30-69: while held for sale, silver salute fireworks (count 1) were sold to a child, and cherry bombs (counts 2, 3, 4) were sold to FDA inspectors, which resulted in such fireworks being banned hazardous substances in that they were toys which were flammable substances and generated pressure through explosion when ignited; 2(q)(1)(A).

The defendants pleaded not guilty and moved to dismiss the indictment on the grounds that (1) the Federal Hazardous Substances Act did not prohibit the sale of banned hazardous substances that have been shipped in interstate commerce and (2) the silver kings and cherry bombs were exempt as common fireworks. The court denied the motion and the case came on for trial before the court. The court found both defendants guilty. In its opinion, the court said:

"A. Defendants Chalaire and Latapie did and caused the doing of an act with respect to a hazardous substance by selling silver kings and cherry bombs.

"Selling a hazardous substance is 'the doing of any act with respect to a hazardous substance.' The legislative history of the Act clearly shows that Congress intended 'to ban the sale of toys and other children's articles containing hazardous substances.' 1966 U.S. Code Congressional and Administrative News 4095 (Emphasis added). The Supreme Court has so interpreted an analogous provision of the Food, Drug and Cosmetic Act. *U.S. v. Wiesenfeld Warehouse Co.*, 376 U.S. 86 (1964). * * *

"Here, the evidence showed beyond a reasonable doubt that the silver king and cherry bombs were (1) flammable, (2) generated pressure through decomposition and heat, and (3) may cause substantial personal injury as a proximate result of any reasonably foreseeable handling or use.

"Both defendants are liable for selling the hazardous substances. Section 1263(b) expressly provides that 'The following acts and the causing thereof are hereby prohibited' (Emphasis added). The evidence that defendant Latapie personally sold the cherry bombs in Counts 2, 3 and 4 is undisputed. Defendant Chalaire is liable on all 4 counts because he caused the sales. *U.S. v. Dotterweich*, 320 U.S. 277 (1943); *Palmer v. U.S.*, 340 F.2d 48 (5 Cir. 1964). Here, Chalaire admitted that he owned the bar, purchased the inventory of silver kings and cherry bombs, advertised them, hired persons to sell them and collected the profits. The fact that Chalaire did not personally do the selling is immaterial.

"B. The silver kings and cherry bombs were held for sale after shipment in interstate commerce.

"The interstate shipment of a product is proved if the evidence shows that the product was found within a state, and that the product was either not manufactured there or was manufactured in another state. *Palmer v. U.S.*, 340 F.2d 48 (5 Cir. 1964). Here, the evidence showed that no

Louisiana business had ever been licensed to manufacture silver kings or cherry bombs. In fact manufacture of those type fireworks (Class B) was prohibited. In addition an expert in the chemical analysis of fireworks testified that the silver kings were manufactured in Ohio and the cherry bombs were manufactured in New Jersey. I find beyond a reasonable doubt that they were so manufactured.

"C. The sale of the silver kings and the cherry bombs resulted in those hazardous substances being 'banned hazardous substances.' * * *

"Silver kings and cherry bombs are 'toys' within the meaning of the Act. The Act itself expressly excludes Class C (common) fireworks but not Class B fireworks. 15 U.S.C. §1261(q)(1)(ii). Also the legislative history of the Act clearly shows that Congress intended to include silver kings and cherry bombs (Class B fireworks) within the definition of toy. 1966 U.S. Code Congressional and Administrative News, 4095, 4096, see especially 4099.

"The silver kings and cherry bombs are not exempt from the definition of banned hazardous substances because (1) they are not common fireworks and (2) they were not intended and used for bona fide agricultural purpose.

"Here the evidence showed that the silver kings and cherry bombs produced audible effects by a charge of more than 2 grains of pyrotechnic composition. The cherry bombs contained 20 grains and the silver kings about 40 grains. The evidence also showed that the fireworks were not intended or used for bona fide agricultural purposes. The buyers were never asked whether they intended to use the fireworks for agricultural purposes and the fireworks never were so used.

"The sale of silver kings and cherry bombs to a child or to an adult without first asking the adult whether a child would use them results in those hazardous substances being a banned hazardous substance. The purpose of the Child Protection Act is to protect children. This is accomplished by banning hazardous toys from channels of interstate commerce that lead to children. All fireworks are not absolutely banned. Class B fireworks are not banned from channels of interstate commerce leading to persons who use them for bona fide agricultural purposes. But Class B fireworks are banned from channels that lead to children. Of course Class C fireworks are not banned at all even if the channel leads to children.

"Here, Chalaire is liable for the sale of silver kings to Dolese because Dolese was a child at the time of the sale. Chalaire admitted that Dolese was a child and should not have been sold Class B fireworks as a matter of common sense. The fact that the cherry bombs in Counts 2, 3 and 4 were sold to an adult is immaterial. The cherry bombs were toys. No one asked the buyer whether children would use them. The seller had a duty to inquire. *cf. U.S. v. Dotterweich*, 320 U.S. 277 (1943). Both Chalaire and Latapie are liable for this sale.

