

JULY-AUGUST 1967

FDA PAPERS

The Review and Processing of
NEW DRUG APPLICATIONS

Establishing and Monitoring
DRUG RESIDUE LEVELS

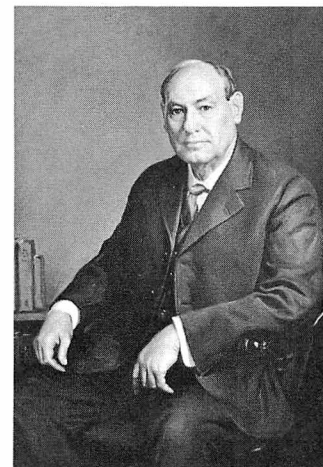
LSD

The False Illusion

FOOD STANDARDS

"To Promote Honesty and Fair Dealing"





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

Harvey W. Wiley

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

"The atrocious crime of being a young man . . . I shall neither attempt to palliate nor deny; but content myself with wishing that I may be one of those whose follies may cease with youth, and not of that number who are ignorant in spite of experience."

So William Pitt answered Walpole's criticism in the House of Commons back in the 18th century.

Today we'd more likely hear:

"It's a gas, man; like you're the fuzz."

Translation: Youth has its follies of which each age must be tolerant. To be ignorant of youth's fads and fancies is to invite their scorn.

Today's adult population has a tendency to be ignorant of the true nature of adolescent fads manifested by bizarre dress and behavior. It is not true, for instance, that long hair, bare feet, and innovative dress are the habit of the drug abuser. The "Hippies" and "Flower Children" may or may not experiment with drugs.

It is a point to be remembered by officials and educators concerned with the drug abuse problem (see page 10). We cannot assume that drug abuse occurs wherever and whenever we see the manifestations of youthful follies. We must make it our business to understand the mercurial nuances of fads and fancies so we can sort out the innocent from the hazardous; so we can be tolerant of the former and protective about the latter.

quotes

“It is the goal of FDA to assure that the labeling and advertising of prescription drugs convey to physicians truthfully, adequately, and effectively the best available drug-use information. This goal simply means: The labeling and advertising of a prescription drug shall faithfully furnish the doctor the information each of us wants him to have in mind when he is about to use a drug on us or on those we love!”

Julius Hauser, Assistant for Regulations, to the Food and Drug Law Institute Seminar at the School of Law, Northwestern University, April 14, 1967.

“The questions ‘Must our products be *Salmonella* free? Will FDA seize every lot of product in which *Salmonella* is found? When will the FDA program go into effect? Will there be any tolerance for *Salmonella* in feeds?’ have been raised frequently. In arriving at answers to these and similar questions, let us look back to the incidence of *Salmonella* contamination in these products—33 to 50 percent, in contrast to the .5 to 3½ percent incidence in other feeds and feed ingredients.

* * * * *

“Our enforcement approach is, and will be, to take regulatory action against the more flagrant offenders; against the contaminated products of those plants that continue to operate with a demonstrated disregard for the recommended Sanitation Guidelines developed by USDA and your association. Our short-time goal is significant reduction in contamination. When the incidence of contamination of your products is reduced to levels comparable to other categories of feeds, that will be the time to reevaluate the situation and consider what further improvements are practicable.”

Kenneth R. Lennington, Salmonella Project Officer, to the National Renderers Association, Inc., Salmonella Workshop, Baltimore, Md., May 9, 1967.

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Food Standards FDA reaffirms its responsibility to the consumer 4 through plans for a stronger food standards program.

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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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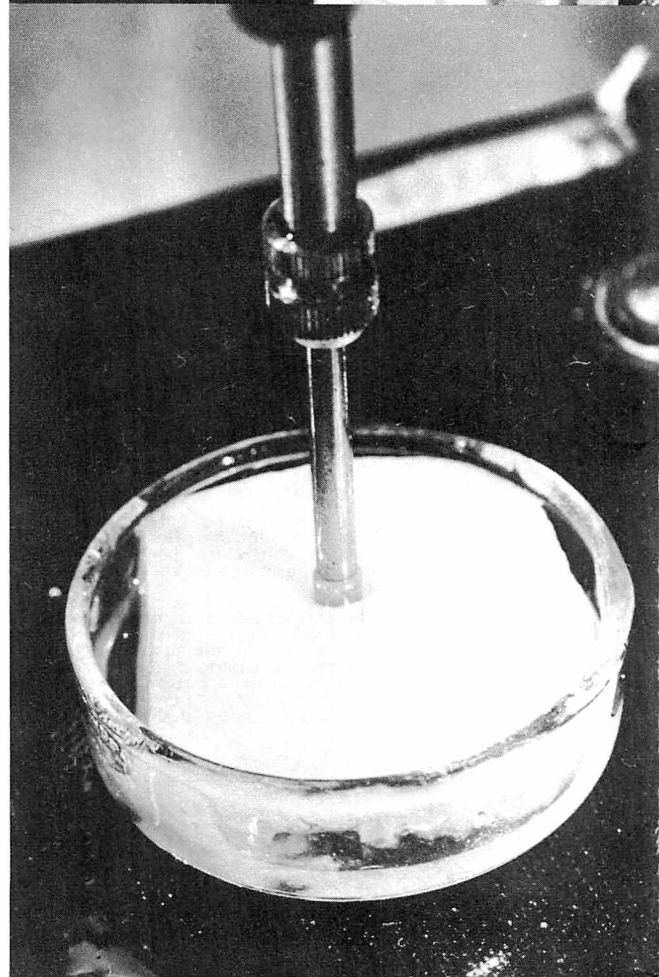
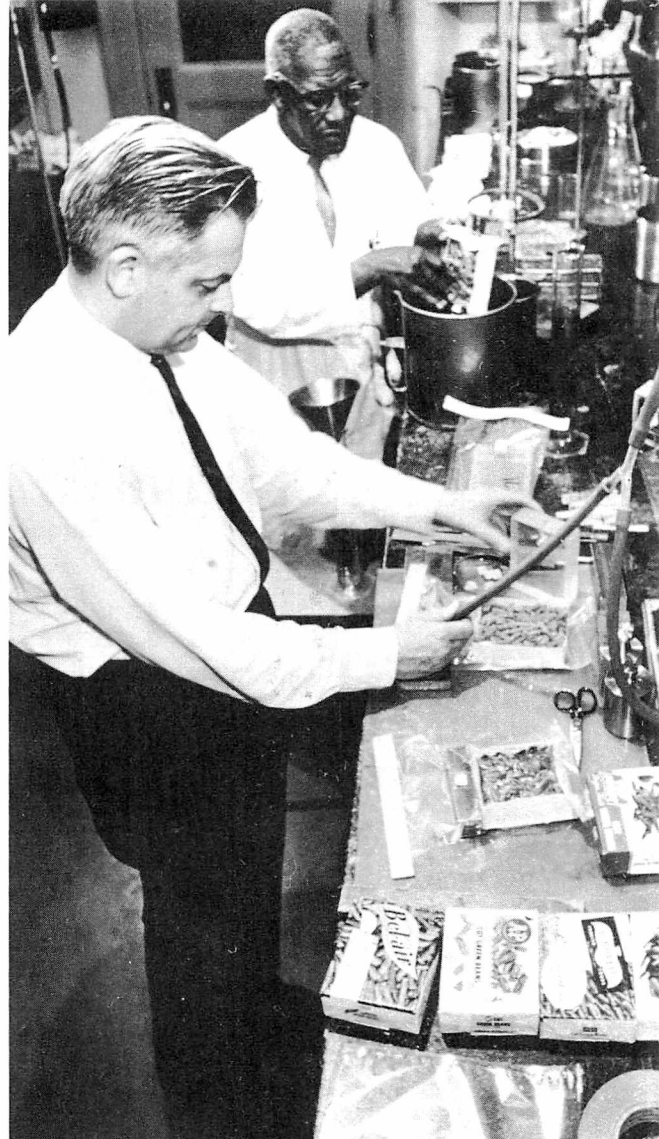
The Food, Drug, and Cosmetic Act authorizes reasonable standards for foods to be established when such action will "promote honesty and fair dealing in the interest of consumers." FDA is now engaged in a new program to carry out the purpose of this authorization. This marks the rejuvenation, renewal, and expansion of a program that achieved substantial results in the late 1930's and early postwar years, when a majority of the more than 365 standards that we now have were established.

food standards

by L. M. Beacham

During World War II, when manpower problems required the Agency to concentrate on essential health matters, FDA's food standards program lagged. Initiative for standards was left to industry and its role has been largely to promote amendments and modifications which would ease the strictures of the existing standards against some change in product or technology. This is entirely commendable if the change results in a product desirable and acceptable to consumers.

However, this sort of industry incentive is not to be accepted as meeting fully the guideline "to promote honesty and fair dealing in the interest of consumers." FDA has not changed its view of that congressional language; the Agency has not forgotten that the emphasis is on the phrase: *in the interest of consumers*. Food standards are not a device to be used in



“to promote honesty and fair dealing in the interest of consumers”

To keep pace with the proliferation of convenience foods and other changes in the food industry, FDA is renewing and expanding its food standards program. For instance, today's consumers buy a variety of frozen foods that were unheard of a generation ago. Above, scientists measure the filler content of packages of frozen beans. Testing for a current standard on canned peaches is shown at left. To meet the standard for firmness, the peach must be able to be pierced by a weight of not more than 300 grams.

the interest of industry to circumvent the consumer's right to choose.

It is with this view that statements have been made by FDA officials in the hope of encouraging industry initiative for the establishment of new standards for foods and food forms that have become commonly accepted in the marketplace since World War II. At present it appears that FDA will have to supply most of the initiative for establishing new standards. We are doing this in the program now under way.

The courts assume that “honesty,” “fair dealing,” or “interest” of the consumer, are words intended to have their everyday, ordinary meanings. Honesty has the connotation of truthfulness or freedom from fraud. Fair dealing suggests informative and truthful labeling, full measure, acceptable quality, and correct weights. The interest of the consumer is economic. Obviously it also extends to matters affecting his health or offending his aesthetic sensibilities, but as the term relates to food standards we believe that it is intended to deal more with economic considerations.

This gives us the frame of reference for a standards program. It should provide for products having integrity in their composition, truthful information in their labeling, and designed to fulfill the consumer's reasonable expectations. Where there is a choice of options in developing the requirements of a standard, the choice should be made that will result in a product having more desirable characteristics (texture, appearance, nutrition, or palatability) or equally acceptable characteristics as other alternatives might furnish, but at a lower cost.

These objectives can often be achieved through a standard of identity specifying the composition of the food, with or without permissible variations, and designating the legal name under which it must be sold, along with other required

labeling information. Further benefits for the consumer are possible through a standard of quality specifying minimum quality characteristics that the food must have unless labeled to show that it does not meet these requirements. There is, of course, no bar to a manufacturer producing a product having higher quality characteristics than the minimum required.

The objective may be approached through a standard of fill prescribing the minimum quantity, either of the total food in the container, or of the more valuable and characterizing ingredient that must be present. For example, a can of tomato juice is required to be not less than 90 percent full, while a can of fruit cocktail must have a minimum quantity of the drained fruit ingredients in addition to the surrounding sirup. Products which are substandard in fill must also bear special labeling.

In planning our food standards program and setting priorities to obtain the maximum consumer benefit with the resources available, we consider the following points.

First, the prospective standard may be needed to correct an abuse that is occurring in the manufacture or marketing of the product.

Second, it may merely articulate and formalize what is essentially a “de facto” standard resulting from years of industry practice and consumer acceptance. Such action will prevent future undesirable changes in manufacturing or labeling practices. Much of our current standards-making falls into this category.

It should be emphasized that a standard, once established, is not intended to hamper or discourage changes in the food product that tend to upgrade it or to afford desirable variations for the consumer's choice. Proposed amendments to accommodate these will always be welcomed, and expedited.

Foods selected for standardization should be those that many people use in fairly substantial

quantities. For example, little consumer benefit could be derived by establishing a standard for an exotic food that one person in a hundred occasionally uses. Other things being equal, priority should go to those foods that are important in the diet of lower income groups. In brief, standards should be established only when a clear-cut consumer benefit, real or prospective, can be expected.

Recently a new factor has arisen that deserves consideration in planning and carrying out a program of new standards. This is the Codex Alimentarius International Food Standards Program, conducted under the joint sponsorship of FAO and WHO. It is designed to establish international standards for processed, semiprocessed, and raw foods. At present approximately 40 countries are participating, with standards for some 75 foods under development.

Soon the United States will be asked to accept these standards or to reject them, either in part or in toto. If we accept them, they will be binding upon domestic shipments as well as exports; if we reject a Codex standard, our exports would still have to comply with it when going to the countries who had accepted it.

If we already have a domestic standard in effect when a Codex standard comes up for consideration, we are in a strong position to influence and guide its provisions. If, on the other hand, the Codex standard is adopted before we have an FDA standard, we will be under pressure to make the provisions of any standard adopted in the future consistent with the corresponding Codex standard. The inevitable result is that Codex Alimentarius Standards will have a very strong influence upon our own standards.

Once the overall desirability of a standard has been determined, consideration as to the specific requirements is in order. The Act provides that, in addition to pro-

moting the honesty and fair dealing in the interest of consumers discussed above, the standards must be "reasonable." This broad and elastic term has been ruled on in many different ways by the courts. As it applies to the requirements of standards, we believe that it relates to the ability of the manufacturer to meet the requirement with the raw material generally available to him, using manufacturing procedures that are in accord with good, current food technology, and employing equipment accessible through normal channels of supply.

To be reasonable, a requirement should keep quality control people on their toes, but not result in increases in cost greatly out of line with that at which the unstandardized product has been able to establish itself in the marketplace. This does not mean that no increase in cost may result, but such an increase must not be exorbitant nor tend to drive the product off the market.

Labeling requirements should be designed to give the consumer the fullest pertinent information possible in concise terms, completely factual and free from any element of trade puffery.

To be reasonable, standards should not have provisions which cannot be enforced, and those which depend entirely upon factory inspection for enforcement should be enacted with caution. Unfortunately, with our present degree of proficiency in analytical chemistry, it is not always possible to determine compliance with some requirements essential for a food standard solely by examining the finished product. In such cases we have to rely upon the observation of our inspectors during the time of manufacture in order to establish compliance.

Consumer participation is obviously desirable in developing standards oriented toward consumer interest. In our current program we make use of surveys conducted by

Testing the consistency of canned corn, a current standard, is shown *above*. The average diameter of the area over which the prescribed sample of corn spreads must not exceed 12 inches.

The author, Lowrie M. Beacham, is Director of the Division of Food Standards and Additives, Bureau of Science. He joined FDA in 1934 as a Seafood Inspector.

An FDA scientist checks "stringless" green beans against the requirements of the standard. Total fibrous material must not exceed 0.15 percent of the weight of the beans after the liquid is drained off (*bottom*).



professional firms to learn consumer views, interests, and preferences. We also rely upon our own staff of Consumer Specialists, assigned to our District offices, who have many opportunities to meet with consumer groups and individuals and discuss such matters. We anticipate that the Commissioner will also hear directly from the public through his Consultant on Consumer Affairs, former Senator Maurine Neuberger.

As a part of the required standards-making procedure, comments from all interested parties are invited when proposals are published. At public hearings, individual consumers and representatives of groups are free to make their views known through direct testimony, and they may cross-examine other witnesses.

Some examples of foods for which we are currently developing standards are:

Frozen vegetables, such as green beans and peas, produced and consumed in tremendous volume. Other frozen vegetables will follow.

Frozen cherry pie, and other pies later, where a requirement for a minimum amount of fruit is needed to correct an abuse that now exists.

Frozen breaded fish sticks, and fish portions, in order to prevent a gradual increase in the breading component at the expense of the fish, such as took place in breaded shrimp before a standard was written.

Canned salmon, to correct labeling abuses relating to variety, color, etc.

Table sirups, e.g., maple, cane, sorghum, and blends of these with corn sirups, to insure authenticity of composition and informative labeling.

In addition, we expect that industry may request standards for the frozen counterpart of preserves, additional macaroni and noodle products, grated and shredded cheeses, fill of container for pineapple, and perhaps others.

We doubt that standards are needed for specialty foods made according to recipes, perhaps developed in experimental kitchens and capitalizing on the culinary skill of the manufacturing firm's experts. At some point along the line from basic staples to exotic novelties, limitations on the food standards program must be set. To quote the Commissioner, "Is it necessary for FDA to expend any man-years at all on the setting of standards for: . . . sardines-in-blankets, Hanover salad, fried Italian squash, Alaska king crab cakes, and sour cream poundcakes?"

In planning a well-balanced program and putting it into effect, it is highly desirable to have constructive participation of industry. The fullest participation occurs when an industry or some particular manufacturer comes in with a proposed standard, fully supported by data to show that it is reasonable and will bring positively identifiable benefits to the consumer.

Lesser degrees of industry participation would include advising us of practices that need correcting, either because they constitute a present abuse or because they represent a trend that will ultimately work to the consumer's disadvantage. Suggestions as to provisions and even actual wording that would bring about the desired correction would be helpful.

Often, before we can propose a standard, it is necessary for us to acquire extensive technical data. Industry frequently has comprehensive knowledge of composition, quality factors, methodology, and other information that we could use, if we had it, to establish better standards, faster. When public hearings are held, industry could assist by sending its experts to testify in support of the standard.

We again invite the fullest cooperation of our food industry, but with or without it we intend to push vigorously for meaningful standards now and in the months ahead.

establishing and monitoring drug

When a New Drug Application involving a drug intended for use in a food-producing animal is submitted to the Food and Drug Administration, personnel responsible for review are confronted with two basic problems: (1) Is the drug safe and effective for the animal when used as recommended? (2) Are edible products from the treated animal safe for human food?

Examination of Subpart D of the Food Additive Regulations will make it clear that practically all NDA's and food additive petitions for drugs intended for use in food-producing animals have been approved by the FDA because it was established that none of the drugs or their metabolites remained in the edible products from treated animals when the drugs were used as recommended. Almost invariably the elimination of the drug substance is accomplished after a certain number of hours or days following the last exposure to the material. In a few instances a safe tolerance, or permitted level, is established for the drug in edible products from the animal receiving the drug, thus shortening the withdrawal time.

Until proved otherwise, the addition of a new chemical entity to the diet of man—even in apparently infinitesimal amounts—presents a potential hazard to health. Before the FDA permits the inclusion of such substances in the diet, convincing evidence of their safety must be submitted. Although certain routine or standard tests have to be included in a request for a tolerance in foods, it should be understood that each drug substance must be regarded individually. The individual characteristics of each substance may dictate additional tests totally unforeseen when the safety testing program is originally planned and organized. FDA demands the submission of all data deemed necessary to demonstrate the absence of any human health hazard before establishing a permitted level of a drug in the diet of man.

The present minimum requirements for establishing a tolerance demand the demonstration of an adequate margin of safety in studies with two species of laboratory animals—one a nonrodent. The studies involve acute toxicity, subacute toxicity and chronic toxicity experiments—the latter of two years' dura-

tion. In most instances, a three-generation reproduction study is also required. Some drugs may require additional studies depending on their specific activity. This is especially true if the studies indicate a species variation.

Acute toxicity studies Acute toxicity is the effect which a drug or a compound produces when given to a test animal in single or multiple doses over periods of 24 hours or less. Multiple doses are required when the volume of the chemical or its solvent is too high for single administration. The most convenient expression of the acute toxicity of a substance is the ED50. This is the amount of the substance (usually expressed in milligrams, grams, or milliliters per kilogram of body weight) which, on the average, will affect one-half of a group of animals of a certain species under specified conditions. This standard of comparison was selected because the dosage required to effect a response in 50 percent of the animals is more reproducible than any other dosage.

Experience has shown that the ED50 will vary from species to species and with environmental conditions so that it is necessary to specify the conditions of the experiment. Species, habitat, route of administration, sex, age, weight range, and state of nutrition of the test animals, as well as the physical state of the chemical, solvent, and its concentration, are the conditions usually specified.

Although the effect most frequently reported is mortality (LD50), an acute toxicity determination is not necessarily limited to the estimation of the lethal dose. Any toxic manifestation, such as emesis, convulsions, hypnosis, etc., may be reported in terms of the ED50.

Because different species of animals and even various strains of the same species may differ widely in sensitivity to drugs, the LD50 should be determined on at least three species of animals, one of which should be nonrodent. An evaluation of these results will give a measure of the species variability, and thus permit the pharmacologist to estimate the toxicity of the test substance for man.

If all of the LD50's are of the same order of magnitude, it is usually safe to assume a similar LD50 for

residue levels

by Fred J. Kingma, D.V.M.

man. If, however, there is a wide variation of LD50's among species of test animals, the estimation of the probable LD50 for man is much more difficult.

