THE CONSUMER SPECIALIST
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Pesticide Methodology
Finding Multiresidues on Foods

DRUG INTERACTIONS
Some Effects of Multiple Dosage

SECRET'S IN THE 'SWOOSH'
Why the United States Gets Only the Best Tea
Since the advent of organic pesticides FDA chemists have worked unremittingly to develop and perfect reliable and practicable ways to detect and measure these chemicals on food products. They have adapted new scientific instruments and techniques to the Agency's regulatory function and have devised many of their own. For a number of years they have bent their principal efforts to developing a single method that can detect many pesticides at once (see page 4).

The current FDA multiresidue method identifies and measures about 60 pesticides, including those that are most toxic or persistent. To detect and measure these chemicals, FDA has found that as a penultimate step it must remove essentially all nonpesticide substances from the sample, leaving the pure or nearly pure pesticide chemicals. Otherwise, the sensitive instruments which identify and measure the chemicals will not function or will give erratic or unreliable results. There is no present or foreseeable method that admits bypassing this important step of isolating the chemicals. Nor has the FDA method been so simplified that it can be used with dependable results by other than experienced chemists.

Perfection of this method to the current state comes from years of experimentation, refinements, validity tests, and, above all, dedication. But, in a sense, this work has scarcely begun. For multiple detection methods have yet to be developed for many pesticides, to say nothing of new ones that will be put to use in the future. FDA feels that its multiresidue method may be the basis of a system that, with further research, could permit detection and measurement of pesticides in various other parts of the environment.
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Drug Interactions  How the introduction of two or more different drugs in the body may produce unintended results.

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PESTICIDE MULTIRESIDUE METHODOLOGY

by J. William Cook

Before the Food and Drug Administration establishes a tolerance for use of a pesticide chemical on food products as required under the Pesticide Chemicals Amendment to the Food, Drug, and Cosmetic Act, the Agency requires that there shall have been developed a method of analysis to enforce that tolerance: a method capable of detecting and measuring the amount of the chemical in the food products on which it is to be used.

To assess the significance of pesticide residues in the food supply we need a practical method of chemical analysis sensitive and reliable enough to provide the data needed for assessment. The pesticide residue research chemist has made tremendous progress in fulfilling these requirements but he still has much to do.

Up to 1944 the primary pesticide chemicals were a few inorganic chemicals such as compounds of arsenic, lead, sulfur, and fluorine. Today the problem of chemical analysis is of considerably greater magnitude than for these few inorganic elements. Since the advent of the organic pesticide chemical DDT in 1944 the number of organic pesticide chemicals has steadily increased, and today there are some 800 on the market. Many are used in food production and for each, theoretically, an analytical method is needed.

As new chemicals have been introduced, new, specific methods have been developed to detect them. Although a single specific method for a given chemical may be adequate to determine the amount present in food at any given time after application to the growing food plant, the regulatory chemist is not in a position to know which of the many chemicals may have been used on the food crop before it enters the channels of commerce. Therefore, he cannot know which specific method to apply. This problem has been compounded because the action of light and air or of enzymes inside the plant or animal, it was found, caused many pesticide chemicals to convert to other compounds after application. Since these altered compounds often were the important toxic chemicals, the chemist needed methods to measure the amount of any of these chemicals present.

To the FDA chemist it was obviously impossible to monitor the food supply effectively by the specific methods since there simply were not enough chemists or facilities at hand. FDA pesticide chemists thus directed their research toward multiresidue methods—those which measure many different chemicals simultaneously. In this multiresidue methodology FDA chemists have been leaders. Those groups besides the FDA which are primarily concerned with food products of unknown spray history include State food and drug laboratories and government laboratories of other nations. Others concerned with residue analysis of foods are more likely to know which chemicals have been applied to the food and thus to know the specific analysis method needed.

The ideal method of analysis would be a universal one which detected and measured all of the parent or original pesticide chemicals and all the significant alteration products which may form. Although FDA scientists and others have not achieved this ideal, they have made considerable progress toward that end.

Pesticide chemicals can be divided into general groups, each group member possessing chemical characteristics similar to those of the others in that group. The largest group includes those organic compounds which contain organically bound chlorine, such as DDT, BHC, dieldrin, and heptachlor; another large group contains phosphorus: malathion, parathion, Phosdrin, and Trithion; still others contain nitrogen or sulfur. Some contain two or more of these elements. Trithion, for instance, contains chlorine, phosphorus, and sulfur, but is classified as an organophosphate because its toxicity is due largely to the presence of phosphorus.

Using the current FDA multiresidue methodology, a chemist with the proper training, experience, and equipment can analyze a sample of any of a large variety of food products and simultaneously obtain a high degree of certainty in identifying about 60 different residue chemicals and measuring them quantitatively—all in the span of a few hours. This is more than can be accomplished in a matter of days by 50 or more chemists performing separate analyses for each residue. It is economically and physically impracticable to provide meaningful food monitoring by the specific methods, but FDA does it quite economically by the multiresidue method. The analyses must be performed or supervised by a competent pesticide residue chemist. For although the method potentially can produce accurate and sensitive analytical results, it is complex and has many parameters which, if not fully understood and well controlled, may produce results which can be misleading or misinterpreted, with detrimental implications for public health.

The present methodology has been well studied and validated for many chemicals in many food products of plant and animal origin. Validation work has shown consistent recovery of 90 percent or more of the residue present for any of about 60 pesticides, mostly from the organochlorine group. A few of the organophosphorus compounds are recovered and measured, but not their metabolic or alteration products.
The method is sensitive to well below the legal tolerance established for many pesticide chemicals. It is adequately sensitive for the highly toxic compounds, and since the analysis is made for all compounds simultaneously, the results depend on the chemistry instead of the toxicity. Therefore, many are measured much below the legal tolerance figure.

Although some people have expressed belief that the methods are more sensitive than needed, this fine sensitivity has many advantages. For instance, FDA has analyzed a number of “total diet” or “market basket” samples, the results of which are helpful to FDA as well as other national and international health agencies. High sensitivity is important in the analysis because these “total diet” samples are composites of a number of products, and if the methods were not highly sensitive, significant amounts in part of the samples in the composite might be diluted by the other parts of the composite to below the detectable level.

FDA has been able to develop and improve multiresidue analysis over the past 15-20 years by taking advantage of the many new techniques that have become available to chemistry and adapting them so as to enhance the method’s capabilities. Since the Agency has had to evaluate so many parameters, it has taken an organizational approach in which a number of research chemists, largely in the Pesticides Branch of the Division of Food and later the same Branch in Division of Food Chemistry, oriented their research toward the common goal of developing the multiresidue method.

The current multiresidue system is referred to as a gas chromatographic method, but gas chromatography is only part of the process, albeit an important one. Generally the method can be divided into these four major steps: (1) sampling, (2) extraction, (3) isolation (commonly called cleanup in residue work), and (4) determination (both identity and measurement). Gas chromatography is used primarily in the determination step. Although sampling (Fig. 1) is an important part of any analysis, we will not treat it further here except to say that unless a sample adequately represents the entire lot of any product analyzed, there is no value in running the rest of the analysis.

The three remaining steps are interrelated and in some instances hardly distinguishable from each other. Except in a few instances—for example, some radioactivity analysis—it is almost always necessary to dissolve the chemical for which the analysis is designed away from the bulk of the sample before determination can be made. This is certainly so where there is usually at least one million times more food product than residue chemical.

Ideally the extraction process (Figs. 2 & 3) should dissolve all the residue and as little of the other parts of the food product as possible. But almost invariably much more material than the pesticide residues is extracted and, therefore, the pesticides must be isolated or separated from the coextracted impurities. Isolation removes the pesticide from most of the dissolved food product so that nearly pure chemicals are available for the determinative step.

Most of the early organic pesticide chemicals (the organochlorine ones) were oil soluble, so organic solvents such as benzene, hexane, and petroleum ether were used as the extractants. Chemists then believed that the residues were borne primarily on the surface of most products. Extraction consisted of washing the surface of food products with these solvents. This proved effective to some extent. But A. K. Klein, an FDA chemist, showed in 1958 that certain residues, even surface residues, were not removed efficiently with these solvents—which are immiscible with water. Only a small fraction of the residue in products such as frozen vegetables was extracted by the surface wash process.

Dr. Klein experimented with the technique of using a Waring Blender to grind and mix the food product with isopropyl alcohol (a water miscible solvent) and petroleum ether into a one-phase system. This one-phase system proved much more effective in solubilizing residues of the chlorinated compounds than the older, immiscible systems. But it also dissolved more impurities, so the need was greater for an efficient isolation procedure. Other organic solvents miscible with water such as acetone and dimethyl formamide were found to be just as effective as the isopropyl alcohol-petroleum ether solvent mixture in extracting both residues and interfering materials.

In 1959 R. Moddes and the writer, as FDA chemists, found that acetonitrile was a particularly effective extraction solvent for organophosphorus pesticides and did not dissolve as much impurities as other solvents. P. A. Mills and other FDA chemists studied acetonitrile extensively as an extractant for diverse residues, and found it so effective that it has been adopted as the extraction solvent for the FDA multiresidue method. FDA chemists have proved that 90-100 percent of the residue present from each of the 60 chemicals included in the multiresidue method may be extracted from most food products by this solvent.

The isolation (or cleanup) step is vital to the process and must be carried out effectively before reliance can be placed on the last step of the procedure—that is, the determinative step for multiresidue analysis. Some chemists advocate skipping
FOUR SECTIONS TO ANALYTICAL OPERATIONS

1 A small representative sample is prepared by compositing equal portions of each of a number of units of the food product.

2 The composite sample is extracted by grinding in the solvent, acetonitrile, in a power blender.

3 The solvent is separated from the insoluble material by filtration.
The first step of isolation or purification is a solvent partitioning process in which immiscible solvents are chosen so that the pesticide favors one solvent and the unwanted plant material favors the other solvent. The solvents are thoroughly mixed by shaking the funnel shown; then the mixture is allowed to stand until the solvents separate.

The second step in the isolation utilizes column chromatography. The solvent containing the pesticide is poured through the column which adsorbs the pesticide and some plant material (the plant pigments and others) and allows some plant material to pass through; this is discarded. Then a different solvent is chosen to elute all the pesticide and as little plant material as possible from the column. This solvent is caught in the double flask.

An aliquot of the concentrated pesticide solution is injected into the gas chromatograph where the individual pesticides are separated and recorded as peaks on the strip chart. The position on the chart is characteristic of the individual pesticide and the size of the peak is dependent on quantity.

The solvent is evaporated to concentrate the pesticide in the small flask at the bottom.
the isolation process to save time. But FDA feels it is imperative that good isolation techniques be followed rigorously if we are to accurately determine identity and quantity.