"D. Knowledge and willfulness are not elements of the offense. But in any event knowledge and willfulness were proved beyond a reasonable doubt.

"Knowledge and willfulness are not an element of 15 U.S.C. §1263(b). Nowhere in the statute is this element mentioned. It is clear from the legislative history of the statute that Congress intended that knowledge and willfulness not be an element. The Child Protection Act of 1966 amended the Federal Hazardous Substances Labeling Act of 1960. The prohibited Acts section of the latter Act is 'patterned after the corresponding section of the Federal Food Drug and Cosmetic Act [21 USC §331]'. 1960 U.S. Code Congressional and Administrative News 2840. The Supreme Court and the Fifth Circuit have interpreted 21 U.S.C. §331 as not requiring knowledge and willfulness. *U.S. v. Dotterweich*, 320 U.S. 277 (1943); *U.S. v. Wiesenfeld Warehouse Company*, 379 U.S. 86 (1964); *Palmer v. U.S.*, 340 F.2d 48 (5 Cir. 1964)." * * * (49)

NOTICES OF JUDGMENT on Injunction Action

Maizel Labs, Inc., and Benjamin L. Maizel, president, Chicago, N. Dist. Ill.

Charged 10-3-69 in complaint for injunction: that the defendants were engaged in manufacturing, packing, and labeling various drugs, in holding a number of such drugs for sale after shipment of one or more of their components in interstate commerce, and in distributing a number of such drugs in interstate commerce; that the circumstances of the defendants' manufacture, packing, and holding lacked conformity with current good manufacturing practice; that a number of the drugs differed in strength from, and their quality and purity fell below, the U.S.P. and N.F. standards, or that which the drugs themselves purported and were represented to possess; that the labeling of a number of drugs contained false and misleading statements concerning the identity, quality, and strength of the drugs; and that the labeling of a number of drugs lacked adequate directions and did not comply with the Rx drug exemption requirement for disclosure of information; and that the defendants had distributed a new drug, Robese Gel, without an effective approved New Drug Application; 501(a)(2)(B), 501(b), 501(c), 502(a), 502(f)(1), 505(a).

A consent decree of permanent injunction was entered enjoining the defendants from the violations complained of, and enjoined the further interstate shipment and the manufacture of drugs at the defendants' plant unless and until a number of specified good manufacturing practices were established, assays were made of drugs in possession of the defendants, recalls were made of such assayed drugs as were necessary, and the assayed and recalled drugs were destroyed or brought into compliance with the law. (50)

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 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.

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

Published by direction of the Secretary of Health, Education, and Welfare.

Charles C. Edwards, M.D., Commissioner of Food and Drugs
Washington, D.C., March 1, 1971



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Announcements

HANDBOOK AVAILABLE The American Pharmaceutical Association announces that its new, revised 1971 edition of the *Handbook of Non-prescription Drugs* is off the press and available for immediate order. In a special prepublication period that ended in January, nearly 5,000 copies of the *Handbook* were sold, APhA said, indicating its exceptional acceptance by pharmacists and other health professionals. The new 202-page *Handbook* is 20 percent larger than the previous (1969) edition and contains 31 chapters, each devoted to a specific class of home remedies. It includes the formulas of more than 1,000 different brand-name products in almost 1,200 dosage forms, and, in addition to a cross-reference product index, it has an index of nearly 300 manufacturers, 76 pages containing tables and charts of products, and a score of medical illustrations and scientific graphs.

The *Handbook* is available at \$6.50 per copy from the Order Desk, American Pharmaceutical Association, 2215 Constitution Avenue, N.W., Washington, D.C. 20037. Orders under \$10 must be accompanied by payment.

ANNUAL IFT MEETING The 31st Annual Meeting and Exposition of the Institute of Food Technologists will be held May 23-27 at the Americana Hotel in New York City. IFT's New York Section will be host and has built its program around the theme, "New York—New Ideas."

For further information contact George R. Foster, Director of Field Services, Institute of Food Technologists, Suite 2120, 221 North LaSalle Street, Chicago, Illinois 60601.

STATISTICAL SUMMARY OF INDUSTRY PARTICIPATION IN FDA WORKSHOPS, SEMINARS, AND CONFERENCES / JULY 1, 1970—MARCH 31, 1971

District Workshops and In-Plant Seminars

	No.	ATTENDANCE	
		Firms	People
Chemical Contamination	3	92	120
Bacterial Contamination	6	214	448
Bacterial In-Plant	2	2	71
Sanitation	18	822	1248
Sanitation In-Plant	1	1	400
Cosmetics	3	300	525
Total	33	1431	2812

National Conference

	No.	ATTENDANCE	
		Firms	People
Food and Drug Law Institute	1	400	725

These workshops and conference are designed to respond to the needs of the regulated industries for information about various problems in compliance, and to clarify for industry any fine points of the laws administered by the Food and Drug Administration. Normally, these workshops are initiated in FDA Districts because they are most familiar with industry's needs in their geographical areas. The Office of Compliance, Bureau of Foods, is gratified by the cooperation from industry to date in these areas.