In some cases the estimate can be based upon man's position in the phylogenetic scale in relation to the test animals. In other cases the estimate must be based upon biochemical and metabolic similarities of man with the test animals. For example, a chemical that may produce methemoglobinemia as its characteristic effect can be tested in the cat or dog, known to yield this response similarly to man. Tests in monkeys, rats, and rabbits, which are known to produce practically no methemoglobinemia in response to such chemicals as acetanilide and nitrobenzene, would obviously be of little value in estimating this particular hazard for man. Where adequate knowledge of similarities between man and the test animal is not available, it is safest to assume that man is at least as sensitive as the most sensitive species of animal tested.

Of all the factors which influence the LD50 of a drug, the route of administration is the one most apt to modify the toxic effects. For most chemicals the oral and intravenous LD50's are sufficient. However, for drugs which may enter the body by some other route, such as inhalation, the acute toxicity determination must be designed so that the results are applicable to actual use conditions. Other factors which influence absorption and, thus, indirectly the toxicity are: (1) the physical state of the drug—dry chemicals are more slowly absorbed than those administered in solution; (2) solvents—substances dissolved in oil are absorbed more slowly than those in water; (3) concentration of the drug—concentrated solutions are usually more rapidly absorbed than the administration of the same amount in a more dilute form; and (4) presence of other substances—suspending agents may hinder absorption partly by absorption of the drug, partly by blocking its access to the absorbing surface. Food in the alimentary tract has this action. On the other hand, the presence of surface active agents may hasten absorption.

In practice the chemical or drug is usually given orally to animals which have been fasted overnight. The substance may be administered by stomach tube, capsules, or by mixing with the animal's food. Where the recommended administration of the drug is by

the parenteral route, the experimental administration of the drug (subcutaneous, intraperitoneal, intramuscular, or intravenous injections) must be related to the recommended usage. In no case is it necessary or advisable to anesthetize the animals in order to administer the test dose. The relationship between the intravenous and oral LD50 usually indicates the extent and rate of intestinal absorption.

The interpretation of the acute toxicity data for the purpose of estimating a safe or therapeutic dose is not based upon a simple mathematical formula. Among the factors which are weighed in evaluating the data are:

1. Adequacy of the data from a statistical viewpoint—a sufficient number of animals is employed so that the chemical can be characterized with respect to its LD50 and slope of the dosage-response curve and the errors of these estimates;
2. Interspecies variation—susceptibility of man as compared to the experimental animals; generally, man is six times as sensitive as the dog and 10 times as sensitive as the rat to the toxic effects of drugs;
3. Intraspecies variation—differences in susceptibility which normally occur in a general population (age, sex, state of health and nutrition, stress, etc.);
4. Usefulness of chemical or drug—whether the benefits derived warrant the risks.

Subacute toxicity studies Fitzhugh and Schouboe define subacute toxicity as the type of toxicity that produces functional and/or anatomical changes in animals when repeated exposure to a compound is experienced for periods ranging from a few days to a year. Subacute toxicity studies should be conducted after the acute and before the chronic toxicity studies are done. These experiments are designed to pinpoint the maximum tolerated and the minimum grossly toxic doses; establish the biological nature of the toxic effects; determine variations in species sensitivity; and permit decisions as to the desirability and exact design of chronic studies. Subacute experiments are designed to cover a 3-month period. In some special cases they are extended to 4 or 6 months or even to a year. *cont'd on page 31*

LSD: the false illusion

*The wish for instant paradise
is as old as man himself.
For ages, people have
searched for artificial means
to improve their condition, and
drugs have played an
important role in this quest.*

Although drugs under adequate supervision have a powerful potential to serve mankind by alleviating pain and promoting cure for many illnesses, they have often been misunderstood and diverted to other, less constructive goals.

In primitive times drugs served religious, magical, and social needs. He who controlled the drugs, herbs, or potions was vested with magical powers making him the spiritual and sometimes the secular leader of the tribe. By ritualized practices, the tribe used drugs to promote their social goals and further their culture. Informal control of drugs was based on habits, beliefs, customs; their complete acceptance depended on the fact that certain forms of behavior were allowed by the group, while others were not. Such taboos of primitive medicine guarded against the abuse or violation of drug practices; they embodied folk wisdom and protected the tribe.

In more sophisticated societies, however, drugs have served more limited goals—those of treatment and prevention of disease. The study of drugs is as old as recorded history, while the effects of hallucinogenic drugs, particularly, have been studied by one method or another for a long time. In 1888, Louis Lewin, one of the earliest pioneers in psychopharmacology, called to the attention of scientists the effects of peyote and many other psychotogens. Albert Hofman synthesized LSD from other ingredients in Sandoz's Pharmaceuticals Laboratory in 1938. In 1943,



Spanfeller

Part I by Jean Paul Smith, Ph.D

he observed its peculiar qualities because of an accidental ingestion of the substance at the laboratory. He described the effects in his journal and wrote that:

"I noted with dismay that my environment was undergoing progressive change. Everything seemed strange and I had the greatest difficulty in expressing myself. My visual fields wavered and everything appeared deformed as in a faulty mirror. I was overcome by a feeling that I was going crazy, the worst part of it being that I was clearly aware of my condition. The mind and power of observation were apparently unimpaired."

LSD comes from the semisynthetic derivative of the ergot fungus of rye, a black substance that grows on the grain. There are several possible ways of producing it, the easiest of which involves a parent substance, several hours of laboratory time, and relatively uncomplicated equipment.

Chemically, LSD is an amine alkaloid resembling ergonovine and has oxytocic action but with only slight vasoconstrictive effect. LSD acts primarily on the central nervous system, and doses as low as 20 to 30 micrograms may affect individuals who are especially susceptible. The central effect of the chemical mimics sympathetic or autonomic system activation, and includes such symptoms as widely dilated pupils, lower temperature, goose bumps, increased blood sugar, and rapid heartbeat. LSD also appears to inhibit the action of 5-hydroxytryptamine, at least its peripheral effects. Some similarity exists between the changes induced

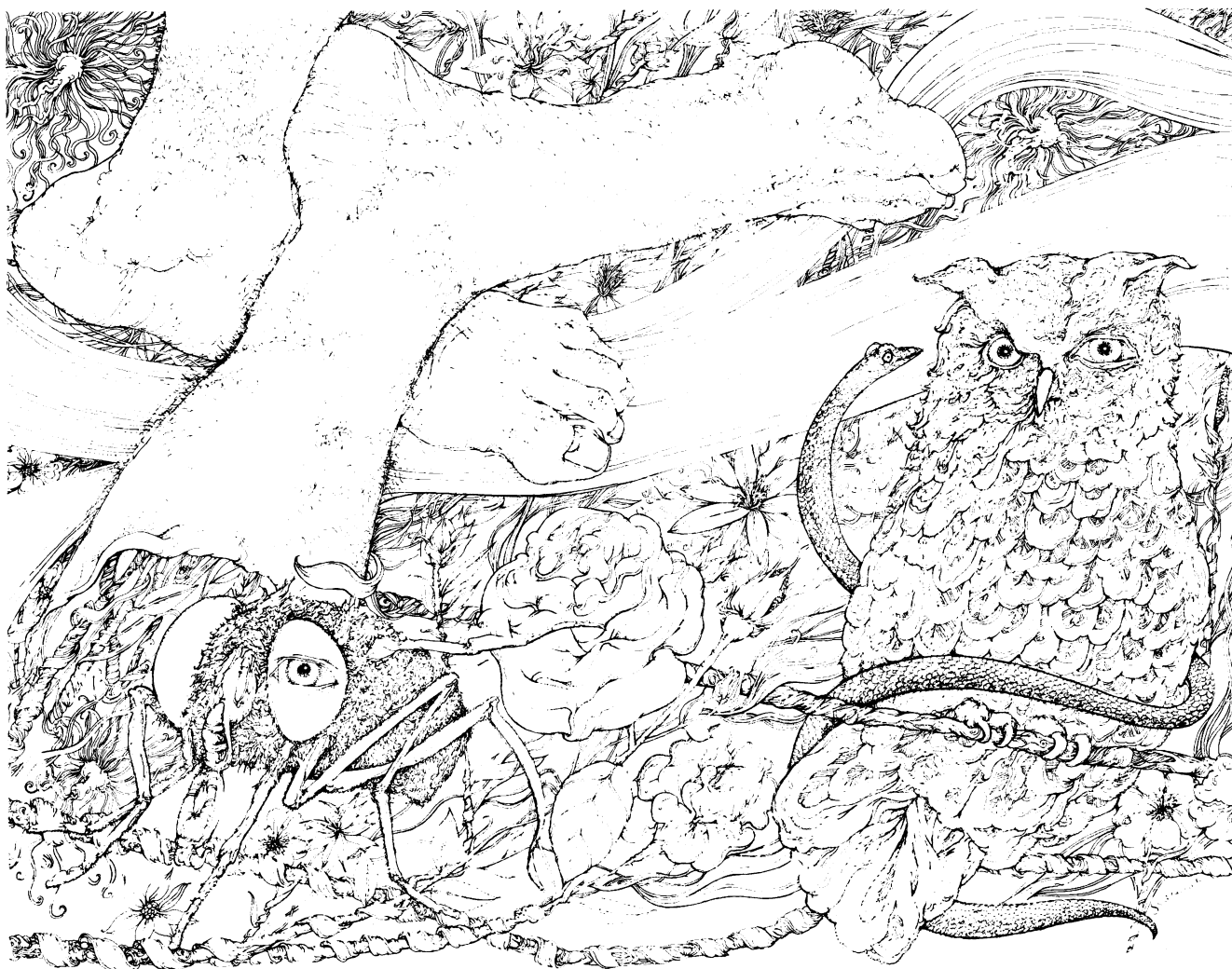
by LSD in man and the clinical picture of schizophrenia, but the use of the chemical to induce a "model psychosis" has largely been displaced by its use for the study of the brain's action and an examination of the possible therapeutic potential of the drug.

Humans show tolerance to LSD within a few days, and a cross-tolerance between LSD, mescaline, and psilocybin has been demonstrated. After oral administration, LSD is rapidly distributed throughout the body with greater concentration in the liver than the brain. Excretion from the liver in certain forms has been shown.

Although LSD has been observed to cause respiratory failure in animals, there appears to be no record of human deaths directly attributable to the drug.

However, LSD has indirectly caused a number of deaths by thwarting or removing natural protective attitudes, sensible judgment, or the ability to perceive and evaluate common dangers.

Thus, a student at the Berkeley Campus of the University of California recently jumped out of a window to his death, in the apparent belief that either he could fly, or in the attempt to flee from a panic that had seized him. A Los Angeles juvenile was killed while walking on the freeway, convinced that he was invisible to everyone. A young man in Brooklyn murdered his mother-in-law for no reason that was apparent to him after he got through his LSD episode. A girl in London "flew" out of a window—proposed destination, USA—



and ended up dead on the pavement.

The record of such incidents is increasing. But evidence is now coming in to show that the indirect effects of LSD may also be quite serious; the drug has been shown to cause chromosome damage, and studies are now underway to determine possible teratogenic effects.

The effects caused by any drug depend upon a whole range of factors. Among these are the *set* that that person has, or what he expects to happen, and the *setting* in which he takes the drug. Personal attitudes have a strong effect on the experience that results from LSD, because attitudes structure the drug experience and determine what

"labels" are applied to interpret the experience. Even with a positive set to begin with, most "triers" and users go through intensely frightening and terrifying experiences under the drug.

The setting in which the LSD usage occurs has a very strong effect on the individual's attitude toward self-control and his ability to cope with crises during the drug state. When professional help and psychotherapists are present, he feels that there are trained and competent persons who will take care of him if things go too far. He also is certain that, should he attempt self-destruction or any other irrational act, the LSD session can be aborted by chemotherapy. The setting also is important because it affects the degree to which the action of the drug can be focused on

specific results.

Where scientific investigations of the drug are carried out, as at the Spring Grove Hospital in Maryland and the National Institute of Mental Health, they are, of course, directed at specific psychiatric problems, such as neurosis or alcoholism. In these highly controlled settings, there is the professional help necessary for the solution of specific personality problems.

The particular group and surroundings in which an individual takes the drug may facilitate the helpful, or increase the harmful, reactions to the drug. Thus, the "experimentation" carried on by groups of young people who obtain their LSD supplies through illegal channels and take the drug under highly unsupervised conditions can only lead to tragic results. There is

no attempt at directing the drug at specific psychiatric problems, only a desire to go on a "trip" without direction, supervision, or knowledge of the psychiatric and physical dangers involved. Most of the abuse of LSD is in settings where only immature or untrained peers are available to assist those who encounter problems.

After ingestion of LSD no immediate change may be noticed. Although there is no definite sequence or series of invariable effects of LSD, certain types of changes typically occur. Twenty to forty-five minutes later there may be an experience of visual changes where objects unexpectedly begin to "move." Feelings may become more intense and rapid changes in mood may occur; the subject may become extremely emotional with uncontrolled laughing or crying. He may or may not be responsive to his environment, and meaningful communication with him may prove difficult. Intensified and distorted tactile sensations are most frequent, and illusory phenomena are found more often than true hallucinations. When they do occur, hallucinations may overwhelm the individual, especially if panic and an intense feeling of losing one's mind accompany the hallucinations.

In the cognitive or intellectual sphere, the subject may show confusion or impaired thinking. Time judgment under LSD is more variable, and time may "slow down" or appear to stand still. His image of his own body may change so that he no longer feels the parts of his

body or limbs connected in the usual way, a very disturbing feeling.

Users of LSD generally tend to take other controlled drugs, such as psilocybin, marijuana, peyote, methedrine, or mescaline. A general drug-interest factor is often seen. Among the "hippy" set, whether or not repeated use of drugs is found, the values and philosophy espoused by such people seem similar: stimulate the senses as much as possible, change the internal world with drugs, and ignore constructive actions to improve the external world.

In their search for values and a sense of personal identity, most young people see through the flimsy logic of the drug equation. They realize "dropping out" hurts them and does nothing to improve our society with its vast problems.

An important aspect of the LSD experience—one that has not been sufficiently studied—is the difference between what the user says and what he does. Advocates of LSD claim they show more "love of fellow man" and "relatedness." However, this claim is illusory for most users. The fact is that the LSD user interprets his drug-induced experience as a salutary one, although his behavior may begin to decline and achievement to diminish. What he appears to acquire is the language set to talk about "love for his fellow man" and "relatedness," often without developing a change in behavioral patterns on

which to base such language. Under the influence of the drug, ability to communicate verbally is definitely impaired, although researchers feel that much work remains to be done in this area.

The function of LSD for many of the "hippy" groups is that it provides an easy and automatic means to membership. An ingroup-outgroup type of thinking may prevail and a pharmacocentric ideology is followed, involving the rejection of others who are free of the drug interests. Proselytizing is very common and allegiance to drug values is regarded as a "loyalty test."

Personality patterns of people who ingest LSD indicate strongly that they are less able to postpone pleasure and to withstand the frustrations of everyday life. Drug dependence of the LSD type is more often found among those searching for something meaningful in life, a system of values by which they can live. Researchers viewing the problem from several perspectives feel that prior personality disorder does not, by itself, predict those who will develop a psychosis from LSD ingestion.

In testimony before congressional hearings, a number of public health officials and medical experts have described the types of severe disturbance that can result from uncontrolled use of LSD. Psychotic disorders of depressive, paranoid, and schizophrenic types with acute and intermittent phases are likely to occur among those who are prone to such high risks. Chronic anxiety reactions and dissocial behavior patterns subsequent to LSD



use are quite common among repeated users. Even more serious and prevalent than these negative reactions are the adverse consequences of so-called "positive trips" which lead the user to feel that he has found the answers to life's problems, a chemically centered religion, or values that transcend his society and culture. As a consequence, he only too often winds up disengaging himself from productive, focused personal and social activities and drifts aimlessly through life without social achievements to enrich his personal life.

Sandoz Pharmaceuticals made its first contact with the Food and Drug Administration on its own initiative in 1953 to discuss clinical investigations it was planning to pursue in the United States. LSD was regarded as a "new drug" and FDA agreed to its distribution only to research psychiatrists, properly qualified to investigate the drug and use it solely as an investigational drug.

For 10 years, from 1953 to 1963, experimental investigations with LSD took place in this country.

In 1962, the Kefauver-Harris Drug Amendments were enacted by Congress. This new law modified the definition of a new drug and required that a drug be effective as well as safe before it could be marketed commercially. The investigational studies of LSD, which had been conducted until that time in Europe as well as in the United States, did not establish the safety

or the efficacy of LSD. The unpredictability of its effects, as well as information concerning serious contraindications, side effects, precautions, and indications for the drug were major questions to be resolved by research before clearance for distribution could be granted.

In June of 1963, the Food and Drug Administration issued new regulations for new drug investigations. Among other things they required that the sponsor of an investigational new drug prepare and file with the Food and Drug Administration an acceptable, rational program of experimentation including adequate preclinical testing. In short, the program had to be reasonably safe and responsibly conducted.



Jean Paul Smith is Acting Director of the Division of Drug Studies and Statistics, Bureau of Drug Abuse Control. In the first of a two-part series, Dr. Smith presents the LSD problem from the psychologist's point of view. Part II, scheduled for September, will tell the LSD story through the experience of FDA's Criminal Investigators.

Sandoz Pharmaceuticals drew up and filed a basic investigational plan for testing LSD under the new regulations. Eventually, about 70 researchers received LSD and were sponsored by Sandoz under their investigational exemption.

During the period from about 1960 to the present, illegal production, distribution, and use of LSD began to mushroom. Researchers at Harvard University began to give the drug to students outside a proper research setting and this practice spread until, by cultural diffusion, a drug ethos began to develop. It was spurred on by publicity and by "cause seekers" who came to view LSD as a symbol of protest against cultural values held by the society at large.

Public reaction to the rather widespread abuse of LSD and other hallucinogens began to mount. Congress conducted extensive hearings into the abuse of depressant, stimulant, and hallucinogenic drugs, and determined that a significant hazard to health and safety existed. The Drug Abuse Control Amendments were passed by the 89th Congress and signed by President Johnson on July 15, 1965, taking effect February 1, 1966. This legislation established a series of controls over the depressants, stimulants, and hallucinogens, and made special provision for research and study of these classes of drugs.

In April 1966, Sandoz Pharmaceuticals decided to withdraw its sponsorship of investigations using LSD and psilocybin. With the threat of all research on these potentially valuable agents coming to

a halt, the FDA discussed the problem with the National Institute of Mental Health and the Veterans Administration and agreed to allow a group of investigators to continue their studies. After termination of the Sandoz investigational sponsorship of LSD, the firm transferred its remaining stock of approximately 22 grams of LSD to the National Institute of Mental Health. Currently, the only legal supply of LSD in the United States for clinical research on humans is either at NIMH, or held by the investigators approved to continue studies.

In July 1966, FDA published a regulation in the *Federal Register* which requires that all research, including LSD, psilocybin, mescaline, dimethyltryptamine and peyote—whether clinical, animal, or *in vitro*—be submitted for the Commissioner's approval prior to initiation. This regulation clarified the special provisions granted to researchers under the Drug Abuse Control Amendments.

In this manner, the dual review of LSD research evolved with NIMH having the LSD supply and FDA having statutory responsibility for controlling the chemicals. In order to speed up the processing of requests for research, the dual review is being replaced by a combined committee action, making recommendations to the Commissioner of FDA and to the Surgeon General of PHS. The Joint Advisory Committee on Psychotomimetic Agents (the LSD Committee) began processing research protocols in June 1967, facilitating



efforts to study many aspects of the psychotogens.

The efficiency of formal social controls expressed in laws and regulations ultimately rests upon the informal social controls that exist in the form of customs, habits, and ideologies reflecting the will of society.

The ultimate goal of legal controls is to help people achieve self-control. Toward this end, FDA reflects a philosophy emphasizing both enforcement and education. Enforcement measures state society's expectations and set limits on what is acceptable behavior in the use of drugs. Enforcement operations rest on laws which provide for a system of penalties that limit and punish illegal behavior,

thereby reducing the availability of drugs and discouraging the offender.

With the passage of the Drug Abuse Control Amendments of 1965, a realistic and effective approach to the control of drugs was outlined by Congress. The penalties are designed to reduce illegal traffic and control the supply. Thus, under Federal laws, possession of LSD for personal use is not a crime; but selling, giving, or distributing LSD is illegal and violators are subject to 1 year in prison and a \$1,000 fine, or both. The laws do not aim to stop drug abuse by convicting the curious, adventuresome, or misguided person who tries LSD.

Under Drug Abuse Control Amendments, any drug having a potential for abuse because of its

depressant, stimulant, or hallucinogenic effect on the central nervous system, may be brought under the record-keeping, distribution, and control system established by Congress. Other hallucinogens, as they become known, will be referred to the group of experts who advise FDA in drug abuse matters, the Advisory Committee for Depressant and Stimulant Drugs.