In the FDA multiresidue method the final substeps in the isolation are to remove oily or waxy compounds from the acetonitrile solution by treating it with a solvent derived from petroleum, called petroleum ether (a petroleum fraction), which is immiscible with acetonitrile. When the two solvents are shaken vigorously in a separatory funnel (Fig. 4), the oily and waxy materials migrate to the petroleum ether and the pesticides remain in the acetonitrile. Next the pesticides are forced out of the acetonitrile into fresh petroleum ether by adding a large volume of water to the acetonitrile. The petroleum ether is put onto an adsorption column of Florisil (Figs. 5 & 6), a granular adsorbing material, which removes both the pesticide and the remaining impurities; the latter include much of the natural coloring material of plants. The pesticides then are washed or eluted from the Florisil with selective solvent mixtures and the impurities remain. The pesticides are now sufficiently pure for the current determinative step—gas chromatography (Fig. 7).

The determinative step has taken a number of forms in its evolution since 1944. The first procedure for a number of compounds was the "total chlorine" method. This consisted of burning the chemicals or otherwise liberating all the chlorine from the compounds, then measuring all the chlorine, then calculating the residue based on the known percent of chlorine in the pesticides. This procedure had some use until the more highly toxic compounds were introduced. FDA established very low tolerances, such as 0.1 or 0.2 parts per million or zero for these compounds.

The total chlorine method did not work for the low tolerance compounds because food products known to have had no treatment with organochlorine pesticides, and the reagents used in the analysis, contained small amounts of chlorine which, when calculated to pesticide, caused the food to appear to contain 0.1 - 0.3 ppm of pesticide. These values are called untreated blank values. When these 0.1 - 0.3 ppm values are low in relation to the amount of chemical expected—such as 7 ppm for DDT—they can be subtracted with little effect on the total. But when they equal or exceed the tolerance—such as 0.1 ppm dieldrin or zero endrin tolerance—the blank value invalidates the results for those compounds. No isolation (or cleanup) procedure was found that would substantially remove this blank value. Of equal importance to FDA, it was necessary for us to know which chemicals were present to make a valid calculation of amount.

Bioassay is another technique that was studied extensively by FDA and others. It was first used for DDT by E. P. Laug, an FDA chemist, in 1946. The technique consists of exposing certain organisms to varying amounts of the toxic chemicals under standardized conditions and noting the amount of chemical required to kill 50 percent of the test subjects. The amount of chemical that kills 50 percent of the test organisms is called the lethal dose 50 or LD 50. Then the same number of organisms under the same conditions are exposed to varying amounts of extracts from food products. The amount of extract which kills 50 percent of the test organisms is considered to have an amount of pesticide equivalent to that level of mortality. Various organisms have been used in tests with this method, such as houseflies, fruit flies, mosquitos larvae, and brine shrimp.

The bioassay procedure had merit and was used to some extent but was found to have disadvantages upon close study. During the early use of the bioassay technique FDA had no established means of identifying the chemicals which might possibly be present in a residue extract from samples of unknown spray history. We attempted to interpret the mortality from a sample of unknown pesticide history in general terms—that is, toxicity equivalent to that for so much DDT. But this was of little value in tolerance enforcement activity because invariably the toxicity to the test organisms is different from the toxicity values for the higher animals that are used to establish tolerances. For instance, some common pesticides are 50 times more toxic to houseflies than others; an LD 50 can be obtained from a small amount of lindane or a large amount of TDE, even though the general legal tolerances for lindane have been set somewhat higher than those for TDE. The bioassay technique was useful, however, where only one known pesticide was present, as in agricultural experimentation work.

Another serious problem arose because oily and waxy residues in the extract either killed the test organisms by suffocation or did not permit the pesticide to come into contact with the organism. Thus, the results obtained were either false positive or false negative.

During the years 1956-1959, in the application of the bioassay technique to analysis of pesticide residues in fluid market milk, P. A. Clifford and later he and P. A. Mills, both FDA chemists, found that dependable mortality was possible only after thorough isolation of the pesticide from the fatty components of milk. They also used a process called paper chromatography...
In paper chromatography, a mixture of chemicals is placed on a piece of porous paper near the edge and the paper is barely dipped into a proper solvent, much like putting the edge of a blotter in a solvent. As the solvent is absorbed, it migrates up the paper by capillary action. As the solvent passes through the mixture of chemicals, the chemicals begin to migrate up the paper with the solvent, depending on their solubility. When the proper solvent or solvents are used, the piece of paper becomes a chromatogram in which the mixture of chemicals is separated into components as discrete spots. The process is quite effective in separating and isolating the compounds. The distance each component migrates in relation to the distance the solvent migrates is characteristic of each and thus the ratio can be used to help identify the compound. (This migration characteristic provides presumptive proof of identity. Other methods are used for definite identification.) Extracts that are impure yield chromatograms that are difficult to interpret. It became evident that when the compounds are well enough isolated for valid mortality measurements and identity, the quantity can be estimated from the paper nearly as well as from the bioassay. Thus, the bioassay was gradually eliminated and paper chromatograms were used for identity and quantitation.

Shortly after paper chromatography was established for this purpose, there was developed a somewhat similar technique called thin-layer chromatography. It is similar in principle, but the paper is replaced by a thin layer of adsorptive material on a glass plate backing. This has certain advantages over paper chromatography.

Gas chromatography, or more accurately, gas-liquid chromatography, entered the field about the same time as thin-layer chromatography. In most respects gas chromatography, properly used, is far superior for the determination phase and has become widely used.

Gas liquid chromatography (GLC) was developed during the 1950's and proved useful for many analytical purposes, but the early detectors were not useful for pesticide residue analysis for reasons we shall explain later. GLC equipment consists of a long tube of small diameter which is filled with an inert granular material called packing, at the end of which is the detector. This packing is coated with a small amount of nonvolatile liquid (the liquid phase of GLC). The packed tube is heated to a relatively high temperature and a carrier gas such as nitrogen is passed through the heated tube at a known rate. Then a small amount of the purified extract is injected by hypodermic needle onto the same end of the column as the gas enters and is vaporized into the carrier gas (the gas phase of GLC). As the heated gas passes over the heated liquid on the inert packing, the different chemicals pass through the column at a rate depending on their relative solubilities in the gas and liquid phases at the given temperature.

For GLC of pesticides, choices are made of temperature, type of gas, gas flow rate, type and amount of liquid, type and size of packing, and type of tubing material and its length and diameter. Selected combinations are chosen to attempt to completely separate the pesticides on the column so they emerge as discrete, pure compounds. It is essential that those nonvolatile impurities not removed from the extract during the isolation process remain at the entrance so that they do not react with the pesticide chemicals or deter them from emerging in their characteristic time.

After the chemicals emerge they must be detected and measured. The detector is an important part of the GLC system. The earlier detectors, called thermistors, responded to any chemical that emerged. Therefore, they were nonselective in response. But they were relatively low in sensitivity, so they did not respond to the very small amounts of pesticide chemicals available in pesticide residue analysis.

The first selective and highly sensitive detector found useful for pesticide residue analysis was devised in 1960 by D. Coulson and others of Stanford Research Institute. This detector—called a microcoulometer—continuously measures the amount of hydrochloric acid formed from the chlorine in the pesticide. After the chemicals pass through the column, they are burned in a furnace to form hydrochloric acid, which then passes onto the microcoulometer.

Those who worked with the microcoulometer hoped that the column would perform the isolation step of analysis and that the microcoulometer would perform the determination step. They soon found that difficulties arose when extracts not subjected to an isolation procedure were put into the column. These impure extracts cause some pesticides to be lost completely, and cause others to be converted to new compounds which chromatograph at different times than the parent, etc. The detector also becomes damaged and fails to respond properly. When so many anomalies arose with the addition of impure extracts, the FDA chemists tried extracts purified by the isolation process described above for bioassay and paper chromatography. These produced gas chromatographic results that were
Detection devices other than the microcoulometer later became available and were found useful for the organochlorine pesticides. One, called an electron capture detector, was found to be more sensitive than the microcoulometer to many compounds containing chlorine and it was considerably easier to maintain and operate. For most studies it has replaced the microcoulometer. But this detector, too, is subject to damage from impure extracts, and since it is used in conjunction with the same columns that are useful for microcoulometry, the need here for a good isolation process before gas chromatography is equally important. The electron capture detector is not as specific for compounds containing chlorine as is the microcoulometer. However, few of the compounds that capture electrons are extracted, isolated, or gas chromatographed. If there is a suspicious response it must be checked. Often the microcoulometric detector is used to prove the presence of a pesticide containing chlorine.

The electron-capture detector principle is incorporated in the design of a number of different detectors. Such devices have a radiotracive element as a source of ions. Different radioactive elements are used in different detectors. FDA chemists studied the design and performance of a number of these detectors, including the geometric design and voltage needed, and chose those parameters which yielded best conditions for routine quantitative measurement in residue analysis. We incorporated the best design and operating parameters into the multiresidue method.

Some organophosphorus compounds capture electrons even when these compounds contain no chlorine. (The response is not due to the phosphorus.) The electron capture detectors are useful for these few organophosphorus compounds but not for all. In 1964, Mrs. L. Giuffrida of FDA's laboratories announced the discovery of a new device called a thermionic detector that is highly sensitive and highly selective for compounds containing phosphorus. Gas chromatography has been well worked out for the organophosphorus pesticide chemicals with use of the thermionic detector, but modification of the extraction and isolation procedures was necessary; this has required extensive experimentation. Many of the organophosphorus pesticides are water soluble or convert to water soluble compounds in the presence of light and plant and animal enzymes. Water soluble compounds are not as easily isolated from food products as the oil soluble compounds containing chlorine. We hope we can devise for full use fairly soon a multiresidue method for the important members of the organophosphorus group.

Many of the compounds containing sulfur are members of the organochlorine and organophosphorus groups. There also is available a detector that is sensitive to sulfur and thus fairly useful for sulfur compounds that do not fit into the other groups. Many pesticides contain sulfur and nitrogen and many of these are fungicides. The extraction and isolation steps for this group have not been developed, even though the sulfur detector is available.

The only available detector sensitive to nitrogen has not been perfected to a sensitivity and reliability sufficient to determine the pesticide compounds which contain nitrogen. There is a need for a good multiresidue method for the insecticidal carbamates and other pesticides which contain nitrogen alone as an important element.

The chemist has improvised and innovated to provide methods of analysis capable of yielding meaningful results for a large number of pesticide chemical residues. There is an urgent need for continued research on this type of methods development. Many chemicals do not fit into the methods described above. We must make efforts to incorporate them. Methods for the phosphorus and the nitrogen compounds must be perfected before a meaningful survey of the food supply can be made for those residues. New chemicals are being introduced regularly. We need research to find whether these compounds can be incorporated into the existing methods or whether these new compounds will interfere with determination of the older ones.

The multiresidue method for organochlorine compounds is useful for domestic edible animal tissues. We feel that it would provide a good basis to develop analytical methods for residues in animal species such as fish and other wildlife and other factors in our environment such as soil, water, and river muds. It should be as applicable to human tissues as to edible animal tissues. For the use of these methods in environmental studies some research would be necessary to help interpret results, because many industrial chemicals other than pesticides may be present and may interfere with identification of the pesticide chemical.

We have made much progress in the field of methods of analysis, but we need much more to continue to assure prompt and effective protection of the Nation’s food from harmful amounts of pesticide residues.
DRUG INTERACTIONS

by John J. Schrogie, M.D.

Most of the drugs used throughout the history of human therapeutics have been compounds made up of both common and rare naturally occurring substances from many parts of the world. Some of these mixtures have contained dozens of drug substances. Most of these compounds were of low potency and specific effect. If these drugs often did little for the patient, at least they were seldom responsible for adverse effects.

Today diagnoses of diseases are more specific, and the biochemical basis of disease is better understood. As a result, rational drug development has proceeded apace, and a multitude of specific and potent drug products, of both natural and synthetic origin, have become available for treatment of various diseases. The Food and Drug Administration is responsible for assuring that these products are not only chemically pure but also safe and effective in clinical use.

Modern drug therapy may require the use of several drug compounds for treatment of one or more diseases. For instance, one hospitalized patient often receives as many as a dozen drugs during his stay and during posthospitalization treatment. Along with this increasing use of multiple drugs has come a new problem—drug interaction.

The effect of a drug in the human system may be influenced by a variety of factors both in the environment of the individual and in his own genetic makeup. When any one of these factors acts to modify the expected response to a particular dose of a given drug, it may be said that the drug has “interacted” with this factor and together they have caused an unintended or undesirable effect to be produced.

Such a modification of the expected dose response may be either an increase or a decrease in the drug’s effect and usually accounts for instances otherwise attributed to increased “sensitivity” or “resistance” to a drug. Thus it is the magnitude of a drug’s effect that is influenced rather than the nature of the effect. Further, not only may the principal, overt effect be influenced, but some ordinarily more subtle effect may also be enhanced or magnified, and this merits particular attention.

Given adequate knowledge of the pharmacology of a particular compound, we can often predict these effects of interaction, even though the detailed knowledge required is not often available until an investigation after the fact. This contrasts with the relatively unpredictable events of idiosyncrasy, or allergy, where effects are more often revealed only by direct trial of the drug in a particular individual.

Although a drug is usually administered with the intention of influencing a particular target organ or system in the body, it is obvious, but not often fully appreciated, that the drug will be absorbed, transported throughout the body, metabolized, and excreted like many other drugs or like many chemicals or hormones produced within the body—endogenous substances. Further, in its pharmacological effect a drug may either behave like, add to, replace, or block some naturally occurring physiological substance. It is placed amid and subjected to the full spectrum of controlling influences which regulate and modify the precisely balanced metabolic scheme of the body. The introduction of a drug may disrupt this scheme in a variety of ways; similarly, a change in any of these factors may disrupt a previously established equilibrium between the organism and the drug.

The complex setting into which drugs are placed following administration is primarily influenced by the presence of other drugs, by dietary factors, and by the genetic constitution of the individual. The influence of one drug on another is of particular interest and importance, since of the three, this phenomenon is the most readily controlled and the most amenable to investigation.

Although as previously described, drugs follow multiple steps in the pathway between ingestion and excretion, the effects of drugs upon the metabolism of other drugs have been of concern recently. A great variety of commonly used drugs are metabolized by enzymes located in the liver. This metabolic step is necessary so the drug can be changed into a chemical form more easily excreted by the kidneys.

There is considerable variation in the rate at which these enzymes metabolize certain drugs. For example, in humans the rate at which the anticoagulant bis-hydroxycoumarin is metabolized varies widely among individuals. Metabolism in some persons is six times slower than in others. The ability of rabbits and humans to rapidly acetylate isoniazid is inherited as a dominant characteristic. The results of studies in human twins suggest that the metabolism of phenylbutazone is a genetically determined characteristic.

These liver enzymes may be affected by environmental factors which influence liver function in general. In starved female rats, for example, the metabolism of barbi-
compounds apparently are also slowed by these drugs and in some studies, reduction of serum cholesterol levels has been observed.

An important potential influence upon a drug's effect is the extent to which the drug is bound to plasma protein. Most drugs are bound to the albumin portion. Since there seems to be little if any variation in the properties of albumin among individuals of the same species, differences in degree of binding of drugs are due essentially to varying affinity between the drug and its binding site on the albumin molecule. The fraction of drug bound to plasma protein is generally regarded as not pharmacologically active; it is the free portion that is available to produce the pharmacological effect. If a drug is highly bound to plasma protein, a relatively small percent change in the free portion can produce a markedly increased pharmacological effect.

Such changes may occur when two drugs that are bound to albumin are competing for the same site. The drug with the greater chemical affinity for the protein will displace a fraction of the other drug and thus increase the latter drug's free or unbound portion. Such effects have been consistently observed when drugs such as clofibrate and phenylbutazone are given concurrently with the coumarin anticoagulants, warfarin andbishydroxycoumarin. These latter drugs have a strong affinity for albumin and are highly bound to plasma protein; a small increase in the amount of free anticoagulant causes a marked increase in pharmacological effect. On the basis of results of studies performed in vitro, similar effects may be produced by fatty acids, which are also strongly bound to albumin.

Possibly beneficial effects of this displacement phenomenon have been suggested by certain studies in animals. Displacement of penicillin by sulfonamides increases the therapeutic effect of penicillin in rats; however, endogenous substances such as bilirubin may also be displaced by sulfonamides, resulting in hyperbilirubinemia, leading to the disease kernicterus in newborn infants.

The binding of thyroid hormone to plasma globulins may be increased by estrogen therapy or decreased by androgens; although the protein-bound iodine is changed, there is no demonstrable change in thyroid function. It should be clear from the foregoing that the plasma proteins are common carriers for many substances both introduced from outside the body and found within, which, added to each other, may change a physiological measurement or influence an expected therapeutic effect.

The amount of drug absorbed by the body is also affected by a variety of factors relating to the contents of the gastrointestinal tract. These may relate to the age of the individual, pH of the gut, motility, and bacterial flora among others. For example, ingestion of antacids containing large amounts of calcium decreases the absorption of tetracyclines. A state of malabsorption produced by dietary changes, disease, or certain antibiotics may reduce the amount of vitamin K available and, as a result, increase the response to a dose of anticoagulant. The ingestion of compounds which produce surface-active effects or of suspensions may also directly influence the absorption of drugs.

Aside from the general influence of age or renal disease, changes in
excretion of a drug produced by another drug are related mostly to changes in urinary pH. Acidic drugs such as phenobarbital or aspirin are excreted more rapidly when the urine is alkaline, while basic drugs such as amphetamine and meperidine are more promptly excreted at an acid pH. Many commonly used home remedies contain sufficient ammonium chloride or sodium bicarbonate to contribute, perhaps, to a change in therapeutic effect due to changed excretion rate.

Recent studies concerning the sensitivity of receptor sites in the body to drugs have suggested the profound basic importance of this factor in clinical therapeutics. Much of the work exploring the identity of these receptor systems has laid the basis for our knowledge about the pharmacology of the sympathetic and parasympathetic nervous systems. It seems likely that most receptors are proteins, probably enzyme systems, which react with the drug (substrate) to produce a response. The affinity of these receptors for certain drugs may be genetically controlled. A kindred which is resistant to anticoagulants because of decreased receptor-drug affinity has been described. Further, hormones may act to modulate the sensitivity of these systems. It has been suggested that the increased effect of anticoagulants in patients receiving dextrothyroxine may be based on this mechanism.

Perhaps the simplest type of interaction occurs when two substances which produce the same basic effect are used together. Initially, the substances may be thought to be so disparate that an additive effect is not anticipated. Administration of sympathomimetic amines such as ephedrine or phenylpropanolamine or ingestion of certain cheeses containing tyramine may cause exaggerated hypertensive responses in patients taking monoamine oxidase inhibitors. Similarly, the antihypertensive effects of guanethidine may be reversed by the use of the antidepressant, desipramine.

Many interactions have been described involving the anticoagulant drugs. In no small measure this is because methods for assaying these drugs in biological fluids are readily available and their pharmacological effect is relatively easy to measure and to reproduce. As more refined methodology becomes available for the estimation of other drugs, we hope that less precisely defined observations of drug interactions can be characterized more clearly.

FDA monitors known instances of drug interactions, and when reliable information is documented, the drug package insert is revised accordingly. It is doubly important that a person should not take drugs prescribed or recommended for another. The patient should inform the prescribing physician what other drugs he is taking and the physician for his part should take a careful drug history.

Tabulations of many drug interactions have been carried in other publications, and a selected bibliography on this relatively new topic is available from the author upon request. This article is not intended as a comprehensive or exhaustive listing of all interactions which have been noted between environmental and hereditary factors. It does present a general perspective of the mechanisms by which these interactions can occur. A careful assessment of drug effects which takes these principles into consideration is likely to lead to a rational explanation of unusual or unexpected pharmacological events.
The Secret’s in the ‘Swoosh’
by Robert H. Dick

Why the United States Gets Only the Best Tea

On December 16, 1773, a band of men disguised as Indians boarded the British vessel Dartmouth anchored in Boston harbor. They proceeded to break open the 114 chests of tea in the cargo and dump the contents into the harbor. The event was representative of the enraged reaction of American Colonists to the hated tax on tea imposed by the mother country, and this patriotic gesture, ironically, may have been the beginning of a prejudice which helped predispose Americans to favor coffee over tea as a beverage. The Boston Tea Party, aside from its historical significance, might be considered the first rejection of tea in this country.

Today, teas are still rejected, though not in so flamboyant a manner. The Import Tea Act, one of the less-publicized acts which FDA administers, governs the importation of all tea into the United States and prohibits the entry of tea that is inferior to the appropriate standard in purity, quality, and fitness for consumption. The Import Tea Act was passed in 1897, superseding the Act of 1883, at the request of the tea trade, which at that time was plagued by numerous deliveries of unsound or worthless teas from the Orient. The trade was attempting to set up a system by which the importer could legally refuse a delivery with the backing of the U.S. Government. Thus consumer protection, while very real, was incidental to the original purpose of the Act. This difference in background led to a number of differences in provisions between the Tea Act and the later 1906 Pure Food and Drugs and subsequent Acts.

For instance, the Import Tea Act sets up a minimum standard of quality as well as of purity and fitness for consumption. It provides that the tea be examined according to the customs and usages of the trade, though other methods may be used if necessary. The decision of the examiner may be protested whether the tea is rejected or passed. The Board of Tea Appeals may use the services of trade experts. Finally, each tea entry must be examined and released or rejected specifically by certification of the examiner on the Release Permit.