The enforcement efforts of FDA's Bureau of Drug Abuse Control to date are impressive. From May 1, 1966, to the end of March 1967, 382 cases were investigated and over a million and a half dosage units of hallucinogens were seized, most of these LSD. The street value of these drugs on the black market would be just under \$9 million, and the indirect savings in terms of human problems and

mental disturbance prevented by these seizures are inestimable.

There are no reliable statistics on the quantity of LSD used throughout the Nation or in specific areas. Various figures are quoted in the popular press, but no scientific sampling is completed at this time upon which such estimates can be based. Several studies funded through NIMH's Center for Study of Narcotics and Drug Abuse will provide reliable estimates for regional drug misuse.

Despite the vigorous efforts of BDAC, one bureau or agency simply cannot handle the tremendous task of drug abuse control by itself. International traffic in hallucinogens is watched closely, and liaison with foreign governments stimulates international cooperation to reduce the illegal drug flow across borders. Close cooperation with Federal agencies such as the FBI, Customs, and Bureau of Narcotics increases the effectiveness of control measures. BDAC is also developing close contact with local police departments and campus security officers across the country. The Bureau issues a Law Enforcement Bulletin to over 1,700 persons and frequently holds local Law Enforcement Institutes to educate police officers on such topics as drug identification, pharmacology, investigative techniques, and social-psychological patterns of drug users.

Preventive measures are the most productive means of solving the problem of drug abuse. By partici-

pating in information and education programs, people of all ages develop respect for the power of drugs. Education helps them to build in a positive direction, it points out the risks of self-experimentation with powerful drugs. FDA's efforts here are directed toward getting LSD users to see the social consequences of their personal experience which affect not only themselves, but also their family, friends, and community. Programs directed at alienated or disengaged youth must make them understand that the social system, whether family, community, or nation, establishes controls on certain types of risk-taking behavior for the benefit of all people, of all ages, in all conditions.

Many steps have been taken to educate the public to the hazards of LSD. In July 1966, Commissioner Goddard sent a letter to college presidents, alerting them to the hazards of drug abuse by students. Letters have been addressed to, and leadership conferences and briefing sessions were given for, pharmacy groups. Under an FDA contract with the National Association of Student Personnel Administrators, approximately 1,450 college deans discussed the problems of drug abuse on campus with experts from many fields and what can be done about it. Evaluation of these NASPA Conferences, which were held early this year across the country, will provide the first hard data on the college administrator's perceptions of LSD as compared with other drugs, including narcotics. The NASPA program will

continue this fall.

In the calendar year ending in March 1967, field agents delivered 284 speeches, reaching an audience of approximately 1,230,000 people, on drug abuse topics. A special FDA film on LSD, entitled "The Mind Benders," will be available in late summer or early fall; its target audience is the 16- to 30-year-old age group, and the film will be distributed without cost through the Public Health Service, Audio-visual Facility, Atlanta, Ga. An FDA pamphlet "Runningawayness" was published to give parents an insight of the problem. A Manual on Drug Abuse, for educators, has just been released by Smith Kline and French for distribution by the National Education Association. A brochure on LSD will be available this summer providing some of the answers to questions often asked about the drug.

The control of drug abuse in any of its forms is fraught with difficulties. As the depressant, stimulant, and hallucinogenic drugs proliferate, the answers to the problems they pose are likely to become not simpler, but more complicated. Traditional law enforcement methods alone cannot cope with the situation, because they do not take into account the sociological and psychological origin of the drug problems.

However, given an increasing application of the social and physical sciences, together with traditional enforcement procedures, there is every reason to believe that in time the social danger of drug abuse can be effectively controlled.



drugs of abuse

The Problem There is widespread abuse and illegal trafficking in depressant, stimulant, and hallucinogenic drugs. Lives are being shackled in chemical chains because the users do not recognize the potential dangers of these drugs. The users can become physically or emotionally dependent upon these drugs, but they do not yet have the same social stigma that is associated with use of the narcotic drugs. The use of LSD has been openly and irresponsibly promoted for alleged mind-expanding effect. Experience has shown, however, that users of LSD may actually lose their capability to think clearly, to reason, to create, or otherwise use their minds productively. In addition, LSD can cause serious and permanent mental changes, nervous breakdowns, and lead to violence and self-destruction.

The Abusers The chronic abuse of drugs is generally considered a symptom of mental or emotional illness. Drug abusers may come from any occupational, educational, religious, and socioeconomic group. Regardless of how or why people start taking drugs, they soon come to depend on them as a chemical crutch to solve the everyday problems of life.

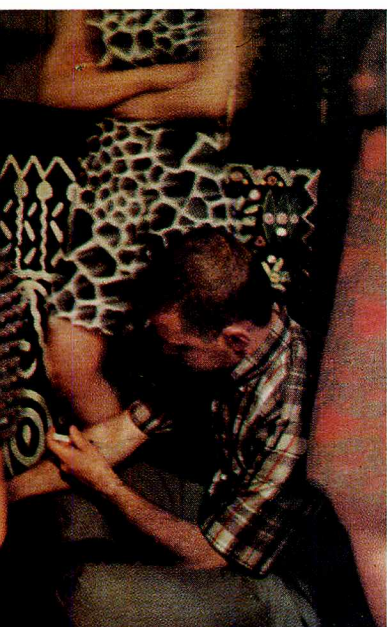
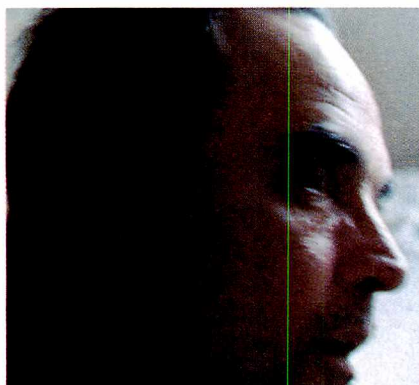
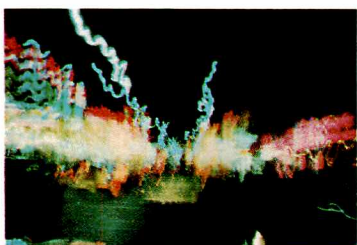
Drug abusers seldom find it possible to live successful lives. The drugs become their master and they lose interest in school, job, and family. They generally drift away from normal social contacts and seek the company of other drug users.

The Federal Law The Federal statute controlling these drugs is the Drug Abuse Control Amendments to the Federal Food, Drug, and Cosmetic Act. This law (United States Code Title 21) prohibits, among other acts, the following:

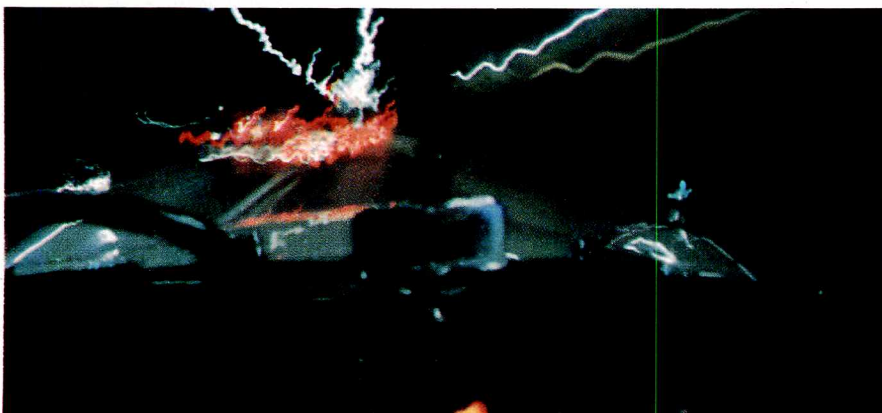
- sale or disposition not covered by legal prescriptions.
- illegal possession for resale (possession for personal use is not prohibited under Federal law).
- failure to register as a manufacturer or wholesaler of controlled drugs.
- failure to keep records of receipt and distribution of controlled drugs.

The Penalties Anyone who produces or sells dangerous drugs illegally is subject to a maximum penalty of one year's imprisonment and/or a \$1,000 fine; a second offense can bring a maximum penalty of three years' imprisonment and/or a \$10,000 fine. The growing abuse of drugs by teenagers is a particularly tragic and disturbing aspect of the entire drug abuse problem. The Amendments provide special penalties for peddlers and pushers over 18 years of age who sell or give drugs to anyone under 21 years old. For a first offense, the punishment may be imprisonment for not more than two years or a fine of not more than \$5,000, or both. Second violations may carry a penalty of not more than six years' imprisonment and a fine of not more than \$15,000, or both.

Identification of Controlled Drugs In general, the abuse of depressants and stimulants involves drugs that have been diverted from legitimate channels of distribution. The more popular brand name depressant or stimulant drugs bear trademarks or other identifying symbols. Presumptive visual identification is often possible because of the distinctive colors, shapes, or markings of the trade name drugs. However, many controlled drugs have no specific identifying characteristics and may be similar in appearance to many noncontrolled drugs. Laboratory analysis is therefore necessary for the positive identification of controlled drugs.



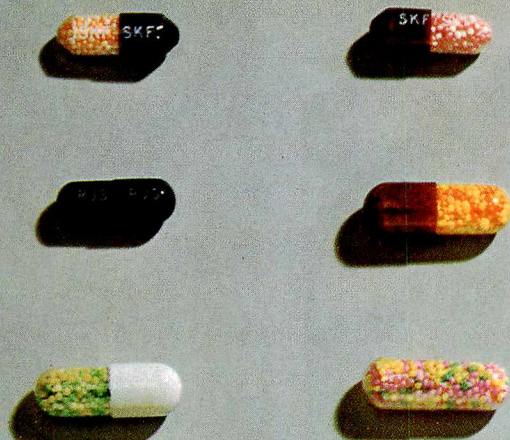
Stimulants—Why Taken The stimulants act directly on the central nervous system. They produce a feeling of excitement which manifests itself in appetite loss, increased activity with a feeling of energy, and the ability to go without sleep for prolonged periods. During these periods the victim's body uses up its reserve of energy which may eventually cause the mind to "black out." Highway accidents may be the result of drivers using these drugs. The stimulants are often relied on by criminals to increase their nerve. They may be the cause of reckless behavior in juveniles. The body develops a tolerance to these drugs and abusers increase their dosage, exaggerating the normal effects.



Look For The abuser may exhibit restlessness or nervousness, with tremor of hands, dilated pupils, dryness of mouth, and heavy perspiration. He may be talkative and have delusions and hallucinations if he has used a large quantity. In the serious cases, amphetamines cause a psychosis which may resemble paranoid schizophrenia. In short, the person abusing stimulants may exhibit dangerous, aggressive behavior with anti-social effects. The stimulants are usually taken orally; however, the mainlining of these drugs is also encountered.

Stimulants

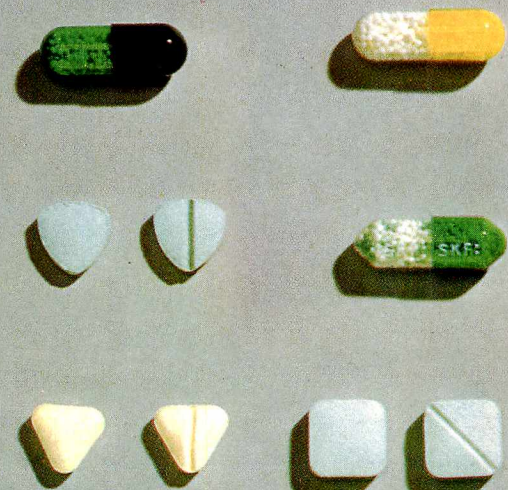
Called by such names as "speed," "dexies," "pep pills," "ups," "A's," "bennies," "drivers," "cross-roads," "footballs," etc.



AMPHETAMINE CAPSULES



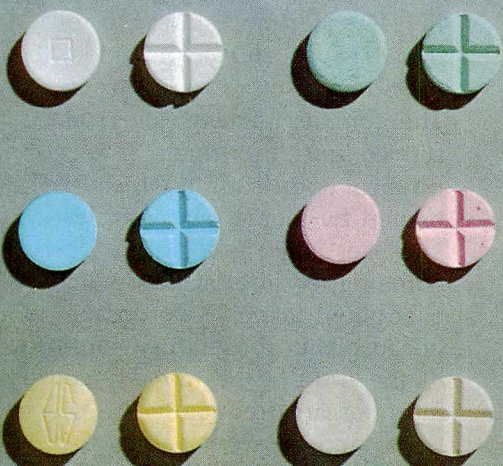
AMPHETAMINE TABLETS



AMPHETAMINE-BARBITURATE COMBINATIONS



AMPHETAMINE TABLETS



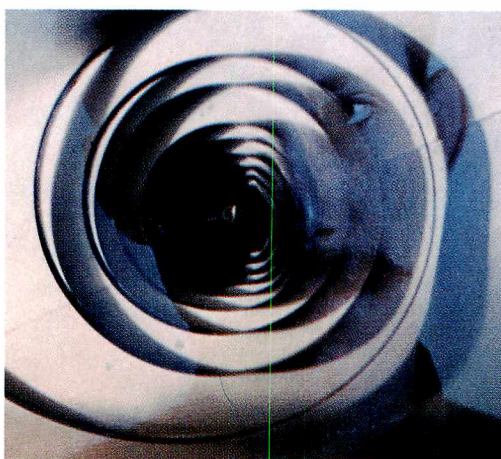
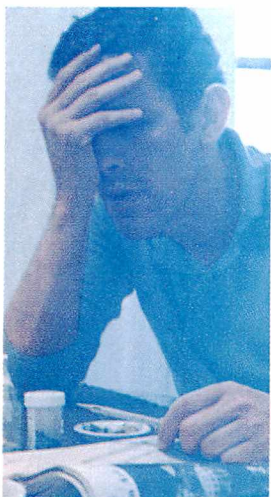
AMPHETAMINE TABLETS



DOSAGE FORMS OF METHAMPHETAMINE



PHENMETRAZINE TABLETS



Depressants — Why Taken The barbiturates and tranquilizers depress the central nervous system to relieve tension or produce sleep. They are abused for the alcohol-like euphoria they give. Barbiturates and alcohol taken together can, and have caused accidental death. Tranquilizers are sometimes used to “come down” from hallucinogens or stimulants. Depressants are both physically and psychologically addicting. Withdrawal from addiction to barbiturates can be more dangerous than withdrawal from the opiates.

Look For The abuser of depressants will exhibit the common symptoms of drunkenness but there is no odor of alcohol unless both have been taken. A small amount of the drug makes him believe he is relaxed, sociable, and good-humored. The drug makes him less alert and slower to react. Increased doses cause sluggishness, depression, and for some users a quarrelsome disposition. The tongue thickens and speech becomes slurred and indistinct. There is a loss of physical coordination which may be accompanied by mental and emotional instability. The user may slump into a deep sleep or a coma depending on how much of the drug has been taken. Overdosage is common because the abuser may forget how much of the drug he has already consumed. Barbiturates are frequently the cause of intentional and accidental suicides.



Depressants

Referred to as "downs," "Barbs," "Redbirds," "yellow jackets," "goofballs," "blue heavens," etc.



PENTOBARBITAL CAPSULES



SECOBARBITAL CAPSULES



AMOBARBITAL CAPSULES



AMOBARBITAL WITH SECOBARBITAL



PHENOBARBITAL TABLETS



MISCELLANEOUS BARBITURATE TABLETS

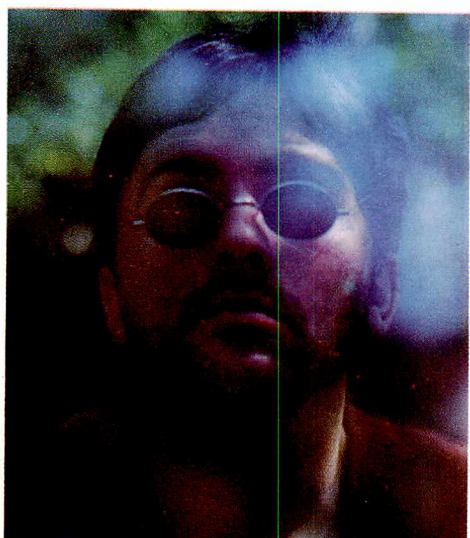


OTHER DEPRESSANT DRUGS

The hallucinogenic drugs in illicit channels of distribution originate from clandestine laboratories. They have no standard dosage forms or markings that make visual identification possible. The hallucinogenic drugs may be encountered as home-made capsules or tablets. They may also be encountered as nondescript powders or liquids. The physical properties of the hallucinogenic drugs are such that they can be easily disguised as various powders or liquids commonly encountered on the person or in the household. These drugs are frequently applied to common objects carried on the person. LSD, for example, has been encountered on sugar cubes, chewing gum, hard candy, candy mints, crackers, wafers, blotter paper, postage stamps, handkerchiefs, aspirins, vitamins, antacid tablets, beads, and other personal jewelry.



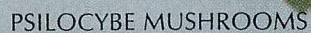
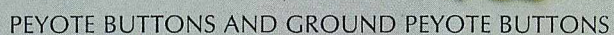
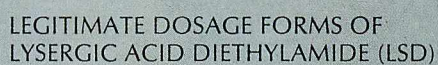
Hallucinogens—Why Taken The hallucinogenic drugs have been irresponsibly promoted as a means of expanding consciousness. Some promoters who openly urge such use have adopted the slogan "Turn On—Tune In—and Drop Out." The abuse of hallucinogenic drugs has also been part of a more subtle promotional theme involving "rock and roll" music, psychedelic books, magazines, and newspapers. Unfortunately, use of these drugs is considered the "in" thing to do by many. Youth are especially susceptible to the current glamorization of drug-taking by nonconformist groups. Since adolescence is a stage of experimentation and "finding one's way" in life, youngsters may find the urge to "try" drugs attractive.



Look For When the user takes hallucinogenic drugs, he experiences distortion and intensification of sensory perception with lessened ability to discriminate between fact and fantasy. These users often speak of seeing sounds, tasting colors, etc. There is a dilation of the pupils and dark glasses are often worn, even at night. The user may be restless with an inability to sleep until the drug wears off. He may, however, exhibit no noticeable physical signs of drug intoxication. The mental effects are quite unpredictable, but may include illusions, panic, psychotic or antisocial behavior, and sometimes impulses toward violence and self-destruction.

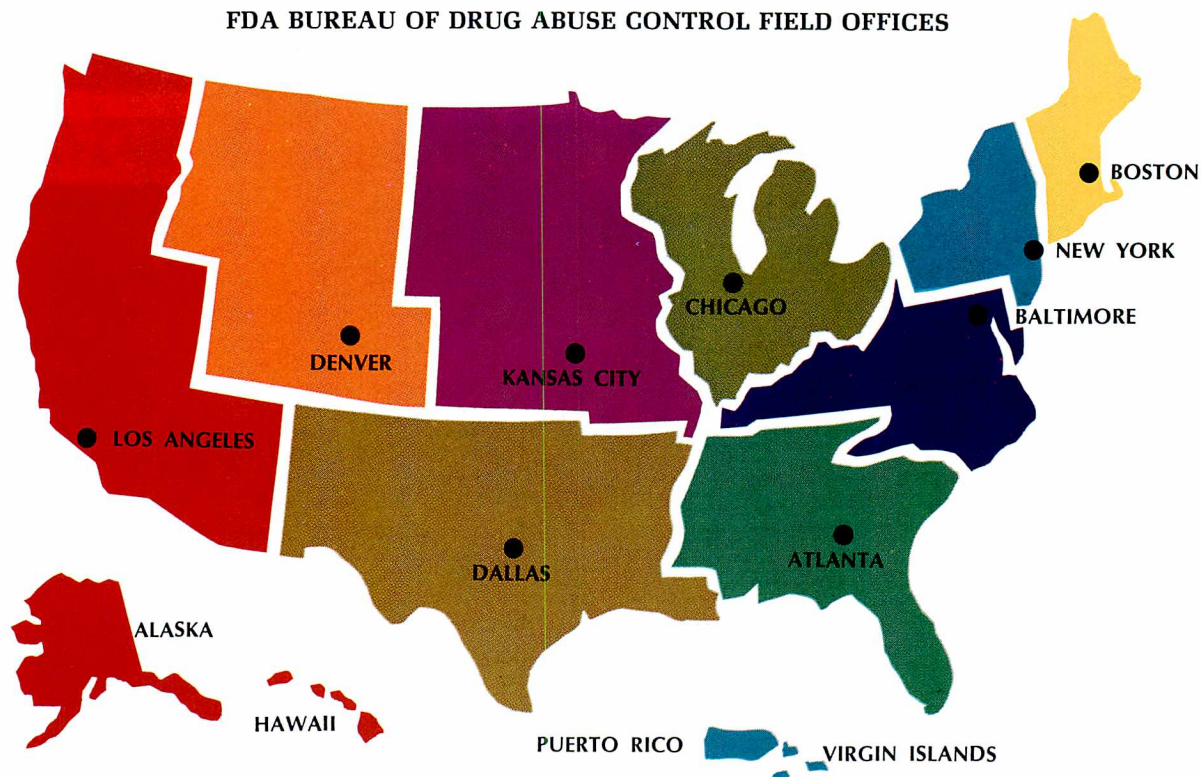
Referred to as "LSD," "LSD-25," "acid,"
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For additional information or assistance contact the
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The Bureau of Drug Abuse Control is a new law enforcement organization. Its enforcement action is being pushed on two fronts: (1) Criminal investigations are initiated against the profiteers making and selling the drugs which wreck others' lives. This is normally accomplished by undercover investigations where peddlers sell controlled drugs to Agents; (2) To dry up the traditional sources of drugs, the diversion of drugs from the legal to the illegal channels, businesses must keep records on their drugs. Penalties are imposed on firms and

their drugs seized when they cannot legitimately account for their controlled drugs. These activities do not supplant existing State laws, they supplement them.