Whatever the original intent, the result has been to supply the U.S. consumer with a higher average quality of tea than any other country in the world. The trade also has realized benefits. In depression years when economic considerations forced a cut in legislative appropriations, representatives of the tea trade appeared before a congressional committee and asked that a tea testing fee be levied on all imports of tea so as to continue the enforcement of the Act. Since 1940, every tea importer has had to pay an inspection fee on all tea at time of entry. Revenues from this fee go into the general fund of the U.S. Treasury.

The use of tea as a beverage has a long history. Some Chinese legends regarding tea go back to about 2700 B.C., but the first authenticated mention of tea, recognizable as such, occurred around 350 A.D. By the ninth century the forms of manufacture were much the same as today. The traditional types of manufacture produce green tea, black tea, and oolong tea.

Green tea is treated with heat at the beginning of the manufacturing process. This serves to kill the enzyme responsible for producing black tea. The leaf is then rolled and progressively dried to produce the final product with a moisture content of around 6 percent.

Black or “fermented” tea is produced when the leaf is first allowed to wither, then rolled. The rolling breaks the cell walls and exposes the cell contents to the air. The enzyme then fosters the reaction, called “fermentation” in the trade, in which the leaf gradually turns a bright coppery color and develops a fragrant odor. Although black tea is termed fully fermented, the reaction is stopped at this point by application of heat. If fermentation were allowed to proceed, the leaf would change to a dark, dull brown and the brew obtained would be a dull, almost black liquor with little aroma and none of the pleasant flavor associated with tea. The reaction is thus stopped at the optimum point and the leaf dried to a moisture content of around 6 percent, as in the green leaf.

Oolong tea is manufactured in much the same way but fermentation is stopped sooner, usually when only the outer edges of the leaf have developed the coppery color. Interestingly enough, good oolongs apparently can be produced only by the use of Formosa Leaf, although there are lower quality oolongs made in mainland China. There are some high-grown Ceylon teas whose manufactured leaf is quite similar in appearance to the part green-part copper color of oolong. However, the beverage produced is definitely black rather than oolong in character. In the case of black teas, in particular, the higher the elevation at which the tea is grown the better the quality of the tea. Thus, high-grown usually means good and low-grown means lower quality. The one exception is tea grown in Assam in Northern India at an altitude of only 100-200 feet. This tea is outstanding in strength and flavor, qualities which give body to the best black tea blends.

Fifty years ago, green and black tea each accounted for about 40 percent of our imports. Oolong made up...

MIDDLE: Tea examiners ply their highly specialized trade at revolving round tables. Mary C. Harrigan recently retired from Boston District. Anthony W. Daly examines some of the exotically packaged teas arriving in San Francisco District from the Orient. Robert H. Dick of New York District, the author and Supervisory Tea Examiner, joined FDA at San Francisco in 1937 and has been taste testing tea since 1949.

BELOW: Import inspector at port of New Orleans warehouse removes a sample of tea grown in Ceylon from one of the standard size tea chests used to ship the bulk of tea imports. These teas will be blended in this country with others. The sample will be forwarded to New York District for examination.
the remaining 20 percent. Gradually the consumption of both green and oolong has dropped in this country. Now black comprises about 98 percent of our imports and the better quality greens and oolongs, especially the latter, are almost unobtainable.

Surprisingly, considering the trend in consumption, a good Formosa oolong never fails to bring expressions of delight at its pleasing and penetrating aroma from the tea drinker lucky enough to taste it. In contrast, the aroma of the best greens, such as the natural leaf or Gyokuro from Japan, is very delicate, as is the color of the liquor, a clear, pale green.

The tea most admired by Western connoisseurs, however, is a black tea, Darjeeling, though some prefer a high-grown Ceylon. Darjeeling, produced in the Himalayan foothills of Northern India around the city of the same name, has a distinctive flavor and aroma and strength of brew that has not been duplicated in any other tea-growing area of the world. It should be mentioned that this distinctive character appears only in the early part of the season, reaching a peak during the second flush, or new growth, around July. Actually, the major portion of the annual production is manufactured during the rainy season in the late summer and early autumn and has little or none of the Darjeeling character. So a tea produced in Darjeeling is not always one of outstanding quality, although, to many people, Darjeeling, though some prefer a high-grown Ceylon. Darjeeling, produced in the Himalayan foothills of Northern India around the city of the same name, has a distinctive flavor and aroma and strength of brew that has not been duplicated in any other tea-growing area of the world. It should be mentioned that this distinctive character appears only in the early part of the season, reaching a peak during the second flush, or new growth, around July. Actually, the major portion of the annual production is manufactured during the rainy season in the late summer and early autumn and has little or none of the Darjeeling character. So a tea produced in Darjeeling is not always one of outstanding quality, although, to many people, Darjeeling is synonymous with the highest quality.

Another popular misconception equates orange pekoe or pekoe with high quality tea. Actually, these two terms refer to leaf sizes of black tea separated by sieving at the end of the manufacturing process. They are derived from the nomenclature of the plucked green leaf. Tea is made from only the tip leaves of the tea plant, usually two leaves and the leaf bud. The bud is called Flowery Orange Pekoe, the next final leaf Orange Pekoe and the lower and larger leaf, Pekoe.

Tea examiners are stationed at three FDA District Offices: Boston, New York, and San Francisco. The San Francisco examiner, A. W. Daly, handles all teas entered at Pacific Coast ports and inland ports to and including Denver. Recently he took over examination of teas formerly handled by Honolulu. The total volume of tea examined is relatively small at San Francisco, averaging about 7 million pounds annually during the past 3 years. But this volume is compensated for by variety, since San Francisco receives many small shipments imported by various ethnic groups of Oriental descent. San Francisco is the only port regularly receiving tea packed in colorful boxes, handsome lacquered tins, and even porcelain caddies, with names like Sui Sin, Lung Chin, Ti Lo Hon, Ti Kwan Yin, Tencha, Sencha, and Gyokuro. One variety pack associates Lung Ching with wisdom, Jasmine with happiness, Sui Sin with power, Lichee with wealth, and oolong with longevity, each packet being appropriately illustrated.

Boston District handles teas imported through all New England ports. Mary C. Harrigan, examiner for the past 15 years, retired recently. Her post has been taken by her understudy, Phyllis Skyrme. The New England area once preferred oolong tea and many of the finest of this type entered through Boston. Times have changed, however, and Boston imports, which average 10-12 million pounds annually, now are made up almost entirely of black tea.

Of the current total imports of 135-140 million pounds of tea annually, the New York District office examines the greatest part, averaging about 120 million pounds. The New York examiner receives all samples from the Atlantic ports except those from New England and those on Gulf of Mexico and inland ports west to Denver. In these other ports, Bureau of Customs personnel collect and forward samples to New York. After examination in New York, the results are returned to the various District Directors of Customs. The one exception is New Orleans, the only nonexaminer port where tea samples are collected by FDA personnel. Incidentally, approximately 20 million pounds of tea entered each of the ports of Norfolk, Galveston, and New Orleans last year, making them second, third, and fourth in tea importations, respectively.

Each of the examiners analyzes imports in the same manner, organoleptically, that is, by the senses of taste, smell, and sight. He sits by a large rotating table with a recessed edge on which handleless cups of approximately 5-ounce capacity are placed along with the corresponding sample in a bag or tin. He weighs a uniform amount of tea in each cup (usually 35 grains), pours on boiling water, and smells the aroma of the hot wet leaves which he removes with a spoon. When the brew has cooled enough, he sucks a spoonful into his mouth with a “swoosh” that sends an atomized spray onto his palate and the aroma up into his nose. He then rolls the brew around the inside of his mouth before spitting it out into a large oversize cuspidor, inelegantly referred to as a garboon. While he is doing all this, he is mentally comparing the taste, flavor, and strength with that of the appropriate standard. It is this comparison that most often determines whether the tea is passed or rejected.

Like other imported products, tea is checked at the pier and samples are taken. The imports inspector, under special instruction from the tea examiner, looks continued on page 21
COSMETICS

how the consumer is protected
Americans spend nearly $4 billion every year on cosmetics. FDA is responsible for protecting the public from injury to health from poisonous or deleterious substances in cosmetics or their containers, from unclean or decomposed substances in cosmetics or their manufacture or holding under insanitary conditions, from deceptive labeling and packaging, and from color additives not certified as safe or not exempted from such certification. Injury to health from poisonous or deleterious substances may come from toxicity, irritation, sensitivity, or carcinogenesis by penetration, ingestion, or inhalation. The law specifically exempts coal-tar hair dyes (but not those used on eyebrows and eyelashes) provided the label warns users of possible skin irritation and against use around the eyes.

The law's restraints against filthy or decomposed substances in cosmetics and insanitary conditions of manufacture or holding are based on both health and esthetic considerations.

Prohibitions against deceptive labeling and packaging include omission of the identification of the maker or distributor of a cosmetic, and label information that is deceptive or difficult to read and understand.

The law deems a color additive in a cosmetic unsafe (1) unless it is used and labeled in conformity with regulations prescribing conditions for safe use of that additive, and unless it is from a batch certified by FDA as safe for use under general or specified conditions; or (2) unless it has been exempted from the requirement of certification for such use.
The Bureau of Science's Division of Colors and Cosmetics is responsible for all chemical analysis work involving color additives and cosmetics, including certification of colors for use in foods, drugs, and cosmetics, and for evaluation of petitions to place a proposed color on FDA's lists of colors considered safe under specific conditions, including labeling requirements.

The permitted colors usually are different for cosmetics and food and drugs, but some are used in all three. Certification of each batch of certain colors is required. For these colors the manufacturer submits a sample from each batch to the Division, where it is analyzed to see that it meets the specifications. The Division examines samples of foods, drugs, and cosmetics to determine if the colors present are those permitted by the regulations. It also analyzes samples of cosmetics for the presence of potentially harmful ingredients. Major emphasis in analysis of cosmetics is on examination of those about which there has been a consumer complaint.

In the photos at near left, a scientific aide (top) is using a columnar chromatographical process on a color sample to separate "intermediates" (noncolored components used in the preparation of color). FDA sets limits on the amount of these intermediates that may be present to maximize purity and minimize possible toxic effects. A chemist (middle) uses an atomic absorption instrument to test a color sample for content of lead, which is toxic. A chemist (bottom) tests a color sample with a flask filtering process to determine if the insoluble matter exceeds the specified minimum.

In the next two photos at bottom, a chemist (top) uses columnar chromatography separation to determine the identity and number of basic colors in a hair tint, while (below) a chemist uses thin-layer chromatography to separate the several colors in a nail polish for identity.

The chemist and the toxicologist work as a team in evaluating cosmetic safety, the toxicologist performing tests on animals and man to evaluate cosmetic safety. Sensitivity (allergy) of some persons to hair dyes presents the most common toxicity problem. Other common problems involve hair grooming preparations, eye makeup, and suntan preparations. The increasing tendency of people to decorate the area around the eye is causing concern because the cosmetic may get into the eye accidentally or may irritate or penetrate the very sensitive skin in this area.

At a Department of Agriculture facility at Beltsville, Md., used by FDA for experiments with miniature pigs, scientists of the Division of Pharmacology and Toxicity (far left, top) are inoculating a pig with a cosmetic ingredient in a test for skin sensitivity. A sensitivity reaction is shown on the pig's skin (below). FDA is finding increasing use for the pig as a test animal because its skin more closely resembles human skin than that of most other species. Other uses of the pig currently being looked into involve phototoxicity and photosensitivity from sun and other light rays.
Above (at left), a chemist separates cosmetic ingredients by solvent extraction in a separatory funnel. At right (top), a chemist uses a gas chromatograph to separate perfume ingredients. The infrared spectrophotometer (middle) is being used by a chemist to establish the identity of a material separated from a cosmetic. Below (left) are shown some of the essential oils and other ingredients that go into perfumes, and (right) a chemist separating cosmetic ingredients with a column chromatograph.
for indications of damage such as stains on the outer surface of the chests containing the tea and reports his findings to the tea examiner who decides whether to accept or reject all or part of a lot. There are other reasons for rejection, such as contamination with an impurity. The contaminant may be detected organoleptically or by chemical analysis when necessary. In one case, a medicinal odor in tea was traced to drums of a swimming pool disinfectant which had been stored next to the tea on the piers. In another instance, a chemical test was used to demonstrate the presence of excessive amounts of sand.

Comparison between the sample and the standard is most important to the FDA tea examiner, but like his colleague in the trade, he enjoys making other organoleptic distinctions by which he can identify not only the type of tea but also the country of origin, or even the province or district and in some few cases the very garden which produced it.

Because of differences in climate, soil, and variations in local manufacturing practices, teas produced in a single area have a remarkably uniform character that is difficult to produce in other areas. A good examiner may be able to identify several hundred different growths, and to distinguish hundreds more. It is always a pleasant surprise to an examiner to come across a good Darjeeling, Ceylon, or other flavory tea. This makes up for the boring routine of looking at tens or even hundreds of so-so teas.

FDA tea examiners report to the Bureau of Customs any teas they believe to be black Congou, teas originating from the Chinese mainland, and are sometimes called upon to identify batches of this tea which have been smuggled into this country. Importation of products originating from mainland China is prohibited under the Trading with the Enemy Act.

Two other groups are indispensable to the functioning of the Tea Act. The first is the U.S. Board of Tea Experts. This Board is made up of seven experts in the examination of tea, appointed by the Secretary of Health, Education, and Welfare. Six are selected from the trade and the seventh is the New York examiner, who also acts as the permanent executive secretary. The presiding officer of the Board is the Chairman, who is elected at each annual meeting. This yearly gathering is usually held in the office of the New York examiner, who, because he is an interested party, is barred from the room during the appeal. The importer is also barred but may attend sample-taking. The decisions of the Board are final on questions of fact but may be appealed to the Federal Courts on points of law.

There have been many changes in the tea industry in the 70 years since the Tea Act became law. Consumer preferences have shifted almost entirely to black tea, whereas 50 years ago green tea was just as much in demand as black, and oolong accounted for one-fifth of the market. With this change, the consumption of iced tea has increased and now accounts for about 60 percent of the tea being drunk. With the introduction of the tea bag and instant tea, brewing habits have also changed. Last year, of the 107 million pounds sold in grocery stores, tea bags accounted for 56,900,000 pounds, instant tea for 30,900,000 pounds, and loose tea trailed with only 19,200,000 pounds.

Any tea expert knows that proper brewing with loose tea will produce the best cup, but the consumer prefers the convenience of the tea bag or instant tea and the industry strives to cater to his taste. And FDA tea examiners are ready to assure the consumer that he will not get a tea of poor quality, no matter how he prefers to drink it.
The American Consumer is big business—indeed the biggest business in the United States. From his pocket comes two-thirds of all the money that goes into the American economy.

It's no wonder then that the consumer is the object of mass advertising. He is constantly importuned by slogans, product claims, and tuneful ditties promoting the outpour of products from the cornucopia of American industry and from abroad.

Unfortunately, some of the products are inferior or harmful and some of the claims for them are false or misleading. Each year approximately 15 million Americans fall victims to sales promotions in "nutritional science." The U.S. consumer spends about $250 million a year, for instance, on worthless remedies for arthritis. That the welfare and protection of the consumer is a matter of national concern is evident in the ethical standards of the large majority of American industry, and even more so in the number of statutes enacted and Government organizations created by the Congress to help the consumer get the most for his money and to protect his health and welfare. The Food and Drug Administration has a particular interest in the consumer's well-being and his education at home and in the marketplace. A large part of this educational and informational program is carried out by FDA's trained staff of Consumer Specialists.

The first Consumer Specialists were hired in 1952 on a part-time basis after a Consumer Advisory Committee appointed by Commissioner of Food and Drugs George P. Larrick reported its belief that citizens were largely unaware of the protection afforded them by FDA and recommended that each District establish a liaison between the Agency and the consumer to make the Agency's programs and areas of jurisdiction better known. As FDA's role broadened from that of routine enforcement of the Food, Drug, and Cosmetic Act to a wider concept of consumer protection, the role of the Consumer Specialist became more vital. In 1964, each District was assigned a full-time specialist as part of the FDA Consumer Education Program. FDA now has 31 Consumer Specialists. These women are located in all 17 of the Agency's Districts across the country. Each holds at least one college degree in the field of home economics.

The FDA Consumer Education Program relies heavily on the Consumer Specialist in achieving its goals. Implicit in the program's thrust is the belief of the Agency that an educated and informed consumer is necessary for economic and social improvements. The basic purposes of the consumer specialists' program are to provide channels of communication through which consumer opinions and questions about foods, drugs, cosmetics, and related products can reach FDA and promote improved functioning; to provide a source of comment and criticism by which an evaluation may be made of the effectiveness of FDA's activities from the consumer's point of view; to inform consumer groups about protection afforded by laws administered by FDA; and to promote more intelligent action by the consumer in buying and using products whose manufacture and distribution are regulated by these laws.

Simply stated, the goal of the Consumer Specialist is to educate Americans as consumers of foods, drugs, cosmetics, and therapeutic devices. To achieve these goals the Consumer Specialist must work closely with many organized groups. She is an adviser to industry and serves as liaison with other consumer protection groups. She usually belongs to certain professional groups such as the Home Economics Association, American Dietetic Association, and the American Public Health Association. She must maintain close contacts with newspapers, radio, and television, as well as with community leaders in education and health through whom information may be passed on to large numbers of consumers. She works with other Government agencies which also serve the consumer, such as the Administration on Aging of the Department of Health, Education, and Welfare, and the Department of Agriculture's Cooperative Extension Service.

The educational goals are so wide-ranging and the groups the Consumer Specialist must work with so diversified that she must set up priorities. The Consumer Services Staff at FDA Headquarters, headed by Theresa Demus, Acting Coordinator, establishes the broad goals of the District Consumer Specialists and provides them with some of the educational materials used. The Consumer Services Staff in turn works closely with the President's Committee for Consumer Affairs headed by Betty Furness. This Committee advises the President on consumer problems and represents the consumer before Congress.

The Consumer Services Staff has established three priority target areas: labor-low income, education, and aging. Each District is free, of course, to tailor its programs within these guidelines to fit the needs of its particular area and population.

The Consumer Specialist realizes that individual consumers, as well as the professional, industrial, and
consumer interest groups, have different educational requirements which she must serve.

In one subject area, such as labeling, the Consumer Specialist may set up a question and answer exchange of information between industry and the consumer. In the San Francisco District, a labeling conference held in conjunction with the Federal Trade Commission before a consumer and industry audience presented to industry the objections by consumers to certain labels and acquainted consumers with information on labeling from industry representatives.

The Consumer Specialist may, as in the case of Lorena Myers, Kansas City District, give a speech on labeling from the consumer-safety standpoint. Her speech, entitled “Read, then Heed the Label,” was given to 155 industrial employees as part of the company’s safety program. Direct contact with industry may be part of the Consumer Specialist’s campaign, as in the Chicago District, where Consumer Specialists Marguerite Robinson and Marie Abdisho work closely with a large food processing and merchandising industry to advise management on label requirements.

Mass communication is one of the most potent educational tools available to the Consumer Specialist. Through time or space provided by radio, television, and newspapers, she and her staff can broadcast consumer protection messages which reach millions of Americans each year. Often the message is prepared in advance by the Consumer Specialist and her staff. There are times, however, when FDA and its Consumer Specialist, in their role of consumer protectors, are called on by the media to provide commentary on news developments. For example, Joan Bergy, Seattle District’s Consumer Specialist, was asked to appear on a half-hour panel discussion presented by a local TV station on “How Safe Are Oral Contraceptives?” Philadelphia District Consumer Specialist Jeanne Devers, invited to appear on the “Mike Douglas Show” on ABC-TV, exhibited articles seized by FDA in the marketplace and thus explained to a large segment of the U.S. population the purposes of FDA’s consumer protection.

Exhibits are another tool used by the Consumer Specialist to reach and educate as many people as possible. Subject matter can range from “Fair Packaging and Labeling,” shown by the Baltimore District in a Maryland State office building (and viewed by an estimated 3,000 people), to the planned Community Health Week Exhibit this month in the Kansas City District. This exhibit is being shown a full week, in conjunction with 75 other organizations which have been invited to participate, and it is estimated that approximately 150,000 people will visit the shopping center where the displays are being shown. One of the largest quackery exhibits in the world is now housed in the St. Louis Medical Museum as a result of the efforts of Loretta Johnson, Kansas City District Consumer Specialist.

Community participation in educational projects sponsored by FDA and its District Consumer Specialist sometimes can be overwhelming. This was the case in the Los Angeles District when a 1-day conference report, “Drugs in Our Society,” attracted 20,000 people to the Las Vegas Convention Center. Over 8,000 were turned away because of seating limitations. The conference’s success was attributed to the local newspaper cosponsorship as well as the high community interest in the subject.

Although it is satisfying to the Consumer Specialist to see such spontaneous public interest in areas of consumerism, and to have the opportunity to face the buying public in person, one of her major functions is to “educate” the educators—the leaders in industry and local government. Conferences and workshops with health departments, boards of education, public health nutritionists and dietitians, doctors, nurses, Office of

Newspapers are responsible for what may be the largest load of information carried to the American home, and offer the Consumer Specialist an opportunity to provide useful and informational items on matters ranging from advice on storing foods to warnings on quackery. The Chicago District has established a close working relationship with city newspapers and provides editors with FDA-related articles and ideas for special coverage. The informational exchange is two-way. For example, the Chicago American runs a women’s section column called “Playback,” answering questions from the housewife on foods, drugs, etc. When a question pertains to consumer areas covered by FDA, the newspaper forwards it to Misses Robinson and Abdisho, who respond both to the interested consumer and to the newspaper.