The Bureau of Drug Abuse Control is a relatively small force of investigators. They must, of necessity, concentrate on the major traffickers and producers of controlled drugs. Its mission has been greatly assisted by the leads and cooperation received from other law enforcement organizations, and interested citizens.

John Finlator
Director
200 C Street, S.W., Washington, D.C. 20204

by Robert Hodges, M. D.

Under the law, the Food and Drug Administration must process New Drug Applications within 180 days after they have been submitted. Yet, in January of 1967, there were 301 NDA's of which 98 were substantially older than 180 days, and the backlog was increasing daily as new applications arrived in the Bureau of Medicine.

In September 1966, Commissioner Goddard met with the President and the problem of clearing NDA's was discussed. Dr. Goddard reported that steps were being taken to eliminate the backlog. Today, less than a year after the commitment was made, the Bureau of Medicine has successfully dealt with the situation; as of July, all New Drug Applications are being processed within 180 days.

To understand how the backlog developed, how it was dealt with, and how similar backlogs will be prevented in the future, it is necessary to go both into the law and the manner in which its requirements affected the FDA, the pharmaceutical manufacturers, and the general public whose protection is the primary aim of the Agency.

Under the original Food and Drugs Act of 1906, the Government had no control over introduction of new drugs in the United States. The only condition for drugs moving in interstate commerce was that they were not to be adulterated or misbranded.

Then, in 1937, more than 100 people died after they had taken sulfanilamide elixir made with diethylene glycol, a highly toxic chemical that is a main ingredient of automobile antifreeze.

As a result, Congress passed the 1938 Food, Drug, and Cosmetic Act which contained the provision that a drug must be shown to be safe when used as directed in its labeling before it could be approved for marketing. It was not necessary to show that claims for efficacy were valid.

It was only natural, however, that the administration of the new law necessitated some consideration for efficacy, which could not be entirely divorced from safety. No active drug is absolutely safe, and relative safety is a fact of life. Thus, the degree of hazard allowed had to be considered in connection

with the therapeutic value of a new drug; where a new drug promises to be an effective therapeutic agent in a life-threatening medical situation, both doctor and patient are more willing to run the risk of side effects than they would be were a minor condition involved.

Over the course of the next two decades it became increasingly apparent that there were important deficiencies in the regulations governing new drugs, particularly where the control of investigational drugs and the required procedures for handling New Drug Applications were involved. However, these problems had not yet attracted public attention.

Public opinion, and thereby legislative action, is often stimulated by a tragedy or near-tragedy. Thus, the 1962 amendments to the Food, Drug, and Cosmetic Act followed the thalidomide incident of that year.

The thalidomide problem was the result of insufficient investigation, and less than optimal use of the new drug in such investigations as were carried out. In consequence, the new law provided, among other things, for effective regulation of the use of investigational drugs, and required that a New Drug Application must include substantial evidence of the effectiveness of the drug in the conditions for which it is recommended.

The efficacy requirement of the 1962 amendments necessitates investigations which are better planned and conducted than were those in the past. The requirement reflects the fact that today's drugs are far more sophisticated and potent. The more sophisticated a drug, the greater is the danger of undesirable or unforeseen side effects, or problems of toxicity or teratology.

It also means that the evaluation of New Drug Applications requires considerable judgment and is far more time-consuming than it was when safety was the only factor to be considered.

It is in the nature of the obligations imposed upon the Food and Drug Administration that the reports submitted by drug sponsors must undergo the closest and most detailed scrutiny; that additional data are often required; and that the utmost precautions

the review and processing of **new drug applications**

must be taken to insure the American public of the safety and efficacy of drugs.

In recognition of these problems, the 1962 amendments extended the time allowed for new drug processing to 180 days. Provisions were made for increasing the staff of the Bureau of Medicine, but the implementation of these provisions was slow. In June of 1963, the available staff was barely adequate to deal with the increased work involved. In that month alone, approximately 1,000 Notices of Claimed Investigational Exemption for Investigational Drugs were received. By the end of the year, it was apparent that the majority of New Drug Applications could not be reviewed within the statutory 180 days; indeed, the prompt review intended by Congress of all Investigational New Drug Notices could not possibly be attained. Increased surveillance of those drugs already on the market was an added responsibility requiring skilled scientists, particularly physicians, who were in short supply.

Reorganizational changes were carried out in late 1963 and again in mid-1964 in an attempt to cope with the problem. Automation of data processing was initiated, but the benefits from the system were not to be seen until 1966, and full utilization is still several years in the future.

The term "backlog" began to be applied to New Drug Applications which had been in process in excess of the 180 days allowed. The problem was most critical in the medical area. The pharmacologists and chemists managed to remain more or less current in their review of New Drug Applications.

Various measures were taken to remove applications from the backlog. But the NDA backlog grew from virtually none in 1962 to 98 on January 1, 1967. On that date, a total of 301 New Drug Applications was under review; many of these were only weeks away from the 180-day limit.

Under the existing organization, the investigational drugs were handled in one unit, NDA's in another, and manufacturing controls in a third unit of the same division. Pharmacological and toxicological evaluations were made by members of the Bureau of Science, which was both geographically and administratively separated from the Bureau of Medicine. The logistics slowed movement of applications among bureaus and divisions to the point of inexcusable inefficiency.

This intolerable state of affairs was recognized early in 1966, and measures were taken to bring efficiency into this basic function of the FDA. In line with the Miles Committee Report to Secretary Gardner, a fully coordinated system for processing new and investigational drugs was put into operation in July 1966.

Applications for marketing new drugs or for investigating experimental drugs are now processed by

specialized units dealing with drugs in six pharmacological and physiological classifications: Cardiopulmonary and Renal Drugs; Dental and Surgical Adjuncts; Metabolism and Endocrine Drugs; Anti-Infective Drugs; Oncology and Radiopharmaceuticals; and Neuropharmacological Drugs.

Each division is responsible for one pharmacological category of drugs and contains all the scientific personnel necessary for the review of applications involving new or investigational drugs.

The team concept implied in the review of drug applications has proved successful. Physicians and pharmacologists now work closely together; files do not travel from bureau to bureau, but are reviewed in a cooperative effort where the difficulties of communication are reduced to a minimum. Specialists in various fields exchange views and opinions, and thus gain a broad over-view rather than a small aspect of problems involving their particular specialty. Physicians, pharmacologists, and other scientists learn from each other, and cooperate efficiently.

The close cooperation of the various scientific teams also results in other, less tangible benefits. It is in the nature of this kind of teamwork that drug applications are at least to some degree treated according to the importance of their pharmaceutical benefits. A drug which promises an important breakthrough will capture the team's professional attention and enthusiasm.

The appointment of Dr. Herbert L. Ley, Jr., as the new head of the Bureau of Medicine gave further impetus to the reorganization. A former professor at the Harvard School of Public Health and department head at George Washington University, Dr. Ley has been active in medical research, including field work in Korea, Malaya, and Viet Nam while he was in the Army between 1947 and 1958.

Since Dr. Ley's appointment, the shortage of medical personnel in the Bureau of Medicine has been alleviated to a considerable extent with the cooperation of the Public Health Service. Approximately 70 physicians have been detailed to the Food and Drug

Dr. Robert M. Hodges is Associate Director for New Drugs, Bureau of Medicine. He joined FDA as a Medical Officer in 1963.





An FDA scientist checks an NDA for technical data (*above*). A single NDA may fill dozens of folders. A computer printout shows the current status of review of all NDA's pending (*below*).



Administration for a 2-year period of duty. The majority recently completed their internship, but in some instances have further training, including completed residencies in some specialties. Following an intensive training course conducted by senior members of George Washington University Medical School, with a guest faculty drawn from FDA, industry and medical schools, these physicians have been assigned the task of reviewing Investigational New Drug Applications under the supervision of Senior Medical Officers who are relieved of this responsibility and thus are able to devote more time to the review of NDA's. Following on-the-job training, a number of the PHS Officers have also been assigned New Drug Applications for review under supervision.

By their enthusiastic and refreshing attitude, background scientific research, continued training and hard work, the young physicians have made a gratifying contribution to the solution of the Bureau's medical personnel problem.

Improved managerial methods, such as the introduction of an NDA status report, have enabled su-

pervisory and executive personnel up to the level of the Commissioner to assess accurately the progress made on each application, by each professional member of the various Divisions. This enables assignment of personnel and concentration of effort in key areas to increase the efficiency of reviewing the applications. As an off-shoot of the system, the applicants now receive at intervals of three months (one month where the application exceeds the 180-day limit) a copy of the same status report for each application that is available to the Director of the Office of New Drugs.

The reorganization of the Bureau of Medicine had the immediate effect of decreasing the backlog; the accompanying chart shows the improvement in the situation. In the future, only exceptional cases will take the full 180 days for processing New Drug Applications.

Contributing to this objective is the improvement in the organization of IND's and NDA's as submitted by the sponsor. In the past, most of the work of the Bureau of Medicine was impeded by less than satisfactory organization of Investigational or New Drug Applications. Some of these applications represented

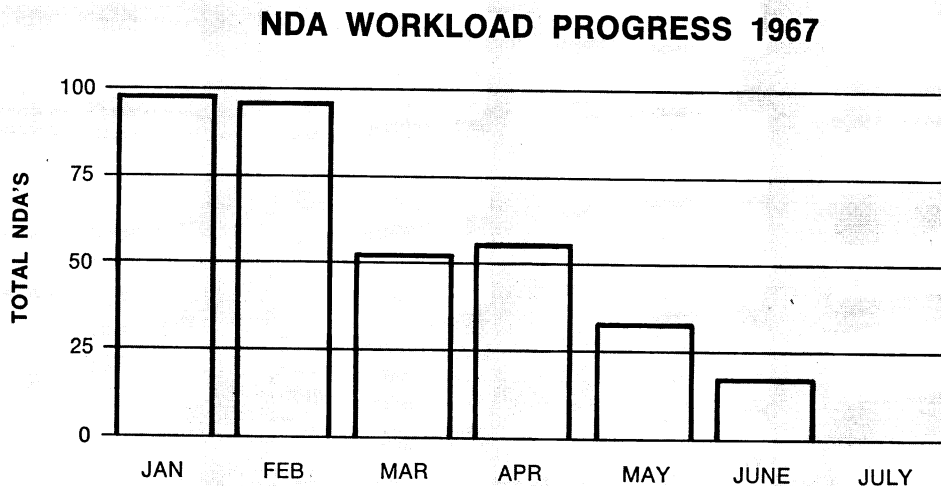
cation upon its scientific merit was adopted; where the overall picture unquestionably demonstrated the safety and efficacy of the drug when used according to its labeling, approval was recommended in disregard of irrelevant technical deficiencies. Where problems have been found, the manufacturer was made aware of specific deficiencies so that they could be corrected for expeditious processing of his application.

While the Bureau of Medicine has been successful in reducing the backlog, it should be emphasized that the emphasis the Bureau places on the quality of studies can only increase. For example, as a result of the ocular effects of certain drugs observed in recent studies on man and animals, there is now a requirement of satisfactory ophthalmic evaluation of all new drugs.

In the future, the processing of New Drug Applications will be considerably expedited by the requirement that applications be submitted in a rational, orderly tabulation with satisfactory summaries.

A number of applications recently submitted have already followed this format; in consequence, the time necessary for processing is significantly shorter

Backlog of NDA applications from January 1 to June 26, 1967. Applications substantially older than 180 days have decreased sharply from 98 to 0 in 6 months.



a bewildering complexity of data presented without any underlying rationale; many of them lacked complete pharmacological data, such as the presently recommended teratology and reproduction studies. Clinical studies were often so poorly planned and coordinated that their results were invalid. Others, having been submitted several years ago, did not meet the manufacturers' own standards of today.

Following discussion with the applicants, many of those applications were completely withdrawn. In other cases, the policy of reviewing the entire appli-

than was the case for a comparable application a year ago.

The correction of many of the deficiencies, and the improved quality of submissions in support of new drugs, particularly during the investigational new drug stage, should enable the Bureau to make more effective use of its available manpower. With the cooperation of the pharmaceutical industry, the Food and Drug Administration in its new, reorganized form, will be able to discharge effectively its responsibilities to the American people.

**“ . . . it is safest to assume
that man is at least as sensitive
as the most sensitive species of animal tested.”**

Properly designed and conducted, the subacute experiment will provide many of the basic observations for screening purposes, for an understanding of the pharmacology of the chemical, and for a guide for additional toxicity study. Even when chronic experiments are to be conducted later, the observations made here will help to evaluate the safety or the potential hazard of the substance. Therefore, a concentration of effort should be made in performing the subacute experiment to provide the best available information on the possible deleterious changes.

The first step in this procedure should be the literature search. A thorough understanding of the chemical nature, purity, and stability of the compound, the physiological activity of similar compounds, and a knowledge of techniques for measuring suspected chemical and biological changes is essential to the proper design of the experiment.

Another necessary step preliminary to the initiation of the subacute study is the range-finding experiment. Results of the range-finding experiment provide essential information on the order of magnitude of dosages to be selected. At this time two important decisions must be made: namely, selection of the experimental species, and route of administration.

The techniques employed should determine the effects of the compound, both anatomical and functional, if any. The lowest dosage level at which these effects occur should be determined. The evaluation of all effects in relation to dosage and use will indicate the desirability and the exact design

of any proposed chronic toxicity experiments.

The following points should be observed when conducting subacute toxicity studies:

1. At least two species should be employed, one of which is a non-rodent.

2. Studies should be designed for at least 90 days.

3. At least three dosage levels should be used — plus a control group. One dosage level should be toxic.

4. If rats are employed, use at least 20 animals per group with the sexes equally divided. When dogs are employed, there should be at least two males and two females in each group when testing with drugs. This number must be doubled if a pesticide is being tested.

5. The following minimum observations should be made: growth, food consumption, general appearance and behavior, mortality, organ weights, clinical laboratory tests (blood, urine, organ function, enzymatic, and metabolic), and gross and microscopic tissue examinations. All animals which die before the termination of the study should be subjected to careful and detailed gross and microscopic examination.

A successful study should establish the maximum tolerated dosage, the biological activity of the drug, and an estimate of the “no-effect” dosage.

Chronic toxicity studies The third of the basic or minimum studies essential when requesting the establishment of a tolerance for drug residues in edible products from treated animals is described by

Fitzhugh. The purpose of such basic studies is to provide data adequate to evaluate the safety of drug residues when ingested by man. In this respect toxicity should be interpreted broadly to include *any* change from the normal. It may be a result of changes in nutritional values of the food as well as direct effects of the chemical on any of the physiological systems of the experimental animals. When a drug is to be used in conjunction with the intake of food, or in certain cases of repetitive usage, evidence must be obtained to indicate the absence of any chronic toxicity. When metabolic pathways are not known or cannot be explained, and where subacute toxicity tests have produced only minor effects, chronic toxicity tests should be carried out on the proposed drugs. Chronic tests, in contrast to subacute studies, will determine with certainty that we are not encountering a case where the effect of exposure to a *small amount* of a compound for a *long time* differs markedly from an exposure to a *large amount* of the drug for a *short time*.

If a drug appears in animal feeds, the following factors must be considered: the form in which the drug will be found in the animal; the concentration of the drug or harmful metabolite in edible parts of the animal; the form and concentration level at which the drug can be tolerated without adverse effect when ingested by humans for prolonged periods; the pharmacodynamics of the drug in the form in which it is encountered and how the drug is metabolized; any harmful metabolites that might be produced dur-

ing the breakdown of the drug in the body; and the ultimate pathological manifestations, functional or organic, which might be expected from exposure to excessive quantities of the drug. In other words, the drug must *not only be safe for the animal, but also any drug residue, including metabolites, in the food must be demonstrated to be safe for man.*

The lowest dosage level is adjusted so that no damage can be expected to occur within the experimental period, and the highest dosage *should* cause some deaths. No general statement is adequate to define feeding levels for food additives, including pesticides. In most instances a drug must show "no effect" when fed for 2 years to the most sensitive laboratory species at a minimum of 100 times the requested tolerance before it can be permitted in the total human diet.

Although data from all dosages bear on the evaluation of safety, *only* the "no-effect" level in the most sensitive species can be used to establish the definite margin of safety. Where there is a broad interval between the "no-effect" dosage and the next one with a slight effect, this factor may cause an interpretation of toxicity greater than the actual.

In some studies it is desirable to sacrifice one or two rats of each sex at various intervals, such as 6, 12, and 18 months. If this is done, the total number in each group should not be reduced below 40 rats. Since the usual strain of albino rats is not inbred, weanling animals are assigned to the various groups according to litter mates. A litter of four males and four females, with a

variation of no more than five grams within the litter, is distributed with one male and one female in each of the four groups as follows: (1) a control group; (2) a group on a low level which is expected to produce no damage; (3) a group in a middle level which may or may not produce damage; (4) a group on a high level which approaches the tolerated amount.

In a similar experiment, dogs are used in groups of eight each on the four dosage levels. Since there should be a minimum of four dogs remaining in each group at the termination of the experiment, the exact number used at the beginning depends upon the desirability of sacrificing animals during the experimental period and the accepted risk of losing animals from natural causes. Animals are selected from litters of young from a known breed, and are assigned in groups of four males and four females to each dosage in a manner which will give an even distribution according to age and weight.

A critical evaluation of all data on the effects of a compound, whether biochemical, pharmacological, or morphological, will permit a logical decision to be reached regarding any possible hazard resulting from the use of the proposed substance. Usually, for a substance proposed for use in food, the chronic experiments in *two* species of animals will be adequate for this evaluation. However, for certain types of additives, such as a drug residue in milk, a dietary constituent necessary for the very life of the young, the invalid, and the old, more extensive investigations are necessary. To assure an added margin of safety in this instance,

supplemental studies are recommended as follows:

1. The regular reproduction studies which are described below for rats;

2. A breeding study in another mammal (dogs may be used in groups of two females each, with establishment of a "no effect" and a toxic dosage to the newborn and to the young up to 4 months of age);

3. A 90-day study in rats and dogs in which milk is a major component of the diet; and

4. Groups of animals with injured livers are given different test dosages of the drug to simulate conditions found when milk diets containing the drug are given to persons with liver ailments.

It must be remembered that chronic toxicity studies do not stand alone but are part of the overall picture, following and adding to information gained in acute, subacute, and biochemical tests, and possibly indicating the necessity of further work. Each drug tested presents different problems and must be approached in a sound and practical manner. Since the effect of a drug in man can never be predicted with certainty from other species, the effects on the most susceptible species will be adopted in making extrapolations. In the absence of reasonable certainty concerning a "no-effect" level for food additives, *no risk will be taken.*

The following points should be observed when conducting chronic toxicity studies:

1. At least two species should be employed, one of which is a non-rodent.

**“In the absence of reasonable certainty
concerning a ‘no-effect’ level for food additives,
no risk will be taken.”**

2. The studies should be designed to cover a 2-year period.

3. At least three dosage levels should be used—plus a control group. One dosage level should be toxic.

4. If rats are used, each group should consist of 50 animals with the sexes equally divided. When dogs are used, there should be at least four males and four females in each group.

5. The following minimum observations should be made: growth, food consumption, general appearance and behavior, mortality, organ weights, clinical laboratory tests (blood, urine, enzymatic, metabolic, and organ function, especially as related to the expected type of response demonstrated in short term tests), gross examination of animals throughout the experimental period, and gross and microscopic examination of tissues and organs at autopsy. Animals which die before the termination of the study should be similarly examined.

Reproduction studies Reproduction studies must be performed when requesting a tolerance for drug residues in edible products. These studies should be designed as follows:

1. A minimum of one species shall be used—two species are preferable.

2. There should be at least two dosage levels, plus, a control group.

3. One of the dosage levels should be toxic, another should have no effect.

4. The group should consist of at least 20 females and 10-20 males.

5. The study should extend over

three successive generations in the rat.