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The Consumer Specialist introduces consumer education materials to many varied groups. Pictured from top left to bottom, she works with community health departments, school administrators, and teacher workshops, describing available literature and teaching aids, and helping plan programs and conferences.

She may also be called on to work with industry in an advisory capacity. In second from bottom photo, Chicago Consumer Specialists Marguerite Robinson (second from right) and Marie Abdisho (right), discuss labeling requirements with officials of the Canteen Corp. In bottom left photo, they look at labels for sandwiches dispensed by the company’s vending machines.

The news media are valuable tools in broadcasting helpful consumer messages. Above left, Philadelphia Consumer Specialist Jeanne Devers (second from left) appears on the "Mike Douglas Show." Above right, Chicago Consumer Specialist Abdisho talks with Marie Jilke (right), Food Editor of the Chicago Sun-Times newspaper.
Economic Opportunity groups, and women's clubs, bring the Consumer Specialist in contact with professionals and leaders who in turn are responsible for educating the consumer in their areas. A workshop with 10 teachers, for example, may in a year's time bring the Consumer Specialist's message to hundreds of students. In the Denver District, a presentation in August to the School Food Services Division of the Colorado Department of Education was addressed to 450 participants. These professionals represented a larger sphere of influence than their numbers indicated. Each one carried back information from FDA and involved others in the educational processes initiated by the Consumer Specialist.

Professionals in one field may be the target audience of a particular conference, or interrelated groups of professionals may be the target of a particular subject matter presented in workshop form. An example of the latter is the Detroit District's International Poison Control Conference planned in March 1970 in Cleveland, Ohio. A similar conference was held 4 years ago in which 625 experts from Canada, Indiana, Ohio, Michigan, and Illinois participated. The same size attendance is expected for the 1970 meeting, when the total scope of poison control (including chemical, bacterial, and botanical) will be discussed.

It is natural to think of education in terms of schools. It is equally natural that the Consumer Specialists should work closely with public education systems to introduce and increase consumer education curricula. Some States have introduced accredited consumer courses into elementary and secondary schools. A notable example is the work done in New York State. The State of Illinois, last spring became the first State to pass laws requiring a Consumer Education program in grades 8 through 12. Consequently, the Chicago District Consumer Specialists have been called on to aid in the development of educational materials and to advise the Illinois State Board of Education.

Although these courses are required only at junior high and high school levels, many Illinois elementary schools have introduced similar consumer oriented programs with the aid of Chicago District Consumer Specialists. Miss Robinson and Miss Abdisho, for example, have provided in-teacher training, using such educational tools as slides and FDA Fact Sheets, to Berkeley Junior High (grades 7 and 8) teachers, and have distributed information on topics such as Salmonella to the Berkeley PTA's Health Committee. At the Benjamin Wright Raymond Elementary School in Chicago, they work with Mrs. Elma Douglas, a teacher, who conducts a unit for 4th, 5th, and 6th graders on "Becoming a Smart Shopper." The youngsters put classroom learning to practical use in grocery-shopping field trips, where they read labels, compare prices, and make the "best" buy. After such an expedition, one child wrote, "I am . . . one of Mrs. Douglas' Smart Shoppers. We went to the super-mart. That is a mixed up store. It has groceries, hardware, meat and a bakery . . . There is a big bag of rice. It was five pounds for only 69 cents. Now me and Freddie will fix lunch for Mrs. Douglas."

The consumer in the street, who may not have access to some of the Consumer Specialists' more formal education courses, still has access to the "governmental ear." In six Districts—Chicago, Los Angeles, Dallas, New York, Minneapolis, and New Orleans—a consumer phone service is in operation. The consumer can listen to recorded messages on topics of interest such as artificial sweeteners, storage of drugs in the home, and safe use of household cleaners by dialing a widely advertised phone number. The program has proved to be extremely successful. In the Dallas District, for example, Consumer Specialist Leona Allman reports a total of 2,415 calls for the month of August. Since the program was initiated last October, the District has received over 45,000 calls.

Letters to the Consumer Services Staff and to the District Consumer Specialists are another avenue the individual consumer can take to request information or to register a complaint. Whether citizens request material for a school term paper or ask why a certain drug has been removed from the market, these letters are always answered. FDA Headquarters alone receives about 2,200 consumer letters a month.

The effectiveness of the Consumer Specialists' educational programs is illustrated by the increased demands for their time and services. Within the past 4 months, four additional full-time specialists have been added to District staffs. Marie Abdisho joined the Chicago District staff, Loyce Wallace joined the Dallas District, Katherine Knarr joined the Cincinnati District, and Lilyan Goossens joined Detroit District and will work out of Cleveland. Each has increased the scope of existing activities and contributed to the development of new programs.

The Consumer Specialist's reason for being is to help the consumer. She realizes the educated buyer is one of the soundest building blocks of the American economic system.
Scientific Colleagues Honor FDA Trio

On September 17 a small crowd of around 40 people gathered in a conference room of the Food and Drug Administration in Washington. Their purpose: to honor three senior FDA scientists for their long careers of accomplishments in behalf of better foods and drugs.

The occasion was the dedication of one issue of the monthly British journal, *Food and Cosmetics Toxicology*, to Drs. Arnold J. Lehman, O. Garth Fitzhugh, and Arthur A. Nelson.

Dr. Leon Golberg, editor of *Food and Cosmetics Toxicology*, explained that the magazine made the unusual tribute because the three of himself, Commissioner Herbert L. Ley, Jr., M.D., who could not attend the ceremony, and the entire Agency. Other notables in the scientific world and FDA colleagues extended their best wishes to the three.

Mr. Rankin noted that the honorees, along with their associates, beginning in the mid-1940's, "built a laboratory of such excellence that it is recognized throughout the world."

Dr. Golberg in his talk called the FDA "the world's fountainhead of regulatory activity in the field of food additives, drugs, pesticides, feedstuff additives, food packaging materials, and many other components of our chemical environment."

FDA men "have dedicated their lives to ensure the safety of food additives, agricultural chemicals, packaging materials, drugs, cosmetics, and a host of other chemicals to which the public is exposed."

The three scientists during the brief ceremony were presented bound copies of the August issue of the magazine, which included biographical sketches of each, including some major accomplishments.

Dr. William H. Summerson, Director of FDA's Bureau of Science, acted as master of ceremonies, and Winton Rankin, Deputy Commissioner of Food and Drugs, congratulated the three scientists on behalf of himself, Commissioner Herbert L. Ley, Jr., M.D., who could not attend the ceremony, and the entire Agency. Other notables in the scientific world and FDA colleagues extended their best wishes to the three.

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He said the British Industrial Biological Research Association, publisher of *Food and Cosmetics Toxicology*, in establishing itself leaned heavily "on the procedures that these men and their colleagues had developed, on their published and unpublished research, and on the mighty edifice of regulations that they had helped to erect." In a foreword to the three biographical sketches in the magazine, he said:

"To a handful of men within the FDA we owe the fact that today, within the U.S.A. and elsewhere, there is order and progress where there might well have been chaos or stagnation. That some measure of international agreement on food additive regulation does exist is in part attributable to the significant influence of the internationally respected scientists in the FDA. In such areas as food-packaging legislation, many countries have reason to be grateful for the FDA guidance on which they have depended for so long." The biographical sketches of the three scientists were written for the magazine by scientific colleagues.

Dr. Lehman, who is Director of the Division of Pharmacology and Toxicology, is internationally known for leadership in the scientific study of materials to which the general public is frequently exposed.

Dr. Fitzhugh, Toxicological Adviser to the Bureau of Science, has specialized in studying chronic experimental toxicology and in application of findings to determination of safe levels of pesticides and additives in foods.

Dr. Nelson, now retired, headed the Pathology Branch of the Bureau of Science, and made major contributions in applying pathology to the evaluation of the safety of chemicals in foods, drugs, and cosmetics.
ATLANTA DISTRICT The Great Southern Wholesale Grocery Corp., Miami, Fla., and its president, Albert Baitcher, pleaded nolo contendere on August 23 in Miami District court to one count of allowing flour to become infested with insects while it was stored in a warehouse accessible to rodents and insects. Each defendant was fined $500. The firm had previously pleaded not guilty to a five-count information charging similar violations involving flour, cornmeal, cake mix, and Danish dough mix. Upon accepting the nolo contendere plea, the court dismissed the remaining counts.

A trial court conviction of Akin Distributors of Florida, Inc., Jacksonville, was upheld on July 29 by the U.S. Court of Appeals for the Fifth Circuit. The firm had been fined a total of $2,000 on November 9, 1967, in Jacksonville, after a District court judge found it guilty of holding whole wheat flour, white flour, wheat germ meal, and soya flour under insanitary conditions which allowed the articles to become insect and rodent contaminated. On November 16, 1967, the firm filed to appeal the conviction.

Baltimore District Cotton swabs valued at $353 were seized August 8 in Baltimore because they were not sterile as labeled. The 470 cartons of swabs, manufactured by Torrent Manufacturing Co., Inc., Lake Geneva, Wis., were found to be contaminated with viable mold.

Boston District A Connecticut firm on August 16 was enjoined by a District court at Hartford from shipping poultry byproducts contaminated with Salmonella micro-organisms in interstate commerce.

The preliminary injunction against Hartford Poultry, Inc., Willimantic, Conn., was the first action under a cooperative FDA-U.S. Department of Agriculture program of policing animal and poultry byproducts intended for feed for possible Salmonella contamination.

Under the cooperative arrangement (see State Actions, FDA Papers, February 1968), the Agricultural Research Service's Animal Health Division conducts routine inspections of renderers and other manufacturers of animal and poultry byproducts intended for feed use for sanitation and absence of Salmonella. In accordance with this arrangement, the Animal Health Division has been inspecting Connecticut Bi-Products, Inc., a bankrupt corporation, which Hartford Poultry, Inc., had leased for use in the manufacture of its poultry byproducts. During the inspections, which started in 1967, ARC noted alleged insanitary conditions which could lead to Salmonella contamination. Unable to effect any improvement by recommendations, USDA referred the firm to the Boston District. After inspections of its own, the District concurred in the findings of USDA and instituted the injunction action alleging Salmonella contamination of the firm's products.

A hearing was to have been held in September to determine whether Hartford Poultry, Inc., should be permanently enjoined.

Buffalo District Two shipments of Canadian radishes were detained in August when they were found to contain excess residues of the pesticide chemicals Diazinon and Thiodan. The shipper was Louth Garden Produce, St. Catherines, Ontario.

Chicago District Evidence of rodent defilement in a carload of wheat from Geisel Grain Co., Glen Elder, Kans., resulted in the Chicago consignee's rejection of the shipment. Report was made to the Illinois Health Department, Division of Food and Drug Inspectors who, in cooperation with FDA Inspectors, sampled the carload. Laboratory analysis showed excessive rodent pellets and the shipper was notified by wire with confirming letter of the findings. Told that the grain was condemned for human consumption, the shipper voluntarily diverted the carload from trade channels for human food.

Cincinnati District "Estrovag Suppositories" valued at $580 were seized at Knoxville, Tenn., because of low potency. The drug was in possession of Southern Drug and Manufacturing Co., Inc., which manufactured the drug from raw material received in interstate commerce.

Dallas District A report that serum to treat botulism was delivered to a Houston hospital precipitated a joint investigation by the District and the Texas State Department of Health. Investigation disproved botulism poisoning, but revealed that the hospital had treated members of two families from the same household who had used flour contaminated by the pesticide Trithion. The flour had been purchased from a local salvage dealer. Another family, it was discovered, had also used contaminated flour purchased from the same dealer but had not become ill. More than 30,000 parts per million of Trithion was discovered in one of the families' bag of flour. The source of contamination was never found.

Detroit District Seizure of 22 cases of "Automatic Choke Cleaner" was made in Brooklyn, N.Y., because the product, a hazardous substance in a pressurized container, did not bear proper label warn-
ings. The label also omitted the common name of the chemical “xylene,” the component in the product responsible for the required special warnings.

An inspectional warning and a warning letter had been sent to the manufacturer, Woodhill Chemical Corp., Cleveland, Ohio.

KANSAS CITY DISTRICT The manufacturing formula used for the production of a drug and the strength and quality claims for the same drug could not and did not match, the FDA declared, when U.S. marshals seized 673 bottles of “Myci-Cort Nasal Spray” and one bulk drum of Hydrocortisone U.S.P. on August 8 in Springfield, Mo. The spray and chemical were in possession of Misemer Pharmaceuticals, Inc.

The Government charged that the methods and controls used in manufacturing the drug did not comply with good manufacturing practices to assure that the strength and quality of the drug were the same as they were represented to be. The drug’s manufacturing formula could not have resulted in a nasal spray solution containing one milligram of hydrocortisone in each cubic centimeter of solution since it is impossible to dissolve this quantity of hydrocortisone in solution when manufactured under the firm’s formula.

Contaminated eggs were seized August 8 by the U.S. marshal at Wakefield, Nebr. The 22,500 dozen eggs, shipped by a Mississippi firm, contained the pesticide chemical dieldrin for which there is no tolerance or exemption from tolerance in eggs. The Mississippi firm forfeited the eggs and they were ordered destroyed by the Chief Judge for the U.S. District court, District of Nebraska.

LOS ANGELES DISTRICT A weight reduction drug, “Robese Injection,” was seized because it lacked an approved New Drug Application. Valued at $34,875, the 7,318 vials were seized in possession of the distributor, Rocky Mountain Pharmacal Co., Phoenix, Ariz., and two Phoenix reducing clinics.

Cooperation between FDA, the California Department of Agriculture, and Tijuana, Mexico, health officials brought under control the incidence of unusually high residues of DDT on purslane, a leafy fresh vegetable imported from Tijuana into the Los Angeles area. The high residues were first noticed in market sample findings by the State of California laboratory and confirmed by the Los Angeles District. FDA then advised the Tijuana officials who investigated and found that the pesticide had been applied just prior to harvest. The health department caused the growers to discontinue this practice and later shipments showed very little pesticide. The two small original lots with high residues were voluntarily destroyed by the dealer.

MINNEAPOLIS DISTRICT The first phase of a comprehensive educational program in St. Paul-Minneapolis on questionable business practices and consumer fraud was initiated with a 1-day program September 3, entitled “Project Consumer.” The program was intended to communicate to the community organizers of several social service agencies a greater understanding of the problems of the marketplace. The consumer education and protection series is being sponsored by the Better Business Bureau of St. Paul, the Ramsey County Citizens’ Committee for Economic Opportunity, the Minneapolis FDA District, and other regulatory agencies.

NEW YORK DISTRICT The New York City Department of Health and the District are entering the first phase of their single system concept of inspection after an agreement to begin a joint program of intensive Salmonella inspection of all egg noodle and Chinese noodle manufacturers in the city. The joint program requires District training of City Health Inspectors in making bacteriological inspections, including collecting of in-line aseptic samples, filing out collection reports, writing narrative reports, and filling out Plant Evaluation Forms.

Training at first will be carried out on joint inspection tours. Then the inventory of noodle manufacturers will be divided with District and New York Inspectors making independent inspections of the remaining firms. The city has agreed to use its resources in analyzing finished product samples and raw material samples collected on inspection tours. For all in-line samples, the New York District, due to limited facilities, has made arrangements for analyses at the Cincinnati District.

The first of the joint training inspections started August 12.

NEW ORLEANS DISTRICT An extensive investigation of dieldrin residues in shell eggs in the Jackson, Miss., area, in August resulted in Federal seizure of 750 cases of eggs shipped to Wakefield, Nebr., and the voluntary destruction of 600 cases shipped to El Paso, Tex., and 750 cases shipped to Ghent, N.Y. The producer, Garth Enterprises, Pelahatchie, Miss., voluntarily destroyed the few cases of eggs still on hand from the contaminated flocks of 19,000 laying hens, and voluntarily slaughtered and buried the hens. The firm estimated the total value of destroyed eggs and hens to be more than $50,000.

At the invitation of the Mississippi Commissioner of Agriculture and the State Chemist, New Orleans District representatives attended a joint planning conference in September to discuss the problem and procedures for handling any future episodes of this type.

In charges involving adulterated and misbranded medicated animal feeds, Allied Mills, Inc., Memphis, Tenn., changed a prior plea of not guilty to nolo contendere. The court assessed a fine of $100 against the corporation on each of 10 counts, for a total of $1,000.
PHILADELPHIA DISTRICT The death of a 3-year-old Minneapolis child who swallowed a quantity of brake fluid resulted in an investigation at the manufacturer. The firm contends the product was a blend of two chemical compounds, each with a maximum of 9.5 percent diethylene glycol. Products containing 10 percent or more of diethylene glycol require special warning labels. The District collected an official sample and sent it to Washington along with results of analysis. FDA Headquarters, in view of the reported death, will consider whether to require special labeling of the product, based on human experience with it.

Two lots of “Magnatril,” an aluminum and magnesium hydroxide antacid, were voluntarily recalled from the market by the Lannett Co., Philadelphia, after a complaint from a Philadelphia hospital. The hospital claimed positive findings of Pseudomonas aeruginosa bacteria in the product and this was confirmed by the District. The Bureau of Medicine has termed danger from the product as unlikely, though it constitutes a moderate health hazard. Results in debilitated patients may be more serious. Distribution of the two lots involved, Nos. 11960 and 12080, was confined to Pennsylvania and New Jersey. Cooperative local and State health officials have been notified of the recalls.

SAN FRANCISCO DISTRICT A criminal information was filed in June against J. Sosnick & Son, Inc., a food warehouse in South San Francisco, when investigation showed adulteration of stored food products with insects and rodent excreta. On August 8, the defendants, Robert S. Sosnick and the corporation, filed pleas of nolo contendere to two of the 15 counts. At the time of sentencing on September 5, a fine of $1,000 was imposed on the corporation and Robert S. Sosnick was placed on a 1-year probation. The remaining counts were dismissed on motion of the U.S. attorney.

SEATTLE DISTRICT An injunction was filed against Stanley Drug Products, Inc., Portland, Oreg., based on factory evidence showing lack of conformance to current Good Manufacturing Practices Regulations. As required by the injunction, an in-plant investigation was started on August 12 by the District. Investigation revealed the presence of products older than 3½ years and extensive inadequacies in analytical methodology and record keeping. As a result, a series of products are being quarantined pending re assay and the firm has decided to remove warehouse stocks of products manufactured or purchased prior to January 1, 1965, pending re assay or destruction. The firm is releasing products into interstate commerce based on positive evaluation by FDA of the adequacy of production and analytical history of the specific drug or vitamin.
State Actions

Joint Action on Cabbage  Representatives of the Virginia Department of Agriculture and Commerce and FDA’s Baltimore District joined in checking cabbage fields in the Hillsville area of Virginia after the County Extension Agent reported an unusually heavy infestation of cabbage looper caterpillars.

The State collected and examined field samples of cabbage and found varying degrees of toxaphene. A number of samples showed residues in excess of the tolerance. As a result, the State embargoed cabbage from high residue fields until examinations showed the residue to be within tolerance.

Several samples of cabbage shipped interstate and collected and examined by Baltimore District showed residues of toxaphene, but within the tolerance permitted.

State Halts Illegal Sales  The Chicago Board of Health Inspectors, in a routine grocery store inspection, found an unlabeled butterlike product for sale. A check of invoices and carton labeling showed that the product, “Sweet Cream Butterite,” was 50 percent butter and 50 percent margarine. Inspectors were unable to show that the store had sold the product as butter. They referred the matter to the Illinois Department of Health, Division of Food and Drugs, which sampled the original product lot from the grocery store as well as the parent lot in the warehouse. The product was embargoed and analysis showed it to be half butter and half margarine.

The shipper, Sloan Brothers, Inc., was called to a hearing June 20 by the Illinois Division of Food and Drugs. Although the firm said the product was for sale only to bakeries and manufacturers, Dr. Roy W. Upham, Chief, explained that it was illegal to sell such a product in Illinois unless labeled as “margarine.” After the hearing, the firm destroyed the remaining 3,090 pounds of the original 3,160 pounds shipped to Illinois.

Refrozen Fish Destroyed  The Albuquerque, N. Mex., Health Department reports the voluntary destruction of 3,026 pounds of frozen raw fish which had thawed in transit and had then been refrozen. The shipper was Boston Bonnie, Inc., Boston, Mass.

Consumer Protection Action  New programs emphasizing consumer protection are being developed by the New Mexico Environmental Sanitation Service. According to Larry Gordon, Director, the ESS is asking for a State hazardous substances act and for legislation updating the New Mexico Pure Food Act.

Warning Letter Used  A Nebraska Agriculture Department official recently adopted use of a warning letter similar to one now used by FDA in reporting adverse findings to firms when insanitary conditions are noted or other objectionable findings are made on their premises. Warren G. McCubbin, Chief, Bureau of Dairies and Foods, Nebraska Department of Agriculture, sent the letter as a warning to a Nebraska cheese manufacturing plant to enable the firm to correct insanitary conditions and thus avoid facing possible embarrassment or interruption of business.