6. It is desirable to have two litters per generation.

7. Both the males and females should be treated for 60 days prior to breeding. The second and third generations are treated from weaning throughout the breeding period.

8. The following minimum observations must be made: fertility, length of gestation, number of live births, stillbirths, survival at 4 days and at weaning, sex of newborn and of weanlings, body weight, gross abnormalities, and microscopic examination of tissues of young in last generation (10 animals per group).

Monitoring permissible drug residue levels Since the enactment into law of the Food Additives Amendment of 1958, tolerances for drug residues in edible products derived from treated animals have been established for about 50 drugs. Zero tolerances have been established for 45 of these drugs, and finite tolerances for five drugs: zoalene, amprolium, arsenic, chlortetracycline, and oxytetracycline.

Various meat and poultry products may be sampled and tested by the Government for any of these drugs at any time.

Recently, the FDA has requested and obtained considerable data regarding the duration of antibiotic residues in edible tissues of treated animals. The long withdrawal times needed for animals and poultry to excrete all traces of some of the antibiotics have convinced FDA that a large-scale residue surveil-

lance program for antibiotic residues should be instigated.

This anticipated program will be a cooperative venture with the Consumer and Marketing Service, USDA. C & MS will do their sampling at the packing plants. A total of 5,200 samples per year, with approximately 3,900 red meat and 1,300 poultry samples, are to be analyzed for the presence or absence of antibiotic residues. The tissues will be tested for as many antibiotics as possible, including penicillin, streptomycin, chlortetracycline, and tylosin. The current procedure of sampling all carcasses which show possible injection lesions will continue. Carcasses and edible organs found to contain antibiotic residues will be condemned for food.

The FDA plans call for a random sampling of meat and poultry products at the retail level. This will include processed foods. When the results of this survey are compiled, we will then know if a hazard to human health actually exists.



Dr. Fred J. Kingma, Deputy Director of the Bureau of Veterinary Medicine, presented this paper on June 6, 1967, to the National Academy of Sciences—National Research Council.

field reports

ATLANTA DISTRICT For illegal sales of prescription drugs to FDA inspectors, three Georgia men were sentenced to prison terms on April 28. The convictions followed intensive investigations in the Milledgeville, Ga., area in 1964 and 1965. Thomas P. Garrison, James Hill, and Lawrence W. Barrington were each sentenced to 6 months in prison.

BALTIMORE DISTRICT Trinacria Macaroni Works, Baltimore, Md., was fined \$500, plus court costs, on April 7 for shipping in interstate commerce macaroni and spaghetti products which had been manufactured in an insanitary factory and which were contaminated with insects and insect filth.

BOSTON DISTRICT Maurine Neuberger, Special Consultant to the Commissioner, was among the speakers at a conference on aging April 28 in Brookline, Mass. More than 100 professional persons who work in the area of aging in New England attended the conference, sponsored by the District and the Boston Regional Office of the Administration on Aging. The purpose of the meeting was to promote health and pocketbook protection for the aged by educating them to make: safe and effective use of drugs, wise selection of health products and services, and discriminating evaluation of advertising.

BUFFALO DISTRICT A manufacturer of frozen baked goods destroyed 507 cases of cream pies because of bacteriological contamination. Inspection of Town Square Foods, Inc., Lake City, Pa., in early January revealed insanitary conditions, and analysis of samples confirmed the contamination. Seizure was made of 384 cases. The firm was cited, and at a hearing indicated it had taken corrective actions. The day after the hearing, District Inspectors visited the plant, found insanitary conditions, and took in-plant samples of raw materials and finished products. The firm then destroyed the 507 cases under FDA supervision, and authorized the A & P Tea Co. retail stores to destroy all of the pies distributed out of the firm's Buffalo and Syracuse warehouses. The firm is keeping FDA informed of its progress in cleaning up its plant.

CINCINNATI DISTRICT A Cincinnati, Ohio, orphanage benefited in April from an FDA seizure. Kenner Products Co., Cincinnati, a toy manufacturer, donated a number of toy ice cream freezers to the orphanage after the mixes accompanying the freezers were seized because of misbranding. Chocolate toppings and

Freeze Queen mix were both short weight, and the mix was not labeled "imitation."

DALLAS DISTRICT Because of *E. coli* contamination, shelled pecans, valued at \$480,000, were embargoed at Standard Brands, Inc., San Antonio, Tex., by Texas officials. The District had worked closely with the Texas Division of Food and Drugs on the case. The firm initiated a voluntary recall of its shelled pecans on April 28 from warehouses throughout the Nation. Several seizures of the pecans had previously been made in various parts of the country. The recalled, seized, and embargoed pecans will be salvaged under supervision.

DENVER DISTRICT Various herbs, liquids, and promotional leaflets were seized from "Dr." C. P. Sundance, "Master of Herbalism," in Ogden, Utah, in April. FDA charged that the cancer remedies and other herbal preparations were misbranded, and that "Dr." Sundance thus violated terms of a permanent injunction against him. In September 1964, the U.S. District Court in Idaho enjoined the 87-year-old "doctor" from misbranding drugs in interstate commerce.

The labels of the seized preparations did not state the ingredients or manufacturer's address. "Dr." Sundance is not registered as a drug establishment as required under the Federal Food, Drug, and Cosmetic Act; he indicates that his products are not drugs, but herbs. "Dr." Sundance misbranded similar herbal preparations while practicing in Idaho, where he claimed to treat "all ailments of men and women."

An "In-Plant Bacteriological Sanitation" workshop was cosponsored by the District, the Potato Processors of Idaho Association, and the Idaho Department of Health on April 13 in Burley, Idaho. The workshop instructed plant managers, quality control personnel, and production supervisors from 15 firms in basic in-plant sanitation and cleanliness. The firms represented 90 percent of the Idaho processed potato manufacturers.

DETROIT DISTRICT "Ahead Hair Grower for new hair growth" has been seized in Detroit, Mich., and elsewhere in the Nation because the product was a new drug shipped without an approved NDA. Seizures totaling about \$140,000 were made during March and April in Encino, El Segundo, and Los Angeles, Calif.; Wilmington, Del.; Pittsburgh, Pa.; and Detroit. FDA inspection of the manufacturer,

Kelly Products, Inc., Royal Oak, Mich., indicated the product is an emollient hair dressing with no medicated ingredients. The manufacturer claims it is a cosmetic and not a drug.

The District first learned of the product from Los Angeles District, which reported a very active promotional campaign by radio, TV, and newspaper. Similar advertising campaigns have been reported in a number of other large cities throughout the United States.

KANSAS CITY DISTRICT Dehydrated potatoes and frozen custard pies were seized in April due to *E. coli*, excessive coliforms, and total bacteria. On April 4, 90 pounds of potatoes, valued at \$625, were seized at Trenton Foods, Trenton, Mo. At Empire Cold Storage Co., Kansas City, Mo., 618 pies, valued at \$618, were seized on April 12.

Due to decomposition, 3,600 pounds of frozen chicken fat and 25,674 pounds of frozen chickens, valued at \$9,146, were seized at U.S. Cold Storage Corp., Kansas City, Mo., on April 12.

LOS ANGELES DISTRICT Because of *Salmonella* contamination, Johnston Pie Co., Los Angeles, Calif., recalled more than 100,000 frozen custard and pumpkin pies in April. Inspection of the firm which supplied liquid eggs to the bakery revealed inadequate pasteurization. The pie firm had not made adequate bacteriological tests and merely assumed that the eggs were pasteurized. The pies were distributed in the western part of the United States. The bakery has now set up better bacteriological testing, and uses dried instead of liquid eggs.

Growers and shippers of fresh vegetables and pesticide applicators participated in a pesticide workshop sponsored by the District in Phoenix, Ariz., on April 27. Cosponsor was the Central Arizona Vegetable Growers and Shippers Association. About 35 persons representing 13 firms and 7 State and county agencies attended. Talks made by personnel from FDA, USDA, Arizona Health Department, and industry covered the uses, legal controls, and health aspects of pesticides.

MINNEAPOLIS DISTRICT Lip Ivo and New-Vita-27 Food Supplement tablets and capsules were seized in the District during April. Due to misbranding, more than 27,000 tubes of Lip Ivo were seized in Minneapolis, Minn. Label statements suggested that the product is effective for cold sores and fever blisters, and failed to give the quantity of contents and the

name of the manufacturer, processor, or distributor. The distributor plans to relabel the seized goods. Because they contained more iodine than is permitted, the food supplement tablets were seized in Racine, Wis. The labeling was also false and misleading, for it wrongfully stated that the need in human nutrition for vitamin E, biotin, calcium pantothenate, manganese, zinc, and protein had not been established.

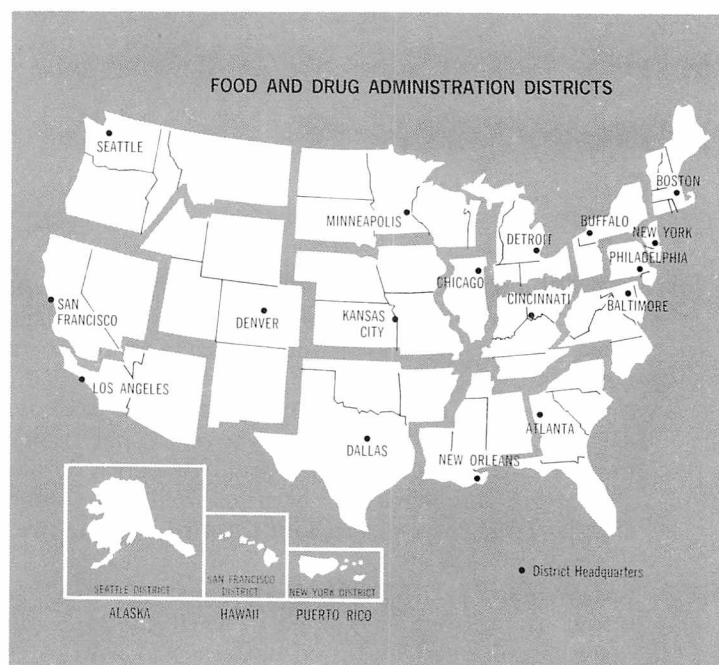
NEW YORK DISTRICT A large-scale food poisoning investigation developed recently in the District following discovery of *Salmonella* contamination of frozen desserts. The New York City Health Department, the Communicable Disease Center of the U.S. Public Health Service, and the District investigated the outbreaks in the New York City area involving 2-3,000 people. The poisonings occurred at catered affairs held from April 5 to April 11, and were caused by frozen desserts manufactured by Country Club Frozen Desserts, New York. The firm immediately shut down its plant and ceased production and distribution until proper equipment and processing modifications could be made. The contamination was ultimately traced to nonpasteurized, sugared egg yolks used in the desserts and manufactured by Manhattan Egg Co., New York. The firm halted distribution of nonpasteurized egg products. The products were linked to *Salmonella* outbreaks in New Jersey, and had also been distributed in Massachusetts, Connecticut, and Michigan. State and local health officials in these States were involved in the investigations.

In New York City, 166 confirmed illnesses were reported. Various consignees reported an attack rate of 25-35 percent of the guests at catered affairs. The manufacturers will not produce any further products until cleared by health officials.

Following the sudden death of a child recently, the New Jersey Department of Health, in cooperation with the District, embargoed 141 bottles of H.R. Eurema, a combination liquid solder flux and metal polish. The 18-month-old girl died 25 minutes after swallowing a small quantity of the solution her father used to clean coins. The product was manufactured by Hammel, Ringlander, Inc., New York, N. Y. The labeling for the product did not contain a Hazardous Substances Act warning statement to "Keep out of the reach of children," and did not indicate that the preparation contains sodium cyanide. The label also did not bear the name and address of the manufacturer or distributor.

PHILADELPHIA DISTRICT After *Salmonella* was found in the firm's chocolate coatings, Klein Chocolate Co., Elizabethtown, Pa., voluntarily recalled 18,000 pounds of coatings and more than 2,000 pounds of candy from nationwide distribution. FDA made a factory inspection of the firm after receiving a report that it was using a lot of nonfat dry milk received from Otsego Sanitary Milk Products Co., Otsego, Mich., in which *Salmonella* has been detected. Laboratory findings confirmed the presence of *Salmonella*. In addition to the recalled products, 60,000 pounds of coatings and 18,000 pounds of candy were embargoed in the manufacturer's warehouse. Cincinnati, Minneapolis, Boston, and Detroit Districts are also investigating distribution of the candy and coatings.

SAN FRANCISCO DISTRICT To discuss the analysis of LSD, the District held a seminar March 31 for representatives of State and local law enforcement agencies. Arrangements for the seminar were made by Los Angeles BDAC Field Station. Analysts discussed the chemistry of LSD and related compounds, the presumptive field tests for LSD, and laboratory analyses. Giving expert court testimony in drug cases was also discussed.



SEATTLE DISTRICT Due to rodent filth, a 123,000-pound railcar load of bulk wheat was seized April 26 at Great Northern Railway Co., Spokane, Wash. Shipper of the wheat, valued at \$4,500, was Cargill, Inc., Valier, Mont.

Due to nonsterile packaging, 425 I.V. catheters, valued at \$297, were seized at the U.S. Public Health Service Hospital, Seattle, Wash., on April 25. Manufacturer was Paramed, Inc., Portland, Oreg. Seizure had been made earlier of a similar lot in the District.

FDA DISTRICT OFFICES

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

BALTIMORE 900 Madison Avenue
Baltimore, Maryland 21201

BOSTON 585 Commercial Street
Boston, Massachusetts 02109

BUFFALO 599 Delaware Avenue
Buffalo, New York 14202

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

CINCINNATI 1141 Central Parkway
Cincinnati, Ohio 45202

DALLAS 3032 Bryan Street
Dallas, Texas 75204

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

DETROIT 1560 E. Jefferson Avenue
Detroit, Michigan 48207

KANSAS CITY 1009 Cherry Street
Kansas City, Missouri 64106

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

MINNEAPOLIS 240 Hennepin Avenue
Minneapolis, Minnesota 55401

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

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

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

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

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

FDA BUREAU OF DRUG ABUSE CONTROL FIELD OFFICES

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

BALTIMORE 401 Water Street
Baltimore, Maryland 21202

BOSTON J. F. Kennedy Federal Bldg.
Rm. E-311/Boston, Massachusetts 02203

CHICAGO Engineer Bldg.
Rm. 1700/205 West Wacker Drive
Chicago, Illinois 60606

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

DENVER New Customhouse Bldg.
Rm. 228/721 19th Street
Denver, Colorado 80202

KANSAS CITY U.S. Courthouse
Rm. 225/811 Grand Avenue
Kansas City, Missouri 64106

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

NEW YORK 201 Varick Street
Rm. 1051-A/New York, New York 10014

state actions

Poor Potatoes Passed As No. 1

Due to a large stock of poor quality potatoes this year, growers are attempting to market their crop in other States, primarily the poverty areas of Southern States, reports the Michigan Department of Agriculture. Overloaded trucks operated by independent haulers take routes planned well in advance to bypass the regulatory inspectors and the highway scales. The potatoes are alleged to be unclassified, but are in U.S. No. 1 grade bags. Ohio State officials tracked down and seized two known shipments, and later refused another shipment of 10,000 bags of potatoes originating in Michigan.

Michigan Adopts Hazardous Regs

Michigan adopted the Federal regulations on hazardous substances as its own in February.

Frozen Meat Embargoed The Washington Department of Agriculture placed an embargo against 40,050 pounds of frozen meat in March after it had been rejected by both Canadian Customs officials and USDA meat inspectors as unfit for human consumption. The frozen plate trimmings had been stored at Tacoma Cold Storage, Tacoma, Wash. The meat had been shipped by the Union Packing Co., out of Los Angeles, Calif.

Pesticide Found In Franks When a terminal manager in Seattle, Wash., observed a pesticide chemical scattered around a shipment of frankfurters, he immediately called the local FDA office. The office contacted the Washington Department of Agriculture, which sent an inspector out immediately. The residue turned out to be Phorate, an extremely toxic pesticide. The 630 pounds of meat were embargoed in March.

Candy Eggs Withheld Just before Easter, the Georgia Department of Agriculture issued withhold-from-sale orders against candy Easter eggs packaged in egg-type cartons without an overwrap. Such cartons subjected the eggs to contamination by micro-organisms or insects. One packer of the product rewrapped all stocks of his products in the State; another manufacturer requested that the candy being held be donated to a charitable institution.

Outstanding Sanitarian Chosen

The Kentucky Association of Milk, Food and Environmental Sanitarians named Shelby Johnson, Director of the Food and Drug Program of the Kentucky State Department of Health, the outstanding sanitarian of the year in February. The award, a plaque and a \$100 savings bond, is given annually for work in milk and food regulation and other health department activities.

Fire Damages Grains Following a recent early morning fire at Inter-mountain Farmer's Association, Draper, Utah, which caused an estimated \$200,000 damage to buildings, stored grains, and medicated feed mixes, a Utah State Inspector supervised the segregation of fire-damaged goods and witnessed their destruction.

Feed Mixes Cross-contaminated

Cross-contamination of medicated feed mixes was discovered in April by a factory inspection team of Colorado and FDA personnel. Analysis of samples taken from Farmer's Union Co-op, Milliken, Colo., confirmed that the dairy herd feed had been contaminated with diethylstilbestrol. Colorado officials traced the local shipment to a producing dairy and embargoed the suspected milk.

Salmonella Research Sponsored

Pennsylvania State University will undertake a 2-year *Salmonella* research study under a grant by the Chocolate Manufacturers Association of the United States. Initially the work will concern the effect of heat treatments on *Salmonella* in chocolate and the actions of *Salmonella* in high fat mediums.

Florida Stops Tomato Sales

The Florida Department of Agriculture and Atlanta District Inspectors coordinated their schedules and inspected all tomato canning plants in Florida during the past season. Some inspections were joint. Problems with *Drosophila* and peel were the worst seen in the last 5 to 10 years. The District recommended nine seizures; Florida officials issued more than 18 stop-sale notices.

Chicago Embargoes Bean Sprouting Operations

Live cockroaches crawling all over bean resprouting rooms of China Farm, Chicago, Ill., led to temporary closure of the firm by the Chicago Board of Health in April. When District Inspectors first surveyed the plant, the walls of the bean sprouting rooms contained many cracks, and protruding rotten wood from the ceiling provided excellent harborage for cockroaches. A cat and cat excreta were also found in the repacking area where the bean sprouts were prepared for shipment. Informed of these conditions, the Chicago Board of Health investigated and placed an embargo on the bean sprouting operations. The plant was closed for 3 weeks until the cracks in the walls and ceiling were fixed and the cockroach infestation eradicated. The firm was ordered to destroy 31,320 pounds of sprouting beans.

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 110 seizure actions to remove adulterated, misbranded, and unsafe products from the consumer market were reported in April. These included 46 seizures of foods: 4 because of poisonous and deleterious substances, 36 be-

cause of contamination, and 6 because of economic violations. Other seizures included 10 of vitamins and dietary foods, 40 of drugs, 6 of medical devices (including 2 of prophylactics), and 8 of hazardous substances.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD / Poisonous and Deleterious Substances		
Alfalfa Seed Screenings/Vancouver, Wash. 3/7/67	Nevada Alfalfa Seed Co./Orovada, Nev. (S)	Contains toxaphene, a pesticide chemical not in conformity with regulations.
Harrisburg, Oreg. 4/17/67	W. R. Grace Co./Sunnyside, Wash. (M, S)	"
Squash/Scranton, Pa. 3/23/67	David G. Bowen Co./Pompano Beach, Fla. (S)	Contains endrin, a pesticide chemical not in conformity with regulations.
Yeast, dried/Loma Linda, Calif. 3/2/67	Lake States Div., St. Regis Paper Co./Rhineland, Wis. (M, S)	Contains poisonous Salmonello micro-organisms.
Contamination, Spoilage, Insanitary Handling		
Beans, Azuki/San Francisco, Calif. 4/5/67	Hoslett Co./San Francisco, Calif. (D)	Held under insanitary conditions.
kidney/Vicksburg, Miss. 3/23/67	Hill City Mills/Vicksburg, Miss. (D)	"
mung/San Jose, Calif. 4/13/67	William Dair Co./San Jose, Calif. (D)	"
pink/San Juan, P.R. 4/7/67	Jose Malgert Co., Inc./San Juan, P.R. (D)	"
pinto/Deming, N. Mex. 2/25/67	Mimbres Valley Farmers Assn., Inc./Deming, N. Mex. (D)	"
Buttermilk Powder/Dallas, Tex. 3/24/67	Frozen-Rite Products, Inc./Dallas, Tex. (D)	"
Chickens and Chicken fat, frozen/Kansas City, Mo. 4/12/67	Motts, Inc./Water Valley, Miss. (P, S)	Decomposed.
Cocoa Powder/Los Angeles, Calif. 3/15/67	Overland Terminal Warehouse/Los Angeles, Calif. (D)	Held under insanitary conditions.
Corn Husks/Los Angeles, Calif. 3/10/67	Los Angeles Nut House/Los Angeles, Calif. (D)	Insect-infested and moldy husks.
Custard Pies/Kansas City, Mo. 4/12/67	Johnston Pie Co./Los Angeles, Calif. (M, S)	Excessive bacteria and coliforms.
Flour/Big Spring, Tex. 2/13/67	Stripling Supply Co./Big Spring, Tex. (D)	Held under insanitary conditions; rodent contaminated.
Carthage, Tex. 4/11/67	Magnolia Grocery Co./Carthage, Tex. (D)	"
Krakus Brand Pork Luncheon Meat/Bufalo, N.Y. 4/10/67	Atlanta Prod. Co./Jersey City, N.J. (S)	Decomposed.
Mixes, various pie and cake/Youngstown, Ohio 4/12/67	Edgar A. Miller Co., Inc./Youngstown, Ohio (D)	Held under insanitary conditions; rodent contaminated.
Olives/Minneapolis, Minn. 3/23/67	Mario's Food Products Co./Detroit, Mich. (P, S)	Prepared and packed under insanitary conditions.
Peaches, canned/Dorchester, Mass. 3/23/67	California Packing Corp./Sacramento, Calif. (P, S)	" ; decomposed and moldy.
Peanuts/Hopkins, Minn. 3/31/67	Johnson Nut Co./Hopkins, Minn. (D)	Held under insanitary conditions; rodent contaminated.
Jackson, Tenn. 3/17/67	Central Warehouse Co./Jackson, Tenn. (D)	"
Fort Smith, Ark. 2/9/67	RMB Produce Co./Fort Smith, Ark. (D)	"
Minneapolis, Minn. 3/31/67	Hancock Peanut Co./Courtland, Va. (P, S)	Rodent contaminated on arrival after shipment.
Peas, green, split/Sutter, Calif. 3/16/67	West Los Angeles Milling Co./Sutter, Calif. (D)	Held under insanitary conditions; rodent contaminated.
Pecans/Albuquerque, N. Mex. 3/15/67	Azar Brothers, Inc./El Paso, Tex. (P, S)	Prepared and packed under insanitary conditions; E. coli.
Lawton, Okla. 3/9/67	"	"
Phoenix, Ariz. 3/21/67	"	"
Omaha, Nebr. 3/23/67	"	"
Detroit, Mich. 2/17/67	Azar & Solomon/San Antonio, Tex. (P, S)	"
Philadelphia, Pa. 3/23/67	Roper Pecan Co./Hickman, Ky. (P, S)	"
Fort Worth, Tex. 3/13/67	Wynnewood Pecan Co./Wynnewood, Okla. (P, S)	"
Mansfield, La. 3/14/67	Louisiana Pecan Shelling Co./Mansfield, La. (orig. S), returned from Joplin, Mo.	"
St. Paul, Minn. 3/22/67	Louisiana Pecan Shelling Co./Mansfield La. (S)	"
Pepper Strips, canned/Everett, Mass. 3/2/67	Vita Food Products, Inc. of Md./Chestertown, Md. (P, S)	Decomposed.
Potatoes, crushed, dehydr./Trenton, Mo. 4/4/67	Idaho Potato Foods, Inc./Idaho Falls, Idaho (P, S)	Excessive bacteria, E. coli, and coliforms.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Contamination, Spoilage, Insanitary Handling (cont'd)		
Sorghum and Corn Syrup/Grand Rapids, Mich. 2/23/67	Kentucky Sorghum Growers' Coop. Assn./Hawesville, Ky. (P, S)	Prepared and packed under insanitary conditions; rodent contaminated.
Walnut Meats/Chicago, Ill. 2/21/67	Oregon Filbert Growers/Salem, Oreg. (P, S)	Prepared and packed under insanitary conditions; E.coli.
Wheat/Garnett, Kans. 3/3/67	Jones Grain Co./Vermillion, Kans. (S)	Rodent contaminated.
Kansas City, Kans. 2/27/67	Evans Grain Co./Hastings, Nebr. (S)	"
Economic Violations		
Candy Suckers/Alexandria, La. 3/17/67	Blackburn Candy Co./Alexandria, La. (D)	Contain nonnutritive objects—coins—imbedded.
Fruit Cocktail, canned/Kansas City, Kans. 4/13/67	Duffy-Mott Co., Inc./Santa Clara, Calif. (P, S)	Fails to conform to definition and standard of identity of fruit cocktail.
Ribbon Cane Syrup/Columbia, Miss. 3/30/67	Norris Brothers Syrup Co., Inc./West Monroe, La. (M, S)	A sweetening substance other than cane syrup has been substituted for cane syrup.
Kosciusko, Miss. 3/23/67	"	"
San Augustine, Tex. 4/11/67	"	"
Tunafish, canned/Los Angeles, Calif. 3/15/67	Nichimen Co., Ltd./Tokyo, Japan (S)	Not in conformity with standard of fill of container.
Vitamins—Dietary Food		
Beef Tea/Minneapolis, Minn. 2/6/67	Smithers Sons, Ltd./Chicago, Ill. (M, S)	False and misleading claims to reduce blood lipids and body weight, prevent cancer, diabetes, artery disease, and heart attack.
Candy, sugarless/Milwaukee, Wis. 3/14/67	Sugarless Candy Corp. of America/Chicago, Ill. (M, S)	Misleading dietary statements; short weight.
Juvespan Capsules/Whittier, Calif. 3/8/67	Hilco Drug Distributors/Whittier, Calif. (D)	Deficient in declared vitamins A and B ₁ .
Multi-Vitamin Tablets, Vitamin Mineral Tablets, and Protein Wafers/Terminal Island, Calif. 2/19/67	Rudnat Corp./Gardena, Calif. (D)	Below labeled strength; deficient in vitamins.
Nutri-Bio and Baby-Bio/Richmond Hill, N.Y. 4/3/67	Nutri-Bio Corp./Los Angeles, Calif. (M, S)	Deficient in vitamin C.
Organic Mineral Salt/Bronx, N.Y. 1/18/67	Dr. Bronner & Assoc./Escondido, Calif. (M, S)	Contains iodine in excess of permitted daily maximum.
Pro-Tab Wafers, Sorbi-Plus Liquid, and Derma-Vites Tablets/Philadelphia, Pa. 3/13/67	Vitamin Specialties Co./Philadelphia, Pa. (D)	Contain folic acid, a food additive not in conformity with regulations; insufficient information on dietary properties.
Super Hemo Tablets/Panorama City, Calif. 3/24/67	Boncqnet Laboratories/Panorama City, Calif. (D)	Deficient in vitamin C.
Vigortol Capsules/Saugus, Calif. 3/30/67	Rider's Limited/Saugus, Calif. (D)	Contains iodine not in conformity with regulations.
"Zip" Breakfast Cereal/Solana Beach, Calif. 3/8/67	Bernard Jensen Products/Solana Beach, Calif. (D)	Insufficient information on dietary properties.
DRUGS / Human Use		
Acne-Biotic Tablets/Saugus, Calif. 2/28/67	Rider's Ltd., Inc./Saugus, Calif. (D)	False and misleading claims; label lacks R _x legend for bile salts.
Ahead Hair Restorer/Wilmington, Del. 4/11/67	Kelly Products, Inc./Royal Oak, Mich. (M, S)	New drug not approved for safety and efficacy.
Los Angeles, Calif. 3/17/67	"	"
Pittsburgh, Pa. 3/30/67	"	"
Encino, Calif. 3/14/67	"	"
El Segundo, Calif. 3/14/67	"	"
Santa Fe Springs, Calif. 3/15/67	"	"
Taylor, Mich. 3/17/67	"	"
Alergimist/Goleta, Calif. 3/23/67	Brunson Corp./Miami, Fla. (M, S)	"
Aminol 90, Ketovite Tablets, Multi-Vitamin Mineral Preparation, Nucleic Acid Tablets, Profood 51, Sidamine/Cedar Rapids, Iowa 2/2/67	Professional Foods/Cedar Rapids, Iowa (D)	False and misleading health claims.
Amphetamine Tablets and Powder/Knoxville, Tenn. 2/10/67	Floyd S. Foreman, t/a Darigon Corp./Knoxville, Tenn. (M, D)	Contraband items owned and held by persons not duly registered.
Appetite Management Tablets Formula 1575/Cleveland, Ohio 4/13/67	Formulations, Inc./Milwaukee, Wis. (M, S)	New drug not approved for safety and efficacy.
Barbeloid 100 Tablets/Pasadena, Calif. 2/28/67	United Laboratories, Inc./Pasadena, Calif. (D)	Below labeled strength.
BD-BU Plan Tablets, Bon-Grow Tablets, Adwate Liquid, Liver Life Tablets, Super Protein Tablets/West New York, N.J. 3/21/67	Weider Barbell Co., Inc./West New York, N.J. (D)	Misbranded; insufficient information on special dietary properties.

seizure actions

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Drugs / Human Use (cont'd)		
Boric Acid Solution N.F./Portland, Oreg. 1/9/67	Stanlabs Warehouse/Gardena, Calif. (S)	Not in conformity with labeling regulations.
Butabarbital Sodium/Los Angeles, Calif. 3/3/67	B & B Laboratories, Inc./Los Angeles, Calif. (D)	Below USP standard.
Chaulmoogra Oil Capsules/Bell, Calif. 4/4/67	Seal-In Laboratories, Inc./Bell, Calif. (D)	False and misleading claims for treatment of arthritis.
Cough Syrup/Gary, Ind. 1/19/67	Kaplan Supply Co., Inc./Gary, Ind. (D)	Inadequate warning against misuse.
Desoxycorticosterone Acetate Tablets/ Pasadena, Calif. 3/22/67	United Laboratories, Inc./Pasadena, Calif. (D)	Inadequate directions for use.
Dextro-amphetamine Sulfate Capsules/ Chicago, Ill. 2/14/67	Shaw Pharmacal Co./St. Louis, Mo. (M, S)	Below labeled strength.
Ethinyl Estradiol/Glendale, Calif. 1/24/67	Lanpar Co./Dallas, Tex. (M, S)	Below USP standard.
Ethionamide INH Tablets/Brooklyn, N.Y. 3/30/67	Amfre-Grant, Inc./Brooklyn, N.Y. (D)	New drug not approved for safety and efficacy.
Hi-Cee Grams, Hi-Cee Injectable, Titen-Zem Paint/Hialeah, Fla. 2/9/67	Zirin Laboratories Int'l., Inc./Hialeah, Fla. (D)	False and misleading claims to treat vitamin C deficiency; label fails to bear established name of each active ingredient.
Hygenol Powder, Calciolysin 12, Ceremil, Neurocerebral Tonic/Coral Gables, Fla. 4/6/67	Pharmaceutical Enterprises/Atlanta, Ga. (M, S)	Inadequate directions for use; inadequate warnings against misuse; incorrect minimum daily requirement.
Hypercin Antacid Tablets/Chicago, Ill. 3/14/67	Consolidated Royal Chemical Corp./Chicago, Ill. (D)	Misbranded; inadequate directions for use.
Lift Compound w/Vitamins/Chicago, Ill. 3/21/67	Mechanical Servants, Inc./Chicago, Ill. (D)	Inaccurate statements of quantity and name of ingredients.
Mann's Ulcer Medicine/Ottawa, Kans. 3/22/67	Seyler Drug Co./Ottawa, Kans. (D)	Inadequate directions for use.
Medi-Stims/Los Angeles, Calif. 3/16/67	Iodent Chemical Co./Detroit, Mich. (M, S)	False and misleading claims to promote healthy gums, fight decay, and kill bacteria.
Mucovata Laxative/Lafayette, Calif. 4/6/67	Seroyal Brands, Inc./Lafayette, Calif. (D)	False and misleading claims to remove accumulations of putrefactive bacteria and mucus formations from within the gastrointestinal tract.
Potassium Chloride Tablets/Dallas, Tex. 3/9/67	Lanpar Co./Dallas, Tex. (D)	Not in conformity with food manufacturing practices; below labeled quality and USP standard.
Quinidine Sulfate USP/Portland, Maine 12/28/66	Brewer & Co., Inc./Worcester, Mass. (M, S)	Below USP standard for strength.
Sargon Pills, Severa's First Aid Treatment, Dr. Whetzel's Liquid Prescription, Ox Bile Extract and Pancreatin, Quintaline/ Warren, Pa. 4/5/67	Myers Laboratories/Warren, Pa. (D)	Inadequate directions for use; no required warnings.
4 Sulfas & A/Winslow, Maine 3/28/67	Eastern Laboratories, Inc./Vineland, N.J. (M, S)	Below labeled strength; 77.9 percent of declared sulfonamides.
Venolax Tablets/Miami, Fla. 4/14/67	Roger Pharmacal Co./Miami, Fla. (D)	Inadequate directions for use.
Veterinary / Medicated Feed		
GTA Arsanilic Acid Premix/Minot, N. Dak. 3/17/67	Farmers Union Grain Terminal Assn./ Sioux Falls, S. Dak. (M, S)	Below labeled strength.
Mastitis Treatment/Garnavillo, Iowa 3/7/67	G. E. Brandt, D.V.M./Garnavillo, Iowa (D)	Not certified.
Nutrena Egg Ration A/Hankinson, N. Dak.	Cargill, Inc./Gluek, Minn. (S)	Below labeled strength; false and misleading claim to be effective for increasing egg production.
P-N-P Fortified Mastitis Treatment/ Columbus, Ohio 4/4/67	Masti-Kure Products Co./Norwich, Conn. (M, S)	Not certified.
Swisher Pig Starter/Judyville, Ind. 3/30/67	William Davies Co., Inc./Danville, Ill. (S)	Not certified; below labeled strength.
Wayne Tail Curler/Covington, Ind. 2/24/67	Allied Mills, Inc./Peoria, Ill. (M, S)	"
MEDICAL DEVICES		
Bed Wedge Foam Incliner/Atlantic City, N.J. 3/28/67	Sturdi-Crafters, Inc./Philadelphia, Pa. (S)	False and misleading claims to treat respiratory and circulatory ills, shortness of breath, and relieve aches caused by varicose veins.
Eye Sweep/Philadelphia, Pa. 3/23/67	Fulton Drug Co./New York, N.Y. (S)	Inadequate directions for use; no "Caution" statement.
I.V. Catheter/Seattle, Wash. 3/22/67	Paramed, Inc./Portland, Oreg. (M, S)	Below labeled quality; nonsterile.
Selectronair Air Purifier/Silver Spring, Md. 3/27/67	Alben Sales Co./Union City, N.J. (S)	False and misleading claims to relieve allergies, pollen asthma, sinus conditions.
Prophylactics		
Rubber/Louisville, Ky. 3/7/67	Dean Rubber Co./Kansas City, Mo. (M, S)	Defective; holes.
Lexington, Ky. 2/28/67	"	"

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
HAZARDOUS SUBSTANCES		
Gas Lighter Refill/Chicago, Ill. 3/22/67	Durazone-Choice International, Ltd./London, England (M, S)	Lacks consumer protection information required by the Fed. Hazardous Substances Act.
Mosaic Tile Cement and Mosaic Tile Hobby Kits/Adrian, Mich. 3/23/67	Howe & French, Inc./Boston, Mass. (M, S)	"
Neo-Celva Lacquer, Touch Up Paint/Torrance, Calif. 3/21/67	Toyota Motors, Ltd./Nagoya, Japan (S)	"
Rag Dolls/New York, N.Y. 2/3/67	E. Christian & Co./London, England (M, S)	Highly flammable.
Brooklyn, N.Y. 3/21/67	"	"
New York, N.Y. 3/29/67	Coopexim/Warsaw, Poland (M, S)	"
Long Island City, N.Y. 3/30/67	"	"
Water Seal/Seattle, Wash. 3/31/67	E. A. Thompson Co., Inc./San Francisco, Calif. (M, S)	Lacks consumer protection information required by the Fed. Hazardous Substances Act.

DACA ACTIONS

charging violation of the Drug Abuse Control Amendments of 1965 are published when they are reported by the Bureau of Drug Abuse Control Field Offices.

NAME, PLACE & DATE	PRODUCT	CHARGES & DISPOSITION	NAME, PLACE & DATE	PRODUCT	CHARGES & DISPOSITION
Veltex, Inc. Birmingham, Ala. Mar. 2, 1967	700,000 units, 37 gals. of liquid, 17½ lbs. of powder stimulant and depressant drugs.	Discrepancies, false invoices, no inventory. Seized by BDAC Agents.	Fred E. Hawk, D.O. Kansas City, Mo. Apr. 18, 1967	650,625 units controlled drugs.	No initial inventory, inadequate records. Seized by BDAC Agents.
William B. Hogue, D.O. Norwalk, Calif. Apr. 14, 1967	400,000 units of stimulant drugs.	Inadequate records, no inventory, shortages. Seized by BDAC Agents.	City Chemical Corp. Jersey City, N.J., and New York, N.Y. Apr. 19, 1967	204,540 units, 15,000 tablets, 1,000/10-cc. vials stimulant and depressant drugs; 586,160 units depressant and 1,228,500 units stimulants.	Failure to register, inadequate records. Seized by BDAC Agents.
Dr. E. C. Masters Advance, Mo. Apr. 14, 1967	167,125 units stimulant drugs.	No inventory, refusal to permit inspection. Seized by BDAC Agents.	David R. Faringer, M.D. Philadelphia, Pa. Apr. 18, 1967	14,570 units.	No inventory, inadequate records. Seized by BDAC Agents.
Edward R. Geagan, D.O. Kansas City, Mo. Apr. 24, 1967	439,247 units controlled drugs.	No inventory, inadequate records. Seized by BDAC Agents.	Saye Drug Co. Fountain Inn, S.C. Mar. 16, 1967	1,250 units of stimulants, 2,068 units of depressants.	Inadequate records. Consent decree for reconditioning.
Zenith Laboratories, Inc. Englewood, N.J. Mar. 23, 1967	1,038,100 units, 360¾ lbs. granules, 119½ lbs. in-process depressants, 3,030,940 units, 234½ lbs. powder, 2,030¾ lbs. granules, 336 lbs. in-process stimulants.	Inadequate records, incomplete inventory. Seized by BDAC Agents.	Varrian O. Tritt, D.O. Salt Lake City, Utah Apr. 3, 1967	26,000 units.	Inadequate records. Seized by BDAC Agents.
			Howe's Products, Inc. Seattle, Wash. May 3, 1967	409,000 units of depressants and stimulant drugs.	Inadequate records. Seized by BDAC Agents.

POST OFFICE DEPARTMENT

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

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

May 10, 1967: Foreign Fraud Order No. 67-46, against **Horizon Publishing Co.**, Toronto, Ontario, Canada. Using the mails to advertise and obtain remittances for a publication titled "Black Sexual Power," one chapter of which is represented as revealing, for the

first time, the hidden powers of reputed aphrodisiacs and information as to foods, potions, and recipes capable of increasing sexual powers.