Joint Inspection Agreement  The Wisconsin Department of Agriculture and the Minneapolis District of FDA have adopted a cooperative program in which the State will assume primary responsibility for dairy plant inspections and FDA will be responsible for inspection of State food canneries. Under the agreement, the District will also investigate use of agricultural pesticides, collecting samples and making analyses of raw agricultural products. There will be a complete exchange of information about program plans, inspectional reports, and areas of violation.

Through this cooperation, the two groups hope to prevent duplication of effort and to provide optimum protection to Wisconsin consumers.

Thermometer Standards Checked  To insure that food canners maintain adequate time and temperature controls, the Oregon Department of Agriculture tests the indicating thermometers on all retorts and pressure cookers at these firms. Under the Oregon Food Processing Establishment Law, regulations which became effective January 1, 1968, require annual testing of the thermometers’ proof of accuracy to within 1 degree Fahrenheit.

Using portable equipment which permits thermometer testing in the canneries, the Department to date has tested 427 indicating thermometers in 45 commercial and custom fruit, vegetable, and seafood canneries. The accuracy standard was met by 200 of the thermometers, another 190 met standards after adjustment, and only 37 were condemned.

Duplicate Inspection Eliminated  Around 20 county, city, and urban health departments have entered into a cooperative retail dairy store licensing program with the Division of Food and Drugs of the Illinois Department of Public Health. Under this cooperative agreement, the local health department conducts the licensing inspections and forwards the status reports to the State health department in Springfield. The program seems to be working well and is eliminating duplicate inspection by both State and local inspection personnel, participants report.
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 28 seizure actions to remove adulterated, misbranded, and unsafe products from the consumer market, were reported in August. These included 6 seizures of foods; 1 because of poisonous and deleterious substances, and 5 because of contamination. Other seizures included 4 of vitamins and dietary foods, 10 of drugs, and 8 of hazardous substances.

<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eggs/Wakefield, Nebr. 8/8/68</td>
<td>Garth Enterprises/Pelahatchie, Miss. (S)</td>
<td>Contain dieldrin, a pesticide chemical not in conformity with regulations.</td>
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<tr>
<td>Contamination, Spoilage, Insanitary Handling</td>
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<tr>
<td>Bel Din Super Vitamins/Phoenix, Ariz. 5/9/68 Dr. Bronner's Calcium Food, Calcium-Lemon-ettes, Dulse Sea Lettuce, Organic-Mineral-Bouillon/Tulsa, Okla. 7/25/68</td>
<td>S-K Research Laboratories/Phoenix, Ariz. (D) Dr. E. H. Bronner &amp; Associates/Escondido, Calif. (M,S)</td>
<td>Contain folic acid and cobalt, food additives not in conformity with regulations; deficient in vitamins A and C. Contain iodine, a food additive not in conformity with regulations; deficient in vitamin C, iron, and protein; false and misleading claims; represented as food for special dietary use without sufficient dietary information. Contain iodine, a food additive not in conformity with regulations; deficient in protein; false and misleading claims; insufficient dietary information.</td>
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<tr>
<td>Vitamins—Dietary Foods</td>
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<tr>
<td>DRUGS / Human Use</td>
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CHARGES

P/G Forte/Turner, Kans. 8/21/68 Myers-Carter Laboratories, Inc./Glendale, Ariz. (M,S) False and misleading claims for relief of cough due to cold; no warning statement.
Phenyl-Koff cough syrup, fever tablets/ Manchester, Conn. 8/16/68 Jaymass, Inc./Manchester, Conn. (D) New drug not approved for safety and efficacy.
Robese injection/Phoenix, Ariz. 8/8/68 Rocky Mountain Pharmacal, Medical Clinic, Bio Products Research Lab./Tempe, Ariz. (D) New drugs not approved for safety and efficacy; false and misleading labels; inadequate directions for use; dangerous to health when used as prescribed.

HAZARDOUS SUBSTANCES

Aerial Flash Bombs, Skyrockets, Cherry Bombs, Silver Salutes/Crescent Beach, S.C. 6/28/68 White House Fireworks/Crescent Beach, S.C. (D) Banned hazardous substances since they are flammable solids generating pressure; lack consumer protection information required by Fed. Hazardous Substances Act.
Cherry Grove Beach, S.C. 6/28/68 Woods Fireworks/Cherry Grove Beach, S.C. (D)
Kent Kannon Crackers, Cherry Bomb Salutes/ Harlem, Mont. 8/21/68 Hi-Way Grocery/Harlem, Mont. (D)
M-80 Flash Salutes, Cherry Salutes, Silver Salutes/Florence, S.C. 6/28/68 Larry’s Superette/Florence, S.C. (D)
Potassium nitrate, dextrine, charcoal/ Columbus, Wis. 8/1/68 Sheard Science Supplies, Inc./Columbus, Wis. (D)
Solid fuel pellets/Los Angeles, Calif. 8/12/68 Aristocrat Distinctive Miniatures/Newark, N.J. (M,S)

POST OFFICE DEPARTMENT

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

Complaints filed by the General Counsel Under 39 U.S.C. 4005 (Fraud)

August 12, 1968: Virtu Imports, Los Angeles, Calif. Solicitations of orders and sale through the mails of books on aphrodisiacs and sex stimulants.
August 13, 1968: Premier Products, Los Angeles, Calif. Solicitations of orders and sale through the mails of an artificial penis prosthetic device.

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

July 29, 1968: Edward I. Winkler, d/b/a/Vib-Erect Co., was sentenced in Federal court, Los Angeles, Calif., to 6 months’ imprisonment, fined $6,000, and placed on probation for 5 years on condition that he not engage in any mail-order business. Winkler was convicted on 24 counts of mail fraud on May 8, 1968, incident to his nationwide advertising and sale through the mails of so-called sex devices.
Charged 7-22-67: when shipped by Otvos, Yuma, Ariz., the article contained the sometimes contaminated fresh eggs, 402(a)(3), 402(a)(4). Consent decree authorized release to shipper for salvaging. (33)

Soybean, at Butte, Dist. Mnt.
Charged 7-3-67, 9-10-67, when shipped by Protein Manufacturers Co., Clinton, Miss., and 7-22-67, when shipped by Great Western Corn Products, Inc., Kansas City, Mo., the article contained a grossly adulterated soybean meal. 402(a)(1), 402(a)(3). Consent decree authorized release to dealer for salvaging. (34)

You are reading natural text.
Calcium gluconate injection, N.F

Vita-27 food supplement tablets and capsules, at Racine, E. Dist. Wis.

Chloral hydrate, U.S.P.

Amphetamine, barbiturate, and other depressant or stimulant drugs, at Walgreen Co., Chicago, Ill.

A.C.N, water-adsorbible vitamin tablets, at Binghamton, N. Dist. N.Y.

Absorbine arthritic pain lotion, at Binghamton, N. Dist. N.Y.

Sorbi-Plus vitamin and iron combination liquid and Derma-Vites tablets, at Philadelphia, Pa.

Calcium gluconate injection, N.F

New Vita-27 food supplement tablets and capsules, at Racine, E. Dist. Wis.

Chloral hydrate, U.S.P.

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Absorbine arthritic pain lotion, at Binghamton, N. Dist. N.Y.

Sorbi-Plus vitamin and iron combination liquid and Derma-Vites tablets, at Philadelphia, Pa.
studies by the six witnesses, variously placed in Chicago, Cleveland, San Francisco, Philadelphia, and Brooklyn, that the Government seeks to depose them for the purpose of cross-examining them regarding the six witnesses' testimony.

The government is seeking to depose the witnesses to substantiate the findings of the six witnesses, who are experts in the field of medical devices and have conducted a thorough review of the products in question.

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99.5 percent); the bottles of fluid lacked required conspicuous label statement that presented a special hazard because of its methyl alcohol content (a

Charged 10-3-67: when shipped by North American Chemical Co., Kansas City, W. Dist. Mo., the article was a flammable substance presenting special hazards because of its methanol content.

Charged 6-27-67: when shipped by Viking Manufacturing Co., Inc., Natick, Mass., the article was a flammable substance presenting special hazards because of its methanol content.

Default decree ordered destruction. (104)

Charged 9-8-67: when shipped by Powell Industries, Inc., Denver, Colo., the article was a flammable substance presenting special hazards because of its methanol content.

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"Drugs and Your Body"

A Message of Life and Death

Drugs are chemicals that range from the common aspirin to the potent, mind-bending hallucinogens. A drug can be a killer or a valuable aid to health. Because there are some 7,000 drugs available today on the American market, it is especially important that our citizens be as well informed as possible about the proper and improper use of drugs. Such information could save their lives.

FDA has prepared a 64-page publication, "Drugs and Your Body," as a means of helping to educate both the school teacher and the intermediate student in the safe and beneficial use of drugs. This illustrated booklet describes the effects of various drugs on the body's systems and functions, prescription drugs compared with over-the-counter drugs, the dangers of improper use of drugs, and precautions that should be taken to guard against mistakes in dosage or accidental use of drugs.

TRAINING SEMINARS PLANNED  A series of three Government/industry/university regional training seminars on drug manufacturing control procedures is planned for late winter and early spring 1969.

Sponsored by the colleges of pharmacy of three leading universities, in cooperation with the Food and Drug Administration and the Pharmaceutical Manufacturers Association, the meetings are designed to:

1. Provide source materials on self-inspection and in-plant training for drug manufacturers; and
2. Serve as the model for a continuing series of FDA District workshops on good manufacturing practices in drug production.

The seminars are to be held in the New York-New Jersey metropolitan area, under the sponsorship of Rutgers State University; in Chicago, in conjunction with the College of Pharmacy of the University of Illinois; and in Los Angeles, in cooperation with the School of Pharmacy of the University of Southern California.

Leading authorities on quality controls in drug production from Government, industry, and the academic world will serve as lecturers and panelists at the seminars.

Each seminar will be an "academic short course" of 2½ days. The "student body" will consist of drug firm employees who are responsible for on-the-job training of operating personnel, and first line supervisors responsible for specific quality control, manufacturing, and laboratory operations.

Specific dates and other details of the seminars will be announced later.

FDA INDUSTRY WORKSHOPS  During December, January, and February, FDA Districts 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), foods (microbiological contamination, chemical residues, and sanitation), and labeling of hazardous household substances. Anyone desiring to attend should contact the nearest District.

SCHEDULE OF FDA WORKSHOPS AND REGIONAL CONFERENCES  DECEMBER 1968 AND JANUARY & FEBRUARY 1969

<table>
<thead>
<tr>
<th>FDA District</th>
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<tr>
<td>Boston</td>
<td>December 5</td>
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<td>New Bedford, Mass.</td>
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<td>Microbiological-Sanitation — Canneries &amp; Freezers</td>
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<tr>
<td>New Orleans</td>
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<td>Baton Rouge, La.</td>
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<td>Dallas</td>
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