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

Dr. Bernarr Zovluck, a chiropractor with offices at 126 W. 42nd Street, New York, N. Y., was indicted May 15, 1967, by a Federal grand jury on 12 counts of mail fraud relating to an alleged scheme to misrepresent that he was offering "free" service to patients, mostly indigents, as a corollary to Medicare and Medicaid. It was alleged that victims were subsequently required to sign contracts for treatments, and that strong collection efforts were made thereafter under circumstances suggesting the Government was demanding

payment. The chiropractor is charged with discouraging patients from consulting their own doctors, and of warning them they were gambling with their health and life if they declined to continue treatments with him. At the time of the arrest, **Dr. Elvin Eisenstein**, a chiropractic associate of Dr. Zovluck, impeded and resisted the entrance of Postal Inspectors and United States Marshals to the clinic and was arrested for interfering with Federal officers in the performance of their duties (18 U.S.C. 111).

notices of judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD / Poisonous and Deleterious Substances

- Eggs, frozen**, at Chicago, N. Dist. Ill.
Charged 1-10-66: when shipped by Sibley Egg & Poultry Co., Sibley, Iowa, the article contained an added poisonous and deleterious substance, *Salmonella* micro-organisms; 402(a)(1). Consent decree authorized release to shipper for reconditioning. (1)
- Milk product, nonfat, dry**, at Columbus, S. Dist. Ohio.
Charged 9-9-66: when shipped by Crystal Dairy Products, Inc., Lebanon, Ind., the article contained *Salmonella* micro-organisms; 402(a)(1). Consent decree ordered release to shipper for conversion into stock feed. (2)
- Wheat**, at Berthoud, Dist. Colo.
Charged 9-13-61, amended 11-27-61: while held for sale, the article contained the pesticide chemicals, DDT and lindane, for which there were no tolerances or exemption, and a quantity of the pesticide chemical, aldrin, over the tolerance; 402(a)(2)(B), 408. Consent decree authorized release to Colorado Milling & Elevator Co., Denver, Colo., for reconditioning. Such reconditioning was unsuccessful and the article was destroyed. (3)
- Wheat**, at Kansas City, Dist. Kans.
Charged 4-6-66: when shipped by Walsh Grain Co., Minneapolis, Minn., the article contained a pesticide chemical, a mercurial compound; 402(a)(2)(B), 408. Default decree ordered destruction. (4)
- FOOD / Contamination, Spoilage, Insanitary Handling**
- Casings, meat**, at Detroit, E. Dist. Mich.
Charged 11-16-66: while held for sale, the article contained insect filth; 402(a)(3). Default decree ordered destruction. (5)
- Cochineal, ground**, at North Bergen, Dist. N.J.
Charged 11-3-66: while held by Meer Corp., North Bergen, N.J., the article, which had been repacked by the dealer, contained mold; 402(a)(3). Consent decree authorized release to dealer for export to original foreign supplier. (6)
- Eggs, frozen**, at Amarillo, N. Dist. Tex.
Charged 5-18-64: while held by Avery Egg Co., Amarillo, Tex., the article, prepared and packed by the dealer, contained decomposed eggs; 402(a)(3). Consent decree authorized release to dealer, after segregation. (7)
- Flour**, at Mayaguez, Dist. P.R.
Charged 11-15-66: while held by Arbona Hermanos Division, Nabisco, Mayaguez, P.R., the article contained insect filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (8)
- Nutmeg, cracked and ground**, at Revere and Boston, Dist. Mass.
Charged 2-19-65: while held for sale, the article contained rodent and insect filth; 402(a)(3). Default decree ordered destruction. (9)
- Nuts, brazil, shelled**, at Los Angeles, S. Dist. Calif.
Charged 4-7-65: when shipped by J. F. Braun & Sons, Inc., New York, N.Y., the article was moldy and contained insect filth; 402(a)(3). Consent decree authorized release to shipper for reconditioning. (10)
- Nuts, mixed, Holiday Brand**, at Columbus, S. Dist. Ohio.
Charged 12-8-66: when shipped by Robert L. Berner Co., Chicago, Ill., the article contained insect filth, and rancid, decomposed, and shriveled nuts; 402(a)(3). Default decree ordered destruction. (11)
- Peanuts, shelled**, at Seattle, W. Dist. Wash.
Charged on or about 3-17-66: while held by Oscar Lucks Co., Seattle, Wash., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (12)
- Peanuts, unshelled**, at Santa Fe Springs, S. Dist. Calif.
Charged 12-14-65: while held for sale, the article contained moldy, decomposed peanuts; 402(a)(3). Consent decree authorized release to Shipper's Express Co., Santa Fe Springs, Calif., for reconditioning. (13)
- Peas, canned, Blue Plate**, at Atlanta, N. Dist. Ga.
Charged 11-17-66: when shipped by King Pharr Canning Operations, Inc., Cullman, Ala., the article labeled in part "Crowder Peas Distributed by Southern Shell Fish Co., Inc. New Orleans, La.," contained insect filth; 402(a)(3). Default decree ordered destruction. (14)
- Pecans, shelled, Wilco**, at New Orleans, E. Dist. La.
Charged 12-6-66: when shipped by Williams Pecan Products Co., Gulfport, Miss., the article contained insect filth and *E. coli*, and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (15)
- Potato flakes**, at Dallas, N. Dist. Tex.
Charged 11-17-66: while held by Contract Packaging Association, Inc., Dallas, Tex., the article contained rodent filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for reconditioning. (16)
- Roll, cake, and cocoa mixes, rice, popcorn candy, macaroni, and split peas**, at Detroit, E. Dist. Mich.
Charged 9-16-66: while held by State Wholesale Grocers, Detroit, Mich., the articles contained insect filth, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (17)
- Shrimp, canned, Buffay**, at Indianapolis, S. Dist. Ind.
Charged 10-20-66: when shipped by Robinson Canning Co., Inc., Westwego, La., the article contained decomposed shrimp; 402(a)(3). Default decree ordered destruction. (18)
- Shrimp, breaded, frozen**, at Denver, Dist. Colo.
Charged on or about 11-4-66: when shipped by Booth Fisheries, Brownsville, Tex., the article contained staphylococci, and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (19)

- frozen, stuffed**, at North Miami, S. Dist. Fla.
Charged on or about 11-14-66: when shipped by Sea Pak Corp., St. Simons Island, Ga., the article contained staphylococci and bacterial filth, and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (20)
- pieces, breaded**, at Walterboro, Dist. S.C.
Charged on or about 11-16-66: when shipped by Singleton Packing Corp., Tampa, Fla., the article contained *E. coli*, staphylococci, and bacterial filth, and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (21)
- Sugar, Catherine Cane**, at Chicago, N. Dist. Ill.
Charged 1-14-66: when shipped by J. Supple's Sons Planting Co., Ltd., Bayou Goula, La., the article contained rust fragments; 402(a)(3). Consent decree authorized release to SuCrest Corp., Chicago, Ill., for reconditioning. (22)
- Walnuts, brazil nuts, and pecans, unshelled**, at Joplin, W. Dist. Mo.
Charged 12-29-66: while held by Interstate Grocer Co., Joplin, Mo., the articles contained rodent filth, and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (23)

FOOD / Economic Violations

- Pretzels, Becker's**, at Alexandria, E. Dist. Va.
Charged 6-14-66: when shipped by Becker Pretzel Bakeries, Inc., Baltimore, Md., the article's label lacked the complete name and place of business of the manufacturer, packer, or distributor. Default decree ordered destruction or delivery to public/charitable institution. (24)
- Tomatoes, canned**, at Olean, W. Dist. N.Y.
Charged 4-13-66: when shipped by Kings Creek Canning Co., Inc., Princess Anne, Md., the article labeled in part "Elmdale Tomatoes . . . Distributed by Eastern Retailer-Owned Grocers Cooperative, Inc., New York, N.Y." contained excess peel, 403(h)(1). Default decree ordered destruction. (25)

VITAMINS / DIETARY FOODS

- Nutri-Bio vitamin and mineral tablets, Baby-Bio powder, and dietary food supplement wafers**, at Santurce, Dist. P. R.
Charged 10-7-64: when shipped by Nutri-Bio, Los Angeles, Calif., the labeling contained false and misleading nutritional and therapeutic claims; and, while held for sale, some of the wafers contained insect filth; 403(a), 502(a), 402(a)(3). Default decree ordered destruction. (26)
- Safflower capsules, Vitamin A capsules, Wheat Germ Oil capsules, and Waran Enzyme capsules**, at Burbank and Hollywood, S. Dist. Calif.
Charged 11-24-64: while held by Waran-Pacific Corp., Hollywood, Calif., after repacking portions of the articles, the labeling contained false and misleading nutritional and therapeutic claims; 403(a), 502(a). Consent decree authorized release of the enzyme capsules to the dealer for relabeling, and default decree ordered destruction of the other articles. (27)

ANIMAL FEEDS

- Ful-O-Pep dairy feed**, at St. Joseph, W. Dist. Mo.
Charged 9-20-66: when shipped by Quaker Oats Co., Memphis, Tenn., the article contained the nonconforming food additives, DDT and malathion, added pesticide chemicals; 402(a)(2)(C), 409. Default decree ordered destruction. (28)
- Milk replacer, medicated, Calf Glo**, at Rochester, Dist. Minn.
Charged 3-11-66: when shipped by Vita Plus Corp., Madison, Wis., the labeling of the article contained false and misleading therapeutic claims, since use as directed provided an inadequate level of chlortetracycline; 502(a). Consent decree authorized release to shipper for relabeling. (29)
- Poultry premix, and poultry feed, medicated**, at Teutopolis, E. Dist. Ill.
Charged 3-23-64: while Siemer Milling Co., Teutopolis, Ill., held the feed for sale, and premix for use in the manufacture of the feed, both articles contained food additives, 3, 5-dinitrobenzamide and acetyl (para-nitrophenyl) sulfanilamide, which were unsafe because they and their intended use for feeding separately (free choice) with grain to chickens failed to conform to regulation or exemption, and the medicated feed lacked exemption from antibiotic certification; 402(a)(2)(C), 502(l). Consent decree authorized release to the dealer for destruction of the medicated feed and delivery of the premix to manufacturer. (30)

DRUGS / Human Use

- Alco-Vite vitamin combination capsules**, at Kansas City, Dist. Kans.
Charged 12-21-65: when shipped by Klug Labs., Inc., Kansas City, Mo., the article was a new drug without an effective New Drug Application; and its labeling contained false and misleading therapeutic claims and lacked adequate directions for the uses recommended in a promotional leaflet being distributed by the shipper to doctors and others; 505(a), 502(a), 502(f)(1). Default decree ordered destruction. (31)
- Allergimist intranasal solution A**, at Clarksburg, N. Dist. W. Va.
Charged 10-6-65: when shipped by Brunson Corp., Miami Springs, Fla., the article was a new drug without an effective New Drug Application; 505(a). Default decree ordered destruction. (32)
- at Dallas, N. Dist. Tex.**
Charged on or about 7-22-66: when shipped by Brunson Corp., Miami, Fla., the article was a new drug without an effective New Drug Application; 505(a). Default decree ordered destruction. (33)
- Allergimist intranasal solutions A and B**, at Houston, S. Dist. Tex.
Charged 8-18-66: when shipped by Brunson Corp., Miami Springs, Fla., the articles were new drugs without effective New Drug Applications; 505(a). Default decree ordered destruction. (34)
- at Savannah, S. Dist. Ga.**
Charged 8-29-66: when shipped by Brunson Corp., Miami, Fla., the articles were new drugs without effective New Drug Applications; 505(a). Default decree ordered destruction. (35)

- at Clarksburg, N. Dist. W. Va.**
Charged 3-16-66: when shipped by Brunson Corp., Miami Springs, Fla., the articles were new drugs without effective New Drug Applications; 505(a). Default decree ordered destruction. (36)
- at Covina and Los Angeles, C. Dist. Calif.**
Charged 12-9-66: when shipped by Brunson Corp., Miami, Fla., the articles were new drugs without effective New Drug Applications; 505(a). Default decree ordered destruction. (37)
- Amphetamine-containing tablets**, at Salt Lake City, Dist. Utah.
Charged 2-28-66: while in possession of Varrian O. Tritt, D.O., a prohibited act occurred because the practitioner had acted outside the course of his professional practice in selling and dispensing the stimulant drug without a prescription; 301(q)(3). Default decree ordered destruction. (38)
- Del Manso camphor-benzocaine combination liniment**, at Tucson, Dist. Ariz.
Charged 12-6-66: when shipped by De La Cruz Products, Los Angeles, Calif., the labeling of the article contained false and misleading therapeutic claims; and lacked adequate warnings and directions for use, including adequate topical anesthetic and counterirritant warnings in both Spanish and English; 502(a), 502(c), 502(f)(1) & (2). Default decree ordered destruction. (39)
- Den-C-Lone prednisolone solution**, at Dallas, N. Dist. Tex.
Charged 3-16-66: while held for sale by Wrlner Labs., Inc., Dallas, Tex., the article lacked adequate directions for use and was not exempt since it was a new drug and its labeling was not authorized by an approved New Drug Application; and the article lacked the prescription legend; 502(f)(1), 503(b)(4). Consent decree ordered destruction. (40)
- Dextro-amphetamine sulfate time disintegration capsules**, at Chicago, N. Dist. Ill.
Charged 1-19-67: when shipped by Shaw Pharmacal Co., St. Louis, Mo., the strength of the article was deficient, and the label contained false and misleading statements, since the article was deficient in dextro-amphetamine sulfate (approx. 44 percent); 501(c), 502(a). Default decree ordered destruction. (41)
- Dibucaine ointment**, at Valley Stream, E. Dist. N.Y.
Charged on or about 3-11-66: when shipped by Day-Baldwin, Inc., Hillside, N.J., the conditions of the article's manufacture, processing, packing, and holding, lacked conformity with current good manufacturing practice; and the strength was deficient (approx. 40 percent), and the labeling false and misleading as to content; 501(a)(2)(B), 501(c), 502(a). Default decree ordered destruction. (42)
- Dipyrone injectable**, at El Paso, W. Dist. Tex.
Charged 9-22-66: when shipped by Interstate Pharmaceuticals, San Gabriel, Calif., the article, labeled in part "Dipyrone . . . Manufactured for Del Nore Pharmaceuticals . . . El Paso, Tex.," was a new drug without an effective New Drug Application; its labeling lacked adequate directions and information for use; and it was dangerous to health when used as directed; 505(a), 502(f)(1), 502(j). Default decree ordered destruction. (43)
- Entemicyn and pectomicyn**, at Rio Piedras, Dist. P.R.
Charged 1-17-66: while held for sale by Chemoplex of Puerto Rico, Inc., Rio Piedras, P.R., the strength of the articles, which had been manufactured by the dealer from neomycin sulfate shipped in interstate commerce, was deficient, and the labeling was false and misleading, since the articles were deficient in neomycin sulfate (between approx. 19 and 20 percent), and the articles' neomycin sulfate was not from a certified batch; 501(c), 502(a), 502(l). Default decree ordered destruction. (44)
- EK-25 Hydrochlorothiazide and Potassium Gluconate tablets**, 2 seizure actions at El Paso and Midland, W. Dist. Tex.
Charged 9-30-63 and 10-11-63: when shipped by Western Research Laboratories, Denver, Colo., the labeling made false and misleading claims that the drug was for investigational use only, and lacked adequate directions for use; and the article was a new drug without an approved New Drug Application and was not exempt from such requirement; 502(a), 502(f)(1), 505(a). After the shipper as claimant was ordered by the court to answer the Government's interrogatories, a consent decree of destruction was entered. (45)
- Fermodyl hair products**, at Los Angeles, S. Dist. Calif.
Charged 4-5-66: when shipped by Laboratorios Montecarlo, Niagara, Mexico, the article was a new drug without an effective New Drug Application; 505(a). Default decree ordered destruction. (46)
- Menestrex quinine sulfate, antihistaminic analgesic capsules**, at Atlanta, N. Dist. Ga.
Charged on or about 4-15-66: when shipped by Rex Laboratory, Nashville, Tenn., the labeling of the article contained false and misleading claims about scanty or difficult menstruation, and lacked adequate warnings against unsafe use; 502(a), 502(f)(2). Default decree ordered destruction. (47)
- Mineral oil, U.S.P. and boric acid, U.S.P.**, at Macon, M. Dist. Ga.
Charged 2-25-66: while held by Coleman, Meadows, Pate Drug Co., Macon, Ga., the labeling of the articles lacked adequate directions for use, and the labeling of the mineral oil lacked adequate warnings against misuse as a laxative; 502(f)(1), 502(f)(2). Default decree ordered destruction. (48)
- Nasal spray**, at Los Angeles, S. Dist. Calif.
Charged 4-20-66: while held for sale, the strength of the article was deficient, and the labeling was false and misleading, since the article was deficient in phenylephrine hydrochloride (approx. 13 percent) and pyrilamine maleate (approx. 26 percent); 501(c), 502(a). Default decree ordered destruction. (49)
- Prohem rectal fluid**, 2 seizure actions at Columbus and Cincinnati, S. Dist. Ohio.
Charged 3-22-66 and 3-23-66: when shipped by Oleum Products, Inc., Chesapeake, Ohio, from Huntington, W. Va., the article was a new drug without an effective New Drug Application; 505(a). Default decrees ordered destruction. (50)
- Prondol Brand tablets of dipyrone with phenobarbital sodium**, at Gravette, W. Dist. Ark.
Charged 6-5-64: when shipped by Philadelphia Laboratories, Inc., Philadelphia, Pa., the labeling lacked adequate directions for use and was not exempt from such requirement; 502(f)(1). Consent decree authorized release to Dunhall, Inc., Gravette, Ark., for bringing into compliance with the law. Thereafter, a consent order of destruction was entered. (51)
- Quinidine sulfate tablets, U.S.P., and quinine sulfate capsules, N.F.**, at Dallas, N. Dist. Tex.
Charged 8-30-66: when shipped by P. M. Wholesale Co., Van Nuys, Calif., the articles fell below official standards and the label statements of identity were false and misleading, since niacin tablets had been substituted for some quinidine sulfate tablets, and capsules containing aspirin, phenacetin, and caffeine had been substituted for some quinine sulfate capsules; 501(b), 502(a), 501(d)(2). Default decree ordered destruction. (52)
- Thyroid powder, U.S.P.**, at Portland, Dist. Oreg.
Charged on or about 8-8-66: when shipped by Cudahy Laboratories, Omaha, Neb., the article contained a poisonous and deleterious substance, *Salmonella* micro-organisms; 501(b). Default decree ordered destruction. (53)
- Thyroid powder with iodine**, at Brooklyn, E. Dist. N.Y.
Charged on or about 8-17-66: when shipped by Elasto-Chemical Corp., New York, N.Y., to Portland, Oreg., and returned, the article, labeled in part "Biofac A/S Copenhagen Denmark . . . Thyroid Pulver mit 0.3% Jodgenhalt," contained a poisonous and deleterious substance, *Salmonella* micro-organisms; 501(c). Default decree ordered destruction. (54)

DRUGS / Veterinary

- Dyna-K potassium chloride**, at Des Moines, S. Dist. Iowa.
Charged 10-31-66: when shipped by International Minerals & Chemical Corp., Carlsbad, N. Mex., the article was a new drug without an effective New Drug Application, and was a nonconforming food additive, since it was labeled for use in the control and prevention of urinary calculi in cattle and sheep; 505(a), 402(a)(2)(C), 409. Default decree ordered destruction. (55)
- Livo-balt injectable and peptonized iron veterinary injectable**, at San Gabriel, S. Dist. Calif.
Charged 4-5-66: when shipped by Austin Pharmaceuticals, Inc., Island Park, N.Y., the purity and quality of the articles were deficient, and the labeling was false and misleading as to sterility since the articles were not sterile; and the articles' labels lacked the name and place of business of the manufacturer, packer, or distributor; 501(c), 502(a), 502(b)(1). Default decree ordered destruction. (56)
- Sustone veterinary tablets**, at Edison, Dist. N.J.
Charged on or about 5-4-66: when shipped by Barrows Chemical Co., Inc., the strength of the article, labeled in part "Sustone . . . contains diethylstilbestrol 0.05 mg. . . Sussex Drug Products Co. Edison, N.J.," was deficient (approx. 58 percent); 501(c). Default decree ordered destruction. (57)

MEDICAL DEVICES

- CME Water Conditioner tanks**, at Denver, Dist. Colo.
Charged 12-28-66: while held by Living Water of Denver, Denver, Colo., the accompanying promotional literature used by the dealer contained false and misleading therapeutic claims; 502(a). Consent decree authorized release to Kenneth J. Marshall, t/a Living Water of Denver, for destruction of leaflets and relabeling of article. (58)
- Catheters, vinyl**, at Newport, N. Dist. Ala.
Charged 9-22-66: when shipped by Sterilon Corp., Buffalo, N.Y., the article lacked adequate directions for use and was not exempt as a prescription device since it lacked the prescription legend and information for administration by licensed practitioners; 502(f)(1). Default decree ordered destruction. (59)
- Chin vibrator**, at Boston and Wellesley Hills, Dist. Mass.
Charged 9-13-66: while held by Joseph Breck & Sons Corp., Boston, Mass., accompanying labeling such as Breck's 1566 catalog, a promotional letter and circulars, and the carton insert contained false and misleading therapeutic claims; 502(a). Consent decree authorized release to dealer for relabeling. (60)
- Enjoy-A-Sauna steam bath cabinet**, at St. Paul, Dist. Minn.
Charged 8-31-66: when shipped by John J. McKune & Sons Co., Inc., Chicago, Ill., the article's name and labeling contained false and misleading claims, including false therapeutic claims, and the false claim that it was a sauna device; and its labeling lacked adequate warnings against unsafe use; 502(a), 502(f)(2). Default decree authorized delivery to FDA. (61)
- Normandy Saunette sauna bath cabinet**, at Maple Heights, N. Dist. Ohio.
Charged 12-3-64: when shipped by Normandy Products, Div. of DuKane Supply Co., Inc., Pittsburgh, Pa., the accompanying leaflets, reprints and letters contained false and misleading therapeutic claims; 502(a). Consent decree authorized release to James C. Sima, Maple Heights, Ohio, for relabeling. (62)
- Swiveled platform exerciser, Slim-Twist**, at Kennewick, E. Dist. Wash.
Charged 3-5-65: when shipped by Vogt Appliance Co., Kalamazoo, Mich., the accompanying leaflets, posters, and the name of the device made false and misleading therapeutic claims; 502(a). The case was removed to the E. Dist. Mich. With the consent of the shipper a decree of destruction was entered. (63)
- Teethers, water filled, Kiddy-Kool**, at Squantum, Dist. Mass.
Charged 2-15-66: while held for sale by Kiddie Products, Inc., Squantum, Mass., the article's purity and quality were deficient and the label was false and misleading as to sterility, since the water in the plastic article contained viable organisms; 501(c), 502(a). Default decree ordered destruction. (64)

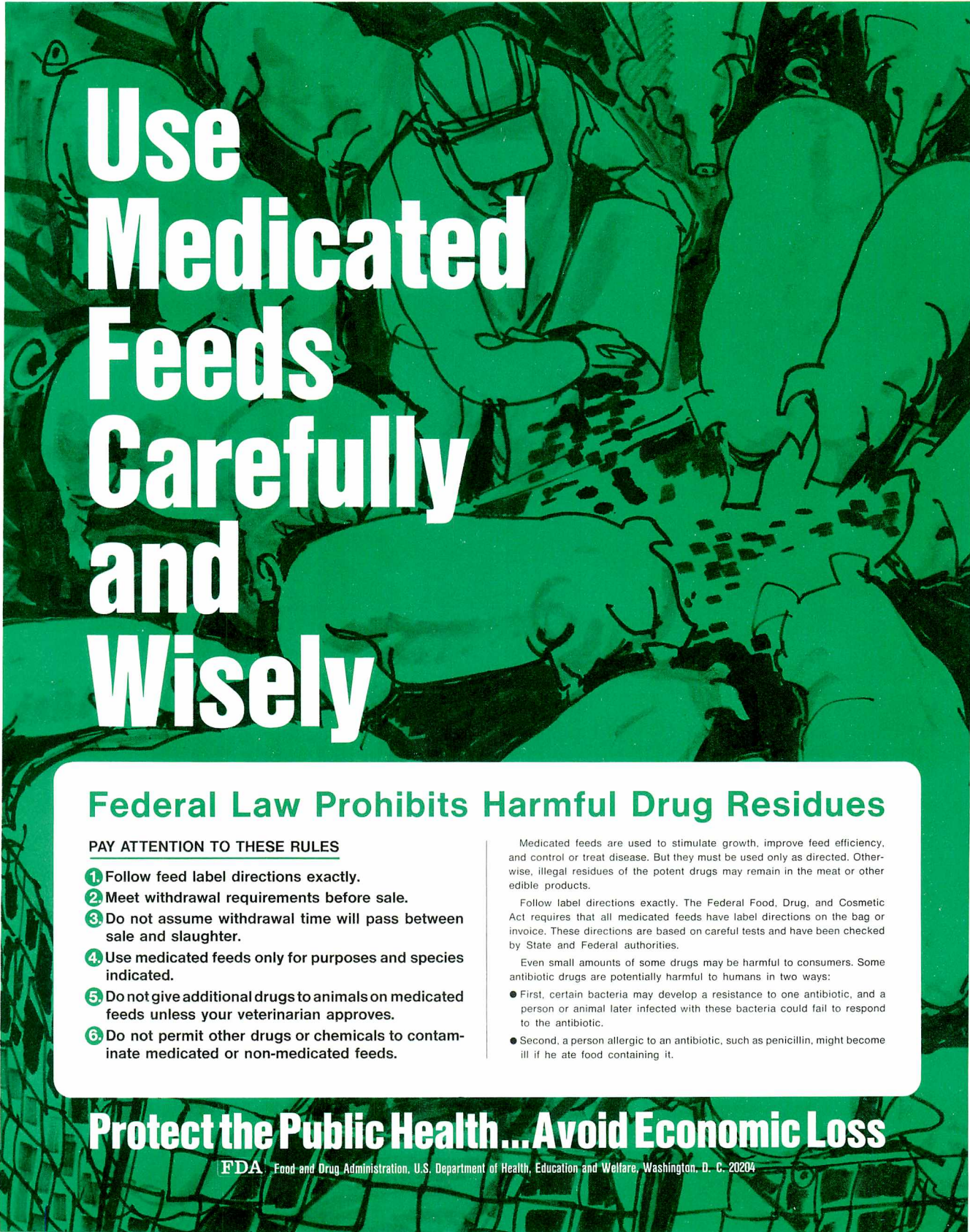
PROPHYLACTICS

- Rubber prophylactics, Spartans**, at Chicago, N. Dist. Ill.
Charged 8-3-66: when shipped by M&M Rubber Co., Kansas City, Mo., the quality of the article was deficient, and the labeling false and misleading, since the article contained holes (approx. 0.74 percent); 501(c), 502(a). Default decree ordered destruction. (65)
- Rubber prophylactics, Preps**, at Knoxville, E. Dist. Tenn.
Charged 9-20-66: when shipped by Akwell Corp. (National Hygienic Products Corp.), Dothan, Ala., the quality of the article was deficient, since the article contained holes (approx. 3.4 percent); 501(c). Default decree ordered destruction. (66)

HAZARDOUS SUBSTANCES

- Fixatives, and retouching and mastic picture varnishes, Deltex**, at Atlanta, N. Dist. Ga.
Charged 4-18-66: when shipped by Delta Brush Corp., Mount Vernon, N.Y.,

- the mastic picture varnish contained turpentine (approx. 74 percent) and the other articles contained ethyl alcohol (between approx. 76 and 82 percent); they were toxic substances; the mastic picture varnish presented special hazards due to its turpentine content; and their containers lacked required conspicuous label statements; mastic picture varnish—2(p)(1) B,G & J), 3(b); other articles—2(p)(1)(D,E,G & J). Consent decree authorized release to shipper for relabeling. (67)
- Gun blue**, at Richmond, E. Dist. Va.
Charged on or about 1-26-67: while held for sale, the article contained selenium (approx. 0.68 percent) and was a toxic and irritant substance, and its immediate and outside containers lacked required conspicuous label statements; 2(n)(1), 2(p)(1)(B,D,E,F,G & J). Default decree ordered disposal pursuant to law. (68)
- Lighter, self-starting, and lighter fluid**, at Fort Worth, N. Dist. Tex.
Charged 2-7-66: when shipped by New Method Manufacturing Co., Bradford, Pa., the lighter fluid contained methyl alcohol (approx. 96 percent) and was a toxic and flammable substance presenting special hazards; and the immediate and outside containers lacked required conspicuous label statements; 2(n)(1), 2(p)(1)(A,B,E,F,G,I & J), 3(b). Default decree ordered destruction. (69)
- Liquid-embroidery fluids, marker, spray coating and cleaner-solvent, Tri-Chem**, at Torrance, S. Dist. Calif.
Charged 4-26-66: when shipped by Tri-Chem, Inc., Belleville, N.J., the articles were toxic substances presenting special hazards because of their xylene or toluene content; the cleaner-solvent was a flammable substance; the spray coating was an extremely flammable substance; and their immediate and outer containers lacked required conspicuous label statements; liquid-embroidery fluid (plain)—2(p)(1)(B,D,F & J), 3(b); Spark-L-On Sparkling Liquid-embroidery fluid—2(n), 2(p)(1)(B,D,F & J), 3(b); marker—2(n), 2(p)(1)(B,D,F & J), 3(b); spray coating—2(p)(1)(B,C,E & I), 3(b); cleaner-solvent—2(p)(1)(B & F), 3(b), 2(p)(2). Consent decree authorized release to Tri-A-Craft, Inc., Torrance, Calif., for reconditioning. (70)
- Liquid sandpaper, Clean-N-Sand**, at San Leandro, N. Dist. Calif.
Charged 10-12-66: when shipped by Montgomery Ward, Chicago, Ill., the articles were toxic substances containing methyl alcohol (approx. 32 percent) and toluene (approx. 20 percent) and presented special hazards, and their containers lacked required conspicuous label statements; 2(p)(1)(B & G), 3(b). Default decree ordered destruction. (71)
- Magic kit, chemical**, at Oklahoma City, W. Dist. Okla.
Charged 1-16-67: while held for sale, the article contained in part a magic solution of approximately 40 percent sodium silicate which was a toxic and irritant substance, and the article's immediate and outside containers lacked required conspicuous label statements; 2(n)(1), 2(p)(1)(A,D,E,F,G & J). Default decree ordered destruction. (72)
- Sealer, silicone rubber gum, and lubricant, silicone spray**, at Yonkers, S. Dist. N.Y.
Charged 8-20-66: when shipped by Aeroseal Corp., New Kingston, Pa., the articles labeled in part "Toppo-All Products Co., Inc., Yonkers, N.Y." were in self-pressurized containers, were extremely flammable substances, and generated pressure, and the sealer was a toxic substance presenting special hazards because of its toluene content (approx. 30 percent) and the articles' containers lacked required conspicuous label statements; sealer—2(p)(1)(B,C,E,F,I & J), 3(b); lubricant—2(p)(1)(C,E,F,I & J). Default decree ordered destruction. (73)
- Cleanser, Siliseal**, at Muskegon, W. Dist. Mich.
Charged 9-2-66: while held by Shaw-Walker Co., Muskegon, Mich., the article, repacked by the dealer, was a toxic substance presenting special hazards because of its petroleum distillate content (approx. 39 percent) and its immediate and outside containers lacked required conspicuous label statements; 2(n)(1), 2(p)(1), 3(b). Consent decree authorized release to dealer for relabeling. (74)
- Stain, translucent, Velva-Glo**, at Salem, Dist. N.H.
Charged 4-13-66: when shipped by Jacquelyn Ceramic Art, Syracuse, N.Y., the article was a toxic substance presenting special hazards due to petroleum distillate content, and its containers lacked required conspicuous label statements; 2(p)(1)(B & J), 3(b). Consent decree authorized release to shipper for relabeling. (75)
- Stains, wood, Shakertown**, at Cleveland, N. Dist. Ohio.
Charged 9-27-66: when shipped by Shakertown Corp., Winlock, Wash., the articles were toxic substances presenting special hazards by reason of their petroleum distillate content; 2(p)(1)(B & J), 3(b). The white, brown, and slate-grey stains were also flammable substances, and their containers lacked additional required conspicuous label statements; 2(p)(1)(E & I). Consent decree authorized release to shipper for relabeling. (76)
- Trick matches, exploding**, at River Grove, N. Dist. Ill.
Charged 8-25-66: when shipped by Atlas Novelty Supply Co., Lancaster, Tex., the article was an extremely flammable substance (explosive), and its container lacked required conspicuous label statements; 2(p)(1)(A,C,E,I & J). Default decree ordered destruction. (77)
- COSMETIC**
- Toothpicks, Cinnamon Hot**, at San Jose, N. Dist. Calif.
Charged 5-23-66: when shipped by Baden's, Independence, Kans., the article contained the added poisonous or deleterious substance, oil of cinnamon, which might render it injurious to users under customary or usual conditions of use; 601(a). Default decree ordered destruction. (78)
- NOTICES OF JUDGMENT ON CRIMINAL CASES / FOOD**
- Chowan Milling Co., Inc., and Davis B. Spiers, Jr.**, vice president, Como, E. Dist. N.C.
Charged 4-28-65 by grand jury: when shipped, cornmeal contained insect filth, and was prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Nolo contendere pleas; fines suspended and probations. (79)
- Ray M. Day Co.**, Turlock, N. Dist. Calif.
Charged 4-4-66: green split peas and pinto beans were held in a building accessible to rodents, and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (80)
- Emma Creamery Co., and Homer H. Dierking**, treasurer and manager, Emma, W. Dist. Mo.
Charged 1-26-66: bulk cheddar cheese containing manure fragments was shipped and delivered to the holder of a guaranty; 402(a)(3). Guilty plea by corporation; fine, plus costs. Guilty plea by individual; fine, suspended. (81)
- James W. Fletcher, Jr.**, partner in warehouse firm, Murfreesboro, M. Dist. Tenn.
Charged 6-21-66: cake mix, macaroni, spaghetti, rice, and pancake mix were held in a building accessible to insects and rodents, and were contaminated with insect filth; 402(a)(3), 402(a)(4). Nolo contendere plea; fine. (82)
- Seven-Up Bottling Co. of Denison, Donald L. Russell**, vice president, and **Gordon R. Gumaer**, plant manager, Denison, E. Dist. Tex.
Charged 3-4-65: when shipped, Seven-Up, NuGrape, and Mission carbonated beverages contained mold and insect filth, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty pleas; fines. (83)
- Taylor Grocery Co., and Hugh Taylor**, partner, Newport, E. Dist. Tenn.
Charged 10-3-66: oatmeal cereal and popcorn were held in a building accessible to insects, and were contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty pleas; fine. (84)
- DRUGS**
- Donald W. Berry, t/a Berry's Pharmacy**, Salem, W. Dist. Ky.
Charged 10-24-66: Librium capsules and thyroid tablets were dispensed without a prescription; 503(b)(1). Nolo contendere plea; fine. (85)
- Broadmoor Drug, Inc., Robert P. Graham**, president, and **Forrest J. Jones**, pharmacist, Hobbs, Dist. N. Mex.
Charged 1-12-66: secobarbital sodium capsules, Dexedrine tablets, and Equanil tablets were dispensed without a prescription; 503(b)(1). Nolo contendere plea by corporation; fine. Nolo contendere plea by Graham; probation. Nolo contendere plea by Jones; fine and probation. (86)
- William M. Brown**, truck driver, Texarkana, E. Dist. Tex.
Charged 1-7-66: dextro-amphetamine sulfate capsules, amphetamine sulfate tablets, dextro-amphetamine sulfate tablets, and amphetamine-phenobarbital combination tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment and probation. (87)
- Willard J. Cleland, t/a Cleland Drug Store**, and **James W. Cleland**, pharmacist, Wa Keeney, Dist. Kans.
Charged 3-21-66: Dexamyli Spansule capsules and Librium capsules were dispensed as unauthorized refills; 503(b)(1). Guilty plea by Willard Cleland; imprisonment suspended, fine, plus costs. Guilty plea by James W. Cleland; imprisonment suspended, fine, plus costs, and probation. (88)
- Robert L. Davis and Mrs. Essie Davis**, service station operators, Cumberland Gap, E. Dist. Tenn.
Charged 11-15-65: desoxyephedrine hydrochloride tablets were dispensed without a prescription; 503(b)(1). Not guilty plea by Robert L. Davis. After trial by jury of Robert L. Davis, verdict of guilty; imprisonment and probation. Guilty plea by Mrs. Davis during trial; probation. (89)
- Louis A. Dempsey, t/a Dempsey's Pharmacy**, Newport, E. Dist. Ky.
Charged 3-29-66: Librium capsules, phenobarbital tablets, and Butisol Sodium tablets were dispensed without a prescription; 503(b)(1). Guilty plea; fine, plus costs. (90)
- Anthony Diokakis**, truck-stop employee, Leavittsburg, N. Dist. Ohio.
Charged 1-19-65: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; probation. (91)
- Frost Drug Co., Eldon L. Frost**, president, and **Gerald K. Okabe**, pharmacist, Kaysville, Dist. Utah.
Charged 5-10-66: pentobarbital sodium capsules, methyltestosterone tablets, and meproamate tablets were dispensed as unauthorized refills; 503(b)(1). Guilty pleas; fines. (92)
- Herbert Guest**, garage operator, Athens, M. Dist. Ga.
Charged 4-22-66: amphetamine sulfate tablets and dextro-amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea entered during trial; imprisonment. (93)
- Nick Kosinski**, truck driver, and **Billy Gail Schoch, D.O.**, San Antonio, W. Dist. Tex.
Charged 11-22-65: dextro-amphetamine sulfate tablets and amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty pleas; imprisonment. (94)
- Ted Moore**, Charleston, E. Dist. S.C.
Charged 7-9-65: diphenylhydantoin sodium capsules, d-propoxyphene hydrochloride capsules, benzotropine mesylate tablets, and phenformin hydrochloride tablets were dispensed without a prescription; 503(b)(1). Guilty plea; probation. (95)
- W. D. Nash**, truck driver, Mount Pleasant, E. Dist. Tex.
Charged 2-7-66: methamphetamine hydrochloride tablets and amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; imprisonment suspended, and probation. (96)
- Jimmie Ervin Rushing**, service station employee, Vernon, N. Dist. Tex.
Charged 4-5-66: amphetamine sulfate tablets were dispensed without a prescription; 503(b)(1). Guilty plea; fine and probation. (97)
- Spencer Pharmacy, Inc., Morris Salusky**, president, and **Nicola Giacobbe**, pharmacist, Everett, Dist. Mass.
Charged 2-3-67: Dexedrine Spansule capsules and Nembutal capsules were dispensed as unauthorized refills, and penicillin tablets were dispensed without a prescription; 503(b)(1). Guilty plea by corporation; fine. Nolo contendere pleas by individuals; imprisonment suspended, fines, and probations. (98)
- Francis P. Toland, t/a Willey Drug Store**, and **Stanley Zeramby**, pharmacist, South Boston, Dist. Mass.
Charged 4-12-66: V-Cillin K tablets, Equanil tablets, pentobarbital sodium capsules, and dextro-amphetamine sulfate capsules were dispensed without a prescription; 503(b)(1). Guilty plea by Toland; imprisonment suspended, fine, and probation. Guilty plea by Zeramby; imprisonment suspended and probation. (99)
- Waters Drug Co. and Melvin James Waters**, president, Breckenridge, Dist. Minn.
Charged 2-28-66: Preludin tablets were dispensed without a prescription; 503(b)(1). Guilty pleas; fines. (100)
- Notices of Judgment are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act and section 13 of the Federal Hazardous Substances Labeling Act. Notices of Judgment report cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizure proceedings are civil actions taken against *goods* alleged to be in violation, and criminal and injunction proceedings are against *firms or individuals* charged to be responsible for violations. The cases generally involve foods, drugs, devices, cosmetics, or hazardous substances which were alleged to be adulterated or misbranded, or otherwise violative of the law when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. Published by direction of the Secretary of Health, Education, and Welfare.
- JAMES L. GODDARD, Commissioner of Food and Drugs.**
WASHINGTON, D.C., July 1, 1967



Use Medicated Feeds Carefully and Wisely

Federal Law Prohibits Harmful Drug Residues

PAY ATTENTION TO THESE RULES

1. Follow feed label directions exactly.
2. Meet withdrawal requirements before sale.
3. Do not assume withdrawal time will pass between sale and slaughter.
4. Use medicated feeds only for purposes and species indicated.
5. Do not give additional drugs to animals on medicated feeds unless your veterinarian approves.
6. Do not permit other drugs or chemicals to contaminate medicated or non-medicated feeds.

Medicated feeds are used to stimulate growth, improve feed efficiency, and control or treat disease. But they must be used only as directed. Otherwise, illegal residues of the potent drugs may remain in the meat or other edible products.

Follow label directions exactly. The Federal Food, Drug, and Cosmetic Act requires that all medicated feeds have label directions on the bag or invoice. These directions are based on careful tests and have been checked by State and Federal authorities.

Even small amounts of some drugs may be harmful to consumers. Some antibiotic drugs are potentially harmful to humans in two ways:

- First, certain bacteria may develop a resistance to one antibiotic, and a person or animal later infected with these bacteria could fail to respond to the antibiotic.
- Second, a person allergic to an antibiotic, such as penicillin, might become ill if he ate food containing it.

Protect the Public Health...Avoid Economic Loss

FDA Food and Drug Administration, U.S. Department of Health, Education and Welfare, Washington, D. C. 20204

OFFICIAL BUSINESS

Announcements

CORRECTIONS: In the June 1967 issue of FDA Papers, correct page 5, right column, first paragraph, second sentence to read "Figure 1 shows the geographic representation of 49,044 domestic objective samples obtained during the period July 1, 1963 - June 30, 1966.*" Insert following footnote at bottom of page: * A total of 49,356 domestic samples and 3,836 import samples were examined during this period.

The calculations in charts on page 8 are incorrect. The correct values are:

	Calculated from Total Diet Samples (mg/kg body weight)
Malathion (upper chart)	0.0001
Dieldrin (lower chart)	0.00009
Heptachlor Epoxide (lower chart)	0.00004

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

SCHEDULE OF FDA WORKSHOPS AND CONFERENCES / JULY & AUGUST 1967

FDA District or BDAC Field Office	Date	Location	Subject Area
Dallas	July 13	Oklahoma City, Okla.	Food Warehousing
	July 18	Houston, Tex.	Food Warehousing
Boston	August 22	Boston, Mass.	Food Warehousing
	August 24	Hartford, Conn.	Food Warehousing
Kansas City	August 30	Des Moines, Iowa	Food Warehousing